Introduction to DOE-ORO Quality Assurance
July 2006

Overview

This required-reading training activity is **mandatory** for all Oak Ridge Office staff and direct/support service contractors. At completion, you will be able to:

- Describe the basic principles and requirements of the Quality Assurance (QA) regulations and their application to the Department of Energy (DOE) and Oak Ridge Office (ORO).
- Recognize that quality assurance processes apply to all aspects of ORO's work – technical, non-technical, and administrative.

This training activity provides:

- An introduction to the formal quality assurance process to those persons in non-technical positions.
- A refresher for persons in technical positions.

After you complete this activity, fill out the ISMS Self-Certification Form to indicate that you have read and understand the information contained in this training.

This training activity has been incorporated into the ORO ISMS Training as Track 1 Activity 3, and Track 2 Activity 14. It also fulfills Competency 17 of the DOE Defense Nuclear Facilities Technical Personnel General Technical Base Qualification Standard (DOE-STD-1146-2001).

Note: When regulations, DOE directives, or other industry standards are referenced in this training, please use the most recent versions.

Introduction

This training introduces the concept of quality assurance as a total management system and the basic philosophy of quality assurance as prescribed through DOE Order (O) 414.1, *Quality Assurance* and 10 CFR 830, Subpart A, *Quality Assurance Requirements*. Quality assurance activities are also prescribed in the ORO directive ORO O 410, *Management*, Chapter III, "Quality Assurance," which establishes the elements of an effective ORO Quality Assurance Program (QAP).

What is Quality?

- *Quality* means the condition achieved when an item, service, or process meets or exceeds the user's requirements and expectations.
- *Quality assurance* means all those actions that provide confidence that quality is achieved.

These definitions are taken from DOE O 414.1, *Quality Assurance.*

Quality Assurance at ORO means that for all work (safety-related or otherwise):

- There should be a process in place to assure that the quality of work meets the expectations of the organizations or persons for whom the work is being performed.
  - For example, this may be as simple as an automatic double check of the work, using a checklist of review items, or having a second person verification or peer review of the work.
- The goal of this quality assurance program is to consistently produce the best quality product (or service) within the allotted budget and schedule.

The 10 Quality Assurance Criteria

DOE Offices must develop their quality assurance programs by applying the following quality assurance criteria, using a graded approach, to all their technical and non-technical activities. Each criterion description includes the applicable requirements excerpted from DOE O 414.1 and a short discussion of its application at ORO. Note that the 10 criteria in 10 CFR 830, Part A, are defined similarly.

Criterion 1: Program

A written QAP must be developed, implemented, and maintained. The QAP must describe the organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work. The QAP must describe the management processes, including planning, scheduling, and resource considerations.

Discussion

- The QAP is a total management system that outlines management's mission, policies, and objectives.
- The QAP applies to every unit and employee in the organization.
- The QAP describes either directly or through reference, the organization's structure, functional responsibilities, levels of authority, and interfaces.
- The QAP identifies work performed by outside organizations and the reporting relationships between them and the owner/manager.
- Using these concepts, employees can strive to do their jobs "right the first time."
- Development of the QAP must be a collaborative effort on the part of all involved parties: management, those performing the work, and those assessing work.
- The QAP is an ever-changing management system that reflects the dynamics of an organization's operation.

At ORO

- The ORO Quality Assurance Program Description (QAPD) is contained in Chapter III of ORO O 410. Lower level QAPDs may be developed when appropriate.
- The ORO Management System Description, along with the supporting Assistant Manager for Environmental Management (AMEM) Management System Description and Laboratory Management System Description, identifies the systems and controls needed to continue to

implement and improve ORO's integrated safety management system processes and practices.

Criterion 2: Personnel Training and Qualification

Personnel must be trained and qualified to ensure they are capable of performing their assigned work. Personnel must be provided continuing training to ensure that job proficiency is maintained.

Discussion

- All personnel, including managers, must be qualified to perform their assignments.
- The purpose of training is to provide the skills and knowledge that are needed for qualification.
- The training program should be structured to ensure that curricula address the specific needs of employees and the overall organization.
- This requires that training be planned and carried out using clearly defined objectives that are in concert with established management policy.

At ORO

- This requirement is fulfilled by the individual development plan (IDP) process, the training needs assessment, and the identification of such organizational and mandatory training needs as compliance and directed training. All of this information is specified in the Human Resources Management Plan prepared by the Human Resources Division.
- ORO's Technical Qualification Program (TQP) and the accompanying office and facility-specific qualification standards are examples of how ORO implements this requirement.

Criterion 3: Quality Improvement

Processes to detect and prevent quality problems must be established and implemented. Items, services, and processes that do not meet established requirements must be identified, controlled, and corrected according to the importance of the problem and the work affected. Correction must include identifying the causes of problems and working to prevent recurrence. Item characteristics, process implementation, and other quality-related information must be reviewed and the data analyzed to identify items, services, and processes needing improvement.

Discussion

- Management must establish and implement a process to promote continuous improvement by promoting a culture in which every employee believes that they can make a difference in the quality of the organization's products and services.
- Although the primary purpose of the quality improvement process is to prevent the occurrence of problems, they will still occur. Provisions must be made to identify, resolve, and prevent their recurrence.
- To ensure success, management must foster a "no fault" attitude to encourage employees to identify problems that could compromise facility safety or reliability.

At ORO

- Quality improvement processes and tools include such operational event and corrective action databases as DOE Occurrence Reporting and Processing System (ORPS) and ORO Issues and Corrective Action Management Program (ORION, Version 3). These databases provide a mechanism to initiate, resolve and track the status of safety issues, concerns, and other significant items (such as assessment results or safety concerns raised by ORO employees) that need to be followed through closure.
- Contractors' QAPs, radiation protection programs (RPPs), and project execution plans (PEPs) provide mechanisms to identify ongoing improvements in safety.
- ORO's Manager's Assurance Memorandum requires a self-evaluation of our management processes, including QA, safety and health action plans for areas needing improvement, and tracking.
- Another important way ORO employees contribute to safety improvement is for them to exercise their authority to stop work until an effective corrective action has been taken.

Criterion 4: Documents and Records

Documents must be prepared, reviewed, approved, issued, used, and revised to prescribe processes, specify requirements, or establish design. Records must be specified, prepared, reviewed, approved, and maintained.

Discussion

- QAP documents include drawings, calculations, procedures, specifications, computer codes, purchase orders, vendor-supplied documentation, work instructions, and operator aids.
- QAP should address both active and inactive records.
- Records that require special processing and control, such as computer codes and software and information stored on high-density media or optical disks, should be maintained and controlled to ensure they are readily retrievable and useable.

At ORO

- An example of how this requirement is met is the directives management system. An ORO directive is a document that specifies how ORO carries out its duties and responsibilities.
- An example of a record is an employee's completed time and attendance report.
- As specified in DOE O 200.1, *Information Management Program*, and ORO O 410, ORO processes its records in accordance with 36 CFR, *Parks, Forests, and Public Property*, Chapter XII, "National Archives and Records Administration," which sets forth policies and procedures concerning the creation, collection, use, documentation, dissemination, and disposition of records maintained by Federal Agencies. Of particular importance for safety-related records is that ORO and the contractors process their applicable records to their final disposition.

Criterion 5: Work Processes

Work must be performed to established technical standards and administrative controls, using approved instructions, procedures, or other appropriate means. Items must be identified and controlled to ensure their proper use. Items must be maintained to prevent their damage, loss, or deterioration. Equipment used for process monitoring or data collection must be calibrated and maintained.

Discussion

- Each employee must take responsibility for the quality of the work they perform.
- Work must be planned, authorized, and performed under suitably controlled conditions. It must be performed by competent individuals using standards, instructions, procedures, or other appropriate documents.
- Documents that govern the work should match its complexity and importance (graded approach).
- Whenever possible, administrative controls should be simplified to minimize the burden on the worker.

At ORO

- Work is performed in accordance with approved procedures (or directives). For example, accident investigations are conducted adhering to the requirements and guidance in ORO O 220, *Assessments*, Chapter X, "Accident Investigations." This procedure was applied during the spring 2003 investigation of an electrical incident at ORNL.
- For procurement activities, ORO follows the requirements and guidance described in the Federal Acquisition Regulation (FAR), the supplemental DOE Acquisition Regulation (DEAR), and the DOE Acquisition Guide.

Criterion 6: Design

Items and processes must be designed using sound engineering/scientific principles and appropriate standards. Design work, including changes, must incorporate applicable requirements and design bases. Design interfaces must be identified and controlled. The adequacy of design products must be verified or validated by individuals or groups other than those who performed the work. Verification and validation work must be completed before approval and implementation of the design.

Discussion

- Design inputs must consider all pertinent information, such as the design basis and reliability requirements.
- Changes to final designs should be justified and subjected to measures appropriate to the original design. Design changes include field changes, permanent and temporary modifications, and certain type of problem resolutions.
- Design verification should be performed by qualified individuals or groups other than those who performed the original design but may be from the same organization. Some typical design

verification methods include design review, alternate calculations, and qualifications testing.

At ORO

- At ORO, an example of the design process is the way a directive (or procedure) is developed.
  - Once a concept or practice is articulated and documented, it is checked to make sure it will do what it is supposed to do. This is also known as the verification and validation process.
  - Once cleared through this step, the directive goes through a review and approval process before it can be implemented.
  - An important feature to this design process is that the process is controlled to ensure that it will be carried out consistently and accurately.
- Facilities Management recently redesigned and relined the Federal Building parking spaces. Traffic flow, parking direction, and size of parking space were among the considerations addressed during the project design process.

Criterion 7: Procurement

Procured items and services must meet established requirements and perform as specified. Prospective suppliers must be evaluated and selected on the basis of specified criteria. Processes to ensure that approved suppliers continue to provide acceptable items and services must be established and implemented.

Discussion

- Management must ensure that purchased items and services, including those purchased as commercial grade, meet expectations.
  - Procurement actions must be based on established technical and administrative criteria, taking into consideration the intended application of the procured item or service.
  - Technical and administrative requirements include specifications, codes, standards, tests, and inspection requirements.

At ORO

- For procurement activities, ORO follows the requirements and guidance described in the Federal Acquisition Regulation (FAR), the supplemental DOE Acquisition Regulation (DEAR), and the DOE Acquisition Guide.
- This includes the use of such contractual and purchasing mechanisms as contract statements of work and purchase orders. For example, the Training and Development Group often uses a purchase order to buy a training course, and the purchase order will specify the course objectives, duration, and materials to be provided by the instructor.

Criterion 8: Inspection and Acceptance Testing

Inspection and testing of specified items, services, and processes must be conducted using established acceptance and performance criteria. Equipment used for inspections and tests must be calibrated and maintained.

Discussion

This criterion describes activities that are generally technical in nature and are specified in Federal or local regulations and procedures.

- ***Inspection –*** Management must identify the types of work that require formal inspections. Types of inspections include source, in-process, final, receipt, maintenance, and in-service.
- ***Testing –*** Appropriate tests should be conducted to demonstrate that items and processes will perform as intended. The test process should include bench tests, proof tests before installation, pre-operational tests, operational tests, post-modification tests, and post-maintenance tests.
- ***Measuring and Test Equipment (M&TE) –*** M&TE is used for in-process or final acceptance inspection of an item or to control any process parameter which influences the quality of an item characteristic. M&TE must be properly calibrated, maintained, accounted for and used.

At ORO

- Some organizations have equipment that need to be inspected and calibrated. For example, security cameras, radiation detection monitors, emergency lighting, and fire extinguishers all are regularly checked (and calibrated or refilled as necessary) to ensure that they are in good working order.
- Another example of inspection and testing is when an employee pilots a presentation. The results of the pilot would be incorporated into the final presentation.

Criterion 9: Management Assessment

Managers must assess their management processes. Problems that hinder the organization from achieving its objectives must be identified and corrected.

Discussion

- The purpose of management assessment is to identify, correct, and prevent management problems that hinder the achievement of the organization's objectives.
- The assessments focus on broad categories of management issues to determine the effectiveness of the integrated management system.
- The results of management assessments should be treated in such a way as to ensure that some level of formality is afforded the process.
- Decisions and related actions resulting from management assessment recommendations should be promptly followed up to evaluate their effectiveness.

At ORO

- ORO O 410 Chapter IV, " Management Control Program" (which correlates to DOE O 413.1), requires an annual Summary Management Review.
- The Underlying Management Principles for the Management Control System are shown below. (the corresponding Quality Assurance Criteria from DOE O 414.1A in parentheses).
  - Policies and objectives have been established and are understood and accepted (Criterion 1).
  - Roles and responsibilities have been assigned and are understood and accepted (Criterion 1).
  - Work is planned and controlled to ensure that objectives are met (Criteria 5, 6 and 7).

- Employees are capable of performing their assigned tasks and are adequately supervised (Criterion 2).
- Responsibilities for critical verifications and approvals are assigned to separate employees and/or organizations (Criterion 10).
- Decisions are based upon accurate, up-to-date information (Criteria 4 and 6).
- Work is assessed to ensure it meets expectations (Criteria 8, 9 and 10).
- General and application control activities are in place for information systems (Criterion 8).
- Problems are identified and corrected (Criteria 3 and 9).

- The output from this management review is the Manager's Assurance Memorandum. It requires a self-evaluation of our management processes, including QA, safety, health, action plans for areas needing improvement, and tracking.
- The goal is to establish reasonable assurance that management controls are working effectively.
- Management's safety walkthroughs or walkdowns are forms of management assessments.

Criterion 10: Independent Assessment

Independent assessments must be planned and conducted to measure item and service quality, to measure the adequacy of work performance, and to promote improvement. The group performing independent assessments must have sufficient authority and freedom from the line to carry out its responsibilities. Persons conducting independent assessments must be technically qualified and knowledgeable in the areas assessed.

Discussion

- The independent assessment process should be structured and conducted using a performance-based approach. The concept of performance-based independent assessments is simple: observe and then evaluate.
- A person performing a performance-based independent assessment should base their work on the following concepts.
  - Assessments are performed on activities that make a difference—not trivial with no real impact on the facility or organizational performance.
  - Assessments are performed in a manner that emphasizes safety, reliability, and performance.
  - Assessments are performed by qualified personnel who have the necessary technical capabilities to observe and evaluate an activity accurately.
- Independent assessment personnel should evaluate implementation of the quality assurance program that has been approved by DOE.

At ORO

- Independent assessments are common; for example, the DOE Environment, Safety and Health (EH) organization, often conducts an external independent assessment of how well ORO is doing.
- An example of an internal independent assessment is the operational readiness review (ORR) or the readiness assessment (RA) that ORO conducts on the safety activities of contractors and itself.
- Another example is the October 2003 reverification of ORO's ISMS that was conducted by an

independent team of subject matter experts.

What We've Learned

- Quality assurance programs and activities at Oak Ridge Office encompass all work activities, not just technical and nuclear facility work.
- The application of quality assurance principles and practices can be simple or complex, depending on such factors as direct or indirect impact on personnel and public safety. The structure (in depth and scope) of each organization's quality assurance program will depend on some of these factors.
- The goal of everyone at ORO is to produce work that is of the highest achievable quality.

Scope of the Key Regulations

- DOE O 414.1:
  - Applies to DOE elements and contractors.
  - Requires adequate protection of the workers, the public, and the environment, taking into account the work to be performed and the associated hazards.

  These quality assurance criteria are discussed elsewhere in this document.

- 10 CFR 830, Subpart A:
  - Focuses on DOE nuclear facilities.
  - Establishes QA requirements for contractors.
- ORO O 410, Chapter III:
  - Reflects the requirements of the DOE O 414.1 and 10 CFR 830.
  - Specifies that the Quality Assurance Program "is a management system which ensures that ORO's missions, policies, and objectives are integrated into standard business practices and work processes for Federal operations and contractor oversight."
- DOE O 413.1:
  - Applies to programs and administrative functions.
  - Contains nine underlying management principles.
  - Holds Department managers accountable for the performance, productivity, operations, and integrity of their programs through the use of management controls.
  - Prescribes management controls that are the organization, procedures, and methods that managers use to achieve their goals.
  - Prescribes management controls that include processes for planning, organizing, directing, and controlling operations to reasonably assure that programs achieve intended results.

To Learn More

Click on the links below for more information about DOE's and ORO's Quality Assurance process.

- DOE O 414.1, *Quality Assurance*
- DOE O 413.1, *Management Control Program*
- ORO O 410, *Management*, Chapter III, "Quality Assurance"

- ORO O 410, *Management*, Chapter IV, "Management Control Program"
- DOE G 414.1-1, *Management Assessment and Independent Assessment Guide*
- DOE G 414.1-2, *Quality Assurance Management System Guide*
- DOE P 411.1-1, *Safety Management Functions, Responsibilities, and Authorities Policy*
- DOE O 420.1, *Facility Safety*
- DOE M 411.1-1, *Safety Management Functions, Responsibilities, and Authorities Manual*
- ORO M 411.1-1, *Manual of Safety Management Functions, Responsibilities, and Authorities, Level III, for Oak Ridge Office*

DOE Environment, Safety, and Health Quality Assurance Homepage

DOE Environment, Safety, and Health Quality Assurance Training for DOE O 414.1 and Rule 10 CFR 830, Subpart A (29 Slides)

Now that you have completed this training and have read and understand the information contained, please complete the ISMS Self-Certification Form.

If you have any questions about ORO's quality assurance policies and practices, call the Key Points of Contact listed below:

QA Engineers:

Jack Weese, 865-576-9107, weeseja@oro.doe.gov

Mike Smith, 865-576-0973, smithmc@oro.doe.gov

Tyrone Harris, 865-576-0953, harrist@oro.doe.gov

Donna Riggs, 865-576-0063, riggsdrh@oro.doe.gov

David Rosine, 865-574-8640, rosinedb@ornl.gov

Karen Kadas, 865-241-2224, kadask@oro.doe.gov

Lessons Learned:

Mike Henderson, 865-576-0705, hendersonmd@oro.doe.gov

Teresa Perry, 865-576-0831, perrytc@oro.doe.gov

Les Ginn, 865-576-7317, ginnfl@ornl.gov

Steven Oldham, 865-576-7070, oldhamsk@oro.doe.gov

ORPS:

Teresa Perry, 865-576-0831, perrytc@oro.doe.gov

ORION, Version 3:

John Murmann, 865-576-1820, murmannj@oro.doe.gov

Teresa Perry, 865-576-0831, perrytc@oro.doe.gov

Corrective Action Tracking System (CATS):

Teresa Perry, 865-576-0831, perrytc@oro.doe.gov

Safety Software QA:

Donna Riggs, 865-576-0063, riggsdrh@oro.doe.gov

Teresa Perry, 865-576-0831, perrytc@oro.doe.gov

Suspect/Counterfeit Items:

Mike Smith, 865-576-0973, smithmc@oro.doe.gov

ORO Integrated Assessment Program:

Telicia Mims, 865-576-4201, mimstl@oro.doe.gov

Teresa Perry, 865-576-0831, perrytc@oro.doe.gov