

SUBJECT: QUALITY ASSURANCE

1. PURPOSE.

- a. To ensure that Department of Energy (DOE), including National Nuclear Security Administration (NNSA), products and services meet or exceed customers' requirements and expectations.
- b. To achieve quality for all work based upon the following principles:
 - (1) All work, as defined in this Order, is conducted through an integrated and effective management system;
 - (2) Management support for planning, organization, resources, direction, and control is essential to quality assurance (QA);
 - (3) Performance and quality improvement require thorough, rigorous assessments and effective corrective actions;
 - (4) All personnel are responsible for achieving and maintaining quality; and
 - (5) Risks and adverse mission impacts associated with work processes are minimized while maximizing reliability and performance of work products.
- c. To establish additional process-specific quality requirements to be implemented under a Quality Assurance Program (QAP) for the control of suspect/counterfeit items (S/CIs), and nuclear safety software as defined in this Order.

2. CANCELLATION. DOE O 414.1D AdminChg 1, *Quality Assurance*, dated 5-8-13. 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contract unless and until the contract or regulatory commitment is modified to either eliminate requirements that are no longer applicable or substitute a new set of requirements.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 paragraph 3.c., this Order applies to all Departmental elements, and their associated field element.¹

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.

- (1) The Administrator of NNSA must assure that NNSA employees comply with their respective 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, including work for nuclear and non-nuclear facilities.
 - (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.
- 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 a DOE-owned or -leased facility (i.e., those contracts that include the clause at 48 C.F.R. (DEAR) 970.5204-2, laws, regulations and DOE directives) 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 and Exemptions for DOE O 414.1D. 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. Consistent with Secretarial Delegation Order Number 00-033.00B to the Administrator and Chief Executive Office of the Bonneville Power Administration (BPA), this Order does not apply to BPA.

- (3) 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.

4. REQUIREMENTS.

- a. Quality Assurance Program Development and Implementation. Each Departmental element and associated field element(s) must identify and assign a senior manager to have responsibility, authority, and accountability to ensure the development, implementation, assessment, maintenance, and improvement of the QAP. Using a graded approach, the organization must develop a QAP and implement the approved QAP. The QAP must do the following:

- (1) Describe the graded approach used in the QAP.
- (2) Implement QA criteria as defined in Attachment 2, as well as the requirements in Attachment 3 for all facilities, and for nuclear facilities, the requirements in Attachment 4.

Note: This requires that all software meet applicable QA requirements in Attachment 2, using a graded approach.

- (a) Describe how the criteria/requirements are met, using the documented graded approach.
- (b) Flow down the applicable QA requirements and responsibilities throughout all levels of the organization,
- (c) Use appropriate national or international consensus standards in whole or in part, consistent with regulatory requirements and Secretarial Officer direction. When standards do not fully address these requirements, the gaps must be addressed in the QAP. Examples of currently acceptable standards include:

- 1 ASME NQA-1-2008 with the NQA-1a-2009 addenda, Quality Assurance Requirements for Nuclear Facility Applications;
- 2 ANSI/ISO/ASQ Q9001-2008, Quality Management System-Requirements; and,
- 3 ANSI/ASQ Z 1.13-1999, Quality Guidelines for Research.

- (d) Clearly identify which standards, or parts of the standards, are used.
- b. Quality Assurance Program Approval and Changes. Each Departmental element and associated field element(s) must:
- (1) Submit a QAP to the designated DOE approval authority.
 - (2) Review the QAP annually, or on a periodic basis defined in the QAP, and update the QAP, as needed. Submit a summary of the review of the QAP and, if necessary, also submit the modified QAP to the DOE approval authority. Editorial changes to the QAP, that do not reduce or change commitments, do not require approval.
 - (3) Regard the QAP as approved 90 calendar days after receipt by the 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) are achieved as defined 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 safety software quality assurance (SSQA) activities of defense nuclear facilities must be qualified in SSQA 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).

Note: Personnel training and qualification requirements for weapons quality assurance are contained in the NNSA Defense Programs (NA-10) Weapons Quality Assurance Procedures Manual (WQAPM), which includes requirements for the use of DOE-STD-1025-2008, *Weapons Quality Assurance (WQA) Qualification Standard (FAQS)*.

5. RESPONSIBILITIES.

- a. 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 Health, Safety, and Security (HSS).

b. Secretarial Officers.

- (1) Notify cognizant contracting officers, (for other than field-issued contracts), of those contractors that should include the CRD or its requirements, as appropriate. 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 Secretarial Officers, other than the NNSA, act as the 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 approval authority for QAPs within the Secretarial Officer's organization.
- (3) Provide direction and resources for implementing QA and SSQA 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.
- (5) Ensure reviews are performed of their Secretarial Office's QAP per paragraph 4.b.(2).
- (6) For Secretarial Officers, 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 Secretarial Office, 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.
- (8) Ensure review of safety documentation for the facility or activity to validate that safety software has been properly identified.
- (9) Ensure review of grading levels of safety software for approval by the QAP approval authority.

- c. Field Element Manager (FEM).
- (1) Notify contracting officers for field-issued contracts as to 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, review 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, review 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.
 - (5) Ensure reviews are performed of the field element QAP per paragraph 4.b.(2) and update as necessary. Submit to the approval authority the modified QAP.
 - (6) Ensure review of safety documentation for the facility or activity to validate that safety software has been properly identified.
 - (7) Ensure review of grading levels of safety software for approval by the QAP approval authority.
- d. Contracting Officers. Incorporate the CRD into contracts in a timely manner upon notification of its applicability.
- e. Chief Health, Safety and Security Officer. In addition to Secretarial Officer duties prescribed in paragraph 5.b., the Chief Health, Safety and Security Officer 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 and 10 C.F.R. Part 830 Subpart A, *Quality Assurance*), 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 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.
- (c) Supports the management of the DOE SSQA program, including the Safety Software Central Registry.
- (d) Develops and proposes requirements and guidance for safety software after formal coordination with the Office of Chief Information Officer.

(3) Independent Assessments. Include assessment of QA implementation within the scope of independent assessment activities.

6. INVOKED TECHNICAL STANDARDS. The following industry standard is invoked as a required method in this Order in accordance with the applicability and conditions described within this Order. Any technical standard or industry standard that is mentioned in or referenced by this Order, but is not included in the list below, is not invoked by this Order. Note: DOE O 251.1D, Appendix J provides a definition for “invoked technical standard.”

ASME NQA-1-2008 with the NQA-1a-2009 addenda, *Quality Assurance Requirements for Nuclear Facility Applications*. This standard is required to be applied for new Hazard Category -1, -2, and -3 nuclear facilities, major modifications, and safety software at these facilities. See Attachment 1, Section 1.c.(1) and Attachment 4 for specific requirements. Heads of Departmental Elements may authorize the use of a later edition of this Standard to fulfill these requirements.

7. DEFINITIONS. (Note: Parenthetical provides the source document for the definition).

- a. Acceptance Testing. The process of exercising or evaluating a system or system component by manual or automated means to ensure that it satisfies the specified

requirements and to identify differences between expected and actual results in the operating environment. (ASME NQA-1-2008 with the NQA-1a-2009 addenda)

- b. Administrative Controls. The provisions relating to organization and management, procedures, record keeping, assessment, and reporting necessary to ensure safe operation of a facility. (10 C.F.R. § 830.3)
- c. Assessment (Assess). A review, evaluation, inspection, test, check, surveillance, or audit to determine and document whether items, processes, systems, or services meet specified requirements and perform effectively.
- d. Configuration Management. The process that controls the activities, and interfaces, among design, construction, procurement, training, licensing, operations, and maintenance to ensure that the configuration of the facility is established, approved, and maintained. (ASME NQA-1-2008 with the NQA-1a-2009 addenda)
- e. Corrective Action. Measures taken to rectify conditions adverse to quality and, where necessary, to preclude repetition. (ASME NQA-1-2008 with the NQA-1a-2009 addenda)
- f. Critical Decision 1 (CD-1). CD-1 approval marks the completion of the Project Definition Phase and the Conceptual Design. Approval of CD-1 provides the authorization to begin the Project Execution Phase and allows Project Engineering and Design (PED) funds to be used. (DOE O 413.3, current version)
- g. Design Authority. The engineer designated by the Acquisition Executive to be responsible for establishing the design requirements and ensuring that design output documentation appropriately and accurately reflect the design basis. The Design Authority is responsible for design control and ultimate technical adequacy of the design process. These responsibilities are applicable whether the process is conducted fully in-house, partially contracted to outside organizations, or fully contracted to outside organizations. The Design Authority may delegate design work [authorities] but not its responsibilities. (DOE O 413.3, current version)
- h. 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)
- i. Hazard. A source of danger (i.e., material, energy source, or operation) with the potential to cause illness, injury, or death to personnel or damage to a facility or to the environment (without regard to the likelihood or credibility of accident scenarios or consequence mitigation). (10 C.F.R. § 830.3)
- j. Hazard Controls. Measures to eliminate, limit, or mitigate hazards to workers, the public, or the environment, including:
- (1) physical, design, structural, and engineering features;
 - (2) safety structures, systems, and components (SSCs);
 - (3) safety management programs;
 - (4) technical safety requirements; and
 - (5) other controls necessary to provide adequate protection from hazards. (10 C.F.R. § 830.3)
- k. Independent Assessment. An assessment conducted by individuals within the organization or company but independent from the work or process being evaluated, or by individuals from an external organization or company. (DOE G 414.1-1, current version)
- l. Item. An all-inclusive term used in place of appurtenance, assembly, component, equipment, material, module, part, structure, product, software, subassembly, subsystem, system, unit, or support systems. (10 C.F.R. § 830.3)
- m. Management Assessment. A periodic introspective self-analysis, conducted by management, to evaluate management systems, processes, and programs ensuring the organization's work is properly focused on achieving desired results. (DOE G 414.1-1, current version)
- n. Nonreactor Nuclear Facility. A facility, activity, or operation that involves or will involve radioactive and/or fissionable materials in such a 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. (10 C.F.R. § 830.3)

- o. 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 established by 10 CFR 830. (10 C.F.R. § 830.3)
- p. Process. A series of actions that achieves an end or result. (10 C.F.R. § 830.3)
- q. Quality. The condition achieved when an item, service, or process meets or exceeds the user's requirements and expectations. (10 C.F.R. § 830.3)
- r. Quality Assurance. All those actions that provide confidence that quality is achieved. (10 C.F.R. § 830.3)
- s. Quality Assurance Program. 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. (10 C.F.R. § 830.3)
- t. Safety. An all-inclusive term to encompass protection of the public, workers, and the environment (used synonymously with environment, safety, and health).
- u. Safety Software. Includes the following:
- v. Safety System Software. Software for a nuclear facility that performs a safety function as part of an SSC and is cited in either (a) a DOE-approved documented safety analysis; or, (b) an approved hazard analysis per DOE P 450.4, current version and 48 C.F.R. 970-5223.1.
- w. Safety and Hazard Analysis Software and Design Software. Software that is used to classify, design, or analyze nuclear facilities. This software is not part of an SSC but helps to ensure the proper accident or hazards analysis of nuclear facilities or an SSC that performs a safety function.
- x. Safety Management and Administrative Controls Software. Software that performs a hazard control function in support of nuclear facility or radiological safety management programs or technical safety requirements or other software that performs a control function necessary to provide adequate protection from nuclear facility or radiological hazards. This software supports eliminating, limiting, or mitigating nuclear hazards to workers, the public, or the environment as addressed in 10 C.F.R. Parts 830 and 835, the DEAR Integrated Safety Management System clause, and 48 C.F.R. 970-5223.1.
- y. Safety Software Central Registry. An information repository designated to contain the list of the Department's safety software toolbox code including code-specific gap analysis documents, guidance documents, and contact information.
- z. Service. The performance of work, such as design, manufacturing, construction, fabrication, assembly, decontamination, environmental remediation,

environmental restoration, waste management, laboratory sample analyses, safety software development/validation/testing, inspection, nondestructive examination/testing, environmental qualification, equipment qualification, training, assessment, repair, and installation or the like. (10 C.F.R. § 830.3)

- aa. Software. Computer programs and associated documentation and data pertaining to the operation of a computer system. (ASME NQA-1-2008 with the NQA-1a-2009 addenda)
- bb. Suspect/Counterfeit Items (S/CIs). An item which is suspect when inspection or testing indicates that it may not conform to established Government or industry-accepted specifications or national consensus standards or whose documentation, appearance, performance, material, or other characteristics may have been misrepresented by the vendor, supplier, distributor, or manufacturer. A counterfeit item is one that has been copied or substituted without legal right or authority or whose material, performance, or characteristics have been misrepresented by the vendor, supplier, distributor, or manufacturer. Items that do not conform to established requirements are not normally considered S/CIs if non-conformity results from one or more of the following conditions (which must be controlled by site procedures as nonconforming items):
 - (1) defects resulting from inadequate design or production quality control;
 - (2) damage during shipping, handling, or storage;
 - (3) improper installation;
 - (4) deterioration during service;
 - (5) degradation during removal;
 - (6) failure resulting from aging or misapplication; or,
 - (7) other controllable causes. (IAEA-TECDOC-1169)
- cc. Testing. An element of verification for the determination of the capability of an item to meet specified requirements by subjecting the item to a set of physical, chemical, environmental, or operating conditions. (ASME NQA-1-2008 with the NQA-1a-2009 addenda)
- dd. Validation. The process of: (a) evaluating a system or component during, or at the end of the development process to determine whether it satisfies specified requirements; or, (b) providing evidence that the software, and its associated products, satisfies system requirements allocated to software at the end of each life-cycle activity, solves the right problem (e.g., correctly models physical laws, implements business rules, uses the proper system assumptions), and satisfies the intended use and user needs. (IEEE Standard 1012-2004)

- ee. Verification. The process of: (a) evaluating a system or component to determine whether the products of a given development phase satisfy the conditions imposed at the start of that phase; or, (b) providing objective evidence that the software and its associated products conforms to requirements (e.g., for correctness, completeness, consistency, accuracy) for all life-cycle activities during each life-cycle process (acquisition, supply, development, operation, and maintenance); satisfies standards, practices, and conventions during life-cycle processes; and, successfully completes each life-cycle activity and satisfies all the criteria for initiating succeeding life-cycle activities (e.g., building the software correctly). (IEEE Standard 1012-2004)
 - ff. Work. A defined task or activity such as: research and development; manufacturing; operations; environmental remediation; maintenance and repair; administration; software (including safety software) development, validation, testing, and use; inspection; safeguards and security; or, data collection and analysis.
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. Executive Order 12344, *Naval Nuclear Propulsion Program*, dated 02-01-82.
 - b. P.L. 106-65, Department of Defense Authorization Act of 2000.
 - c. 10 Code of Federal Regulations (C.F.R.) 830, *Nuclear Safety Management*.
 - d. 48 C.F.R. § 970.5223-1, Integration of Environment, Safety, and Health into Work Planning and Execution.
 - e. DOE P 450.4, *Integrated Safety Management Policy*, current version.
 - f. DOE O 210.2, *DOE Corporate Operating Experience Program*, current version.
 - g. DOE O 221.1, *Reporting Fraud, Waste and Abuse to the Office of Inspector General*, current version.
 - h. DOE O 226.1, *Implementation of Department of Energy Oversight Policy*, current version.
 - i. DOE O 227.1, *Independent Oversight Program*, 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 426.1, *Department of Energy Federal Technical Capabilities*, current version.
- o. DOE G 413.3-2, *Quality Assurance Guide for Project Management*, current version.
- p. DOE G 414.1-1, *Management and Independent Assessments Guide*, current version .
- q. DOE G 414.1-2, *Quality Assurance Program Guide*, d current version.
- r. DOE G 414.1-4, *Safety Software Guide for Use with 10 CFR 830, Subpart A, Quality Assurance Requirements, and DOE O 414.1C, Quality Assurance*, current version.
- s. DOE-STD-1150-2013, *Quality Assurance Functional Area Qualification Standard*, dated April 2002 (or latest version).
- t. DOE-STD-1172-2011, *Safety Software Quality Assurance Functional Area Qualification Standard*, dated December 2003 (or latest version).
- u. DOE-STD-1189-2008, *Integration of Safety into the Design Process*, dated March 2008 (or latest version).
- v. DOE-STD-1025-2008, *Weapon Quality Assurance Qualification Standard*, dated September 2008 (or latest version).
- w. Institution of Electrical and Electronics Engineers (IEEE) Standard 610.12-1990, *IEEE Standard Glossary of Software Engineering Terminology*.
- x. IEEE Standard 1012-2004, IEEE Standard for Software Verification and Validation.
- y. International Atomic Energy Agency (IAEA) standard, IAEA-TECDOC-1169, *Managing Suspect and Counterfeit Items in the Nuclear Industry*, dated August 2000. (http://www-pub.iaea.org/MTCD/publications/PDF/te_1169_prn.pdf)
- z. American Society of Mechanical Engineers (ASME), NQA-1-2008 with the NQA-1a-2009 addenda, *Quality Assurance Requirements for Nuclear Facility Applications*.
- aa. American Society of Mechanical Engineers (ASME), NQA-1-2000, *Quality Assurance Requirements for Nuclear Facility Applications*.
- bb. ANSI/ISO/ASQ Q9001-2008, *Quality Management System-Requirements*.

- cc. ANSI/ASQ Z 1.13-1999, Quality Guidelines for Research.
9. CONTACT. Questions concerning this Order should be addressed to the Office of Quality Assurance Policy and Assistance, 301-903-5452.

BY ORDER OF THE SECRETARY OF ENERGY



MARK W. MENEZES
Deputy Secretary

CONTRACTOR REQUIREMENTS DOCUMENT
DOE O 414.1D CHG 2, *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, to the extent necessary, to subcontractors at any tier, as well as vendors and suppliers, to ensure the contractor's compliance with the requirements and the safe performance of work. When the contractor conducts activities or provides items or services that affect or may affect the safety of DOE (including National Nuclear Security Administration [NNSA]) nuclear facilities, it must conduct work in accordance with the quality assurance (QA) requirements of 10 C.F.R. Part 830 Subpart A and the additional requirements of this CRD, unless the work falls within one or more of the exclusions found in 10 C.F.R. § 830.2. Requirements of this CRD that overlap or duplicate Nuclear Regulatory Commission (NRC) requirements are not applicable to facilities or activities (including design, construction, operation, deactivation and decommissioning) subject to a NRC license (including construction authorization) and related NRC regulatory authority. Other requirements in this CRD may be applied to the extent determined appropriate by the responsible Program Office.

In addition to the requirements set forth in this CRD, Attachments 2, 3 and 4 to DOE O 414.1D are made a part of this CRD and provide program requirements and/or information applicable to contracts in which this CRD is inserted.

1. QUALITY ASSURANCE PROGRAM DEVELOPMENT AND IMPLEMENTATION.

The contractor must identify and assign an individual to have responsibility, authority, and accountability to ensure the development, implementation, assessment, maintenance, and improvement of the QAP. The contractor, using a graded approach, must develop a QAP and conduct work in accordance with the approved QAP that meets the requirements of this CRD. The QAP must do the following:

- a. Describe the graded approach used in the QAP.
- b. Implement QA criteria as defined in Attachment 2, as well as the requirements in Attachment 3 for all facilities, and the requirements in Attachment 4 for nuclear facilities, and describe how the criteria/requirements are met, using the documented graded approach.

Note: This requires that all software meet applicable QA requirements in Attachment 2, using a graded approach.

- c. Use appropriate national or international consensus standards consistent with contractual and regulatory requirements, and Secretarial Officer direction. Clearly identify which standards, or parts of the standards, are used. When standards do not fully address the CRD requirements, the gaps must be addressed in the QAP. Select and document the appropriate choice below.

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

- (a) Existing facilities, or new facilities and major modifications to existing facilities achieving Critical Decision 1 (CD-1) prior to the issuance of the Order containing this CRD, continue to use the consensus standard cited in the DOE-approved QAP consistent with Secretarial Officer direction.
- (b) New facilities and major modifications to existing facilities achieving Critical Decision 1 (CD-1) after the Order containing this CRD has been issued use ASME NQA-1-2008 with the NQA-1a-2009 addenda (or a later edition), *Quality Assurance Requirements for Nuclear Facility Applications*, Part I and applicable requirements of Part II.

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

- (c) Consensus standard(s) that provide an equivalent level of quality requirements as required in paragraphs 1.c.(1).(b) may be used in lieu of those specified to implement the requirements of this CRD. The QAP must document how this consensus standard is (or a set of consensus standards are) used, as well as how they are equivalent to the consensus standard listed in 1.c.(1).(b).
- (2) For other activities and facilities (e.g., less than hazard category 3, non-nuclear, or chemically hazardous) use in whole or in part appropriate standards. Examples of appropriate standards include:
- (a) ASME NQA 1-2008 with the NQA-1a 2009 addenda, *Quality Assurance Requirements for Nuclear Facility Applications*, Part I and applicable requirements of Part II;
 - (b) ASME NQA 1-2000, *Quality Assurance Requirements for Nuclear Facility Applications*, Part I and applicable requirements of Part II;
 - (c) ANSI/ISO/ASQ Q9001-2008, Quality Management System: Requirements; and,
 - (d) ANSI/ASQ Z 1.13-1999, Quality Guidelines for Research.

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

- a. Submit a QAP to DOE for approval within 90 days of being awarded a DOE contract.
- b. Implement the QAP as approved by DOE.

- c. 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 QAP to the DOE approval authority. Editorial changes, that do not reduce or change commitments, do not require approval.
- d. Regard a QAP as approved by DOE, 90 calendar days after receipt by DOE, unless approved or rejected by DOE at an earlier date. Receipt includes acknowledgement by the receiving organization, and every official submittal to DOE restarts the 90 day clock.
- e. For subcontractor, vendor, and supplier activities that are not governed by the contractor's DOE-approved QAP, evaluate their program to ensure they meet applicable QA requirements.

QUALITY ASSURANCE CRITERIA

This attachment provides information and/or requirements associated with DOE O 414.1D and is applicable to contracts in which the associated CRD (Attachment 1) is inserted.

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.

SUSPECT/COUNTERFEIT ITEMS PREVENTION

This attachment provides information and/or requirements associated with DOE O 414.1D and is applicable to contracts in which the associated CRD (Attachment 1) is inserted.

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 applications¹ and other applications that create potential hazards. Also address the use of supporting engineering

¹ Safety applications are those whose failure could adversely affect the environment, safety, or health of the public or workers. This term includes safety systems in nuclear facilities (see 10 C.F.R. § 830.3).

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 221.1, *Reporting Fraud, Waste, and Abuse to the Office of Inspector General*, current version.
- i. Collect, maintain, disseminate, and use the most accurate, up to date information on S/CIs and suppliers. Sources are identified on the DOE S/CI website (<http://www.hss.energy.gov/sesa/corporatesafety/sci/>).
- j. Conduct trend analyses for use in improving the S/CI prevention process.

Note: DOE O 210.2, *DOE Corporate Operating Experience Program*, current 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 232.2, *Occurrence Reporting and Processing of Operations Information*, current version.

SAFETY SOFTWARE QUALITY ASSURANCE REQUIREMENTS FOR NUCLEAR FACILITIES

This attachment provides information and/or requirements associated with DOE O 414.1D and is applicable to contracts in which the associated CRD (Attachment 1) is inserted.

1. PURPOSE.

- a. Prescribe the safety software quality assurance (SSQA) requirements for DOE nuclear facilities.
- b. Software, other than safety software as defined in this Order, is not subject to requirements in this Attachment¹.

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. DOE-approved QAPs applicable to safety software based on requirements from DOE O 414.1C are acceptable. The standards used must be specified by the user and approved by the designated DOE approval authority. Management 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.

¹ 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.

- (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