

ISMS Training Document
Track 1, Activity 3 – September 2011
DOE-ORO Quality Assurance Program (QAP)

Activity

Describe the key requirements of an Integrated Safety Management System (ISMS) as listed in DOE P 450.4A, Safety Management System Policy and SCMS Procedures or other Oak Ridge Office documents.

At the completion of this activity, fill out the Self-Certification Form certifying that you have read this activity sheet.

Note: When regulations, Department of Energy (DOE) directives, or other industry standards are referenced in this ISMS activity, please use the most recent version. In addition, please note that DOE Guides provide preferred, non-mandatory, supplemental information about acceptable methods for implementing requirements, including lessons learned, suggested practices, instructions, and suggested performance measures. Guides do not impose requirements but may quote requirements if the sources are adequately cited. Alternate methods may be used if it can be demonstrated that they provide an equivalent or better level of performance.

Key Documents

- [DOE O 413.1B, *Internal Control Program* \(Oct 28, 2008\)](#)
 - [DOE O 414.1D, *Quality Assurance*](#) (Apr 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* \(Sep 27, 2007\)](#)
 - [DOE G 414.1-2B, Admin Change 1, *Quality Assurance Program Guide*](#) (Aug 16, 2011)
 - [DOE O 420.1B Chg 1, *Facility Safety*](#) (Dec 22, 2005)
 - [DOE P 450.4A, *Integrated Safety Management Policy*](#) (Apr 25, 2011)
 - [DOE Office of Health, Safety and Security *Quality Assurance Homepage*](#)
 - [SCMS “QA and Oversight” Procedures or other Oak Ridge Office documents](#)
 - [ORO Directives Management Group, *Key Management Documents*](#) (Internal Link)
 - [ORO Management System Description/Quality Assurance Program – Part A \(MSD\)](#) (Internal Link)
 - [ORO Management System Description/Quality Assurance Program – Part B \(QAP\)](#) (Internal Link)
 - [Integrated Support Center Quality Management System Description \(QMSD\)](#) (Internal Link)
 - [Environmental Management Quality Implementation Plan \(EM-QIP\)](#) (Internal Link)
-

What’s In It For Me

The completion of this activity is expected to help you become familiar with the requirements of DOE Quality Assurance (QA) and the Oak Ridge Office (ORO) QA Program; so that you are able to apply the QA concepts to your job, whether it is technical or nontechnical in nature. The DOE ORO QA Program is based upon the consensus standards ISO 9001-2008 for most work activities and NQA-1-2004 for

ISMS Training Document
Track 1, Activity 3 – September 2011
DOE-ORO Quality Assurance Program (QAP)

the ORO Environmental Management Program nuclear work activities. The ORO MSD-QAP and the Science Management System (SCMS) cover all DOE employees plus the Environmental Management employees have additional requirements in the EM-Quality Improvement Plan (QIP).

QAP Objective DOE has established [Quality Policy](#), [Principles](#) and [Value Added Requirement Attributes](#) that apply to all work and are focused on performance, customer expectations, and improvement. When properly implemented, the principles and requirements form a management system to plan, perform, assess, and improve work. The requirements are performance oriented and offer flexibility implementation. The DOE quality management system moves beyond the traditional quality assurance requirements that had become narrowly focused on safety systems, paper, compliance, and inspections. The management system is designed to link with an organization's strategic plan to support mission achievement and the delivery of products and services. The Department's commitment to environment, safety, and health also relies upon work being conducted within an effective management system. DOE line managers and contracting officers must understand these two fundamental purposes for the QA requirements and ensure the QA Order and rule are specified in each major contract (including those contracts using the Work Smart Standards process to satisfy DOE Acquisition regulation 48 CFR 970.5223-1).

Quality Policy It is the policy of the Department of Energy to establish quality requirements to ensure that risks and environmental impacts are minimized and that safety, reliability, and performance are maximized through the application of effective management systems commensurate with the risks posed by the facility or activity and its work. The Department implements this policy through the QA Order and the QA rule directives to ensure quality assurance requirements are clearly specified for the broad spectrum of work performed by DOE and its contractors. The objective of the QA requirements is to establish an effective management system (i.e., quality assurance programs) using the performance requirements coupled technical standards where appropriate that ensure:

- Senior Management provides planning, organization, direction, control, and support to achieve DOE's objectives;
 - Line organizations achieve quality;
 - Line organizations minimize environment, safety, and health risks and impacts while maximizing reliability and performance;
 - Line organizations have a basic management system in place that is consistent with the principles and functions of the Integrated Safety Management System Policy (DOE P 450.4A); and,
 - Each DOE element reviews, evaluates, and improves their overall performance and that of their contractors using a rigorous assessment process based upon an approved Quality Assurance Program (ref. 48 CFR 970.1100).
-

ISMS Training Document
Track 1, Activity 3 – September 2011
DOE-ORO Quality Assurance Program (QAP)

**Underlying
Quality
Principles**

These principles are consistent with Integrated Safety Management Policy, P 450.4A and support ISM implementation.

- **Define Policies and Objectives--Ensure they are Understood and Accepted.**
Management must set expectations for the organization before employees are tasked to do their jobs, satisfy customers' expectations, as well as statutory and regulatory requirements, and strive to improve the quality of their work. This is accomplished by developing and implementing specific policies and objectives that reflect the operating philosophy of the organization's management. Once these policies and objectives have been established, all managers must take the necessary actions to ensure that each employee shares their vision of the organization's purpose.
 - **Specify Roles and Responsibilities--Ensure they are Understood and Accepted.**
Each employee must take responsibility for the work they perform. Everyone contributes to the quality and to meeting the performance objectives established by management. It is management's obligation to ensure that the employees understand what is being asked of them. Individual and team performance is the key to achieving management's objectives.
 - **Specify and Communicate Expectations--Identify and Allocate Resources to Achieve Them.**
Management must identify resources and capable individuals for carrying out the organization's work. Management must provide employees with the material and training necessary to accomplish their tasks. Before taking responsibility for their work, employees must possess the following:
 - knowledge of management's expectations
 - knowledge of why the task is being performed
 - empowerment to carry out assigned tasks
 - **Strive to Improve.**
Management is responsible for creating an environment that encourages employees to improve the quality of the work and work processes with which they are associated. Employees must consistently seek new, more innovative ways to increase quality, efficiency, and effectiveness.
 - **Ensure People are Competent at the Work They Do.**
Management must ensure that each employee is capable of performing his/her assigned tasks. Employees should be afforded the appropriate education and training, including professional development and on-the-job training.
 - **Ensure the Right People have the Right Information at the Right Time.**
Decision-making must be based on accurate information. Information that is the basis for the decision-making process must be available to employees when they need it.
-

ISMS Training Document
Track 1, Activity 3 – September 2011
DOE-ORO Quality Assurance Program (QAP)

- **Seek and Use Relevant Experience.**
Management must make use of information, such as new technology or lessons learned, from internal and external organizations that could potentially affect its operations. By recognizing the failures and successes of the past, management will be better prepared to promote a culture committed to excellence.
 - **Plan and Control the Work.**
Work must be carefully planned and executed with established controls to ensure that management's objectives are met. This needs to be thought out, goals and objectives identified, lines of communication established, required manpower and training provided, and work controls established.
 - **Use the Right Material, Tools, and Processes--Control any Changes to Them.**
Management must ensure that the right material, tools, and processes are in place and are used so that the organization's products and services are of the highest possible quality. Establish, document, and implement effective controls and processes to ensure items and services meet specified requirements and to control any changes.
 - **Assess Work to Ensure It Meets Expectations.**
All employees must critically assess their efforts and determine if they have accomplished what they set out to do as part of meeting management's expectations. As a way of providing additional assurance that the product and service quality has been attained, a system of assessments must be established and implemented by management. In carrying out these assessments, work performance should be measured against defined standards. The assessments must be performed by competent individuals who are performance-oriented and focused on improving the product and service quality.
 - **Identify and Remedy Errors and Deficiencies.**
All problems must be identified, documented, analyzed, resolved, and followed up. Management must be committed to preventing problems where problems are viewed as opportunities for improvement.
 - **Periodically Review Management Processes to Improve Effectiveness and Efficiency.**
Management, at all levels, must continually assess its systems and processes. These management assessments should be conducted to determine the effectiveness of the management process, rather than establishing compliance with organizational and statutory requirements. They should address broad categories of management issues, such as the mission of the organization, employee understanding of the mission and of management's objectives, customer expectations, and if the expectations are being met in the most cost-efficient manner.
-

ISMS Training Document
Track 1, Activity 3 – September 2011
DOE-ORO Quality Assurance Program (QAP)

**Value Added
Attributes of
the QA
Requirements**

- **Senior Management Ownership**
Senior management must take full ownership of the quality assurance program. These managers should establish policies and objectives focused on achieving the organization's mission while improving the quality of the organization's products and services. They must create an environment that promotes quality and the improvement of quality throughout the entire organization.
 - **Line Organization Responsibility**
People who are responsible and accountable for the work being performed have the greatest affect on item and process quality. They should be empowered. They determine the extent to which management's objectives are met. Individual employees should seek ways to improve the quality of their work by suggesting product and process improvements.
 - **Effective Assessment**
The self-assessment process consists of three types of assessments: worker, management, and independent.
 - Worker assessment deals with the individual taking responsibility for their work as part of their work ethic. As work is performed, workers should critically assess their efforts and determine if they have accomplished what they set out to do, that is, meet management's objectives.
 - Management assessment identifies, corrects and prevents problems that hinder the achievement of the management's objectives. The assessments focus on broad categories of issues to determine the effectiveness of the integrated management system.
 - An independent assessment may be an audit, surveillance, “for cause” review or inspection conducted by individuals within the organization but independent from the work or process being evaluated, or by individuals from an external organization. Independent assessments evaluate the performance of work processes with regard to requirements, compliance, and expectations for safely performing the work and achieving the goals of the organization. The focus of independent assessments should be the items and services produced and their associated processes. Thus, management receives an objective view of the assessed activity. In their role of assessing item quality and process effectiveness, independent assessment personnel act on behalf of and as an advisor to, senior management. Personnel performing assessments should be technically qualified and performance-oriented.
 - **Quality Results**
A measure of the success of an organization is the quality of the services and products it provides. Product and service quality, rather than rigorous programs, procedures, and documentation, is the organization's primary measure of success.
 - **Cost and Schedule**
To achieve quality products and services, managers must take into account resource considerations, such as cost and schedule. These considerations must be
-

ISMS Training Document
Track 1, Activity 3 – September 2011
DOE-ORO Quality Assurance Program (QAP)

an integral part of management's decision-making process.

- **Training and Qualification**
Every individual must be capable of doing his/her job. The Order requires that all personnel, including managers, receive the appropriate training to ensure they are capable of performing their assignments.
- **Quality Improvement**
Problem prevention is more desirable than problem correction. The Order emphasizes that DOE and DOE contractor management is responsible for continuously pursuing enhancements to their products and services--not just complying with the minimum set of requirements. Everyone must strive to find new and innovative ways to ensure that the quality of products and services are continually improved. Process and product problems must be identified, documented, and corrected with the goal of promoting higher levels of quality.
- **Graded Approach**
Not all items, processes and services have the same effect on safety and reliability. The rigor with which the QAP should be applied must be determined using a graded approach. Specific information should be considered, such as the relative importance of safety, safeguards, and security; the management of any hazard; life cycle stage; programmatic mission; characteristics of the facility; consequences of failure; complexity or uniqueness of design or fabrication; special controls; ability to demonstrate functional compliance; quality history; degree of standardization; impact on the environment; and impact on cost or schedule or both.

To Learn More

- Become familiar with Management System Descriptions and associated procedures for your work activities in the SCMS. <http://scms.sc.doe.gov>
 - Talk to your management about the location of local procedures, manuals, standard review plans, templates, checklists, or any other tools used by your organization to ensure work products meet internal and external requirements and expectations.
-