E R R A T A S H E E T

This Errata Sheet transmits the following minor change to DOE O 414.1C, *Quality Assurance*, dated 6-17-05. Paragraph 5f, Director, Office of Aviation Safety, should read "Director, Office of Aviation Management."

The change is reflected in this Order.

This Errata Sheet must remain with DOE O 414.1C.

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

ORDER

DOE O 414.1C

Approved: 6-17-05
Review: 6-17-07

SUBJECT: QUALITY ASSURANCE

1. OBJECTIVES.

   a. To ensure that 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 QA 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 (S/CIs), safety issue corrective actions, and safety software.

2. CANCELLATIONS. This Order cancels DOE O 414.1B, *Quality Assurance,* dated 4-29-04, and DOE N 411.1, *Safety Software Quality Assurance Functions, Responsibilities, and Authorities for Nuclear Facilities and Activities,* dated 8-27-03. Cancellation of a directive does not, by itself, modify or otherwise affect any contractual obligation to comply with the directive. Cancelled directives that are incorporated by reference in a contract must remain in effect until the contract is modified to delete the requirements in the cancelled directives.

3. APPLICABILITY.

   a. Primary DOE Organizations, including NNSA Organizations. Except for the exclusions in paragraph 3c, this Order applies to all Primary DOE Organizations and their associated field elements (see Attachment 1). This Order automatically

applies to Primary DOE Organizations and their associated field elements created after the Order is issued.

This Order includes a requirement to integrate multiple QAP drivers imposed by QA regulations [Title 10 Code of Federal Regulations (CFR) 830], the Nuclear Regulatory Commission, and other Federal agencies. The Order includes 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. Where a work activity, process or item is specifically identified as within the scope of a QA regulation (e.g. 10 CFR 830 or 10 CFR 63), that regulation prevails. In the event of a conflict between this Order and any QA regulation, the regulation prevails. [See QAP integration requirement, paragraph 4a(4).]

The Administrator of NNSA shall assure that NNSA employees and contractors comply with their respective responsibilities under this order.

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.

(4) Regardless of the performer of the work, the contractor with the CRD incorporated into its contract is responsible for compliance with the requirements of the CRD. An affected contractor is responsible for flowing down the requirements to subcontractors at any tier to the extent necessary to ensure the contractors' compliance with the requirements and the safe performance of work.

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. Quality Assurance Program Requirements. Each DOE organization must develop and implement a QAP that does the following.

(1) Implements QA 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 national or international consensus standards where practicable and consistent with contractual or regulatory requirements (e.g., 10 CFR 830) and identifies the standards 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 nonnuclear activities); and

(c) ANSI/ASQ Z 1.13, *Quality Guidelines for Research,* 1999 (for nonnuclear 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). [Note: These standards are sometimes referred to as "voluntary standards." However, once a practicable standard(s) is adopted through regulation, code, contract, QAP, or procedure, compliance with the standard is required and is not voluntary.]

(4) Integrates, where practicable and consistent with contract or regulatory requirements, quality management system requirements as defined in this Order, the S/CI prevention process (Attachment 3), the Corrective Action Management Program (CAMP, Attachment 4), and Safety Software Quality Requirements (Attachment 5) with other quality or management system requirements in DOE directives and external requirements, including as applicable—

(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;* and

(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.

(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.

(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.

(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, S/CI prevention requirements (Attachment 3), CAMP requirements (Attachment 4), and Safety Software Quality requirements (Attachment 5). Identify the senior management position specifically assigned this responsibility.

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

(4) Review and approve new and revised field element QAPs. [NOTE: 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 (FEM). [NOTE: 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 calendar days of receipt.

(7) Report management assessment results periodically to the Deputy Secretary and Assistant Secretary for Environment, Safety and Health describing the effectiveness of QA implementation.

(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 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, S/CI prevention requirements (Attachment 3), CAMP requirements (Attachment 4), and

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

Safety Software Quality requirements (Attachment 5). Identify the senior management position assigned this responsibility.

(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. [NOTE: The scope and rigor of review must be graded based on the status of the contractor's prior quality performance (e.g., past regulatory/contract noncompliance, performance metrics, or any third-party QAP certification). QAPs must be reviewed and approved or rejected within 90 calendar days of receipt.]

(4) Perform independent assessments of contractor organizations to evaluate the adequacy and QAP implementation effectiveness. [NOTE: 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.]

(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 followup review on the effectiveness of the corrective actions in resolving and preventing recurrence of all findings. Approve the effectiveness review report and followup 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 QA 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 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 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) Submits to the Deputy Secretary periodic line management updates from SOs (ref. paragraph 5b7) on the effectiveness of QA policy implementation across the Department.

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

(d) Manages the DOE Safety Software Central Registry (Attachment 5).

(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 Web site 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 cochairs the DOE Corrective Action Management (CAM) Team.

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

f. Director, Office of Aviation Management. Conducts safety management assessments of DOE aviation facilities and reports assessment results to the Assistant Secretary for Environment, Safety and Health and the assessed organization.

g. 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 O 470.2B, *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 414.1-1A, *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; and DOE P 450.5, Line ES&H Oversight Policy,* dated 5-31-01.

b. DOE G 414.1-2A, *Quality Assurance Management System Guide for Use with 10 CFR 830 Subpart A and DOE O 414.1C, Quality Assurance,* dated 6-17-05.

c. DOE G 414.1-3, *Suspect/Counterfeit Items Guide for Use with 10 CFR 830 Subpart A, Quality Assurance Requirements, and DOE O 414.1B, Quality Assurance,* dated 11-03-04.

d. 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,* dated 6-17-05.

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

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

7. DEFINITIONS.

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-1-2000)

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 CFR 830)

c. 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.

d. Configuration Management. The process of identifying and defining the configuration items in a system (i.e., software and hardware), controlling the release and change of these items throughout the system's life cycle, and recording and reporting the status of configuration items and change requests. (ASME NQA-1-2000)

e. Graded Approach. The process of ensuring that the levels of analyses, documentation, and actions used to comply with requirements are commensurate with— (10 CFR 830)

(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.

f. Hazard Controls. Measures to eliminate, limit, or mitigate hazards to workers, the public, or the environment, including— (10 CFR 830)

(1) physical, design, structural, and engineering features;

(2) safety structures, systems, and components;

(3) safety management programs;

(4) technical safety requirements; and

(5) other controls necessary to provide adequate protection from hazards.

g. 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 CFR 830)

h. 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 CFR 830)

i. Process. A series of actions that achieves an end result. (10 CFR 830)

j. Quality. The condition achieved when an item, service, or process meets or exceeds the user's requirements and expectations. (10 CFR 830)

k. Quality Assurance. All those actions that provide confidence that quality is achieved. (10 CFR 830)

l. 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 CFR 830)

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

n. Safety Management Program. A program designed to ensure a facility is operated in a manner that adequately protects workers, the public, and the environment by covering a topic such as quality assurance; maintenance of safety systems; personnel training; conduct of operations; inadvertent criticality protection; emergency preparedness; fire protection; waste management; or radiological protection of workers, the public, and the environment. (10 CFR 830)

o. Safety Software. Includes the following.

(1) Safety System Software. Software for a nuclear facility[2] that performs a safety function as part of a structure, system, or component and is cited in either (a) a DOE approved documented safety analysis or (b) an approved hazard analysis per DOE P 450.4, *Safety Management System Policy,* dated 10-15-96, and the DEAR clause.

(2) 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 a structure, system, or component (SSC) but helps to ensure the proper accident or hazards analysis of nuclear facilities or an SSC that performs a safety function.

(3) 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

[2]Per 10 CFR 830, quality assurance requirements apply to all DOE nuclear facilities including radiological facilities (see 10 CFR 830, DOE STD 1120, and the DEAR ISMS clause).

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 CFR 830, 10 CFR 835, and the DEAR ISMS clause.

p. 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 or the like. (10 CFR 830)

q. Software. Computer programs, procedures, and associated documentation and data pertaining to the operation of a computer system. (NQA-1-2000)

r. Suspect/Counterfeit Items (S/CIs). An item 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 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):

(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.

s. Technical Safety Requirements. The limits, controls, and related actions that establish the specific parameters and requisite actions for the safe operation of a nuclear facility and include, as appropriate for the work and the hazards identified in the documented safety analysis for the facility: safety limits, operating limits, surveillance requirements, administrative and management controls, use and application provisions, and design features, as well as a bases appendix. (10 CFR 830)

t. Verification and Validation. The process of determining whether the requirements for a system or component are complete and correct, the products of each development phase fulfill the requirements or conditions imposed by the previous phase, and the final system or component complies with specified requirements. (IEEE Std-610.12-1990)

u. 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; or data collection and analysis.

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

SAMUEL W. BODMAN
Secretary of Energy

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 Administration
Office of Civilian Radioactive Waste Management
Office of Congressional and Intergovernmental Affairs
Office of Counterintelligence
Office of Economic Impact and Diversity
Office of Electricity Delivery and Energy Reliability
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
Southeastern Power Administration
Southwestern Power Administration
Western Area Power Administration

CONTRACTOR REQUIREMENTS DOCUMENT
DOE O 414.1C, *QUALITY ASSURANCE*

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 and the safe performance of work. 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 Administration (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 QA 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 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. Where a work activity, process, or item is specifically identified as within the scope of a QA regulation (e.g., 10 CFR 830 or 10 CFR 63), that regulation prevails. In the event of a conflict between this CRD and any QA regulation, the regulation prevails. [See QAP integration requirement, paragraph 2a(4) below.]

1. OBJECTIVES.

   a. To ensure that DOE, including 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 QA 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 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 (S/CIs) and control of safety software.

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 does the following.

(1) Implements QA criteria as defined in paragraph 3 of this CRD, S/CI prevention requirements as defined in paragraph 4, and safety software as defined in paragraph 5, using a graded approach and describing how the QA criteria and graded approach are applied. See paragraph 2 of this CRD for guidance on compliance.

(2) Uses the appropriate 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 nonnuclear activities).

(c) ANSI/ASQ Z 1.13, 1999, *Quality Guidelines for Research, (*for nonnuclear 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). [Note: These standards are sometimes referred to as "voluntary standards." However, once the practicable standard(s) is adopted through regulation, code, contract, QAP, or procedure, compliance with the standard is required and is not voluntary.]

(4) Integrates, where practicable and consistent with contract or regulatory requirements, quality management system requirements as defined in this CRD, the S/CI prevention process (Paragraph 4) and Safety Software Quality Requirements (Paragraph 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 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 04-29-04) to address enhancements required by this CRD.

(5) Regard a QAP as approved by DOE 90 calendar 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.

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

(1) 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; and DOE P 450.5, Line ES&H Oversight Policy, dated 5-31-01.

(2) *DOE G 414.1-2A, Quality Assurance Management System Guide for Use with 10 CFR 830 Subpart A Quality Assurance Requirements and DOE O 414.1C, Quality Assurance,* dated 6-17-05.

(3) *DOE G 414.1-3, Suspect/Counterfeit Items Guide for Use with 10 CFR 830 Subpart A, Quality Assurance Requirements, and DOE O 414.1B, Quality Assurance,* dated 11-03-04.

(4) *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,* dated 6-17-05.

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.

(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 using individuals or groups other than those who performed the work.

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

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 ITEM 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 Suspect/Counterfeit Items. 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.

(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 onsite.

(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 Operations (www.inpo.org).

(c) DOE Occurrence Reporting and Processing System (http://www.eh.doe.gov/paa/orps.html).

(d) DOE S/CI Web site (http://www.eh.doe.gov/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.

(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 nonsafety 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 as per DOE O 231.1A Change 1, *Environment, Safety, and Health Reporting,* dated 06-03-04, and DOE O 221.1, *Reporting Fraud, Waste, and Abuse,* dated 03-22-01, to—

(a) the responsible DOE/NNSA line management offices;

(b) the Office of Environment, Safety and Health; and

(c) the Office of the Inspector General.

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

5. SAFETY SOFTWARE QUALITY REQUIREMENTS. These requirements are necessary to ensure that DOE/NNSA safety software in nuclear facilities performs its intended specific functions in relation to structures, systems, or components (SSCs) and that the classification, design, and analysis associated with nuclear facility operations is correct. These requirements complement those of 10 CFR 830 and provide detail for work associated with safety software that is conducted under the nuclear facility QAP compliant with 10 CFR 830.

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

[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).

a. Facility design authority involvement in identifying software specification, acquisition, design, development, verification and validation (including inspection and test), configuration management, maintenance, and retirement.

b. Identify, document, and maintain safety software inventory.

c. Establish grading levels for safety software. Document those grading levels in the QAP.

d. Using the grading levels established and approved above, select and implement the applicable software QA work activities from the following list to ensure that safety software performs its intended functions. ASME NQA-1-2000, *Quality Assurance Requirements for Nuclear Facility Applications,* or other national or international consensus standards that provide an equivalent level of quality assurance requirements as NQA-1-2000, must be used to implement these work activities. The standards used must be specified by the user and approved by DOE. DOE G 414.1-4 provides acceptable implementation strategies and appropriate standards for these work activities.

(1) Software project management and quality planning

(2) Software risk management

(3) Software configuration management

(4) Procurement and supplier management

(5) Software requirements identification and management

(6) Software design and implementation

(7) Software safety

(8) Verification and validation

(9) Problem reporting and corrective action

(10) Training of personnel in the design, development, use, and evaluation of safety software

SUSPECT/COUNTERFEIT ITEMS PREVENTION

1. DOE-WIDE SUSPECT/COUNTERFEIT ITEMS (S/CI) PREVENTION PROCESS. The Department of Energy (DOE) Office of Environment, Safety and Health operates a DOE-wide S/CI prevention process as a service to DOE, including the National Nuclear Security Administration (NNSA) and its contractors. The process 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.

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

2. SUPPLEMENTAL QUALITY MANAGEMENT SYSTEM REQUIREMENTS FOR SUSPECT/COUNTERFEIT ITEMS. An S/CI prevention process must be developed and implemented as a part of the organization's quality assurance program (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 DOE G 414.1-3, *Suspect/Counterfeit Items Guide for Use with 10 CFR 830 Subpart A, Quality Assurance Requirements, and DOE O 414.1B, Quality Assurance,* dated 11-03-04. 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);

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

(c) DOE Occurrence Reporting and Processing System (http://www.eh.doe.gov/paa/orps.html); and

(d) DOE S/CI Web site (http://www.eh.doe.gov/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; and

(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[1] 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 nonsafety 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.

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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).

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

h. Reporting S/CIs as per DOE O 231.1A Change 1, *Environment, Safety, and Health Reporting,* dated 06-03-04, and DOE O 221.1, *Reporting Fraud, Waste, and Abuse to the Office of Inspector General,* dated 03-22-01, to—

(1) the responsible DOE/NNSA line management offices;

(2) the Office of Environment, Safety and Health; and

(3) the Office of the Inspector General.

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

CORRECTIVE ACTION MANAGEMENT PROGRAM

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

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

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

   c. findings identified by the Office of Aviation Management, Office of Management, Budget and Evaluation (DOE O 440.2B, *Aviation Management and Safety,* dated 11-27-02); or

   d. 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) appropriate 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 Volume 2, Appendix G, of DOE G 450.4-1B, *Integrated Safety Management System Guide,* dated 03-01-01.

         NOTE: DOE O 470.2B, *Independent Oversight and Performance Assurance Program,* dated 10-31-02, includes additional CAP 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 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 a thorough analysis of the underlying causal factors to determine whether systemic program weaknesses exist,

2 steps to address the cause(s) of the finding,

3 detailed descriptions of corrective action(s) to resolve each finding and prevent recurrence, and

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

(e) For each corrective action the CAP must address—

1 deliverable(s) that will signify completion,

2 responsible individuals and organizations,

3 dates actions will be initiated,

4 dates actions are planned to be completed,

5 how actions will be tracked to completion, and

6 mechanisms for independent verification of closure.

(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., Office of Environment, Safety and Health, Office of Science) 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.

(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 the formal process for requesting 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 he status of the CAP and associated corrective actions to closure in the DOE CATS database (see http://www.eh.doe.gov/catsentry.html and guidance for accessing and using CATS outlined in the *DOE CATS User's Guide* and *CATS Data Dictionary* online at http://www.eh.doe.gov/camp/trackingsys.html);

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

(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 that 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 Corrective Action Descriptive Status fields on a frequent 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 the finding. In some instances completed corrective actions have failed to effectively resolve or 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

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

(2) Conduct of Effectiveness Reviews.

(a) Upon completion of the corrective actions, the FEM must initiate a followup review of the completed corrective actions to verify they are closed, ensure all findings were effectively resolved, and ensure the same or similar findings will not recur. 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 reviews include the following.

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

2 Effectiveness reviews can be initiated at any time during CAP implementation.

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 Effectiveness reviews are performed by Federal and/or contractor personnel who are not associated with the 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,

e interviews,

f trending of performance,

g monitoring performance metrics based on operational data,

h tracking performance utilizing targeted assessments, and

i performing tailored scheduled assessments to gather the data.

(3) Reporting and Followup.

(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).

(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." Information on the status of the review and the revised planned approval date 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 description of the effectiveness review results and followup 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 whether 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).

f. Corrective Action Management 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 of ES&H and cochaired by a SO representative and the Office of ES&H.

SAFETY SOFTWARE QUALITY REQUIREMENTS

1. OBJECTIVE. To prescribe the following safety software requirements and responsibilities.

   a. Grading software quality assurance (SQA) requirements based on risk, safety, facility life cycle, complexity, and project quality requirements.

   b. Performing safety reviews of software configuration items that are consistent with DOE nuclear safety rules (10 CFR 830).

   c. Developing procurement controls for acquisition of computer software and hardware.

   d. Applying SQA requirements to software life cycles.

   e. Documenting and tracking customer requirements.

   f. Managing software configuration throughout the life cycle.

   g. Performing verification and validation.

   h. Training personnel in the design, development, use, and evaluation of safety software.

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

   a. Federal personnel with SQA responsibilities must have technical competency to carry out their duties. Technical qualification requirements will be specified in technical qualification standards. This process is coordinated with the Federal Technical Capability Panel (FTCP) in accordance with the requirements of DOE M 426.1-1A, *Federal Technical Capability Manual,* dated 5-18-04, and DOE-STD-1172-2003, *Safety Software Quality Assurance Functional Area Qualification Standard,* dated December 2003.

   b. The Assistant Secretary for Environment, Safety, and Health (ES&H) has lead responsibility for promulgating requirements and guidance for safety software through the Directives System after formal coordination with the Office of the Chief Information Officer (OCIO). ES&H is also responsible for managing the

safety software central registry for the Department (http://www.eh.doe.gov/sqa/central_registry.htm).

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

(1) Facility design authority involvement in the identification of software requirements specification, acquisition, design, development, verification and validation (including inspection and testing), configuration management, maintenance, and retirement.

(2) Identify, document, and maintain safety software inventory.

(3) Establish grading levels for safety software. Document those grading levels in the QAP.

(4) Using the grading levels established and approved above, select and implement applicable SQA work activities from the following list to ensure that safety software performs its intended functions. ASME NQA-1-2000, *Quality Assurance Requirements for Nuclear Facility Applications,* or other national or international consensus standards that provide an equivalent level of quality assurance requirements as NQA-1-2000, must be used to implement these work activities. The standards used must be specified by the user and approved by DOE. DOE G 414.1-4 provides acceptable implementation strategies and appropriate standards for these work activities.

(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.

(h) Verification and validation.

(i) Problem reporting and corrective action.

(j) Training of personnel in the design, development, use, and evaluation of safety software.