U.S. Department of Energy
Washington, D.C.

ORDER

DOE O 414.1C

Approved: mm-dd-yy
Review: mm-dd-yy

SUBJECT: QUALITY ASSURANCE

1. OBJECTIVES.

   a. To ensure that the quality of Department of Energy (DOE), including National Nuclear Security Administration (NNSA), products and services meet or exceed customers' expectations.

   b. To achieve quality assurance (QA) for all work based upon the following principles:

      (1) That quality is assured and maintained through a single, integrated, effective quality assurance program (i.e., management system).

      (2) That management support for planning, organization, resources, direction, and control is essential to QA.

      (3) That performance and quality improvement require thorough, rigorous assessment and corrective action.

      (4) That workers are responsible for achieving and maintaining quality.

      (5) That environmental, safety, and health risks and impacts associated with work processes can be minimized while maximizing reliability and performance of work products.

   c. To establish quality process requirements to be implemented under a QA Program (QAP) for the control of suspect/counterfeit items and safety issue corrective actions.

2. CANCELLATIONS. This Order cancels the following.

   a. DOE O 414.1B, *Quality Assurance*, dated 4-29-04.

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Deleted: <#>Portions of DOE O 440.1A, *Worker Protection Management for DOE Federal and Contractor Employees*, dated 3-27-98, as follows: ¶ <#>Attachment 1, paragraph 8, Suspect and Counterfeit Item (S/CI) Controls, and ¶ <#>Attachment 2, paragraph 22, Suspect and Counterfeit Item (S/CI) Controls. ¶

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b. Cancellation of an Order does not, by itself, modify or otherwise affect any contractual obligation to comply with the Order. Canceled Orders that are incorporated by reference in a contract must remain in effect until the contract is modified to delete the requirements in the canceled Orders.

3. APPLICABILITY.

a. Primary DOE Organizations, Including NNSA Organizations. Except for the exclusions in paragraph 3c, this Order applies to all Primary DOE Organizations (see Attachment 1 for a complete list of Primary DOE Organizations). This Order automatically applies to Primary DOE Organizations created after it is issued.

(1) This Order includes a requirement to integrate multiple QA Program drivers imposed by QA regulations [Title 10 (Code of Federal Regulations (CFR) 830], the Nuclear Regulatory Commission, and other Federal agencies. The Order includes supplemental activity-specific requirements for work that also may need to comply with QA regulations. This integration requirement supplements but does not supersede or alter compliance with any QA regulations. In the event of a conflict between this Order and any nuclear safety regulation, the regulation prevails. [See QAP integration requirement, paragraph 4a(4).]

(2) Note that only the NNSA Administrator can direct NNSA employees. Wherever this Order gives direction to NNSA employees, it should be understood that this direction is provided only for the convenience of the Administrator and is not intended to assume or replace the authority of the Administrator's direction.

b. Contractors.

(1) Except for the exclusions in paragraph 3c, the Contractor Requirements Document (CRD), Attachment 2, sets forth requirements of this Order that will apply to contractors whose contracts include the CRD.

(2) This CRD must be included in contracts that require or involve responsibility for work or operations at DOE sites or facilities. This includes work that may take place outside the physical boundaries of a DOE facility, such as design or analysis services.

(3) Secretarial Officers (SOs) are responsible for notifying contracting officers which contractors are affected by this Order. Once notified, contracting officers are responsible for incorporating the CRD into the contracts of affected contractors via the laws, regulations, and DOE directives clause of the contracts.

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(4) As the laws, regulations, and DOE directives clause of site/facility management contract states, regardless of the performer of the work, site/facility management contractor with the CRD incorporated into its contract is responsible for compliance with the requirements of the CRD.

(a) An affected contractor is responsible for flowing down the requirements of this CRD to subcontractors at any tier to the extent necessary to ensure the contractors' compliance with the requirements.

(b) In doing so, the contractor will not unnecessarily or imprudently flow down requirements to subcontractors. That is, the contractor will both —

1 ensure that it and its subcontractors comply with the requirements of the CRD to the extent necessary to ensure the contractor's compliance and

2 incur only costs that would be incurred by a prudent person in the conduct of competitive business.

c. Exclusions.

(1) This Order does not apply to the DOE/NNSA Naval Reactors Program in accordance with Executive Order 12344, statutorily prescribed by Public Law 98-525 [42 United States Code (U.S.C.) 7158, note].

(2) This Order does not apply to the Bonneville Power Administration (BPA), in accordance with Secretarial delegation Order Number 00-033.00A to the BPA Administrator and Chief Executive Officer, dated 9-27-02.

4. REQUIREMENTS.

a. QAP Requirements. Each DOE organization must develop and implement a QAP that—

(1) Implements quality assurance criteria as defined in paragraph 4b using a graded approach and describing how the criteria and graded approach are applied (see paragraph 6 for compliance references).

(2) Uses voluntary national or international consensus standard where practicable and consistent with contractual or regulatory requirements and identifies the standard used. Appropriate standards include the following.

(a) ASME NQA-1-2000, *Quality Assurance Requirements for Nuclear Facility Applications* (for nuclear-related activities);

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(b) ANSI/ISO/ASQ Q 9001-2000, *Quality Management System - Requirements* (for non-nuclear activities); and

(c) ANSI/ASQ Z 1.13, *Quality Guidelines for Research*, 1999 (for non-nuclear research activities).

(3) Applies 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).

(4) Integrates quality management system requirements, Suspect/Counterfeit Items Prevention Process (see Attachment 3), and the Corrective Action Management Program (see Attachment 4) as defined in this Order, and Supplemental Safety Software Quality Requirements (see Attachment 5); with other quality or management system requirements in DOE directives and external requirements, including as applicable—

(a) DOE P 450.4, *Safety Management System Policy*, dated 10-15-96.

(b) DOE P 450.5, *Line Environment, Safety and Health Oversight*, dated 06-26-97.

(c) NNSA *Quality Management Policy*, QC-1, (quality management system for the nuclear weapons complex and weapons-related activities).

(d) DOE/RW-0333P DOE Office of Civilian Radioactive Waste Management, *Quality Assurance Requirements and Description*.

(e) DOE/CBFO-94-1012, DOE Carlsbad Field Office, *Quality Assurance Program Description*, (for the Waste Isolation Pilot Plant and related activities).

NOTE: This integration requirement does not establish or imply a hierarchy of quality requirements or programs.

b. Quality Assurance Criteria. The QAP must address the following management, performance, and assessment criteria.

(1) Management/Criterion 1—Program.

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

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

(2) Management/Criterion 2—Personnel Training and Qualification.

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

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

(3) Management/Criterion 3—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) Management/Criterion 4—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) Performance/Criterion 5—Work Processes.

(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) Identify 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.

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(6) Performance/Criterion 6—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/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.

(7) Performance/Criterion 7—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) Performance/Criterion 8—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) Assessment/Criterion 9—Management Assessment. Ensure that managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives.

(10) Assessment/Criterion 10—Independent Assessment.

(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.

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

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

a. Deputy Secretary. Provides leadership for QA implementation issues and quality problem resolution with the support of the Office of Environment, Safety and Health.

b. Secretarial Officers.

(1) Ensure that Headquarters, field elements, and contractors implement requirements of this Order in an integrated manner and coordinate the resolution of quality issues among these organizations.

(2) Develop, approve, and implement QAPs governing the work of their organizations, including safety software development/use in accordance with the requirements defined in paragraph 4 of this Order; Suspect/Counterfeit Items Prevention requirements (Attachment 3); the Corrective Action Management Program requirements (Attachment 4); and the Supplemental Safety Software Quality requirements (Attachment 5). Identify the senior management position specifically assigned this responsibility.

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(3) Provide direction and resources for implementing the requirements for work within their purview.

(4) Review and approve new and revised field element QAPs. The scope and rigor of a review must be graded according to the status of prior quality performance (e.g., past regulatory/contract noncompliance, performance metrics, or any third-party QAP certification).

(5) Review and approve new and revised contractor QAPs within their purview or delegate authority to the field element manager. The scope and rigor of a review must be graded according to the status of prior quality performance (e.g., past regulatory/contract noncompliance, performance metrics, or any third-party QAP certification).

(6) Review/resolve differences of opinion and approve or reject QAPs within 90 days of receipt.

(7) Report management assessment results periodically to the Deputy Secretary (through the Under Secretary) describing the effectiveness of QA implementation.

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(8) Provide the contracting officer necessary information and direction in order to specify —

(a) each procurement requiring application of the CRD to this Order (Attachment 2) and 10 CFR 830 Subpart A,

(b) requirements for flow down of provisions of the CRD to subcontractors or subawards, and

(c) provisions of the CRD with which contractors or subcontractors are to comply.

(9) Approve CAMP Corrective Action Plans (CAPs) developed by the field element manager (FEM) within 60 calendar days from the date the assessment report was issued.

c. Field Element[1] Managers.

(1) Develop and implement approved QAPs governing the work under their purview, including software development/use, in accordance with requirements defined in paragraph 4 of this Order; suspect/counterfeit items (S/CI) prevention requirements (Attachment 3); CAMP requirements (Attachment 4); and Supplemental Safety Software Quality requirements (Attachment 5). Identify the senior management position assigned this responsibility.

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(2) Submit QAPs to the appropriate SOs for review, resolution of differences of opinion, and approval.

(3) Review and where delegated authority to do so, approve new and revised QAPs for contractors within their purview. 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 any third-party QAP certification). QAPs must be reviewed and approved or rejected within 90 days of receipt.

(4) Perform independent assessments of contractor organizations to evaluate the adequacy and QAP implementation effectiveness. The frequency and scope of assessments must be graded based on the status of prior quality performance and any third-party QAP certification. Other suitable methods may be used in combination with independent assessments.

[1] Operations offices, service centers, site offices, area offices, field offices, and regional offices of federally staffed laboratories.

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(5) Periodically report management assessment results to their organizations' SOs describing the effectiveness of field element and contractor QA implementation.

(6) Prepare and implement a CAP to address all findings in the CAMP assessment report and enter, track, and report the status of the CAP in the Corrective Action Tracking System (CATS).

(7) Complete the CAP and conduct follow up review on the effectiveness of the corrective actions in resolving and preventing recurrence of all findings. Approve the effectiveness review report and follow up report recommendations.

d. Contracting Officers. Include the CRD in contracts falling within the scope of this Order in a timely manner, as directed by the SO.

e. Assistant Secretary for Environment, Safety and Health. Acts as DOE's independent element responsible for safety aspects relative to public and worker health and safety and environmental protection. The Assistant Secretary has the following quality assurance responsibilities in addition to SO duties prescribed in paragraph 5b.

(1) Quality Policy.

(a) Develops and maintains QA policy requirements (including this Order and 10 CFR 830 Subpart A, Quality Assurance), guides, and standards for all DOE work.

(b) Provides advice and assistance (including QAP reviews) to DOE elements and contractors concerning implementation of this Order.

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

(d) Reviews proposed statutes, regulations, standards, DOE Directives, and Defense Nuclear Facility 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) Submits to the Deputy Secretary periodic updates on the effectiveness of QA policy implementation across the Department.

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(c) Manages the DOE S/CI prevention process (Attachment 3).

(d) Manages the DOE Safety Software Quality Program (Attachment 5).

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(3) CAMP and Corrective Action Tracking System (CATS).

(a) Manages CAMP and develops and maintains CAMP policies, procedures and guidelines (Attachment 4).

(b) Maintains CATS and assists FEMs in accessing and editing CAP data. Maintains a CAMP website that provides background and information on the program.

(c) Coordinates status and maintenance of CAMP with SOs, FEMs, and assessing organizations, including periodic reports on program status.

(d) Sponsors and co chairs the DOE Corrective Action Management (CAM) Team.

(e) Manages crosscutting issues as directed by the Secretary or Deputy Secretary.

f. Director, Office of Independent Oversight and Performance Assurance.

(1) Conducts various independent assessments of SO, field element, and contractor implementation of this Order and 10 CFR 830 Subpart A, Quality Assurance (see DOE O470.2B, *Independent Oversight and Performance Assurance Program*, dated 10-31-02), including aspects of QA related to environment, safety, health, safeguards, and security.

(2) Reports assessment results to the appropriate Under Secretary, the Assistant Secretary for Environment, Safety and Health, and the assessed organization.

6. REFERENCES. The following provide guidance and requirements for implementing this Order.

a. DOE G 414.1-2, *Quality Assurance Management System Guide for Use with 10 CFR 830.120 and DOE O 414.1*, dated 6-17-99.

b. DOE G 414.1-1A, *Management Assessment and Independent Assessment Guide for Use with 10 CFR, Part 830, Subpart A, and DOE O 414.1A, Quality Assurance; DOE P 450.4, Safety Management System Policy; DOE P 450.5, Line ES&H Oversight Policy*, dated 5-31-01.

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c. DOE G 440.1-6, *Implementation Guide for Use with Suspect/Counterfeit Items Requirements of DOE O 440.1, Worker Protection Management; 10 CFR 830.120; and DOE 5700.6c, Quality Assurance*, dated 6-30-97.

d. DOE G 414.1-4, *Implementation Guide for Use with Supplemental Safety Software Quality Requirements of DOE O 414.1, Quality Assurance*.

e. DOE M 411.1-1C, *Safety Management Functions, Responsibilities, and Authorities Manual*, dated 12-31-03.

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Deleted: *Quality Assurance Standards for Safety Software in Department of Energy Nuclear Facilities*, dated 9-30-03 (http://www.deprep.org/2003/AttachedFile/tb03s30g_enc.pdf).

7. DEFINITIONS.

a. Assessment. 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.

b. Graded Approach. The process of ensuring that the level 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 non-radiological hazards, and

(7) any other relevant factors.

c. 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.

d. Process. A series of actions that achieves an end result.

e. Quality. The condition achieved when an item, service, or process meets or exceeds the user's requirements and expectations.

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f. Quality Assurance. All those actions that provide confidence that quality is achieved.

g. 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.

h. Safety. An all-inclusive term used synonymously with environment, safety, and health to encompass protection of the public, the workers, and the environment.

i. Safety Software. Includes the following.

(1) Safety System Software, which performs a safety system function as part of a structure, system, or component (SSC) that has been functionally classified as safety class (SC) or safety significant (SS). Includes human-machine interface software, network interface software, programmable logic controller (PLC) programming language software, and safety management databases that are not part of an SSC but whose operation or malfunction can directly affect SS and SC SSC function (see 10 CFR 830.2).

(2) Safety Analysis and Design Software, which is not part of an SSC but is used in the safety classification, design, and analysis of nuclear facilities to ensure the proper accident analysis of nuclear facilities; the proper analysis and design of safety SSCs; and the proper identification, maintenance, and operation of safety SSCs.

j. Service. Work, such as design, construction, fabrication, decontamination, environmental remediation, waste management, laboratory sample analysis, safety software development/validation/testing, inspection, nondestructive examination/testing, environmental qualification, equipment qualification, training, assessment, repair, and installation.

k. Suspect/Counterfeit Items (S/CI). An item is suspect when visual 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 supplier 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 supplier or manufacturer. Items that do not conform to established requirements are not normally considered S/CIs if nonconformity results from one or more of the following conditions (which must be controlled by site procedures as nonconforming items):

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(1) defects resulting from inadequate design or production quality control;

(2) damage during shipping, handling, or storage;

(3) improper installation; deterioration during service;

(4) degradation during removal;

(5) failure resulting from aging or misapplication; or

(6) other controllable causes.

l. Work. A defined task or activity such as research and development, operations, environmental remediation, maintenance and repair, administration, safety software development/validation/testing and use, inspection, safeguards and security, data collection and analysis.

8. CONTACT. Address questions concerning this Order to Office of Quality Assurance Programs, 301-903-2954.

BY ORDER OF THE SECRETARY OF ENERGY:

KYLE E. McSLARROW
Deputy Secretary

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PRIMARY DOE ORGANIZATIONS TO WHICH DOE O 414.1C IS APPLICABLE

This Order is applicable to the following DOE organizations and their associated field elements:

Office of the Secretary
Chief Information Officer
Departmental Representative to the Defense Nuclear Facilities Safety Board
Energy Information Administration
National Nuclear Security Admi nistration
Office of Civilian Radioactive Waste Management
Office of Congressional and Intergovernmental Affairs
Office of Counterintelligence
Office of Economic Impact and Diversity
Office of Electric Transmission and Distribution
Office of Energy Assurance
Office of Energy Efficiency and Renewable Energy
Office of Environment, Safety and Health
Office of Environmental Management
Office of Fossil Energy
Office of General Counsel
Office of Hearings and Appeals
Office of Independent Oversight and Performance Assurance
Office of Intelligence
Office of Legacy Management
Office of Management, Budget and Evaluation/Chief Financial Officer
Office of Nuclear Energy, Science and Technology
Office of Policy and International Affairs
Office of Public Affairs
Office of Science
Office of Security
Office of Security and Safety Performance Assurance
Office of the Inspector General
Secretary of Energy Advisory Board
Southeastern Power Administration
Southwestern Power Administration
Western Area Power Administration

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CONTRACTOR REQUIREMENTS DOCUMENT

DOE O 414.1C, *Quality Assurance*

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Regardless of the performer of the work, the contractor is responsible for complying with the requirements of this Contractor Requirements Document (CRD). The contractor is responsible for flowing down the requirements of this CRD to subcontractors at any tier to the extent necessary to ensure the contractor's compliance with the requirements. In doing so, the contractor must not unnecessarily or imprudently flow down requirements to subcontracts. That is, the contractor will ensure that it and its subcontractors comply with the requirements of this CRD and only incur costs that would be incurred by a prudent person in the conduct of competitive business.

When the contractor conducts activities or provides items or services that affect, or may affect, the safety of Department of Energy (DOE), including National Nuclear Security Agency (NNSA), nuclear facilities, it must conduct work in accordance with the quality assurance QA requirements of 10 CFR 830 Subpart A.

This CRD includes a requirement to integrate multiple Quality Assurance Program (QAP) drivers imposed by QA regulations [see Title 10 Code of Federal Regulations (CFR) 830], the Nuclear Regulatory Commission, and other Federal agencies. The CRD includes supplemental activity-specific requirements for work that also may need to comply with QA regulations. This integration requirement supplements but does not supersede or alter compliance with QA regulations. If this CRD conflicts with any nuclear safety regulation, the regulation prevails. [See QAP integration requirement, paragraph 2a(4).]

1. OBJECTIVES.

a. To ensure that the quality of Department of Energy (DOE), including National Nuclear Security Administration (NNSA), products and services meet or exceed customers' expectations.

b. To achieve QA for all work based upon the following principles:

(1) That quality is assured and maintained through a single, integrated, effective quality assurance program (i.e., management system).

(2) That management support for planning, organization, resources, direction, and control is essential to QA.

(3) That performance and quality improvement require thorough rigorous assessment and corrective action.

(4) That workers are responsible for achieving and maintaining quality.

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(5) That environmental, safety, and health risks and impacts associated with work processes are minimized while maximizing reliability and performance of work products.

c. To establish quality process requirements to be implemented under a QAP for the control of suspect/counterfeit items.

2. GENERAL QUALITY REQUIREMENTS.

a. Quality Assurance Program Development and Implementation. A contractor must assign and identify a senior management position responsible for the development, implementation, assessment, and improvement of a QAP that—

(1) Implements QA criteria as defined in paragraph 3 of this CRD and suspect/counterfeit items (S/CI) prevention requirements as defined in paragraph 4 and Supplemental Safety Software Quality Requirements as defined in paragraph 5 using a graded approach and describing how QA criteria and graded approach are applied. (See paragraph 2c of this CRD for guidance on compliance.)

(2) Uses the appropriate voluntary national or international consensus standard where practicable and consistent with contractual or regulatory requirements, and identifies the standard used. Appropriate standards include the following.

(a) ASME NQA-1-2000, *Quality Assurance Requirements for Nuclear Facility Applications* (for nuclear-related activities);

(b) ANSI/ISO/ASQ Q 9001-2000, *Quality Management System - Requirements* (for non-nuclear activities); and

(c) ANSI/ASQ Z 1.13, 1999, *Quality Guidelines for Research*, (for non-nuclear research activities).

(3) Applies 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).

(4) Integrates quality or management system requirements as defined in this CRD with DOE directives and similar external requirements. Similar requirements include the following.

(a) DOE P 450.4, *Safety Management System Policy*, dated 10-15-96;

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(b) DOE P 450.5, *Line Environment, Safety and Health Oversight*, dated 06-26-97;

(c) NNSA *Quality Management Policy*, QC-1, (quality management system for the nuclear weapons complex and weapons-related activities);

(d) DOE/RW-0333P, DOE Office of Civilian Radioactive Waste Management, *Quality Assurance Requirements and Description*,;

(e) DOE/CBFO-94-1012, DOE Carlsbad Field Office, *Quality Assurance Program Description*, (for the Waste Isolation Pilot Plant and related activities); and

(f) NOTE: This integration requirement does not establish or imply a hierarchy of quality requirements or programs.

b. Quality Assurance Program Approvals and Changes. The contractor must—

(1) Submit a QAP to DOE for approval before beginning work under a DOE contract.

(2) Implement the QAP as approved and modified by DOE.

(3) Indicate in the submittal any third-party certification affecting the QAP.

(4) Revise an existing QAP that was approved in accordance with previous versions of this CRD (e.g., CRD to DOE O 414.1B, *Quality Assurance*, dated 4-29-04) to address enhancements required by this CRD.

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(5) Regard a QAP as approved by DOE 90 days after DOE receipt, unless approved or rejected by DOE at an earlier date, and include any modification made or directed by DOE.

(6) Submit QAP changes made the previous year annually to DOE for review and approval. In the submittal, identify the changes, the reason for the changes, and the basis for concluding that the revised QAP continues to satisfy the requirements of this CRD.

(a) The contractor may make changes to an approved QAP at any time.

(b) Editorial changes made to correct spelling, punctuation, grammar, etc., do not require explanation.

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c. Quality Guidance Usage. The contractor must consider QA guidance in developing and implementing a QAP. The following guidance documents [most recent revision] are available at http://www.directives.doe.gov/.

(1) DOE G 414.1-2, *Quality Assurance Management System Guide for Use with 10 CFR 830.120 and DOE O 414.1*, dated 6-17-99;

(2) DOE G 414.1-1A, *Management Assessment and Independent Assessment Guide for Use with 10 CFR, Part 830, Subpart A, and DOE O 414.1A, Quality Assurance; DOE P 450.4, Safety Management System Policy; DOE P 450.5, Line ES&H Oversight Policy*, dated 5-31-01;

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(3) DOE G 440.1-6, *Implementation Guide for Use with Suspect/Counterfeit Items Requirements of DOE O 440.1, Worker Protection Management; 10 CFR 830.120; and DOE 5700.6c, Quality Assurance*, dated 6-30-97; and,

(4) DOE G 414.1-4, *Implementation Guide for Use with Supplemental Safety Software Quality Requirements of DOE O 414.1, Quality Assurance.*

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3. QUALITY ASSURANCE CRITERIA. The QAP must address the following management, performance, and assessment criteria.

a. Management/Criterion 1—Program.

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

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

b. Management/Criterion 2—Personnel Training and Qualification.

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

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

c. Management/Criterion 3—Quality Improvement.

(1) Establish and implement processes to detect and prevent quality problems.

(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.

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(4) Review item characteristics, process implementation, and other quality-related information to identify items, services, and processes needing improvement.

d. Management/Criterion 4—Documents and Records.

(1) Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design.

(2) Specify, prepare, review, approve, and maintain records.

e. 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.

(2) Identify and control items to ensure proper use.

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

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

f. 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.

(4) Verify/validate the adequacy of design products through individuals or groups other than those who performed the work.

(5) Verify/validate work before approval and implementation of a design.

g. Performance/Criterion 7—Procurement.

(1) Procure items and services that meet established requirements and perform as specified.

(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.

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h. 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.

i. Assessment/Criterion 9—Management Assessment. Ensure that managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives.

j. Assessment/Criterion 10—Independent Assessment.

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

(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.

4. DOE-WIDE SUSPECT/COUNTERFEIT ITEMS (S/CI) PREVENTION PROCESS. The process is operated by the DOE Office of Environment, Safety and Health as a service to DOE and its contractors, and provides for collecting, analyzing, and disseminating S/CI information; notifying Secretarial Officers (SOs) when specific actions must be taken to investigate and resolve S/CI quality and safety issues; and tracking and reporting the status of corrective actions.

NOTE: This service does not relieve the contractor from complying with the requirements defined in this CRD.

a. Supplemental Quality Management System Requirements for S/CIs. An S/CI prevention process must be developed and implemented as a part of the contractor's QAP and must be commensurate with the facility/activity hazards and mission impact. The QAP must be applied to identifying, analyzing, and removing S/CIs, and preventing them from being supplied to DOE/NNSA and its contractors. The QAP must address the following elements for S/CI prevention.

(1) Preventing the introduction and use of S/CIs through engineering involvement, design, procurement, testing, inspection, maintenance, evaluation, disposition, reporting, trend analysis, and lessons learned work process controls.

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(2) Training and informing managers, supervisors, and workers on S/CI processes and controls (including prevention, detection, and disposition of S/CIs).

(3) Identifying and disposing of S/CIs on site.

(4) Restricting S/CI use to only those items that have been found acceptable through engineering analysis and formal disposition process .

(5) Collecting, maintaining, disseminating, and using the most accurate, up-to-date information on S/CIs and associated suppliers using all available sources. S/CI information sources include the following.

(a) Government-Industry Data Exchange Program (www.gidep.org);

(b) Institute of Nuclear Power Operators (www.inpo.org);

(c) DOE Occurrence Reporting and Processing System; and

(d) DOE S/CI website (http://tis.eh.doe.gov/paa/sci/).

(6) Identifying the management point of contact responsible for these activities to ensure that the DOE Office of Environment, Safety and Health has a viable recipient for S/CI information notices.

b. Work Process Controls. Work processes must be developed and implemented using available S/CI information, and must include the following elements.

(1) Engineering involvement in the development of procurement specifications; during inspection and testing; and when replacing, maintaining, or modifying equipment.

(2) Procurement processes that prevent introduction of S/CIs by—

(a) identifying technical and QA requirements in procurement specifications;

(b) accepting only those items that comply with the procurement specifications consensus standards, and commonly accepted industry practices; and

(c) inspecting inventory and storage areas to identify, control, and disposition S/CIs.

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(3) Inspection, identification, evaluation, and disposition of S/CIs installed in all safety applications[1] and other applications that create potential hazards.

(4) Engineering evaluations and disposition of S/CIs installed in safety applications/systems or in applications that create potential hazards. The evaluations must consider potential risks to the public and worker and cost/benefit impact, and include a schedule for replacement (if required).

(5) Ensuring that S/CIs identified in non-safety applications during routine maintenance and/or inspection are reported, evaluated, and dispositioned to prevent future use in safety applications.

(6) Contacting the DOE Inspector General (IG) before destroying or disposing of S/CIs and their documentation to determine whether to retain them for criminal investigation or litigation.

(7) Testing procured or installed S/CIs as necessary using approved engineering test methods.

(8) Reporting S/CIs to responsible DOE/NNSA line management offices; the Office of Environment, Safety and Health; and the IG. [DOE O 231.1A, *Environment, Safety, and Health Reporting*, dated 8-19-03, and DOE O 221.1, *Reporting Fraud, Waste, and Abuse*, dated 3-22-01.]

(9) Conducting trend analysis and issuing lessons learned reports for use in improving the S/CI prevention.

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5. SUPPLEMENTAL SAFETY SOFTWARE QUALITY REQUIREMENTS. Safety software quality requirements are necessary to ensure that the Department of Energy (DOE)/National Nuclear Security Administration (NNSA) safety software in nuclear facilities performs its intended specific safety functions in relation to SSCs and the classification, design, and analysis associated with nuclear facility operations. These requirements complement those of 10 CFR 830 and provide detail for work associated with safety software that would be conducted under the nuclear facility QAP.

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Work processes must be developed and implemented using voluntary national or international consensus standards and must include the following elements:

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[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 CFR 830.2).

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a. Engineering involvement in the identification of software specifications, Software safety design, development, acquisition, maintenance, inspection, testing and retirement.

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b. Establish processes to identify, document, and maintain the set of safety software utilized in:

(1) Safety system software (instrumentation and control, network interfaces, safety management, and administrative controls)

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(2) Analysis and design (safety analysis, design & analysis)

c. Designate the grading level of all safety software according to the following:

(1) Level A: This grading level includes high safety consequence software applications that meet one or more of the following criteria:

(a) Software applications where failure could have an adverse effect on nuclear safety systems (i.e., Safety Class or Safety Significant SSCs), toxic material or chemical hazard protection systems that are credited in the facility safety analysis for protecting against or limiting exposure to the general public and workers below regulatory or evaluation guidelines.

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(b) Software applications where failure could result in non-conservative safety analysis, misclassification of SSCs, or inappropriate safety related decisions.

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(2) Level B: This grading level includes low safety consequence software applications that meet one or more of the following criteria:

(a) Software applications whose failure would cause a reduction in the degree of safety or defense-in-depth.

(b) Software application that supports safety management decisions regarding a facility or system operating activity (e.g., software whose failure would not impact performance of a safety function, but could result in: missed surveillances; confusion regarding system status; or, noncompliance with nuclear safety regulatory laws, environmental permits or regulations and/or commitments to compliance).

Note: These grading levels are described in terms of safety consequence and regulatory compliance. There may be other considerations (such as importance to mission, protection of assets, or avoiding adverse publicity or inconvenience) that would result in similar grading levels for the purpose of ensuring that appropriately rigorous software quality practices

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are applied. DOE G 414.1-4 may provide stakeholders of specific software applications guidance to apply software quality and assessment practices identified for Level A or B.

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d. Using the grading levels above, select and apply the following software quality assurance practices in accordance with NQA-1 or equivalent voluntary national or international consensus standards. DOE G 414.1-4 provides acceptable implementation strategies for these practices.

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(1) Software project management
(2) Software safety design
(3) Software risk management
(4) Software requirements identification and management
(5) Software design and implementation
(6) Software configuration management
(7) Problem reporting and corrective action
(8) Independent verification and validation
(9) Acceptance testing
(10) Procurement and vendor management
(11) Continuous improvement, measurement and metrics
(12) Training

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SUSPECT/COUNTERFEIT ITEMS PREVENTION

1. DOE-WIDE SUSPECT/COUNTERFEIT ITEMS (S/CI) PREVENTION PROCESS. A DOE-wide S/CI prevention process is operated by the DOE Office of Environment, Safety and Health as a service to DOE and its contractors, and provides for—

   a. collecting, analyzing, and disseminating S/CI information;

   b. notifying Secretarial Officers (SOs) when specific actions must be taken to investigate and resolve S/CI quality and safety issues; and

   c. tracking and reporting the status of corrective actions.

   d. NOTE: This service does not relieve organizations from complying with the requirements of this Attachment.

2. SUPPLEMENTAL QUALITY MANAGEMENT SYSTEM REQUIREMENTS FOR S/CIs. An S/CI prevention process must be developed and implemented as a part of the organization's QAP 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/NNSA and its contractors.

   a. For guidance in compliance with requirements see G 440.1-6, *Implementation Guide for Use with Suspect/Counterfeit Items Requirements of DOE O 440.1, Worker Protection Management; 10 CFR 830.120; and DOE 5700.6c, Quality Assurance*, dated 6-30-97. The QAP must address the following for S/CI prevention:

      (1) preventing the introduction and use of S/CIs through engineering involvement, design, procurement, testing, inspection, maintenance, evaluation, disposition, reporting, trend analysis, and lessons learned work process controls;

      (2) training and informing managers, supervisors, and workers on S/CI processes and controls (including prevention, detection, and disposition of S/CIs);

      (3) identifying and disposing of S/CIs on site;

      (4) restricting the use of an S/CI to only those items that have been found acceptable through engineering analysis and formal disposition process;

      (5) collecting, maintaining, disseminating, and using the most accurate, up-to-date information on S/CIs and suppliers using all available sources including—

         (a) Government Industry Data Exchange Program (www.gidep.org);

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(b) Institute of Nuclear Power Operators (www.inpo.org);

(c) DOE Occurrence Reporting and Processing System, and

(d) DOE S/CI website (http://tis.eh.doe.gov/paa/sci/).

b. Identifying the management position responsible for these activities and for serving as a point of contact with the Office of Environment, Safety and Health.

3. WORK PROCESS CONTROLS. Work processes must be developed and implemented using available S/CI information and must include the following elements.

a. Engineering involvement in the development of procurement specifications; during inspection and testing; and when replacing, maintaining, or modifying equipment.

b. Procurement processes that prevent introduction of S/CIs by—

(1) identifying technical and QA requirements in procurement specifications;

(2) accepting only those items that comply with procurement specifications, consensus standards, and commonly accepted industry practices;

(3) inspecting inventory and storage areas to identify, control, and disposition S/CIs.

c. Inspection, identification, evaluation, and disposition of S/CIs that have been installed in safety applications and other applications that create potential hazards.

d. Engineering evaluations and disposition of S/CIs installed in safety applications/systems or in applications that create potential hazards. Evaluations must consider potential risks to the public and workers cost/benefit impact, and a schedule for replacement (if required).

e. Ensuring that S/CIs in non-safety applications identified during routine maintenance and/or inspection are reported, evaluated, and dispositioned to prevent future use in safety applications.

f. Contacting the DOE Inspector General (IG) before destroying or disposing of S/CIs and their documentation to determine whether to retain them for criminal investigation or litigation.

[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 CFR 830.2).

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g. Testing procured or installed S/CIs as necessary using approved engineering test methods.

h. Reporting S/CIs to responsible program offices; the Office of Environment, Safety and Health; and the IG in accordance with DOE O 231.1A, *Environment, Safety, and Health Reporting*, dated 8-19-03, and DOE O 221.1, *Reporting Fraud, Waste, and Abuse*, dated 3-22-01.

i. Conducting trend analysis and issuing lessons learned reports for use in improving the S/CI prevention.

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CORRECTIVE ACTION MANAGEMENT PROGRAM

1. OBJECTIVE. To prescribe process requirements and responsibilities for DOE line managers to effectively perform corrective actions that resolve safety issues arising from—

   a. Findings identified by the Offices of Independent Oversight and Performance Assurance; Environment, Safety, and Health (ES&H); and Emergency Management (DOE O 470.2B, *Independent Oversight and Performance Assurance Program*, dated 10-31-02);

   b. Judgment of needs identified by Type A accident investigations (DOE O 225.1A, *Accident Investigations*, dated 11-26-97); or

   c. Other sources as directed by the Secretary or Deputy Secretary, including crosscutting safety issues.

2. REQUIREMENTS.

   a. Reporting Findings. The assessing organization (see paragraph 1) submits the final assessment report within 10 calendar days of issuance to the—

      (1) applicable field element managers (FEMs) and Secretarial Officers (SOs); and

      (2) Office of ES&H along with a synopsis of assessment report findings.

   b. Corrective Action Plan (CAP) Development, Approval, and Review.

      (1) Development. The FEM in consultation with the appropriate SO must prepare a comprehensive CAP in writing to address assessment findings and field and Headquarters corrective actions for each finding. Guidance for implementing these requirements is outlined in Appendix G of DOE G 450.4-1B, *Integrated Safety Management System Guide*. Note that DOE O 470.2B, *Independent Oversight and Performance Assurance Program*, dated 10-31-02, includes additional reporting requirements.

         (a) When findings and/or corrective actions to be addressed apply to more than one SO, a lead SO must be appointed by mutual agreement or be appointed by the Deputy Secretary to coordinate and approve the CAP.

         (b) When findings and/or corrective actions to be addressed involve multiple sites or organizations, to include DOE Headquarters

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organizations or other elements, the lead SO must designate a lead FEM as overall manager to coordinate and develop the CAP and track and report CAP data in the Corrective Action Tracking System (CATS) database.

(c) Other responsible sites/organizations must forward their portions of the CAP to the designated lead FEM for consolidation and submission. Failure to provide this information will be brought to the attention of the lead SO for action.

(d) For each finding, the CAP must address—

1 extent of conditions,

2 causal factors that led to the finding,

3 detailed descriptions of corrective action(s) to resolve the finding, and

4 a general outline for the conduct of the proposed independent corrective action effectiveness review (see paragraph 2d).

(e) For each corrective action the CAP must include a detailed description, deliverable(s) that will signify completion, a single responsible manager accountable for timeliness and effectiveness of the correction action, and planned completion date.

(2) Approval. The CAP must be prepared on a schedule that will allow for review and approval by the SO or designee within 60 calendar days from the date the transmittal forwarding the formal final assessment/investigation report was issued.

(a) The SO or designee must approve the CAP and all proposed corrective actions from responsible sites/organizations for each finding.

(b) When a finding addresses a deficiency in DOE policy, the applicable DOE policy organization (e.g. Assistant Secretary for Environment, Safety and Health, Office of Science, etc.) must develop and implement appropriate corrective actions. Corrective actions must be included in the CAP addressing all other findings in the assessment report or a separate CAP must be developed by the policy organization for approval, tracking and reporting.

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(c) Separate CAPs developed by a DOE policy organization must be approved by organization directors.

(d) When a proposed CAP cannot be submitted to the SO for approval within the required 60 days or the SO does not approve the proposed CAP, the DOE *CATS User's Guide* outlines a process to formally request an extension from the SO.

(3) Review. The SO or designee must forward copies of an approved CAP to the organization that conducted the assessment for review and to the Office of ES&H.

(a) The organization that conducted the assessment must review the approved CAP and provide comments to the SO and FEM within 30 calendar days from the date the approved CAP was transmitted.

(b) The SO must evaluate comments from the organization that conducted the assessment and provide written response on how the comments will be addressed. If the SO decides the CAP must be revised, the FEM must be notified to revise and resubmit the CAP for SO approval within a specified timeframe not to exceed 60 calendar days from the date the SO directed the revision. The revised CAP must be submitted to the organization that conducted the assessment for review and a copy provided to the Office of ES&H.

(c) Disagreements that cannot be resolved between the organization that conducted the assessment and the SO must be elevated through the organizational level of management hierarchy up to the Office of the Secretary, if necessary for resolution.

c. Tracking and Reporting Implementation.

(1) The FEM—

(a) is responsible for implementing the approved CAP and ensuring timely and effective completion of all corrective actions;

(b) must enter, track and report the status of the CAP and associated corrective actions to closure in the DOE CATS database (see http://tis.doe.gov/portal/catsentry.html and guidance for accessing and using CATS outlined in the *DOE CATS User's Guide* and *CATS Data Dictionary* online at http://tis.eh.doe.gov/ism/cats.html;

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(c) must enter CAP and corrective action data as stated in the approved CAP for each finding in CATS within 10 working days after approval.

(d) must ensure that all corrective actions are tracked and their status reported to completion and verification.

(2) Completion of each corrective action must be annotated in the CATS Descriptive Status and Completion Date fields.

(3) Other sites/organizations who forwarded portions of the CAP and corrective actions to the lead FEM [see paragraph 2b (1)(c)] must track and provide the FEM updates of their portions of the CAP and corrective actions to completion and verification within the timeframes specified in this Order.

(4) The FEM must update the CAP Status field and Descriptive Status fields frequently basis (e.g., monthly) and enter the date at the beginning of each update.

(5) Requests for CAP changes in CATS (i.e. planned corrective action completion date) must be approved by the SO who approved the CAP and submitted as outlined in the *CATS Users Guide*.

(6) Information in CATS will be used to provide periodic (e.g. quarterly) status reports to assist senior DOE management in monitoring the status of the CAMP.

d. Corrective Action Effectiveness Review.

(1) Purpose.

(a) Evaluation of findings and implementation of corrective actions is conducted to correct the underlying causes for corrective action failure to prevent recurrence of the same or similar assessment findings.

(b) Effectiveness reviews will—

1 determine whether completed corrective actions have or have not effectively resolved and prevented recurrence of the same or similar findings at the performance level;

2 identify additional actions necessary to effectively resolve the findings and prevent recurrence; and

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3 collect effectiveness data for subsequent analyses and sharing of lessons learned.

(2) Conduct of Reviews.

(a) Upon completion of corrective actions, the FEM must initiate a follow up review to verify closure and effectiveness in ensuring resolution of each finding and preventing recurrence. A formal review report approved by the FEM must be completed within 6 months after the CAP completion date (the date when all corrective actions for all findings listed in the CAP have been completed).

NOTE: This requirement is effective on the approval date of this Order for all CAPs that have not been approved, CAPs that have been approved but are not complete (all corrective actions in the CAP are not complete and there is not a CAP Completion Date), and all future CAPs. The FEM will determine—

1 how the review is conducted,

2 who conducts the review,

3 what specific completed corrective actions are reviewed for each finding,

4 when the review is initiated, and

5 how the review report will be formatted.

(b) Other sites/organizations that tracked and provided updates of their responsible corrective actions to completion and verification must coordinate effectiveness review activities with the lead FEM for consolidation and submission.

(c) For each finding, the FEM will select for review a sufficient number of completed corrective actions to allow an objective, accurate assessment of effectiveness in resolving the finding and preventing recurrence. Standards for conducting effectiveness review include the following.

1 A 100 percent review of all corrective actions is not required to determine effectiveness.

2 Review can be initiated at any time during CAP implementation.

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3 Reviews are initiated based on

a severity of a finding,

b length of time needed to review selected corrective actions,

c availability of resources to review corrective actions, and

d length of time before all corrective actions for the finding are to be completed.

4 Reviews are performed by Federal and/or contractor personnel who are not associated withthe findings or corrective actions.

5 Mechanisms used to conduct effectiveness reviews are determined by the FEM and may include

a document reviews,

b performance analyses,

c work observations/facility tours,

d performance testing, interviews,

e trending of performance,

f monitoring performance metrics based on operational data,

g tracking performance utilizing targeted assessments, and

h performing tailored scheduled assessments to gather the data.

(3) Reporting and Follow Up.

(a) A formal report documenting the results of the effectiveness review must be completed and approved by the FEM no later than 6 months after the CAP completion date (the date all corrective actions are completed).

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(b) If the FEM determines that additional time is required to successfully complete the effectiveness review, the Effectiveness Review Approval Date field in the CAP Data section of CATS must be updated to read, "See CAP Status," and an explanation must be entered into the CAP Status field in the CAP Data section.

(c) The report includes an executive summary outlining overall scope, results, conclusions, rating and recommendations. A separate report form for each finding describing which corrective actions were reviewed, review activities and results, conclusions, rating (i.e. effective, partially effective, ineffective) and any recommendation for completion is to be attached to the executive summary.

(d) FEM approval of the report must be recorded in the Effectiveness Review Approval Date field in the CAP Data section of CATS. A review results and follow up actions must be outlined in the Effectiveness Review Results field.

(e) Upon FEM approval, report recommendations must be implemented and followed up as directed by the FEM. The report and supporting documents must be retained in accordance with the local records management process.

(f) If the FEM revises the completed CAP based on report recommendations, the CAP revision with additional or revised corrective actions, as applicable, must be approved by the SO.

(g) Upon approval, CAP revisions must be entered into CATS and tracked to successful completion. Guidance for entering the revisions is outlined in the *CATS User's Guide.*

e. Lessons Learned.

(1) At any time during the CAMP process, the FEM must develop and implement, lessons learned identified from the assessment findings, corrective actions in response to the findings, and results of corrective action effectiveness reviews, as applicable.

(2) The FEM must evaluate proposed lessons learned to determine if they are applicable to the wider DOE community and distribute the information to a select list of recipients through the DOE Lessons Learned Information Services Web site (http://tis.eh.doe.gov/ll).

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f. Corrective Action Management (CAM) Team.

(1) The CAM Team, a cross-organizational working group of representatives from Headquarters and field offices, must be maintained to support and coordinate effective line management implementation of the CAMP.

(2) A charter outlining mission, functions, operations, membership, and leadership of the team must be maintained. The CAM Team is sponsored by the Office ES&H and co-chaired by a SO representative and the Office of Environment, Safety and Health.

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SUPPLEMENTAL SAFETY SOFTWARE QUALITY REQUIREMENTS

1. OBJECTIVE. To prescribe supplemental safety software requirements and responsibilities for DOE to address:

   a. Grading SQA requirements based on risk, safety, facility lifecycle, complexity, and project quality requirements;
   b. Performing safety reviews of software configuration items that are consistent with nuclear safety rules ;
   c. Developing procurement controls for acquisition of computer software and hardware;
   d. Applying SQA requirements to software lifecycles;
   e. Documenting and tracking customer requirements;
   f. Managing software configuration throughout the lifecycle;
   g. Performing verification and validation testing; and
   h. Training of personnel who use software in safety applications.

2. REQUIREMENTS.

Safety software quality requirements are necessary to ensure that the Department of Energy (DOE)/National Nuclear Security Administration (NNSA) safety software in nuclear facilities performs its intended specific safety functions in relation to SSCs and the classification, design, and analysis associated with nuclear facility operations. These requirements complement those of 10 CFR 830 and provide detail for work associated with safety software that would be conducted under the nuclear facility QAP.

a. Federal personnel with SQA responsibilities shall have the necessary technical capabilities to carry out their duties. Technical qualification requirements shall be specified in the appropriate Technical Qualification Standards. This process shall be coordinated with the Federal Technical Capability Panel (FTCP) in accordance with the requirements of the DOE M 426.1, *Federal Technical Capability Manual*.

b. The Assistant Secretary for Environment, Safety, and Health (EH) shall have the lead responsibility for promulgating requirements and guidance through the directives system for safety software after formal coordination with the Office of the Chief Information Officer (OCIO).

c. Work processes must be developed and implemented using voluntary national or international consensus standards and must include the following elements:

   (1) Engineering involvement in the identification of software specifications, design, development, acquisition, maintenance, inspection, testing and retirement.

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(2) Establish processes to identify, document, and maintain safety software.

(3) Designate the grading level of all safety software according to the following:

(a) Level A: This grading level includes high safety consequence software applications that meet one or more of the following criteria:

1 Software applications where failure could have an adverse effect on nuclear safety systems (i.e., Safety Class or Safety Significant SSCs), toxic material or chemical hazard protection systems that are credited in the facility safety analysis for protecting against or limiting exposure to the general public and workers below regulatory or evaluation guidelines.

2 Software applications where failure could result in non-conservative safety analysis, misclassification of SSCs, or inappropriate safety related decisions.

(b) Level B: This grading level includes low safety consequence software applications that meet one or more of the following criteria:

1 Software applications whose failure would cause a reduction in the degree of safety or defense-in-depth.

2 Software application that supports safety management decisions regarding a facility or system operating activity (e.g., software whose failure would not impact performance of a safety function, but could result in: missed surveillances; confusion regarding system status; or, noncompliance with nuclear safety regulatory laws, environmental permits or regulations and/or commitments to compliance).

Note: These grading levels are described in terms of safety consequence and regulatory compliance. There may be other considerations (such as importance to mission, protection of assets, or avoiding adverse publicity or inconvenience) that would result in similar grading levels for the purpose of ensuring that appropriately rigorous software quality practices are applied. DOE G 414.1-4 may provide stakeholders of specific software applications guidance to apply software quality and assessment practices identified for Level A or B.

(4) Using the grading levels above, select and apply the following software quality assurance practices in accordance with NQA-1 or equivalent

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voluntary national or international consensus standards. DOE G 414.1-4 provides acceptable implementation strategies for these practices.

(a) Software project management
(b) Software safety design
(c) Software risk management
(d) Software requirements identification and management
(e) Software design and implementation
(f) Software configuration management
(g) Problem reporting and corrective action
(h) Independent verification and validation
(i) Acceptance testing
(j) Procurement and vendor management
(k) Continuous improvement, measurement and metrics
(l) Training

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