

PART III – LIST OF DOCUMENTS, EXHIBITS, AND OTHER ATTACHMENTS

SECTION J – LIST OF ATTACHMENTS

ATTACHMENT J-7 – QUALITY ASSURANCE PROJECT GRADED APPROACH

Contractor shall submit a QA Program compliant with EM Corporate QAP (EM-QA-001 Rev 1) using the graded approach as prescribed in the following criteria from DOE O 414.1D.

Graded Approach.

The process of ensuring that the levels of analyses, documentation, and actions used to comply with requirements are commensurate with:

- (1) the relative importance to safety, safeguards, and security;
- (2) the magnitude of any hazard involved;
- (3) the life-cycle stage of a facility or item;
- (4) the programmatic mission of a facility;
- (5) the particular characteristics of a facility or item;
- (6) the relative importance to radiological and nonradiological hazards; and,
- (7) any other relevant factors. (10 C.F.R. § 830.3)

QUALITY ASSURANCE CRITERIA

1. Criterion 1— Management/Program

- 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.

2. Criterion 2— Management/Personnel Training and Qualification

- a. Train and qualify personnel to be capable of performing their assigned work.
- b. Provide continuing training to personnel to maintain their job proficiency.

3. Criterion 3— Management/Quality Improvement

- 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.

4. Criterion 4— Management/Documents and Records

- a. Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design.
- b. Specify, prepare, review, approve, and maintain records.

5. Criterion 5— Performance/Work Processes

- a. Perform work consistent with technical standards, administrative controls, and other hazard controls adopted to meet regulatory or contract requirements using approved instructions, procedures, or other appropriate means.
- b. Identify and control items to ensure proper use.
- c. Maintain items to prevent damage, loss, or deterioration.
- d. Calibrate and maintain equipment used for process monitoring or data collection.

6. Criterion 6— Performance/Design

- a. Design items and processes using sound engineering/scientific principles and appropriate standards.
- b. Incorporate applicable requirements and design bases in design work and design changes.
- c. Identify and control design interfaces.
- d. Verify or validate the adequacy of design products using individuals or groups other than those who performed the work.
- e. Verify or validate work before approval and implementation of the design.

7. Criterion 7— Performance/Procurement

- a. Procure items and services that meet established requirements and perform as specified.
- b. Evaluate and select prospective suppliers on the basis of specified criteria.

- c. Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services.

8. Criterion 8— Performance/Inspection and Acceptance Testing

- 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.

9. Criterion 9— Assessment/Management Assessment.

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

10. Criterion 10— Assessment/Independent Assessment.

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

SUSPECT/COUNTERFEIT ITEMS PREVENTION

1. **PURPOSE.** To set forth requirements for DOE and its contractor organizations, as part of their 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. **REQUIREMENTS.** The organization's QAP must:
 - a. Include a S/CI oversight and prevention process commensurate with the facility/activity hazards and mission impact.
 - b. Identify the position responsible for S/CI activities and for serving as a point of contact with the Office of Health, Safety, and Security.
 - c. Provide for training and informing managers, supervisors, and workers on S/CI processes and controls (including prevention, detection, and disposition of S/CIs).
 - d. Prevent introduction of S/CIs into DOE work by—
 - (1) engineering involvement:
 - (a) in the development of procurement specifications;
 - (b) during inspection and testing; and
 - (c) when maintaining, replacing, or modifying equipment;
 - (2) identifying and placing technical and QA requirements in procurement specifications;
 - (3) accepting only those items that comply with procurement specifications, consensus standards, and commonly accepted industry practices; and
 - (4) inspecting inventory and storage areas to identify, control, and disposition for S/CIs.
 - e. Include processes for inspection, identification, evaluation, and disposition of S/CIs that have been installed in safety applications and other applications that create potential hazards. Also address the use of supporting engineering evaluations for acceptance of installed S/CI as well as marking to prevent future reuse.
 - f. Conduct engineering evaluations to be used in the disposition of identified S/CIs installed in safety applications/systems or in applications that create potential hazards. Evaluations must consider potential risks to the environment, the public and workers along with a cost/benefit impact, and a schedule for replacement (if required).

- g. Perform the evaluation to determine whether S/CIs installed in non-safety applications pose potential safety hazards or may remain in place. Disposition S/CIs identified during routine maintenance and/or inspections to prevent future use in these applications.
- h. Report to the DOE Inspector General per paragraph 3. below, and DOE O 221.1B, *Reporting Fraud, Waste, and Abuse to the Office of Inspector General*, dated 09-27-16 (or latest version).
- i. Collect, maintain, disseminate, and use the most accurate, up to date information on S/CIs and suppliers. Sources are identified on the Suspect/Counterfeit and Defective Items website (<https://energy.gov/ehss/policy-guidance-reports/databases/suspectcounterfeit-and-defective-items>).
- j. Conduct trend analyses for use in improving the S/CI prevention process.

Note: DOE O 210.2A, *DOE Corporate Operating Experience Program*, dated 04-08-11 (or latest version) requires review of existing lessons learned reports and submittal of new lessons learned reports for use in improving the S/CI prevention process.

3. INSPECTOR GENERAL. Contact the DOE Inspector General (IG), before destroying or disposing of S/CIs and corresponding documentation, to allow the IG to determine whether the items and documentation need to be retained for criminal investigation or litigation.
4. OCCURRENCE REPORTING. S/CIs must be reported in accordance with DOE O 232.2A, *Occurrence Reporting and Processing of Operations Information*, dated 08-30-11 (or latest version).

SAFETY SOFTWARE QUALITY ASSURANCE REQUIREMENTS FOR NUCLEAR FACILITIES

1. PURPOSE.

- a. Prescribe the safety software quality assurance (SSQA) requirements for DOE nuclear facilities.
- b. Software, other than safety software as defined below, is not subject to these requirements (for example, software used solely for consequence assessment purposes in establishing the technical basis of an emergency program or during emergency response is not considered safety software).

2. REQUIREMENTS.

- a. Safety software must be acquired, developed and implemented using ASME NQA-1-2008 with the NQA-1a-2009 addenda (or a 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. The standards used must be specified by the user and approved by the designated DOE approval authority. Management of safety software must include the following elements.
 - (1) Involve the facility design authority, as applicable, in: the identification of; requirements specification; acquisition; design; development; verification and validation (including inspection and testing); configuration management; maintenance; and, retirement.
 - (2) Identify, document, control and maintain safety software inventory. The inventory entries must include at a minimum the following: software description; software name; version identifier; safety software designation (e.g., safety system software, safety and hazard analysis software and design software, safety management and administrative controls software); grade level designation; specific nuclear facility application used; and, the responsible individual.
 - (3) Establish and document grading levels for safety software using the graded approach. Grading levels must be submitted to and approved by the responsible DOE approval authority.
 - (4) Using the consensus standard selected and the grading levels established and approved above, select and implement applicable SSQA work activities from the list below.
 - (a) Software project management and quality planning
 - (b) Software risk management
 - (c) Software configuration management
 - (d) Procurement and supplier management
 - (e) Software requirements identification and management
 - (f) Software design and implementation
 - (g) Software safety analysis and safety design methods
 - (h) Software verification and validation
 - (i) Problem reporting and corrective action
 - (j) Training of personnel in the design, development, use, and evaluation of safety software