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

Policies, Procedures, and Plans

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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). The QAP is the EM management system to ensure we "do work correctly." The QAP meets the requirements of DOE O 414.1C, *Quality Assurance*, and 10 CFR 830 Subpart A "Quality Assurance Requirements." It is intended that the requirements of DOE O 414.1C and 10 CFR 830 Subpart A are met by implementing this QAP. The QAP provides EM expectations for implementing quality assurance (QA) across the EM complex. The QAP demonstrates how QA and the Integrated Safety Management System (ISMS) are fully integrated in EM.

The objective of this QAP is to provide consistent QA implementation across EM while allowing both for grading based on importance to the EM mission and safety, and for site-specific requirements to be addressed (e.g., DOE/RW-0333P, *Quality Assurance Requirements and Description*; Environmental Protection Agency [EPA] requirements; state permit requirements; etc.).

2.0 SCOPE

The requirements of the QAP are applied in a graded fashion commensurate with the type of work being performed and the importance of the work contributing to safe completion of the EM mission. EM expects applicable requirements will be passed down to subcontractors.

3.0 APPLICABILITY

The requirements contained within this document apply to EM Headquarters (HQ), EM Field/Project Offices, and EM contractors 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 a contractor's legal obligation to comply with 10 CFR 830 or other regulations

affecting QA. EM adopts American Society of Mechanical Engineers (ASME) NQA-1-2004, *Quality Assurance Requirements for Nuclear Facility Applications*, and addenda through 2007. 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; transuranic [TRU] waste disposal activities; Environmental media, waste characterization, and effluent discharge sampling and analysis operations driven by EPA QA requirements associated with CERCLA, RCRA, Clean Water Act, Clean Air Act, and TSCA regulations; special processes; inspections; use of measuring and test equipment; etc.). Exceptions to implementing NQA-1, 2004 Subparts I and II based on their applicability of the work scope being performed, will be justified and documented in the QIP, and approved on a case-by-case basis.

4.0 REQUIREMENTS & REFERENCES

4.1 REQUIREMENTS

4.1.1 DOE O 414.1C, *Quality Assurance*

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

4.1.3 10 CFR 830, Subpart A, "Quality Assurance Requirements" (i.e., QA Rule)

4.2 REFERENCES

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

4.2.2 DOE G 414.1-2A, *Quality Assurance Management System Guide*

4.2.3 DOE G 414.1-3, *Suspect/Counterfeit Items Guide*

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

4.2.5 DOE G 414.1-5, *Corrective Action Program Guide*

4.2.6 DOE P 450.4, *Safety Management System Policy*

4.2.7 Office of Environmental Management Integrated Safety Management System Description (ISMSD), dated April 2007

5.0 DEFINITIONS & ACRONYMS

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

5.2 Acronyms are defined upon first usage in this document.

6.0 RESPONSIBILITIES

QAP implementation, assessment, and improvement are senior management responsibilities.

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

6.1.1 Develop and implement an approved QIP governing the work under their purview, including as applicable software development/use, in accordance with requirements defined in this document. Identify the senior management position assigned this responsibility.

6.1.2 Submit their QIP to their organizational reporting office (i.e., Contractor through the DOE Field Office to the DOE HQ Office (unless delegated); DOE Field/Project Office through the DOE HQ Office to the Secretarial Office; DOE HQ Office to the Secretarial Office) for review, comment resolution, and approval.

6.1.3 Review and, if authorized through delegation, approve new and revised QIPs for contractors within their purview and as required by applicable contract, QA Rule, and DOE Orders.

NOTE: The scope and rigor of review must be 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.). QIPs must be reviewed and approved or rejected within 90 calendar days of receipt.

6.1.4 EM HQ, EM Field/Project Office, and EM contractors will perform a QA effectiveness review and submit an annual declaration report that demonstrates QA implementation similar to the annual ISMS declaration process.

6.2 Office of Safety Management and Operations (EM-60)

6.2.1 EM-60, as delegated by EM-1, is responsible for the development and maintenance of this QAP. This includes defining expected annual performance objectives, measures, and commitments (POMC).

6.3 EM HQ, EM Field/Project Office, and EM contractor personnel are responsible for implementing this QAP in accordance with their applicable QIPs.

7.0 EM QA PROGRAM

As stated in Section 3.0 above, EM adopts NQA-1-2004 and addenda through 2007. EM implements Parts I and II of the NQA-1 standard in a graded approach, as applicable to the activity (for application of requirements and guidance the use of the term "nuclear power plant" shall not be a limiting factor). 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 their QAP. Unless more appropriate guidance is available, NQA-1 Parts III and IV guidance should be considered where 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 unique/specific work activities, the standards shall be identified within the QIP.

The vast majority of EM work involves nuclear materials and/or systems, activities or services that may impact nuclear safety. The balance of our work involves other types of hazardous facilities, high cost facilities, other Federal and state regulations such as RCRA or CERCLA, and legal commitments that warrant graded application of a rigorous management system approach offered by NQA-1. Therefore, NQA-1 is the appropriate standard to ensure safety, quality, and rigor in our work activities. Through careful application of the graded approach, NQA-1 is also an acceptable standard to ensure safety and rigor in associated non-nuclear work activities, thus leveraging efficiencies of standardization for all EM work.

The following sections define the EM QAP. 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. QIPs may be developed using the sample EM QIP as a template (Attachment G, "Quality Assurance Implementation Plan"). Plans, processes, procedures, and other documents (such as a previously approved QAP or QA Program Description written to meet DOE O 414.1C/ 10 CFR 830 Subpart A) may be used or referenced in the QIP to demonstrate how the requirements of the EM QAP are implemented. Organizations should perform a gap analysis to determine the procedures and documents needed to meet the EM QAP. When employees comply with the processes, procedures, and other documents identified in their organization's approved QIP, they are implementing the EM QAP. EM-1 retains the overall responsibility for the development, execution, and maintenance of the EM QAP.

The following sections describe the implementation of the 10 QA Criteria from DOE O 414.1C and 10 CFR 830, Subpart A (i.e., QA Rule). They also provide alignment with the 18 requirements of ASME NQA-1 (see Attachment E, additionally, Subpart 4.5 of NQA-1 provides a comparison Guide to NQA-1 and 10 CFR 830 and DOE O 414.1). The connection between ISMS core functions/guiding principles and QA requirements can be found in EM-HQ ISMSD, Table 2. The EM graded approach is described in Attachment D. Attachment F defines EM's ISMS expectations.

7.1 PROGRAM

The following are the **Management/Criterion 1 – Program** requirements cited in DOE O 414.1C, Attachment 2 and 10 CFR 830.122, "Quality assurance criteria":

(a) Establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing work.

(b) Establish management processes, including planning, scheduling, and providing resources for work.

The following table illustrates the relationship between the Management/Criterion 1 – Program requirements and the ASME NQA-1 requirements used to implement them. Implementation of these requirements **supports all five ISMS core functions**.

Management/Criterion 1 – Program Requirements	ASME NQA-1 Requirements
(a) Establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing work. *(b) Establish management processes, including planning, scheduling, and providing resources for 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 – Certification of Qualification 500 – Records Non-Mandatory Appendix 1A-1 should be considered to aid in Organizational development during QA documentation.

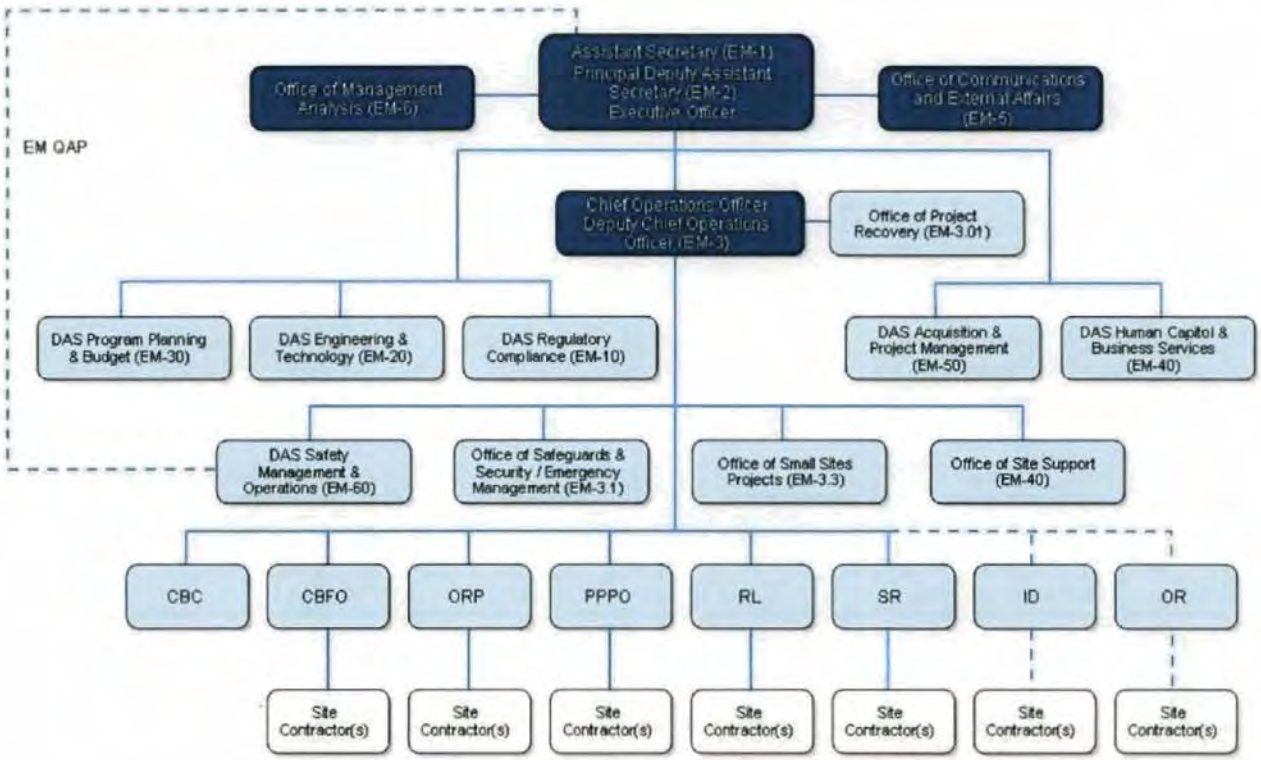
7.1.1 General Information

Management Expectations:

- Employees shall be familiar with and facilitate achievement of the management expectations included in the organizational QIP.
- Management shall establish and implement processes and procedures for EM or EM site mission-related activities in a controlled manner.
- This QAP and associated QIPs shall be maintained current.
- This QAP and associated QIPs should be developed and maintained using the guidance provided in DOE G 414.1-2A, *Quality Assurance Management System Guide*.

Line management for execution of the work extends from EM-3, through the Field/Project Office, to the contractor. The authority for development and implementation of this EM QAP, as defined in DOE O 414.1C, has been delegated by EM-1 to EM-60.

The EM line management organizational structure is as follows:



Where necessary, EM sites coordinate and integrate activities with EM HQ. Lines of communication, feedback mechanisms, and interfaces with stakeholders, regulators, HQ, and support organizations are established and documented. 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 Manual (FRAM) is used to ensure requirements are identified and associated responsibilities are assigned. The dotted lines in the organization chart above reflect functional responsibilities. The QIP defines these linkages to each QA criterion (see Attachment G, "Quality Assurance Implementation Plan").

7.1.2 Implementation

(a) This QAP complies with DOE O 414.1C and with 10 CFR 830 Subpart A (i.e., QA Rule), aligns with ASME NQA-1 requirements, and integrates with the EM ISMSD. 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, 10 CFR 830 and DOE O 414.1.

(b) Each associated (both Federal and Contractor) QIP shall reflect the organizational structure (i.e., organization chart), roles/responsibilities, levels of authority, and interfaces in the organization.

(c) A Functions, Responsibilities, and Authorities (FRA) manual for the DOE organizations is provided to ensure requirements and functional responsibilities are identified and assigned. Each organization's (including contractors) QIP will also identify organizational functions and responsibilities.

(d) The Senior DOE or Contractor Official, 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.

The following elaborates on the relationship between the EM QAP, DOE O 414.1C, and the QA Rule. As stated above in Section 7.0, "EM QA Program," 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 DOE O 414.1C and 10 CFR 830 Subpart A into "requirements" and "implementation." Nothing in this approach affects the contractor's legal liability to comply with 10 CFR 830. The EM QAP meets DOE O 414.1C and 10 CFR 830 Subpart A QAP requirements in the following way:

1. EM Secretarial Officer (i.e., Program Secretarial Officer [PSO]) develops and provides an approved corporate QAP;
2. DOE Field/Projects 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/Projects 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.

7.2 PERSONNEL TRAINING AND QUALIFICATION

The following are the **Management/Criterion 2 – Personnel Training and Qualification** requirements from DOE 414.1C, Attachment 2 and 10 CFR 830.122:

(a) Train and qualify personnel to be capable of performing assigned work.

(b) Provide continuing training to personnel to maintain job proficiency.

The following table illustrates the relationship between the Management/Criterion 2 – Personnel Training and Qualification requirements and the ASME NQA-1 requirements used to implement them. Implementation of these requirements **supports all five ISMS core functions**.

Management/Criterion 2 – Personnel Training and Qualification	ASME NQA-1 Requirements
(a) Train and qualify personnel to be capable of performing assigned work. *(b) Provide continuing training to personnel to maintain job proficiency.*	**Requirement 2 – Quality Assurance Program** 100 – Basic 200 – 202 Indoctrination and Training 300 – 305 Qualification Requirements 400 – Certification 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 General Information

Management Expectations:

The success of any organization requires members of the organization to be competent in the work they perform. Initial and continuing training shall be 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, if necessary, to improve knowledge or skills specific to the job and/or organization.

Training includes formal and informal training, education, and developmental and other learning assignments. Training also includes the application of acquired knowledge, skills, and experience to workplace responsibilities and can be used as a tool to recruit and maintain a talented, diverse, and versatile workforce. Methods of training include, among others, reading assignments, observation and performance of activities, lessons learned, on-the-job training, feedback from co-workers and managers, briefings, and formal training classes. The extent of training is commensurate with the scope, complexity, and nature of the respective task and as required by the approved QIP. Education, experience, formal, and on-the-job training comprise the basis for qualification.

Employee-specific training needs shall be documented and updated as required to ensure the maintenance of competence required by the position.

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 must be demonstrated before performance (e.g., Office of Personnel Management [OPM] minimum qualification requirements, NQA-1 Lead Auditor qualification, etc.) or within a specified timeframe after entering the position (e.g., Technical Qualification Program [TQP] qualification within 18 months of entering the position); and/or

- Whether a specialized certification may be required.

Based on the review, qualification requirements that provide evidence of employee proficiency through a practical and/or written examination process may be established.

7.2.2 Implementation

(a) The method and process for ensuring personnel are trained, qualified and capable of performing assigned work is identified in training and qualification procedures as described in the applicable QIP.

(b) Specific initial and continuing training includes such things as General Employee Training, Job-Specific Training, Assessment and Oversight Training, Lead Auditor Training, Technical Qualification Training (including Safety Software Quality Assurance per Attachment C, "Safety Software Quality Requirements"), and Professional Qualification/Certification Training, as applicable.

7.3 QUALITY IMPROVEMENT

The following are the **Management/Criterion 3 – Quality Improvement** requirements from DOE 414.1C, Attachment 2 and 10 CFR 830.122:

(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.

The following table illustrates the relationship between the Management/Criterion 3 – Quality Improvement requirements and the ASME NQA-1 requirements used to implement them. Implementation of these requirements **supports ISMS Core Function 5.**

Management/Criterion 3 – 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*	**Requirement 2 – Quality Assurance Program** 100 – Basic 200 – 202 Indoctrination and Training 300 – 305 Qualification Requirements 400 – Certification of Qualification 500 – Records **Requirement 15 – Control of Nonconforming Items** 100 – Basic 200 – Identification 300 – Segregation

Management/Criterion 3 – Quality Improvement	ASME NQA-1 Requirements
planning. *(d) Review item characteristics, process implementation, and other quality-related information to identify items, services, and processes needing improvement.*	400 – 405 Disposition **Requirement 16 – Corrective Action** 100 – Basic Non Mandatory Appendices 2A-4, 16A-1 should be considered to aid in Quality Improvement implementation.

7.3.1 General Information

Management Expectations:

- Management shall set performance goals and standards.
- Management shall establish metrics that monitor performance to identify processes needing improvement.
- Nonconforming items will be identified, segregated, and dispositioned. Nonconforming items shall be controlled to prevent inadvertent installation or use.
- Corrective/preventive actions shall be developed and implemented for problems/ findings related to item characteristics, process implementation, or services.
- Identify the causes of problems, and include prevention of recurrence as a part of corrective action planning.
- An "Extent of Condition" determination should be considered. Deficiencies identified as significant (as defined in NQA-1) shall be documented, extent of conditions identified, and corrective/preventive actions implementation verified.
- Completed corrective/preventive actions shall be independently verified for implementation and closure.

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 or 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 or inconsistencies with a requirement, or failures to meet customer, or management expectation.

Problems with potential programmatic or safety significance or that are widespread, continuing, multiple, or repetitive in nature should be afforded special attention. Such problems must be entered into a database and identified to management for proper attention.

Responses to findings identified during Independent Oversight; Environment, Safety, and Health evaluations; Security or Cyber Security evaluations; and Emergency Management assessments, Judgments of Need for Type A Accident investigations, and for other sources as directed by the Secretary or Deputy Secretary are subject to the requirements identified in Attachment B, "Corrective Action Management Program." This includes requirements to prepare a comprehensive corrective action plan (CAP) and to track and report CAP data to HQ using the DOE Corrective Action Tracking System (CATS).

The EM Issues/Action Management System requires that the receiving organization (e.g., the EM site Senior DOE Official) designate a point-of-contact (POC) for items subject to Attachment B. The POC is required to manage the process in strict compliance with the requirements identified in Attachment B. The designated POC is responsible for coordinating responses, transmitting the CAP, and preparing closeout documentation in accordance with the requirements. Nonconformance and corrective action processes shall meet the requirements of their approved QIP.

Management shall identify the causes of problems, and include prevention of recurrence as a part of corrective action planning. Formal root cause analysis should be considered based on the complexity of the identified issue. Root causes should be identified and documented using an authoritative methodology for root cause identification, such as DOE G 231.1-2, *Occurrence Reporting Causal Analysis Guide*, and be performed by root cause analysis-trained personnel.

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

Processes to detect, communicate, and prevent quality problems and processes that do not meet established requirements can be associated with operational awareness activities such as facility tours/walkthroughs, work observation, document reviews, meeting attendance and participation, and ongoing interactions with contractor workers, support staff, and management.

Other processes include assessments/audits of facilities, operations, and programs; assessments/audits of contractor assurance systems; evaluations of contractor performance; and self-assessment of DOE line management functions and performance.

Implementing procedures and documents for quality improvement are defined in the EM HQ, Field/Project Offices, and contractors' QIPs.

7.4 DOCUMENTS AND RECORDS

The following are the **Management/Criterion 4 – Documents and Records** requirements from DOE 414.1C, Attachment 2 and 10 CFR 830.122:

(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.

The following table illustrates the relationship between the Management/Criterion 4 – Documents and Records requirements and the ASME NQA-1 requirements used to implement them. Implementation of these requirements **supports ISMS Core Functions 1, 2, 3, and 4**.

Management/Criterion 4 – 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 General Information

Management Expectations:

- New or revised requirements shall be analyzed to determine impact on implementing procedures and/or contracts.
- Policies, procedures, and plans shall be maintained current and deployed in a manner that makes the documents readily available to the users.
- Procedures shall identify records that need to be created and maintained.
- Records shall be maintained until they are transferred to permanent storage.
- Records shall be transferred to permanent storage in a timely manner when they are no longer needed by the organization.

Documents

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

Requirements typically originate from laws, state or Federal regulations (e.g.,10 CFR 830, Subpart A; RCRA; CERCLA; Clean Water Act; Clean Air Act; TSCA), DOE directives (e.g., DOE O 414.1C), 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 to be identified by each organization (EM HQ, EM Field/Project Offices, and EM contractors) and maintained current.

Records

In general terms, a record is recorded information, in any format, that is created in the course of business, received for action, or needed to document work activities. Records are typically the outcome of implementing documents and reflect what was done. 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 records in a manner that makes the record retrievable, useable, and auditable. Written procedures govern records required to support ongoing activities (active records) as well as records transferred to records retention areas (inactive records). Records must accurately reflect the work performed, be legible, and be traceable to the applicable work and the responsible personnel.

Completed records are maintained in active files until they are no longer required to support ongoing activities or have met legal retention requirements. While in the custody of the responsible personnel, these records are protected from loss or damage by employing filing equipment suitable for the level of protection required as defined in records management regulations. When records are no longer required to support ongoing activities, the responsible personnel transfer them from active files to long-term, secured storage of the records or as determined by legal requirements. The records management program addresses the lifecycle of records, which is the period of time that records are in the custody of Federal agencies. The lifecycle consists of three stages: creation or receipt; maintenance or use; and disposition.

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

7.4.2 Implementation

Implementation documents are identified in the applicable QIP.

7.5 WORK PROCESSES

The following are the **Performance/Criterion 5 – Work Processes** requirements from DOE 414.1C, Attachment 2 and 10 CFR 830.122:

(a) Perform work consistent with technical standards, administrative controls, and hazard controls adopted to meet regulatory or contract requirements using approved instructions, procedures, etc.

(b) Identity and control items to ensure their proper use.

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

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

The following table illustrates the relationship between the Performance/Criterion 5 – Work Processes requirements and the ASME NQA-1 requirements used to implement them. Implementation of these requirements **supports ISMS Core Functions 1, 2, 3, and 4**.

Performance/Criterion 5 – Work Processes	ASME NQA-1 Requirements
(a) Perform work consistent with technical standards, administrative controls, and hazard controls adopted to meet regulatory or contract requirements using approved instructions, procedures, etc. *(b) Identity and control items to ensure their proper use.* *(c) Maintain items to prevent their damage, loss, or deterioration.* *(d) Calibrate and maintain equipment used for process monitoring or data collection.*	**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** 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

Performance/Criterion 5 – Work Processes	ASME NQA-1 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 Subpart 2.7 needs to be utilized in conjunction with Req. 3 (para. 800) and Req. 11 (para. 400). Non-Mandatory Appendix 11A-1 and Subparts 4.1 and 4.4 should be considered.

7.5.1 General Information

Management Expectations:

- Management processes that are routinely performed shall be incorporated into each EM HQ, Field/Project Offices, and contractor's QIP.
- Documents shall clearly establish the roles and responsibilities for employees.
- Employees shall follow approved processes written to accomplish the EM mission and meet regulatory and contract requirements when performing assigned tasks.
- Employees shall identify and assist in making changes that improve project processes and documents.
- Safety software shall be managed and controlled in accordance with the requirements of DOE O 414.1 C, Attachment 2, Section 5 (EM contractors) and Attachment 5 (EM HQ and EM Field/Project offices).

- Non-safety, quality-related software for nuclear facility or EM mission critical applications shall be managed and controlled in accordance with the requirements of NQA-1-2004 Part II, Subpart 2.7, "Quality Assurance Requirements for Computer Software for Nuclear Facility Applications."

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.

Safety- and quality-related software must have the appropriate controls in place as required by DOE O 414.1C and NQA-1 2004, even if it is off-the-shelf. It is anticipated that only the prime contractors purchase or develop safety- or quality-related software. However, if EM HQ or EM Field/Project Offices should directly purchase or develop safety- or quality-related software, the applicable requirements of DOE O 414.1C and NQA-1-2004 must be implemented. (See also Attachment C, "Safety Software Quality Requirements.")

Typically, EM HQ or EM Field/Project Offices do not perform work activities applicable under Criterion 5 (b), (c), or (d). EM delegates 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

Implementing procedures and documents are identified in the organizational QIPs.

7.6 DESIGN

The following are the **Performance/Criterion 6 – Design** requirements from DOE 414.1C, Attachment 2 and 10 CFR 830.122:

(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/validate the adequacy of design products using individuals or groups other than those who performed the work.

(e) Verify/validate work before approval and implementation of the design.

The following table illustrates the relationship between the Performance/Criterion 6 – Design requirements and the ASME NQA-1 requirements used to implement them. Implementation of these requirements **supports ISMS Core Functions 1, 2, 3, and 4**.

Performance/Criterion 6 – 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/validate the adequacy of design products using individuals or groups other than those who performed the work.* *(e) Verify/validate work before approval and implementation of the design.*	**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 NQA-1 Part II, Subpart 2.7 – Quality Assurance Requirements for Computer Software for Nuclear Facility Applications** 100 – 102 General 200 – 204 General Requirements 300 – 302 Software Acquisition 400 – 407 Software Engineering Method 500 – Standards, Conventions, and Other Work Practices 600 – 602 Support Software 700 – References Non-Mandatory Appendix 3A-1, and Subpart 4.1, should be considered to aid in the development of Design Control.

7.6.1 General Information

Management Expectations:

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

7.6.2 Implementation

EM HQ or EM Field/Project Offices do not generally perform work activities applicable under Criterion 6. EM delegates implementation authority for design 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 DOE O 414.1C and NQA-1-2004 as applicable to the work being performed.

Each organization shall have plans, procedures and documents identified in their QIP describing and controlling the activities for which they are responsible.

7.7 PROCUREMENT

The following are the **Performance/Criterion 7 – Procurement** requirements from DOE O 414.1C, Attachment 2 and 10 CFR 830.122:

(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.

The following table illustrates the relationship between the Performance/Criterion 7 – Procurement requirements and the ASME NQA-1 requirements used to implement them. Implementation of these requirements **supports ISMS Core Functions 1, 2, 3, and 4**.

Performance/Criterion 7 – 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 Services** 100 – Basic 200 – Supplier Evaluation and Selection 300 – Bid Evaluation 400 – Control of Supplier Generated Documents 500 – 507 Acceptance of Item or Service 600 – Control of Supplier Nonconformances 700 – 705 Commercial Grade Items and Services 800 – Records Non-Mandatory Appendix 4A-1, 7A-1 should be considered to aid in the development of Procurement processes.

7.7.1 General Information

Management Expectations:

- Develop and maintain an integrated acquisition strategy to ensure work is accomplished in compliance with applicable laws, acquisition regulations, state/Federal regulations, and DOE Orders and directives.
- Oversight shall focus on verifying that work is being performed at a cost that provides reasonable value to the government and that contract terms and conditions are satisfactorily accomplished.
- Government-furnished services/items (GFS/I) shall be provided according to contract provisions.

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 contract award and administration of contracts for a variety of goods and services. EM contractors conduct contract work scope including associated technical, QA, structural, systems, components, spare/replacement parts and materials procurement activities. Suspect/counterfeit items (S/CI) prevention requirements from DOE O 414.1C, Attachment 3 are addressed in Attachment A 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. The procurement process includes the following:

- Developing program and acquisition strategies and plans;
- Establishing requirements;
- Evaluating and selecting qualified contractors;
- Providing direction to the contractor;
- Reviewing and approving of 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
- Furnishing GFS/I in a timely manner.

Because of the lead-time required to place a contract, acquisition planning must be 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 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, and (3) relative risk of 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 integrated safety management system is effective. Projects review performance data and other relevant information quarterly and provide timely GFS/I.

7.7.2 Implementation

The method and processes for ensuring services meet established requirements and performance expectations are evaluated using the following processes including: Acquisition Planning, Vendor Surveys, Bid Evaluations, Contractor Oversight, Contract Administration, Source Evaluation, etc.

Implementation documents are identified in the applicable QIP.

7.8 INSPECTION AND ACCEPTANCE TESTING

The following are the **Performance/Criterion 8 – Inspection and Acceptance Testing** requirements from DOE 414.1C, Attachment 2 and 10 CFR 830.122:

(a) Inspect and test specified items, services, and processes using established acceptance and performance criteria.

(b) Calibrate and maintain equipment used for inspections and tests.

The following table illustrates the relationship between the Performance/Criterion 8 – Inspection and Acceptance Testing requirements and the ASME NQA-1 requirements used to implement them. Implementation of these requirements **supports ISMS Core Function 5**.

Performance/Criterion 8 – 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 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 **Requirement 8 – Identification and Control of Items** 100 – Basic 200 – 202 Identification Methods 300 – 303 Specific Requirements
(8)(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

Performance/Criterion 8 – Inspection and Acceptance Testing	ASME NQA-1 Requirements
	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 General Information

Management Expectations:

The contractor will conduct inspections and tests to verify the physical and functional aspects of items, services, and processes to meet requirements and that systems and components are fit for use and acceptable. The procedures that address these processes will be identified in the QIP.

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 and testing equipment
- Documentation and records

7.8.2 Implementation

EM typically delegates 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, Field/Project Office, and EM contractors address the oversight functions performed by the DOE organizations and the performance functions performed by the EM contractors by identification of the applicable requirements and reference to the implementing procedures.

7.9 MANAGEMENT ASSESSMENT

The following is the **Assessment/Criterion 9– Management Assessment** requirement from DOE 414.1C, Attachment 2 and 10 CFR 830.122:

> *Ensure that managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives.*

The following table illustrates the relationship between the Assessment/Criterion 9– Management Assessment requirements and the ASME NQA-1 requirements used to implement them. Implementation of these requirements **supports ISMS Core Function 5**.

Performance/Criterion 9 – 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 – Certification of Qualification 500 – Records **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, and 18A-1 should be considered to aid in organizational development of assessment processes.

7.9.1 General Information

Management Expectations:

- Management assessments shall be one of the means for identifying areas needing correction and/or improvement.
- Management assessments will be performed by managers knowledgeable in the subject area and trained in assessment techniques.
- Managers within all organizations (EM HQ, Field/Project Office, and contractor) will 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 shall consolidate the ISMS and QA annual validation and declaration activities.
- Results of management assessments shall be documented, and deficiencies identified and tracked with corrective actions taken.
- Management assessments should consider guidance provided in DOE G 414.1-1B *Management Assessment and Independent Assessment Guide*.

Management assessment is a method used to achieve continuous improvement and/or to identify barriers that hinder improved performance. Managers must periodically evaluate the performance of their organizations in comparison with their mission, responsibilities, and priorities. Management assessments include verifying that roles and responsibilities are known and understood, processes and procedures are effective, 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.

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 System 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 shall be documented. Assessment results requiring corrective actions shall be 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

Implementation documents and procedures are identified in the applicable QIP.

7.10 INDEPENDENT ASSESSMENT

The following are the **Assessment/Criterion 10– Independent Assessment** requirements from DOE 414.1C, Attachment 2 and 10 CFR 830.122:

(a) Plan and conduct independent assessments to measure item and service quality and the adequacy of work performance and to promote improvement.

(b) Establish sufficient authority and freedom from line management for independent assessment teams.

(c) Ensure that persons conducting independent assessments are technically qualified and knowledgeable in the areas to be assessed.

The following table illustrates the relationship between the Assessment/Criterion 10 – Independent Assessment requirements and the ASME NQA-1 requirements used to implement them. Implementation of these requirements **supports ISMS Core Function 5**.

Performance/Criterion 10 – Independent Assessment	ASME NQA-1 requirements
(a) Plan and conduct independent assessments to measure item and service quality and the adequacy of work performance and to promote improvement. *(b) Establish sufficient authority and freedom from line management for independent assessment teams.* *(c) Ensure that persons conducting 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 – Certification 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**

Performance/Criterion 10 – Independent Assessment	ASME NQA-1 requirements
	100 – Basic 200 – Test Requirements 300 – Test Procedures (Other Than for Computer Programs) 400 – Computer Program Test Procedures 500 – Test Results 600 – 602 Test Records **Requirement 15 – Control of Nonconforming Items** 100 – Basic 200 – Identification 300 – Segregation 400 – 405 Disposition **Requirement 16 – Corrective Action** 100 – Basic **Requirement 18 – Audits** 100 – Basic 200 – Scheduling 300 – 303 Preparation 400 – Performance 500 – Reporting 600 – Response 700 – Follow-up Action 800 – Records Non-Mandatory Appendices 2A-1, 2A-3, 2A-4, 8A-1, 10A-1, 11A-1, and 16A-1 should be considered to aid in the development of independent assessment processes.

7.10.1 General Information

Management Expectations:

- Organizations will 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.
- Independent assessments will be performed by personnel knowledgeable in the subject area and trained in assessment techniques.
- Audits will be performed by auditors and lead auditors qualified in accordance with NQA-1.

- Results of independent assessments/audits shall be documented; deficiencies tracked, corrective action plans reviewed and corrective actions verified.
- Independent assessments should be consistent with guidance provided in DOE G 414.1-1B, *Management Assessment and Independent Assessment Guide*.
- Audits should be consistent with NQA-1 guidance.

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.

Deficiencies identified as significant (as defined in NQA-1) shall be documented, extent of conditions identified, and corrective/preventive actions implementation verified.

7.10.2 Implementation

Implementation documents are identified in the applicable QIP.

8.0 ATTACHMENTS

Attachment A – Suspect/Counterfeit Items Prevention
Attachment B – Corrective Action Management Program
Attachment C – Safety Software Quality Requirements
Attachment D – Graded Approach
Attachment E – Application of ASME NQA-1
Attachment F – Integrated Management System
Attachment G – Quality Assurance Implementation Plan

ATTACHMENT A – SUSPECT/COUNTERFEIT ITEMS PREVENTION

The following are **DOE O 414.1C, Attachment 3, Suspect/Counterfeit Items (S/CI) Prevention** requirements:

> (2) An S/CI prevention process must be developed and implemented as a part of the organization's quality assurance program (QAP) [or QIP] and commensurate with the facility/activity hazards and mission impact. The QAP must be applied to identifying and analyzing S/CIs, removing them, and preventing S/CIs from being supplied to DOE/[National Nuclear Security Administration]NNSA and its contractors per DOE O 414.1C, Attachment 3 (Contractor Requirements Document, Attachment 2, paragraph 4).
>
> (3) Work processes must be developed and implemented using available S/CI information per DOE O 414.1C, Attachment 3 (Contractor Requirements Document, Attachment 2, Paragraph 4).

Implementation of these requirements **supports ISMS Core Functions 2 and 3**.

GENERAL INFORMATION

Management Expectations:

- S/CI prevention processes should meet requirements consistent with guidance provided in DOE G 414.1-3, *Suspect/Counterfeit Items Guide*.
- Use the latest information on S/CI awareness, 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 delegates implementation authority for S/CI prevention through contracts and/or technical direction. EM monitors S/CI prevention practices through oversight activities.

Implementation documents are identified in the applicable QIP.

ATTACHMENT B – CORRECTIVE ACTION MANAGEMENT PROGRAM

The following is the **DOE O 414.1C, Attachment 2, Contractor Requirements Document (CRD) Criterion 3**, "Quality Assurance Criteria," requirement applicable to contractors:

Identify the cause(s) of problems and include prevention of recurrence as a part of corrective action planning

The following are **DOE O 414.1C, Attachment 4, Corrective Action Management Program** requirements applicable to EM HQ and Field/Project Office:

Line managers must perform corrective actions per DOE O 414.1C, Attachment 4, that effectively resolve safety, quality and other issues arising from – (a) findings identified during Independent Oversight; Environment, Safety, and Health evaluations; Security or Cyber Security evaluations; and Emergency Management assessments (DOE O 470.2B, *Independent Oversight and Performance Assurance Program*); (b) judgments of need identified by Type A accident investigations (DOE O 225.1A, *Accident Investigations*); (c) findings identified by the Office of Aviation Management, Office of Management, Budget and Evaluation (DOE O 440.2B, *Aviation Management and Safety [sic]*); or (d) other sources as directed by the Secretary or Deputy Secretary, including crosscutting safety issues.

Implementation of these requirements **supports ISMS Core Function 5**.

GENERAL INFORMATION

Management Expectations:

- Effective implementation of the following requirements should be consistent with guidance provided in DOE G 414.1-5, *Corrective Action Program Guide*:
  - (a) Reporting findings
  - (b) Corrective action plan development, approval, and review
  - (c) Tracking and reporting implementation
  - (d) Corrective action effectiveness review
  - (e) Lessons learned
- Comply with nonconformance and corrective action processes in approved QIP.

IMPLEMENTATION

Implementation documents are identified in the applicable QIP.

ATTACHMENT C – SAFETY SOFTWARE QUALITY REQUIREMENTS

The following are **DOE O 414.1C, Attachment 5, Safety Software Quality Assurance Requirements** (Contractor Requirements Document, Attachment 2, paragraph 5):

(a) Personnel with software quality assurance (SQA) responsibilities must have technical competency to carry out their duties. Technical qualification requirements will be specified in technical qualification standards. This process is coordinated with Federal Technical Capability Panel (FTCP) in accordance with the requirements of DOE M 426.1-1A, *Federal Technical Capability Manual*, and DOE-STD-1172-2003, *Safety Software Quality Assurance Functional Area Qualification Standard.*

(b) Work processes involving safety software must be developed and implemented using national or international consensus standards and must include the following elements.

(1) Facility design authority involvement in the identification of software requirements specification, acquisition, design, development, verification and validation (including inspection and testing), configuration management, maintenance, and retirement.
(2) Identify, document, and maintain safety software inventory.
(3) Establish grading levels for safety software. Document those grading levels in the QAP [or QIP].
(4) Using the grading levels established and approved above, select and implement applicable SQA work activities from the following list to ensure that safety software performs its intended functions. ASME NQA-1-2004, *Quality Assurance Requirements for Nuclear Facility Applications*, or other national or international consensus standards that provide an equivalent level of quality assurance requirements as NQA-1-2004, must be used to implement these work activities. The standards used must be specified by the user and approved by DOE. DOE G 414.1-4 provides acceptable implementation strategies and appropriate standards for these work activities.

- Software project management and quality planning.
- Software risk management.
- Software configuration management.
- Procurement and supplier management.
- Software requirements identification and management.
- Software design and implementation.
- Software safety.
- Verification and validation.
- Problem reporting and corrective action.
- Training of personnel in the design, development, use, and evaluation of safety software.

Implementation of these requirements **supports ISMS Core Functions 3 and 4**.

GENERAL INFORMATION

Management Expectations:

- Safety SQA processes should be consistent with guidance provided in DOE G 414.1-4, *Safety Software Guide*.

IMPLEMENTATION

EM typically delegates implementation authority for safety SQA through contracts and/or technical direction. EM monitors SQA practices through oversight activities.

Implementation documents are identified in the applicable QIP.

ATTACHMENT D – GRADED APPROACH

Note: EM is developing a model approach to grading as part of the Project Focus Area #4 of the EM QA Improvement Project Plan. This section will be modified to reflect the results of this effort when complete. Non-Mandatory Appendix 2A-2, of Part III, provides additional clarification on a graded approach within NQA (particularly paragraph 502).

The following are **DOE O 414.1C Graded Approach** requirements:

Implement the DOE O 414.1C 10 QA criteria using a graded approach and describe how the criteria and graded approach are applied.

GENERAL INFORMATION

DOE O 414.1C 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 applicability of the QAP and QIP requirements to any activity and the extent of rigor in applying them. 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. 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 to implement shall be documented in the respective QIPs and submitted for EM approval.

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: (1) application of EM policies procedures related to safety and regulatory issues; (2) providing program and acquisition direction; (3) review of contractor prepared documents such as those related to safety, regulatory, design, etc.; (4) evaluation of contractor performance; (5) investigation of employee concerns; (6) interfacing where commitments or agreements are established with DOE HQ or regulating agencies; (7) definition, preparation, and control of records; (8) review or conduct of evaluations or investigations of safety-related events; (9) implementation and evaluation of corrective actions; (10) obtaining safety and environmental related services or activities; and (11) 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 quality level determination process and quality program application process used.

ATTACHMENT E – APPLICATION OF ASME NQA-1

The following are **DOE O 414.1C National or International Consensus Standards Applications** requirements:

DOE O 414.1C requires –

(a) The use of national or international consensus standards where practicable and consistent with contractual or regulatory requirements (e.g., 10 CFR 830) and identify the standards used. Appropriate standards include the following:

- ASME NQA-1-2000, *Quality Assurance Requirements for Nuclear Facility Applications* (for nuclear-related activities);
- ANSI/ISO/ASQ Q 9001-2000, *Quality Management System Requirements* (for nonnuclear activities); and
- ANSI/ASQ Z 1.13, *Quality Guidelines for Research*, 1999 (for nonnuclear research activities).

(b) The application of additional standards where practicable and consistent with contractual or regulatory requirements and as necessary to address unique/specific work activities (e.g., development and use of safety software or establishing the competence of a testing and calibration laboratory).

GENERAL INFORMATION

Management Expectations:

- EM HQ, EM Field/Project Offices and EM contractors shall apply ASME NQA-1-2004, *Quality Assurance Requirements for Nuclear Facility Applications*, and addenda through 2007.

IMPLEMENTATION

EM adopts American Society of Mechanical Engineers (ASME) NQA-1-2004, *Quality Assurance Requirements for Nuclear Facility Applications*, and addenda through 2007. EM implements Parts I and II of the NQA-1 standard in a graded approach, as applicable to the activity (for application of requirements and guidance the use of the term "nuclear power plant" shall not be a limiting factor), and within QA Implementation Plans (QIP) consideration shall be made and determination documented on the use of NQA-1 Parts III and IV that are applicable to the workscope. If additional standards are required to address unique/specific work activities, the standards shall be identified within the QIP. Organizational QIPs will include a matrix or linkage to implementing procedures showing the implementation relationship between the ASME NQA-1 program requirements, the DOE O 414.1C criteria, and the organization's implementing procedures.

APPLICATION OF ASME NQA-1
TO THE DEPARTMENT OF ENERGY
QUALITY ASSURANCE PROGRAM (QAP)
EM Federal Programs

DOE O 414.1C Criteria *(See Note A)*	**QA Requirements**	Program	Personnel Training and Qualification	Quality Improvement	Documents and Records	Work Processes	Design	Procurement	Inspection and Acceptance Testing	Management Assessment	Independent Assessment	Safety Software Quality Requirements	Suspect/Counterfeit Items	Corrective Action Management Program	**Implementing Documents**
ASME NQA-1 Requirements *(See Note B)*															
1. Organization		●									●				
2. Quality Assurance Program		●	●	●						●	●				
4. Procurement Document Control								●							
5. Instructions, Procedures, & Drawings					●	●									
6. Document Control					●										
7. Control of Purchased Items & Services								●				●			
16. Corrective Action				●							●			●	
17. Quality Assurance Records					●										
18. Audits										●	●				

Notes:

A. The 10 Criteria from DOE O 414.1C are listed followed by requirements from DOE O 414.1C, Attachments 3, 4, and 5.

B. ASME NQA-1 Requirements 3, 8, 9, 10, 11, 12, 13, 14 and 15, are not directly applicable to DOE EM activities. Where site-specific project applications vary from this base determination, a revised matrix is needed as part of the approved site QIP.

C. Part II of Standard is topic specific, so for the most part the Subparts of this Part will not be specifically called out in this document – but does not eliminate the need to consider and state applicability. Additionally, Part IV material will not be specifically addressed by this document, but still should be considered as appropriate during implementation.

APPLICATION OF ASME NQA-1
TO THE DEPARTMENT OF ENERGY
QUALITY ASSURANCE PROGRAM (QAP)
EM Contractor Programs

DOE O 414.1C Criteria	**QA Requirements**	Program	Personnel Training and Qualification	Quality Improvement	Documents and Records	Work Processes	Design	Procurement	Inspection and Acceptance Testing	Management Assessment	Independent Assessment	Safety Software Quality Requirements	Suspect/Counterfeit Items	Corrective Action Management Program	**Implementation Documents**
ASME NQA-1 Requirements															
1. Organization		●									●				
2. Quality Assurance Program		●	●	●						●	●				
3. Design							●		●			●			
4. Procurement Document Control								●							
5. Instructions, Procedures, & Drawings					●	●						●			
6. Document Control					●										
7. Control of Purchased Items & Services								●				●	●		
8. Identification & Control of Items						●			●				●		
9. Control of Special Processes						●									
10. Inspection									●		●		●		
11. Test Control									●		●	●			
12. Control of Measuring & Test Equipment						●			●						
13. Handling, Storage, & Shipping						●									
14. Inspection, Test & Operating Status						●			●						
15. Control of Nonconforming Items				●							●		●		
16. Corrective Action				●							●				
17. Quality Assurance Records					●										
18. Audits										●	●				

Note: Where site-specific EM project contractual, local, state, or Federal applications is needed as part of the QA Management System the applicable requirements must be included and approved in site/contractor(s) QIP.

ATTACHMENT F – INTEGRATED MANAGEMENT SYSTEM

The following are **DOE O 414.1C Integrated Management System** requirements:

DOE O 414.1C requires –

The integration, where practicable and consistent with contract or regulatory requirements, quality management system requirements as defined in DOE O 414.1C, the S/CI Prevention process (Attachment 3), the Corrective Action Management Program (Attachment 4), and Safety Software Quality Requirements (Attachment 5) with other quality or management system requirements in DOE directives and external requirements, including as applicable:

- DOE P 450.4, *Safety Management System Policy*;
- DOE P 226.1A, *Department of Energy Oversight Policy*;
- NNSA, *Quality Management Policy*, QC-1 (quality management system for the nuclear weapons complex and weapons-related activities);
- DOE/RW-0333P DOE Office of Civilian Radioactive Waste Management, *Quality Assurance Requirements and Description*; and
- DOE/CBFO-94-1012, DOE Carlsbad Field Office, *Quality Assurance Program Description*, (for the Waste Isolation Pilot Plant and related activities).

GENERAL INFORMATION

Management Expectations:

- Integration of EM HQ, EM Field/Project Offices, and EM contractor QIPs with other quality or management system requirements should be consistent with guidance provided in DOE G 414.1-2A, *Quality Assurance Management System Guide*.

IMPLEMENTATION

Where specific additional quality or management system requirements are needed, integration is implemented and documented in the applicable QIP. A sample QA/ISM alignment "wheel" is provided below for consideration as an example of documenting system integration.

QA Alignment with ISMS

QA Rule/DOE Order 414.1C/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 - CRD 4

Safety Software Quality Assurance (SQA) - CRD 5

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 414.1C/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

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ATTACHMENT G – QUALITY ASSURANCE IMPLEMENTATION PLAN (QIP)

INTRODUCTION

QIPs 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.

SAMPLE – QA IMPLEMENTATION PLAN

DOE O 414.1C Criteria	Processes	Procedures and Documents
Management/Criterion 1—Program		
1. Establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing work.	Planning Scheduling Resource Allocation Graded Approach NQA-1 Application	EM Organization Chart EM Strategic Plan EM Mission and Function Statement EM FRAM Definitions & Acronyms EM Quality Assurance Program
2. Establish management processes, including planning, scheduling, and providing resources for work.		
Management/Criterion 2—Personnel Training and Qualification		
1. Train and qualify personnel to be capable of performing assigned work.	Training Technical Qualification Professional Qualification	Training and Qualification for Federal Employees Technical Qualification Program
2. Provide continuing training to personnel to maintain job proficiency.		
Management/Criterion 3—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	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.		

DOE O 414.1C Criteria	Processes	Procedures and Documents
4. Review item characteristics, process implementation, and other quality-related information to identify items, services, and processes needing improvement.	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	
Management/Criterion 4—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.		
Performance/Criterion 5—Work Processes		
1. Perform work consistent with technical standards, administrative controls, and hazard controls adopted to meet regulatory or contract requirements using approved instructions, procedures, etc.	Quality Assurance Integrated Safety Mgt ISSM Cyber Security Emergency Mgt Business Operations	Preparation, Review, Approval, Revision, and Distribution of EM Implementing Procedures EM Quality Assurance Program 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 their proper use.		
3. Maintain items to prevent their damage, loss, or deterioration.		
4. Calibrate and maintain equipment used for process monitoring or data collection.		
Performance/Criterion 6—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.		

DOE O 414.1C Criteria	Processes	Procedures and Documents
4. Verify/validate the adequacy of design products using individuals or groups other than those who performed the work.		
5. Verify/validate work before approval and implementation of the design.		
Performance/Criterion 7—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.		
3. Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services.		
Performance/Criterion 8—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.		
Assessment/Criterion 9—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
Assessment/Criterion 10—Independent Assessment		
1. Plan and conduct independent assessments to measure item and service quality and 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 that persons conducting independent assessments are technically qualified and knowledgeable in the areas to be assessed.		

DOE O 414.1C Criteria	Processes	Procedures and Documents
Appendix A – Suspect/Counterfeit Items Prevention		
Appendix B – Corrective Action Management Program		
	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
Appendix C – Safety Software Quality Requirements		

Legend:
Blue (Criteria 1 – 5, 7, 9, 10, & Appendix B) – DOE and Contractor Implementation
Yellow (Criteria 6, 8, Appendix A, & Appendix C) – DOE Oversight and Contractor Implementation