

U.S. Department of Energy Orders Self-Study Program

DOE O 414.1B
QUALITY ASSURANCE



**NATIONAL NUCLEAR SECURITY ADMINISTRATION
SERVICE CENTER**

**DOE O 414.1B, QUALITY ASSURANCE
FAMILIAR LEVEL**

OBJECTIVES

Given the familiar level of this module and the resources listed below, you will be able to do the following:

1. State the purpose of implementing DOE O 414.1B, Quality Assurance.
2. Define the following terms:
 - graded approach
 - safety system software
 - suspect/counterfeit items (S/CI)
 - quality assurance (QA)
3. State the responsibilities for the following positions:
 - Field Element Managers
 - Contracting Officers
 - Assistant Secretary for Environment Safety and Health
 - Director, Office of Independent Oversight and Performance Assurance
4. State the requirements of a quality assurance program (QAP).
5. Describe the approved QAP approval and change process.
6. Explain the relationship between QA and the following criteria:
 - quality assurance program
 - personnel training and qualification
 - quality improvement
 - documents and records
 - work processes
 - design

Change No: 1
DOE O 414.1B
Level: Familiar
Date: 11/01/04

- procurement
 - inspection and acceptance testing
 - management assessment
 - independent assessment
7. State the requirements for personnel training and qualification.
 8. Explain the attributes looked for during an independent assessment.
 9. Discuss the corrective action management program (CAMP).
 10. Discuss the S/CI prevention process.

Note: If you think that you can complete the practice at the end of this level without working through the instructional material and/or the examples, complete the practice now. The course manager will check your work. You will need to complete the practice in this level successfully before taking the criterion test.

RESOURCES

DOE O 414.1B, Quality Assurance, 4/29/04.

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, 5/31/01.

DOE G 414.1-2, Quality Assurance Management System Guide for use with 10 CFR 830.120 and DOE O 414.1, 6/17/99.

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, June 1997.

DOE N 411.1, Safety Software Quality Assurance Functions, Responsibilities, and Authorities for Nuclear Facilities and Activities, 8/27/03.

DOE P 450.4, Safety Management System Policy, 10/15/96.

10 CFR 830.120–122, Quality Assurance Requirements.

Change No: 1 DOE O 414.1B Level: Familiar Date: 11/01/04

INTRODUCTION

In this module we will discuss the important elements of DOE O 414.1B and 10 CFR 830.120–122. The module is divided into three sections. The first and second sections provide an introduction of DOE O 414.1B and 10 CFR 830.120–122. These sections include statements of objectives, definitions, requirements, and a description of the implementation guides that support the requirements of the Order. Section 3 provides an overview of the following quality program elements: S/CI prevention process, corrective action management program, and software quality assurance. Examples and a practice have been provided in the module to help familiarize you with the material. The practice will help prepare you for the criterion test.

Before continuing, you must obtain a copy of the resources. Copies of these documents are available on the Office of Management and Administration's Web site at <http://www.directives.doe.gov> or through the course manager. You may need to refer to these documents to complete the examples, practice, and criterion test.

Change No: 1 DOE O 414.1B Level: Familiar Date: 11/01/04

SECTION 1 – INTRODUCTION

PURPOSE

DOE O 414.1B was developed to ensure the quality of the DOE products and services that will meet or exceed customer expectations for all work based on the following principles:

- That quality is assured and maintained through a single, integrated, effective quality assurance program (i.e., management system).
- That management support for planning, organization, resources, direction, and control is essential to QA.
- That performance and quality improvement require thorough, rigorous assessment and corrective action.
- That workers are responsible for achieving and maintaining quality.
- That environmental, safety, and health risks and impacts associated with work processes can be minimized while maximizing reliability and performance of work products.
- That quality process requirements to control S/CI items and safety issue corrective actions will be implemented.

OTHER QUALITY REQUIREMENTS.

DOE elements may impose additional quality requirements and/or specific standards as necessary for certain types of work to ensure that the work meets their expectations and the requirements of this Order.

RESPONSIBILITIES

In this section, we will discuss the major responsibilities associated with DOE O 414.1B. A complete list of responsibilities is available in the Order.

Deputy Secretary

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

Secretarial Officers (SOs)

- Develop, approve, and implement QAPs governing the work of their organizations
- Review and approve new and revised field element QAPs.
- Report management assessment results periodically to the Deputy Secretary (through the Under Secretary) describing the effectiveness of QA implementation.

Field Element Managers

- Develop and implement approved QAPs governing the work under their purview.
- Identify the senior management position assigned this responsibility.
- Perform independent assessments of contractor organizations to evaluate the adequacy and QAP implementation effectiveness.
- Prepare and implement a correction action plan (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).

Contracting Officers

- Include the contractor requirements document (CRD) in contracts falling within the scope of this Order in a timely manner, as directed by the SO.

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, with specific responsibilities for quality policy, quality program support, CAMP, and CATS.

Director, Office of Independent Oversight and Performance Assurance

- Conducts various independent assessments of SO, field element, and contractor implementation of this Order and 10 CFR 830 Subpart A, Quality Assurance
- Reports assessment results to the appropriate Under Secretary, the Assistant Secretary for Environment, Safety, and Health, and the assessed organization.

REQUIREMENTS

The requirements of this Order and 10 CFR 830.121-122 provide a description of the Quality Assurance Program and the Quality Assurance Criteria. Additional information is available in the DOE guides listed at the beginning of this module.

Change No: 1 DOE O 414.1B Level: Familiar Date: 11/01/04

DOE endorses the use of a single integrated QAP to satisfy the requirements for the regulated work, quality assurance drivers (10 CFR 830, Nuclear Regulatory Commission and other federal agencies), any additional quality requirements imposed by DOE elements, and the requirements of this Order.

Quality Assurance Program (QAP)

10 CFR 830.120–121 and this Order list the requirements for a QAP. Contractor requirements are specified in the CRD provided in this Order. DOE elements must:

- Implement the QA criteria using a graded approach and describing how the criteria and graded approach are applied.
- Use voluntary national or international consensus standards where practicable and consistent with contractual or regulatory requirements and identify the standard(s) used.
- Apply additional standards, where practicable and consistent with contractual or regulatory requirements.
- Describe how the contractor responsible for a nuclear facility ensures that subcontractors and suppliers satisfy the quality assurance criteria.
- Integrate quality management system requirements, S/CI prevention process, and the corrective action management program with quality or management system requirements in DOE directives and external requirements, including, as applicable
 - DOE P 450.4, Safety Management System Policy, dated 10-15-96
 - DOE P 450.5, Line Environment, Safety and Health Oversight, dated 06-26-97
 - NNSA Quality Management Policy (QC-1)

Note: You do not have to do example 1 on the following pages, but it is a good time to check your skill and knowledge of the information covered. You may do example 1 or go to section 2.

Change No: 1 DOE O 414.1B Level: Familiar Date: 11/01/04

EXAMPLE 1

1. List four responsibilities of field element managers.
2. Explain the purpose of DOE O 414.1B.
3. State the responsibilities of the contracting officer.
4. Describe the type of information in the QAP.

Note: When you are finished, compare your answers to those contained in the example 1 self-check. When you are satisfied with your answers, go to section 2.

EXAMPLE 1 SELF-CHECK

1. List four responsibilities of field element managers (any four of the following constitute a complete answer).
 - 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 (DOE O 414,1B, Attachment 3); and CAMP requirements (DOE O 414,1B, Attachment 4). Identify the senior management position assigned this responsibility.
 - Submit QAPs to the appropriate SOs for review, resolution of differences of opinion, and approval.
 - 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.
 - Perform independent assessments of contractor organizations to evaluate the adequacy and implementation effectiveness of the QAP. 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.
 - Periodically report management assessment results to their organizations' SOs describing the effectiveness of field element and contractor QA implementation.
 - 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 CATS.
 - 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.

2. Explain the purpose of DOE Order 414.1B.

- To ensure that the quality of Department of Energy (DOE), including National Nuclear Security Administration (NNSA), products and services meet or exceed customers' expectations.
- To achieve QA for all work based upon the following principles: (1) that quality is assured and maintained through a single, integrated, effective QAP (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; and (5) that environmental, safety, and health risks and impacts associated with work processes can be minimized while maximizing reliability and performance of work products.
- To establish quality process requirements to be implemented under a QAP for the control of S/CI and safety issue corrective actions.

3. State the responsibilities of the contracting officer.

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

4. Describe the type of information in the QAP.

- 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).
- Uses voluntary national or international consensus standard where practicable and consistent with contractual or regulatory requirements and identifies the standard used.
- 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).

Change No: 1
DOE O 414.1B
Level: Familiar
Date: 11/01/04

- Integrates quality management system requirements, Suspect/Counterfeit Items Prevention Process, and the Corrective Action Management Program as defined in this Order with other quality or management system requirements in DOE directives and external requirements, including as applicable

SECTION 2 – QUALITY ASSURANCE CRITERIA

QUALITY ASSURANCE CRITERIA

The QAP must address the following management, performance, and assessment criteria.

Management

Criterion 1 – Program

Organizations must

- Establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing work.
- Establish management processes, including planning, scheduling, and providing resources for work.

Introduction: The principal factor representing the performance of an organization is the quality of its products and services. The goal of a quality management system is to deliver safe, reliable products and services that meet or exceed the customer's requirements, needs, and expectations. To do so, the quality management system must describe methods for planning, performing, and assessing the adequacy of work, including work assigned to parties outside the organization. The quality management system is intended to support the Department's integrated safety management system (ISMS).

The rule and Order requirements are stated as performance expectations and do not specify methods for achieving the desired performance. Consequently, organizations must identify, document, and use appropriate standards to develop and implement the management system. In many cases, the particular standards to be adopted are specified by the customer. Organizations with multiple customers must often develop their management system using several standards.

Responsibilities: Management retains the primary responsibility and accountability for the scope and implementation of the management system. However, every individual in the organization is responsible for achieving quality in his or her activities.

Graded Approach: The graded approach must be used to evaluate hazards or risks and to determine the appropriate controls to address those hazards or risks. This process is

accomplished by ensuring the level of analyses, documentation, and actions used to comply with requirements are commensurate with the following:

- the relative importance to safety, safeguards, and security;
- the magnitude of any hazard involved;
- the life-cycle stage of a facility or item;
- the programmatic mission of a facility;
- the particular characteristics of a facility or item;
- the relative importance of radiological and non-radiological hazards; and
- any other relevant factors.

The first step in the grading process is to identify the consequences and probability of a failure. The second step is to identify the specific requirements to be applied. The third step is to determine the depth, extent, and degree of rigor necessary to comply with the requirements. The final step is to communicate and implement the requirements using documented procedures and controls.

Criterion 2 – Personnel Training and Qualification

Organizations must

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

Introduction: An essential element in any mission is that all personnel can perform their assigned tasks. Qualification and training processes ensure that personnel achieve and maintain the required capabilities.

Responsibilities: Management must commit resources to facilitate the training and qualification processes for personnel in their organizations and to ensure that personnel hired or transferred into positions meet the appropriate requirements. Each level of the organization must describe its training and qualification needs. These descriptions must include requirements, interfaces, training methods, training responsibilities, and duties of line and training organizations.

Qualified Personnel: Policies and procedures that describe personnel selection, training, and qualification requirements must be established for each function. These must include

the minimum applicable requirements for education, experience, skill level, and physical condition. Personnel may be qualified based on

- previous experience, education, and training;
- a performance demonstration or test to verify previously acquired skills;
- completion of a training or qualification program; and
- on-the-job training.

Training: Training goals, lesson plans, and other training materials must be consistently developed, reviewed by experienced personnel, approved by management, and used to effectively deliver training. Training effectiveness must be monitored. Worker performance must be evaluated to ensure that the training program conveys all required knowledge and skills.

Training can be grouped into three general categories: project-specific, facility-specific, and institutional.

- *Project-specific training* must impart the knowledge required for personnel to perform their assigned duties safely and successfully. This training may include project goals and schedules, implementing procedures, safety and hazard controls, methods, requirements, process metrics, and skills. Project-specific training requirements must be defined by project managers and workers.
- *Facility-specific training* must convey the safety, emergency plans, security, and operations information necessary for personnel to prepare for and perform their assigned duties in the facility. Management is responsible for defining training requirements and ensuring that the training is administered.
- *Institutional training* must convey general information about the organization's mission, vision, goals, and management system. It may also include general knowledge or skills training.

Criterion 3 – Quality Improvement

Organizations must

- Establish and implement processes to detect and prevent quality problems.
- Identify, control, and correct items, services, and processes that do not meet established requirements.

- Identify the causes of problems and include prevention of recurrence as a part of corrective action planning.
- Review item characteristics, process implementation, and other quality-related information to identify items, services, and processes needing improvement.

Introduction: As used in this guide, a quality problem is a collective term that may be

- a deficiency in an activity, product, service, item characteristic, or process parameter;
- a noncompliance with a legal, contractual, or other requirement; or
- the existence of a substandard condition or a S/CI.

Quality improvement is a management process that is designed to improve an item, service, product, or process. The process must include the use of lessons learned from the local organization and other organizations. Identified improvement actions must also be shared with other organizations. Management must track the actions to ensure they are providing the anticipated improvements.

Identification of Quality Problems: A quality problem must be identified, documented, and evaluated to determine its significance. Usually, identification of a problem comes in the form of feedback from workers and from internal and external customers. If the quality problem is likely to affect safety or mission significantly, the impacted items or processes must be controlled to prevent their further use. Problems that are insignificant and cannot be corrected on the spot must be identified, documented, and handled expeditiously. The method for determining the significance of a problem and the process for handling problems must be documented in the quality management system.

Resolution of Quality Problems: Management should be involved in approving corrective/preventive actions for significant quality problems and following them through to closure. Quality problems identified by internal and external sources (e.g., DOE Office of Oversight, DOE Office of Enforcement and Investigation, or customers) should be tracked through resolution.

Criterion 4 – Documents and Records

Organizations must

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

Introduction: Documents and records are required for managing, performing, and assessing work. Documents and records include applicable requirements for indicating that work has been properly specified and accomplished. Management must identify any documents and records that must be developed and controlled. Management must commit the resources necessary to satisfy the document and record requirements.

Documents: Documents are required by organizations, projects, or programs for controlling policy, administrative, and technical information. A document control system must be established to supply the documents that are necessary for personnel to perform their assigned responsibilities safely. Document systems ensure that the mechanisms developed to implement the safety management functions of DOE P 450.4 are properly prepared, controlled, and available for managers and the workers.

Records: A record contains information that is retained for its expected future value. Records must be sufficient to support technical and regulatory decisions. Records may be in a variety of forms (e.g., electronic, written or printed, microfilm, photographs, radiographs, or optical disks). Records are compiled into a records management system that ensures appropriate records are maintained. The system must include provisions for record retention, protection, preservation, change, traceability, accountability, and retrievability. The hardware and software required to ensure retrievability and usability of archived records must be maintained.

Performance

Criterion 5 – Work Processes

Organizations must

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

Introduction: All work is a process. Work processes consist of a series of actions by qualified workers using specified work procedures and equipment under administrative, technical, and environmental controls to achieve an end result.

Work Performance: Management must ensure that the following are clearly identified and conveyed to workers before beginning work:

- customer and data requirements for the work and the final product;
- acceptance criteria applicable to work and the final product;
- hazards associated with the work;
- technical standards applicable to the work and the final product; and
- safety, administrative, technical, and environmental controls to be employed during the work.

Procedures, work instructions, or other means used to define work processes must be documented. The scope and detail of documentation must be commensurate with the complexity and importance of the work.

Workers are responsible for the quality of their work. Workers must do their work correctly the first time, in accordance with established procedures and work instructions. Since workers are the best resource for contributing ideas for improving work processes, products, and services, they must be involved in work process design and process evaluation, and they must provide feedback for improvement.

Item Identification and Use Control: A process for the identification and control of items must be established and implemented to

- prevent the use of incorrect or defective items,
- identify and control S/CI, and
- provide for the control and maintenance of items.

Item Protection: Work processes must be established and implemented to protect items from damage, loss, or deterioration. Work processes must specify protective methods for sensitive or perishable items and for items requiring special protective environmental controls.

Criterion 6 – Design

Organizations must

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

Introduction: A formal design process must be established that provides control of design inputs, outputs, verification, configuration and design changes, and technical and administrative interfaces appropriate to the importance of the design.

Design Process: The design process must translate design input into design output documents that are technically correct and compliant with the end-user's requirements. Aspects critical to the performance, safety, or reliability of the designed items must be identified during the design phase.

Computer software used to originate or analyze design solutions during the design process must be validated for the intended use. The design organization must perform design analyses and checks to ensure that design output documents meet design input requirements and that any changes have been approved and documented.

Change No: 1 DOE O 414.1B Level: Familiar Date: 11/01/04

Design Output: The completed design must be recorded in design output documents, such as drawings, specifications, test/inspection plans, maintenance requirements, and reports. As-built drawings and shop drawings must be maintained after production or construction to show actual configuration.

Design Verification: Design verification is a formal, documented process for ensuring that the resulting items will comply with the requirements. Design verification methods include technical reviews, peer reviews, alternate calculations, and qualification testing.

Technically knowledgeable persons other than those who developed the design must perform design verification. Interim verifications may occur at predetermined stages of design development. The extent and number of design verifications must be based on a graded approach and must depend on the designed product's complexity and importance to safety and project success.

Criterion 7 – Procurement

Organizations must

- Procure items and services that meet established requirements and perform as specified.
- Evaluate and select prospective suppliers on the basis of specified criteria.
- Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services.

Introduction: The procurement process must ensure that items provided by suppliers meet the requirements and expectations of the end user. The stringency of procurement requirements must be commensurate with the importance of the purchased items to the project.

Procurement Documents: The procurement documents must clearly state test requirements and acceptance criteria for purchased items. Procurement documents must include any specifications, standards, and other documents referred to by the design documents.

Change No: 1 DOE O 414.1B Level: Familiar Date: 11/01/04

Supplier Qualification: Potential suppliers must be evaluated early in the design and procurement process to determine their capabilities. An effective evaluation method is an assessment of personnel and processes conducted at the supplier's facilities. This method may be used in combination with

- a review of the supplier's history for providing identical or similar items or services;
- a review of shared supplier quality information;
- an evaluation of certifications or registrations awarded by nationally accredited third parties; and
- an evaluation of documented qualitative and quantitative information provided by the supplier.

Supplier Performance Monitoring: The qualified supplier's performance must be evaluated periodically to confirm its continuing capabilities. Suppliers must be monitored to ensure that acceptable items or services are produced and schedule requirements are being met. Monitoring may include

- surveillance of work activities;
- inspection of facilities and processes;
- review of plans and progress reports;
- processing of change information;
- review and disposition of nonconformances; and
- selection, qualification, and performance monitoring of sub-tier suppliers.

Inspection: The procurement process must provide for identifying the need for inspections and tests. Requirements for inspections and tests must be obtained from design documents. Inspections must be adequate to ensure conformance with purchase requirements. Inspection may include the following methods:

- inspections of materials or equipment at the supplier's plant,
- receipt inspection of the shipped items,
- review of objective evidence such as certifications and reports, and
- verification or testing of items prior to or following shipment.

Change No: 1 DOE O 414.1B Level: Familiar Date: 11/01/04

Supplier Documentation: Supplier-generated documents must be accepted through the procurement system and controlled and processed by the end-user organization according to the provisions of DOE O 414.1B, Criterion 4, Documents and Records. These documents may include certificates of conformance, drawings, analyses, test reports, maintenance data, nonconformances, corrective actions, approved changes, waivers, and deviations.

Suspect/Counterfeit Items: The selection of suppliers and the purchase of commercial-grade materials must be evaluated to prevent the procurement of suspect/counterfeit items and to detect them before they are released for use.

Criterion 8 – Inspection and Acceptance Testing

Organizations must

- Inspect and test specified items, services, and processes using established acceptance and performance criteria.
- Calibrate and maintain equipment used for inspections and tests.

Introduction: Inspections/tests are accomplished to verify that physical characteristics and functions of systems, structures, and components are acceptable to the organization that will use them.

Process: Technically qualified personnel that have the freedom of access and the ability to communicate inspection and test results must perform inspections and tests. Results of these activities must be documented and retained as project records. Inspection and test documents must contain provisions for the following:

- identification of characteristics to be examined;
- required qualifications of individuals who perform the examination;
- a description of the examination methods, including equipment and calibration requirements;
- acceptance and rejection criteria;
- suitable environmental conditions;
- required safety measures; and
- mandatory hold points.

Inspection records must identify

- item tested
- date of test
- tester or data recorder
- observations
- results and acceptability
- action taken concerning any deviations noted

Control of Measuring and Test Equipment: Measuring and test equipment (M&TE) used for inspection, tests, and monitoring or data collection must be calibrated and maintained using a documented process. M&TE must also be checked before its use to ensure that it is the proper type, range, accuracy, and that it is uniquely identified and traceable to its calibration data.

Assessment

Criterion 9 – Management Assessment

Organizations must

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

Introduction: Managers at every level must periodically assess the performance of their organization to determine how well leadership is being provided to enable the organization to continuously meet the customer's requirements and expectations. DOE has developed expanded guidance on this subject in DOE G 414.1-1A, Management Assessment and Independent Assessment Guide.

Responsibility: Managers must retain overall responsibility for management assessments. Direct participation by managers is essential to the success of the process since management is in a position to view the organization as a total system. Delegating management assessment to a consultant or internal audit group is inconsistent with the requirement and will diminish the assessment's value. The manager's personal

involvement will yield the most meaningful information for that manager to use in taking actions to improve organizational performance.

Process: Management assessments must focus on the identification and resolution of systemic and cultural management issues and problems. Strengths and weaknesses affecting the achievement of organizational objectives must be identified so that meaningful action can be taken to improve quality. Processes being assessed must include strategic planning, organizational interfaces, cost control, use of performance indicators, staff training and qualifications, and supervisory oversight and support.

Criterion 10 – Independent Assessment

Organizations must –

- Plan and conduct independent assessments to measure item and service quality and the adequacy of work performance, and to promote improvement.
- Establish sufficient authority and freedom from line management for independent assessment teams.
- Ensure that persons conducting independent assessments are technically qualified and knowledgeable in the areas to be assessed.

Introduction: Senior management must establish and implement a process to obtain an independent assessment of the organization's programs, projects, contractors, and suppliers. The purpose of this type of assessment is to evaluate performance with regard to customer's requirements and expectations. The results of independent assessments provide an objective form of feedback to senior management that is useful in confirming acceptable performance and must be used for identifying improvement opportunities.

The independent assessment process must use a performance-based approach to focus on results. Performance-based assessments are conducted on activities that

- relate directly to final objectives,
- emphasize safety and reliability, and
- measure item or service performance.

Performing Organization: Independent assessments advise senior management on the quality of items, services, and processes produced by or for the organization.

Change No: 1 DOE O 414.1B Level: Familiar Date: 11/01/04

Consequently, the persons or organization conducting independent assessments must report to a sufficiently high level in the organization. This is to ensure organizational independence from the work and access to the levels of management that are authorized to coordinate and implement corrective actions.

Additionally, personnel performing independent assessments must have the technical knowledge to accurately observe and evaluate activities being assessed. They must not have any direct responsibility for the work or organization they are assessing.

Process: The type and frequency of independent assessments must be based on the status, complexity, risk, and importance of the activities or processes being assessed. The criteria used for assessments must describe acceptable work performance and must promote improvement of the process or activity. Assessments must also address management processes that affect work performance, such as planning, program support, training, and ISMS.

SAFETY ISSUE CORRECTIVE ACTION MANAGEMENT PROGRAM (CAMP)

The Safety Issue Corrective Action Program contains the supplemental quality requirements for DOE elements. As noted in attachment 4 of DOE O 414.1B, the objective of this attachment is to prescribe process requirements and responsibilities for DOE line managers to effectively perform corrective actions that resolve safety issues arising from the following:

- Findings identified by the Offices of Independent Oversight and Performance Assurance; ES&H; and Emergency Management;
- Judgment of needs identified by Type A accident investigations; or
- Other sources as directed by the Secretary or Deputy Secretary, including crosscutting safety issues.

General Requirements

After an assessment report is issued, a comprehensive CAP must be prepared to address each finding. The CAP must address the following:

- extent of conditions,
- causal factors that led to the finding,
- detailed descriptions of corrective action(s) to resolve the finding and

Change No: 1 DOE O 414.1B Level: Familiar Date: 11/01/04

- a general outline for the conduct of the proposed independent corrective action effectiveness review.

The CAP must be prepared and allow for review and approval by the Secretarial Officer or designee within 60 calendar days from the formal final assessment report issuance date.

Field element managers

- are responsible for implementing the approved CAP and ensuring timely and effective completion of all corrective actions;
- must enter, track and report the status of the CAP and associated corrective actions to closure in the DOE CATS database;
- must enter CAP and corrective action data as stated in the approved CAP for each finding in CATS within 10 working days after approval; and
- must ensure all corrective actions are tracked and their status reported to completion and verification.

Once corrective actions are completed, the field element managers must initiate a follow-up review to verify closure and effectiveness in ensuring resolution of each finding within six months of the CAP completion date.

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.

Change No: 1 DOE O 414.1B Level: Familiar Date: 11/01/04

SECTION 3 – QUALITY PROGRAM IMPLEMENTATION

This section of the module summarizes the suspect/counterfeit items (S/CI) prevention process described in DOE O 414.1B, Attachment 3 and safety software quality program requirements discussed in the Order as well as DOE N 411.1. The following draft directives may be released to provide additional guidance:

DOE G 414.1-2X, Quality Assurance Management System Guide for Use with 10 CFR 830 Subpart A, Quality Assurance Requirements, and DOE O 414.1C, Quality Assurance

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

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

SUSPECT/COUNTERFEIT ITEMS (S/CI) PREVENTION PROCESS

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. To prevent the installation of S/CIs, a process is required to be defined.

S/CI Prevention Process

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.

The DOE Office of Environment, Safety, and Health provides the following as a service to DOE and its contractors:

- collecting, analyzing, and disseminating S/CI information;
- notifying 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.

Change No: 1 DOE O 414.1B Level: Familiar Date: 11/01/04

S/CI Quality Management System Requirements

In addition to the requirements specified in section 2, the QAP must include the management position responsible for S/CI prevention and address the following:

- 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;
- training and informing managers, supervisors, and workers on S/CI processes and controls (including prevention, detection, and disposition of S/CIs); and
- identifying and disposing of S/CIs on site.

Work Process Controls

Work processes must be developed and implemented using available S/CI information and include the following:

- engineering involvement in the development of procurement specifications; during inspection and testing; and when replacing, maintaining, or modifying equipment,
- procurement processes that prevent introduction of S/CIs;
- inspection, identification, evaluation and disposition of S/CIs that have been installed in safety applications and other applications that create potential hazards;
- conducting trend analysis and issuing lessons learned reports for use in improving the S/CI prevention.

SAFETY SOFTWARE QUALITY ASSURANCE

Throughout this Order, references to include provisions for safety system software quality are made. The QAP is to address work involving safety software use. Safety software is defined as the following:

- 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 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).

Change No: 1
DOE O 414.1B
Level: Familiar
Date: 11/01/04

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.

Responsibilities

This Order identifies the following positions as having responsibilities for safety software quality assurance. Additional responsibilities are provided in supplemental guides to this Order.

- Secretarial Officers
- Field Element Managers
- Assistant Secretary for Environment, Safety, and Health

Note: You do not have to do example 2 on the following pages, but it is a good time to check your skill and knowledge of the information covered. You may do example 2 or go to the practice.

EXAMPLE 2 SELF-CHECK

1. List five facility-specific factors that are the basis for a graded approach.
Any five of the following constitute a complete, correct answer.
 - The relative importance to safety, safeguards, and security;
 - The magnitude of any hazard or risk involved;
 - The life-cycle stage of a facility;
 - The impact/consequences on programmatic mission of a facility;
 - The particular characteristics of a facility or activity;
 - The nuclear safety classification or hazard category of the item or activity;
 - The adequacy of existing safety documentation;
 - The complexity of products or services involved; and
 - History of problems at a site or facility.

2. List three positions in DOE Order 414.1B that have responsibilities for safety software quality assurance.
 - Secretarial Officers
 - Field Element Managers
 - Assistant Secretary for Environment, Safety, and Health

3. Describe four measures for evaluating and selecting suppliers.
 - Review of the supplier's history for providing identical or similar items or services;
 - Review of shared supplier quality information;
 - Evaluation of certifications or registrations awarded by nationally accredited third parties; and
 - Evaluation of documented qualitative and quantitative information provided by the supplier.

Change No: 1 DOE O 414.1B Level: Familiar Date: 11/01/04

4. Describe the purpose and process of a management assessment.

5. Discuss the purpose of the CAMP.

6. Explain how the quality management system integrates with the safety management system.

7. Describe the two types of software that are referred to as safety software.

Change No: 1 DOE O 414.1B Level: Familiar Date: 11/01/04

11. List the nine steps of the independent assessment planning approach described in appendix D of DOE G 414.1-1A, Management Assessment and Independent Assessment Guide for use with 10 CFR 830.120, 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.

Change No: 1 DOE O 414.1B Level: General Date: 11/01/04
--

DOE O 414.1B, QUALITY ASSURANCE GENERAL LEVEL

OBJECTIVES

Given the familiar level of this module, and a scenario, you will be able to perform the following:

1. List the key elements you would look for in the contractor's action plan to correct the situation described in the scenario.
2. State which requirements, sections, or elements of DOE O 414.1B, its associated guides, and 10 CFR 830.120–122 apply to the situation described in the scenario.

Note: If you think that you can complete the practice at the end of this level without working through the instructional material and/or the examples, complete the practice now. The course manager will check your work. You will need to complete the practice in this level successfully before taking the criterion test.

RESOURCES

DOE O 414.1B, Quality Assurance, 4/29/04.

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, 5/31/01.

DOE G 414.1-2, Quality Assurance Management System Guide for use with 10 CFR 830.120 and DOE O 414.1, 6/17/99.

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, June 1997.

DOE P 450.4, Safety Management System Policy, 10/15/96.

10 CFR 830.120–122, Quality Assurance Requirements.

Change No: 1 DOE O 414.1B Level: General Date: 11/01/04
--

INTRODUCTION

The familiar level of this module introduced the purpose and scope of DOE O 414.1B and its accompanying guides. Several definitions and the requirements associated with these documents were discussed. In the general level of this module, students are asked to apply the information contained in the familiar level and the Order to a scenario related to the Order. Please refer to the resources listed on the previous page to make your analysis and answer the questions. You are not required to complete the example. However, doing so will help prepare you for the practice and the criterion test.

Note: You do not have to do the example on the following page, but it is a good time to check your skill and knowledge of the information covered. You may do the example or go on to the practice.
--

EXAMPLE SCENARIO

Please review the following scenario, and then answer these questions.

1. Is the contractor's action plan correct? If not, state what should have been done.
2. Were the correct DOE documents or requirements cited? If not, state the correct documents or requirements.

SCENARIO

On April 11, 1995, during troubleshooting of electrical power systems associated with the core sampling truck, it was discovered that wiring from the portable 37.5 KVA transformer to the power supply leads coming from the transformer were improperly connected.

It was determined that fabrication of the transformer distribution wiring resulted in a ground wire being improperly connected to a 120-122 volt hot lead. When the power supply leads coming from the transformer were connected to the water supply truck, the truck platform, normally connected to ground, was energized by 120-122 volts.

No personnel injuries resulted from this event.

An investigation of the situation revealed the following:

- The power cable used to route power from the skid-mounted transformer was improperly fabricated. When one end of the cable was plugged into the transformer, the green, or ground, lead of the cable connected to the black, or hot, lead coming from the transformer. This resulted in the ground wire carrying current from the transformer to the water truck's grounding system.
- Lack of supervision was identified as a contributing cause that resulted in the fabrication of parts that were not consistent with the design documents. Inadequate design documents were also identified as a contributing cause. The reels specified did not allow the equipment ground to be continuous through the circuit. Additionally, male plugs on the end of the cables were specified where the female socket should have been. Another factor was that the design document did not specify quality control's (QC's) involvement.

Change No: 1 DOE O 414.1B Level: General Date: 11/01/04
--

- The acceptance test procedure did not specify testing of the complete system and, therefore, none was performed. This procedure did not specify acceptance test criteria or final inspections.
- The cable used to route power from the transformer to the water truck was not tested to ensure reliability.

The following actions were taken by the contractor:

- The portable transformer was taken out of service.
- A critique was held with operations, maintenance, safety and engineering to determine immediate corrective actions necessary to prevent the use of the portable electrical distribution equipment.
- Two unused, similar transformers manufactured by a different group were also removed from service, pending completion of corrective actions.
- An inspection of all three transformers was completed, documented, and photos were taken.
- A restart team was formed to review all electrical fabrication work affected by the stop work order. The focus of the review was to ensure work packages are technically complete and contain sufficient safeguards to ensure quality and safety of the delivered product.
- A supervisor with electrical experience was assigned to supervise work in the fabrication shops.
- Requirements were established that all future electrical work performed by site fabrication services will require the following:
 - a design review
 - an approved QC plan
 - a post-fabrication inspection
 - a functional test
 - formal customer acceptance of work accomplished
 - customer notification of final inspection and testing so they can participate

Change No: 1 DOE O 414.1B Level: General Date: 11/01/04
--

The DOE requirements that apply to this scenario are

- Train and qualify personnel to be capable of performing assigned work. (DOE Order 414.1B, paragraph 4.b.[2][a])
- Design items and processes using sound engineering/scientific principles and appropriate standards. (DOE Order 414.1B, paragraph 4.b.[6][a])

Take some time to review the example scenario and the actions the contractor took or did not take to correct the situation. Then decide if the contractor's actions were complete and correct; determine if the requirements cited in the scenario were appropriate.

Write your answers below and then compare them to the ones contained in the example self-check.

Change No: 1 DOE O 414.1B Level: General Date: 11/01/04
--

EXAMPLE SELF-CHECK

Your answers do not have to match the following exactly. You may have added more corrective actions or cited other requirements from the Order that apply. To be considered correct, your answer must include at least the following:

The contractor took all the appropriate actions.

The DOE requirements cited were correct, but not complete. Additional requirements are

- Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design. (DOE O 414.1B, paragraph 4.b.[4][a])
- Perform work consistent with technical standards, administrative controls, hazard controls adopted to meet regulatory or contract requirements using approved instructions, procedures, etc. (DOE O 414.1B, paragraph 4.b[5][a])
- Inspect and test specified items, services, and processes using established acceptance and performance criteria. (DOE O 414.1B, paragraph 4.b.[8][a])

PRACTICE

This practice is required if your proficiency is to be verified at the general level. The practice will prepare you for the criterion test. You will need to refer to the Orders and the implementation guide to answer the questions in the practice correctly. The practice and criterion test will also challenge additional analytical skills that you have acquired in other formal and on-the-job training.

Please review the scenario and answer the following questions:

1. List the key elements you would look for in the contractor's action plan to correct the situation described in the scenario.
2. Was the list of DOE requirements, sections, and elements complete and correct? If not, state the correct or omitted requirements.

SCENARIO

The FB-Line facility performs calibrations and calibration checks at predetermined intervals for certain pieces of instrumentation and other related equipment. On 11/12/94, four pressure switches associated with two of the FB-Line ventilation interlocks were calibrated with a Loveland instrument that did not meet the 1:1 waiver requirement. This resulted in calibrations that were indeterminate.

BACKGROUND

Before starting work on 11/11/94, maintenance determined that the 4:1 ratio uncertainty could not be obtained. (The 4:1 ratio is that all measuring and test equipment [M&TE] specified in procedures and used to calibrate installed process instrumentation [IPI] shall have an uncertainty of four times less than the specified tolerance of the IPI being calibrated. If the uncertainty requested does not meet the 4:1 rule, engineering must provide an evaluation and approve a waiver if applicable for use. However, in no cases shall the uncertainty of the M&TE be greater than the tolerance of the IPI being calibrated.) Maintenance found that almost 2:1 could be obtained using another 1-psi Loveland calibrator. Maintenance obtained the 4:1 waiver based on the use of this equipment. On 11/12/94, the job was reassigned. The 1-psi Loveland calibrator did not

Change No: 1 DOE O 414.1B Level: General Date: 11/01/04
--

pass the bench check and another calibrator was selected. The mechanics performed the job with a -15 to 25-psi Loveland calibrator. The mechanics performing the job found that the as-found reading for the switches were out of tolerance and proceeded to calibrate them. Engineering, upon reviewing the out-of-tolerance data, noticed that the as-found figures were further out than readings should have been for a usually reliable pressure switch. At this point, engineering discovered that the calibrating equipment used was not within the required uncertainty for the switches. The interlocks were declared inoperable.

An investigation of the situation revealed the following:

- The mechanics failed to perform a 4:1 ratio calculation on the second Loveland calibrator that they selected to perform this calibration. If the calculation had been performed, the mechanics would have realized that the Loveland calibrator that they selected could not be used to perform this calibration.
- The engineering manual, or the quality manual, does not provide guidance on the level of reviews required for calibration calculations.
- The information contained in the M&TE database assumed the same accuracy for every port for the M&TE item, and the range of each port was not specified. These items led to the mechanics choosing the wrong piece of calibrating equipment and made the 4:1 calculation difficult to perform correctly. In addition, there were instances found where the actual information from the standards lab did not agree with the database information provided to the mechanics. The M&TE database did not include which calibrators had waivers issued for them and the resulting conditions that had to be met.
- Mechanics in FB-Line did not receive formal training demonstrating proficiency on the 4:1 calculation. The mechanics were not aware that the calculation needed to be performed when another piece of M&TE was selected. The mechanics did not perform a 4:1 calculation on the other calibrator because they believed that the existing waiver covered any calibrator selected. The requirements in the waiver were not understood.

Change No: 1 DOE O 414.1B Level: General Date: 11/01/04
--

The following actions were taken by the contractor:

- Engineering assisted in developing and providing training on 4:1 ratio calculations to mechanics.
- Engineering reviewed all 4:1 calculations until proper training had been provided to the mechanics.
- A lessons learned was initiated through the operating experience program.
- Engineering and quality assurance reviewed and/or revised the appropriate procedures.
- Engineering and maintenance corrected the M&TE database to provide accuracy and the range for each port.
- Engineering provided or developed training on the M&TE database to mechanics and engineers.
- Engineering reviewed information in the M&TE database to ensure correct information from the standards lab was included and waivers and conditions were specified.

DOE requirements related to this scenario are

- Training should help personnel acquire knowledge of the correct and current processes and methods to accomplish assigned tasks. It should also enable personnel to understand the fundamentals of the work, the associated hazards, the context within which the work is performed, and the reasons for any special work requirements. (DOE G 414.1-2, section 4.2.4, page 7)
- A document control system should be established to supply the documents necessary for personnel to perform their assigned responsibilities safely and correctly. Document systems ensure that the mechanisms developed to implement the safety management functions are properly prepared, controlled, and available for managers and the workers. (DOE G 414.1-2, section 4.4.2, page 11)
- Procedures, work instructions, or other means used to define work processes should be documented. The scope and detail of documentation should be commensurate with the complexity and importance of the work, the skills required to perform the work, and the hazards and risks or consequences of quality problems in the product, process, or service. Control of processes, skills, hazards, and equipment should be

Change No: 1 DOE O 414.1B Level: General Date: 11/01/04
--

clearly specified, understood, and fully documented. (DOE G 414.1-2, section 4.5.2, page 13)

Take some time to review the scenario and the actions the contractor took or did not take to correct the situation. Then decide if the contractor's actions were complete and correct; determine if the requirements, sections, or elements of DOE O 414.1B, its accompanying guides, and 10 CFR 830.120–122 cited in the scenario were correct.

Write your answer below and then take the completed practice to the course manager for review.

Note: The course manager will check your practice and verify your success at the general level. When you have successfully completed this practice, the course manager will give you the criterion test.
