Office of Environmental Management (EM)
Quality Assurance Program (QAP)

for Robert Murray

RECOMMENDED: _____
Office Director for the Office of Standards and Quality Assurance

APPROVAL: _____
Deputy Assistant Secretary for Safety, Security, and Quality Assurance

OFFICE OF ENVIRONMENTAL MANAGEMENT CORPORATE QUALITY POLICY

The Office of Environmental Management (EM) has committed to completing work safely as a first priority and also understands it is essential to complete the work correctly, or both safety and quality are jeopardized. While plans, procedures, and instructions are commonly understood elements of any quality program, individuals make quality happen and allow us to deliver on our commitments. EM has the expectation that each individual will be properly trained and supported to achieve the highest quality performance of which he or she is capable. Senior EM management is responsible for providing resources to ensure that quality is supported during execution of the mission consistent with budgets and schedules.

The EM Quality Assurance Program (EM-QA-001) provides the basis and template for achieving quality across the EM complex in accordance with 10 CFR 830 Subpart A, *Quality Assurance* (QA Rule) and DOE Order 414.1D (or most current revision), *Quality Assurance,* (QA Order). The EM policy is that EM implements the requirements of the QA Rule and QA Order.

Implementation includes evaluating the appropriate consensus standard to be applied, determining the applicable elements of that consensus standard for the scope of work, and grading the rigor of implementation of the applicable criteria. This grading is based on the relative importance to safety, safeguards, and security; the magnitude of any hazard involved; the life-cycle state of a facility or item; the programmatic mission of a facility; the particular characteristics of a facility or item; the relative importance to radiological and non-radiological hazards; and any other relevant factors. EM-QA-001 provides recommendations for consensus standards based on the hazard of the associated facility and activity which may be used in combination with other DOE orders and standards to meet the associated QA requirements. Due to the high hazards and costs of our activities and facilities, it is important that work activities and scopes are evaluated to determine the proper consensus standard without implementing excessive requirements.

The intent of this EM policy is that each EM organization and contractor will evaluate the proper methods for meeting the requirements of the QA Rule and QA Order and obtain the appropriate approval for that process from the QA approval authority.

EM-QA-001 defines how EM-HQ implements the requirements of the QA Order and serves as a possible template for field offices and contractors in the development of their QA Programs. EM Contractors conducting activities, including providing items or services that affect or may affect nuclear safety of DOE nuclear facilities implement the requirements of the QA Rule and QA Order in the development of their QA Programs.

A strong quality program supports EM emphasis on safety and efficiency through more disciplined management and operational processes. The result will be that we plan, manage, implement, and monitor mission performance consistent with established regulatory requirements.

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1.0 PURPOSE AND OBJECTIVE

This document describes the U.S. Department of Energy (DOE), Office of Environmental Management (EM) Quality Assurance Program (QAP) and how the QA criteria are satisfied. The DOE-EM mission is to complete the safe cleanup of the environmental legacy resulting from decades of nuclear weapons development and government-sponsored nuclear energy research. Performing work in a quality manner using approved procedures, qualified personnel, and proper tools is a necessary element to achieving the safe, efficient cleanup goal stated in the EM mission. This QAP documents the management system that ensures EM work is planned, managed, implemented; and mission performance is monitored consistent with established regulatory and contractual specifications to perform quality work and achieve the EM safety and cleanup goals. This QAP defines how DOE-EM HQ will implement the requirements of DOE O 414.1D (or most current revision), *Quality Assurance*, (QA Order) including oversight. In addition, this QAP serves as a template that contractors may use to implement the requirements of the QA Order and 10 CFR 830 through Subpart A, *Quality Assurance Requirements* (QA Rule). This document further demonstrates how QA and the Integrated Safety Management System (ISMS) are fully integrated in EM per DOE P 450.4A Change 1, *Integrated Safety Management Policy*. The oversight required by the QA Order and referenced in this QAP are met by implementation of DOE Order 226.1B (or most current revision), *Implementation of Department of Energy Oversight Policy*, including oversight of Assurance Systems. Note that the quality requirements for implementation of off-site packaging and transportation per DOE O 460.1D, *Hazardous Material Packaging and Transportation Safety*, are implemented in accordance with the *Packaging Quality Assurance (QA) Approval Program* found at the website https://rampac.energy.gov/home/quality-assurance.

The objective of this document is to describe how the QA requirements applicable to EM work are implemented by the EM-HQ, while allowing for use of a graded approach to implement the requirements. This document does not include site-specific requirements that may be imposed by other regulatory bodies or organizations (e.g., 10 CFR Part 71, *Packaging and Transportation of Radioactive Material*; Environmental Protection Agency (EPA) requirements; state permit requirements; etc.). Such additional requirements must be included in the site or project QA program documents.

2.0 SCOPE

The scope of the EM QAP is to be applied in a graded approach and provides:

- Requirements for how EM-HQ will conduct work activities including implementation of project lifecycle activities such as planning, design, development, procurement, production, operations and maintenance, support, recapitalization and final disposition;
- A template that field offices may use to implement quality requirements from the QA Order for work within their purview; and
- A template that prime contractors, as well as their respective subcontractors, vendors, and suppliers, may use for development of a QAP.

3.0 APPLICABILITY

This QAP applies to EM HQ and provides an acceptable template for EM Field/Project/Operations Offices (herein collectively referred to as EM Field Offices) and EM prime contractors (including subcontractors, vendors, and suppliers) as applicable to the work being performed by each entity. This QAP does not alter any legal obligations of any organization to comply with the QA Rule, QA Order, other laws and regulations, or existing contract language.

The use of voluntary consensus standards for quality is required in the development and implementation of an organization's QAP, where practicable and consistent with contractual and regulatory requirements.

For facilities, activities, or operations that are Hazard Category 2 or 3 (HC2 or HC3), EM recommends the use of the American Society of Mechanical Engineers (ASME) Quality Assurance Requirements for Nuclear Facility Applications (NQA-1) standard version 2008 with 2009 addendum (ASME NQA-1a-2009) (or later editions) as the consensus standard that meets the intent of the QA Rule and QA Order. Note that NQA-1a-2009 Parts III and IV are non-mandatory and not required for EM work.

For facilities, activities, or operations that are less than Hazard Category 3, EM recommends the use of ASME NQA-1a-2009 (or later editions) or International Standards Organization (ISO) standard 9001:2008 (or later editions) to address the requirements in the QA Order. Safety software that may be included or associated with structures, systems, or components (SSCs) for less than hazard category 3 facilities will need to meet the safety software requirements in the Order. The determination of what constitutes safety software should be made based on its application and the safety consequences of its postulated failure to perform its intended function.

For research and development activities EM recommends the use of ASME NQA-1a-2009 (or later editions) or American National Standards Institute (ANSI) standard Z 1.13-1999 (or later editions) to address the requirements of the QA Order.

Use of consensus standards different from those referenced above requires justification and approval by the QA Approval Authority. Regardless of the consensus standard chosen, any requirements in the QA Order that are not addressed in the consensus standard must be addressed separately in the QAP.

4.0 REQUIREMENTS AND REFERENCES

4.1 REQUIREMENTS

4.1.1 10 CFR 830, Subpart A, *Quality Assurance Requirements*

4.1.2 10 CFR Part 71, *Packaging and Transportation of Radioactive Material*

4.1.3 36 CFR Chapter XII, Subchapter B, *Records Management*

4.1.4 Department of Energy Acquisition Regulation

4.1.5 DOE O 226.1 (latest revision), *Implementation of Department of Energy Oversight Policy*

4.1.6 DOE O 227.1 (latest revision), *Independent Oversight Program*

4.1.7 DOE O 232.2 (latest revision), *Occurrence Reporting and Processing of Operations Information*

4.1.8 DOE O 243.1 (latest revision), *Records Management Program*

4.1.9 DOE O 341.1 (latest revision), *Federal Employee Health Services*

4.1.10 DOE O 410.1 (latest revision), *Central Technical Authority Responsibilities Regarding Nuclear Safety Requirements*

4.1.11 DOE O 413.3 (latest revision), *Program and Project Management for the Acquisition of Capital Assets (including Code of Record)*

4.1.12 DOE O 414.1 (latest revision), *Quality Assurance*

4.1.13 DOE O 420.1 (latest revision), *Facility Safety*

4.1.14 DOE O 422.1 (latest revision), *Conduct of Operations*

4.1.15 DOE O 425.1 (latest revision), *Verification of Readiness to Start Up or Restart Nuclear Facilities*

4.1.16 DOE O 426.1 (latest revision), *Federal Technical Capability Program*

4.1.17 DOE O 426.2 (latest revision), *Personnel Selection, Training, Qualification, and Certification Requirements for DOE Nuclear Facilities*

4.1.18 DOE O 433.1 (latest revision), *Maintenance Management Program for DOE Nuclear Facilities*

4.1.19 DOE O 440.1 (latest revision) *Worker Protection Program for DOE (Including the National Nuclear Security Administration) Federal Employees*

4.1.20 DOE O 442.1 (latest revision), *Department of Energy Employee Concerns Program*

4.1.21 DOE O 450.2 (latest revision), *Integrated Safety Management*

4.1.22 DOE O 460.1 (latest revision), *Hazardous Material Packaging and Transportation Safety*

4.1.23 DOE O 470.3 (latest revision), *Design Basis Threat (DBT) Order*

4.1.24 DOE O, 541.1 (latest revision), *Appointment of Contracting Officers and Contracting Officer Representatives*

4.1.25 DOE Standard 1090 (latest revision), *Hoisting and Rigging*

4.1.26 Federal Acquisition Regulation

4.2 REFERENCES

4.2.1 ISO 9001:2008, *Quality management systems -- Requirements*

4.2.2 *Office of Environmental Management Integrated Safety Management System Description (ISMSD)*, April 2013

4.2.3 DOE-STD-1150 (latest revision), *Quality Assurance Functional Area Qualification Standard*

4.2.4 DOE-STD-1172 (latest revision), *Safety Software Quality Assurance Functional Area Qualification Standard*

4.2.5 DOE-HDBK-1221 (latest revision), *DOE Suspect/Counterfeit Items (S/CI) Resource Handbook*, August 2016

4.2.6 Standard Review Plan Review Modules

4.2.7 *Office of Environmental Management Interim Policy, Code of Record for Nuclear Facilities*

4.2.8 ISM-QAP Template Incorporating a Quality Assurance Program (QAP) with an Integrated Safety Management System (ISMS) Description

4.2.9 ASME V&V 20-2009, *Standard for Verification and Validation in Computational Fluid Dynamics and Heat Transfer*

4.2.10 DOE P 450.4 (latest revision), *Integrated Safety Management Policy*

4.2.11 ASME NQA-1-2004, *Quality Assurance Requirements for Nuclear Facility Applications*, and addenda through 2007

4.2.12 ASME NQA-1-2008, *Quality Assurance Requirements for Nuclear Facility Applications*, and addenda through 2009

4.2.13 DOE/EM/PCP/QA-2010-1, *Quality Assurance Guidance for Packaging of Radioactive and Fissile Materials*

4.2.14 *U.S. Department of Energy Office of Environmental Management Guidance Document for Integrating Quality Assurance During the Design and Construction Life Cycle*, EM QA Corporate Board deliverable

4.2.15 *U.S. Department of Energy Office of Environmental Safety and Quality Guidance for Commercial Grade Dedication*, EM QA Corporate Board deliverable

4.2.16 ASME NQA-1-2015, *Quality Assurance Requirements for Nuclear Facility Applications*

4.2.17 *Graded Approach Model and Expectation*, EM QA Corporate Board deliverable

4.2.18 EM Graded Approach with Examples (*in development*)

4.2.19 ASME NQA-1-2017, *Quality Assurance Requirements for Nuclear Facility Applications*

4.2.20 DOE G 414.1-1 (latest revision), *Management Assessment and Independent Assessment Guide*

4.2.21 DOE G 414.1-2 (latest revision), *Quality Assurance Program Guide*

4.2.22 DOE G 414.1-4 (latest revision), *Safety Software Guide for Use with 10 CFR 830 Subpart A, Quality Assurance Requirements, and DOE O 414.1C, Quality Assurance*

4.2.23 ANSI Z 1.13-1999, *Quality Guidelines Research*

5.0 DEFINITIONS AND ACRONYMS

5.1 No new definitions are created in this document. See requirements/references documents for applicable definitions.

5.2 Graded Approach is defined in the QA Rule and QA Order as the process of ensuring that the level of analysis, documentation, and actions used to comply with requirements are commensurate with:

1) The relative importance to safety, safeguards, and security;
2) The magnitude of any hazard involved;
3) The life cycle stage of a facility;
4) The programmatic mission of a facility;
5) The particular characteristics of a facility;
6) The relative importance of radiological and nonradiological hazards; and
7) Any other relevant factor.

5.3 **Hazard** is defined in the QA Rule and QA Order as: a source of danger (i.e., material, energy source, or operation) with the potential to cause illness, injury, or death to a person or damage to a facility or to the environment (without regard to the likelihood or credibility of accident scenarios or consequence mitigation).

5.4 **Nuclear facility** is defined in the QA Rule and QA Order as: a reactor or nonreactor nuclear facility where an activity is conducted for or on behalf of DOE and includes any related area, structure, facility, or activity to the extent necessary to ensure proper implementation of the requirements established by the QA Rule.

5.5 **Nonreactor nuclear facility** is defined in the QA Rule and QA Order as those facilities, activities or operations that involve, or will involve, radioactive and/or fissionable materials in such form and quantity that a nuclear or a nuclear explosive hazard potentially exists to workers, the public, or the environment, but does not include accelerators and their operations and does not include activities involving only incidental use and generation of radioactive materials or radiation such as check and calibration sources, use of radioactive sources in research and experimental and analytical laboratory activities, electron microscopes, and X-ray machines.

5.6 Use of the term "records" throughout this document refers to QA records unless otherwise noted.

5.7 Acronyms are defined upon first usage in this document.

6.0 EM CORPORATE RESPONSIBILITIES

EM places the responsibility for achieving quality in work products upon those performing the work, and the responsibility for verifying that quality was achieved upon the QA organizations. Implementation of QAP requirements is therefore the responsibility of

everyone including the individual performing the work. However, ultimate responsibility for QAP implementation, assessment, and improvement rests with senior management.

The Assistant Secretary for the Office of Environmental Management (EM-1) as the Secretarial Officer, retains the overall responsibility for the development, execution, and maintenance of the EM QAP and provides direction and resources for implementing management assessments within EM.

6.1 EM HQ Senior Official and EM Field Office Senior Official:

6.1.1 Provide adequate resources and qualified staff to develop and effectively implement an approved QAP governing the work under their purview.

6.1.2 Identify the senior management position assigned responsibility for development, execution, and maintenance of their respective QAP.

6.1.3 Submit the QAP to the designated DOE Approval Authority for review, comment resolution, and approval.

NOTE: Editorial changes to the QAP that do not reduce or change commitments, do not require submittal to the designated DOE Approval Authority.

6.1.4 The designated DOE Approval Authority is responsible for reviewing and approving or rejecting new and revised QAPs within their purview.

6.1.5 Perform an annual, or periodic as defined in the QAP, review of their QAP to determine if any changes are necessary to maintain QA program effectiveness.

6.2 Office of Safety, Security, and Quality Assurance

6.2.1 As delegated by EM-1, responsible for the development, maintenance, and revision of the EM QAP.

6.2.2 Responsible for supporting EM-1 and the Chief Technical Authority in the effective oversight and maintaining awareness of the implementation of quality programs (including software) at EM sites and Field Offices.

7.0 EM QA PROGRAM

EM HQ, EM Field Offices, and EM prime contractors will prepare a site-specific QAP that documents all QA requirements applicable to their scope of work. The respective QAP must describe how the QA criteria of the QA Rule and QA Order are satisfied. The organizational QAPs may use this EM QAP as a template. The implementation of requirements in program documents may be documented using a requirements traceability matrix or a Quality Implementation Plan (QIP) (see Attachment A for an example of a QIP).

The following sections of the EM QAP demonstrate how the requirements of the QA Order (for federal and contractor staff) and the QA Rule (for contractor staff) may be implemented using ASME NQA-1a-2009 or ISO 9001:2008 as the selected consensus standard combined with other DOE orders and standards. The tables in each section illustrate how the elements of these consensus standards, DOE orders, and DOE standards map to the DOE QA Criteria/Requirements. EM expectations not addressed in the consensus standards are

included for each section of this QAP. These expectations are derived from lessons learned, EM management directives, or other commitments. For Field Offices and contractors, these expectations serve as templates and not requirements. The Field Office and contractors may use the expectations presented in whole, in part, or develop their own expectations for inclusion in the associated QAP.

QAPs must do the following:

- Identify the QA program requirements applicable to all work being performed,
- Describe the graded approach used to implement those requirements,
- Select a consensus standard to support implementation of the requirements,
- Determine the applicability of the various sections of the consensus standard,
- Grade the implementation of the various sections of the consensus standard, and
- Flow down the applicable QA requirements and responsibilities throughout all levels of the organization.

EM differentiates between *applicability* determinations and *grading*. When developing a QA program for EM, the applicability of consensus standard elements must be determined before grading, consistent with contractual requirements for DOE orders and standards. Applicability determines which sections contained in the consensus standard must be applied to the items or activities being controlled by the QAP. Applicability determinations may result in sub-elements of consensus standards being applied to a scope of work while other sub-elements are not applied.

A graded approach is the process of ensuring that the level of analysis, documentation, and actions used to comply with a QA requirement are commensurate with: (1) the relative importance to safety, safeguards, and security; (2) the magnitude of any hazard involved; (3) the life cycle stage of a facility; (4) the programmatic mission of a facility; (5) the particular characteristics of a facility; (6) the relative importance of radiological and non-radiological hazards; and (7) any other relevant factor. A graded approach must be used, where appropriate, to implement the requirements of the QA Rule and QA Order and the basis of the graded approach used must be submitted to the appropriate approval authority for approval (e.g., via the QAP). Grading is not to be used for removing requirements of the QA Rule or QA Order.

When selecting a consensus standard for use in development and implementation of the QAP, organizations must understand that consensus standards alone will not be sufficient in and of themselves to meet the QA Order. For example, NQA-1 indicates that the standard addresses "work" as activities affecting quality. However, NQA-1 then indicates that DOE uses "work" more broadly than NQA-1 as the definition for DOE is derived from multiple sources in the QA Rule and QA Order. The individual organizations must ensure the requirements from the section/criterion in the QA Order are met, even when they are not met by the selected consensus standard. These QA requirements may be met by implementing DOE Orders, DOE standards, and contract requirements.

The following sections of EM-QA-001 are structured to provide a cross-walk table between the QA Order and QA Rule requirements, the recommended NQA-1 and ISO consensus standards, and associated DOE orders and standards that may be used in implementation of the QA requirements. The sections also provide General, EM-HQ, EM Field Office and Contractor expectations.

EM-HQ implements in a graded approach, the QA requirements from the QA Order, NQA-1a-2009, the general expectations, and the EM-HQ expectations of EM-QA-001 to ensure compliance with the QA Order. The link between ISMS and QA is shown in Attachment B and the specifics for Commercial Grade Dedication are discussed in Attachment C.

For EM Field Offices, EM-QA-001 serves as an example or template for the Field Office QAP. Field Offices should recognize that, consistent with DOE Order 226.1, some expectations contained within this document are better achieved by Field Office staff other than by the office's QA organization. While the EM Field Office may develop their own QAP with different or additional expectations, the sections of EM-QA-001 that would be applicable to the Field Offices for consideration include the cross-walk table, the General Expectations, and the EM Field Office Expectations. If the EM Field Office utilizes a different approach to this template, the Field Office must demonstrate compliance with the requirements of the QA Order in the associated QAP. A Field Office may also adopt the expectations from this QAP (EM-QA-001) by reference in their site QAP. This approach would require the Field Office QAP to only include the site specific information required in the QA Order such as organizational structure. The site QAP would still require approval by EM-HQ.

For contractors, EM-QA-001 also serves as an example or template for the contractor QAP. While the EM Contractors QAP may have different or additional expectations, the sections that would be applicable to contactors for consideration include the cross-walk table, General Expectations, and the Contractor Expectations. The contractors must make an informed decision on what to include in their QAP based on their scope of work. While this document provides a template, the contractors must ensure the appropriate requirements from the QA Rule and QA Order are appropriately addressed in the contractor QAP and that additional expectations are addressed where needed, based on the scope of work for the organization. The expectations in this QAP do not reduce the requirements associated with the QA Order or QA Rule.

7.1 CRITERION 1 - MANAGEMENT/PROGRAM

The purpose of a QA program is to ensure that quality of DOE products and services meet customers' expectations. Quality is assured and maintained through an effective QAP. Management support for planning, organization, resources, direction, and control is essential to QA. It is the role of senior management to establish and cultivate principles that integrate quality requirements into daily work. Management retains primary responsibility and accountability for the scope and implementation of the quality management system. However, every individual in the organization is responsible for achieving quality in their activities.

The following table illustrates the relationship between Criterion 1 Management/Program requirements of the QA Rule/ QA Order, other related DOE orders and standards, and relevant sections of the recommended consensus standards.

<table>
<tr><th colspan="2">Criterion 1 – Management / Program</th></tr>
<tr><td colspan="2">(a) Establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work.
(b) Establish management processes, including planning, scheduling, and providing resources for the work.</td></tr>
<tr><th colspan="2">Related DOE Orders/Standards</th></tr>
<tr><td colspan="2">• DOE Order 226.1 (latest revision), Implementation of Department of Energy Oversight Policy
• DOE Order 450.2 (latest revision), Integrated Safety Management
• DOE Policy 450.4 (latest revision), Integrated Safety Management Policy
• Department of Energy Acquisition Regulation</td></tr>
<tr><th colspan="2">Consensus Standards</th></tr>
<tr><th colspan="2">ASME NQA-1 Requirements (Recommended for HC2 and 3)</th></tr>
<tr><td>1 – Organization
100 – Basic
200 - 202 – Structure & Responsibility
300 – Interface Control</td><td>2 – Quality Assurance Program
100 – Basic
200 - 202 – Indoctrination & Training
300 - 305 – Qualification Requirements
400 – Records of Qualification
500 – Records
Applicable sections of Part II to supplement the applicable Part I requirements.</td></tr>
<tr><th colspan="2">ISO Requirements (Recommended for < HC3)</th></tr>
<tr><td colspan="2">4 - Quality Management System
5 - Management Responsibility
6 - Resource Management
8 – Measurement, analysis and Improvement</td></tr>
</table>

7.1.1 **General Expectations:**

- Senior Management within an Organization:
  - Be identified within their respective organization.
  - Retain responsibility for overall achievement of quality within the organization.
  - Provide adequate planning, scheduling, and resources to implement the requirements of the QAP utilizing the graded approach and document the basis for adequacy.
  - Endorse and submit the QAP to the designated approval authority.
  - Ensure that the QA organization reports to a management level such that the required authority and organizational freedom are provided, including sufficient independence from cost and schedule.

- Stop work when conditions warrant such action, identify compensatory measures to continue work with conditions, and corrective actions to lift the stop work.
- Develop and establish a QAP that meets the requirements of the QA Rule (contractor organizations) and QA Order (federal and contractor organizations), considering this EM QAP and the guidance provided in DOE G 414.1-2 (latest revision), *Quality Assurance Program Guide*, including program documents, and procedures.
- Ensure adequate QA coverage and staffing of qualified personnel to carryout QA and quality control assignments.

- Line Organizations:
  - Implement activities in accordance with the QAP.
  - Retain responsibility for the achievement of the quality performed by delegated organizations or individuals.
  - Stop work when conditions warrant such action.
- QA Organizations:
  - Verify that a process is in place to control activities affecting quality in accordance with appropriate requirements.
  - Stop work when conditions warrant such action.
- All Personnel/Workers
  - Conduct work through integrated and effective management systems.
  - Achieve and maintain quality in all work activities.
  - Stop work when conditions warrant such action.

7.1.2 **EM-HQ Expectations**

- EM-HQ will maintain documents that describe the EM-HQ functional responsibilities and authorities, and organizational lines of communications for activities affecting quality. Specifically, the EM line management organizational structure is found on the EM website at http://www.energy.gov/em/about-us. In addition, the Functions, Responsibilities and Authorities (FRA) document (EM HQ FRA) is used to ensure requirements are identified and associated responsibilities are assigned per DOE Order 450.2.
- The responsibility for development and implementation of this EM QAP, as defined in the QA Order, has been assigned by EM-1 to the Office of Safety, Security, and Quality Assurance.
- As delegated by EM-1, the Deputy Assistant Secretary for the Office of Safety, Security, and Quality Assurance approves the Field Office QAPs in accordance with the QA Order.

- EM-1 approves the EM QAP in accordance with the QA Order. The Deputy Assistant Secretary for the Office of Safety, Security, and Quality Assurance concurs with the EM QAP.
- Where appropriate, the Deputy Assistant Secretary for the Office of Safety, Security, and Quality Assurance delegates approval of QA Program documents to EM Field Managers for their Contractor Organizations (with conditions when warranted).
- The Office of Standards and QA is delegated development, implementation, and maintenance responsibility for EM-QA-001 at EM-HQ. This includes oversight of implementation of EM-QA-001 at EM-HQ.
- The Office of Standards and QA serves as the authority for interpretation of EM-QA-001.
- All EM-HQ personnel are familiar with, implement, and facilitate achievement of the management processes defined in this QAP and the EM-HQ specific QIP.
- EM-HQ management establishes and implements QA processes and procedures for EM-HQ mission-related activities in a controlled manner.
- Lines of communication, feedback mechanisms, and interfaces with stakeholders, regulators, EM-HQ, EM Field Offices, and support organizations are established and documented.
- Consistent with ISMS principles, EM-HQ ensures processes are implemented such that resources are planned, scheduled, and allocated to accomplish work.
- Ensure oversight processes are implemented at EM-HQ in accordance with DOE Order 226.1 to evaluate DOE programs and management systems, including site assurance systems, for effectiveness of performance.
- Support EM-1 in ensuring Field Elements perform effective oversight in all relevant areas in accordance with DOE Order 226.1.
- Support the Central Technical Authority in maintaining awareness of the implementation of requirements in accordance with DOE Order 226.1.
- The Office of Safety, Security, and QA is responsible for coordinating, tracking, trending, and development of an integrated schedule for all EM-HQ oversight per the EM-HQ assurance system.

7.1.3 **EM Field Office Expectations**

- The Field Office Manager is responsible to assure adequate planning, scheduling, and resources are provided to implement the QA program.
- When delegated, approve the QA Program documents for their Contractor Organizations.
- Develop, submit to the approval authority, and implement a QAP including description of the graded approach that will be used in implementation of the QAP.

- Maintain documents that describe the Field Organization functional responsibilities and authorities, and organizational lines of communications for activities affecting quality.
- Ensure oversight processes are implemented at the Field Office in accordance with DOE Order 226.1 to evaluate all Field Office programs and management systems, including site assurance systems, for effectiveness of performance.
- Evaluate contractor and DOE programs and management systems, including site assurance systems, for effectiveness of performance in accordance with DOE Order 226.1 and hold personnel accountable for implementing those programs and processes.

7.1.4 **Contractor Expectations**

- Develop, submit to the DOE, and implement a QAP including description of the graded approach that will be used in implementation of the QAP.
- Per the QA Order, submit a QAP to DOE for approval within 90 days of being awarded a DOE contract and when changes are made to the QAP. Editorial changes, that do not reduce or change commitments, do not require approval. The QAP must be approved prior to execution of field work.
- Flow-down applicable requirements, to the extent necessary, to subcontractors at any tier, as well as vendors, and suppliers to ensure the contractor's compliance with the requirements and the safe performance of work. Note that this flow-down may include the specific requirements that need implemented via the contract and not flow-down of the entire consensus standard used by the contractor.
- Management establishes and implements processes and procedures in a controlled manner which include tasks or activities such as research and development; manufacturing; operations; environmental remediation; maintenance and repair; administration; software (including safety software) development, validation, testing, and use; inspection; safeguards and security; or, data collection and analysis.
- Implement a CAS in accordance with DOE Order 226.1 and flow down the requirements of DOE Order 226.1 to subcontractors at any tier to the extent necessary to ensure the contractor's compliance with the requirements.
- Monitor and evaluate all work performed under the contract, including the work of subcontractors, to ensure work performance meets the applicable requirements for environment, safety, and health, including QA and integrated safety management; safeguards and security; cyber security; emergency management; property; business; and financial matters.
- Ensure all nonreactor nuclear facilities (as defined in the QA Rule) meet the QA rule and the QA Order.

7.2 CRITERION 2 - MANAGEMENT/PERSONNEL TRAINING AND QUALIFICATION

Personnel indoctrination, training, and qualification processes are implemented in a manner that ensures personnel are appropriately indoctrinated, trained, and qualified prior to

performing activities within the scope of the QAP. Managers are responsible for ensuring personnel are fully qualified for their positions. The method and process for ensuring personnel are trained, qualified and capable of performing assigned work are identified in training and qualification procedures.

The following table illustrates the relationship between Criterion 2 Management/Personnel Training and Qualification requirements of the QA Rule/QA Order, other related DOE orders and standards, and relevant sections of the recommended consensus standards.

Criterion 2 – Management/Personnel Training and Qualification
(a) Train and qualify personnel to be capable of performing their assigned work. *(b) Provide continuing training to personnel to maintain their job proficiency.*
Related DOE Orders/Standards
• DOE Order 341.1 (latest revision), *Federal Employee Health Services* (applicable to Federal Employees only) • DOE Order 413.3 (latest revision), *Program and Project Management for the Acquisition of Capital Assets* • DOE Order 420.1 (latest revision), *Facility Safety* • DOE Order 426.1 (latest revision), *Federal Technical Capability Program* (applicable to Federal Employees only) • DOE Order 426.2 (latest revision), *Personnel Selection, Training, Qualification, and Certification Requirements for DOE Nuclear Facilities* • DOE Order 440.1 (latest revision), *Worker Protection Program for DOE (Including the National Nuclear Security Administration) Federal Employees* (applicable to Federal Employees only) • DOE Order 442.1 (latest revision), *Department of Energy Employee Concerns Program* • DOE Order, 541.1 (latest revision), *Appointment of Contracting Officers and Contracting Officer Representatives* (applicable to Federal Employees only)
Consensus Standards
ASME NQA-1 Requirements (Recommended for HC2 and HC3)
2 – Quality Assurance Program 100 – Basic 200 - 202 – Indoctrination and Training 300 - 305 – Qualification Requirements 400 – Records of Qualification 500 – Records Applicable sections of Part II to supplement the applicable Part I requirements.
ISO Requirements (Recommended for < HC3)
6 – Resource Management

7.2.1 **General Expectations**

- Line Organizations:
  - Train and qualify personnel to be capable of performing their assigned work.

- Provide continuing training to personnel to maintain their job proficiency.
- Implement general training requirements (e.g., DOE orders etc).

7.2.2 **EM-HQ Expectations**

- Develop training in accordance with DOE Order 426.1 (current revision), as appropriate.
- Identify EM-HQ employees/positions required to complete qualification under the qualification programs based on DOE requirements (e.g., DOE Orders).
- Ensure identified EM-HQ employees complete qualification under the qualification programs as required by DOE requirements (e.g., DOE Orders).
- Maintain qualifications via designated databases [e.g., TQP, Project Management Career Development Program (PMCDP), CO, COR].
- Federal EM-HQ personnel responsible for the oversight of quality requirements governing defense nuclear facilities are qualified in accordance with DOE-STD-1150-2013 (or latest version), *Quality Assurance Functional Area Qualification Standard*.
- Federal EM-HQ personnel responsible for oversight of safety software QA activities of defense nuclear facilities are qualified in accordance with DOE-STD-1172-2011 (or latest version), *Safety Software Quality Assurance Functional Area Qualification Standard*.
- Ensure EM-HQ personnel meet Field Office and/or Contractor site access training, as appropriate, when visiting a field office or contractor site.

7.2.3 **EM Field Office Expectations**

- Develop training in accordance with DOE Order 426.1A, as appropriate.
- Identify EM Field Office employees/positions required to complete qualification under the qualification programs based on DOE requirements (e.g., DOE Orders).
- Ensure identified EM Field Office employees complete qualification under the qualification programs as required by DOE requirements (e.g., DOE Orders).
- Maintain qualifications via designated databases (e.g., TQP, PMCDP, CO, COR).
- Federal EM field office personnel responsible for the oversight of quality requirements governing defense nuclear facilities are qualified in accordance with DOE-STD-1150-2013 (or latest version), *Quality Assurance Functional Area Qualification Standard*.
- Federal EM field office personnel responsible for oversight of safety software QA activities of defense nuclear facilities are qualified in accordance with DOE-STD-1172-2011 (or latest version), *Safety Software Quality Assurance Functional Area Qualification Standard*.
- Ensure Field Office personnel meet site access training, as appropriate.

7.2.4 **Contractor Expectations**

- Develop training in accordance with DOE Order 426.2 (latest revision), as appropriate.
- Maintain a process for identifying and determining competency requirements for personnel performing work and ensure personnel are trained, qualified and capable of performing assigned work. This process is identified in training and qualification procedures.
- Ensure identified contractor employees complete specified competency requirements.
- Maintain documents for contractor employees' competency requirements.
- Ensure specialized design, engineering, construction, and operational training include formal and informal training, education, and developmental and other learning assignments.
- Qualifications for specific job categories are based on requirements established by the organization's personnel management, DOE directives, other requirement documents, or management.
- Management reviews and documents the positions within their organization to:
  - Determine if critical and unique job functions or tasks require highly technical, specialized skills.
  - Determine whether competency is demonstrated before performance or within a specified timeframe after entering the position.
  - Determine whether a specialized certification may be required.
  - Determine whether a practical, physical, and/or written examination process should be established for qualification requirements that provide evidence of employee proficiency.
  - Develop a training implementation matrix or training program description in accordance with DOE O 426.2 and implement the results.

7.3 CRITERION 3 - MANAGEMENT/QUALITY IMPROVEMENT

Assessments and other operational awareness processes are critical to detect, identify, communicate, and prevent quality issues in an effective and timely manner. Effective quality improvement of these issues requires a issues management system that ensures issues are identified, categorized, and tracked, and that measures are implemented to correct and close these issues in a timely manner.

The following table illustrates the relationship between Criterion 3 Management/Quality Improvement, requirements of the QA Rule/QA Order, other related DOE orders and standards, and relevant sections of the recommended consensus standards.

<table>
<tr><th colspan="2">Criterion 3 – Management / Quality Improvement</th></tr>
<tr><td colspan="2">(a) Establish and implement processes to detect and prevent quality problems.
(b) Identify, control, and correct items, services, and processes that do not meet established requirements.
(c) Identify the causes of problems, and include prevention of recurrence as a part of corrective action planning.
(d) Review item characteristics, process implementation, and other quality related information to identify items, services, and processes needing improvement.</td></tr>
<tr><th colspan="2">Related DOE Orders/Standards</th></tr>
<tr><td colspan="2">• DOE Order 226.1 (latest revision), Implementation of Department of Energy Oversight Policy
• DOE Order 227.1 (latest revision), Independent Oversight Program
• DOE Order 232.2 (latest revision), Occurrence Reporting and Processing of Operations Information
• DOE Order 450.2 (latest revision), Integrated Safety Management
• DOE Policy 450.4 (latest revision), Integrated Safety Management Policy
• Department of Energy Acquisition Regulation</td></tr>
<tr><th colspan="2">Consensus Standards</th></tr>
<tr><th colspan="2">ASME NQA-1 Requirements (Recommended for HC2 and HC3)</th></tr>
<tr><td>2 – Quality Assurance Program
100 – Basic
200 - 202 – Indoctrination and Training
300 - 305 – Qualification Requirements
400 – Records of Qualification
500 – Records</td><td>15 – Control of Nonconforming Items
100 – Basic
200 – Identification
300 – Segregation
400 - 405 – Disposition
16 – Corrective Action
100 – Basic
Applicable sections of Part II to supplement the applicable Part I requirements.</td></tr>
<tr><th colspan="2">ISO Requirements (Recommended for < HC3)</th></tr>
<tr><td colspan="2">5 – Management Responsibility
8 – Measurement, Analysis, and Improvement</td></tr>
</table>

7.3.1 **General Expectations**

- All Personnel:
  - Stop work when conditions warrant such action.
  - Use established systems developed by the organization as appropriate for the work activities.
- Senior Management within an Organization:
  - Sets performance goals and standards.
  - Establishes metrics that monitor project/program performance to identify processes needing improvement.

  - Ensure the issues management program serves to ensure issues are corrected and, where necessary, actions put in place to preclude recurrence.

- Line Organizations:
  - Develop and implement corrective actions and issues management processes in accordance with DOE Order 226.1.
  - Verify that tracking and trending of issues to identify and prevent recurrence is being performed.

7.3.2 **EM-HQ Expectations**

- Using a graded approach, monitor and evaluate work of EM-HQ, EM field offices, and as appropriate, EM-HQ prime contractors.
- Monitor Performance Objectives, Measures and Commitments (POMC) and Performance Evaluation and Measurement Plan (PEMP) oversight by EM field offices as appropriate.
- Maintain an issues management process to track issues identified by EM-HQ at the EM field office, prime contractor, and EM-HQ office.
- Coordinate tracking of HQ related issues in EM field office systems where appropriate.
- Ensure the EM-HQ issues management processes utilize and are consistent with DOE O 226.1, *Implementation of Department of Energy Oversight Policy*; DOE O 227.1, *Independent Oversight Program*; and DOE G 414.1-2B, *Quality Assurance Program Guide*.
- Ensure a process to determine the significance of identified issues is developed.
- Establish a process to utilize formal cause analysis based on the complexity of the identified significant issue.
- When required, identify and document causes using a disciplined methodology for cause identification and ensure the analysis is performed by properly trained and qualified personnel. Reference DOE Order 232.2A, *Occurrence Reporting and Processing of Operations Information*.
- For significant conditions, perform an Extent of Condition and extent of cause determination and include prevention of recurrence as a part of corrective action planning.
- Evaluate proposed corrective actions to ensure they will effectively address the underlying QA performance issues.
- Independently verify completed actions as appropriate.

7.3.3 **EM Field Office Expectations**

- Using a graded approach, utilize proper functional area expertise to monitor and evaluate work of prime contractors.

- Maintain an issues management process to track field office issues.
- Utilize the contractor's CAS as an important and integral role in ensuring effective contractor performance.
- Review and approve POMCs submitted by the contractor.
- Evaluate the contractor PEMP to promote process improvement as appropriate.

7.3.4 **Contractor Expectations**

- Monitor and evaluate all work performed under their contracts, including the work of subcontractors to ensure performance meets applicable requirements.
- Maintain a structured issues management process for issues (as required by the CAS of DOE Order 226.1).
- The insights and results provided by the CAS per DOE Order 226.1 should be leveraged to the extent possible to facilitate continuous quality improvement.
- On an annual basis, review and update, for DOE approval, safety performance objectives, performance measures, and commitments consistent with and in response to DOE's program and budget execution guidance and direction
- Perform in accordance with the PEMP, as appropriate, to ensure effective and efficient performance.
- Provide specific processes to address problems with potential programmatic or safety significance or that are widespread, continuing, multiple, or repetitive in nature.

7.4 CRITERION 4 - MANAGEMENT/DOCUMENTS AND RECORDS

Quality and services are prescribed by and performed in accordance with approved program documents. A records system is established by the responsible organization at the earliest practicable time consistent with the schedule for accomplishing activities.

The requirements in this document for quality records are implemented in addition to the Federal laws [e.g., National Archives and Records Administration (NARA)] and DOE requirements.

The following table illustrates the relationship between Criterion 4 Management/Documents and Records, requirements of the QA Rule/QA Order, other related DOE orders and standards, and the relevant sections of the recommended consensus standards.

Criterion 4 – Management / Documents and Records
(a) Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design. *(b) Specify, prepare, review, approve, and maintain records.*
Related DOE Orders/Standards
• DOE Order 243.1 (latest revision), *Records Management Program*
Consensus Standards

Relevant ASME NQA-1 Requirements (Recommended for HC2 and HC3)	
5 – Instructions, Procedures, & Drawings 100 – Basic **6 – Document Control** 100 – Basic 200 – Document Control 300 - 302 – Document Changes	**17 – Quality Assurance Records** 100 – Basic 200 – Generation of Records 300 – Authentication of Records 400 - 402 – Classification 500 – Receipt Control of Records 600 - 603 – Storage 700 – Retention 800 – Maintenance of Records Applicable sections of Part II to supplement the applicable Part I requirements.
ISO Requirements (Recommended for < HC3)	
4 – Quality Management System	

7.4.1 **General Expectations**

- Line Organizations:
  - Maintain and deploy policies, procedures, and plans in a manner that makes current revisions readily available to the users.
  - Create, maintain, and disposition quality records in accordance with Federal law (e.g., 44 U.S.C. and 36 CFR), DOE requirements (e.g., QA Order and DOE Order 243.1), and the selected consensus standard.

7.4.2 **EM-HQ Expectations**

- Maintain and implement a process for identifying and controlling EM-HQ records, (including letters of direction, memorandum, emails), in accordance with selected consensus standards, Federal laws, and DOE requirements (e.g., QA Order and DOE Order 243.1). For example, this includes maintenance of TQPs in the e-TQP, PMCDP qualifications in the Acquisition Career Management Information System, contracting qualifications in the Federal Acquisition Institute Training Application System, and contract direction.
- New or revised requirements are analyzed to determine impact on implementing procedures and affected documents are revised to address changes, as appropriate.
- Procedures identify records that are created and maintained in the implementation of the procedure.
- Identify records on a File Plan including the proper categorization and the QA records cutoff, if longer than the DOE Records Disposition Schedule cutoff.
- EM HQ personnel performing work prepare, collect, protect, and retain Federal records in a manner that ensures records are retrievable, useable, and auditable.
- Documents that describe the methods for implementing the requirements of this QAP are identified and maintained current.

- When the records become inactive, the responsible personnel transfer the records to inactive records storage that meets Federal law and DOE requirements, and the records are maintained for their retention period in accordance with the DOE Records Disposition Schedules.

7.4.3 **EM Field Office Expectations**

- Maintain and implement a process for identifying and controlling EM field office records, (including letters of direction, memorandum, emails), in accordance with selected consensus standards, Federal laws, and DOE requirements (e.g., QA Order and DOE Order 243.1). For example, this includes maintenance of TQPs in the e-TQP, PMCDP qualifications in the Acquisition Career Management Information System, contracting qualifications in the Federal Acquisition Institute Training Application System, and contract direction.
- New or revised requirements are analyzed to determine impact on implementing procedures and contracts. Affected documents are revised to address changes, as appropriate.
- Field office procedures identify records that are created and maintained in the implementation of the procedure.
- Identify records on a File Plan including the proper categorization and the QA records cutoff, if longer than the DOE Records Disposition Schedule cutoff.
- Field office personnel performing work prepare, collect, protect, and retain Federal records in a manner that meets selected consensus standards, Federal laws, and DOE requirements (e.g., QA Order and DOE Order 243.1).
- Documents that describe the methods for implementing the requirements of the field office QAP are identified and maintained current.

7.4.4 **Contractor Expectations**

- Maintain and implement a process for identifying and controlling records in accordance with selected consensus standards, Federal laws, and DOE requirements (e.g., QA Order and DOE Order 243.1).
- New or revised directives are analyzed to determine impact on implementing procedures and contracts. The contractor should notify DOE of any requirements that are not appropriate for the execution of the scope of work. Affected documents are revised to address changes, as appropriate, for any new or revised directives added to the contract.
- Contractor documents that describe the methods for implementing requirements are identified and maintained current.
- Identify records on a File Plan including the proper categorization and the QA records cutoff, if longer than the DOE Records Disposition Schedule cutoff.

- Contractor personnel performing work prepare, collect, protect, and retain Federal records in a manner that meets selected consensus standards, Federal laws, and DOE requirements (e.g., QA Order and DOE Order 243.1).
- Contractor documents identify records that are created in implementation of the document and properly control those records (e.g., Federal laws, consensus standard, and DOE requirements)

7.5 CRITERION 5 - PERFORMANCE/WORK PROCESSES

EM assigns implementation authority for these activities through contracts and/or technical direction. EM monitors these practices to ensure proper implementation through oversight and assessment activities.

The following table illustrates the relationship between Criterion 5 Performance/Work Processes, requirements of the QA Rule/QA Order, other related DOE orders and standards, and the relevant sections of the recommended consensus standards.

Criterion 5 – Performance / Work Processes
(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. *(b) Identify and control items to ensure proper use.* *(c) Maintain items to prevent damage, loss, or deterioration.* *(d) Calibrate and maintain equipment used for process monitoring or data collection*
Related DOE Orders/Standards
• DOE Order 226.1 (latest revision), *Implementation of Department of Energy Oversight Policy* • DOE Order 420.1 (latest revision), *Facility Safety* • DOE Order 422.1 (latest revision), *Conduct of Operations* • DOE Order 425.1 (latest revision), *Verification of Readiness to Start Up or Restart Nuclear Facilities* • DOE Order 433.1 (latest revision), *Maintenance Management Program for DOE Nuclear Facilities* • DOE Order 450.2 (latest revision), *Integrated Safety Management* • DOE Policy 450.4 (latest revision), *Integrated Safety Management Policy* • DOE Standard 1090-2011, *Hoisting and Rigging* • Department of Energy Acquisition Regulation
Consensus Standards
ASME NQA-1 Requirements (Recommended for HC2 and HC3)

5 – Instructions, Procedures, & Drawings 100 – Basic **8 – Identification and Control of Items** 100 – Basic 200 - 202 – Identification Methods 300 - 303 – Specific Requirements **9 – Control of Special Processes** 100 – Basic 200 - 203 – Process Control 300 – Responsibility 400 – Records **12 – Control of Measuring & Test Equipment** 100 – Basic 200 – Selection 300 - 304 – Calibration and Control 400 - 402 – Records	**13 – Handling, Storage, and Shipping** 100 – Basic 200 – Special Requirements 300 – Procedures 400 – Tools and Equipment 500 – Operators 600 – Marking or Labeling **14 – Inspection, Test, & Operating Status** 100 – Basic **15 – Control of Nonconforming Items** 100 – Basic 200 – Identification 300 – Segregation 400 - 405 – Disposition Applicable sections of Part II to supplement the applicable Part I requirements.
ISO Requirements (Recommended for < HC3)	
4 – Quality Management System **7 – Product Realization** **8 – Measurement, Analysis, and Improvement**	

7.5.1 **General Expectations**

- Line Organizations:
  - Perform work in accordance with approved plans and procedures.
  - Maintain inventories of all software used in their organization.

7.5.2 **EM-HQ Expectations**

- EM-HQ performs routine work under QA Order Criteria 5 (a); however, EM-HQ does perform work under QA Order Criterion 5 (b), (c), and (d) as part of information technology and institutional software programs. EM-HQ assigns implementation authority for other activities through contracts and technical direction.
- Monitor and evaluate work of EM-HQ, EM field offices, and as appropriate, EM-HQ prime contractors using the EM-HQ assurance system to ensure proper implementation of the Work Processes requirements.
- Comply with EM Field Office and Prime Contractor procedures and requirements when observing field activities.
- As needed, implement a SQA program for EM-HQ software (see Attachment E of this QAP for more details).

7.5.3 **EM Field Office Expectations**

- EM Field Offices typically perform work under QA Order Criterion 5 (b), (c), and (d) only as part of information technology and institutional software programs. EM Field Offices assign implementation authority for other activities through contracts and technical direction.
- Field Office personnel monitor and evaluate work of EM field offices and Prime Contractors using the Field Office oversight processes and contractor's assurance systems to ensure proper implementation of the Work Processes requirements.
- Field Office personnel ensure proper implementation of the contractor's CAS per DOE Order 226.1.
- Comply with Contractor procedures and requirements when observing field activities.
- As needed, implement a SQA program for Field Office software (see Attachment E for more details).

7.5.4 **Contractor Expectations**

- Implement Work Process requirements per contract for all work activities.
- As needed, implement a SQA program for contractor software (see Attachment E for more details).
- Implement and control computer models (see Attachment F for more details).

7.6 CRITERION 6 - PERFORMANCE/DESIGN

EM assigns authority for design through contracts and/or technical direction. Where authority for design has been assigned, the role of EM HQ and Field Office organizations is monitoring design practices to ensure proper implementation through oversight activities.

The following table illustrates the relationship between Criterion 6 Performance/Design requirements of the QA Rule/QA Order, other related DOE orders and standards, and the relevant sections of the recommended consensus standards.

Criterion 6 – Performance/Design
a) Design items and processes using sound engineering/ scientific principles and appropriate standards. *b) Incorporate applicable requirements and design bases in design work and design changes.* *c) Identify and control design interfaces.* *d) Verify or validate the adequacy of design products using individuals or groups other than those who performed the work.* *e) Verify or validate work before approval and implementation of the design.*
Related DOE Orders/Standards
• DOE Order 413.3 (latest revision), *Program and Project Management for the Acquisition of Capital Assets* (including Code of Record) • DOE Order 420.1 (latest revision), *Facility Safety*

Consensus Standards	
ASME NQA-1 Requirements (Recommended for HC2 and HC3, required for safety software)	
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	Applicable sections of Part II to supplement the applicable Part I requirements.
ISO Requirements (Recommended for < HC3, not to be used for safety software)	
7 – Product Realization	

7.6.1 **General Expectations**

- Ensure design requirements are defined, controlled, and verified.
- Ensure design activities are consistent with DOE EM mission goals. Specifically, ensure design activities consider the potential life span, purpose, and hazards of the facility and do not implement unnecessary activities and requirements.

7.6.2 **EM-HQ Expectations**

- Where appropriate, monitor EM Field Offices and Prime Contractors to ensure proper implementation of the requirements associated with this criterion from the QA Order.
- Perform responsibilities designated in DOE Order 413.3B, such as:
  - EM-1 serves as the Project Management Executive (PME) for projects designated per DOE Order 413.3B and delegates that authority where appropriate.
  - Project Management Executive, as defined in DOE Order 413.3B, designates a Design Authority for all capital project nuclear facilities.
  - Appoint and obtain approval from the Project Management Executives for individuals serving as a Federal Project Director.
- Provide recommendations for the Field Office with respect to approval and configuration control of the Code of Record.
- EM-HQ typically performs work under QA Order Criterion 6 only as part of information technology and institutional software programs. EM-HQ assigns implementation authority for other activities through contracts and technical direction.

7.6.3 **EM Field Office Expectations**

- Where appropriate, monitor Prime Contractors to ensure proper implementation of the requirements associated with this criterion from the QA Order.

- Perform responsibilities designated in DOE Order 413.3B and delegated by EM-HQ, such as:
  - Direct initial project planning and execution roles for projects assigned by the PME.
  - Perform functions as a Project Management Executive when so delegated.
- EM Field Offices typically perform design work only as part of information technology and institutional software programs. EM Field Offices assign implementation authority for other activities through contracts and technical direction.
- When performing design work t (e.g., serving as the design authority), the EM Field Office will be responsible for implementing applicable design processes and requirements.
- Ensure the contractor maintains configuration control of the Code of Record throughout the CD process and for the remainder of the nuclear facility's life-cycle.
- Ensure the contractor performs design verification.
- Ensure design technical specifications for procurement are consistent with the design requirements to meet the DOE-EM mission and are appropriate for the end use of the item or service.

7.6.4 **Contractor Expectations**

- Ensure design requirements are validated and traceable to the implementation in design.
- Ensure the basis for the chosen approach is technically justified when design approaches deviate from consensus approaches in appropriate standards (DOE Standards, consensus standards, etc.).
- Ensure personnel using design analysis software are trained or knowledgeable in the use of the specific computer program being used and the software meets applicable SQA requirements.
- Obtain approval from the design authority for any change to the design bases.
- Ensure the current configuration of the facility is documented in drawings, specifications, procedures, and other appropriate documents for design and construction activities/projects.
- Ensure designs are based on appropriate national standards and industry recognized engineering practices.
- Utilize the Code of Record as a management tool and source of requirements to design and construct nuclear facilities using a graded approach.
- Maintain configuration control of the Code of Record throughout the CD process and for the remainder of the nuclear facility's life-cycle.
- Incorporate applicable design bases in design work and design changes.
- Identify and control design interfaces.

- Implement design reviews using individuals or groups other than those who performed the work.
- Implement a design control system/process.
- Perform design verification including:
  - Identifying and documenting the particular design verification method(s) used.
  - Ensure design verifications are performed by competent individuals other than those who performed the original design.
  - Ensure design verification is completed prior to releasing the design for procurement, manufacture, construction, or use by another design organization, or in special cases where this is not possible, the unverified portion of the design is identified and controlled.
  - Ensure design verification is completed prior to relying upon the component, system, structure, or computer program to perform its function.
  - Ensure any modifications to the design are verified prior to release or use.
  - Evaluate the needed extent of the design verification using a graded approach.
- Ensure design technical specifications for procurement are consistent with the design requirements to meet the DOE-EM mission and are appropriate for the end use of the item or service.

7.7 CRITERION 7 - PERFORMANCE/PROCUREMENT

The applicable QA requirements are flowed down to subcontractor, supplier, and vendor organizations during the procurement process. The procuring organization retains overall responsibility for ensuring the quality of the procured items or services. Note the technical requirements are determined by engineering and subject matter experts not QA personnel. QA personnel ensure the work is performed correctly given the requirements determined by the subject matter experts. Identification of proper specifications and technical requirements is essential for effectiveness of the procurement.

The following table illustrates the relationship between the Criterion 7 Performance/Procurement requirements of the QA Rule/QA Order, other related DOE orders and standards, and the relevant sections of the recommended consensus standards.

Criterion 7 – Performance/Procurement
(a) Procure items and services that meet established requirements and perform as specified. *(b) Evaluate and select prospective suppliers on the basis of specified criteria.* *(c) Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services.*
Related DOE Orders/Standards
• Federal Acquisition Regulation • Department of Energy Acquisition Regulation
Consensus Standards

ASME NQA-1 Requirements (Recommended for HC2 and HC3)	
4 – Procurement Document Control 100 – Basic 200 – 207 Content of Procurement Documents 300 – Procurement Document Review 400 – Procurement Document Changes	**7 – Control of Purchased Items & Services** 100 – Basic 200 – Supplier Evaluation and Selection 300 – Bid Evaluation 400 – Control of Supplier-Generated Documents 500 – 507 Acceptance of Item or Service 600 – Control of Supplier Nonconformances 700-705 Commercial Grade Items & Services 800 – Records Applicable sections of Part II to supplement the applicable Part I requirements.
ISO Requirements (Recommended for < HC3)	
7 – Product Realization	

7.7.1 **General Expectations**

- Procuring Organizations:
  - Specify appropriate requirements in contracts to assure adequate quality is included or referenced in documents for procurement of items and services consistent with importance and/or complexity of the item or service being procured.
  - Specify appropriate technical requirements in the procurement documents. Note that this flow-down may include the specific elements that need implemented via the contract (e.g., appropriate test or inspection) and not flow-down of the entire consensus standard used by the procuring organization.
  - When plans or program documents are required as part of an offeror's response to procurement documents, they are reviewed by qualified personnel during the evaluation process.

7.7.2 **EM-HQ Expectations**

- Ensure EM field office contracts reflect the applicable requirements.
- Ensure applicable requirements are included in Prime Contracts with EM-HQ. Normally EM-HQ support service contractors work under the EM-HQ QAP and EM-HQ Prime Contractors work under an EM-HQ approved QAP.
- Ensure a graded approach is utilized in determining the level of analysis, documentation, and actions used to comply with the requirements.
- Ensure a QA Contract Clause, consistent with Attachment D, is included in new contracts to address the requirements for higher-level contract quality from the Federal Acquisition Regulations.

7.7.3 **EM Field Office Expectations**

- Ensure contracts reflect the applicable requirements.
- Ensure applicable QA requirements are included in contracts. Support service contractors normally work under the field office QAP and Prime Contractors work under a DOE approved QAP.
- Ensure a graded approach is utilized in determining the level of analysis, documentation, and actions used to comply with the requirements.
- As appropriate, evaluate the flow-down of applicable requirements from Prime Contractors to subcontractors.
- Ensure a QA Contract Clause, consistent with Attachment D, is included in new contracts to address the requirements for higher-level contract quality from the Federal Acquisition Regulations.

7.7.4 **Contractor Expectations**

- Ensure only applicable sections of the selected consensus standard are used in the development and implementation of the QAP, consistent with regulatory and contractual requirements.
- Utilize a graded approach in determining the level of analysis, documentation, and actions used to comply with the requirements.
- Flow-down applicable requirements to subcontractors, vendors, and suppliers to ensure compliance with the DOE approved QAP. Note that this flow-down may include the specific elements that need implemented via the contract and not flow-down of the entire consensus standard used by the contractor. However, all work must be performed in compliance with the DOE approved QAP.
- Ensure applicable requirements for Suspect/Counterfeit Items are addressed in procurements.
- Implement an effective integrated procurement process (including development of a clear statement of work planned for subcontracting by the prime contractor and associated QA requirements, subcontractor evaluation and selection process, and subcontractor work performance monitoring).
- As applicable and as required by DOE Order 413.3 (latest revision), utilize an acquisition strategy to ensure work is accomplished in compliance with applicable laws, acquisition regulations, state/Federal regulations, and DOE Orders and directives, and is responsive to the project or facility specifications and needs.
- Maintain ultimate responsibility for complying with the requirements regardless of whether work is self-performed or performed by lower tier subcontractors.

7.8 CRITERION 8 - PERFORMANCE/INSPECTION AND ACCEPTANCE TESTING

Tests and inspections are a critical element to ensuring structures, systems, components, and software meet established requirements. The process for inspection and acceptance testing must address the requirements from the QA Order and the selected consensus standard.

The following table illustrates the relationship between the requirements of Criterion 8 Performance/Inspection and Acceptance Testing requirements of the QA Rule/QA Order, other related DOE orders and standards, and the relevant sections of the recommended consensus standards.

<table>
<tr><th colspan="2">Criterion 8 – Performance / Inspection and Acceptance Testing</th></tr>
<tr><td colspan="2">a) Inspect and test specified items, services, and processes using established acceptance and performance criteria.
b) Calibrate and maintain equipment used for inspections and tests.</td></tr>
<tr><th colspan="2">Related DOE Orders/Standards</th></tr>
<tr><td colspan="2">• DOE Order 433.1 (latest revision), Maintenance Management Program for DOE Nuclear Facilities</td></tr>
<tr><th colspan="2">Consensus Standards</th></tr>
<tr><th colspan="2">ASME NQA-1 Requirements (Recommended for HC2 and HC3)</th></tr>
<tr><td>3 – Design Control
100 – Basic
200 – Design Input
300 – Design Process
400 - 402 – Design Analysis
500 -501.3 – Design Verification
600 - 601.9 – Change Control
700 – Interface Control
800 - 802.3 – Software Design Control
900 – Documentation and Records
8 – Identification & Control of Items
100 – Basic
200 - 202 – Identification Methods
300 - 303 – Specific Requirements
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</td><td>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
12 – Control of Measuring & Test Equipment
100 – Basic
200 – Selection
300 - 304 – Calibration and Control
400 - 402 – Records
14 – Inspection, Test, & Operating Status
100 – Basic
Applicable sections of Part II to supplement the applicable Part I requirements.</td></tr>
<tr><th colspan="2">ISO Requirements (Recommended for < HC3)</th></tr>
<tr><td colspan="2">7 – Product Realization</td></tr>
</table>

8 – Measurement, Analysis, and Improvement

7.8.1 **General Expectations**

- Line Organizations
  - Conduct measures to prevent introduction of suspect/counterfeit items.
- QA Organization:
  - Verify hold and witness points are included in inspections and tests.

7.8.2 **EM-HQ Expectations**

- This criterion is generally not applicable to EM-HQ since federal employees do not typically perform inspection or testing functions. EM-HQ typically assign implementation authority for this criterion through contracts and technical direction.
- When EM-HQ owns software, ensure acceptance testing of software is in accordance with the applicable requirements from the QA Order (see Attachment E of this QAP for more detail).
- Monitor EM Field Offices through assessment and oversight activities to ensure proper implementation of the requirements associated with this criterion from the QA Order. Include review of contractor activities to the extent necessary to evaluate the implementation and effectiveness of the Field Office's oversight of its contractors.

7.8.3 **EM Field Office Expectations**

- This criterion is generally not applicable to EM field offices since federal employees do not typically perform inspection or testing functions. EM field offices typically assign implementation authority for this criterion through contracts and technical direction.
- When the EM Field Office owns software, ensure acceptance testing of software is in accordance with the applicable requirements from the QA Order (see Attachment E of this QAP for more detail).
- As appropriate, monitor EM Prime Contractors through assessment and oversight activities to ensure proper implementation of requirements. A key element of these activities is to ensure the Prime Contractors implement a CAS per DOE Order 226.1.

7.8.4 **Contractor Expectations**

- Ensure that tests and inspections are planned and executed by qualified personnel to demonstrate that items/components perform satisfactorily in service.
- Ensure measures are established such that equipment used in activities affecting quality are properly controlled and calibrated.
- Ensure performance expectations are defined by applicable industry standards, codes, safety basis, associated risk, etc.
- Ensure acceptance testing of software is in accordance with the applicable requirements from the QA Order (see Attachment E of this QAP for more detail).

- Consistent with contractual provisions, conduct inspections and tests to verify that physical and functional aspects of items, services, and processes meet requirements and that systems and components are acceptable and fit for use.
- Implement a calibration program to ensure instrument/equipment readings for process and quality control are appropriate.
- Conduct oversight functions performed of functional areas, as well as their supply chain, e.g., subcontractors, fabricators, vendors, and suppliers. Define performance expectations by utilizing applicable industry standards, codes, design documents, specifications, inspection and acceptance test requirements and implementing procedures.

7.9 CRITERION 9 - ASSESSMENT/MANAGEMENT ASSESSMENT

Management assessments are conducted on a periodic basis to evaluate effectiveness of all levels within an organization. The management assessment program encompasses the overall evaluation of an organization's systems and processes in comparison with their mission, responsibilities, and priorities.

The following table illustrates the relationship between Criterion 9 Assessment/Management Assessment requirements of the QA Rule/QA Order, other related DOE orders and standards, and the relevant sections of the recommended consensus standards.

Criterion 9 – Assessment / Management Assessment	
Ensure that managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives.	
Related DOE Orders/Standards	
• DOE Order 226.1 (latest revision), *Implementation of Department of Energy Oversight Policy*	
Consensus Standards	
ASME NQA-1 Requirements (Recommended for HC2 and HC3)	
2 – Quality Assurance Program 100 – Basic **16 – Corrective Action** 100 – Basic	*Note: NQA-1-2008 with 2009 addendum does not fully address management assessments.*
ISO Requirements (Recommended for < HC3)	
5 – Management Responsibility **8 – Measurement, Analysis, and Improvement**	

7.9.1 General Expectations

- Organization Management:
  - Participate in management assessments within their organization relevant to their mission, responsibilities, and priorities.

- Use management assessments to verify that roles and responsibilities are known and understood, processes and procedures are effectively implemented, appropriate measurement systems are in place and functional, evidence of continuous improvement is readily available, procedures are being complied with, organizational activities are consistent with the mission, and customer requirements and expectations are satisfied.
- Use management assessments as one of the means for identifying areas needing correction and/or improvement.
- Ensure management assessments are performed by personnel knowledgeable in the subject area and trained in assessment techniques.
- Ensure issues from management assessments are documented and tracked to ensure the issues are corrected and trended as appropriate.

7.9.2 **EM-HQ Expectations**

- Ensure all levels of management actively participate in the performance of management assessments.
- Ensure that management assessments evaluate the processes under the cognizance of the manager directly responsible for the work activities.
- Ensure the results of management assessments are documented, corrected, tracked, and trended.
- Consider use of applicable portions of DOE Guide 414.1-1C, *Management and Independent Assessments Guide*.

7.9.3 **EM Field Office Expectations**

- Ensure all levels of management actively participate in the performance of management assessments.
- Ensure that management assessments evaluate the processes under the cognizance of the manager directly responsible for the work activities.
- Ensure the results of management assessments are documented, corrected, tracked, and trended.
- Consider use of applicable portions of DOE Guide 414.1-1C, *Management and Independent Assessments Guide*.

7.9.4 **Contractor Expectations**

- Ensure all levels of management actively participate in the performance of management assessments.
- Ensure that management assessments evaluate the processes under the cognizance of the manager directly responsible for the work activities.
- Ensure the results of management assessments are documented, corrected, tracked in accordance with the requirements of the CAS.

- Consider use of applicable portions of DOE Guide 414.1-1C, *Management and Independent Assessments Guide*.

7.10 CRITERION 10 - ASSESSMENT/INDEPENDENT ASSESSMENT

Independent assessments involve review, evaluation, surveillance, or audit to determine whether items, processes, systems, or services meet specified requirements and perform effectively.

The following table illustrates the relationship between Criterion 10 Assessment/Independent Assessment requirements of the QA Rule/QA Order, other related DOE orders and standards, and the relevant sections of the recommended consensus standards.

<table>
<tr><th colspan="2">Criterion 10 – Assessment / Independent Assessment</th></tr>
<tr><td colspan="2">(a) Plan and conduct independent assessments to measure item and service quality, to measure the adequacy of work performance, and to promote improvement.
(b) Establish sufficient authority and freedom from line management for independent assessment teams.
(c) Ensure persons who perform independent assessments are technically qualified and knowledgeable in the areas to be assessed.</td></tr>
<tr><th colspan="2">Related DOE Orders/Standards</th></tr>
<tr><td colspan="2">• DOE Order 226.1 (latest revision), Implementation of Department of Energy Oversight Policy</td></tr>
<tr><th colspan="2">Consensus Standards</th></tr>
<tr><th colspan="2">ASME NQA-1 Requirements (Recommended for HC2 and HC3)</th></tr>
<tr><td>1 – Organization
100 – Basic
200 - 202 – Structure & Responsibility
300 – Interface Control
2 – Quality Assurance Program
100 – Basic
200 - 202– Indoctrination & Training
300 - 305 – Qualification Requirements
400 – Records of Qualification
500 – Records</td><td>16 – Corrective Action
100 – Basic
18 – Audits
100 – Basic
200 – Scheduling
300 - 303 – Preparation
400 – Performance
500 – Reporting
600 – Response
700 – Follow-up Action
800 – Records
Applicable sections of Part II to supplement the applicable Part I requirements.</td></tr>
<tr><th colspan="2">ISO Requirements (Recommended for < HC3)</th></tr>
<tr><td colspan="2">5 – Management Responsibility
8 – Measurement, Analysis, and Improvement</td></tr>
</table>

7.10.1 General Expectations

- Line Organizations:

  - Perform assessments independent of the work being conducted.
- QA Organizations
  - Conduct independent assessments to verify implementation of appropriate processes.
- Organization Management:
  - Ensure issues from management assessments are documented and tracked to ensure the issues are corrected and trended as appropriate.

7.10.2 **EM-HQ Expectations**

- Ensure independent assessments are planned on a periodic basis for all program elements applicable to the organization.
- Ensure independent assessments are conducted by individuals independent of the work or process being evaluated.
- Ensure independent assessments are performed by personnel knowledgeable in the subject area and properly trained.
- Ensure the results of independent assessments are documented, corrected, tracked, and trended.
- Ensure the EM Field Office programs are reviewed on a periodic basis not to exceed three years.
- Consider use of applicable portions of DOE Guide 414.1-1C, *Management and Independent Assessments Guide*.

7.10.3 **EM Field Office Expectations**

- Ensure independent assessments are planned on a periodic basis for all program elements applicable to the organization.
- Ensure independent assessments are conducted by individuals independent of the work or process being evaluated.
- Ensure independent assessments are performed by personnel knowledgeable in the subject area and properly trained.
- Ensure the results of independent assessments are documented, corrected, tracked, and trended.
- Ensure the EM Prime Contractor QA programs are reviewed on a periodic basis not to exceed three years.
- Consider use of applicable portions of DOE Guide 414.1-1C, *Management and Independent Assessments Guide*.
- Develop and implement a comprehensive plan and schedule to independently assess and conduct audits of Prime Contractor organizations against technical, programmatic, administrative, contractual, and quality program requirements.

7.10.4 **Contractor Expectations**

- Ensure independent assessments are planned on a periodic basis for all program elements applicable to the organization.
- Ensure independent assessments are conducted by individuals independent of the work being evaluated.
- Ensure independent assessments are performed by personnel knowledgeable in the subject area and properly trained.
- Ensure the results of independent assessments are in accordance with the requirements of the CAS.
- Utilize independent assessments to validate the effectiveness of the CAS.
- Ensure the CAS includes a method for validating the effectiveness of the assurance system processes. The CAS may include third party audits, peer reviews, independent assessments, and external certification to complement, but not replace, internal assurance systems.
- Consider use of applicable portions of DOE Guide 414.1-1C, *Management and Independent Assessments Guide*.
- Develop and implement a comprehensive plan and schedule to independently assess and conduct audits of organizations against technical, programmatic, administrative, and quality program requirements.
- Consider a formal cause analysis for significant issues based on a graded approach.

8.0 ATTACHMENTS

Attachment A – Quality Assurance Implementation Plan
Attachment B – Integrated Safety Management System
Attachment D – Quality Assurance Contract Clause
Attachment C – Dedication of Commercial Grade Items and Services (EM Guidance)
Attachment E – Software Quality Requirements
Attachment F – Model Development, Use, and Validation
Attachment G - QA Requirements Supplemental to NQA-1 QA Programs for Application to High-Level Waste Custodians
Attachment H – Revision History

ATTACHMENT A – QUALITY ASSURANCE IMPLEMENTATION PLAN

The QIP defines the linkages to each QA criterion and will identify applicable procedures and documents that directly implement the applicable requirements of the QAP. A QIP may be developed using the example QIP below as a template and may be included in the organization's QAP or may be a stand-alone document. The specific organization performs a gap analysis to determine the necessary procedures and documents for their specific needs. This is included within their QIP with reference to procedures as required. QIPs are not required to list revisions of the instructions, procedures, plans, and drawings being used to implement the requirements. Verification of procedures and documents listed in the QIP can be performed during the review and approval of the QIP, and/or during the ongoing management and independent assessment process. EM sites will incorporate additional site-specific and consensus standard requirements into their QIP based on activities being performed. If additional standards are required to address specific QA requirements, the standards will also be identified within the QIP. This QIP serves as an example that may be used by the Field Offices and contractors if so desired.

EXAMPLE QA IMPLEMENTATION PLAN

QA Order Criteria	Processes	Procedures and Documents
Criterion 1 – Management/Program		
a) Establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work.	Planning Scheduling Resource Allocation Graded Approach Consensus standard Application	EM Organization Chart EM Strategic Plan EM Mission and Function Statement EM FRA Definitions & Acronyms EM QAP
b) Establish management processes, including planning, scheduling, and providing resources for the work.		
Criterion 2 – Management/Personnel Training and Qualification		
a) Train and qualify personnel to be capable of performing their assigned work.	Training Technical Qualification Professional Qualification	Training and Qualification for Federal Employees Technical Qualification Program
b) Provide continuing training to personnel to maintain their job proficiency.		
Criterion 3 – Management/Quality Improvement		
a) Establish and implement processes to detect and prevent quality problems.	Oversight Facility Tours Walkthroughs Work Observation Document Reviews Meeting Attendance & Participation Ongoing Interaction w/Contractor w/Workers, Support w/Staff, & Mgt Site Visits Facility Assessments Operations Assessments Program Assessments Contractor Assurance Systems Worker & Customer Feedback Causal & Root Cause Analysis Corrective Actions Improvement Actions Performance Evaluations Trending Analysis Verifications & Validations Assessments	EM Oversight and Assessment Program EM Issues/Action Management System Operating Experience/Lessons Learned
b) Identify, control, and correct items, services, and processes that do not meet established requirements.		
c) Identify the causes of problems, and include prevention of recurrence as a part of corrective action planning.		
d) Review item characteristics, process implementation, and other quality related information to identify items, services, and processes needing improvement.		

QA Order Criteria	Processes	Procedures and Documents
Criterion 4 – Management/Documents and Records		
a) Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design.	Document Control Records Management	Preparation, Review, Approval, Revision, and Distribution of EM Implementing Procedures Records Management Policy Vital Records Identification and Protection Identifying, Filing & Maintaining Records File Plan Creation and Maintenance EM Records Disaster, Prevention, Mitigation, and Recovery Plan Electronic Records Management Disposition of Records
b) Specify, prepare, review, approve, and maintain records.		
Criterion 5 – Performance/Work Processes		
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.	QA Integrated Safety Management ISMS Cyber Security Emergency Management Business Operations	Preparation, Review, Approval, Revision, and Distribution of EM Implementing Procedures EM QAP EM Oversight and Assessment Program Regulatory Compliance documents (list) ISMS documents (list) Cyber Security documents (list) Emergency Management documents (list)
b) Identify and control items to ensure proper use.		
c) Maintain items to prevent damage, loss, or deterioration.		
d) Calibrate and maintain equipment used for process monitoring or data collection.		
Criterion 6 – Performance/Design		
a) Design items and processes using sound engineering/scientific principles and appropriate standards.	Not applicable to EM-HQ	Not applicable to EM-HQ
b) Incorporate applicable requirements and design bases in design work and design changes.		
c) Identify and control design interfaces.		
d) Verify or validate the adequacy of design products using individuals or groups other than those who performed the work.		
e) Verify or validate work before approval and implementation of the design.		
Criterion 7 – Performance/Procurement		
a) Procure items and services that meet established requirements and perform as specified.	Acquisition Planning Vendor Surveys Bid Evaluations Contractor Oversight Contract Admin Source Evaluation	Procurement Authorities, Delegations, and Responsibilities
b) Evaluate and select prospective suppliers on the basis of specified criteria.		

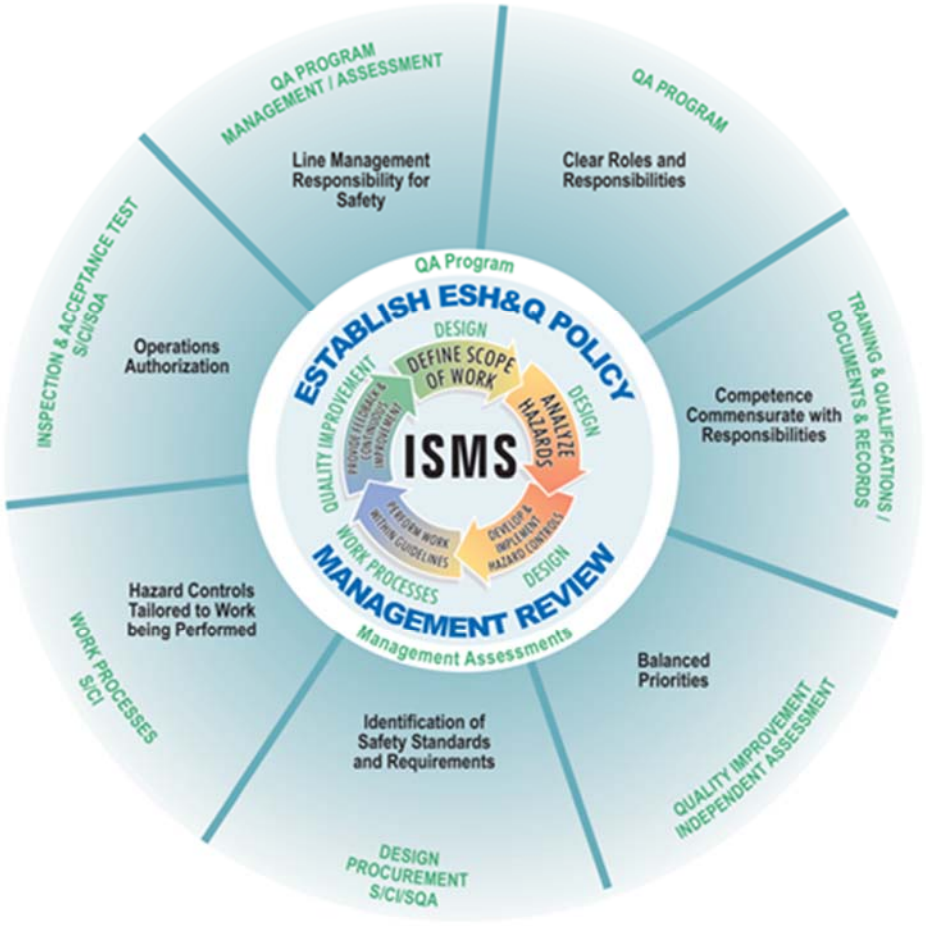
QA Order Criteria	Processes	Procedures and Documents
c) Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services.		
Criterion 8 – Performance/Inspection and Acceptance Testing		
a) Inspect and test specified items, services, and processes using established acceptance and performance criteria.	Not applicable to EM-HQ	Not applicable to EM-HQ
b) Calibrate and maintain equipment used for inspections and tests.		
Criterion 9 – Assessment/Management Assessment		
a) Ensure that managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives.	Assessment	EM Oversight and Assessment Program EM Issues/Action Management System Operating Experience/Lessons Learned
Criterion 10 – Assessment/Independent Assessment		
a) Plan and conduct independent assessments to measure item and service quality to measure the adequacy of work performance and to promote improvement.	Assessment	EM Oversight and Assessment Program EM Issues/Action Management System Operating Experience/Lessons Learned
b) Establish sufficient authority and freedom from line management for independent assessment teams.		
c) Ensure persons who perform independent assessments are technically qualified and knowledgeable in the areas to be assessed.		
QA Order Attachment 3 – Suspect/Counterfeit Items Prevention		
QA Order Attachment 4 – Safety Software Quality Requirements for Nuclear Facilities		
Corrective Action Management Program (by reference in the QA Order to DOE O 226.1, DOE O 227.1, and DOE G 414.1-2B.)		
	Reporting Findings Corrective Action Plan Tracking/Reporting Effectiveness Review Lessons Learned	EM Oversight and Assessment Program EM Issues/Action Management System Operating Experience/Lessons Learned

ATTACHMENT B – INTEGRATED MANAGEMENT SYSTEM

Integration of EM HQ, EM Field Offices, and EM contractor QAPs with other quality or management system requirements is expected to be consistent with DOE P 450.4A and associated Department of Energy Acquisition Regulation (DEAR) clauses.

Where specific additional quality or management system requirements are needed, integration is implemented and documented in the applicable QAP. An example QA/ISMS alignment wheel is provided below for consideration as an example of documenting system integration. Additional information can be found in the *ISM-QAP Template Incorporating a Quality Assurance Program (QAP) with an Integrated Safety Management System (ISMS) Description.*

EM QA Alignment with ISMS



QA Rule/DOE Order 414.1D/10 CFR 830, Subpart A & NQA-1 Alignment with ISMS

Competence Commensurate with Responsibilities
RULE-II,IV,IX,X
NQA-BR-1,2,3,4,6,10,11,15,16,17,18

Define Scope of Work
RULE-IV,V,VI,VII,VIII,IX,X
NQA BR-1,2,3,4,5,6,7,8,10,11,12,14,17,18

Analyze Hazards
RULE-IV,V,VI,VII,VIII,IX,X
NQA BR-1,2,3,4,5,6,7,8,9,10,11,12,14,15,16,17,18

Develop & Implement Hazard Controls
RULE-IV,V,VI,VII,VIII,IX,X
NQA-BR-1,2,3,4,5,6,7,8,9,10,11,12,14,15,16,17,18

Perform Work with Controls
RULE-II,V,VI,VIII
NQA-BR-2,3,6,8,9,10,11,12,13,14,18

Provide Feedback & Continuous Improvement
RULE-III,IV,V,VIII,IX,X
NQA-BR-3,4,6,8,9,12,13,14,17,18

Establish ES&H Policy
RULE-I,IV,V,VIII,IX
NQA-BR-1,2,3,4,6,8,9,12,13,14,17

Management Review
RULE-I,III,IV,IX
NQA-BR-1,2,3,4,6,15,16,17

Line Mgmt Responsible for Safety
RULE-I,IV,IX
NQA-BR-1,2,3,4,6,17

Clear Roles & Responsibilities
RULE-I,IV,IX,X
NQA-BR-1,2,3,4,6,10,11,15,16,17,18

Balanced Priorities
RULE-II,IV,IX,X
NQA-BR-2,3,4,6,10,11,12,15,16,18

Identification of Safety Standards & Requirements
RULE-IV,V,VI,VII,VIII,IX,X
NQA-BR-1,2,3,4,5,6,7,8,9,10,11,12,14,15,16,17,18

Hazard Controls Tailored to Work being Performed
RULE-IV,V,VI,VII,VIII,IX,X
NQA-BR-1,2,3,4,5,6,7,8,9,10,11,12,14,15,16,17,18

Suspect/Counterfeit Items (S/CI) QA Order - Att. 3

Safety Software Quality Assurance (SQA) - Att. 4

ASME NQA-1-2009(a) Part I

BR-1	Organization	BR-10	Inspection
BR-2	QA Program	BR-11	Test control
BR-3	Design Control	BR-12	Control of M&TE
BR-4	Procurement Document Control	BR-13	Handling, storage & shipping
BR-5	Instructions, Procedures & drawings	BR-14	Inspection test & operating status
BR-6	Document Control	BR-15	Control of nonconforming material
BR-7	Control of purchased items & services	BR-16	Corrective Action
BR-8	ID & Control of items	BR-17	QA Records
BR-9	Control of special processes	BR-18	Audits
		Part II - Subpart 2.7 - SQA	

BR = Basic Requirement & Supplemental Requirements as applicable

DOE 414.1D/10 CFR 830 Criteria

I. Program
II. Personnel Training & Qualification
III. Quality Improvement
IV. Documents & Records
V. Work Process
VI. Design
VII. Procurement
VIII. Inspection & Acceptance Testing
IX. Management Assessment
X. Independent Assessment
CRD - S/CI/SQA

Author: R.A. Carter, WCH

ATTACHMENT C – DEDICATION OF COMMERCIAL GRADE ITEMS AND SERVICES (EM GUIDANCE)

For programs utilizing NQA-1-2008 with 2009 addendum or later editions, EM has developed a document providing guidance for an acceptable Commercial Grade Dedication program. If the EM guidance is not used, the Commercial Grade Dedication programs must still demonstrate compliance with the selected and approved consensus standard. The EM guidance on Commercial Grade Dedication is *Guidance for Commercial Grade Dedication* dated August 2018.

ATTACHMENT D – QUALITY ASSURANCE CONTRACT CLAUSE

Clause without QARD:

E.3 FAR 52.246-11 Higher-Level Contract Quality Requirement (Dec 2014)

(a) The Contractor shall comply with the higher-level quality standard(s) listed below.

Quality Assurance Program (QAP) compliant with DOE O 414.1D, Change 1, *Quality Assurance*, for all facilities and activities. Additionally, nonreactor nuclear facilities (as defined in 10 CFR 830, *Nuclear Safety Management*, Section 830.3, *Definitions*) must be compliant with 10 CFR 830, *Nuclear Safety Management*, Subpart A, *Quality Assurance Requirements*. The Contractor shall utilize the Contractor Assurance System per DOE O 226.1B, *Implementation of Department of Energy Oversight Policy*, to monitor and evaluate all work performed under this Contract, including work of subcontractors, to ensure work performance meets the applicable requirements for environment, safety and health, including quality assurance and integrated safety management; safeguards and security; cyber security; and emergency management.

The QAP must describe how the quality assurance criteria from DOE O 414.1D and 10 CFR 830, Subpart A are satisfied. The Contractor shall use voluntary consensus standards in the development and implementation of the QAP, where practicable and consistent with contractual and regulatory requirements. Where appropriate, the Contractor must use a graded approach to implement the QAP that is commensurate with hazards, lifecycle of facilities and other risks. The basis of the graded approach utilized shall be documented and submitted to U.S. Department of Energy (DOE) for approval.

(1) For Hazard Category 1, 2, and 3 nuclear facilities:

(i) Existing facilities, or new facilities and major modifications to existing facilities achieving Critical Decision 1 (CD-1) prior to May 8, 2013, may continue to use the consensus standard cited in the DOE-approved QAP.

(ii) New facilities and major modifications to existing facilities achieving CD-1 use American Society of Mechanical Engineers (ASME) NQA-1-2008, *Quality Assurance Requirements for Nuclear Facility Applications*, with the NQA-1a-2009, *Quality Assurance Requirements for Nuclear Facility Applications Addenda 1a* (or a later edition), *Quality Assurance Requirements for Nuclear Facility Applications*, Part I and applicable requirements of Part II.

Note: where NQA-1, Part II language uses the terms “nuclear power plant” or “nuclear reactor”, these terms are considered equivalent to the term “nuclear facility.”

(iii) Consensus standard(s) that provide an adequate level of quality assurance and meet the intent of paragraphs (ii) above may be used. The QAP must document how the selected consensus standard is (or a set of consensus standards are) used, as well as how the selected consensus standard(s) is appropriate.

(2) For other activities and facilities (e.g., less than Hazard Category 3, non-nuclear, or chemically hazardous), the Contractor shall use, in whole or in part, appropriate standards. Examples of appropriate standards include:

(i) ASME NQA-1a-2009 addenda (or later edition), *Quality Assurance Requirements for Nuclear Facility Applications*, Part I and applicable requirements of Part II;

(ii) ASME NQA-1-2000, *Quality Assurance Requirements for Nuclear Facility Applications*, Part I and applicable requirements of Part II;

(iii) American National Standards Institute (ANSI)/International Organization for Standardization (ISO)/American Society for Quality (ASQ) Q9001-2008 (or later edition), *Quality Management Systems – Requirements*; and

(iv) ANSI/ASQ Z1.13-1999 (or later edition), *Quality Guidelines for Research*.

(b) The Contractor shall include applicable requirements of the higher-level quality standard(s) listed in paragraph (a) of this clause and the requirement to flow down such standards, as applicable, to lower-tier subcontracts, in—

(1) Any subcontract for critical and complex items (see 46.203(b) and (c)); or

(2) When the technical requirements of a subcontract require—

(i) Control of such things as design, work operations, in-process control, testing, and inspection; or

(ii) Attention to such factors as organization, planning, work instruction, documentation control, and advanced metrology.

Clause with QARD:

E.3 FAR 52.246-11 Higher-Level Contract Quality Requirement (Dec 2014)

(a) The Contractor shall comply with the higher-level quality standard(s) listed below.

Quality Assurance Program (QAP) compliant with DOE O 414.1D, Change 1, *Quality Assurance*, for all facilities and activities. Additionally, nonreactor nuclear facilities (as defined in 10 CFR 830, *Nuclear Safety Management*, Section 830.3, *Definitions*) must be compliant with 10 CFR 830, *Nuclear Safety Management*, Subpart A, *Quality Assurance Requirements*. The Contractor shall utilize the Contractor Assurance System per DOE O 226.1B, *Implementation of Department of Energy Oversight Policy*, to monitor and evaluate all work performed under this Contract, including work of subcontractors, to ensure work performance meets the applicable requirements for environment, safety and health, including quality assurance and integrated safety management; safeguards and security; cyber security; and emergency management.

The QAP must describe how the quality assurance criteria from DOE O 414.1D, 10 CFR 830, Subpart A, and the Quality Assurance Requirements and Description (QARD) (as applicable) are satisfied. The Contractor shall use voluntary consensus standards in the development and implementation of the QAP, where practicable and consistent with contractual and regulatory requirements. Where appropriate, the Contractor must use a graded approach to implement the QAP that is commensurate with hazards, lifecycle of facilities and other risks. The basis of the graded approach utilized shall be documented, and submitted to U.S. Department of Energy (DOE) for approval.

(1) For Hazard Category 1, 2, and 3 nuclear facilities:

(i) Existing facilities, or new facilities and major modifications to existing facilities achieving Critical Decision 1 (CD-1) prior to May 8, 2013 may continue to use the consensus standard cited in the DOE-approved QAP.

(ii) New facilities and major modifications to existing facilities achieving CD-1 use American Society of Mechanical Engineers (ASME) NQA-1-2008, *Quality Assurance Requirements for Nuclear Facility Applications*, with the NQA-1a-2009, *Quality Assurance Requirements for Nuclear Facility Applications Addenda 1a* (or a later edition), *Quality Assurance Requirements for Nuclear Facility Applications*, Part I and applicable requirements of Part II.

Note: where NQA-1, Part II language uses the terms “nuclear power plant” or “nuclear reactor”, these terms are considered equivalent to the term “nuclear facility.”

(iii)Consensus standard(s) that provide an adequate level of quality assurance and meet the intent of paragraphs (ii) above may be used. The QAP must document how the selected consensus standard is (or a set of consensus standards are) used, as well as how the selected consensus standard(s) is appropriate.

(2) For other activities and facilities (e.g., less than Hazard Category 3, non-nuclear, or chemically hazardous), the Contractor shall use, in whole or in part, appropriate standards. Examples of appropriate standards include:

(i) ASME NQA-1a-2009 addenda (or later edition), Quality Assurance Requirements for Nuclear Facility Applications, Part I and applicable requirements of Part II;

(ii) ASME NQA 1-2000, *Quality Assurance Requirements for Nuclear Facility Applications*, Part I and applicable requirements of Part II;

(iii) American National Standards Institute (ANSI)/International Organization for Standardization (ISO)/American Society for Quality (ASQ) Q9001-2008 (or later edition), *Quality Management Systems – Requirements*; and

(iv) ANSI/ASQ Z1.13-1999 (or later edition), *Quality Guidelines for Research*.

(b) The Contractor shall include applicable requirements of the higher-level quality standard(s) listed in paragraph (a) of this clause and the requirement to flow down such standards, as applicable, to lower-tier subcontracts, in—

(1) Any subcontract for critical and complex items (see 46.203(b) and (c)); or

(2) When the technical requirements of a subcontract require—

(i) Control of such things as design, work operations, in-process control, testing, and inspection; or

(ii) Attention to such factors as organization, planning, work instruction, documentation control, and advanced metrology.

ATTACHMENT E – SOFTWARE QUALITY REQUIREMENTS

The QA Order requires that all software meet the applicable QA requirements in Attachment 2 of the QA Order. Safety Software must meet the requirements in Attachment 2 and Attachment 4 of the QA Order, using a graded approach. The determination of what constitutes safety software should be made based on its application and the safety consequences of its postulated failure to perform its intended function. Since software can have both safety and non-safety applications, a determination should be made whether the non-safety application could adversely affect the safety application. This determination is also important where software is used to monitor radiological inventory as a means of categorizing a nuclear facility.

Software grading levels must be submitted to and approved by the QAP approval authority. The basis for the levels is documented within the QAP if requested by the QAP approval authority. EM considers the grading method contained in DOE Guide 414.1-4, *Safety Software Guide for Use with 10CFR 830 Subpart A, Quality Assurance Requirements, and DOE O 414.1C, Quality Assurance* to be an acceptable approach. Maintaining a previous DOE-approved approach to grading safety software is also an acceptable approach. EM will provide additional guidance and/or support for grading of software as deemed necessary based on the scope of the field office activities.

Another key area is acceptance of other software (software that is not safety software). Software that has not been previously approved under a program consistent with the QA Order for use in its intended application (e.g., freeware, shareware, procured commercial off-the-shelf, or otherwise acquired software), is evaluated to verify it performs its intended functions. The software is identified and controlled prior to evaluation. The evaluation is performed and documented to determine adequacy to support operation and maintenance and identify the activities to be performed and the documentation that is needed.

This determination is documented and identified as a minimum:

a) capabilities and limitations for intended use

b) test plans and test cases required to demonstrate the capabilities within the limitations

c) instructions for use within the limits of the capabilities

The results of the above evaluation and the performance of the actions necessary to accept the software are reviewed and approved. The resulting documentation and associated computer program(s) will establish the current baseline. Revisions to previously baselined software received from organizations will be evaluated in accordance with this attachment.

ATTACHMENT F – MODEL DEVELOPMENT, USE, AND VALIDATION

EM's computer models provide information that is needed to make decisions about how to clean up the radioactive and hazardous legacy material across the country. This attachment is included to provide EM requirements with respect to managing computer models.

- Model development and approaches to validation are planned, controlled, and documented. Planning for model validation identifies the validation methods and the validation criteria used. If model validation activities are completed after documentation of the model (i.e., using new confirmation test data gathered in the field or laboratory), these activities are described in the work-planning document.
- Documentation of models includes:
  - Definition of the objective (intended use) of the model.
  - Description of conceptual model and scientific basis, as well as alternatives for the selected conceptual model. Rationale for not selecting alternatives should also be included.
  - Results of literature searches and other applicable background information.
  - Identification of inputs and their sources.
  - Identification of, and rationale for, assumptions that are made to develop or apply the model, including model idealizations, as well as those assumptions that support the input to the model and impact model results.
  - Discussion of mathematical and numerical methods that are used in the model, including governing equations, formulas, and algorithms, and their scientific and mathematical bases.
  - Identification of any associated software used, computer calculations performed, and basis to permit traceability of inputs and outputs.
  - Discussion of initial and/or boundary conditions.
  - Discussion of model limitations (i.e., data available for model development, valid ranges of model application, spatial and temporal scaling).
  - Discussion of model uncertainties (e.g., conceptual model, mathematical model, process model, abstraction model, system model, parameters) and how they affect the model.
  - Identification of the originator, reviewer, and approver.
- The intended use of the model and the importance of the model is used to determine the appropriate level of confidence for a model (i.e., models of system components most relied upon are validated with the highest levels of confidence to the extent practical).
- Model validation criteria addresses the following:

- Criteria used to establish the adequacy of the scientific basis for the model are consistent with the model application and justified in the model documentation.
- Criteria are used to demonstrate that the model is sufficiently accurate for its intended use. Model documentation provides an accounting for uncertainties and variability in parameter values and provides the technical basis for parameter ranges, probability distributions, or bounding values used in process, abstraction, and system models.
- The importance of the model for assessing performance is defined.
- The relative level of confidence for the model is described.
- The supporting information needed to substantiate validation is defined.

- The usual progression of a model is from conceptual model to mathematical model to process model to abstraction model to system model. A conceptual model shall be validated when its implementation as a mathematical, process, abstraction, or system-level model is validated. Technical review through publication in a referenced professional journal or review by an external agency may be used to corroborate model validation when used in conjunction with one or more of the following:
  - Corroboration of model results with data acquired from field experiments, analogue studies, laboratory experiments, or subsequent relevant observations (i.e., referenced journals or literature). Data used to develop and calibrate a model shall not be used to validate a model.
  - Peer review or independent technical review.
  - Performance confirmation studies using validation test model predictions prior to comparison with field or laboratory data.
  - Comparison of model results with other results obtained from the implementation of an alternative validated model.

ATTACHMENT G – QA REQUIREMENTS SUPPLEMENTAL TO NQA-1 QA PROGRAMS FOR APPLICATION TO SPENT NUCLEAR FUEL AND HIGH-LEVEL WASTE CUSTODIANS

The purpose of this attachment is to provide flexibility by allowing programs subject to the *Quality Assurance Requirements and Description* (QARD) Document, DOE/RW-0333P, Revision 20 to meet those requirements utilizing a single program based on NQA-1a-2009 combined with this attachment. Implementation of existing programs that meet the QARD Document may be maintained and will remain compliant with this attachment and EM-QA-001.

100 GENERAL

This Attachment provides QA requirements for High-Level Waste (HLW) Custodians while producing, storing, or otherwise managing high-level waste.

This Attachment supplements the requirements of NQA-1a-2009 (or later) Part I and shall be used in conjunction with applicable sections of Part I of that standard. Some requirements in this Attachment reference Part III or Part IV sections of NQA-1-2017 rather than including the content of those sections verbatim within this Attachment. Not all these referenced sections existed in NQA-1a-2009, so the NQA-1-2017 section number references are used to maintain consistency with the current content and numbering scheme in the NQA standard.

DEFINITIONS

High-Level Waste:

(1) The highly radioactive material resulting from the reprocessing of spent nuclear fuel, including liquid waste produced directly in reprocessing and any solid material derived from such liquid waste that contains fission products in sufficient concentrations

(2) Irradiated reactor fuel

(3) Other highly radioactive material consistent with existing law that requires permanent isolation

Repository Owner: The Federal Agency or Office that is the Nuclear Regulatory Commission's (NRC) licensee for a HLW waste repository.

Waste Acceptance Elements (WAE): Items, activities, or services that affect or impact acceptance of the HLW by the repository owner.

HLW Custodian: An organization, excluding NRC licensed commercial nuclear utilities that is in possession of HLW prior to its planned disposition at a geologic repository.

REQUIREMENTS

200 Organization

201.1 Interface Control

Interfaces to other organizations or positions responsible for activities affecting quality of WAE shall be defined. The interface definitions shall include, at a minimum, responsibilities, information to be transferred, and any material transfers between the organizations.

202 Program

The QA program shall identify the WAE, to which these additional requirements apply. These elements include but are not limited to:

a) Structure, systems or components (SSCs) that are part of the waste isolation

b) activities related to SSCs, which include facility and equipment design and construction (i.e., designing, purchasing, fabricating, processes for handling, packaging, shipping, receiving, storing, cleaning, erecting, installing, inspecting, testing, maintaining, repairing, and modifying)

c) HLW forms

d) activities related to HLW forms including:

    1. HLW characterization
    2. acquisition, control, and analysis of samples and data
    3. tests and experiments
    4. scientific studies
    5. qualification of characterization inputs
    6. HLW performance confirmation
    7. conditioning, treatment, and/or canisterization

e) activities related to documenting compliance of HLW forms (i.e., waste form development through qualification, waste form production, and waste form acceptance)

f) records that demonstrate compliance with HLW acceptance criteria

Characterization measurements of HLW used solely for the purpose of satisfying safeguards-related material control and accountability requirements are not activities related to WAE but may be controlled under NQA-1 Part I requirements.

Waste custodians shall maintain an items and services list that are subject to this attachment. The process for resolution of disputes concerning quality of WAE shall be defined in the QA program.

A matrix or other similar cross-reference describing the relationship between this attachment and its implementation in procedures shall be maintained.

Periodic assessments that include independent technical experts to verify proper implementation of ongoing work related to WAE shall be performed.

Senior Management of waste custodians shall, on a biennial basis, perform or direct the performance of management assessments applied to WAE. These assessments shall be performed by personnel above or outside the QA organization, and shall evaluate the adequacy of resources and personnel devoted to the QA program.

202.1 Nondestructive Assay

Nondestructive assay methods for determining the acceptability of WAE are forms of Inspection and Test.

203 Design Control

The scope of design activities subject to Section 7.6 of this QAP, Design Control, shall include WAE. These activities shall include at a minimum:

a) engineered barriers that are WAE

b) software developed for use in WAE

c) features to facilitate monitoring and performance evaluation of WAE

203.1 Design Input

Data from scientific investigation activities not performed under this standard and used as design input shall be qualified using NQA-1-2017 Part IV Subpart 4.2.3 or an equivalent method approved by the repository owner. Data not qualified prior to use in a design product, shall be identified as such and tracked until qualified.

Design inputs based on assumptions or unqualified data that require confirmation shall be identified and controlled as the design proceeds.

203.2 Use of Computer Programs

Computer programs used in WAE shall be controlled in accordance with the software requirements contained in Attachment E of this QAP, considering these programs to be Safety Software.

Modeling activities used in WAE shall be controlled using Attachment F of this QAP.

203.3 Sampling Plans

Development of sampling plans for WAE is a design activity. The basis, including any supporting analyses, for the use of sampling plans shall be documented. Sampling plans for WAE shall be approved by the repository owner. At a minimum, sampling plans shall include:

a) description of the confidence interval and the rationale for its use

b) description of the representativeness of the sampling plan to the population as a whole

204 Procurement Document Control

This Attachment applies to procurement documents related to WAE including Interagency Agreements or other non-standard procurement documents.

204.1 Content of the Procurement Documents

Procurement documents shall include a requirement for suppliers to establish controls to mitigate the procurement and installation of counterfeit or fraudulent items.

Procurement documents shall identify procurement methods, responsibilities, and interfaces between the procurer and supplier.

204.2 Procurement Document Review

Procurement documents shall be reviewed by trained and qualified individuals or groups other than the one who generated the document. Reviews shall ensure that applicable requirements are correctly stated, verifiable, and controllable; there are adequate acceptance and rejection criteria; and the procurement document has been prepared, reviewed, and approved in accordance with the requirements of this section.

Procurement document review shall include participation of representatives from the technical organizations and individuals that are trained and qualified in QA practices and concepts.

204.3 Procurement Document Changes

Changes made as a result of proposal/bid evaluations or pre-contract negotiations shall be incorporated into the procurement documents. An evaluation of these changes and the resulting impact shall be completed before the contract is awarded. The evaluation shall consider:

a) appropriate requirements as specified in this section

b) additional or modified design criteria

c) analysis of exceptions or changes requested or specified by suppliers and a determination of the impact such changes have on the intent of the procurement documents or quality of the item or service to be furnished

204.4 Spare and Replacement Parts

WAE spare and replacement parts shall be subject to QA program controls, codes and standards, and technical requirements equal to or greater than the original requirements, or as required to preclude repetition of defects.

205 Instructions/Procedures/Drawings

Provisions for suspension of work that cannot be accomplished as described in controlled implementing documents shall be included in appropriate plans and procedures.

Instructions, procedures, and drawings used in WAE shall be consistent with the requirements delineated in the QA program description document and shall include the following information as appropriate to the work to be performed:

a) responsibilities and organizational interfaces of the organizations affected by the document

b) identification of the quality records generated by the implementing document

206 Document Control

Reviews of controlled documents shall be performed by knowledgeable individuals other than the preparer.

The document control program shall define retention of comments related to review and approval of documents consistent with their importance to WAE.

Effective dates shall be established for approved implementing documents.

206.1 Document Changes

Implementing documents shall require that a history of changes to QA program documents, including the reasons for the changes, be documented and maintained. This document history shall be reviewed each time additional changes to the document are proposed.

If an activity cannot be performed as prescribed in a document and the change process would cause unreasonable delays, an expedited change may be made at the work location by responsible management.

Implementing documents shall describe the process to control expedited changes according to the following requirements:

a) The level of management with the authority to make expedited changes shall be identified

b) The time limits for processing expedited changes through the normal change process shall be specified

c) An evaluation of the work shall be performed if the normal review process results in a change that is different from the expedited change

207 Control of Purchased Items and Services

When an Interagency Agreement or other such document serves as a procurement document between the waste custodian and other federal agencies, the technical and quality requirements, responsibilities, and interfaces specified in these documents shall be verified to be satisfactorily incorporated into the applicable federal agency's QA program description document prior to starting work.

207.1 Bid Evaluation

The proposal/bid evaluation process shall be performed by designated, technically-qualified individuals or organizations, including individuals that are trained and qualified in QA practices and concepts, and shall include:

a) technical considerations

b) QA program requirements

c) supplier personnel

d) supplier production capability

e) supplier past performance

f) alternatives

g) exceptions

207.2 Supplier Performance Evaluation

The purchaser of items and services shall establish measures to interface with the supplier to verify performance as deemed necessary by the purchaser. The measures shall include:

a) reviewing supplier documents that are prepared or processed during work performed to fulfill procurement document requirements

b) identifying and processing necessary change information

c) establishing the method to be used to document information exchanges between purchaser and supplier

d) establishing the extent of source surveillance and inspection

The extent of verifications shall be a function of the relative importance, complexity, and quantity of items or services being procured and supplier quality performance.

Verification activities shall be accomplished by qualified personnel assigned to check, inspect, audit, or witness supplier activities.

Verifications shall be conducted as early as practical and shall not relieve suppliers of their responsibility for quality achievement.

Verifications shall include the use of audits to evaluate supplier performance and evaluation of purchaser documentation to aid in the determination of the effectiveness of the supplier QA program. This documentation shall include documentation of source surveillance and inspections, audits, receiving inspections, non-conformances, dispositions, waivers, and corrective actions.

An annual performance evaluation shall be performed on each supplier to determine the need to schedule additional verifications. This evaluation shall be documented and based on:

a) review of supplier furnished documents and records (e.g., certificates of conformance, ASME Certificate of Authorization, ASME Quality System Certificate, nonconformance notices, and corrective actions)

b) results of previous source verifications, audits, management assessments, and receiving inspections, including results of audits performed by other parties

c) operating experience of identical or similar products furnished by the same supplier

The use of commercial grade items for WAE shall be controlled per Attachment F of this QAP.

208 Inspection

208.1 Inspection Planning

Inspection plans for WAE shall be developed and maintained as controlled documents. Representatives of the interested technical organizations and individuals that are trained and qualified in QA practices and concepts shall participate in developing and approving inspection plans.

Applicable codes, standards, specifications, and design documents shall be used to develop inspection plans.

The elements of inspection plans shall identify:

a) mandatory hold points, when required

b) measuring and test equipment (M&TE) to be used to perform the inspection to ensure the equipment is of the proper type, range, accuracy, and tolerance to accomplish the intended function

c) if applicable, identification of sampling plans developed in accordance with Section 203 of this attachment

d) methods to record inspection results

208.2 Records

Inspection records shall identify the specific M&TE used during the inspection including the most recent calibration date.

209 Test Control

209.1 Test Planning

Test plans and procedures for WAE shall be developed as controlled documents and include:

a) identification of the documents to be developed to control and perform tests

b) criteria for determining the precision and accuracy requirements of test equipment

c) the timing, sequencing, and methods for performing the tests

d) identification of the item to be tested and the test requirements and acceptance limits contained in applicable design and procurement documents

e) test prerequisites to include:

1. personnel qualifications
2. status of the item and status of other equipment or systems that may affect test performance
3. suitably controlled environmental conditions
4. provisions for data acquisition and storage

f) mandatory inspection hold points for witnessing by the designated organization

g) provisions for ensuring that test prerequisites have been met

209.2 Test Records

Test records shall identify the specific M&TE used during the test including the most recent calibration date.

210 Control of Measuring and Test Equipment

210.1 Calibration

The basis for the calibration acceptance shall be documented and authorized by responsible management. The level of management authorized to perform this function shall be identified.

Embedded computer programs developed or modified by the user shall be controlled in accordance with the software control requirements in Attachment E of this standard.

210.2 Records

M&TE calibration documentation used in verifying WAE shall include the following information:

a) identification of the measuring or test equipment calibrated

b) traceability to the calibration standard used for calibration

c) calibration data

d) identification of the individual performing the calibration

e) identification of the date of calibration and the recalibration due date or interval, as appropriate

f) results of the calibration and statement of acceptability

g) reference to any actions taken in connection with out-of-calibration or nonconforming M&TE, including evaluation results and repeated inspections or tests, as appropriate

h) identification of the implementing document (including revision level) used in performing the calibration

211 Control of Nonconforming Items

211.1 Identification.

Nonconformance documentation shall clearly identify and describe the characteristics that do not conform to specified criteria.

211.2 Disposition

Disposition of WAE that does not meet waste acceptance criteria shall be agreed to by the repository owner and the waste custodian.

212 Corrective Action

Measures shall be established to document, track, classify, report to appropriate levels of management, and resolve conditions adverse to quality.

Significant conditions adverse to quality shall be evaluated for a stop work condition by the QA Organization to determine whether stopping work is warranted. Stop work orders shall be issued to responsible management after a stop work condition has been identified on WAE. Management shall take appropriate action to lift and close (in part or total) the stop work issued based on the resolution of the related significant condition adverse to quality.

Responsible management shall perform investigative action to determine the extent and impact of conditions adverse to quality in WAE.

212.1 Quality Trending

Criteria shall be established for determining adverse quality trends on WAE.

Reports of nonconformances and conditions adverse to quality shall be evaluated to identify adverse quality trends.

Trend evaluation shall be performed in a manner and at a frequency that provides for prompt identification of adverse quality trends and assists in identifying root cause.

Trend evaluations shall be distributed in a timely manner for review and appropriate corrective action.

213 Records

Organizations originating QA records for WAE shall develop implementing documents that identify means for replacement, restoration, or substitution of lost or damaged QA records.

213.1 Records Classification

Lifetime QA records shall also include:

a) Those directly related to waste form or other items that will be supplied to the repository owner. These records shall be transferred to the repository owner for retention and maintenance.

b) Those that provide evidence of the quality of WAE.

c) Those that provide evidence of the quality of HLW characterization data and samples.

d) Those that provide evidence of the quality of the production process for the HLW and acceptability of the HLW product.

e) Those that provide evidence of the quality of those activities associated with characterization of waste being emplaced in the repository.

f) Those that provide evidence of those activities that provide data used to assess the potential dispersion of radioactive materials from the licensed facility.

Lifetime QA records related to items a) through f) above shall be retained and maintained by the waste custodian until transferred to the repository owner.

213.2 Electronic Records Systems

Electronic records systems used to store records of WAE shall be managed using NQA-1-2017 Part III Subpart 3.1-17.2 or an equivalent method approved by the repository owner.

214 Audits

214.1 Audit Plan

Audits and internal audits shall include technical evaluations of the applicable procedures, instructions, activities, and items.

214.2 Audit Scheduling

Audit at each waste generating site shall be conducted annually, unless a decrease in the frequency of oversight activities is determined acceptable by the repository owner based on the scope, performance, and complexity of work. In no case will the frequency be less than once every three years for a site performing work on WAE.

214.3 Personnel

The auditing organization shall select and assign auditors who are independent of any direct responsibility for performance of the activity being audited.

215 Scientific Investigations and Data Qualification

Scientific investigations used for WAE shall be performed using NQA-1-2017 Part IV Subpart 4.2.4 or an equivalent process approved by the repository owner.

Data acquisition and control applications integral to the operations, maintenance, or calibration of scientific investigation testing apparatus, shall be verified or validated in conjunction with the M&TE or test hardware as an operating unit.

Qualification of existing data, including data of indeterminate quality, for use in WAE shall be performed using NQA-1-2017 Part IV Subpart 4.2.3 or an equivalent method approved by the repository owner.

Peer reviews to qualify data or scientific information for use on WAE shall be performed using NQA-1-2017 Part IV Subpart 4.2.7 or an equivalent process approved by the repository owner.

ATTACHMENT H – REVISION HISTORY

Revision Number	Description of Changes	Date
0	Initial Issue	October 2008
1	Updated to address: • Changes in DOE O 414.1D • Adopt NQA-1-2008/2009 • Enhance and clarify management expectations • Include Transportation Quality Assurance • Include validation/verification of software and models	June 2012
2	Major revision/rewrite of the document.	April 2019