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

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1.0 PURPOSE AND OBJECTIVE

The purpose of this document is to describe the U.S. Department of Energy (DOE), Office of Environmental Management (EM) Quality Assurance Program (QAP). Our first priority is to "do work safely." In concert with this, it is also essential to "do work correctly" or both safety and quality are jeopardized. This QAP is the EM management system to ensure we plan, manage, implement, and monitor mission performance consistent with established regulatory and contractual specifications, i.e., "do work correctly." The QAP meets the requirements of 10 CFR 830 Subpart A *Quality Assurance Requirements* (i.e., QA Rule) and Department of Energy Order 414.1D, *Quality Assurance*, (i.e., QA Order). Although not strict requirements, the QAP also provides EM management expectations for implementing quality assurance (QA) across the EM complex. In this context, the EM QAP is sometimes referred to as the EM Corporate QAP. The QAP demonstrates how QA and the Integrated Safety Management System (ISMS) are fully integrated in EM per DOE P 450.4A, *Integrated Safety Management Policy*. In addition to DOE O 414.1D, this QAP also encompasses packaging and transportation QA requirements of DOE O 460.1C, *Packaging and Transportation Safety*. Details for the packaging and transportation part of the QA Program are found in Attachment A.

The objective of this QAP is to provide consistent QA implementation across EM while allowing for grading based on safety, importance to the EM mission, and project-specific complexity and risks. The QAP also allows for site-specific requirements to be addressed [e.g., 10 CFR Part 71, *Packaging and Transportation of Radioactive Material*; Environmental Protection Agency (EPA) requirements; state permit requirements; etc.].

2.0 SCOPE

The scope of the EM QAP is applied in a graded approach and encompasses:

- All work performed by EM within both federal offices [Headquarters (HQ) and Site Offices] and prime contractors, as well as their respective subcontractors, vendors, and suppliers.

- Project lifecycles including design, engineering, construction, commissioning, operation, and post-operation, e.g., surveillance and maintenance, deactivation, decommissioning, and environmental restoration.

3.0 APPLICABILITY

The requirements contained within this document apply to EM HQ, EM Field/Project Offices, and EM contractors (including flow down to subcontractors, vendors, and suppliers) as applicable to the work being performed by each entity. Each organization will have an organizational-specific Quality Assurance Implementation Plan (QIP) describing how the applicable requirements of this QAP are implemented and/or passed down to lower-tier organizations. This requirement does not alter personnel (i.e., federal, contractor, or subcontractor) legal obligations to comply with the QA Rule or other laws and regulations such as those regarding Federal Records. EM adopts American Society of Mechanical Engineers (ASME) NQA-1-2008, *Quality Assurance Requirements for Nuclear Facility Applications*, and addenda through 2009 (referred to as NQA-1a-2009 in the remainder of this document). It is expected that EM sites will incorporate additional site-specific and NQA-1 requirements into their QIP based on activities being performed (e.g., Federal repository-related work; Type B packages; special processes; inspections and tests; use of measuring and test equipment; etc.).

EM sites and projects requesting to use other standards or other versions of NQA-1 to demonstrate their implementation of the EM Corporate QAP are required to provide additional justification as noted in the following discussion:

For facilities, activities, or operations that meet the definition of a nonreactor nuclear facility in the QA Rule (note EM does not manage any nuclear reactor facilities), the requesting site or project must perform a risk-informed evaluation that clearly demonstrates that any identified gaps between the site or project's current QAP and NQA-1a-2009, do not represent any additional risks to quality of EM work, products, or services. This risk-informed evaluation will be documented using Attachment B, *QA Program Variance/Exemption Request* and submitted to the HQ Office of Standards and QA for review and approval**.** For those sites that use NQA-1-2004 with addenda through 2007, EM has completed the required review and concluded that the differences in the standard do not result in any additional risks to the quality of EM work, products or services. As such, a variance or exemption is not required to implement NQA-1-2004 with addenda through 2007. In addition, any projects that have an existing approved variance may continue to operate under that variance approval and no additional submittal is required.

For facilities, activities, or operations that do not meet the definition of a nonreactor nuclear facility in the QA Rule, the requesting site or project must prepare a justification to demonstrate why the nonreactor nuclear facility definition does not apply, including identification of the differing chosen consensus standard, and why the differing chosen consensus standard is deemed appropriate. The justification must be submitted to the appropriate approval authority (e.g., the DOE site office if the authority is delegated), along with the associated QAP/QIP that demonstrates compliance with the requirements of this

QAP. The approval authority will be responsible for concurring with the justification and approving the QAP/QIP for the site/project as discussed in Section 6.2.

For any site or project with an approved QAP that undergoes facility modifications or operational changes, the QAP must be evaluated to address any gaps created by the modification or operational change. A QAP revision that requires more than minor editorial changes must be submitted for review and approval by the appropriate EM approval authority (i.e., EM-HQ or site office).

4.0 REQUIREMENTS AND REFERENCES

4.1 REQUIREMENTS

4.1.1 10 CFR 830, Subpart A, *Quality Assurance Requirements* (i.e., QA Rule)

4.1.2 DOE O 414.1D, *Quality Assurance* (i.e., QA Order)

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

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

4.1.5 DOE O 226.1B, *Implementation of Department of Energy Oversight Policy*

4.1.6 DOE O 232.2, *Occurrence Reporting and Processing of Operations Information*

4.1.7 DOE O 227.1, *Independent Oversight Program*

4.1.8 DOE O 410.1, *Central Technical Authority Responsibilities Regarding Nuclear Safety Requirements*

4.1.9 DOE O 450.2, *Integrated Safety Management*

4.1.10 10 CFR Part 71, *Packaging and Transportation of Radioactive Material*

4.1.11 DOE O 460.1C, *Packaging and Transportation Safety*

4.2 REFERENCES

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

4.2.2 DOE G 414.1-1B, *Management Assessment and Independent Assessment Guide*

4.2.3 DOE G 414.1-2B, *Quality Assurance Program Guide*

4.2.4 DOE G 414.1-4, *Safety Software Guide*

4.2.5 DOE/EM/PCP/QA-2010-1, *Quality Assurance Guidance for Packaging of Radioactive and Fissile Materials* (http://rampac.energy.gov/PBoK.htm#DOE)

4.2.6 DOE P 450.4A, *Integrated Safety Management Policy*

4.2.7 *Office of Environmental Management Integrated Safety Management System Description (ISMSD)*

4.2.8 DOE-STD-1150-2002, *Quality Assurance Functional Area Qualification Standard*

4.2.9 DOE-STD-1172-2011, *Safety Software Quality Assurance Functional Area Qualification Standard*

4.2.10 IAEA-TECDOC-1169, *Managing Suspect and Counterfeit Items for the Nuclear Industry*

4.2.11 Standard Review Plan Review Modules, *http://www.em.doe.gov/Pages/StandardReviewPlanModules.aspx*

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

4.2.13 *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, http://www.em.doe.gov/Pages/QACorporateBoard.aspx.

4.2.14 U*.S. Department of Energy Office of Environmental Safety and Quality Guidance for Commercial Grade Dedication,* EM QA Corporate Board deliverable, http://www.em.doe.gov/Pages/QACorporateBoard.aspx.

4.2.15 *Graded Approach Model and Expectation,* EM QA Corporate Board deliverable, http://www.em.doe.gov/Pages/QACorporateBoard.aspx.

4.2.16 *ISM-QAP Template Incorporating a Quality Assurance Program (QAP) with an Integrated Safety Management System (ISMS) Description*, http://www.hss.doe.gov/nuclearsafety/qa/docs/ISM_QA_Integration_Template_Final_8-23-11.pdf

4.2.17 ANSI/ANS-10.2-2009, *Portability of Scientific and Engineering Software*

4.2.18 ANSI/ANS 10.4-2008, *Verification and Validation of Non-Safety-Related Scientific and Engineering Computer Programs for the Nuclear Industry*

4.2.19 ANSI/ANS-10.5-2011, *Accommodating User Needs in Scientific and Engineering Computer Software Development*

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

5.0 DEFINITIONS AND ACRONYMS

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

5.2 Acronyms are defined upon first usage in this document.

5.3 Use of "records" throughout this document refers to QA records unless otherwise noted.

6.0 RESPONSIBILITIES

The implementation of QAP requirements in accordance with applicable QIPs is the responsibility of the individual performing the work. However, ultimate responsibility for QAP implementation, assessment, and improvement rests with senior management.

6.1 EM-1 retains the overall responsibility for the development, execution, and maintenance of the EM Corporate QAP.

6.2 EM HQ Senior Official, EM Field/Project Office Senior Official, and EM Contractor Senior Manager:

6.2.1 Provide adequate resources and qualified staff to develop and effectively implement an approved QAP/QIP governing the work under their purview, including as applicable software development/use; and prevention of suspect/counterfeit items (S/CI); in accordance with requirements defined in this document. Identify the senior management position assigned this responsibility.

6.2.2 Submit the QAP/QIP to the organizational reporting office (i.e., contractor through the DOE Field Office to the appropriate Secretarial Officer unless delegated; HQ/DOE Field/Project Office to the Secretarial Officer) for review, comment resolution, and approval.

NOTE: Editorial changes to the QAP, that do not reduce or change commitments, do not require approval.

6.2.3 The approval authority is responsible to review and approve or reject new and revised QAPs/QIPs within their purview as required by applicable contract, QA Rule, and DOE Orders. QAPs/QIPs must be reviewed and approved or rejected within 90 calendar days of receipt or will be regarded as approved.

NOTE: The scope and rigor of review is graded based on the status of the contractor's prior quality performance (e.g., past regulatory/contract noncompliance, performance metrics, or third-party certification, etc.). The Standard Review Plan Module: Protocol for EM Review/Field Self-Assessment of Site-Specific QAPs/QIPs provides guidance for approval of QAPs/QIPs and can be found online at the DOE EM Quality Assurance webpage http://www.em.doe.gov/Pages/StandardReviewPlanModules.aspx).

6.2.4 Ensure that programs provide for prevention of S/CI and provide for proper identification and grading of safety software.

6.2.5 Perform a QA effectiveness review and submit a periodic declaration report that demonstrates QA implementation. The EM expectations for the QA effectiveness review are provided in guidance issued for the declaration process.

6.3 Office of Safety, Security, and Quality Programs

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

6.3.2 Establish and communicate guidance and frequency for the QA declaration report.

7.0 EM QA PROGRAM

As stated in Section 3.0, EM adopts NQA-1a-2009. EM implements Parts I and II of the NQA-1 standard in a graded approach, as applicable to the activity (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* used in this QAP). Part III of NQA-1 provides explanatory information and guidance for use by organizations in developing and implementing their programs. Part IV of NQA-1 provides comparisons and additional guidance for the application of NQA-1, and the use of the Subparts within Part IV can enhance the effectiveness of the QAP. Unless more appropriate guidance is available, NQA-1 Parts III and IV guidance should be considered as applicable to the work scope, and those portions of NQA-1 Parts III and IV that are applied to the work scope will be documented in the QIP. If additional standards are required to address specific QA requirements, the standards shall be identified within the QIP. Other standards required to address unique/specific work activities (i.e., not specific to QA requirements) should be identified within the appropriate implementing, design, technical specification, or work control documents.

NQA-1 is the appropriate standard to ensure safety, quality, and rigor in work activities. The vast majority of EM work involves nuclear materials and/or systems, activities or services that may impact nuclear safety. The balance of EM work involves other types of hazardous facilities, high cost facilities, other Federal and state regulations such as the Resource Conservation and Recovery Act (RCRA) or Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), and legal commitments that warrant graded application of a rigorous management system approach offered by NQA-1.

EM HQ, EM Field/Project Offices, and EM contractors shall prepare a site specific QAP or can choose to adopt the EM QAP. Each organization shall prepare a QIP that demonstrates how the EM QAP requirements are met and implemented. QIPs may be developed using the sample EM QIP as a template (Attachment C, *Quality Assurance Implementation Plan*). Plans, processes, procedures, and other documents (such as a previously approved QAP or QA Program Description written to meet the QA Order and QA Rule) may be used or referenced in the QIP to demonstrate how the requirements of the EM QAP are implemented using the process discussed in Section 3.0 as applicable. When personnel (Federal, contractors, and subcontractors) comply with the processes, procedures, and other documents identified in their organization's approved QIP, they are implementing the EM QAP.

The following sections define the EM QAP by describing the implementation of the 10 QA Criteria from the QA Order and QA Rule and providing alignment with the 18 requirements

of ASME NQA-1. The tables in each section illustrate how NQA-1 can be used to address the DOE QA requirements. Subpart 4.5 of NQA-1 provides a comparison guide to NQA-1, the QA Order, and the QA Rule. Subpart 4.5 also discusses where a DOE QA Program may need to address some specific areas beyond the requirements of NQA-1 to be compliant with the QA Rule and QA Order. As such, the tables reference Subpart 4.5 of NQA-1 where appropriate.

In addition, EM management expectations are included for each section of this QAP. These expectations are intended as a statement of conduct or performance that should be considered in implementation of the QAP requirements, and as such, are not strict requirements. The EM graded approach is described in Attachment D, *Graded Approach*. The connection between ISMS core functions/guiding principles and the 10 QA Criteria can be found in EM-HQ ISMSD, Table 2. Further discussion is provided in Attachment E, *Integrated Management System*, in this document. Attachment F, *Suspect and Counterfeit Items Prevention*, Attachment G, *Software Quality Assurance*, and Attachment H, *Model Development, Use, and Validation*, provide additional discussion on specific issues of interest within EM.

The following elaborates on the relationship between the EM QAP, the QA Order, and the QA Rule. As stated, the EM HQ, EM Field/ Project Offices, and EM contractors shall prepare a site-specific QAP or adopt the EM QAP. Each organization shall prepare a QIP that demonstrates how the EM QAP requirements are met and implemented. EM segregated the QAP requirements contained in the QA Order and QA Rule into *Requirements* and *Implementation*. Nothing in this approach affects the contractor's legal liability to comply with the QA Rule. The EM QAP meets the QA Order and QA Rule QAP requirements in the following way:

1. EM Secretarial Officer develops and provides an approved corporate QAP;
2. DOE Field/Project Offices and/or their contractors can adopt this approved QAP and write a QIP describing how the EM QAP requirements will be implemented, and process the QIP for approval as described in EM QAP, Section 6.0; or
3. DOE Field/Project Offices and/or their contractors can develop their own site-specific QAP describing how the requirements contained in the EM QAP are being met, develop a QIP describing how the site-specific QAP will be implemented, and submit the QAP and QIP for approval as described in EM QAP, Section 6.0; or
4. If the site-specific QAP integrates both the EM QAP and QIP requirements, only a cover memo attached to the integrated site-specific QAP requesting approval per EM QAP Section 6.0 is required.

7.1 MANAGEMENT/PROGRAM (CRITERION 1)

The following table illustrates the relationship between the Criterion 1 – Management/Program requirements and the ASME NQA-1 requirements used to implement them.

Criterion 1 – Management/Program	ASME NQA-1 Requirements
(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.*	**Requirement 1 – Organization** 100 – Basic 200 – 202 Structure and Responsibility 300 – Interface Control **Requirement 2 – Quality Assurance Program** 100 – Basic 200 – 202 Indoctrination and Training 300 – 305 Qualification Requirements 400 – Records of Qualification 500 – Records Non-Mandatory Appendiciesx 1A-1 and 2A-1 should be considered to aid in Organizational development during QA documentation.

7.1.1 Management Expectations:

Line management for execution of the work extends from EM senior management, through the Field/Project Office, to the contractor. The authority for development and implementation of this EM QAP, as defined in the QA Order, has been delegated by EM-1 to the Office of Safety, Security, and Quality Programs. The EM line management organizational structure is found on the EM website at http://www.em.doe.gov.

- Using the graded approach and consistent with ISMS principles, the Senior DOE Official ensures resources are planned, scheduled, and allocated to accomplish work.
- The Functions, Responsibilities and Authorities (FRA) document is used to ensure requirements are identified and associated responsibilities are assigned.
- Lines of communication, feedback mechanisms, and interfaces with stakeholders, regulators, HQ, and support organizations are established and documented.
- Personnel at each level (including subcontractors, as applicable) are familiar with and facilitate achievement of the management processes defined in organization specific QIPs that describe the applicable requirements included in the EM QAP relative to planning, control, and performance of assigned work.
- Management establishes and implements QA processes and procedures for EM or EM site mission-related activities in a controlled manner.
- QAPs and associated QIPs are developed and maintained considering the guidance provided in DOE G 414.1-2B, *Quality Assurance Program Guide*.

7.1.2 Implementation

This QAP complies with the QA Order and QA Rule, aligns with ASME NQA-1 requirements, and integrates with the EM ISMSD per DOE P 450.4A. In the event of a

conflict between this EM QAP and any QA regulation, the regulation prevails. Subpart 4.5 of NQA-1 provides comparison guidance on NQA-1, the QA Rule and the QA Order.

Each associated (both Federal and contractor) QIP shall identify the organizational structure, roles/responsibilities, levels of authority, and interfaces in the organization. As discussed in DOE Order 450.2, *Integrated Safety Management*, the FRA document for the DOE organizations is provided to ensure requirements and functional responsibilities are identified and assigned. The Senior DOE Official or contractor manager, as identified in the respective organizational chart, is responsible to assure adequate planning, scheduling, and resources are provided to implement the QIP. Plans, implementing procedures and documents are referenced in the respective organizational QIPs.

7.2 MANAGEMENT/PERSONNEL TRAINING AND QUALIFICATION (CRITERION 2)

The following table illustrates the relationship between the Criterion 2 – Management/Personnel Training and Qualification requirements and the ASME NQA-1 requirements used to implement them.

Criterion 2 – Management/Personnel Training and Qualification	**ASME NQA-1 Requirements**
(a) Train and qualify personnel to be capable of performing their assigned work. *(b) Provide continuing training to personnel to maintain their job proficiency.*	**Requirement 2 – Quality Assurance Program** 100 – Basic 200 – 202 Indoctrination and Training 300 – 305 Qualification Requirements 400 – Records of Qualification 500 – Records Non-Mandatory Appendices 2A-1 and 2A-3 should be considered to aid in the development of the QAP.

7.2.1 <u>Management Expectations:</u>

The success of any organization requires members of the organization to be competent in the work they perform. Initial and continuing training is provided to employees to develop new skills, maintain or improve job performance, and enhance existing skills. Managers are responsible for ensuring personnel are fully qualified for their positions. Training identified by the supervisor is made available to improve knowledge or skills specific to the job and/or organization. EM management expectations associated with Personnel Training and Qualification consist of:

- 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 the positions within their organization to determine:

  - If critical and unique job functions or tasks require highly technical, specialized skills;
  - Whether competency is demonstrated before performance (e.g., Office of Personnel Management minimum qualification requirements) or within a specified timeframe after entering the position (e.g., Technical Qualification Program qualification within 18 months of entering the position for federal employees); and
  - Whether a specialized certification may be required.
  - Whether a practical, physical, and/or written examination process should be established for qualification requirements that provide evidence of employee proficiency.
- Specialized design, engineering, construction, and operational training include formal and informal training, education, and developmental and other learning assignments.
- Employee-specific training needs are documented and updated as required to ensure the maintenance of competence required by the position.
- Technical qualification records are maintained separately from other training records.

7.2.2 Implementation

The method and process for ensuring personnel are trained, qualified and capable of performing assigned work are identified in training and qualification procedures as described in the applicable QIP. Specific initial and continuing training includes General Employee Training, Job-Specific Training, Assessment and Oversight Training, Lead Auditor Training, Technical Qualification Training (including inspection and test personnel, and Software QA per Attachment G, *Software Quality Requirements*), S/CI per Attachment F, *Suspect/Counterfeit Items Prevention*, and Professional Qualification/Certification Training, as applicable.

Federal personnel responsible for the oversight of quality requirements governing defense nuclear facilities are qualified in accordance with DOE-STD-1150-2002 (or latest version), *Quality Assurance Functional Area Qualification Standard* and federal 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*. Qualifications and competency levels are maintained through continuing education, training etc. as required in the applicable standards.

Plans, implementing procedures and documents are referenced in the respective organizational QIPs.

7.3 MANAGEMENT/QUALITY IMPROVEMENT (CRITERION 3)

The following table illustrates the relationship between the Criterion 3 – Management/Quality Improvement requirements and the ASME NQA-1 requirements used to implement them.

Criterion 3 – Management/Quality Improvement	ASME NQA-1 Requirements
(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.*	**Requirement 2 – Quality Assurance Program** 100 – Basic 200 – 202 Indoctrination and Training 300 – 305 Qualification Requirements 400 – Records of Qualification 500 – Records **Requirement 15 – Control of Nonconforming Items** 100 – Basic 200 – Identification 300 – Segregation 400 – 405 Disposition **Requirement 16 – Corrective Action** 100 – Basic Non Mandatory Appendices 2A-4, 16A-1, and Subpart 4.5 should be considered to aid in Quality Improvement implementation.

7.3.1 <u>Management Expectations:</u>

In order for quality improvement to occur, it is necessary to have systems that identify problems. Problem identification can occur as a result of self-assessments, independent or external assessments, inspections, audits, anomalous behavior of some measured quantity against a predefined metric, benchmarking, failure to achieve performance goals or accomplish improvement plans, or as a result of the occurrence of an event. Problem identification can also result from unfulfilled expectations of customers served by the organization. In most cases, problems are associated with deviations, nonconforming items, inconsistencies with a requirement, or failure to meet customer or management expectations. The insights and results provided by the contractor assurance system (CAS) should be leveraged to the extent possible to facilitate continuous quality improvement. EM management expectations associated with Quality Improvement consist of:

- Management sets performance goals and standards.
- Management establishes metrics that monitor project/program performance to identify QA processes needing improvement.

- Corrective actions are developed and implemented for problems/findings related to item characteristics, products, process implementation, or services.
- Corrective Action Programs utilize and are consistent with:
  - DOE O 226.1B, *Implementation of Department of Energy Oversight Policy*;
  - DOE O 227.1, *Independent Oversight Program*; and
  - DOE G 414.1-2B, *Quality Assurance Program Guide*.
- A process to determine the significance of identified problems/findings is developed.
- In the case of significant conditions adverse to quality, causes of problems are identified, and prevention of recurrence is included as a part of corrective action planning.
- Management identifies the causes of problems and takes corrective actions to address the problems. Formal root cause analysis should be considered based on the complexity of the identified significant issue. Root causes should be identified and documented using an authoritative methodology for root cause identification and be performed by root cause analysis-trained personnel. Reference DOE Order 232.2, *Occurrence Reporting and Processing of Operations Information.*
- An *Extent of Condition* determination is considered for significant conditions adverse to quality.
- In the case of significant conditions adverse to quality, proposed corrective actions are evaluated to ensure they will effectively address the underlying QA performance issues.
- Completed corrective actions are independently verified for implementation and the verification documented to indicate closure.

Problems with potential programmatic or safety significance or that are widespread, continuing, multiple, or repetitive in nature (i.e., significant conditions adverse to quality) should be afforded special attention. Such problems are entered into a tracking system and identified to management for proper attention. Nonconformance and corrective action processes meet the requirements of the approved QIP.

Quality Improvement requirements may be further defined in oversight plans and associated procedures. Oversight plans contribute to providing accurate technical, business, and operational performance information to management and staff. Improvement processes maintained by this management system include: Self-Assessment, Independent Oversight, Lessons Learned, Performance Metrics, and Performance Analysis.

7.3.2 Implementation

Operational awareness processes are critical to detect, communicate, and prevent quality problems and processes in an effective and timely manner. These processes include facility tours/walkthroughs, work observations, document reviews, meeting attendance and

participation, and ongoing interactions with contractor workers, suppliers that provide continuing support, support staff, and management.

Other processes include assessments/audits of facilities, operations, item inspection results, and programs; assessments/audits of CASs; evaluations of contractor performance; and self-assessment of DOE line management functions and performance. The CAS serves an important and integral role in ensuring effective operational awareness.

The corrective action programs serve to ensure issues are corrected and actions put in place to preclude recurrence.

Plans, implementing procedures and documents are referenced in the respective organizational QIPs.

7.4 MANAGEMENT/DOCUMENTS AND RECORDS (CRITERION 4)

The following table illustrates the relationship between the Criterion 4 – Management/Documents and Records requirements and the ASME NQA-1 requirements used to implement them.

Criterion 4 – Management/Documents and Records	ASME NQA-1 Requirements
(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.*	**Requirement 5 – Instructions, Procedures, and Drawings** 100 – Basic **Requirement 6 – Document Control** 100 – Basic 200 – Document Control 300 – 302 Document Changes **Requirement 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 Non-Mandatory Appendices 17A-1, 17A-2, and Subpart 4.4 should be considered to aid in development of document and records efforts.

7.4.1 <u>Management Expectations:</u>

EM management expectations associated with Documents and Records are discussed in the following sections and consist of:

- New or revised requirements are analyzed to determine impact on implementing procedures and/or contracts.
- Policies, procedures, and plans are maintained current and deployed in a manner that makes them readily available to the users.
- Procedures identify QA records that are created and maintained in the implementation of the procedure.
- QA records are maintained in accordance with both NQA-1 and the National Archives and Records Administration (NARA) by incorporating the NQA-1 requirements into the federal records lifecycle.

Records

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

Federal Records

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

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

EM HQ, Field/Project Offices, and contractor personnel performing work prepare, collect, protect, and retain Federal records in a manner that ensures records are retrievable, useable, and auditable.

QA Records

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

[1] United States Code, Title 44, Chapter 33, Sec. 3301, "Definition of records," (44 USC 3301), as amended, et seq.

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

- Documents establish requirements or define how work is to be performed. Documents that establish policy, prescribe work, or specify requirements are prepared, reviewed, approved, issued, used, and revised in a controlled manner using appropriate technical standards, DOE Orders, NQA-1, and/or other quality standards.
- Requirements typically originate from laws, state or Federal regulations [e.g.,the QA Rule; RCRA; CERCLA; Clean Water Act; Clean Air Act; Toxic Substances Control Act (TSCA)], DOE directives (e.g., the QA Order), and selected consensus standards (NQA-1). New or revised requirements documents are analyzed to determine impact on implementing documents and/or contracts.
- Documents that describe the methods for implementing the requirements of this QAP are identified by each organization (EM HQ, EM Field/Project Offices, and EM contractors) and maintained current.

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

7.4.2 Implementation

The requirements included in this document for QA records are implemented in addition to the Federal requirements issued by NARA. The QAP provides additional requirements but does not alleviate any requirements for Federal records. By incorporating the NQA-1 requirements into the Federal records lifecycle, compliance with both NARA and NQA-1 can be achieved. The following shows how the NQA-1 requirements fit into the Federal records lifecycle:

Creation / Receipt:

- Record Identification: Includes identifying QA records within implementing procedures prior to the start-up of work.

Maintenance / Use:

- Retention: Length of time that records must be kept.
  - Federal records (including QA records) are required to be scheduled by content/subject within a specific record series. The record series are found in the NARA-approved DOE Records Disposition Schedules, which provide mandatory instructions for the disposition of Federal records.
- Classification: An additional form of QA record identification for filing purposes.
  - QA records are further classified as *lifetime* or *non-permanent*

  - Lifetime records are required to be maintained for the life of the particular item while it is installed in the plant or stored for future use. Therefore, lifetime QA records are those associated with *items*.
  - Non-permanent records are those required to show evidence that an activity was performed in accordance with applicable requirements, but the records do not need to be retained for the life of the item. Therefore, non-permanent QA records are those associated with *activities*.

- File Arrangement: Arrangement of records by subject (activity/item), chronology, etc., to ensure traceability.
- Authentication: Record that is stamped, initialed, or signed and dated for authentication.
- Receipt Control: Form of validating receipt of records in a centralized location.
- Active Record Storage: QA records are to be stored in 2-hour fire proof cabinets, vault storage or dual storage while in active status.
  - QA records are maintained in active storage that protects the records from loss or damage by employing filing equipment suitable for the level of protection defined in NQA-1 until the item is no longer being used or it is retired from service (lifetime) or until the records are no longer required to support the work activity (non-permanent).
  - When the QA records become inactive, the responsible personnel transfer the QA records to inactive records storage that meets NARA requirements; the records are maintained for their retention period in accordance with the DOE Records Disposition Schedules.

Plans, implementing procedures and documents are referenced in the respective organizational QIPs.

7.5 PERFORMANCE/WORK PROCESSES (CRITERION 5)

The following table illustrates the relationship between the Criterion 5 – Performance/Work Processes requirements and the ASME NQA-1 requirements used to implement them.

Criterion 5 – Performance/Work Processes	ASME NQA-1 Requirements
(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.	**Requirement 5 – Instructions, Procedures, and Drawings** 100 – Basic **Requirement 8 – Identification and Control of Items** 100 – Basic 200 – 202 Identification Methods 300 – 303 Specific Requirements **Requirement 9 – Control of Special Processes**

Criterion 5 – Performance/Work Processes	ASME NQA-1 Requirements
(b) Identity 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.*	100 – Basic 200 – 203 Process Control 300 – Responsibility 400 – Records **Requirement 12 – Control of Measuring and Test Equipment** 100 – Basic 200 – Selection 300 – 304 Calibration and Control 400 – 402 Records **Requirement 13 – Handling, Storage, and Shipping** 100 – Basic 200 – Special Requirements 300 – Procedures 400 – Tools and Equipment 500 – Operators 600 – Marking or Labeling **Requirement 14 – Inspection, Test, and Operating Status** 100 – Basic **Requirement NQA-1 Part I – Introduction** **Requirement NQA-1 Part II, Subpart 2.7 – Quality Assurance Requirements for Computer Software for Nuclear Facility Applications** 100 – 102 General 200 – 204 General Requirements 300 – 302 Software Acquisition 400 – 407 Software Engineering Method 500 – Standards, Conventions, and Other Work Practices 600 – 602 Support Software 700 – References

7.5.1 <u>Management Expectations:</u>

Work performed by Federal and contractor employees focuses on completing the EM project mission through effective management. Procedures identified in each organization's QIP describe how work will be accomplished. The QIP comprises a set of requirements-based processes, procedures, and program descriptions used by the organization's staff to perform their assigned work activities to accomplish the EM mission and meet regulatory or contract requirements. Specific expectations for Work Processes include:

- Documents clearly establish the roles and responsibilities for employees.
- Employees identify and assist in making changes that improve project processes and documents.

Safety- and quality-related software has the appropriate controls in place as required by the QA Order and NQA-1a-2009, even if it is off-the-shelf. (See also Attachment G, *Software Quality Requirements*.)

Typically, EM HQ or EM Field/Project Offices only perform work activities applicable under Criterion 5 (b), (c), or (d) as part of information technology and institutional type software programs. Otherwise, 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.

7.5.2 Implementation

Plans, implementing procedures and documents are referenced in the respective organizational QIPs.

7.6 PERFORMANCE/DESIGN (CRITERION 6)

The following table illustrates the relationship between the Criterion 6 – Performance/Design requirements and the ASME NQA-1 requirements used to implement them.

Criterion 6 – Performance/Design	ASME NQA-1 Requirements
(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.*	**Requirement 3 – Design Control** 100 – Basic 200 – Design Input 300 – Design Process 400 – 402 Design Analyses 500 – 501.3 Design Verification 600 – 601.9 Change Control 700 – Interface Control 800 – 802.3 Software Design Control 900 – Documentation and Records **Requirement NQA-1 Part II, Subpart 2.7 – Quality Assurance Requirements for Computer Software for Nuclear Facility Applications** 100 – 102 General 200 – 204 General Requirements 300 – 302 Software Acquisition 400 – 407 Software Engineering Method 500 – Standards, Conventions, and Other Work Practices 600 – 602 Support Software

Criterion 6 – Performance/Design	ASME NQA-1 Requirements
	700 – References Non-Mandatory Appendix 3A-1, and Subpart 4.1, should be considered to aid in the development of Design Control.

7.6.1 Management Expectations:

The effective integration of QA during design is a major contributor to the ultimate success of EM projects. The *Interim EM Policy on the Code of Record* concept for EM nuclear facilities further illustrates the EM management commitment to sound application and integration of QA during the design phase. A Code of Record serves as a management tool and source for the set of requirements, including QA, that are used to design, construct, operate, and decommission a nuclear facility over its lifespan.

The EM *Guidance Document for Integrating Quality Assurance During the Design and Construction Life Cycle* dated September 2011 or latest version (http://www.em.doe.gov/Pages/QACorporateBoard.aspx) and Standard Review Plan (SRP) Review Module *Quality Assurance for Critical Decision Reviews* (http://www.em.doe.gov/Pages/StandardReviewPlanModules.aspx) provide the detailed EM management expectations related to Design. These expectations, among others, include:

- Designs are based on appropriate national standards and industry recognized engineering practices.
- Applicable design bases are incorporated.
- Design interfaces are identified and controlled.
- Design reviews are implemented using individuals or groups other than those who performed the work.
- Design work is verified before approval and implementation.

7.6.2 Implementation

Typically, EM HQ or EM Field/Project Offices only perform work activities applicable under Criterion 6 as part of information technology and institutional type software programs. Otherwise, EM assigns authority for design through contracts and/or technical direction. Where authority for design has been assigned through contracts and/or technical direction, the role of EM HQ and Field/Project Office organizations is monitoring contracted design practices to ensure proper implementation through oversight activities.

EM contractors are expected to have and implement a complete design control system as required by the QA Order and NQA-1a-2009 as applicable to the work being performed.

Plans, implementing procedures and documents are referenced in the respective organizational QIPs.

7.7 PERFORMANCE/PROCUREMENT (CRITERION 7)

The following table illustrates the relationship between the Criterion 7 – Performance/Procurement requirements and the ASME NQA-1 requirements used to implement them.

Criterion 7 – Performance/Procurement	ASME NQA-1 Requirements
(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.*	**Requirement 4 – Procurement Document Control** 100 – Basic 200 – 207 Content of Procurement Documents 300 – Procurement Document Review 400 – Procurement Document Changes **Requirement 7 – Control of Purchased Items and Service** 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 and Services 800 – Records **Requirement NQA-1 Part II, Subpart 2.7 – Quality Assurance Requirements for Computer Software for Nuclear Facility Applications** 100 – 102 General 200 – 204 General Requirements 300 – 302 Software Acquisition 400 – 407 Software Engineering Method 500 – Standards, Conventions, and Other Work Practices 600 – 602 Support Software 700 – References **Part II, Subpart 2.14 – Quality Assurance Requirements for Commercial Grade Items and Services** 100-101 – General 200 – CGI Definition Applications 300 – Utilization 400-403 – Technical Evaluation 500 – Critical Characteristics 600-606 – Methods of Accepting Commercial Grade Items and Services 700 – Commercial Grade Services 800 – Documentation 900 – References

Criterion 7 – Performance/Procurement	ASME NQA-1 Requirements
	Non-Mandatory Appendix 4A-1, 7A-1 should be considered to aid in the development of Procurement processes.

7.7.1 Management Expectations:

The EM management expectation related to Procurement is that work performed under any of its contracts is in conformance with contractual requirements and specifications.

- This expectation is regardless of whom under the contractor performs the activities, i.e., prime contractor personnel, subcontractors, vendors, or consultants. As such, an effective integrated procurement process (including development of 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) is a critical responsibility of the prime contractor.
- Standard QA Contract language is included in prime contracts and applicable QA requirements are included in subcontracts.
- An integrated acquisition strategy is developed and maintained 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.
- Commercial Grade Dedications utilize the information provided in the EM guidance document *Guidance for Commercial Grade Dedication* dated September 2011 or latest version (http://www.em.doe.gov/Pages/QACorporateBoard.aspx).

The procurement process is defined by the DOE Office of Procurement and Assistance Management through implementation of applicable laws and regulations. Processes include: Acquisition Planning and Management; Contract Management; and Oversight of Contractors.

Procurement functions for EM HQ and EM Field/Project Offices are predominantly related to information technology and institutional type software programs, contract awards, and administration of contracts for a variety of items and services. EM contractors conduct contract work scope including associated technical, QA, structural, systems, components, spare/replacement parts and materials procurement activities. S/CI prevention requirements from the QA Order are addressed in Attachment F, *Suspect/Counterfeit Items Prevention*, of this QAP. The latest information on S/CI awareness can be located at the following DOE website: http://www.hss.energy.gov/csa/csp/sci/.

The procurement process begins with project staff determining the scope of work to be performed, how the work is to be *packaged* (i.e., one contract or multiple contracts and the type of contract that is most beneficial to the government), the duration of the contract, special requirements unique to the scope of work, etc. EM HQ or EM Field/Project Offices

may place and administer a variety of procurement vehicles; e.g., contracts for the cleanup work, interagency agreements for services furnished by other government organizations (e.g., Corps of Engineers), and specialty service contracts. Typical QA aspects of the procurement process include the following:

- Developing program and acquisition strategies and plans;
- Establishing requirements;
- Evaluating and selecting qualified contractors;
- Providing direction to the contractor;
- Reviewing and approving deliverables;
- Evaluating work performed to ensure it meets contract requirements;
- Performing oversight and assessments to ensure work is completed in a cost-effective, safe, and quality manner; and
- Providing Government Furnished Services and Information in a timely manner.

Because of the lead-time required to place a contract, acquisition planning is performed sufficiently early. Acquisition strategies are developed bringing together procurement specialists and site management. When QA plans or program documents are required as part of an offeror's response to procurement documents, they are reviewed by qualified engineers and quality personnel during the evaluation process.

Contractor performance is monitored on an ongoing basis. Project and supplier monitoring includes facility walkthroughs, observations of contractor activities, reviewing contractor work products or reports, and formal assessments/audits/surveillances that are planned, performed, and documented, with corrective actions verified. Sites may vary their level of oversight by application of the graded approach depending on: (1) relative importance of the work to the site mission, (2) past performance of contractor, (3) complexity of the products or services, and (4) relative risk to future work. Project mission element monitoring is focused primarily on verification of costs, work progress, implementation of environmental agreements and permits, verifying quality, and verifying/evaluating completion of work in accordance with applicable QIP and contract requirements.

Special oversight activities are performed as needed to respond to circumstances that cannot be foreseen; e.g., events/incidents, employee concerns, degrading performance, adverse trends, etc. Monitoring is also conducted to verify the contractor's ISMS is effectively implemented. Projects review performance data and other relevant information quarterly and provide timely Government Furnished Services and Information.

7.7.2 Implementation

Each organization will have an organization-specific QIP describing how the applicable requirements of the QAP are implemented and/or flowed down to lower-tier organizations. The prime contractor is ultimately responsible for complying with the requirements of this QAP regardless of whether work is self-performed or performed by lower tier

subcontractors. The contractor is responsible for flowing down the applicable requirements of this QAP, 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. The QAP is not required to be included in all subcontracts; however, it is the responsibility of the prime contractor to determine which aspects of an approved QAP apply to the work scope that is assigned to a subcontractor and what requirements from the QAP need to be flowed down in the body of the contract to each particular subcontractor in order to ensure compliance with the requirements of the QAP. Oversight of the flow-down process is conducted by DOE field elements to ensure that the process is consistent with the requirements outlined in the prime contractor's approved QAP/QIP. The prime contractor is ultimately responsible for all work performed.

The method and processes for ensuring services meet established requirements and performance expectations are evaluated using processes including: acquisition planning, vendor surveys, bid evaluations, contractor oversight, contract administration, source evaluation, etc.

Plans, implementing procedures and documents are referenced in the respective organizational QIPs.

7.8 PERFORMANCE/INSPECTION AND ACCEPTANCE TESTING (CRITERION 8)

The following table illustrates the relationship between the Criterion 8 – Performance/Inspection and Acceptance Testing requirements and the ASME NQA-1 requirements used to implement them.

Criterion 8 – Performance/Inspection and Acceptance Testing	**ASME NQA-1 Requirements**
(a) Inspect and test specified items, services, and processes using established acceptance and performance criteria.	**Requirement 3 – Design Control** 100 – Basic 200 – Design Input 300 – Design Process 400 – 402 Design Analysis 500 – 501.3 Design Verification 600 – 601.9 Change Control 700 – Interface Control 800 – 802.3 Software Design Control 900 – Documentation and Records **Requirement 8 – Identification and Control of Items** 100 – Basic **Requirement NQA-1 Part II, Subpart 2.7 – Quality Assurance Requirements for Computer Software for Nuclear Facility Applications** 100 – 102 General; 200 – 204 General Requirements

Criterion 8 – Performance/Inspection and Acceptance Testing	**ASME NQA-1 Requirements**
	300 – 302 Software Acquisition; 400 – 407 Software Engineering Method 500 – Standards, Conventions, and Other Work Practices 600 – 602 Support Software 700 – References 200 – 202 Identification Methods 300 – 303 Specific Requirements
(b) Calibrate and maintain equipment used for inspections and tests.	**Requirement 10 – Inspection** 100 – Basic 200 – Inspection Requirements 300 – Inspection Hold Points 400 – 402 Inspection Planning 500 – In-Process Inspection 600 – 604 Final Inspections 700 – Inspections During Operations 800 – Records **Requirement 11 – Test Control** 100 – Basic 200 – Test Requirements 300 – Test Procedures (Other Than for Computer Programs) 400 – Computer Program Test Procedures 500 – Test Results 600 – 602 Test Records **Requirement 12 – Control of Measuring and Test Equipment** 100 – Basic 200 – Selection 300 – 304 Calibration and Control 400 – 402 Records **Requirement 14 – Inspection, Test, and Operating Status** 100 – Basic Non-Mandatory Appendices 10A-1 and 11A-1 should be considered to aid in development of inspection and testing processes.

7.8.1 Management Expectations:

Consistent with contractual provisions, the contractor conducts 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.

This criterion is generally not applicable to the EM HQ and EM Field/Project Office organizations since Federal employees do not typically perform inspection or testing functions. Oversight or assessment of the contractor's program, or implementation thereof, to ensure acceptability of work or items may include:

- Inspection/test planning
- Inspection/test methods
- Inclusion of inspection and test acceptance criteria in work and inspection, test implementing documents
- Calibration and control of inspection, measuring and test equipment
- Documentation and records

7.8.2 Implementation

EM typically assigns implementation authority for inspection and acceptance testing through contracts and/or technical direction. EM monitors inspection and acceptance testing practices through assessment and oversight activities.

QIPs for EM HQ and Field/Project Offices address the oversight functions performed by the DOE Federal organizations. EM contractor QIPs also address oversight functions performed of functional areas, as well as their supply chain, e.g., subcontractors, fabricators, vendors, and suppliers. The performance expectations are defined by applicable industry standards, codes, design documents, specifications, inspection and acceptance test requirements and implementing procedures.

Plans, implementing procedures and documents are referenced in the respective organizational QIPs.

7.9 ASSESSMENT/MANAGEMENT ASSESSMENT (CRITERION 9)

The following table illustrates the relationship between the Criterion 9 – Assessment/Management Assessment requirements and the ASME NQA-1 requirements used to implement them.

Criterion 9 – Assessment/Management Assessment	ASME NQA-1 Requirements
Ensure that managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives.	**Requirement 2 – Quality Assurance Program** 100 – Basic 200 – 202 Indoctrination and Training; 300 – 305 Qualification Requirements; 400 – Records of Qualification 500 – Records **Requirement 16 – Corrective Action** 100 – Basic **Requirement 18 – Audits** 100 – Basic 200 – Scheduling 300 – 303 Preparation 400 – Performance 500 – Reporting 600 – Response 700 – Follow-up Action 800 – Records Non-Mandatory Appendices 2A-1, 2A-3, 2A-4, 18A-1, and Subpart 4.5 should be considered to aid in organizational development of assessment processes.

7.9.1 Management Expectations:

Management assessment is a method used to achieve continuous improvement and/or to identify barriers that hinder improved performance. Managers periodically evaluate the performance of their organizations in comparison with their mission, responsibilities, and priorities. These evaluations are performed periodically and also in response to identified issues or concerns. Management assessments include verifying 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. EM management expectations associated with Management Assessments consist of:

- Management assessments are one of the means for identifying areas needing correction and/or improvement.
- Management assessments are performed by personnel knowledgeable in the subject area and trained in assessment techniques.

- Managers within organizations (EM HQ, Field/Project Office, and contractor) assess their organization's performance with regards to such things as safety, quality, mission completion, and performance against technical and financial goals and objectives. Management consolidates the ISMS and QA validation and declaration activities where possible.
- Results of management assessments are documented, and deficiencies identified and tracked with corrective actions taken.
- Management assessments use guidance provided in DOE G 414.1-1B *Management Assessment and Independent Assessment Guide*.

The SRP Modules may be used in the development of Lines of Inquiry for Management Assessments (the review modules can be found online at http://www.em.doe.gov/Pages/StandardReviewPlanModules.aspx). The assessments include evaluating available quality performance and trend analysis data, such as the results of independent or external assessments and data from issue tracking and corrective action systems. Areas that present the greatest consequences of failure and the greatest benefit from improvements, if implemented, should receive particular emphasis.

Management assessments include an introspective evaluation to determine if the Integrated Safety and Quality Management Systems effectively meet strategic goals. Therefore, significant personal participation by the manager in the assessment is an essential element. Management assessments also identify opportunities for improving cost, schedule, safety, and/or quality of performance. Assessment results are documented. Assessment results requiring corrective actions are tracked until corrective actions have been completed and verified.

Oversight plans and associated assessment procedures include requirements to:

- Document improvement actions
- Process lessons learned, as applicable
- Provide a copy of the final assessment report so that follow-up improvement actions resulting from the assessment can be entered into an issues tracking system for tracking and a record of the assessment can be established

7.9.2 Implementation

Plans, implementing procedures and documents are referenced in the respective organizational QIPs.

7.10 ASSESSMENT/INDEPENDENT ASSESSMENT (CRITERION 10)

The following table illustrates the relationship between the Criterion 10 – Assessment/Independent Assessment requirements and the ASME NQA-1 requirements used to implement them.

Criterion 10 – Assessment/Independent Assessment	**ASME NQA-1 requirements**
(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.*	**Requirement 1 – Organization** 100 – Basic 200 – 202 Structure and Responsibility 300 – Interface Control **Requirement 2 – Quality Assurance Program** 100 – Basic 200 – 202 Indoctrination and Training 300 – 305 Qualification Requirements 400 – Records of Qualification 500 – Records **Requirement 10 – Inspection** 100 – Basic 200 – Inspection Requirements 300 – Inspection Hold Points 400 – 402 Inspection Planning 500 – In-Process Inspection 600 – 604 Final Inspections 700 – Inspections During Operations 800 – Records **Requirement 11 – Test Control** 100 – Basic 200 – Test Requirements 300 – Test Procedures (Other Than for Computer Programs) 400 – Computer Program Test Procedures 500 – Test Results 600 – 602 Test Records **Requirement 15 – Control of Nonconforming Items** 100 – Basic 200 – Identification 300 – Segregation 400 – 405 Disposition **Requirement 16 – Corrective Action** 100 – Basic **Requirement 18 – Audits** 100 – Basic 200 – Scheduling 300 – 303 Preparation 400 – Performance

Criterion 10 – Assessment/Independent Assessment	ASME NQA-1 requirements
	500 – Reporting 600 – Response 700 – Follow-up Action 800 – Records Non-Mandatory Appendices 2A-1, 2A-3, 2A-4, 10A-1, 11A-1, 16A-1, and 18A-1 should be considered to aid in the development of independent assessment processes.

7.10.1 Management Expectations:

Independent assessments involve review, evaluation, inspection, surveillance, or audit to determine and document whether items, processes, systems, or services meet specified requirements and perform effectively. An independent assessment is conducted by individuals within the organization or from an external organization that are independent from the work or process being evaluated. EM management expectations associated with Independent Assessments consist of:

- Organizations develop and implement a comprehensive plan and schedule to independently assess and conduct audits of reporting organizations against technical, programmatic, administrative, and quality program requirements.
- As part of the independent assessment process, the federal and contractor offices ensure their QA programs are assessed to verify compliance and effectiveness of the quality requirements implementation at a frequency such that all elements of the QA program are addressed at least triennially.
- Independent assessments are performed by personnel knowledgeable in the subject area and trained in assessment techniques.
- Results of independent assessments/audits are documented; deficiencies tracked; corrective action plans reviewed; and corrective actions verified with the verification documented to indicate closure.
- Independent assessments use guidance provided in DOE G 414.1-1B, *Management Assessment and Independent Assessment Guide*.
- The SRP Modules may be used in the development of Lines of Inquiry for Independent Assessments (the review modules can be found online at http://www.em.doe.gov/Pages/StandardReviewPlanModules.aspx).

In the course of issue identification, proposed solutions or alternative courses of action are brought forward with the objective of seeking to improve organizational excellence. Findings, observations, and recommendations are presented in assessment/audit reports that are transmitted formally to the audited organization. Deficiencies identified as significant

are documented, a formal root cause analysis should be considered based on the complexity of the identified significant issue, extent of conditions identified, and corrective/preventive actions implementation verified.

7.10.2 Implementation

Plans, implementing procedures and documents are referenced in the respective organizational QIPs.

8.0 ATTACHMENTS

Attachment A – Certified Type B and Fissile Packaging Quality Assurance Program
Attachment B – QA Program Variance/Exemption Request Form
Attachment C – Quality Assurance Implementation Plan
Attachment D – Graded Approach
Attachment E – Integrated Management System
Attachment F – Suspect/Counterfeit Items Prevention
Attachment G –Software Quality Requirements
Attachment H – Model Development, Use, and Validation
Attachment I – Revision History

ATTACHMENT A – Certified Type B and Fissile Packaging Quality Assurance Program

Packaging and transportation requirements for EM are included in DOE O 460.1C, *Packaging and Transportation Safety*. The Headquarters Certifying Official (HCO) referenced in DOE O 460.1C (as delegated by the secretarial officer) is currently within the HQ Office of Packaging and Transportation.

DOE/EM/PCP/QA-2010-1, *Quality Assurance Guidance for Packaging of Radioactive and Fissile Materials*, provides DOE and DOE Contractors with a consistent, systematic approach for implementing the 10 CFR Part 71, Subpart H, Quality Assurance, requirements. The guidance document provides information on the criteria used in reviewing and approving transportation QA Programs. The guide is available online at http://rampac.energy.gov/PBoK.htm#DOE.

The DOE Packaging Certification Program within EM has also developed a process for meeting its responsibilities under DOE O 460.1C as well as ensuring that entities continue to operate effectively and efficiently. The process includes the completion of a compliance matrix (provided in this section). Sites and contractors who submit the matrix may continue to use their existing QA Programs subject to review, approval and audit by the Packaging Certification Program. Sites and contractors who do not submit a matrix will not be in compliance with DOE O 460.1C, and will not conduct any activities requiring a QA Program for certified Type B and fissile radioactive materials packagings. DOE Element (e.g., site office, field office, etc.) or DOE Contractors responsible for radioactive material packaging safety shall submit the completed matrix with any reference documents and description of relevant activities for Type B and fissile material packaging (e.g., design, fabrication, procurement, testing, use, maintenance, and/or repair), to the EM Office of Packaging and Transportation. (Note that previous submittals of the matrix remain valid and this attachment is not intended to require re-submittal of an existing approved matrix.)

Each EM entity that offers for transportation or transports radioactive material in a Type B or fissile material packaging certified by the HCO or the U.S. Nuclear Regulatory Commission should register in writing with the HCO. The user registration list is maintained on the DOE Radioactive Material Packaging website (www.rampac.energy.gov).

Instructions for Completing the Following Matrix

1. Column 1 Subpart H, requirement section reference

2. Column 2 Subpart H, requirement section title

3. Column 3 Does this section of Subpart H apply to the QA Program (e.g., Section 71.107, Design Controls, would not necessarily apply to a user only)?

4. Column 4 Applicable section, criterion, and page reference from DOE/EM/PCP/QA-2010-1, *Quality Assurance Guidance for Packaging of Radioactive and Fissile Materials.* Refer to the Section, Criterion, and page reference in the Guide to identify the requirements and applicability of your participation (e.g., design, fabrication, procurement, use, or maintenance).

5. Column 5- Implementing Documents (i.e., Plans, Manuals and/or Procedures). Provide a listing of reference documents that are used to implement the applicable QA requirements.

10CFR71 Subpart H Section	Title	Applicable Section (Y or N)	DOE/EM/PCP/QA-2010-1 QA Guidance (Ref-Section/Criterion/Page #)	Implementing Documents (i.e., Plans, Manuals and/or Procedures)
71.103	Quality Assurance Organization		Section 2.1. Criterion I: Quality Assurance Organization, page 13	
71.105	Quality Assurance Program		Section 2.2. Criterion II: Quality Assurance Program, page 18	
71.107	Package Design Control		Section 2.3. Criterion III: Package Design Control, page 22	
71.109	Procurement Document Control		Section 2.4. Criterion IV: Procurement Document Control, page 27	
71.111	Instructions, Procedures, and Drawings		Section 2.5. Criterion V: Instructions, Procedures, & Drawings, page 30	
71.113	Document Control		Section 2.6. Criterion VI: Document Control, page 33	
71.115	Control of Purchased Material, Equipment, and Services		Section 2.7. Criterion VII: Control of Purchased Material, Equipment, & Services, page 36	
71.117	Identification and Control Materials, Parts, and Components		Section 2.8. Criterion VIII: Identification & Control of Materials, Parts, & Components, page 40	
71.119	Control of Special Processes		Section 2.9. Criterion IX: Control of Special Processes, page 41	
71.121	Internal Inspection		Section 2.10. Criterion X: Internal Inspection, page 44	
71.123	Test Control		Section 2.11. Criterion XI: Test Control, page 48	
71.125	Control of Measuring and Test Equipment		Section 2.12. Criterion XII: Control of Measuring & Test Equipment, page 51	

10CFR71 Subpart H Section	Title	Applicable Section (Y or N)	DOE/EM/PCP/QA-2010-1 QA Guidance (Ref-Section/Criterion/Page #)	Implementing Documents (i.e., Plans, Manuals and/or Procedures)
71.127	Handling, Storage, and Shipping Control		Section 2.13. Criterion XIII: Handling, Storage, & Shipping Control, page 53	
71.129	Inspection, Test, and Operating Status		Section 2.14. Criterion XIV: Inspection, Test, & Operating Status, page 56	
71.131	Nonconforming Materials, Parts, or Components		Section 2.15. Criterion XV: Nonconforming Materials, Parts, or Components, page 58	
71.133	Corrective Action		Section 2.16. Criterion XVI: Corrective Action, page 60	
71.135	Quality Assurance Records		Section 2.17. Criterion XVII: Quality Assurance Records, page 62	
71.137	Audits		Section 2.18. Criterion XVIII: Audits, page 66	

ATTACHMENT B – QA Program Variance/Exemption Request

Risk-Informed Process for HQ Review of QA Exemption/Variance Request				
Requesting Organization - DOE Site/Contractor:				
Specifics of Exemption or Variance	**EM QAP Requirement**	**Delta (from Baseline Requirement)**	**Risk Analysis/Impacts**	**EM-43 or Designee Recommendation**
Document specifically the nature of the variance and/or exemption requested, specific facility or process or operation that will be affected, and the main drivers and justifications for the request	*Identify specific section(s) or aspects of QA requirements from which the variance and/or exemption is being requested*	*Discuss the extent to which request deviates from the objective of the EM QAP and intent of the requirement. Discuss issues such as equivalency or non-applicability due to the nature of the situation and circumstances*	*Provide a qualitative analysis of any potential impacts on project success, if any, including safety and health implications, readiness including Critical Decision (CD) milestones, product quality, cost, schedule, regulatory implications, and any other attributes as applicable.* *Note: Impacts can be categorized as HIGH, MEDIUM, LOW and must be tied to qualitative analysis provided by requestor*	*Provide a risk-informed judgment on EM-HQ acceptability of any anticipated risks as the result of variance and/or exemption request* *Note: this column will be completed by EM-43 during the review/approval process.*

Note: This form is used for variances to specifics of the EM Corporate QAP. Any exemption to DOE O 414.1D must follow the exemption requirements of the Order including Central Technical Authority concurrence.

ATTACHMENT C – QUALITY ASSURANCE IMPLEMENTATION PLAN

INTRODUCTION

The QIP defines these linkages to each QA criterion and will identify applicable procedures and documents that directly implement the applicable requirements of this QAP. A QIP may be developed using the sample QIP below as a template. 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 EM QAP 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. It is expected that EM sites will incorporate additional site-specific and NQA-1 requirements into their QIP based on activities being performed (e.g., Federal repository-related work; nuclear packaging such as industrial packages, Type A packages, Type B packages; TRU waste disposal activities; environmental media, waste characterization, and effluent discharge sampling and analysis operations driven by EPA QA requirements associated with the CERCLA, RCRA, Clean Water Act, Clean Air Act, and TSCA regulations; special processes; inspections and tests; use of measuring and test equipment; etc.). Those portions of NQA-1, Parts III and IV that are applied to the work scope will be documented in the QIP. If additional standards are required to address specific QA requirements, the standards will also be identified within the QIP.

SAMPLE – QA IMPLEMENTATION PLAN

QA Order Criteria	Processes	Procedures and Documents
Criterion 1 – Management/Program		
1. 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 NQA-1 Application	EM Organization Chart EM Strategic Plan EM Mission and Function Statement EM FRA Definitions & Acronyms EM QAP
2. Establish management processes, including planning, scheduling, and providing resources for the work.		
Criterion 2 – Management/Personnel Training and Qualification		
1. 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
2. Provide continuing training to personnel to maintain their job proficiency.		
Criterion 3 – Management/Quality Improvement		
1. 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 Self-Assessments	EM Oversight and Assessment Program EM Issues/Action Management System Operating Experience/Lessons Learned
2. Identify, control, and correct items, services, and processes that do not meet established requirements.		
3. Identify the causes of problems, and include prevention of recurrence as a part of corrective action planning.		
4. 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		
1. 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
2. Specify, prepare, review, approve, and maintain records.		
Criterion 5 – Performance/Work Processes		
1. 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)
2. Identify and control items to ensure proper use.		
3. Maintain items to prevent damage, loss, or deterioration.		
4. Calibrate and maintain equipment used for process monitoring or data collection.		
Criterion 6 – Performance/Design		
1. Design items and processes using sound engineering/scientific principles and appropriate standards.		
2. Incorporate applicable requirements and design bases in design work and design changes.		
3. Identify and control design interfaces.		
4. Verify or validate the adequacy of design products using individuals or groups other than those who performed the work.		
5. Verify or validate work before approval and implementation of the design.		
Criterion 7 – Performance/Procurement		
1. 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
2. Evaluate and select prospective suppliers on the basis of specified criteria.		

QA Order Criteria	Processes	Procedures and Documents
3. Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services.		
Criterion 8 – Performance/Inspection and Acceptance Testing		
1. Inspect and test specified items, services, and processes using established acceptance and performance criteria.		
2. Calibrate and maintain equipment used for inspections and tests.		
Criterion 9 – Assessment/Management Assessment		
1. 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		
1. 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
2. Establish sufficient authority and freedom from line management for independent assessment teams.		
3. Ensure persons who perform independent assessments are technically qualified and knowledgeable in the areas to be assessed.		
Attachment 3 – Suspect/Counterfeit Items Prevention		
Attachment 4 – Safety Software Quality Requirements for Nuclear Facilities		
Corrective Action Management Program (by reference in the QA Order to DOE O 226.1B, 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 D – GRADED APPROACH

The following are the Graded Approach requirements from the QA Order:

> The QA Order requires:
>
> Describe the graded approach used in the QAP.
>
> Implement QA criteria as defined in Attachment 2, as well as the requirements in Attachment 3 for all facilities, and for nuclear facilities, the requirements in Attachment 4.
>
> Note: This requires that all software meet applicable QA requirements in Attachment 2, using a graded approach.
>
> Describe how the criteria/requirements are met, using the documented graded approach.

GENERAL INFORMATION

The QA Order defines the Graded Approach as:

> The process of ensuring that the levels of analysis, documentation, and actions used to comply with requirements is commensurate with:
>
> - the relative importance to safety, safeguards, and security;
> - the magnitude of any hazard involved;
> - the life-cycle stage 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.

The graded approach is used to determine the degree to which QAP and QIP requirements will be applied. The graded approach is the application of controls commensurate with the complexity of the activity, the potential consequences of a failure, and the probability of failure. It is not intended to be used to select some requirements while grading others to zero. The level of control and verification appropriate for a task is dependent upon the consequences of the task not being performed properly. This is defined as applying QA using a graded approach. The basis for the graded approach and process used for implementation shall be documented in the respective QIPs and submitted for EM or the authorized approval authority.

IMPLEMENTATION

Each QA criterion is stated as an expectation for management of work, performance of work, and assessment of work. As such, rigorous QA controls for any high-risk activity at EM and EM projects might include: identifying required and/or appropriate standards; establishing a work plan to prescribe work; assigning responsibilities; specifying personnel qualification and training provisions; developing and implementing work control processes and procedures including configuration control; implementing procurement process control;

instituting verification and validation of items or services performed or procured; and/or performing assessments to verify adequacy of performance and to identify and implement improvement opportunities when performance is unsatisfactory.

Rigorous QA controls should be considered for activities that: (1) involve compliance with laws, regulations, agreements, or directives; (2) could result in failure to achieve enforceable milestones; (3) could have a significant adverse impact on the safety and health of the public, the workers, or the environment; (4) could result in incorrect data or information being released externally; or (5) could result in significant financial loss because of failure to perform an activity correctly or in a timely manner.

Less rigorous or routine QA controls may be considered, when appropriate levels of analysis, documentation, and planned actions allow, for activities such as:

- application of EM policies procedures related to safety and regulatory issues;
- providing program and acquisition direction;
- review of contractor prepared documents such as those related to safety, regulatory, design, etc.;
- evaluation of contractor performance;
- investigation of employee concerns;
- interfacing where commitments or agreements are established with DOE HQ or regulating agencies;
- definition, preparation, and control of records;
- review or conduct of evaluations or investigations of safety-related events;
- implementation and evaluation of corrective actions;
- obtaining safety and environmental related services or activities; and
- conduct of management assessments.

Minimal QA controls may be considered for activities such as the procurement of office supplies or internal correspondence that does not impact any of the above. This attachment does not relax any of the requirements or management expectations contained in this QAP.

Organizational QIPs will address the application of a graded approach to the applicable organizations activities and will identify the processes and procedures utilized to control the application of the graded approach, including the quality level determination process and the quality program application process used.

Note: Non-Mandatory Appendix 2A-2, of Part III, provides additional clarification on a graded approach within NQA (particularly paragraph 502). The *Graded Approach Model and Expectation* EM QA Corporate Board deliverable at http://www.em.doe.gov/Pages/QACorporateBoard.aspx also provides additional guidance.

ATTACHMENT E – INTEGRATED MANAGEMENT SYSTEM

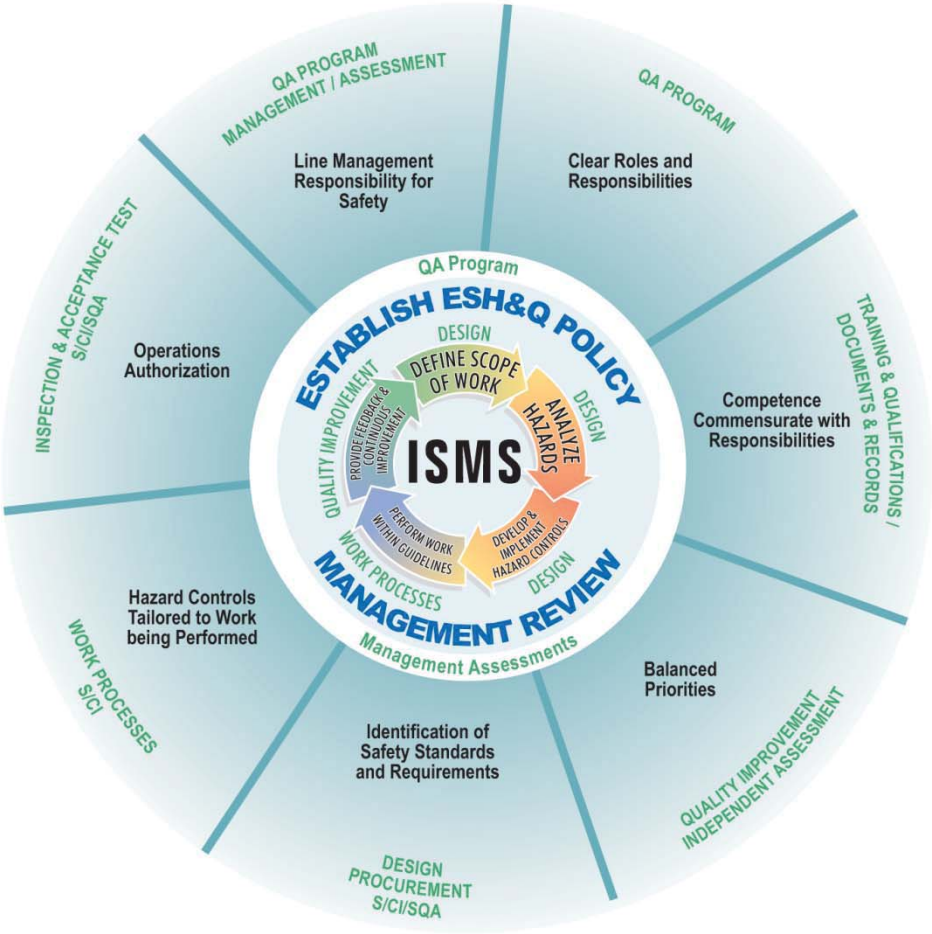
MANAGEMENT EXPECTATIONS:

- Integration of EM HQ, EM Field/Project Offices, and EM contractor QIPs with other quality or management system requirements is consistent with DOE P 450.4.

IMPLEMENTATION

Where specific additional quality or management system requirements are needed, integration is implemented and documented in the applicable QIP. A sample QA/ISMS alignment wheel is provided 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* http://www.hss.doe.gov/nuclearsafety/qa/docs/ISM_QA_Integration_Template_Final_8-23-11.pdf.

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-1-2004 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	VI.	Design
II.	Personnel Training & Qualification	VII.	Procurement
III.	Quality Improvement	VIII.	Inspection & Acceptance Testing
IV.	Documents & Records	IX.	Management Assessment
V.	Work Process	X.	Independent Assessment
		CRD - S/CI/SQA	

Author: R.A. Carter, WCH E0807023_1
(Updated to use DOE O 414.1D)

ATTACHMENT F – SUSPECT/COUNTERFEIT ITEMS PREVENTION

The following are the S/CI Prevention requirements from the QA Order:

(1) Establish DOE and contractor QAPs to establish, document and implement effective controls and processes that will: (1) ensure items and services meet specified requirements; (2) prevent entry of Suspect/Counterfeit Items (S/CIs) into the DOE supply chain; and (3) ensure detection, control, reporting, and disposition of S/CIs.

(2) QAPs shall address and provide for implementation of the requirements in DOE O 414.1D, Attachment 3, and Paragraph 2.

MANAGEMENT EXPECTATIONS:

- Guidance provided in DOE G 414.1-2B, *Quality Assurance Program Guide* and IAEA-TECDOC-1169, *Managing Suspect and Counterfeit Items for the Nuclear Industry* is reviewed and utilized during the preparation process.
- The latest information on S/CI awareness is used, which can be located at the DOE website: http://www.hss.energy.gov/csa/csp/sci/ (click on S/CI Awareness Training Manual)

IMPLEMENTATION

EM assigns implementation authority for S/CI prevention through contracts and/or technical direction. EM monitors S/CI prevention practices through oversight activities.

Plans, implementing procedures and documents are referenced in the respective organizational QIPs.

ATTACHMENT G – SOFTWARE QUALITY REQUIREMENTS

The following are the Software QA Requirements for Nuclear Facilities from the QA Order (note the call outs in the following box are referencing attachments in DOE O 414.1D):

> Implement QA criteria as defined in Attachment 2, as well as the requirements in Attachment 3 for all facilities, and the requirements in Attachment 4 for nuclear facilities, and describe how the criteria/requirements are met, using the documented graded approach. Note: This requires that all software meet applicable QA requirements in Attachment 2, using a graded approach.
>
> Safety software must be acquired, developed and implemented using ASME NQA-1-2008 with the NQA-1a-2009 addenda (or later edition), *Quality Assurance Requirements for Nuclear Facility Applications*, Part I and Subpart 2.7, or other national or international consensus standards that provide an equivalent level of quality assurance requirements as NQA-1-2008. DOE approved QAPs applicable to safety software based on requirements from DOE O 414.1C are acceptable. The standards used must be specified by the user and approved by the designated DOE approval authority.

MANAGEMENT EXPECTATIONS:

- Safety Software QA processes use guidance provided in DOE G 414.1-4, *Safety Software Guide*.
- Computer safety software used to develop or execute the model meets the applicable criteria of NQA-1a-2009 Part I, Subpart 2.7, Subpart 2.14 and DOE-O-414.1D Attachment 4.
- EM model development and operation considers and utilizes the following consensus standards as appropriate:
  - ANSI/ANS-10.2-2009, *Portability of Scientific and Engineering Software*
  - ANSI/ANS 10.4-2008, *Verification and Validation of Non-Safety-Related Scientific and Engineering Computer Programs for the Nuclear Industry*
  - ANSI/ANS-10.5-2011, *Accommodating User Needs in Scientific and Engineering Computer Software Development*
  - ASME V&V 20-2009, *Standard for Verification and Validation in Computational Fluid Dynamics and Heat Transfer*

<u>Software Validation Requirements (safety and non-safety software)</u>

- Software validation activities are planned, documented, and performed for software, software changes, or system configurations that are determined to impact the software.
- The validation test plans, test cases, and test results are documented, reviewed, and approved prior to use of the software.

Software Verification Requirements (safety and non-safety software)

- Software verification activities are planned, documented, and performed for software, software changes, or system configurations that are determined to impact the software.
- Software verification is performed at the end of the requirements, design, and testing life cycle phases to ensure that the products of a given life cycle phase are traceable and fulfill the requirements still applicable from the previous phase and/or previous phases.
- Software verification evaluates the technical adequacy, ensures correctness of the software, and verifies that software is traceable to the software design requirements.
    - Tests and test results from reviews and verifications are included in the acceptance test documentation.
    - Tests conducted as reviews or verifications do not substitute for performing comprehensive, end-of-development acceptance tests.
- Software verification includes review of the test results.
- Software verification is completed prior to approval of the computer program for use.
- Verification reviews identify the reviewer(s) and each reviewer's specific responsibilities during the review.
- Documentation of review comments and their disposition is retained as part of the records package.
- Software verification and validation activities are performed by individuals not associated with the development of the software. In those instances where this level of independence may not be achieved, an individual associated with the development of the software performs these activities with management approval and documented justification.
- As part of the configuration change control, software verifications are performed for the changes, as necessary, to ensure the changes are appropriately reflected in software documentation and to ensure that document traceability is maintained.

IMPLEMENTATION

Typically, EM HQ or EM Field/Project Offices only perform work activities applicable under Software QA as part of information technology and institutional type software programs. Otherwise, EM typically assigns implementation authority for Software QA through contracts and/or technical direction. EM monitors Software QA practices through oversight activities.

Plans, implementing procedures and documents are referenced in the respective organizational QIPs.

ATTACHMENT H – 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 waste across the country. This attachment is included to provide EM management expectations with respect to the overall EM strategy for managing computer models.

MANAGEMENT EXPECTATIONS:

- 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 refereed 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., refereed 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.

IMPLEMENTATION

EM typically assigns implementation authority for model validation through contracts and/or technical direction. EM monitors model validatin practices through oversight activities.

Plans, implementing procedures and documents are referenced in the respective organizational QIPs.

ATTACHMENT I – 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