U. S. Department of Energy
Oak Ridge Office

MSD-QAP
Part B
Quality Assurance Program

Revision 4

SUBMITTED:

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Revision Log

Revision No.	Description of Change	Effective Date
First Issue	To comply with DOE O 5700.6C, *Quality Assurance*, and DOE/OR/1084, *Management Performance and Assessment Program*, dated June 1993.	June 1993
0	Complete rewrite to comply with DOE O 414.1A, *Quality Assurance*.	February 2003
1	Substantive changes made to address compliance to the requirements of DOE O 414.1C, *Quality Assurance*. In addition, improvements made to focus on Implementation in Section C of each criterion.	May 16, 2006
2	Bi-Annual review updates and incorporation of SCMS reference. This revision includes a discussion on Environmental Management's commitment to implement ASME NQA-1 consensus standard. In addition, this revision also eliminated references to ORO orders since all ORO orders have been cancelled.	April 7, 2009
3	Use ISO 9001-2008, SCMS, and ORO Key Management Documents as program basis.	December 30, 2009
4	Incorporate Revisions Suggested in the 2010 Baseline Review. Due to extensive changes for Revision 4, revision bars are not used.	Upon DOE SC HQ Approval

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I. PURPOSE AND SCOPE

In accordance with the U.S. Department of Energy (DOE) Order 414.1C, *Quality Assurance*, the Office of Science (SC) has selected the ISO 9001-2008 as its Quality Assurance Standard. The Oak Ridge Office (ORO) Quality Assurance Program (QAP) is a quality management system description which, when implemented, demonstrates that ORO's missions, policies, and objectives are integrated into standard business practices and work processes for Federal operations and contractor oversight. The goal of the QAP is to achieve continuous improvement while satisfying customer requirements in a cost-effective manner. ORO management has ultimate responsibility for implementing the QAP. The ORO QAP broadly uses American National Standards Institute (ANSI)/International Organization of Standards (ISO)/American Society of Quality (ASQ) Q9001-2008, *Quality Management System* (ISO 9001-2008), as a consensus standard for most of its work. This document serves as the ORO Quality Assurance Program responding to DOE O 414.1C and ISO 9001-2008.

ORO is an SC landlord site; the Office of Environmental Management (EM) and Office of Nuclear Energy (NE) are major programs on the reservation and, as such, are expected to perform under the ISO 9001-2008 program and the Office of Science Management System (SCMS). EM activities under the ISO program include, but are not limited to, site-wide activities such as human resources, legal, financial, information technology (IT), etc. As a subset of this QAP and, more specifically, the ORO EM specific Management System Description (MSD), a quality program based on the American Society of Mechanical Engineers (ASME), Nuclear Quality Assurance (NQA)-1 Standard, *Quality Assurance Requirements for Nuclear Facility Applications*, is required per the EM Assistant Secretary. The EM Headquarters Program is promulgated through the EM Corporate QAP, EM-QA-001. Locally in ORO, EM has a companion NQA-1 implementation program and organizational specific procedures that define the supplemental areas and activities it must implement to meet EM Headquarters direction to use NQA-1.

II. OVERVIEW

SCIENCE MANAGEMENT SYSTEM

To ensure its mission is executed properly, consistently, and effectively, SC uses a web-based management tool called the SCience Management System (http://scms.sc.doe.gov/). This system and its supporting procedures, exhibits, etc., describe how SC offices perform their work, the authorities it operates within, and the management approach to achieve its mission. ORO uses SCMS as the fundamental and primary basis for providing customer support and executing its mission and functions. (There are instances where local/site procedures are followed.)

Attachment 1 provides a crosswalk between DOE Order 414.1C, ISO 9001-2008, and SCMS.

LOCAL REQUIREMENTS

The majority of the requirements and protocols are contained within SCMS, but select DOE Directives also require site-level documents. In these situations, ORO maintains a small number of key management documents to support full implementation of the QAP. These are documents, usually programmatically cross-cutting in scope, which are either required by DOE Directives or Headquarters/ORO Manager mandate to be promulgated and implemented at the ORO site-wide level. ORO Key Management Documents can be found at:
http://www-internal.oro.doe.gov/dmg/oro_keymanagementdoc.htm.

At the discretion of the responsible manager, an ORO organization may create organizationally specific desk references, procedures, etc. This level of document specifies requirements solely for that particular organization as a further supplement to higher level protocols; it does not establish requirements for any activity outside that particular organization. Organizational level documents relevant to quality standards, procedures, or quality-related concerns must adhere to the control protocols specified in SCMS.

INTEGRATED SUPPORT CENTER

The Office of Science has created an Integrated Support Center (ISC) that provides services as requested through the integration of the capabilities of the Oak Ridge Office and Chicago Office (CH). The capabilities of these two offices provide safety, business, technical, legal, emergency management, and administrative support to the SC complex, other DOE program offices and, as appropriate, other Federal agencies.

The ISC organization along with its functions, approach and activities, and capabilities are described in the ISC Service Plan, which is a part of the ISC Quality Management System Description (QMSD). The QMSD addresses the ISC activities; however, ORO has a site specific QAP which further addresses site specific quality management systems.

ORO MANAGEMENT SYSTEM DESCRIPTION/QUALITY ASSURANCE PROGRAM (ORO MSD/QAP)

The ORO MSD/QAP is a two-part document. Part A is the MSD which describes ORO's organization, interfaces, missions, functions, and activities. Part B is the document which serves as the ORO Quality Assurance Program responding to DOE O 414.1C and ISO 9001-2008.

Figure 1 provides a high-level graphic of ORO's QAP (or quality management system) flow of inputs/outputs.

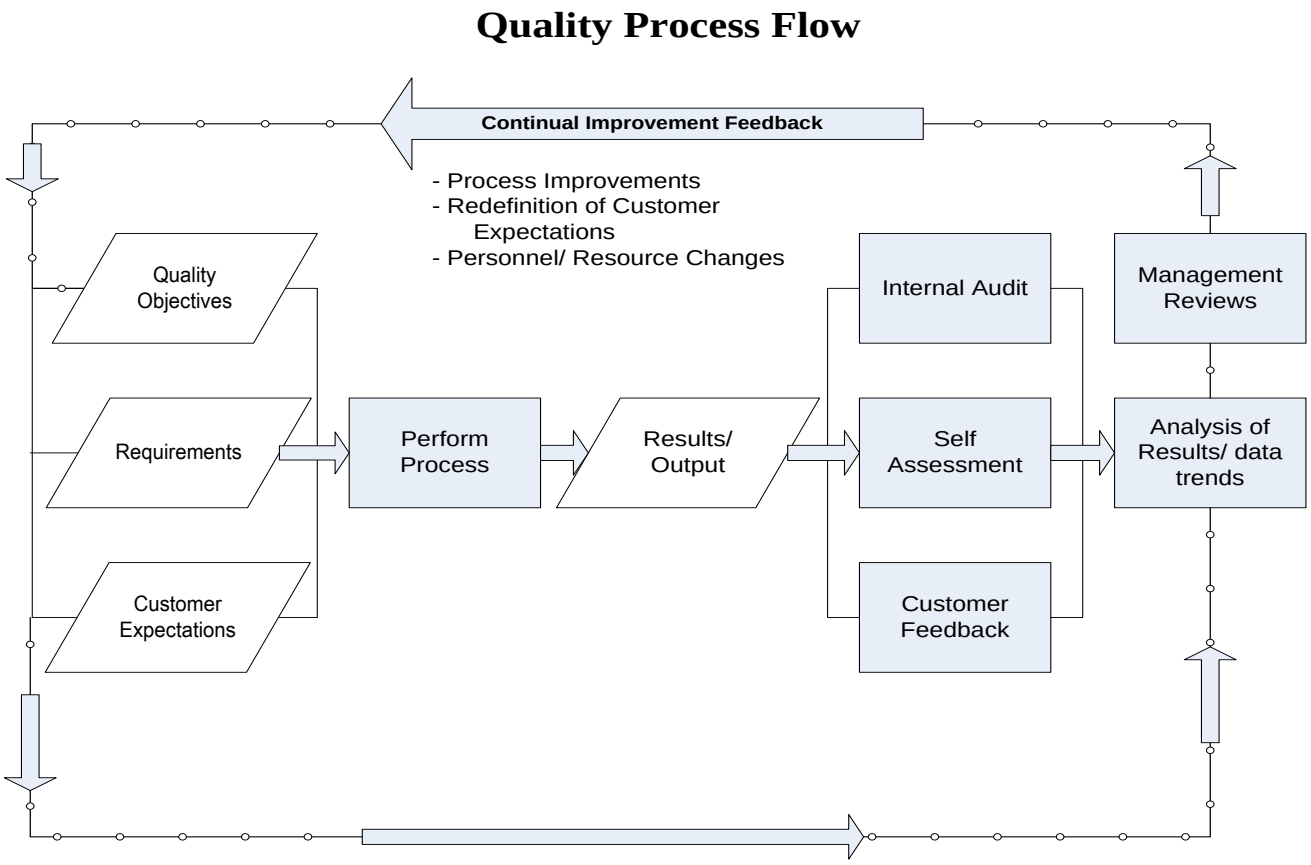

Figure 1

The following key elements or functions are embodied within the graphic to enhance the services ORO provides to its customers:

- clear understanding of customer expectations;
- strong focus upon managing processes and services;
- methods for seeking customer feedback; and
- management reviews that focus upon information and actions to promote continual improvement.

Figure 2 presents a hierarchal perspective of the quality documentation applicable to ORO. This figure displays those documented systems and processes identified by SC and ORO as needed to assure successful operation in a safe and quality manner.

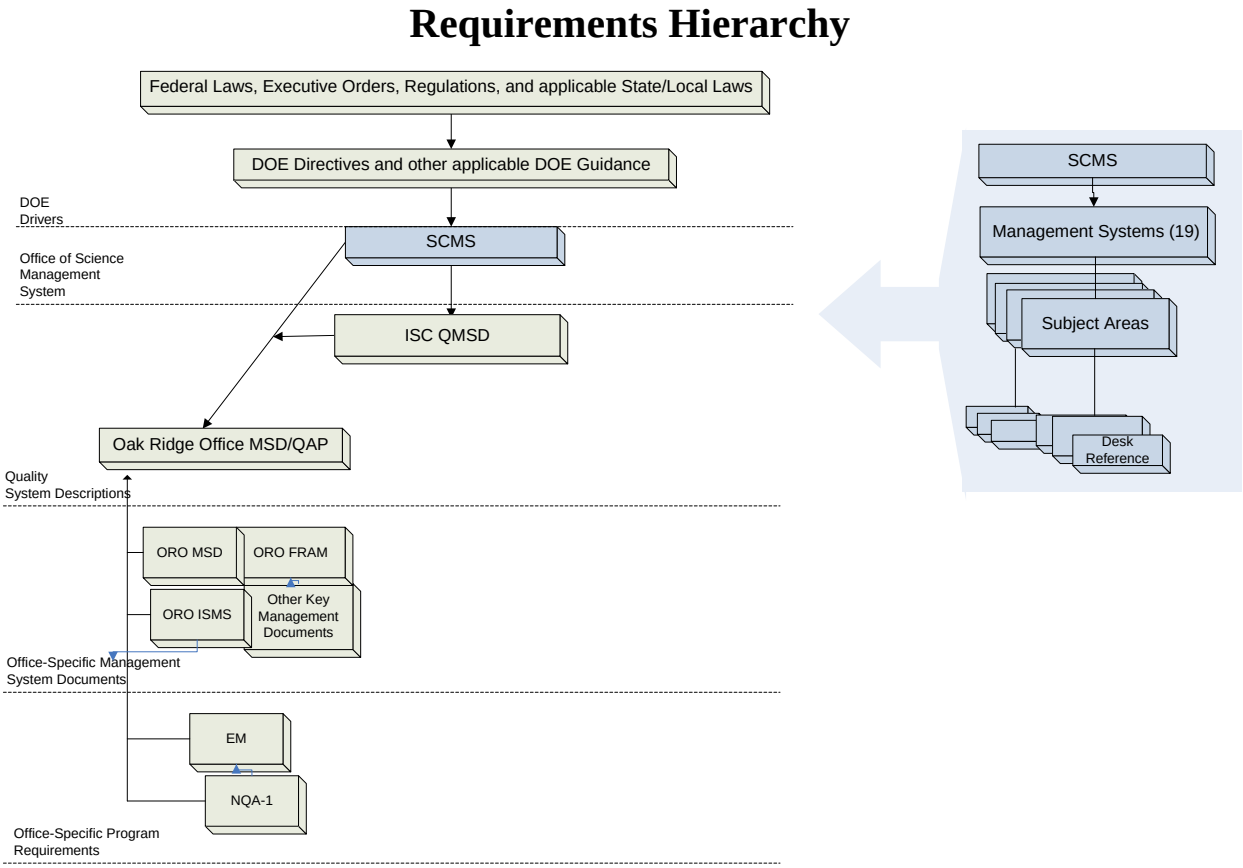

Figure 2

ORO QUALITY POLICY

Adherence to the ORO Quality Policy results in providing products and services that meet or exceed customers' requirements in a safe, secure, and cost effective manner. This policy is expected to be used in all activities. The Quality Policy includes a commitment to comply with regulations and requirements and to continually improve processes and outcomes. The ORO ensures that the quality policy is communicated to each ORO organization. The Policy is reviewed at least annually for suitability during Management Reviews.

The **Quality Policy** is:

"It is the Policy of the ORO to set the example in meeting customer expectations and providing high quality products and services. The ORO will, with the aid of customer feedback, continually improve how we deliver on commitments, meet requirements, operate safely, and respect and reward individuals for their contributions to the success of our mission. Methods are employed to assure services and documents are used to confirm customer satisfaction and implementation of DOE/SC quality requirements."

MANAGEMENT COMMITMENT

Management is committed to the implementation of the QAP and continually improving its services through the quality policy and stated objectives. Management ensures that the quality policy and quality objectives are understood and implemented. ORO Management also communicates to its staff the importance of meeting customer, as well as statutory and regulatory, requirements. This communication is provided through a variety of methods, including all-hands meetings, Manager correspondence, organizational meetings, electronic messages, subject-specific training, employee performance reviews, and periodic posters/DOECASTS, etc.

CUSTOMER FOCUS

ORO focuses on meeting customer requirements through the process of determining what customer needs are, monitoring customer satisfaction, and regular communication. The principal customers are SC Site Offices and SC-HQ, EM, and NE. ORO's primary service mission is functional support, and frequent contact helps to ensure customer interfaces are maintained and issues are properly and mutually addressed.

Examples of customer service considerations include the following commitments to:

- accurately and specifically identify our customers;
- periodically survey our customers to determine the kind and quality of service they need and their levels of satisfaction with existing services;
- develop and communicate customer service standards and measure results against them;
- benchmark our customer service efforts and results against the best comparable organizations;
- survey our employees for ideas on how we can eliminate barriers to better customer service and make improvements;
- provide our customers, wherever possible, with choices and options regarding the services we provide and how we provide them;

- work with our customers to elicit information from them in order to improve and provide superior services;
- make our services and information about them easily accessible; and
- provide mechanisms for responding effectively to customer feedback and complaints.

QUALITY OBJECTIVES

ORO has adopted the following Quality Objectives to achieve the goals set forth in the SC Quality Policy:

- use a customer-focused, process-based approach to managing its work;
- use a factual approach to decision-making;
- recognize the commonalities and synergy between Integrated Safety Management (ISM), Integrated Safeguards and Security Management (ISSM), Quality Assurance (QA) Systems, and Environmental Management Systems (EMS) by using SCMS; and
- continually strive to improve its products, processes, and services.

The ORO Managers are expected to periodically review organizational performance against these quality objectives and may supplement these objectives as deemed necessary.

EXCLUSION/NON-APPLICABILITY

ORO Federal work does not typically include the type of activities addressed in ISO 7.3 through 7.8. In the unlikely event they may become applicable, they are included in the program description; however, these ISO 9001-2008 criteria are considered excluded from the QA Program.

ISO 9000-2008 Clause Number	Clause Title	Rationale for Exclusion
7.3(7.3.1 –7.3.7) 7.4 7.5	Design and Development Purchasing Purchasing Process	ORO does not perform design and development or purchasing of equipment, components, etc., within the specific context of these requirements. Procurement of office supplies, computers, or other equipment incorporate quality provisions commensurate with their importance and intended use.
7.5.2 – 7.5.5	Production and Service Provision	The products and services of ORO are documents and ad hoc consulting, not physical components.
7.6, 7.7, 7.8	Control of Monitoring and Measuring Devices	ORO does not perform control of monitoring and measuring devices, production or validation of same.

The following ISO 9001-2008 Criteria are excluded from this MSD-QAP Part B Quality Assurance Program:
7.3 (7.3.1 – 7.3.7), Design and Development is carried out following DOE project management processes; 7.4, Purchasing; 7.5 (7.5.2 – 7.5.5), Production and Service Provision; and 7.6, Control and Monitoring of Measuring Equipment.

Rationale for Exclusions/Non-applicability

The ORO does not design, develop, or purchase equipment, components, etc. – in the traditional industrial or product sense. The ORO procures services, e.g., contract procurements, common office supplies, motor vehicles, and, on occasion, materials which may be used for building/grounds maintenance. The government products and devices provided by ORO generally entail documents, contracts, consultation, oversight reports, etc., not physical components, equipment, or products; for example, industry fabrication, production, wholesaler, retailer, etc.

Procurements at ORO are typically office supplies, General Services Administration (GSA) routine maintenance items, and service procurements. These purchases are described in processes and protocols outlined by government regulations. Likewise, contracts for services or items are controlled by myriad government regulations. Accordingly, no additional processes or controls are deemed necessary to be included in this quality program document. In some cases, individual organizations may have specific procedures/desk references to address procurements to the extent practicable for their need/application.

Similarly, the ORO does not generally conduct or assist with control of monitoring and measurement devices, production, or validation of same. ORO may perform limited inspection and acceptance testing of items, services, and processes. An example may be using checklists for acceptance of services, materials, etc. ORO may perform limited calibration or maintenance of equipment but, in general, uses contractor-calibrated measuring and test equipment on an as-needed basis. ORO does not normally receive items or services requiring formal or detailed regimented inspection and acceptance testing of these items or services. SCMS will be used commensurate with the ORO need in this area.

NOTE: The following 2008 sections are aligned to follow the DOE Order for Quality Assurance, yet still address ISO 9001-2008 elements.

III. QUALITY ASSURANCE PROGRAM CRITERIA

1.0 PROGRAM

A. Requirements

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 who are managing, performing, and assessing the work. The QAP must describe the management processes, including planning, scheduling, and resource considerations. The QAP integrates quality management system requirements and the suspect/counterfeit items prevention process, as defined in this document, with other quality or management system requirements in DOE directives and external requirements.

B. Description

(1) The ORO QAP is a broad-based management system which ensures that ORO's missions, policies, and objectives are integrated into standard work processes. The QAP applies to every ORO organization and employee.

(2) A crosswalk between DOE O 414.1C, *Quality Assurance*, and ISO 9001-2008 and SCMS is presented in Attachment 1.

(3) The implementing mechanism for ORO's QAP is SCMS, which consists of Management Systems, Subject Areas, Procedures, and exhibits. The SCMS Management Systems and can be found at http://scms.oro.doe.gov/ or http://scms.sc.doe.gov/

(4) ORO uses a small set of Key Management Documents to supplement activities dictated by DOE Directives, SCMS, or ORO Manager direction. Key Management Documents address ORO-wide cross-cutting requirements/expectations. ORO's Key Management Documents are identified in Attachment 3 and can be found at http://www-internal.oro.doe.gov/dmg/oro_keymanagementdoc.htm.

(5) Not all items, services, and processes have the same effect on products, deliverables, safety, and reliability. The rigor with which the QAP is applied is evaluated using a graded approach. The graded approach focuses on plans, schedules, processes, and cost impacts by evaluating the following:

- customer needs and requirements;
- complexity of products/outcomes/services;
- the relative importance to safety, safeguards, and security;
- the magnitude of any hazard or risk involved;
- the life-cycle stage of a facility or activity;
- impact/consequences on the programmatic mission of a facility or activity;
- the particular characteristics of a facility or activity;
- the nuclear safety classification or hazard category of the item or activity;
- adequacy of existing documentation;
- the relative importance of radiological and non-radiological hazards;
- complexity of products or services involved;
- performance history of a facility or activity; and
- any other relevant factors.

C. Implementation

(1) **Organizational Structure** – ORO's organization is described in the ORO MSD/QAP, Part A, (an ORO Key Management Document) which can be found at: http://www-internal.oro.doe.gov/dmg/oro_keymanagementdoc.htm.

(2) **Organizational Interfaces** – The interface between ORO and the Defense Nuclear Facilities Safety Board is defined in DOE M 140.1-1B, *Interface with the Defense Facilities Safety Board*. Interfaces between ORO and its main contractors are defined in the respective contracts. Interfaces with other DOE organizations are generally documented in Memoranda of Understanding (MOU). The Directives Management Group maintains copies of ORO MOUs. ORO, as a multi-program field office, has several headquarter interfaces with the Office of Science, the Lead Program Secretarial Office (LPSO), and Environmental Management and Nuclear Energy as Program Secretarial Offices (PSOs). The Oak Ridge Financial Service Center maintains liaisons with all DOE contracting organizations in order to support payments. For Office of Science, the Oak Ridge and Chicago Offices operate the SC Integrated Support Center. The ISC provides the SC organizations with technical and business management services that aid the SC Offices in achieving their missions.

(3) **Management Systems** – The ORO QAP is primarily implemented by using systems, processes, and procedures within the Office of Science Management System. In addition, the QAP essentially integrates several management systems such as the Integrated Safety Management System (ISMS) and the Environmental Management System (EMS). A crosswalk of the DOE O 414.1C criteria and the Integrated Safety Management guiding principles and core functions are found in Attachment 4, *Crosswalk of Quality and Integrated Safety Management System Elements.* In addition, a crosswalk of the DOE O 414.1C criteria and the EMS elements is found in Attachment 5, *Crosswalk of Quality and Environmental Management System Elements.*

Integrated Safety Management System – The ISMS provides requirements for ORO to implement DOE P 450.4, *Safety Management System Policy*, while supporting DOE P 450.7, *Environment, Safety and Health (ESH) Goals*, and DOE P 411.1, *Safety Management Functions, Responsibilities, and Authorities Policy*. DOE line management responsibilities for ISM are described in DOE M 411.1-1C, *Safety Management Functions, Responsibilities, and Authorities Manual*. Consistent with DOE P 411.1, *Safety Management Functions, Responsibilities, and Authorities Policy*, ORO's safety management functions, responsibilities, and authorities for ensuring adequate protection and safe operations cannot be delegated to contractors. ORO Integrated Safety Management is documented in the ORO *ISMS*, a Key Management Document located at
http://www-internal.oro.doe.gov/dmg/oro_keymanagementdoc.htm

Quality Assurance – ORO's QAP incorporates the requirements of DOE O 414.1C and ISO 9001-2008 for Federal activities. The ORO Manager has overall responsibility for development and implementation of the ORO QAP. ORO Assistant Managers and Directors review the status, adequacy, effectiveness, and compliance aspects of the QAP on a continuing basis. The Assistant Manager for Environment, Safety, and Health is responsible for maintaining the documentation of the ORO QAP. The Deputy Director for Field Operations for the Office of Science, the Lead Program Secretarial Office, is the approval authority for the ORO QAP. The ORO QAP is reviewed annually and revised/updated as needed.

Contractors' QAPs require DOE approval.

2.0 PERSONNEL TRAINING AND QUALIFICATION

A. Requirements

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.

B. Description

(1) All ORO personnel are trained and qualified to perform their assignments. The ORO Training and Qualification Program is structured to ensure the curricula address the specific needs of the employees. The program is planned and carried out using clearly defined objectives, is continuously reviewed to determine when improvements are needed or other enhancements are identified, and is upgraded as needed.

(2) Initial/continuing training and qualification requirements are established for each job position.

(3) Specific training activities are planned and documented in Individual Development Plans (IDPs) and are not limited to attainment of initial qualification, but are used to stimulate the professional development of each employee.

(4) Employee qualification requirements are specified in various approved documents/ programs (e.g., DOE Functional Area Qualification Standards). Employees are qualified based on satisfactory completion of required training courses and/or demonstrated proficiency.

C. Implementation

(1) **Training Process** – Each supervisor, with the assistance of the ORO Human Resources Division (HRD), determines the need for training. Training needs are usually identified in IDPs. IDPs are developed in accordance with DOE O 360.1B, *Federal Employee Training*, and DOE M 360.1-1B, *Federal Employee Training Manual*. Objective evidence of completion of training requirements by each ORO employee is maintained by the ORO HRD.

(2) **Personnel Qualification** – Qualification for specific job categories is based on requirements established by ORO management. These requirements are typically reflected in the individual's Position Description. Management reviews job categories to determine:

- critical and unique job functions or tasks which may require highly technical, specialized skills;
- whether competency must be demonstrated before performance; and
- if a specialized certification may be required.

Based on the review, qualification requirements ensure employee proficiency is established and documented. The responsible supervisor uses the services of the ORO

HRD to maintain the documentation (objective evidence) that attests to the qualification, re-qualification, or certification of proficiency of all assigned staff for which a formal qualification determination is made.

(3) **Training of Technical Personnel** – Supervisors with technical employees whose duties and responsibilities require them to provide assistance, guidance, direction, oversight, or evaluation of contractor activities that could impact quality objectives, products, services, or the safe operation of nuclear and non-nuclear facilities ensure that the technical employees are qualified in accordance with the Technical Qualification Program, which includes Subject Matter Experts, the Safety System Oversight (SSO) Program, the Facility Representative (FR) Program, and the Senior Technical Safety Manager (STSM) Program, defined in DOE O 426.1, *Federal Technical Capability*.

(4) **General Quality Training** – ORO employees are expected to read this QAP upon issuance and revision. In addition, all ORO employees are required annually to take *Integrated Safety Management System (ISMS)* training/refresher training which includes a module on the ORO Quality Assurance Program.

3.0 QUALITY IMPROVEMENT

A. Requirements

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.

B. Description

(1) The ORO management approach to promoting continuous improvement is to maintain a culture in which every employee believes that he or she can make a difference in the quality of products and services. These parameters and processes are described in SCMS. To ensure success, a “no fault” attitude is fostered that encourages employees to participate in solving problems and suggesting improvements.

(2) Processes that detect and prevent quality problems are contained in various programs/quality-related processes, for example:

- Corrective Action Management Program;
- Management and Independent Assessments;
- Contractor Quality Assurance System reviews;
- Operational Awareness activities;
- Effectiveness Reviews;
- Accident Investigations;
- Performance Indicators and Trending Analyses;

- Occurrence Reporting and Processing System;
- Suspect/Counterfeit Items Identification and Notification;
- Performance Charts and Management Meetings;
- Operating Experience Program;
- Safety Attainment Board Meetings;
- Management-Employee Meetings and Other Communications;
- Safety Software Quality Assurance; and
- Employee Concerns.

(3) Data resulting from the above programs/quality-related processes are reviewed and analyzed as necessary by the cognizant organization(s) to identify items and processes needing improvement. Assimilation of this data is not necessarily a formal process; data can be analyzed objectively, empirically, or subjectively.

(4) Quality improvement processes are presented in SCMS.

C. Implementation

(1) **Identification of Quality Problems** –Nonconforming issues are identified via myriad activities, including management and staff, customers, during management and independent assessments, operational awareness activities, surveillances, and inspections, as well as audits by external organizations, etc**.** Issues identified are categorized and/or recorded in accordance with SCMS. Assessments and results are documented and tracked in ORION, ORO's issues management and corrective action tracking database. In addition to the SCMS, the ORION web page provides instruction and guidance for use of the ORION tool for action tracking. When required, corresponding corrective action plans are developed and tracked in the database. For assessments performed by the Office of Health, Safety and Security (HSS), the corrective actions are tracked in the DOE HQ Corrective Action Tracking System (CATS).

(2) **Corrective Action Management** – Corrective Action Management requires quality problems to be analyzed, the causal factors identified, and effective corrective actions be developed and implemented. Corrective actions are directed towards preventing recurrence-preventive action(s).

(3) **Tracking of Corrective Actions** – Formally identified issues and associated actions are tracked to closure using ORO ORION and/or DOE CATS.

(4) **Quality Trending** – To perform meaningful trend analysis, historical data is accumulated and made available. Historical data from periods of acceptable performance or industry benchmarks may establish the reference or performance baseline for determining the acceptability of current trends. SCMS processes and procedures are used to implement tracking and trending requirements.

(5) **Occurrence Reporting and Processing System (ORPS)** – The Occurrence Reporting Program, including the Occurrence Reporting and Processing System (*ORPS*), are described in the DOE Directives System. The objective of ORPS is to

provide timely notification to the DOE complex of events that could adversely affect any or all of the following:

a. public or DOE worker health and safety;
b. the environment**;**
c. national security;
d. DOE's safeguards and security interests; and/or
e. functioning of DOE facilities.

(6) **Operating Experience Program** – The ORO Operating Experience Program objective is to share information from Federal and contractor work activities and industry experience that may be useful in preventing adverse events or in improving performance. The distribution of operational experience/lessons learned generated within the ORO workplace and outside ORO are necessary to satisfy the DOE requirements for feedback and improvement. Lessons learned are shared as widely as possible to promote positive recurrence or to avoid negative recurrence. Lessons learned can be collected from all available sources, including DOE, its contractors and subcontractors, other government agencies, and private industry.

The requirements for feedback and continuous improvement are addressed in SCMS, which also references DOE level requirements and guidelines, e.g., the DOE ISM System Guide and the DOE Operating Experience Program.

SCMS *QA and Oversight* Subject Area *Corporate Operating Experience/Lessons Learned* provides Operating Experience/Lessons Learned points of contact for SC sites (http://scms.sc.doe.gov)

(7) **Software Quality Assurance –** The Software Quality Assurance (SQA) program, as described in SCMS, includes oversight of contractors' programs and control of the limited amounts of nuclear safety software used by Federal personnel. The SQA program is included within the oversight and assessment processes along with the other functional areas. The ORO SQA Point of Contact and backup are in the Office of the Assistant Manager for Environment, Safety, and Health. Federal users of safety software are responsible for applying SQA requirements to the software they use for supporting nuclear facilities.

(8) **Suspect/Counterfeit Items (S/CI) Program** – The objective of the S/CI Program is to meet the requirements of DOE QA and SCMS requirements. This includes preventing the introduction and use of S/CIs; training and informing of managers, supervisors, and workers on S/CI processes and controls; identification and proper disposition of S/CIs on site; restriction of the use of S/CIs, as necessary; and the collection, maintenance, dissemination, and use of information on S/CIs and suppliers. The ORO S/CI Program Coordinator serves as a liaison for ORO and various ORO contractors and with the DOE Headquarters S/CI Program leads.

(9) **Customer Feedback** – Customer feedback is a tool that provides input from product recipients. Determination of feedback processes and periodicity are at the discretion of the responsible manager; however, all organizations providing products or services to a customer(s) are expected to perform and document feedback information to assist in process improvement. Information on performance is gained, the results are evaluated, and potential areas for improvement are identified. Using a combination of

methods to obtain customer feedback is preferred; a single technique to receive such information can limit an accurate portrayal of customer satisfaction. A common method for feedback is the use of survey or feedback forms. These can be used at the end of each task, each deliverable, or requested on a regular basis – quarterly, semi-annually, etc. Periodic (including ad hoc "cold calls") or regular customer interviews/discussions (face-to-face or by telephone), particularly in combination with survey form variations, can be effective to obtain performance information. Performance feedback data should be obtained from customers by an appropriate level manager, results documented, data analyzed, and trended, as appropriate.

4.0 DOCUMENTS AND RECORDS

A. Requirements

Records must be specified, prepared, reviewed, approved, and maintained in accordance with SCMS and any organizationally specific procedures/desk references. Document control requirements are also handled in SCMS and possibly by individual organizations.

B. Documents Description

ORO follows the SCMS procedures for document control. ORO Key Management Documents are managed by the ORO "Change Control Process for Key Management Documents."

C. Records Description

The SCMS records system requires that records (including QA records) be specified, prepared, reviewed, approved, and maintained to accurately reflect completed work and include the following features:

- provisions for the retention and disposition of records to satisfy the requirements of DOE O 200.1A, *Information Technology Management*, and the National Archives and Records Administration's methods to preclude unauthorized access to ORO records;
- provisions for record storage areas that minimize the risk of damage from natural disasters and environmental conditions;
- methods for maintaining record accountability;
- provisions for the retrieval of records; and
- provisions that ensure records are legible, accurate, complete, and traceable to the activities to which they apply.

D. Implementation

(1) Document Control – In addition to SCMS, ORO has in place a process to control key management documents as discussed above.

(2) Records Management – The Document Online Coordination System (DOCs) is used by ORO to retain records such as correspondences and other media received or generated. Individual Managers ensure that appropriate records are maintained in

accordance with approved implementing procedures as deemed appropriate to maintain quality/evidentiary value.

5.0 WORK PROCESSES

A. Requirements

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

B. Description

(1) ORO's work is planned, authorized, and performed by technically competent individuals who provide leadership, direction, and oversight. Work processes are performed using SCMS, technical standards developed or adopted from commercial practice, policies, procedures, and other appropriate means and contain a level of detail commensurate with the complexity and importance of the work being performed (i.e., graded approach). Environment, safety, and health requirements are integrated into ORO's work processes.

Work is reviewed to ensure the expected level of quality/customer satisfaction is achieved and to identify areas needing improvement.

(2) Where appropriate, items are identified and controlled using the graded approach to ensure proper use. Maintenance of selected items is used to prevent damage, loss, or deterioration of items. Process monitoring and data collection equipment are calibrated and maintained, where appropriate.

C. Implementation

(1) If the underlying DOE Order or SCMS does not provide sufficient direction, ORO Assistant Managers may develop and implement organization-specific procedures, manuals, or desk instructions. The organization-specific procedures, manuals, or desk instructions should include sufficient detail to implement the Order or ORO Directive requirements. These documents are applicable solely to the promulgating organization and cannot specify requirements for entities outside the issuing organization. The content and format of organization-specific procedures or desk instructions are implemented according to requirements. In addition, procedures, manuals, or desk instructions are reviewed and revised, as required.

(2) Assistant Managers and Directors are responsible for implementing this aspect of the QA program in their areas of responsibility as defined in the ORO Functions, Responsibilities, and Authorities (FRA).

(3) Oversight of contractor work processes is performed through participation in formal design reviews, readiness reviews, assessments, and deliverable reviews and complies with SCMS and DOE O 226.1A, *Implementation* of *Department of Energy Oversight*

Policy. ORO comments and findings are provided to the contractor through official correspondence and/or communication.

(4) A graded approach is used to determine which items used by Federal personnel are identified and controlled using bar codes or other markings. Copiers, printers, and building equipment are maintained to ensure availability when needed. Process monitoring equipment and data collection equipment, where used by Federal personnel, are calibrated and maintained as appropriate.

EXCLUSION/NON-APPLICABILITY FOR SECTIONS 6.0, 7.0 and 8.0

Refer to Section II for a discussion of applicability.

6.0 DESIGN

A. Requirements

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.

B. Description

ORO does not design items; however, ORO performs oversight on its contractors who design items.

C. Implementation

ORO organizations use the graded approach on design processes in order to meet various requirements. For example, the ORION tracking system was designed using input from users and stakeholders while following various DOE and industry guidance (e.g., DOE Directives, Institute of Electrical and Electronics Engineers, (IEEE)), software standards and information system best practices. Changes have been incorporated based upon management and user requirements. Design interfaces were controlled, and the adequacy of design was verified and validated prior to implementation using documented change control practices. User documentation for ORION is available online via web access, and training is available upon request.

7.0 PROCUREMENT

A. Requirements

Procured items and services must meet established requirements and performance at acceptable quality levels. Prospective suppliers/contractors must be evaluated and selected on the basis of specified criteria. Processes to ensure that suppliers/contractors will continue to provide acceptable items and services must be established and implemented.

B. Description

(1) ORO procures services in accordance with the DOE Acquisition Regulations (DEARs) Federal Acquisition Regulation (FARs), the DOE Acquisition Guide, and SCMS.

(2) ORO's procurement processes are based on established technical and administrative criteria and include the evaluation of quotations, bids, and proposals submitted. In addition, these processes provide methods for accepting procured services (e.g., review of technical data provided, review of objective evidence for conformance to procurement documents, and evaluation of the service provided).

(3) ORO's procurement documents identify the performance requirements that must be fulfilled by the supplier/contractor. These requirements are specified in a results-driven manner. ORO's procurement documents are reviewed to ensure the following provisions are included, as applicable to the service or product being procured:

- Technical Requirements – Applicable technical requirements (e.g., specifications, codes, and standards) are specified in or referenced by specific DOE Directives, regulations, or procedures.
- QAP Requirements – Applicable QAP requirements are developed on the basis of acceptable quality levels while considering contract type.
- Right of Access – The procurement documents specify allowances for access to the supplier/contractor facilities and records for the purpose of evaluation.
- Documentation Requirements – Applicable document requirements are identified.

(4) Suppliers are monitored to ensure their performance meets procurement requirements and/or expectations and that they continue to provide acceptable services and products.

C. Implementation

(1) **Procure Items and Services that Meet Established Requirements and Perform as Specified** – The Procurement function is governed by the FAR, the DEAR, the *DOE Acquisition Guide*, the *ORO Acquisition Guide*, and DOE Directives and SCMS in acquiring products and services that meet the government's needs. The procurement process is implemented by procurement professionals who must meet certification requirements based on their position classification level. Specific training requirements must be achieved in order to obtain the required certification level.

Both formal and informal training are critical components of the procurement professional's training, which serves as an aid for ensuring procured products and services meet established performance requirements.

(2) **Evaluate and Select Prospective Suppliers/Contractors on the Basis of Specified Criteria** – Evaluations of prospective suppliers/contractors and the ultimate selection of the successful supplier/contractor are based on specified evaluation criteria. The evaluation criteria are developed by the customer in conjunction with the procurement professional and are tailored specifically to assist the government in selecting a

supplier/contractor that will provide a quality product and/or service. In addition, the prospective supplier/contractor's eligibility to receive a government contract award is documented by a determination that the company is not included on the Excluded Parties List System (EPLS).

(3) **Establish and Implement Processes to Ensure that Approved Suppliers/Contractors Continue to Provide Acceptable Items and Services** – Performance Work Statements are used to describe service requirements in clear, specific, objective, and measurable outcomes or results. In addition, ORO supplier/contractors' performance is assessed on an annual basis through the Department's automated contractor performance system. Areas assessed using the automated system include the quality of the product or service, the timeliness of performance, cost control, and business relations. Results of these assessment methods are utilized in determining new performance standards, fee payments, exercise of options, and new awards.

8.0 INSPECTION AND ACCEPTANCE TESTING

A. Requirements

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.

B. Description

(1) **Inspection and Acceptance Testing** – ORO may perform limited inspection and acceptance testing of items, services, and processes. An example may be using checklists for acceptance of services, materials, etc.

(2) **Measuring and Test Equipment** – ORO may perform limited calibration or maintenance of equipment but, in general, uses contractor-calibrated measuring and test equipment on an as-needed basis.

C. Implementation

ORO does not normally receive items or services requiring formal or detailed regimented inspection and acceptance testing of these items or services. SCMS will be used commensurate with the ORO need in this area.

9.0 MANAGEMENT ASSESSMENT

A. Requirements

Management must assess its management processes. Issues that hinder the organization in achieving its objectives must be identified and appropriately addressed.

B. Description

(1) The ORO Manager establishes a Management Representative (MR) to ensure the quality management system is established, implemented, and maintained in accordance with ISO 9001-2008 requirements. The MR oversees the ORO continuous improvement processes, which include, in part, analyzing, evaluating, and making recommendations about the efficiency and effectiveness of programs, processes, and performance. The MR for the ORO is appointed by the Assistant Manager for Environment, Safety, and Health.

In the MR role, the MR reports directly to the ORO Assistant Manager for Environment, Safety, and Health in all matters relating to the quality management system. Specific responsibilities of the MR include:

- presenting the management review(s) (usually annually) results and reporting to senior managers on the performance and potential areas of improvement;
- recommending process that may be needed to ORO and/or SCMS leadership; and, upon approval, ensuring they are implemented; and
- ensuring the promotion of awareness of customer requirements throughout the organization.

The MR can delegate any duties relating to these responsibilities.

(2) ORO's management assessment process for Federal activities focuses on how well organizations are implementing the QAP. This process not only assists ORO in achieving its objectives, but also allows ORO to evaluate customer and employee perceptions relative to the following key issues:

- the organization's mission and strategic objectives;
- the employees' role in the organization;
- the customers' expectations and the degree to which those expectations are being met;
- opportunities for improving quality and cost-effectiveness; and
- recognizing and enhancing human resource capabilities.

(3) Problems or issues that hinder ORO's quality processes, and customer goals and objectives are identified and appropriately addressed. Corrective/preventive action decisions and recommendations are documented, acted upon, followed up, and evaluated for effectiveness by the identifying organization.

(4) Results of QAP Management Assessments are periodically reported to DOE HQ, as may be required. Annual ISM oversight activities and declarations of implementation status to HQ may or may not be a part of the QAP Management Assessment.

(5) The objective of the Integrated Assessment Schedule (IAS) is to identify those assessments that are low-volume, high-threshold, and included on the SC IAS quarterly report provided to the SC Deputy Director for Field Operations (SC-3). The SC IAS includes, but is not limited to, assessments that are:

- sensitive to mission, organizational, or legal vulnerabilities;
- mandated by an internal or external entity;
- independent assessments (HSS, General Accounting Office [GAO], etc.);
- startup/restart of a high-visibility or high-risk project/facility; and
- broad-scope assessments that provide information regarding overall program performance.

C. Implementation

ORO uses the processes and procedures in SCMS to conduct management assessments.

10.0 ASSESSMENTS

A. Requirements

Assessments are planned and conducted to evaluate the adequacy of work performance and to promote improvement. Individuals performing independent assessments should not have performed, supervised, or been directly responsible for performing activities in the areas being assessed. Persons conducting independent assessments must be technically qualified and knowledgeable in the areas to be assessed.

B. Description

(1) ORO's functions and activities (including those of the contractors) are subject to periodic independent assessments or reviews; e.g., DOE HQ organizations, Defense Nuclear Facilities Safety Board (DNFSB), Inspector General (IG), GAO, etc. These assessments are intended to improve the quality and effectiveness of all of ORO's functions and activities.

(2) Independent assessments help assure consistent application of the QAP and supporting documents and procedures. Through defined assessment methodologies and techniques, which include the review and evaluation of organization specific management assessments, independent assessments assist to assure that the following goals are achieved:

- problems preventing ORO from meeting its established goals, including potential or fundamental causes, are identified;
- actions are taken to correct/prevent identified issues; and
- lessons learned are applied, where applicable.

(3) Independent assessment personnel meet the following criteria:

- are technically knowledgeable in the areas being assessed;

- do not have direct responsibilities in the areas being assessed;
- act in a management advisory function;
- have sufficient freedom and authority to identify problems;
- experience in monitoring work performance;
- able to identify abnormal performance and precursors of potential problems;
- able to focus on improving the quality of the processes that lead to the end product;
- able to document assessment results;
- experience in verifying satisfactory resolution of problems; and
- able to perform follow-up reviews of deficient areas, as necessary.

C. Implementation

SCMS is used to implement the requirements for conducting independent assessments.

IV. REFERENCES

1. SCMS including the following subject areas and their subsequent procedures:
   a) SCMS Environment, Safety, and Health
   b) SCMS Quality Assurance and Oversight
   c) SCMS Management and Operating (M&O) Contracting
   d) SCMS Non-Management and Operating (Non – M&O)
   e) SCMS Project Management

2. 10 CFR 830, Subpart A, *Quality Assurance Requirement*

3. DOE-HDBK-1188-2006, *Glossary of Environment, Safety and Health Terms*

4. DOE M 140.1-1B, *Interface with the Defense Nuclear Facilities Safety Board*

5. DOE O 200.1A, *Information Technology Management*

6. DOE G 200.1-1, *Software Engineering Methodology*

7. DOE O 210.2, *DOE Corporate Operating Experience Program*

8. DOE G 225.1A-1, *Implementation Guide for Use with DOE O 225.1A, Accident Investigations, Attachment 1*

9. DOE P 226.1A, *Department of Energy Oversight Policy*

10. DOE G 231.1-2, *Occurrence Reporting Causal Analysis Guide*

11. DOE M 231.1-2, *Occurrence Reporting and Processing of Operations Information*

12. DOE O 243.1, *Records Management Program*

13. DOE O 251.1C, *Departmental Directives Program*

14. DOE P 411.1, *Safety Management Functions, Responsibilities, and Authorities Policy*, dated January 28, 1997

15. DOE M 411.1-1C, *Safety Management Functions, Responsibilities, and Authorities Manual*

16. DOE O 414.1C, *Quality Assurance*

17. 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*

18. 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*

19. 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*

20. 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*

21. DOE G 414.1-5, *Corrective Action Program Guide*

22. DOE O 426.1, *Federal Technical Capability*

23. DOE O 426.2, *Personnel Selection, Training, Qualification, and Certification Requirements for DOE Nuclear Facilities*

24. DOE G 430.1-1, *Cost Estimating Guide*

25. DOE G 433.1-1, *Nuclear Facility Maintenance Management Program Guide for Use with DOE O 433.1*

26. DOE P 450.4, *Safety Management System Policy*

27. DOE O 226.1A, *Implementation of Department of Energy Oversight Policy*

28. DOE P 450.7, *Environment, Safety and Health (ESH) Goals*

29. DOE-STD-7501-99, *The DOE Corporate Lessons Learned Program*

30. EM-QA-001, *Office of Environmental Management (EM) Quality Assurance Program (QAP),* Revision 0

31. ANSI/ISO/ASQ Q9001-2008, *American National Standard, Quality Management Systems – Requirements*

V. ACRONYMS AND DEFINITIONS

1.0 ACRONYMS

AM	Assistant Manager
ANSI	American National Standards Institute
ASME	American Society of Mechanical Engineers
ASQ	American Society for Quality
CAMP	Corrective Action Management Program
CATS	Corrective Action Tracking System
CFR	Code of Federal Regulations
CH	Chicago
DEAR	Department of Energy Acquisition Regulation
DNFSB	Defense Nuclear Facilities Safety Board
DOCS	Document Online Coordination System
DOE	Department of Energy
DOE M	Department of Energy Manual
DOE O	Department of Energy Order
EM	Office of Environmental Management
EM-QIP	Environmental Management Quality Implementation Plan
EMS	Environmental Management System
EPLS	Excluded Parties List System
ESH	Environment, Safety, and Health
FAR	Federal Acquisition Regulation
FR	Facility Representative
FRA	Functions, Responsibilities and Authorities (document)
GAO	Government Accounting Office
GSA	General Services Administration
HQ	Headquarters
HRD	Human Resources Division
HSS	Office of Health, Safety and Security
IAS	Integrated Assessment Schedule
IDP	Individual Development Plans
IEEE	Institute of Electrical and Electronics Engineers
IG	Inspector General
ISC	Integrated Support Center
ISM	Integrated Safety Management
ISMS	Integrated Safety Management System
ISO	International Organization of Standards
ISSM	Integrated Safeguards and Security Management

IT	Information Technology
LPSO	Lead Program Secretarial Office
M&O	Management and Operating
MOU	Memorandum of Understanding
MR	Management Representative
MSD	Management System Description
NE	Office of Nuclear Energy
NEPA	National Environmental Policy Act
Non-M&O	Non-Management and Operating
NQA	Nuclear Quality Assurance
OR	Oak Ridge
ORO	Oak Ridge Office
ORPS	Occurrence Reporting and Processing System
PD	Program Description
PSO	Program Secretarial Office
QA	Quality Assurance
QAP	Quality Assurance Program
QMSD	Quality Management System Description
SA	Subject Area
S/CI	Suspect/Counterfeit Items
SC	Office of Science
SCMS	DOE Office of Science Management System
SQA	Software Quality Assurance
SSC	Structures, Systems, and Components
SSO	Safety System Oversight
STD	Standard
STSM	Senior Technical Safety Manager

2.0 DEFINITIONS

A. **Apparent Cause(s)** – The most probable cause(s) that explain why the event happened, that can reasonably be identified, that local or facility management has the control to fix, and for which effective recommendations for corrective action(s) to remedy the problem can be generated, if necessary. [DOE G 231.1-2]

B. **Assessment** – A review, evaluation, inspection, test, check, surveillance, or audit to determine and document whether items, processes, systems, or services meet specified requirements and perform effectively. [DOE O 414.1C]

C. **Desk Reference/Desk Guide** – A document that specifies or prescribes how an activity is to be performed within an Assistant Manager's (AM) organization. These are promulgated at the individual ORO AM organizational level or within his/her subordinate organizational units and do not specify or place requirements for any activity outside that respective AM's organization.

D. **Directive** – The primary means to establish, communicate, and institutionalize policies, requirements, responsibilities, and procedures for multiple Departmental elements. They include policies, orders, notices, manuals, and guides. [DOE O 251.1C]

E. **Document** – Recorded information that describes, specifies, reports, certifies, requires, or provides data or results. [10 CFR 830.3] [DOE-HDBK-1188-2006]

F. **Graded Approach** – The process of assuring that the level of analysis, documentation, and actions used to comply with a requirement in 10 CFR 830 are commensurate with:
- the relative importance to safety, safeguards, and security;
- the magnitude of any hazard or risk involved;
- the life cycle of a facility or activity;
- the programmatic mission of a facility;
- the particular characteristics of a facility or activity;
- the relative importance of radiological and nonradiological hazards;
- the nuclear safety classification or hazard category of the item or activity;
- adequacy of existing safety documentation;
- complexity of products or services involved;
- performance history of a facility or activity; and
- any other relevant factors. [10 CFR 830.3] [DOE G 433.1-1]

G. **Hazard** – A source of danger (i.e., material, energy source, or operation) with the potential to cause illness, injury, or death to a person or damage to a facility or to the environment (without regard to the likelihood or credibility of accident scenarios or consequence mitigation). [10 CFR 830.3]

H. **Item** – An all-inclusive term used in the place of any of the following: appurtenance, assembly, component, equipment, material, module, part, product, sample, software, structure, subassembly, subsystem, system, unit, or support systems, documented concepts, or data. [10 CFR 830.3] [DOE M 231.1-2]

I. **ORION** – ORO's database to track oversight activities (i.e., assessments, walkthroughs), findings, corrective actions, and closure evidence.

J. **ORO Key Management Document** – A document, usually programmatically cross-cutting in scope, which is either required by DOE Directives, Headquarters mandate, or the ORO Site Manager to be promulgated and implemented at the ORO site-wide level.

K. **Procedure**– A document that prescribes a process (a sequence of actions) to be performed to achieve a desired outcome. [DOE G 450.4-1B]

L. **Process** – A series of actions that achieves an end product, result, or service. [10 CFR 830.3] [DOE-HDBK-1188-2006]

M. **Procurement Document** – Purchase requisitions, purchase orders, drawings, contracts, contract task orders, specifications, or instructions used to determine requirements for purchase. [DOE G 430.1-1]

N. **Qualification** – Means education, experience, training, examination, and any special requirements necessary to perform assigned responsibilities for a given position. [DOE O 426.2]

O. **Quality** – The condition achieved when an item, service, or process meets or exceeds the user's requirements and expectations. [10 CFR 830.3] [DOE O 414.1C] [DOE-HDBK-1188-2006]

P. **Quality Assurance** – All those actions that provide confidence that quality is achieved. [10 CFR 830.3] [DOE O 414.1C] [DOE-HDBK-1188-2006]

Q. **Quality Assurance Program** – The overall program (management system) established to assign responsibilities and authorities, define policies and requirements, and provide for the performance and assessment of work.

R. **Quality Assurance Record** – Those that are created and retained as prescribed under a quality assurance program. These records are controlled under the provisions of an approved procedure and retained as prescribed by the DOE records disposition schedules. The records furnish evidence of the quality of items, activities, and processes that affect quality. They are established based on regulatory and environmental requirements and the level of risk established for the item, activity, or process to which the records apply. [DOE O 243.1]

S. **Record** – A completed document or other media that provides objective evidence of an item, service, or process. [10 CFR 830.3] [DOE-HDBK-1188-2006]

T. **Root Cause** – The determination of the causal factors preceding structures, systems, and components (SSC) failure or malfunction – that is, discovery of the principal reason why the failure or malfunction happened leads to the identification of the root cause. The preceding failure or malfunction causal factors are always events or conditions that are necessary and sufficient to produce or contribute to the unwanted results (failure or malfunction). The types of causal factors are: (1) direct causes, (2) contributing causes, and (3) root causes. The direct cause is the immediate event or condition that caused the failure or malfunction. Contributing causes are conditions or events that collectively increase the likelihood of the failure or malfunction, but that individually do not cause them. Thus, root causes are events or conditions that, if corrected or eliminated, would prevent the recurrence of the failure or malfunction by identifying and correcting faults (often hidden) before and SSC fails or malfunctions. [DOE G 433.1-1] [DOE-HDBK-1188-2006]

U. **Root Cause Analysis** – Any methodology that identifies the causal factors that, if corrected would prevent recurrence of the accident. The analysis results in an accurate description of how and why the condition or event occurred. [DOE G 225.1A-1] [DOE-HDBK-1188-2006]

V. **Safety Software** – Includes safety system software, safety and hazard analysis software and design software and safety management and administrative controls software. [DOE O 414.1C]

W. **Service** – The performance of work such as assembly, construction, consultation, contractor oversight, design documentation, environmental qualification, equipment qualification, fabrication, inspection, laboratory sample analysis, manufacturing, nondestructive examination/testing, repair, restoration, producing a product or deliverable, or the like. [10 CFR 830.3] [DOE-HDBK-1188-2006]

X. **Software** – Computer programs, procedures, and associated documentation and data pertaining to the operation of a computer system. [DOE O 414.1C]

Y. **Supplier** – Any individual or organization that furnishes items or services in accordance with a procurement document. This is an all-inclusive term used in place of any of the following: vendor, seller, contractor, subcontractor, fabricator, distributor, consultant, or subtier suppliers. [DOE-HDBK-1188-2006]

Z. **Training** – Is instruction designed for acquisition of knowledge, skills, and abilities to develop or improve job performance. [DOE O 426.2]

AA. **Work** – The process of performing a defined task or activity; for example, research and development, operations, maintenance and repair, administration, software development and use, inspection, safeguards and security, data collection and analysis. ORO work is primarily administration which includes contracting, auditing, assessing, oversight, payment of invoices, budget execution, etc. [DOE G 450.4-1B] [DOE-HDBK-1188-2006]

ATTACHMENT 1 - DOE ORO QAP Implementation Matrix (DOE Order 414.1C/ISO 9001-2008/SCMS)

DOE Order 414.1C Requirements	ISO 9001-2008 Criteria	Office of SCience Management System (SCMS), Management System Description (MSD)/ Program Description (PD)/Subject Area (SA) and Office of Science (SC) Oak Ridge (OR) Implementing Mechanisms
4a. Requirements Each DOE organization must develop and implement a QAP that does the following.	**4.1 General requirements:** The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard. **5.4.2 Quality management system planning:** Top management shall ensure that… b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.	• **MSD:** Office of SCience Management System • **MSD:** Quality Assurance and Oversight – **PD**: SC-Wide Quality Assurance Program Description
1) Implements QA criteria as defined in paragraph 4b using a graded approach and describing how the criteria and graded approach are applied.	**4.1 General requirements:** The organization shall establish, document, implement, and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard. The organization shall a) determine the processes needed for the quality management system and their application throughout the organization (see ISO Standard Section 1.2), b) determine the sequence and interaction of these processes, c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective, d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes, e) monitor, measure where applicable, and analyse these processes, and f) implement actions necessary to achieve planned results and continual improvement of these processes. These processes shall be managed by the organization in accordance with the requirements of this International Standard.	• **MSD:** Office of SCience Management System • **MSD:** Quality Assurance and Oversight – **PD**: SC-Wide Quality Assurance Program Description – **SA:** Assessments o Procedure 1. *Analyzing and Scheduling Assessment Needs* – **SA:** Office of Science (SC) Performing Planning and Evaluation o Procedure 1. *Preparing and Reviewing the SC Annual Performance Plan (APP)* o Procedure 2. *Preparing and Reviewing the SC Annual Assessment Report (AAR)* • **MSD:** Human Resources Services • **MSD:** Financial Assistance • **MSD:** Management and Operating (M&O) Contracting • **MSD:** Non-Management and Operating (Non-M&O) Contracting • SC Guidance: Annual Performance Plans and Assessment Reports

DOE Order 414.1C Requirements	ISO 9001-2008 Criteria	Office of SCience Management System (SCMS), Management System Description (MSD)/ Program Description (PD)/Subject Area (SA) and Office of Science (SC) Oak Ridge (OR) Implementing Mechanisms
	Where an organization chooses to outsource any process that affects product conformity to requirements, the organization shall ensure control over such processes. The type and extent of control to be applied to these outsourced processes shall be defined within the quality management system. **5.3 Quality policy:** Top management shall ensure that the quality policy a) is appropriate to the purpose of the organization, b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system, c) provides a framework for establishing and reviewing quality objectives, d) is communicated and understood within the organization, and e) is reviewed for continuing suitability.	
(2) Uses national or international consensus standards where practicable and consistent with contractual or regulatory requirements (e.g., 10 CFR 830) and identifies the standards used. Appropriate standards include the following. (a) ASME NQA-1-2000, *Quality Assurance Requirements for Nuclear Facility Applications* (for nuclear-related activities); (b) ANSI/ISO/ASQ Q 9001-2000, *Quality Management System: Requirements* (for nonnuclear activities); and	**0.4 Compatibility with other management systems**: During the development of this International Standard, due consideration was given to the provisions of ISO 14000:2004 to enhance the compatibility of the two standards for the benefit of the user community. Annex A shows the correspondence between ISO 9001:2008 and ISO 14001:2004. This International Standard does not include requirements specific to other management systems, such as those particular to environmental management, occupational health and safety management, financial management or risk management. However, this International Standard enables an organization to align or integrate its own quality management system with related management system requirements. It is possible for an organization to adapt its existing management system(s) in order to establish a quality management system that complies with the requirements of this International Standard.	• ORO *MSD-QAP Part B Quality Assurance Program*

DOE Order 414.1C Requirements	ISO 9001-2008 Criteria	Office of SCience Management System (SCMS), Management System Description (MSD)/ Program Description (PD)/Subject Area (SA) and Office of Science (SC) Oak Ridge (OR) Implementing Mechanisms
(c) ANSI/ASQ Z 1.13, *Quality Guidelines for Research*, 1999 (for nonnuclear research activities).		
(3) Applies additional standards, where practicable and consistent with contractual or regulatory requirements and as necessary to address unique/specific work activities (e.g., development and use of safety software or establishing the competence of a testing and calibration laboratory). [Note: These standards are sometimes referred to as "voluntary standards." However, once a practicable standard(s) is adopted through regulation, code, contract, QAP, or procedure, compliance with the standard is required and is not voluntary.]	**7.2.1 Determination of requirements related to the product**: The organization shall determine a) requirements specified by the customer, including the requirements for delivery and post-delivery activities, b) requirements not stated by the customer but necessary for specified or intended use, where known, c) statutory and regulatory requirements applicable to the product, and d) any additional requirements considered necessary by the organization.	• **MSD:** Office of SCience Management System (All Applicable SAs and Procedures) • **MSD:** Quality Assurance and Oversight – **PD**: SC-Wide Quality Assurance Program Description • **MSD:** Requirements Management – **SA:** Requirements Management o Procedure 1. *Identifying and Proposing New or Revised Requirements* o Procedure 2. *Reviewing and Commenting on DOE Justification Memoranda, DOE Policies, and DOE Notices* o Procedure 3. *Reviewing and Commenting on Draft DOE Directives* o Procedure 4. *Processing Approved Requirements*
(4) Integrates, where practicable and consistent with contract or regulatory requirements, quality management system requirements as defined in this Order, the S/CI prevention process (Attachment 3), the Corrective Action Management Program (CAMP, Attachment 4), and Safety Software Quality Requirements (Attachment 5) with other quality or management system requirements in DOE directives and external requirements,	**7.4.3 Verification of purchased product**: The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements. Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information. **8.5.1 Continual improvement:** The organization shall continually improve the effectiveness of the quality management system through	• **MSD:** Quality Assurance and Oversight – **PD**: SC-Wide Quality Assurance Program Description – **SA:** Issues Management o Procedure 1. *Managing Issues Identified in Oversight Activities* o Procedure 2. *Performing Causal Analysis* o Procedure 3. *Developing, Approving, Implementing, and Verifying Preventive and Corrective Actions* o Procedure 4. *Tracking Issues, and*

DOE Order 414.1C Requirements	ISO 9001-2008 Criteria	Office of SCience Management System (SCMS), Management System Description (MSD)/ Program Description (PD)/Subject Area (SA) and Office of Science (SC) Oak Ridge (OR) Implementing Mechanisms
including as applicable— (a) DOE P 450.4, *Safety Management System Policy*, dated 10-15-96; (b) DOE P 450.5, *Line Environment, Safety and Health Oversight*, dated 06-26-97; (c) National Nuclear Security Administration (NNSA) *Quality Management Policy*, QC-1, (quality management system for the nuclear weapons complex and weapons-related activities); (d) DOE/RW-0333P DOE Office of Civilian Radioactive Waste Management, *Quality Assurance Requirements and Description*; and (e) DOE/CBFO-94-1012, DOE Carlsbad Field Office, *Quality Assurance Program Description*, (for the Waste Isolation Pilot Plant and related activities).	the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review. **8.5.2 Corrective action:** The organization shall take action to eliminate the causes of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered. A documented procedure shall be established to define requirements for… **8.5.3 Preventive action:** The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems. A documented procedure shall be established to define requirements for… **Note:** ISO 9001-2008 has no requirements for the DOE Suspect/Counterfeit Items Prevention Process or the specific DOE Corrective Management Program requirements. This is to be expected since ISO 9001-2008 is a consensus standard.	*Preventive and Corrective Actions* o Procedure 5. *Approving and Managing Issues and Corrective Actions Tracked in DOE Corrective Action Tracking System (CATS)* o Exhibits • **MSD:** Financial Assistance • **MSD:** Facilities and Infrastructure • **MSD:** Management and Operating (M&O) Contracting • **MSD:** Non-Management and Operating (Non-M&O) Contracting
Management/Criterion 1 – Program Requirements • Establish an organizational structure, functional	**5.1 Management commitment**: Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by…ensuring the availability of resources. **5.4.1 Quality objectives:** Top management shall ensure that quality	• **MSD:** Office of SCience Management System (All applicable MSDs, SAs, and Procedures) • **MSD:** Quality Assurance and Oversight – **PD**: SC-Wide Quality Assurance Program Description

DOE Order 414.1C Requirements	ISO 9001-2008 Criteria	Office of SCience Management System (SCMS), Management System Description (MSD)/ Program Description (PD)/Subject Area (SA) and Office of Science (SC) Oak Ridge (OR) Implementing Mechanisms
responsibilities, levels of authority, and interfaces for those managing, performing, and assessing work. • Establish management processes, including planning, scheduling, and providing resources for work. **10 CFR 830.122 (a)(1)(2) and DOE O 414.1C 4.b.(1)(a)(b)**	objectives, including those needed to meet requirements for product [see ISO 9001-2008 Section 7.1(a)], are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy. **5.4.2 Quality management system planning:** Top management shall ensure that a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented. **5.5.1 Responsibility and authority:** Top management shall ensure that responsibilities and authorities are defined and communicated within the organization. **6.1 Provision of resources:** The organization shall determine and provide the resources needed a) to implement and maintain the quality management system and continually improve its effectiveness, and…	• **MSD:** Human Resources Services – **SA:** Employee Development • *Office of Science (SC) Environment, Safety and Health (ES&H) Functions, Responsibilities and Authorities Manual (FRAM)*
Management/Criterion 2 – Personnel Training and Qualification • Train and qualify personnel to be capable of performing assigned work. • Provide continuing training to personnel to maintain job	**6.2.1 General:** Personnel performing work affecting conformity to product requirements shall be competent on the basis of appropriate education, training, skills and experience. **6.2.2 Competence, training and awareness:** The organization shall a) determine the necessary competence for personnel performing work affecting conformity to product requirements, b) where applicable, provide training or take other actions to achieve the necessary competence,	• **MSD:** Quality Assurance and Oversight – **PD**: SC-Wide Quality Assurance Program Description • **MSD:** Human Resources Services – **SA:** Employee Development o Procedure 1. *Preparing Individual Development Plans* o Procedure 2. *Processing Training Requests* o Procedure 3. *Implementing Project*

DOE Order 414.1C Requirements	ISO 9001-2008 Criteria	Office of SCience Management System (SCMS), Management System Description (MSD)/ Program Description (PD)/Subject Area (SA) and Office of Science (SC) Oak Ridge (OR) Implementing Mechanisms
proficiency. **10 CFR 830.122 (b)(1)(2) and DOE O 414.1C 4.b.(2)(a)(b)**	c) evaluate the effectiveness of the actions taken, d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and e) maintain appropriate records of education, training, skills and experience (see ISO 9001-2008 Section 4.2.4).	*Management Career Development Program Certification* o Procedure 4. *Implementing Acquisition Career Management Program* o Procedure 5. *Implementing Technical Qualification Program* – **SA:** Organization Management – Implementation and Execution o Procedure 1. *Merit Promotion* o Procedure 2. *Developing Position Descriptions* – **SA:** Organization Management – Planning and Design o Procedure 1. *Enter or View Information in the Department of Energy (DOE) Employee Self Service (ESS) Skills Assessment Tool* o Procedure 2. *Complete Workforce Planning* o Procedure 3. *Complete Staffing Plan* o Procedure 4. *Restructure Organization*
Management/Criterion 3 – 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.	**5.6.1 General:** Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives. Records from management reviews shall be maintained (see ISO 9001-2008 Section 4.2.4). **8.2.1 Customer satisfaction:** As one of the measurements of the performance of the quality management system, the organization shall	• **MSD:** Quality Assurance and Oversight – **SA:** Assessments o Procedure 1. *Analyzing and Scheduling Assessment Needs* – **SA:** Office of Science (SC) Performing Planning and Evaluation o Procedure 1. *Preparing and Reviewing the SC Annual Performance Plan (APP)* o Procedure 2. *Preparing and Reviewing the SC Annual Assessment Report (AAR)*

DOE Order 414.1C Requirements	ISO 9001-2008 Criteria	Office of SCience Management System (SCMS), Management System Description (MSD)/ Program Description (PD)/Subject Area (SA) and Office of Science (SC) Oak Ridge (OR) Implementing Mechanisms

• Identify the causes of problems, and include prevention of recurrence as a part of correcting action planning.
 	
• Review item characteristics, process implementation, and other quality-related information to identify items, services, and processes needing improvement.
 	
10 CFR 830.122 (c)(1)(2)(3)(4) and DOE O 414.1C 4.b.(3)(a)(b)(c)(d)
	monitor information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined.
	
	8.2.2 Internal audit: The organization shall conduct internal audits at planned intervals to determine whether the quality management system
	
	a) conforms to the planned arrangements (see ISO 9001-2008 Section 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization, and
	
	b) is effectively implemented and maintained.
	
	8.3 Control of nonconforming product: The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery…
	
	8.4 Analysis of data: The organization shall determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources.
	
	8.5.1 Continual improvement: The organization shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.
	
	8.5.2 Corrective action: The organization shall take action to eliminate the causes of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered. A documented procedure shall be established to define requirements for…
		– **SA:** Performance Trending
		  o Procedure 1. *Establishing and Implementing a Performance Trending Process*
		  o Procedure 2. *Analyzing, Charting, and Reviewing Performance Trends*
		– **SA:** Issues Management
		  o Procedure 1. *Managing Issues Identified in Oversight Activities*
		  o Procedure 2. *Performing Causal Analysis*
		  o Procedure 3. *Developing, Approving, Implementing, and Verifying Preventive and Corrective Actions*
		  o Procedure 4. *Tracking Issues, and Preventive and Corrective Actions*
		  o Procedure 5. *Approving and Managing Issues and Corrective Actions Tracked in DOE Corrective Action Tracking System (CATS)*

DOE Order 414.1C Requirements	ISO 9001-2008 Criteria	Office of SCience Management System (SCMS), Management System Description (MSD)/ Program Description (PD)/Subject Area (SA) and Office of Science (SC) Oak Ridge (OR) Implementing Mechanisms
	8.5.3 Preventive action: The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems. A documented procedure shall be established to define requirements for…	
Management/Criterion 4 – 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. **10 CFR 830.122 (d)(1)(2) and DOE O 414.1C 4.b.(4)(a)(b)**	**4.2.3 Control of documents:** Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4. A documented procedure shall be established to define the controls needed… **4.2.4 Control of records**: Records established to provide evidence of conformity to requirements and of the effective operation of the quality management system shall be controlled. The organization shall establish a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records. Records shall remain legible, readily identifiable and retrievable.	• **MSD:** Quality Assurance and Oversight – **PD**: SC-Wide Quality Assurance Program Description • **MSD:** Requirements Management – **SA:** Document Control Management o Procedure 1. *Identifying Controlled Documents* o Procedure 2. *Preparing and Submitting SCMS Documents* o Procedure 3. *Reviewing SCMS Documents* o Procedure 4. *Approving SCMS Documents* o Procedure 5. *Canceling an SCMS Document* o Procedure 6. *Annual Review of SCMS Management System Documents* o Procedure 7. *Control of Non-SCMS Documents* • **MSD:** Records Management – **SA:** Records Management o Procedure 1. *Creating and Identifying Federal Records* o Procedure 2. *Ensuring the Adequacy of Documentation* o Procedure 3. *Conducting a Records Inventory* o Procedure 4. *Developing New Records*

DOE Order 414.1C Requirements	ISO 9001-2008 Criteria	Office of SCience Management System (SCMS), Management System Description (MSD)/ Program Description (PD)/Subject Area (SA) and Office of Science (SC) Oak Ridge (OR) Implementing Mechanisms
		Disposition Schedules o Procedure 5. *Maintaining Records Efficiently* o Procedure 6. *Using Records* o Procedure 7. *Transferring and Destroying Records* o Procedure 8. *Managing Vital Records* o Procedure 9. *Coordinating Disaster Planning and Recovery*
Performance/Criterion 5 – Work Processes • 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. **10 CFR 830.122 (e)(1)(2)(3)(4) and DOE O 414.1C 4.b.(5)(a)(b)(c)(d)**	**4.2.3 Control of documents:** Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4. A documented procedure shall be established to define the controls needed… **4.2.4 Control of records:** Records established to provide evidence of conformity to requirements and of the effective operation of the quality management system shall be controlled. The organization shall establish a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records. Records shall remain legible, readily identifiable and retrievable. **7.5.1 Control of production and service provision:** The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable, a) the availability of information that describes the characteristics of the product, b) the availability of work instructions, as necessary, c) the use of suitable equipment,	• See Management/Criterion 4 above for ISO 9001-2008, Section 4.2.3, Control of Documents and Section 4.2.4, Control of Records, and implementing SCMS documents. • **MSD:** Office of SCience Management System • **MSD:** Quality Assurance and Oversight – **PD**: SC-Wide Quality Assurance Program Description – **PD**: Line Management Oversight • **MSD:** Management and Operating (M&O) Contracting • **MSD:** Non-Management and Operating (Non-M&O) Contracting • **MSD:** Project Management • Office of Science Strategic Plan

DOE Order 414.1C Requirements	ISO 9001-2008 Criteria	Office of SCience Management System (SCMS), Management System Description (MSD)/ Program Description (PD)/Subject Area (SA) and Office of Science (SC) Oak Ridge (OR) Implementing Mechanisms
	d) the availability and use of monitoring and measuring equipment, e) the implementation of monitoring and measurement, and f) the implementation of product release, delivery and post-delivery activities. **7.5.3 Identification and traceability:** Where appropriate, the organization shall identify the product by suitable means throughout production realization. The organization shall identify the product status with respect to monitoring and measurement requirements throughout product realization. Where traceability is a requirement, the organization shall control the unique identification of the product and maintain records (see ISO 9001-2008 Section 4.2.4). **(Not applicable for ORO.)** **7.5.5 Preservation of product:** The organization shall preserve the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. As applicable, preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product. **(Not applicable for ORO.)** **7.6 Control of monitoring and measuring equipment:** The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements. The organization shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements. Where necessary to ensure valid results, measuring equipment shall a) be calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded (see	

DOE Order 414.1C Requirements	ISO 9001-2008 Criteria	Office of SCience Management System (SCMS), Management System Description (MSD)/ Program Description (PD)/Subject Area (SA) and Office of Science (SC) Oak Ridge (OR) Implementing Mechanisms
	ISO 9001-2008 Section 4.2.4); b) be adjusted or readjusted as necessary; c) have identification in order to determine its calibration status; d) be safeguarded from adjustments that would invalidate the measurement result; e) be protected from damage and deterioration during handling, maintenance and storage. In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected. Records of the results of calibration and verification shall be maintained (see ISO 9001-2008 Section 4.2.4). When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary. **(Not applicable for ORO.)**	
Performance/Criterion 6 – Design Does not generally perform work activities applicable to Criterion 6. • Design items and processes using sound engineering/scientific principles and appropriate standards. • Incorporate applicable requirements and design bases in design work and design changes.	**7.2.1 Determination of requirements related to the product**: The organization shall determine a) requirements specified by the customer, including the requirements for delivery and post-delivery activities, b) requirements not stated by the customer but necessary for specified or intended use, where known, c) statutory and regulatory requirements applicable to the product, and d) any additional requirements considered necessary by the organization. **7.3.1 Design and development planning:** The organization shall plan and control the design and development of product. During the	• **MSD:** Office of Science Management System • **MSD:** Quality Assurance and Oversight – **PD**: SC-Wide Quality Assurance Program Description • **MSD:** Requirements Management – **SA:** Requirements Management o Procedure 1. *Identifying and Proposing New or Revised Requirements* o Procedure 2. *Reviewing and Commenting on DOE Justification Memoranda, DOE Policies, and DOE Notices* o Procedure 3. *Reviewing and Commenting on Draft DOE Directives*

DOE Order 414.1C Requirements	ISO 9001-2008 Criteria	Office of SCience Management System (SCMS), Management System Description (MSD)/ Program Description (PD)/Subject Area (SA) and Office of Science (SC) Oak Ridge (OR) Implementing Mechanisms
• 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. **10 CFR 830.122(f)(1)(2)(3)(4)(5) and DOE O 414.1C 4.b.(6)(a)(b)(c)(d)(e)**	design and development planning, the organization shall determine a) the design and development stages, b) the review, verification and validation that are appropriate to each design and development stage, and c) the responsibilities and authorities for design and development. The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility. Planning output shall be updated, as appropriate, as the design and development progresses. **7.3.2 Design and development inputs:** Inputs relating to product requirements shall be determined and records maintained (see ISO 9001-2008 Section 4.2.4). These inputs shall include a) functional and performance requirements, b) applicable statutory and regulatory requirements, c) where applicable, information derived from previous similar designs, and d) other requirements essential for design and development. The inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other. **7.3.6 Design and development validation:** Design and development validation shall be performed in accordance with planned arrangements (see ISO 9001-2008 Section 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation shall be completed prior to the delivery or implementation of the product. Records of the results of validation	○ Procedure 4. *Processing Approved Requirements* • **MSD:** Financial Assistance • **MSD:** Facilities and Infrastructure • **MSD:** Management and Operating (M&O) Contracting • **MSD:** Non-Management and Operating (Non-M&O) Contracting

DOE Order 414.1C Requirements	ISO 9001-2008 Criteria	Office of SCience Management System (SCMS), Management System Description (MSD)/ Program Description (PD)/Subject Area (SA) and Office of Science (SC) Oak Ridge (OR) Implementing Mechanisms
	and any necessary actions shall be maintained (see ISO 9001-2008 Section 4.2.4). **7.4.1 Purchasing process:** The organization shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product. The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained (see ISO 9001-2008 Section 4.2.4). **7.4.1 Purchasing information:** Purchasing information shall describe the product to be purchased, including, where appropriate, a) requirements for approval of product, procedures, processes, and equipment, b) requirements for qualification of personnel, and c) quality management system requirements. The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier. **7.4.3 Verification of purchased product:** The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements. Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information.	

DOE Order 414.1C Requirements	ISO 9001-2008 Criteria	Office of SCience Management System (SCMS), Management System Description (MSD)/ Program Description (PD)/Subject Area (SA) and Office of Science (SC) Oak Ridge (OR) Implementing Mechanisms
Performance/Criterion 7 – 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. **10 CFR 830.122(g)(1)(2)(3) and DOE 414.1C 4.b.(7)(a)(b)(c)**	**7.4.1 Purchasing process:** The organization shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product. The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained (see ISO 9001-2008 Section 4.2.4). **7.4.2 Purchasing information:** Purchasing information shall describe the product to be purchased, including, where appropriate, a) requirements for approval of product, procedures, processes, and equipment, b) requirements for qualification of personnel, and c) quality management system requirements. The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier. **7.4.3 Verification of purchased product:** The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements. Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information.	• **MSD:** Quality Assurance and Oversight – **PD**: SC-Wide Quality Assurance Program Description • **MSD:** Financial Assistance (All Procedures) • **MSD:** Facilities and Infrastructure (All Procedures) • **MSD:** Management and Operating (M&O) Contracting (All Procedures) • **MSD:** Non-Management and Operating (Non-M&O) Contracting (All Procedures) • **MSD:** Project Management – **SA:** Critical Decision o Procedure 1. *Critical Decision 0, Approve Mission Need* o Procedure 2. *Critical Decision 1, Approve Alternate Selection and Cost Range* o Procedure 3. *Critical Decision 2, Approve Performance Baseline* o Procedure 4. *Critical Decision 3, Approve Start of Construction* o Procedure 5. *Critical Decision 4, Approve Start of Operations* – **SA:** Project Delivery o Procedure 1. *Managing the Project Initiation Phase* o Procedure 2. *Managing the Project Definition Phase* o Procedure 3. *Managing the Project Execution Phase* o Procedure 4. *Managing the Project Transition/Closeout Phase* – **SA:** Project Reporting

DOE Order 414.1C Requirements	ISO 9001-2008 Criteria	Office of SCience Management System (SCMS), Management System Description (MSD)/ Program Description (PD)/Subject Area (SA) and Office of Science (SC) Oak Ridge (OR) Implementing Mechanisms
		○ Procedure 1. *Managing Project Assessment and Reporting System (PARS) Monthly Project Reporting* ○ Procedure 2. *Managing Contractor's Monthly Reporting*
Performance/Criterion 8 – Inspection and Acceptance Testing Does not generally perform work activities applicable to Criterion 8. • Inspect and test specified items, services, and processes using established acceptance and performance criteria. • Calibrate and maintain equipment used for inspections and tests. **10 CFR 830.122 (h)(1)(2) and DOE O 414.1C 4.b.(8)(a)(b)**	**7.3.3 Design and development outputs:** The outputs of design and development shall be in a form suitable for verification against the design and development input and shall be approved prior to release. Design and development outputs shall… c) contain or reference product acceptance criteria, and d) specify the characteristics of the product that are essential for its safe and proper use. **(Not applicable for ORO.)** **7.6 Control of monitoring and measuring equipment:** The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements. The organization shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements. Where necessary to ensure valid results, measuring equipment shall a) be calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded (see ISO 9001-2008 Section 4.2.4); b) be adjusted or readjusted as necessary; c) have identification in order to determine its calibration status; d) be safeguarded from adjustments that would invalidate the	• **MSD:** Quality Assurance and Oversight – **SA:** Assessments ○ Procedure 1. *Analyzing and Scheduling Assessment Needs* ○ Procedure 2. *Performing Assessments* – **SA:** Issues Management (All Procedures and Exhibits)

DOE Order 414.1C Requirements	ISO 9001-2008 Criteria	Office of SCience Management System (SCMS), Management System Description (MSD)/ Program Description (PD)/Subject Area (SA) and Office of Science (SC) Oak Ridge (OR) Implementing Mechanisms
	measurement result; e) be protected from damage and deterioration during handling, maintenance, and storage. In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected. Records of the results of calibration and verification shall be maintained (see ISO 9001-2008 Section 4.2.4). When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary. **(Not applicable for ORO.)** **8.1 General:** The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed a) to demonstrate conformity to product requirements, b) to ensure conformity of the quality management system, and c) to continually improve the effectiveness of the quality management system. This shall include determination of applicable methods, including statistical techniques, and the extent of their use. **8.2.1 Customer satisfaction:** As one of the measurements of the performance of the quality management system, the organization shall monitor information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined. **8.2.3 Monitoring and measurement of processes:** The organization shall apply suitable methods for monitoring and, where applicable,	

DOE Order 414.1C Requirements	ISO 9001-2008 Criteria	Office of SCience Management System (SCMS), Management System Description (MSD)/ Program Description (PD)/Subject Area (SA) and Office of Science (SC) Oak Ridge (OR) Implementing Mechanisms
	measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate. **8.2.4 Monitoring and measurement of product:** The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see ISO 9001-2008 Section 7.1). Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product for delivery to the customer (see ISO 9001-2008 Section 4.2.4). The release of product and delivery of service to the customer shall not proceed until the planned arrangements (see ISO 9001-2008 Section 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.	
Assessment/Criterion 9 – Management Assessment • Ensure that managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives. **10 CFR 830.122(i) and DOE O 414.1C 4.b.(9)**	**5.1 Management commitment**: Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by… e) ensuring the availability of resources. **5.5.2 Management representative:** Top management shall appoint a member of the organization's management who, irrespective of other responsibilities, shall have responsibility and authority that includes… b) reporting to top management on the performance of the quality management system and any need for improvement, and… **5.6.1 General:** Top management shall review the organization's quality management system, at planned intervals, to ensure its	• **MSD:** Office of SCience Management System • **MSD:** Quality Assurance and Oversight – **PD**: SC-Wide Quality Assurance Program Description – **SA:** Assessments (All Procedures and Exhibits) – **SA:** Performance Planning and Evaluation o Procedure 1. *Preparing and Reviewing the SC Annual Performance Plan (APP)* o Procedure 2. *Preparing and Reviewing the SC Annual Assessment Report (AAR)* – **SA:** Performance Trending o Procedure 1. *Establishing and Implementing a Performance Trending Process*

DOE Order 414.1C Requirements	ISO 9001-2008 Criteria	Office of SCience Management System (SCMS), Management System Description (MSD)/ Program Description (PD)/Subject Area (SA) and Office of Science (SC) Oak Ridge (OR) Implementing Mechanisms
	continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives… **8.2.1 Customer satisfaction:** As one of the measurements of the performance of the quality management system, the organization shall monitor information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined. **8.4 Analysis of data:** The organization shall determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources. The analysis of data shall provide information relating to a) customer satisfaction (see ISO 9001-2008 Section 8.2.1), b) conformity to product requirements (see ISO 9001-2008 Section 8.2.4), c) characteristics and trends of processes and products, including opportunities for preventive action (see ISO 9001-2008 Section 8.2.3 and 8.2.4), and d) suppliers (see ISO 9001-2008 Section 7.4). **8.5.1 Continual improvement:** The organization shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review. **8.5.2 Corrective action:** The organization shall take action to eliminate the causes of nonconformities in order to prevent recurrence.	○ Procedure 2. *Analyzing, Charting, and Reviewing Performance Trends* – **SA:** Issues Management ○ Procedure 1. *Managing Issues Identified in Oversight Activities* ○ Procedure 2. *Performing Causal Analysis* ○ Procedure 3. *Developing, Approving, Implementing, and Verifying Preventive and Corrective Actions* ○ Procedure 4. *Tracking Issues, and Preventive and Corrective Actions* ○ Procedure 5. *Approving and Managing Issues and Corrective Actions Tracked in DOE Corrective Action Tracking System (CATS)* • **MSD:** Human Resources Services – **SA:** Employee Development • *Office of Science (SC) Environment, Safety and Health (ES&H) Functions, Responsibilities and Authorities Manual (FRAM)*

DOE Order 414.1C Requirements	ISO 9001-2008 Criteria	Office of SCience Management System (SCMS), Management System Description (MSD)/ Program Description (PD)/Subject Area (SA) and Office of Science (SC) Oak Ridge (OR) Implementing Mechanisms
	Corrective actions shall be appropriate to the effects of the nonconformities encountered. A documented procedure shall be established to define requirements for…. **8.5.3 Preventive action:** The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems. A documented procedure shall be established to define requirements for…	
Assessment/Criterion 10 – Independent Assessment • 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. **10 CFR 830.122(j)(1)(2)(3) and DOE O 414.1C 4.b.(10)(a)(b)(c)**	**8.2.2 Internal audit:** The organization shall conduct internal audits at planned intervals to determine whether the quality management system a) conforms to the planned arrangements (see ISO 9001-2008 Section 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization, and b) is effectively implemented and maintained. An audit programme shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work. A documented procedure shall be established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results. Records of the audits and their results shall be maintained (see ISO 9001-2008 Section 4.2.4). The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken	• **MSD:** Office of SCience Management System • **MSD:** Quality Assurance and Oversight – **PD**: SC-Wide Quality Assurance Program Description – **SA:** Assessments o Procedure 1. *Analyzing and Scheduling Assessment Needs* o Procedure 2. *Performing Assessments* – **SA:** Issues Management o Procedure 3. *Developing, Approving, Implementing, and Verifying Preventive and Corrective Actions* o Procedure 4. *Tracking Issues, and Preventive and Corrective Actions* o Procedure 5. *Approving and Managing Issues and Corrective Actions Tracked in DOE Corrective Action Tracking System (CATS)* • **MSD:** Human Resources Services – **SA:** Employee Development o Procedure 1. *Preparing Individual Development Plans* o Procedure 2. *Processing Training Requests*

DOE Order 414.1C Requirements	ISO 9001-2008 Criteria	Office of SCience Management System (SCMS), Management System Description (MSD)/ Program Description (PD)/Subject Area (SA) and Office of Science (SC) Oak Ridge (OR) Implementing Mechanisms
	and the reporting of verification results (see ISO 9001-2008 Section 8.5.2). **6.2.2 Competence, training and awareness:** The organization shall a) determine the necessary competence for personnel performing work affecting conformity to product requirements, b) where applicable, provide training or take other actions to achieve the necessary competence, c) evaluate the effectiveness of the actions taken, d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and e) maintain appropriate records of education, training, skills and experience (see ISO 9001-2008 Section 4.2.4).	o Procedure 3. *Implementing Project Management Career Development Program Certification* o Procedure 4. *Implementing Acquisition Career Management Program* o Procedure 5. *Implementing Technical Qualification Program* – **SA:** Organization Management – Implementation and Execution o Procedure 1. *Merit Promotion* o Procedure 2. *Developing Position Descriptions* – **SA:** Organization Management – Planning and Design o Procedure 1. *Enter or View Information in the Department of Energy (DOE) Employee Self Service (ESS) Skills Assessment Tool* o Procedure 2. *Complete Workforce Planning* o Procedure 3. *Complete Staffing Plan* o Procedure 4. *Restructure Organization*

DOE Order 414.1C Requirements	ISO 9001-2008 Criteria	Office of SCience Management System (SCMS), Management System Description (MSD)/ Program Description (PD)/Subject Area (SA) and Office of Science (SC) Oak Ridge (OR) Implementing Mechanisms
Appendix A – Suspect/Counterfeit Items Prevention	**Note**: ISO 9001-2008 has no requirements for the DOE Suspect/Counterfeit Items Prevention Process or the specific DOE Corrective Management Program requirements. This is to be expected since ISO 9001-2008 is a consensus standard. **(Not applicable for ORO.)**	
Appendix B – Corrective Action Management Program	**Note**: ISO 9001-2008 has no requirements for the DOE Suspect/Counterfeit Items Prevention Process or the specific DOE Corrective Management Program requirements. This is to be expected since ISO 9001-2008 is a consensus standard.	• **MSD:** Quality Assurance and Oversight – **SA:** Issues Management o Procedure 5. *Approving and Managing Issues and Corrective Actions Tracked in DOE Corrective Action Tracking System (CATS)*
Appendix C – Safety Software Quality Requirements		• **MSD:** Information Technology

ATTACHMENT 2 - SC Management Systems

Office of SCience Management System (SCMS) (http://scms.sc.doe.gov)
Budget and Financial Management
Communications and Public Affairs
Environment, Safety, and Health
Facilities and Infrastructure
Financial Assistance
Human Resources Services
Information Technology
Legal Services
Management and Operating (M&O) Contracting
Non-Management and Operating (Non-M&O) Contracting
Personal Property Management
Program Management
Project Management
Quality Assurance and Oversight
Real Property Management
Records Management
Requirements Management
Safeguards, Security, and Emergency Management

ATTACHMENT 3 - ORO Key Management Documents

NOTE – These documents are maintained and kept up to date by the "owner" of the document. The Change Control process for updating these documents is coordinated with the Directives Management Group when determined necessary by the owner.	
TITLE	**ORGANIZATION**
ISC Service Plan	M-1
ORO Management System Description / Quality Assurance Program – Part A (MSD)	AD-440
ORO Management System Description / Quality Assurance Program – Part B (QAP)	SE-321
Environmental Management Quality Implementation Plan (EM-QIP)	EM-90
ORO Integrated Safety Management (ISM) Program Description	SE-30
Oak Ridge Office – Level III Functions, Responsibilities, and Authorities (FRA)	SE-31
ORO National Environmental Policy Act (NEPA) Procedure	SE-32
Safety Basis Documents Review Guide Revision 2	SE-30
Federal Employee Occupational Safety and Health Program Description	SE-31
Integrated Support Center Quality Management System Description (QMSD)	SE-30
Control Process for Key Management Documents	AD-440

ATTACHMENT 4 - Crosswalk of Quality and Integrated Safety Management System Elements

Quality Assurance Criteria / ISM Principles and Functions	Program	Training and Qualification	Quality Improvement	Documents and Records	Work Processes	Design	Procurement	Inspection/Acceptance Testing	Management Assessment	Independent Assessment
ISM Guiding Principles										
Line Management Responsibility for Safety	X			X					X	X
Clear Roles and Responsibilities	X			X					X	X
Competence Commensurate with Responsibilities		X		X					X	X
Balanced Priorities	X			X					X	X
Identification of ES&H Standards and Requirements			X	X	X	X	X	X	X	X
Hazard Controls Tailored to Work Being Performed				X	X	X	X	X	X	X
Operations Authorization				X	X	X	X	X	X	X
ISM Core Functions										
Define the Scope of Work				X	X	X	X	X	X	X
Analyze the Hazards				X	X	X	X	X	X	X
Develop and Implement Hazard Controls				X	X	X	X	X	X	X
Perform Work within Controls				X	X	X	X	X	X	X
Provide Feedback and Continuous Improvement			X	X	X			X	X	X

Note: Adapted from DOE G 414.1-2A

ATTACHMENT 5 - Crosswalk of Quality and Environmental Management System Elements

Quality Assurance Criteria / Environmental Management System (ISO 14001 Standard Requirements)	Program	Training & Qualification	Quality Improvement	Documents & Records	Work Processes	Design	Procurement	Inspection/ Acceptance Testing	Management Assessment	Independent Assessment
General Requirements	X									
Environmental Policy	X		X							
Planning										
Environmental aspects	X				X					
Legal and other requirements	X				X					
Objectives, targets, and program(s)	X		X							
Implementation and Operation										
Resources, roles, responsibility, and authority	X		X							
Competence, training, and awareness		X								
Communication			X		X					
Documentation				X						
Control of documents				X						
Operational control					X	X	X	X		
Emergency preparedness and response			X							
Checking										
Monitoring and measurement			X					X	X	
Evaluation of compliance			X						X	
Nonconformity, corrective action, and preventive action			X							
Control of records				X						
Internal audit										X
Management Review			X	X					X	
Environmental Protection Program (DOE O 450.1)										
Environmentally and economically beneficial landscape practices	X									
Centralized procurement and distribution program for toxic and hazardous contents							X			
Pollution Prevention Program implementation and monitoring										X
Pollution Prevention Opportunity Assessments										X
Emergency Planning and Community Right-to-Know Act	X									

Quality Assurance Criteria / Environmental Management System (ISO 14001 Standard Requirements)	Program	Training & Qualification	Quality Improvement	Documents & Records	Work Processes	Design	Procurement	Inspection/ Acceptance Testing	Management Assessment	Independent Assessment
Planning and management requirements for historic property and environmental management	X									
Note: Adapted from DOE O 450.1 and Executive Order 13148, *Greening the Government Through Leadership in Environmental Management*										