U.S. Department of Energy
Washington, DC

ORDER

DOE O 414.1E

Approved: 12-18-2024

SUBJECT: QUALITY ASSURANCE

1. PURPOSE. To establish an integrated Quality Assurance Program (QAP) that assures:

   a. controls for the conduct of work,

   b. requirements are met, and;

   c. achievement of organizational mission needs.

2. CANCELS/SUPERSEDES. DOE O 414.1D Chg. 2 (LtdChg), *Quality Assurance*, dated 9-15-20. Cancellation of a directive does not, by itself, modify or otherwise affect any contractual or regulatory obligation to comply with the directive. Contractor Requirements Documents (CRDs) that have been incorporated into a contract remain in effect throughout the term of the contract unless and until the contract or regulatory commitment is modified to either eliminate requirements that are no longer applicable or substitute a new set of requirements.

3. APPLICABILITY.

   a. Departmental Applicability. Except for the equivalencies and exemptions in paragraphs 3.c. and 3.d., this Order applies to all Departmental elements, and their associated field element.[1] The Administrator of the National Nuclear Security Administration (NNSA) must ensure that NNSA employees comply with their responsibilities under this directive. Nothing in this directive will be construed to interfere with the NNSA Administrator's authority under section 3212(d) of Public Law (P.L.) 106-65 to establish Administration-specific policies, unless disapproved by the Secretary.

      (2) Except for the equivalencies and exemptions in paragraph 3.c., this Order applies to all work conducted by or for DOE.

      (3) Except for the equivalencies and exemptions in paragraph 3.c., applicable requirements of the CRD set forth in this Order apply to government-owned government-operated (GOGO) facilities and federally staffed laboratories.

[1] Operations offices, service centers, site offices, area offices, field offices, government-owned government-operated facilities, and regional offices of federally-staffed laboratories that report directly to a DOE Headquarters office.

b. DOE Contractors. Except for the equivalencies and exemptions in paragraph 3.c., the CRD sets forth requirements of this Order that will apply to contracts that include the CRD. Except for the equivalencies and exemptions in paragraph 3.c., this CRD must be included in contracts for the management or operation of DOE-owned or -leased areas or locations or other areas or locations controlled by DOE where activities and operations are performed at one or more facilities or places by a contractor (i.e., those contracts that include the clause at 48 C.F.R. (DEAR) 970.5204-2, laws, regulations and DOE directives) and that require or involve responsibility for work that affects or may affect DOE sites, facilities, programs or activities (including work that may take place outside the physical boundaries of a DOE facility, such as design or analytical services). For all other contracts involving or requiring this type of work, the applicable requirements set forth in the CRD must be included in the contract terms and conditions.

c. Equivalencies/Exemptions for DOE O 414.1E. Any exemption or equivalency to this Order affecting nuclear facilities requires concurrence from the appropriate Central Technical Authority (CTA) per DOE O 410.1, *Central Technical Authority Responsibilities Regarding Nuclear Safety Requirements*, current version.

(1) Equivalency. In accordance with the responsibilities and authorities assigned by Executive Order 12344, codified at 50 United States Code (USC) sections 2406 and 2511 and to ensure consistency through the joint Navy/DOE Naval Nuclear Propulsion Program, the Deputy Administrator for Naval Reactors (Director) will implement and oversee requirements and practices pertaining to this Directive for activities under the Director's cognizance, as deemed appropriate.

(2) Exemption. Activities and facilities subject to regulation by the Nuclear Regulatory Commission (NRC) are exempt from the requirements of this Order. Requirements in this Order that overlap or duplicate the requirements of the NRC do not apply to facilities or activities (including design, construction, operation, deactivation and decommissioning) that are subject to a NRC license (including construction authorization) and related NRC regulatory authority. Other requirements in this Order may be applied to the extent determined appropriate by the responsible Program Office.

d. Financial Assistance. This Order does not apply to Federal oversight of financial assistance awards.

4. REQUIREMENTS.

a. Quality Assurance Program Development and Implementation. Each Departmental element and associated field element(s) must identify and assign an individual within their organization to have responsibility, authority, and accountability for QAP development, implementation, assessment, maintenance,

and improvement. The organization must develop a QAP and its Quality Assurance Program Description (QAPD), and then implement the approved QAP. The QAP must implement the QA requirements found in Attachment 2 for all work and all facilities. The QAP, as documented in the QAPD, must:

(1) Apply the Graded Approach: Where appropriate, a graded approach must be used to implement the requirements of the QAP.

(a) The implementation of a graded approach is fundamental to a quality assurance program because it ensures that resources are allocated, and efforts are focused in proportion to the risks associated with a product, process, or project.

(b) Graded approach means the process of ensuring that the level of analysis, documentation, and actions used to comply with a requirement are commensurate with:

1 the relative importance to safety, safeguards, and security;

2 the magnitude of any hazard involved;

3 the life-cycle stage of a facility;

4 the programmatic mission of a facility;

5 the particular characteristics of a facility;

6 the relative importance to radiological and nonradiological hazards; and,

7 any other relevant factors. (10 C.F.R. § 830.3)

(c) The basis of the graded approach must be documented for each applicable quality assurance requirement of this Order, and be submitted to DOE as part of the QAPD. The graded approach must not be used to negate any applicable requirements.

(2) The QAPD must describe how the requirements in Attachment 2 are met.

(3) The applicable QA requirements and responsibilities must be flowed down throughout all levels of the Departmental element and associated field office.

(4) Document the selection of appropriate national or international voluntary consensus standard, or other standards.

(a) The necessary level of detail from the standard(s) must be described during development of the QAP to achieve quality

consistent with contractual and regulatory requirements, and Secretarial Officer direction.

(b) Gaps between the selected consensus standard(s) and Attachment 2 must be addressed within the QAPD.

(c) For Hazard Category 1, 2, and 3 nuclear facilities, ASME NQA-1 (NQA-1-2008 with the NQA-1a-2009 addenda or later version) is the preferred standard for use as the basis of the QAP with appropriate gaps (e.g., software and work control) addressed. Other voluntary consensus standards may be used upon approval by the DOE QA Approval Authority.

b. Quality Assurance Program Approval and Changes. Each Departmental element and associated field element(s) must:

(1) Obtain QAPD approval by the designated DOE QA Approval Authority.

(a) The QAPD must adequately prescribe the flow down of quality requirements to working level processes (e.g., procedures, instructions, or any other similar term used in the implementing documents.)

(b) The selection of the voluntary consensus standard(s) used to develop the working level processes of the QAP must be described.

(2) Review the QAP annually and update as needed. Submit a summary of the annual review of the QAP and, if necessary, also submit the modified QAPD to the DOE QA Approval Authority. Editorial changes, that do not reduce or change provisions of the QAP or QAPD, do not require approval.

(3) Implement the QAP as approved.

(4) Regard the QAP as approved 90 calendar days after receipt by the DOE QA Approval Authority, unless approved or rejected at an earlier date.

c. Federal Technical Capability and Qualifications. Qualification for the functional areas identified in paragraphs 4.c.(1) and (2) must be achieved as provided in DOE O 426.1, *Department of Energy Federal Technical Capabilities*, current version.

(1) Federal personnel directly responsible for the oversight of quality requirements governing defense nuclear facilities must be qualified in accordance with the DOE Federal Technical Capability Program (See DOE O 426.1, current version, for specific requirements. See DOE-STD-

1150-2013, Quality Assurance Functional Area Qualification Standard, or latest revision, for other acceptable methods).

(2) Federal personnel directly responsible for oversight of software quality assurance (SQA) activities of defense nuclear facilities must be qualified in accordance with the DOE Federal Technical Capability Program (See DOE O 426.1, current version, for specific requirements. See DOE-STD-1172-2011, Safety Software Quality Assurance Functional Area Qualification Standard, or latest revision, for other acceptable methods).

d. Review and Approval of Contractor Quality Assurance Program. The designated DOE QA Approval Authority must identify the personnel responsible for conducting the review of a contractor's QAP. The personnel responsible for conducting the review of a contractor's QAP must:

(1) When submitted by the contractor per the requirements of Attachment 1, Section 2.

(a) Ensure that the QAPD adequately prescribes the flow down of the Attachment 2 requirements to working level processes.

(b) Ensure an appropriate national or international voluntary consensus standard or portions of standards are selected as the basis for the program.

1 Gaps between the selected consensus standard(s) and Attachment 2 must be addressed within the QAPD.

2 For Hazard Category 1, 2, and 3 nuclear facilities, ASME NQA-1 (NQA-1-2008 with the NQA-1a-2009 addenda or later version) is the preferred standard for use as the basis of the QAP with appropriate gaps (e.g., software and work control) addressed. Other voluntary consensus standards may be used upon approval by the DOE QA Approval Authority.

(2) Document the results of the review including any programmatic gaps.

(3) If the review results and identified programmatic gaps preclude QAP approval, direct the contractor to address the issues preventing approval. Upon correction and resubmittal, review the contractor QAP per section 4.d.(1).

(4) Following a satisfactory review, submit the review documentation to the DOE QA Approval Authority for final approval. Formally document the approval and issue to the contractor.

5. RESPONSIBILITIES. Deputy Secretary.

(1) Ensure implementation of DOE QA requirements throughout the Department.

(2) Provide leadership for QA program development and implementation with the support of the Office of Environment, Health, Safety, and Security (EHSS).

b. Program Secretarial Officers (PSO).

(1) Notify cognizant contracting officers, (for other than field-issued contracts), of those contractors that should include the CRD or its requirements, as appropriate, in their organization's contracts. The PSO has the authority to direct the contracting officer, as necessary, to ensure appropriate quality requirements are implemented by the contractor.

(2) For PSOs, other than the NNSA, act as the QA Approval Authority or delegate such authority, as appropriate, for QAPs within the Secretarial Officer's organization, and the DOE field elements and contractors within the purview of that Secretarial Office. The NNSA Secretarial Officers act as the QA Approval Authority for QAPs within the Secretarial Officer's organization.

(3) Provide direction and resources for implementing QA requirements for work within their purview and ensure that the appropriate staff is qualified as specified in paragraph 4.c.

(4) Ensure development and approval of the QAP governing the work of their respective organization that meets the requirements of paragraph 4 of this Order.

(5) Ensure reviews of their PSO's QAP are performed per paragraph 4.b.(2) of this Order.

(6) For PSOs, other than NNSA, ensure review and approval of new or revised QAPs for:

(a) field elements under their purview; and

(b) contractors within the purview of the PSO if approval authority is not delegated.

(7) Ensure the QAPs are reviewed, and either rejected or approved within 90 calendar days of receipt. Requests for review/approval that are not approved or rejected within 90 calendar days from receipt will be deemed approved.

c. Field Element Managers (FEMs).

(1) Notify contracting officers, for field-issued contracts, which contractors are affected by this Order. The Secretarial Officer has the authority to direct the contracting officer, as necessary, to ensure appropriate quality requirements are implemented by the contractor.

(2) For FEMs of sites, other than NNSA sites, where approval authority is delegated to the FEM, designate a reviewer and approve any new or revised QAPs for work under the FEM's purview. Where authority is not delegated to the FEM, review and comment on, and submit the QAPs to the Secretarial Officer for approval.

(3) For FEMs of NNSA sites, designate a reviewer and approve any new or revised QAPs for work under the FEM's purview, including the FEM and contractor QAPs.

(4) Provide resources and staff to meet the provisions of this Order and ensure that appropriate staff is qualified, as specified in paragraph 4.c of this Order.

(5) Ensure reviews are performed of the field element QAP per paragraph 4.b.(2) of this Order and update, as necessary. Obtain approval of the modified QAPD by the DOE QA Approval Authority.

d. Contracting Officers. Incorporate the CRD into appropriate contracts in a timely manner upon notification of their applicability.

e. Director of the Office of Environment, Health, Safety and Security. In addition to Secretarial Officer duties prescribed in paragraph 5.b., the Director of the Office of Environment, Health, Safety and Security has the following responsibilities:

(1) Quality Policy.

(a) Acts as the Office of Primary Interest (OPI) for this Order by meeting the requirements of the OPI described in DOE O 251.1, *Departmental Directives Program*, current version.

(b) Develops and proposes QA policies and requirements (including those contained in this Order, 10 C.F.R. Part 830 Subpart A, *Quality Assurance*), and related guides and standards for all DOE work.

(c) Provides advice and assistance to DOE elements and contractors concerning implementation of this Order.

(d) Serves as central point of contact for coordination within DOE and the liaison with other agencies and groups for the development of QA policy, requirements, guides, and standards.

(e) Reviews proposed statutes, regulations, standards, DOE directives, and Defense Nuclear Facilities Safety Board documents for applicability to and potential impact on DOE quality programs.

(2) Quality Program Support.

(a) Identifies and proposes resolutions for crosscutting QA issues within the Department to improve implementation.

(b) Manages Suspect/Counterfeit Item (S/CI)-related information and ensures the collection, screening, and communication of S/CI items that could potentially impact DOE operations. When notified by the Inspector General, General Counsel, Office of Intelligence and Counterintelligence, or other source of relevant S/CI issues outside DOE, ensures the DOE complex is appropriately informed.

f. Director, Office of Enterprise Assessments. Plans and conducts independent oversight reviews of implementation of the requirements of this Order and the CRD (see DOE O 226.1B, Implementation of Department of Energy Oversight Policy, and DOE O 227.1A, Independent Oversight Program, for details).

6. INVOKED STANDARDS. This Order does not invoke any DOE technical standards or industry standards as required methods of implementing this Order. Any technical standard or industry standard that is mentioned in or referenced by this Order is not invoked by this Order. Note: DOE O 251.1, current version, provides a definition for "invoked technical standard."

7. DEFINITIONS.

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

b. Nuclear Facility. A reactor or a nonreactor nuclear facility where an activity is conducted for or on behalf of DOE and includes any related area, structure, facility, or activity to the extent necessary to ensure proper implementation of the requirements.

c. Quality Assurance Program (QAP). The overall program or management system established to assign responsibilities and authorities, define policies and requirements, and provide for the performance and assessment of work.

d. Quality Assurance Program Description (QAPD). A document describing how the quality assurance requirements of Attachment 2 to this Order and any additional contractual and federal quality related requirements are met.

e. Suspect/Counterfeit Items (S/CIs). A general term that includes:

(1) Suspect Items. Items that have indications that they may not be genuine but there is not yet definitive proof of counterfeiting or fraud.

(2) Counterfeit Items. Items that are manufactured, refurbished, or altered to imitate original products without authorization in order to be passed off as genuine.

(3) Fraudulent Items. Items that are misrepresented with the intent to deceive, including items provided with incorrect identification or falsified and/or inaccurate certification. They may also include items sold by entities that have acquired the legal right to manufacture a specified quantity of an item but which has produced a larger quantity than authorized and has sold the excess as legitimate inventory.

8. REFERENCES. The following documents provide guidance and/or related requirements for implementing this Order. DOE directives are available at http://www.directives.doe.gov.

a. P.L. 106-65, Department of Defense Authorization Act of 2000.

b. 10 Code of Federal Regulations (C.F.R.) 830, Nuclear Safety Management.

c. Executive Order 12344, Naval Nuclear Propulsion Program, dated 02-01-82.

d. DOE P 450.4A, *Integrated Safety Management Policy*, current version.

e. DOE O 200.1, *Information Technology Management*, current version

f. DOE O 205.1, *Department of Energy Cybersecurity Program*, current version

g. DOE O 210.2, *DOE Corporate Operating Experience Program*, current version.

h. DOE O 221.1, *Reporting Fraud, Waste and Abuse to the Office of Inspector General*, current version.

i. DOE O 226.1, *Implementation of Department of Energy Oversight Policy*, current version.

j. DOE O 232.2, *Occurrence Reporting and Processing of Operations Information*, current version.

k. DOE O 251.1, *Departmental Directives Program*, current version.

l. DOE O 410.1, *Central Technical Authority Responsibilities Regarding Nuclear Safety Requirements*, current version.

m. DOE O 413.3, *Program and Project Management for the Acquisition of Capital Assets*, current version.

n. DOE O 414.1C, *Quality Assurance*, current version.

o. DOE O 426.1, *Department of Energy Federal Technical Capabilities*, current version.

p. DOE O 450.2, *Integrated Safety Management*, current version

q. DOE G 414.1-1, *Management and Independent Assessments Guide*, current version.

r. DOE G 414.1-2, *Quality Assurance Program Guide*, current version.

s. DOE G 414.1-4, *Safety Software Guide for Use with 10 CFR 830, Subpart A, Quality Assurance Requirements*, current version.

t. DOE-STD-1150-2013, *Quality Assurance Functional Area Qualification Standard*, dated December 2013

u. DOE-STD-1172-2011, *Safety Software Quality Assurance Functional Area Qualification Standard*, dated March 2011 (or latest version).

v. DOE-HDBK 1221-2016 Chg. Notice 1, *Suspect/Counterfeit Items Resource Handbook*, dated January 2017

9. CONTACT. Questions concerning this Order should be addressed to the Office of Quality Assurance and Nuclear Safety Management Programs (EHSS-32).

BY ORDER OF THE SECRETARY OF ENERGY:

DAVID M. TURK
Deputy Secretary

ATTACHMENT 1
CONTRACTOR REQUIREMENTS DOCUMENT
DOE O 414.1E, *QUALITY ASSURANCE*

Regardless of the performer of the work, the contractor is responsible for complying with the requirements of this CRD. The contractor is responsible for flowing down the applicable requirements of this CRD throughout its organization, to its subcontractors at any tier and its vendors and suppliers, to ensure compliance with the requirements of this CRD and for the safe performance of work.

This CRD also incorporates Attachment 2 to DOE O 414.1E, referenced in and made a part of this CRD, which provides additional program requirements and/or information applicable to contracts in which this CRD is inserted.

Requests for equivalencies and exemptions to the requirements of this CRD are to be made via the cognizant contracting officer. Any exemption or equivalency to this Order affecting nuclear facilities requires concurrence from the appropriate Central Technical Authority (CTA).

For those activities, items, or services that affect or may affect the safety of DOE (including National Nuclear Security Administration [NNSA]) nuclear facilities, the contractor must comply with 10 C.F.R. Part 830. The requirements contained within this Order do not contradict 10 C.F.R. Part 830. When the regulation(s) are stricter than this CRD, the contractor must comply with the regulation(s), as applicable, and comply with this CRD, in addition to the regulation(s).

Software (including systems and subsystems) are considered an item. The software lifecycle must be addressed and documented within the QAP.

1. QUALITY ASSURANCE PROGRAM DEVELOPMENT.

    a. The contractor is responsible for developing and documenting a quality assurance program (QAP) in compliance with the contract scope of work, while meeting the requirements of this CRD, including Attachment 2 to DOE O 414.1E.

    b. QAP development must account for the integration of additional contractual and federal quality-related requirements.

    c. The contractor must identify and assign an individual within their organization to have responsibility, authority, and accountability for QAP development, implementation, assessment, maintenance, and improvement.

2. QUALITY ASSURANCE PROGRAM APPROVAL AND CHANGES. The contractor must:

    a. Submit a QAPD to DOE or NNSA for approval within 90 days of being awarded a DOE contract containing this CRD.

(1) The QAPD must be a summary of the QAP.

(2) The QAPD must adequately prescribe the flow down of requirements to working level processes (e.g., procedures, instructions, or any other similar term used in the implementing documents.)

(3) The selection of the voluntary consensus standard(s) used to develop the working level processes of the QAP must be described.

(a) Gaps between the selected consensus standard(s) and Attachment 2 of this Order must be addressed within the QAPD.

(b) For Hazard Category 1, 2, and 3 nuclear facilities, ASME NQA-1 (NQA-1-2008 with the NQA-1a-2009 addenda or later version) is the preferred standard for use as the basis of the QAP with appropriate gaps (e.g., software and work control) addressed. Other voluntary consensus standards may be used upon approval by the DOE QA Approval Authority.

(4) The QAPD must also provide a summary explaining the graded approach.

(a) The implementation of a graded approach is fundamental to a quality assurance program because it ensures that resources are allocated, and efforts are focused in proportion to the risks associated with a product, process, or project. Where appropriate, a graded approach must be used to implement the requirements of this CRD.

(b) Graded approach means the process of ensuring that the level of analysis, documentation, and actions used to comply with a requirement are commensurate with:

1 the relative importance to safety, safeguards, and security;

2 the magnitude of any hazard involved;

3 the life-cycle stage of a facility 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)

The basis of the graded approach must be documented for applicable quality assurance requirement in this CRD, and that documentation must be submitted to DOE as part of the QAPD. The graded approach must not be used to negate any applicable requirements.

(5) The QAPD must describe how the requirements of this CRD are met.

(6) The QAP will be regarded as approved by DOE 90 calendar days after receipt by DOE, unless the QAPD is approved or rejected at an earlier date. The QAP will be considered received upon acknowledgement by the receiving organization.

b. Implement the QAP per the approval issued by DOE.

c. Modify the QAP as directed by the designated DOE contracting authority.

d. Review the QAP annually and update as needed. Submit a summary of the annual review of the QAP and, if necessary, also submit the modified QAPD to the DOE QA Approval Authority. Editorial changes, that do not reduce or change provisions of the QAP or QAPD do not require approval by the DOE QA Approval Authority.

ATTACHMENT 2
QUALITY ASSURANCE REQUIREMENTS

This Attachment provides requirements associated with DOE O 414.1E as well as requirements applicable to contracts in which the associated CRD (Attachment 1 to DOE O 414.1E) is inserted. The requirements are in Part A for general QA criteria, Part B for Suspect/Counterfeit Item Prevention, and Part C for Software QA.

Part A – Quality Assurance Criteria

For all work performed by and for the Department, the quality assurance program must establish, identify, and implement processes for:

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. 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.

Part B – Suspect/Counterfeit Item (S/CI) Prevention

Processes for Suspect/Counterfeit Item Prevention must be identified, established, and implemented within the QAP.

1. Suspect/Counterfeit Items Prevention: Ensure items meet specified requirements, prevent entry of S/CIs and software into the DOE supply chain, and ensure detection, control, reporting, and appropriate disposition of S/CIs.

    a. Conduct S/CI oversight and prevention of S/CI entering the DOE supply chain.

    b. Identify the position responsible for prevention, detection, control, reporting, and appropriate disposition of S/CI and for serving as a point of contact.

    c. Inspect inventory and storage areas for S/CIs on a defined recurring basis.

    d. Develop processes for inspection, identification, evaluation, and disposition of installed S/CIs that may present potential hazards. During routine evaluations (e.g., maintenance and/or inspections) determine whether S/CIs are installed. Evaluations must consider potential risks to the environment, the public and workers along with a cost/benefit impact, and a schedule for replacement (if appropriate). Clearly mark S/CIs that remain in use.

    e. Provide training for managers, supervisors, and workers on Suspect/Counterfeit Items (S/CI) processes and controls (including prevention, detection, and disposition) as appropriate.

    f. S/CI processes must include provisions for the collection, dissemination and use of the most accurate, up to date S/CI information.

g. Include applicable provisions for S/CI reporting:

(1) DOE O 210.2A, *DOE Corporate Operating Experience Program*;

(2) DOE O 221.1B, *Reporting Fraud, Waste and Abuse to the Office of Inspector General*; and

(3) DOE O 232.2A, *Occurrence Reporting and Processing of Operations Information*.

h. Coordinate with the DOE Inspector General's Office (IG) before destroying or disposing of S/CIs and corresponding documentation.

Part C – Software Quality Assurance

Processes for software quality assurance must be identified, established, and implemented within the QAP.

1. The graded approach must be applied to the selection, management, control, documentation, and implementation of all software (including software systems and subsystems) through the QAP.

   a. Applicable requirements in this Attachment apply to all software using the graded approach.

   b. The basis for the graded approach used for software must be documented and submitted to/approved by DOE.

2. Software must be documented, managed, and controlled throughout the software's lifecycle. Appropriate national or international software engineering consensus standard(s) must be used, unless contrary to law or otherwise impractical[2], as approved by the DOE QA Approval Authority. The consensus standards could include combinations of standards (e.g., IEEE, NIST, ANS, etc.) or other software engineering standard(s).

3. The QAPD must define the kinds of software that require tracking/inventory beyond typical software practices. As a minimum, this tracking must include (1) software important to mission accomplishment and (2) software related to nuclear safety (e.g., safety basis analysis software used for control selection, software used to determine limits for emergency management, and software used in TSR implementation) as agreed to by the DOE QA Approval Authority.

[2] ''National Technology Transfer and Advancement Act of 1995, Pub. L. No. 104-113