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

DOE O 414.1D

QUALITY ASSURANCE

DOE O 414.1D
QUALITY ASSURANCE
FAMILIAR LEVEL

OBJECTIVES

Given the familiar level of this module and the resources, you will be able answer the following questions:

1. What are the purposes of DOE O 414.1D, *Quality Assurance*?
2. What are the Federal requirements of the Order?
3. What are the field element manager's responsibilities associated with the Order?
4. What are the quality assurance criteria listed in attachment 2 of DOE O 414.1D, *Quality Assurance Criteria*?
5. What are the purpose and requirements of DOE O 414.1D, attachment 3, *Suspect/Counterfeit Items Prevention*?
6. What are the purpose and requirements of DOE O 414.1D, attachment 4, *Safety Software Quality Assurance Requirements for Nuclear Facilities*?

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

RESOURCES

ASME NQA-1-2008 with the NQA-1a-2009 addenda (or a later edition), *Quality Assurance Requirements for Nuclear Facility Applications*, Part I and Subpart 2.7.

DOE O 414.1D, *Quality Assurance*. April 25, 2011.

DOE O 426.1, *Federal Technical Capability*. November 19, 2009.

DOE-STD-1025-2008, *Weapons Quality Assurance* (WQA) *Qualification Standard*. September 2008.

DOE-STD-1150-2002, *Quality Assurance Functional Area Qualification Standard*. April 2002.

DOE STD-1172-2011, *Safety Software Quality Assurance Functional Area Qualification Standard.* March 2011.

INTRODUCTION

The familiar level of this module is divided into two sections. In the first section, we will discuss the purpose, requirements, and field element manager responsibilities of DOE O 414.1D, *Quality Assurance.* In the second section, we will discuss the relevant content of attachments 2, 3, and 4 of the Order. We have provided examples throughout the module to help familiarize you with the material. The examples will also help prepare you for the practice at the end of this module and the criterion test.

Before continuing, you should obtain a copy of the resources. Copies of the Orders and standards are available at https://www.directives.doe.gov/directives and http://www.hss.doe.gov/nuclearsafety/ns/techstds/standard.html respectively, or through the course manager.

SECTION 1: PURPOSE, REQUIREMENTS, AND FIELD ELEMENT MANAGER RESPONSIBILITIES

Purpose

To ensure that DOE, including NNSA, products and services meet or exceed customers' requirements and expectations.

To achieve quality for all work based upon the following principles:

- All work, as defined in this Order, is conducted through an integrated and effective management system.
- Management support for planning, organization, resources, direction, and control is essential to quality assurance (QA).
- Performance and quality improvement require thorough, rigorous assessments and effective corrective actions.
- All personnel are responsible for achieving and maintaining quality.
- Risks and adverse mission impacts associated with work processes are minimized while maximizing reliability and performance of work products.

To establish additional process-specific quality requirements to be implemented under a quality assurance program (QAP) for the control of suspect/counterfeit items (S/CIs), and nuclear safety software as defined in this Order.

Requirements

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

- Describe the graded approach used in the QAP.
- Implement QA criteria as defined in attachment 2 of DOE O 414.1D, as well as the requirements in attachment 3 of DOE O 414.1D for all facilities, and for nuclear facilities, the requirements in attachment 4 of DOE O 414.1D.
    - Describe how the criteria/requirements are met, using the documented graded

approach.
- Flow down the applicable QA requirements and responsibilities throughout all levels of the organization.
- Use appropriate national or international consensus standards in whole or in part, consistent with regulatory requirements and secretarial officer direction. When standards do not fully address these requirements, the gaps must be addressed in the QAP.
- Clearly identify which standards, or parts of the standards, are used.

Quality Assurance Program Approval and Changes
Each departmental element and associated field element(s) must
- submit a QAP to the designated DOE approval authority;
- review the QAP annually, or on a periodic basis defined in the QAP, and update the QAP, as needed. Submit a summary of the review of the QAP and, if necessary, also submit the modified QAP to the DOE approval authority. Editorial changes to the QAP, that do not reduce or change commitments, do not require approval;
- regard the QAP as approved 90 calendar days after receipt by the approval authority, unless approved or rejected at an earlier date.

Federal Technical Capability and Qualifications
Qualification for the functional areas identified in DOE O 414.1D, section 4.c.(1) and (2) are achieved as defined in the DOE O 426.1, *Federal Technical Capability*, 11-19-09.
- Federal personnel directly responsible for the oversight of quality requirements governing defense nuclear facilities must be qualified in accordance with DOE-STD-1150-2002, *Quality Assurance Functional Area Qualification Standard*.
- Federal personnel directly responsible for oversight of safety software quality assurance (SSQA) activities of defense nuclear facilities must be qualified in accordance with DOE STD-1172-2003, *Safety Software Quality Assurance Functional Area Qualification Standard*.

Field Element Manager (FEM) Responsibilities
- Notify contracting officers for field-issued contracts as to which contractors are affected by this Order. The secretarial officer has the authority to direct the contracting officer, as necessary, to ensure appropriate quality requirements are implemented by the contractor.
- For FEMs of sites, other than NNSA sites, where approval authority is delegated to the FEM, review and approve any new or revised QAPs for work under the FEM's purview. Where authority is not delegated to the FEM, review and comment on, and submit the QAPs to the secretarial officer for approval.
- For FEMs of NNSA sites, review and approve any new or revised QAPs for work under the FEM's purview, including the FEM and contractor QAPs.
- Provide resources and staff to meet the provisions of DOE O 414.1D and ensure that appropriate staff is qualified, as specified in section 4.c of this Order.
- Ensure reviews are performed of the field element QAP per DOE O 414.1D, section 4.b.(2) and update as necessary. Submit the modified QAP to the approval authority.
- Ensure review of safety documentation for the facility or activity to validate safety software has been properly identified.

- Ensure review of grading levels of safety software for approval by the QAP approval authority.

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

EXAMPLE 1

Using the familiar level of this module and the resources, answer the following questions.

1. What are two purposes of DOE O 414.1D?

2. What are the departmental and field element requirements for quality assurance program approval and changes mandated by DOE 414.1D?

3. What are three field element manager responsibilities of DOE O 414.1D?

Note: When you have 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. What are two purposes of DOE O 414.1D?

   Note: Any two of the following constitute a correct answer.

   The purpose of DOE O 414.1D is to
   - ensure that DOE, including NNSA, products and services meet or exceed customers' requirements and expectations
   - achieve quality for all work based upon the principles stated in DOE O 414.1D
   - establish additional process-specific quality requirements to be implemented under a QAP for the control of suspect/counterfeit items, and nuclear safety software as defined by DOE O 414.1D

2. What are the departmental and associated field element requirements for QAP approval and changes mandated by DOE O 414.1D?

   Each departmental and associated field element(s) must
   - submit a QAP to the designated DOE approval authority;
   - review the QAP annually, or on a periodic basis defined in the QAP, and update the QAP, as needed. Submit a summary of the review of the QAP and, if necessary, also submit the modified QAP to the DOE approval authority;
   - regard the QAP as approved 90 calendar days after receipt by the approval authority, unless approved or rejected at an earlier date.

3. What are three field element manager responsibilities of DOE O 414.1D?

   Note: Any three of the following constitute a correct answer.

   Field element managers (FEMs) must
   - notify contracting officers for field-issued contracts as to which contractors are affected by this Order;
   - for FEMs of sites, other than NNSA sites, where approval authority is delegated to the FEM, review and approve any new or revised quality assurance programs (QAPs) for work under the FEM's purview;
   - for FEMs of NNSA sites, review and approve any new or revised QAPs for work under the FEM's purview, including the FEM and contractor QAPs;
   - provide resources and staff to meet the provisions of DOE O 414.1D and ensure that appropriate staff is qualified, as specified in section 4.c of this Order;
   - ensure reviews are performed of the field element QAP per DOE O 414.1D, section 4.b.(2) and update as necessary. Submit to the approval authority the modified QAP;
   - ensure review of safety documentation for the facility or activity to validate that safety software has been properly identified;
   - ensure review of grading levels of safety software for approval by the QAP approval authority.

SECTION 2: ATTACHMENTS 2, 3 AND 4

All of the attachments discussed in this section provide information and/or requirements associated with DOE O 414.1D and are applicable to contracts in which the associated contractor requirements document (CRD) is inserted.

Attachment 2, Quality Assurance Criteria

Criterion 1—Management/Program

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

Criterion 2—Management/Personnel Training and Qualification

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

Criterion 3—Management/Quality Improvement

- 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

Criterion 4—Management/Documents and Records

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

Criterion 5—Performance/Work Processes

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

Criterion 6—Performance/Design

- 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 or validate the adequacy of design products using individuals or groups other than those who performed the work
- Verify or validate work before approval and implementation of the design

Criterion 7—Performance/Procurement

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

Criterion 9—Assessment/Management Assessment

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

Criterion 10—Assessment/Independent Assessment

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

Attachment 3, Suspect/Counterfeit Items Prevention

Purpose

To set forth requirements for DOE and its contractor organizations, as part of their QAPs, to establish, document, and implement effective controls and processes that will: 1) ensure items and services meet specified requirements; 2) prevent entry of S/CIs into the DOE supply chain; and 3) ensure detection, control, reporting, and disposition of S/CIs.

Requirements

The organization's QAP must

- include an S/CI oversight and prevention process commensurate with the facility/activity hazards and mission impact;
- identify the position responsible for S/CI activities and for serving as a point of contact with the Office of Health, Safety, and Security;
- provide for training and inform managers, supervisors, and workers on S/CI processes and controls (including prevention, detection, and disposition of S/CIs);
- prevent introduction of S/CIs into DOE work as specified in attachment 3, section 2.d. of DOE O 414.1D;
- include processes for inspection, identification, evaluation, and disposition of S/CIs that have been installed in safety applications and other applications that create potential hazards. Also address the use of supporting engineering evaluations for acceptance of installed S/CI as well as marking to prevent future reuse;
- conduct engineering evaluations to be used in the disposition of identified S/CIs installed in safety applications/systems or in applications that create potential hazards;
- perform the evaluation to determine whether S/CIs installed in non-safety applications pose potential safety hazards or may remain in place;

- report to the DOE Inspector General per attachment 3, section 3 of DOE O 414.1D and DOE O 221.1A, *Reporting Fraud, Waste, and Abuse to the Office of Inspector General*, dated 03-22-01 (or latest version);
- collect, maintain, disseminate, and use the most accurate, up-to-date information on S/CIs and suppliers; and
- conduct trend analyses for use in improving the S/CI prevention process.

Attachment 4, Safety Software Quality Assurance Requirements for Nuclear Facilities

Purpose

- Prescribe the SSQA requirements for DOE nuclear facilities.
- Software, other than safety software as defined in this Order, is not subject to requirements in attachment 4 of DOE O 414.1D.

Requirements

- Safety software must be acquired, developed and implemented using ASME NQA-1-2008 or other national or international consensus standards that provide an equivalent level of QA requirements. DOE-approved QAPs applicable to safety software based on requirements from DOE O 414.1C are acceptable. Management of safety software must include the following elements:
  - Involve the facility design authority, as applicable, in: the identification of requirements specification; acquisition; design; development; verification and validation (including inspection and testing); configuration management; maintenance; and, retirement.
  - Identify, document, control and maintain safety software inventory. The inventory entries must include at a minimum the following: software description; software name; version identifier; safety software designation; grade-level designation; specific nuclear facility application used; and the responsible individual.
  - Establish and document grading levels for safety software using the graded approach.
  - Using the consensus standard selected and the grading levels established and approved in the previous bullet, select and implement applicable SSQA work activities from the list provided in attachment 4, section 2.a.(4).

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

EXAMPLE 2

Using the familiar level of this module and the resources, answer the following questions.

1. What is required by quality assurance criterion 1, management/program?

2. What are five suspect/counterfeit item prevention requirements of an organization's quality assurance program mandated by DOE O 414.1D?

3. What are the minimum entries that must be included in a safety software inventory, as specified in attachment 4 of DOE O 414.1D?

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

EXAMPLE 2 SELF-CHECK

1. What is required by quality assurance criterion 1, management/program?

   Quality assurance criterion 1 requires organizations to
   - establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work; and
   - establish management processes, including planning, scheduling, and providing resources for the work.

2. What are five suspect/counterfeit item S/CI prevention requirements of an organization's QAP mandated by DOE O 414.1D?

   Note: Any five of the following constitute a correct answer.

   An organization's QAP must
   - include an S/CI oversight and prevention process commensurate with the facility/activity hazards and mission impact;
   - identify the position responsible for S/CI activities and for serving as a point of contact with the Office of Health, Safety, and Security;
   - provide for training and informing managers, supervisors, and workers on S/CI processes and controls (including prevention, detection, and disposition of S/CIs);
   - prevent introduction of S/CIs into DOE work as specified in attachment 3, section 2.d. of DOE O 414.1D;
   - include processes for inspection, identification, evaluation, and disposition of S/CIs that have been installed in safety applications and other applications that create potential hazards;
   - conduct engineering evaluations to be used in the disposition of identified S/CIs installed in safety applications/systems or in applications that create potential hazards;
   - perform the evaluation to determine whether S/CIs installed in non-safety applications pose potential safety hazards or may remain in place.
   - report to the DOE Inspector General per attachment 3, section 3 of DOE O 414.1D and DOE O 221.1A;
   - collect, maintain, disseminate, and use the most accurate, up-to-date information on S/CIs and suppliers;
   - conduct trend analyses for use in improving the S/CI prevention process.

3. What are the minimum entries that must be included in a safety software inventory, as specified in attachment 4 of DOE O 414.1D?

   The minimum safety software inventory entries specified in attachment 4 are:
   - Software description
   - Software name
   - Version identifier
   - Safety software designation
   - Grade-level designation
   - Specific nuclear facility application used
   - The responsible individual

Note: When you are satisfied with your example, go on to the practice. The course manager will check your practice and verify your success at the familiar level.

PRACTICE

This practice is required if your proficiency is to be verified at the familiar level. This practice will prepare you for the criterion test that will be required if your proficiency is to be verified at the general level. You will need to refer to DOE O 414.1D to answer the questions in the practice correctly. The practice and criterion tests will also challenge additional skills that you have acquired in other formal and on-the-job training.

1. What are three principles upon which achieving quality for all work is based, as specified in DOE O 414.1D?

2. What is the purpose of establishing, documenting and implementing effective suspect/ counterfeit item (S/CI) controls and processes?

3. What is required by quality assurance criterion 8—performance/inspection and acceptance testing?

4. How must an organization's approved quality assurance program (QAP) implement the criteria and requirements of appendices B, C, and D of DOE O 414.1D?

5. What is the difference between the DOE 414.1D definitions of a management assessment and an independent assessment?

6. What is a QAP?

7. In what four ways must an organization's QAP prevent introduction of S/CI into DOE work?

8. Which of the following answers best describes how each DOE organization must develop a QAP and implement the approved QAP?
   a. As directed by the central technical authority
   b. In accordance with documented safety analysis requirements
   c. With input from the Office of Health, Safety and Security
   d. By using a graded approach

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

DOE O 414.1D
QUALITY ASSURANCE
GENERAL LEVEL

OBJECTIVES

Given the familiar level of this module, a scenario, and an analysis, you will be able to answer the following questions:

1. What are the key elements you would look for in the contractor's action plan to correct the situation described in the scenario?
2. Which requirements, sections, or elements of DOE O 414.1D, 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 Orders Self-Study Program, DOE O 414.1D, Familiar Level. July 2011.

DOE O 414.1D, *Quality Assurance*. April 25, 2011.

DOE G 414.1-1B, *Management and Independent Assessments Guide for Use with 10 CFR Part 830, Subpart A, and DOE O 414.1C, Quality Assurance; DOE M 450.4 -1, Integrated Safety Management System Manual; and DOE O 226.1A, Implementation of DOE Oversight Policy*. September 27, 2007.

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*. June 17, 2005.

DOE P 450.4A, *Integrated Safety Management Policy*. April 25, 2011.

10 CFR 830.120–122, "Quality Assurance Requirements." January 1, 2011.

INTRODUCTION

The familiar level of this module introduced DOE O 414.1D, *Quality Assurance*. Several requirements from the resources were discussed. In the general level of this module, candidates are asked to apply the information contained in the familiar level and DOE O 414.1D to several questions and a scenario that depicts a work situation related to the Order. Please refer to the resources 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 criterion tests.

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, what should have been done?
2. Were the correct DOE documents or criteria/requirements cited? If not, what are the correct documents or criteria/requirements?

On April 11, 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.
- 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

The DOE requirements that apply to this scenario are:

- Train and qualify personnel to be capable of performing their assigned work. (DOE O 414.1D, attachment 2, criterion 2.a.)
- Design items and processes using sound engineering/scientific principles and appropriate standards. (DOE O 414.1D, attachment 2, criterion 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 on the next page, and then compare them to the ones contained in the example self-check.

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 414.1D, attachment 2, criterion4.a.)
- Perform work consistent with technical standards, administrative controls, and other hazard controls adopted to meet regulatory or contract requirements using approved instructions, procedures, or other appropriate means. (DOE O 414.1D, attachment 2, criterion 5.a.)
- Inspect and test specified items, services, and processes using established acceptance and performance criteria. (DOE O 414.1D, attachment 2, criterion 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 resources to answer the questions in the practice correctly. The practice and criterion tests will also challenge additional analytical skills that you have acquired in other formal and on-the-job training.

Please review the following scenario and the answer these questions.

1. What are 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, what are 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 November 12, 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 November 11, 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 case 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 one pound per square inch (psi) Loveland calibrator. Maintenance obtained the 4:1 waiver based on the use of this equipment. On November 12, the job was reassigned. The one-psi Loveland calibrator did not 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 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.

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 assists personnel in acquiring knowledge of the correct and current processes and methods to accomplish assigned tasks. It enables 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 414.1-2A, section 4.2.4)
- A document control system should be in place to control the preparation, review, approval, issue, control, and revision of documents. The document control system should be established to supply the documents necessary for personnel to safely and correctly perform their assigned responsibilities. Document control systems ensure that the mechanisms developed to implement the safety management

functions of DOE P 450.4, *Integrated Safety Management Policy*, are properly prepared, controlled, and available for use. (DOE G 414.1-2A, section 4.4.2)

- Procedures, work instructions, or other appropriate means used to define work processes should be documented and controlled. The scope and detail of documentation should be commensurate with the complexity and importance of the work, the skills required to perform the work, the hazards and risks or consequences of quality problems in the product, process, or service, and the need to meet regulatory and contract requirements. Control of processes, skills, hazards, and equipment should be clearly specified, understood, and fully documented. (DOE G 414.1-2A, section 4.5.2)

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 414.1D, its accompanying guides, and 10 CFR 830.120–122 cited in the scenario were correct.

Write your answers below and on the next page, 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.