



U.S. DEPARTMENT OF  
**ENERGY**

Office of  
Science

**Integrated Support Center (ISC)  
Quality Management System Description  
(QMSD)**



**February 2012**

John Eschenberg, Acting Manager  
Oak Ridge Office

Date: March 1, 2012

Roxanne Purucker, Manager  
Chicago Office

Date: 2/22/12

## Revision Log

**TITLE:** ISC ISO 9001:2008 Quality Management System Description

**DOCUMENT OWNERS:** John K. Adachi, ISC-CH and Mildred S. López-Ferré, ISC-OR

**SCMS MANAGEMENT SYSTEM:** [Quality Assurance and Oversight](#)

**SUBJECT AREA/PROGRAM DESCRIPTION:** [SC-Wide Quality Assurance Program Description](#):

**REVIEW DATE:** February 28, 2013

Revision No.	Date	Description of Change
0	September 2009	Original Issue.
1	August 2010	Incorporate Revisions Suggested in the 2010 ISC Baseline Review.
2	February 2012	Update reference versions and figures; provide web link to SC-ISC Service Plan rather than including it as an appendix; incorporate organizational changes.

## Table of Contents

1.0	Introduction .....	5
1.1	Purpose .....	5
1.2	Scope .....	5
2.0	Integrated Support Center Description .....	5
2.1	Organization.....	5
2.2	ISC Customers and Service.....	6
3.0	ISC Services .....	6
3.1	Overview of ISC Quality Management System .....	7
3.2	SCMS and Other Systems.....	8
3.3	Quality Management System Document Hierarchy .....	9
3.4	Exclusions/Non-Applicability .....	10
4.0	ISC Quality Management System Description .....	10
4.1	General Requirements .....	11
4.2	Documentation Requirements .....	12
4.2.1	General.....	12
4.2.2	Quality Manual.....	12
4.2.3	Control of Documents.....	12
4.2.4	Control of Records .....	12
5.0	Management Responsibility .....	13
5.1	Management Commitment .....	13
5.2	Customer Focus .....	13
5.3	Quality Policy .....	14
5.4	Planning.....	14
5.4.1	Quality Objectives.....	14
5.4.2	Quality Management System Planning.....	15
5.5	Responsibility, Authority and Communication.....	15
5.5.1	Responsibility and Authority.....	15
5.5.2	Management Representative .....	155
5.5.3	Internal Communication .....	16

## Table of Contents continued

5.6	Management Review .....	16
5.6.1	General.....	16
5.6.2	Review Input .....	16
5.6.3	Review Output .....	17
6.0	Resource Management.....	17
6.1	Provision of Resources.....	17
6.2	Human Resources .....	17
6.2.1	General.....	17
6.2.2	Competence, Awareness and Training .....	18
6.3	Infrastructure .....	18
6.4	Work Environment.....	18
7.0	Product Realization .....	19
7.1	Planning of Product Realization.....	19
7.2	Customer-Related Processes .....	19
7.2.1	Determination of Requirements Related to the Product .....	19
7.2.2	Review of Requirements Related to the Product .....	20
7.2.3	Customer Communication .....	20
7.3	Design and Development.....	20
7.4	Purchasing.....	20
7.5	Production and Service Provision .....	20
7.6	Control of Monitoring and Measuring.....	20
8.0	Measurement, Analysis and Improvement .....	20
8.1	General.....	20

**Table of Contents continued**

8.2 Monitoring and Measurement ..... 21

    8.2.1 Customer Satisfaction ..... 21

    8.2.2 Internal Audit – Self-Assessment ..... 21

    8.2.3 Monitoring and Measurement of Processes ..... 22

    8.2.4 Monitoring and Measurement of Product ..... 22

8.3 Control of Nonconforming Product ..... 22

8.4 Analysis of Data ..... 23

8.5 Improvement ..... 23

    8.5.1 Continual Improvement ..... 23

    8.5.2 Corrective/Preventive Action ..... 23

**Appendices**

Appendix A – SCMS Management Systems ..... A-1

Appendix B – SCMS – Crosswalk: ISO 9001:2008 x DOE Order 414.1D x SCMS ..... B-1

## 1.0 INTRODUCTION

### 1.1 Purpose

In accordance with Department of Energy (DOE) Order 414.1D, Quality Assurance, the Office of Science (SC) has selected the ISO Standard 9001-2008 as its Quality Assurance Standard. The purpose of this document is to describe the Quality Management System (QMS) for DOE, SC Integrated Support Center (ISC). To provide direct access to important web sites relevant to the Quality Management System Description (QMSD), hyper-links are embedded periodically in this document.

The ISC QMSD explains the system and tools for providing a comprehensive high-level description of management policy, organizational objectives and quality-based work processes necessary to meet ISC customer expectations and regulatory requirements.

To ensure its mission is executed properly, consistently and effectively, SC uses a web-based management tool called the [Science Management System](#) (SCMS). 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. The ISC uses SCMS as the basis for providing customer support. (There are instances where local/site procedures are followed.)

### 1.2 Scope

This QMSD applies to services provided by the ISC in accordance with the requirements of DOE Order 414.1D and ISO 9001:2008; it also considers the guiding principles of DOE Order 226.1B.

## 2.0 INTEGRATED SUPPORT CENTER DESCRIPTION

### 2.1 Organization

The ISC is a virtual organization that provides services as requested through the integration of the capabilities of the Office of Science-Oak Ridge (SC-OR) and the Office of Science-Chicago (SC-CH) to support the SC mission. Combined support capabilities of the [Chicago](#) and [Oak Ridge](#) Offices provide safety, business, technical, legal and administrative support to the SC complex, other DOE program offices, and as appropriate, other Federal agencies as its customers.

The ISC organization, functions, approach and support assignments and capabilities are described in the [ISC Service Plan](#). The Service Plan is reviewed annually at a minimum; however, it can be revised as necessary.

## 2.2 ISC Customers and Service

The products and services provided by the ISC to the Site Office customers are detailed in the [ISC Service Plan](#). ISC's customers are primarily SC HQ and SC Site Offices. The ISC provides services through the integration of the capabilities of SC-OR and SC-CH. These services are designed to ensure effective customer support and operating efficiency. SC-OR has additional roles and responsibilities beyond the ISC, as it is also responsible for the infrastructure of the Oak Ridge Reservation, and provides support to the other Program Offices in Oak Ridge. The extended scope and extent of SC-OR is further described in SC-OR specific documents. Similarly, SC-CH has additional roles and responsibilities beyond the ISC, as it has been delegated the responsibility for line management oversight of the New Brunswick Laboratory (a government-owned, government-operated nuclear standards laboratory co-located on the Argonne site). The SC-CH line management oversight role for NBL is further described in SC-CH specific documents. The SC-CH and SC-OR Managers jointly develop revisions to the QMSD and are responsible for implementing those aspects of the ISC assigned to them. Support service delivery is a function of capacity, customer needs, schedules, required subject matter expertise and performance.

## 3.0 ISC SERVICES

ISC functional support, service areas and specific customer assignments for SC Site Offices are defined in the Service Provider and Contact Matrices contained in the [ISC Service Plan](#). The Service Provider Matrix identifies the primary office (SC-OR or SC-CH) where an ISC customer is to seek support; the Contact Matrix identifies the primary functional contact within the ISC.

Service requests related to the lead offices identified in the matrix are directed to the applicable point-of-contact contained in the Contact Matrix. Requests for services not identified in the matrix (i.e., "new requests") are initially directed to either the SC-CH Deputy Manager or the SC-OR Deputy Manager who will then work together to analyze capacity for the support, and in concert with this plan, to outline the appropriate source(s) of support.

In accordance with the SC emergency management guidance, the SC Site Offices have the lead responsibility in emergencies and the ISC is to support Site Offices, as requested. The same guidance provides that the ISC supports respective Site Offices' emergency management programs.

### 3.1 Overview of ISC Quality Management System

The ISC operates and manages its mission consistent with DOE Order 414.1D, DOE Order 226.1B and ISO 9001:2008. Accordingly, this QMSD serves as the Quality Manual for the ISC, identifying other supporting documentation, both within SCMS and within the SC-CH and SC-OR Offices.

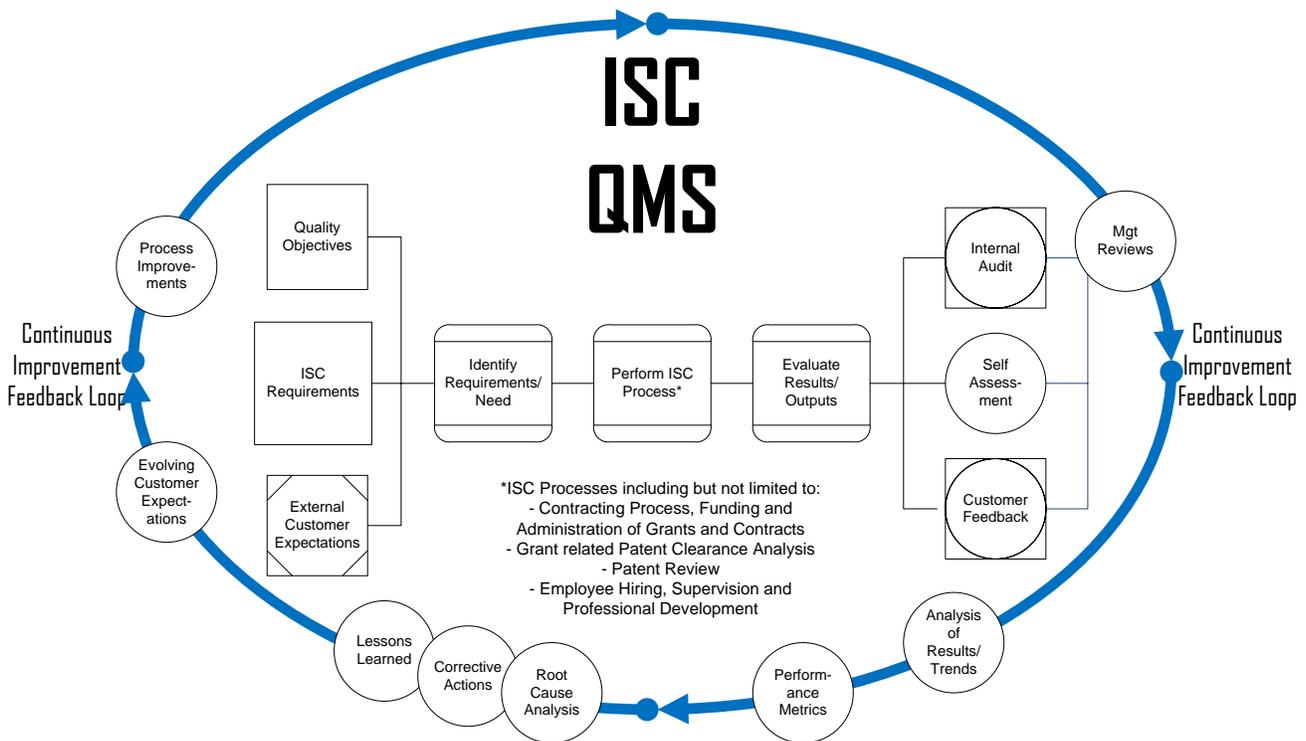


Figure 1

Figure 1 provides a high-level graphic of the ISC's QMS.

The ISC QMS contains the following key elements or functions adopted to enhance the services provided to its customers:

- Clear understanding of ISC customer expectations
- Strong focus upon managing processes and services
- Methods for seeking customer feedback
- Management reviews that focus upon information and actions to promote continual improvement

### **3.2 SCMS and Other Systems**

SCMS documents SC's approach to program and support management, defines roles and responsibilities and provides standard procedures for SC functions including federal operations and contractor oversight. The connection among HQ, ISC, and Site Office organizations and their roles and responsibilities described within SCMS is further described within various documents in each ISC office as required by DOE Directives: e.g., Quality Assurance Program; Integrated Safety Management System; Functions, Responsibilities and Authorities Manual; Integrated Safeguards and Security Manual, etc. Site Office/organizational-specific desk references/procedures may also describe a lower level of operational detail.

SCMS describes SC's integrated management approach, applying roles and responsibilities for the organization against the large set of applicable requirements SC must address in carrying out its mission. SCMS, in combination with the SC Functions, Responsibilities, and Authorities Manual (SC FRAM), serves to document SC's business systems and processes for achieving integrated SC operations and effective mission support. The scope of the SCMS is designed to include responsibilities and processes needed to support the SC mission, including those for both science and operations.

SCMS primarily focuses upon technical and business practices conducted by SC federal employees. It is structured in a tiered manner, beginning with functional responsibilities or Management Systems. Each Management System (nineteen total) describes the SC roles, responsibilities and activities needed to address requirements (i.e., laws, regulations, orders and DOE Directives, etc.) applicable to that system. Each Management System is further divided into Subject Areas, and each Subject Area is in turn supported by one or more implementing procedures and exhibits. Appendix A identifies the nineteen [SCMS Management Systems](#).

### 3.3 Quality Management System Document Hierarchy

Figure 2 presents a hierarchal perspective of the quality documentation applicable to the ISC. This figure displays those documented systems and processes identified by SC and the ISC as needed to assure successful operation in a safe and quality manner. The majority of the ISC's QMS documentation is contained within SCMS, but DOE Directives also require site-level documents to support full implementation of the QMS. The SC-OR and SC-CH Quality Assurance Plans (QAPs) integrate their requirements, incorporate appropriate information from related Management Systems, and make provision for any additional implementing procedures based on a particular need.

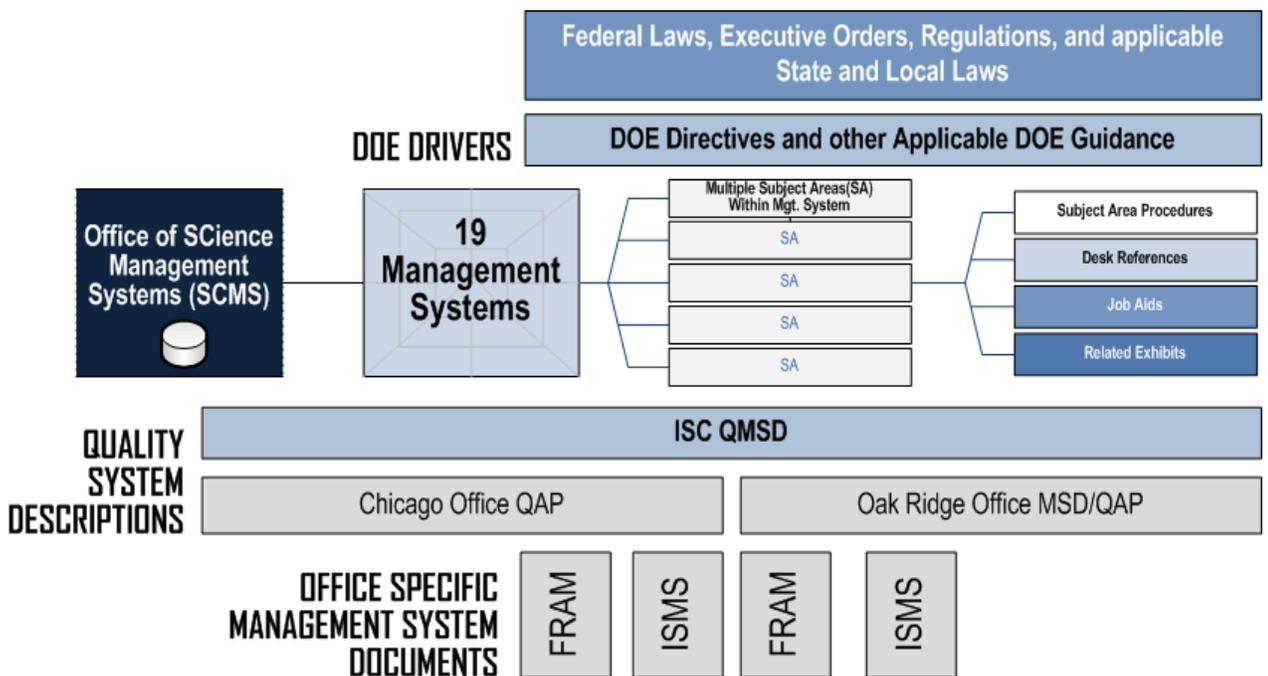


Figure 2

### 3.4 Exclusions/Non-Applicability

The following ISO 9001:2008 criteria are excluded from this ISC QMSD:

<u>QMSD Section Number</u>	<u>ISO 9001-2008 Clause Title</u>
7.3 - all	Design and Development
7.4 - all	Purchasing
7.5 - all	Production and Service Provision
7.6 - all	Control of Monitoring and Measuring Devices

#### **Rationale for Exclusions/Non-Applicability**

The ISC does not perform, design, develop or purchase equipment, components, etc., – in the traditional industrial or product sense. The ISC may, upon request, assist with contract procurement activities. The government products and services provided by the ISC entail documents and ad hoc consulting, not physical components equipment or products as would, for example, industry fabrication, production, wholesaler, retailer, etc.

Similarly, the ISC does not conduct or assist with control of monitoring and measuring devices, production or validation of same.

In general, procurements by the ISC are typically office supplies, GSA routine maintenance items, and service procurements. Procurements at OR for their non-ISC functions range from the basic building maintenance and grounds maintenance services to the more complex procurements for environmental cleanup from years of energy research and weapons production. 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.

### 4.0 ISC QUALITY MANAGEMENT SYSTEM DESCRIPTION

NOTE: The numbering of the following sections is consistent with the format and structure of the ISO 9001:2008 standard.

## 4.1 General Requirements

The ISC QMSD assures conformance to specified requirements during the product/service realization process and provides a framework for continual improvement. Quality assurance is established, documented, implemented, and maintained through execution of this QMSD, implementing procedures within SCMS and, as may be needed, locally at SC-CH and SC-OR.

This QMSD includes general descriptions of the structure and processes used by the ISC to fulfill its mission. Criteria and methods, including internal assessments, established to ensure the operation and control of processes, are effectively implemented and maintained. Performance of important processes and progress toward mission goals are routinely measured and evaluated. A continuous process of seeking improvements is supported by the management review, assessment, issues management, and customer service processes. Continual improvement actions are identified, scheduled, and tracked to completion. An Integrated Assessment Schedule for SC is maintained and also reflects the ISC.

SC-OR and SC-CH Managers ensure the availability of resources and information necessary to support the operation and maintenance of these processes. Overall resource requirements are determined and documented in respective office staffing and funding plans. Individual projects or tasks are evaluated for resources to the degree appropriate to accomplish the job.

The ISC management proactively assesses workload, progress and reallocates or reprioritizes efforts to ensure the most important functions are carried out effectively. Close communication between SC-CH, SC-OR and the customer assure adequate effort and resources are available. Metrics or other methods to monitor, measure, and/or analyze processes are established and used as deemed appropriate for the service organization. This data are reviewed during periodic management reviews. The resulting analysis is used to implement actions necessary to achieve planned results and continually improve ISC processes. The processes in the ISC are managed in accordance with ISO 9001:2008 requirements.

SC-OR and SC-CH management ensure the availability of resources and information necessary to support the operation and maintenance of these processes. Resources are evaluated annually and documented in respective office staffing analysis plans.

## **4.2 Documentation Requirements**

Appendix B provides a crosswalk implementation matrix depicting relational DOE Order 414.1D and ISO 9001:2008 criteria and requirements and which SCMS Management System Descriptions, Subject Areas, procedures and other referenced documents serve to principally implement those criteria and requirements.

### **4.2.1 General**

This QMSD includes documented statements of a Quality Policy ([Section 5.3](#)) and Quality Objectives ([Section 5.4.1](#)); the establishment of a Quality Manual (this QMSD); documented process descriptions required by ISO 9001:2008; and documents needed by the ISC (primarily SCMS), to include records, helping ensure the effective planning, operation, and control of processes.

### **4.2.2 Quality Manual**

This QMSD is the ISC's Quality Manual. The QMSD should be reviewed annually and updated as needed.

### **4.2.3 Control of Documents**

To ensure its mission is executed properly and efficiently, ISC utilizes the SC web-based management tool, [SCMS](#) as the basis for process protocols, procedures, instructions and exhibits. ISC documents are reviewed and approved for adequacy by authorized personnel prior to issue in accordance to SCMS procedures. The SCMS addresses document control for SCMS as well as control of documents/procedures promulgated at site, local, and organizational levels which affect quality.

### **4.2.4 Control of Records**

The ISC may create records to provide evidence of conformity to customer requirements. Since the primary products are services and draft reports, the customer typically retains the materials to support the product and/or accepts the final product deliverable as their own. Records are considered documents that furnish evidence of the quality and completeness of the service/product/report. Other records may include evidence of ISC reviews of the product(s) prior to the

final customer delivery. Customer records and management of these are the responsibility of the customer. ISC records, to the extent they may be retained, are maintained in an action tracking system, organizational files or by other computer assisted means.

## **5.0 MANAGEMENT RESPONSIBILITY**

### **5.1 Management Commitment**

ISC management is committed to the implementation of the QMS and continually improving its services through the quality policy and objectives stated. ISC management ensures that the quality policy and quality objectives established by the QMSD are understood and implemented. SC-OR and SC-CH management 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, and employee performance reviews. SC-OR and SC-CH personnel conduct quality reviews to assist in maintaining the resources to meet quality goals.

### **5.2 Customer Focus**

The ISC focuses on meeting customer requirements through the process of determining what customer needs are, monitoring customer satisfaction, and regular communication with the customer. Considering that the principle customers are SC Site Offices and SC-HQ, the ISC primary service mission is functional support, so frequent contact helps to ensure customer interfaces are maintained and issues are properly and mutually addressed. See the [ISC Service Plan](#).

The ISC customer service program includes 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 so improvements can be made as needed;
- Develop 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;

- Make our services and information about them easily accessible; and
- Provide mechanisms for responding effectively to customer feedback and complaints.

### 5.3 Quality Policy

The SC ISC established a Quality Policy of providing products and services that meet or exceed its customers' requirements in a safe, secure, and cost effective manner. This policy is expected to be used in all ISC activities. The ISC Quality Policy includes a commitment to comply with regulations and requirements and to continually improve processes and outcomes. The ISC ensures that the quality policy is communicated to each office's organization. The Quality Policy is reviewed at least annually during management reviews for suitability.

The Quality Policy is:

"It is the Policy of the SC ISC to set the example in meeting customer expectations and providing high quality products and services. The ISC 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 ISC services and documents are used to confirm customer satisfaction, and implementation of DOE/SC quality requirements."

### 5.4 Planning

#### 5.4.1 Quality Objectives

The ISC has established 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 System (EMS) by using SCMS; and
- Continually improve its products, processes and services.

The ISC Managers periodically review ISC performance against these quality objectives and may supplement these objectives as deemed necessary.

#### **5.4.2 Quality Management System Planning**

SC-OR and SC-CH Managers ensure that planning and implementation of the ISC QMS are effective and that customer requirements and quality objectives are met. The SC Strategic Plan is used as a guide to define the process of developing, approving, implementing, and updating both the ISC QMSD and [ISC Service Plan](#). Thus, the integrity and adequacy of the ISC QMSD is maintained as changes are planned and implemented.

### **5.5 Responsibility, Authority and Communication**

#### **5.5.1 Responsibility and Authority**

DOE, SC and the ISC identify responsibilities and authorities within various documents, including and principally the DOE Directives, SC guidance and policies, FRAMs, and SCMS. DOE allows some delegation of authority when provided formally and issued from the responsible/accountable party to the individual receiving the authority.

#### **5.5.2 Management Representative**

The SC-OR and SC-CH Managers appoint Management Representatives (MRs) to ensure the ISC QMS is established, implemented, and maintained in accordance with ISO 9001:2008 requirements. The MRs are responsible for overseeing the ISC's continuous improvement processes. These responsibilities, in part, include: analyzing, evaluating and making recommendations about the efficiency and effectiveness of programs, business and management information systems; recommending changes to existing systems and processes, or the development of new ones; serving as a focal point for cross-cutting QMSD issues; and ensuring the establishment and implementation of effective quality system assessment processes to measure federal performance.

Each MR periodically reports on the functioning of the QMS to ISC management as a basis for effecting organizational continual improvement. Reporting occurs using various mechanisms including management reviews, reports and studies, and senior staff meetings.

MRs report directly to their respective SC-OR and SC-CH Managers in all matters relating to the ISC QMS. Specific responsibilities of the MRs include:

- Presenting the review(s) results and reporting to the senior managers on the performance of the ISC QMS and any need for improvement;
- Ensuring that processes needed for the ISC QMS are established, implemented, and maintained;
- Ensuring the promotion of awareness of customer requirements throughout the organization; and
- Assuring liaison is maintained with customers and regulatory bodies on matters that relate to the ISC QMS.

The MR can delegate any duties relating to these responsibilities.

### **5.5.3 Internal Communication**

ISC management ensures that appropriate communication takes place regarding the effectiveness of the QMS through a variety of mechanisms, to include process evaluations, feedback from performance on quality objectives, management reviews, and customer feedback. The [SCMS Communications and Public Affairs MSD](#) provides direction and requirements for implementing and maintaining internal employee communication processes.

## **5.6 Management Review**

### **5.6.1 General**

The ISC QMS is subject to an annual management assessment. Reviews will be conducted in accordance with the [processes and procedures in SCMS](#) and [Section 8.0](#) of this QMSD. Records from management reviews shall be maintained in accordance with [Sections 4.2](#). Changes to the ISC QMSD will be coordinated between the ISC Managers.

### **5.6.2 Review Input**

Topics for review may include:

- a. Results of reviews and assessments;
- b. Customer feedback;
- c. Metrics, measures, product (service) conformity, and performance;
- d. Status of preventive and corrective actions;

- e. Follow-up actions from previous management reviews;
- f. Changes that could affect the QMSD; and
- g. Lessons-learned, employee suggestions, and recommendations for improvement.

### **5.6.3 Review Output**

As a follow-up to each periodic management review meeting, the MR from each office will publish a report that addresses implementation and effectiveness of the QMS, to include such subjects as recommended improvements of processes and services related to customer requirements and feedback, and any suggested resource needs. The report will also include decisions, action items, and personnel responsible for each action and follow-up to ensure timely resolution of action items.

## **6.0 RESOURCE MANAGEMENT**

### **6.1 Provision of Resources**

Resource requirements are identified by the customer and arranged between the customer and the ISC organizational entity supporting the activity and provided by Site Office Manager's organizations providing the service.

### **6.2 Human Resources**

#### **6.2.1 General**

ISC is responsible for ensuring that personnel performing activities affecting quality are competent on the basis of appropriate education, training, skills, and experience, and that appropriate records of training are maintained. DOE employees may also be subject to qualification or certification programs based upon their assigned duties and expected competencies. DOE's Technical Qualification Program (TQP), its Acquisition Career Development Program, and the Project Management Career Development Program are examples employed to meet these needs. While an ISC employee is providing support to a site, that employee is responsible to the requesting Site Manager and adhering to applicable site procedures, requirements, etc.

### 6.2.2 Competence, Awareness and Training

SC-OR and SC-CH, and occasionally in consultation with the customer's specific needs, determine the necessary competence for personnel performing work affecting their duties and the QMSD. SCMS, as well as each office, defines competence awareness and training in their respective QAPs including the common requirements listed below:

- a. Personnel Competence: the process for determining, maintaining and developing employee competency including the SC/DOE Technical Qualification Program as well as other discipline training/orientation materials.
- b. Training Fulfillment: identification of knowledge and skill gaps, and how training is identified, prioritized, and authorized.
- c. Training Effectiveness: evaluation of the effectiveness of training.
- d. Personnel Awareness: personnel awareness of the relevance and importance of their activities and the effect on quality objectives.
- e. Records Maintenance: how records of education, training, skills and experience are maintained.

All ISC employees have Individual Development Plans (IDPs) that describe the training and education needs for their work. These IDPs are tailored to the needs of the employee and the office in which the employee works. The implementation of this effort is a program management responsibility within each SC office. Training and continuing education is used to help ensure each employee maintains proficiency in their profession.

### 6.3 Infrastructure

The ISC determines the infrastructure needed to achieve conformity to service requirements. Infrastructure considerations include, as applicable:

- Buildings, workspace, and associated utilities,
- Process equipment (both hardware and software),
- Supporting services (such as communication).

Additional infrastructure items are considered through DOE's ongoing budget processes.

### 6.4 Work Environment

The ISC maintains a suitable working environment free from workplace violence and harassment in accordance with federal and office policies. SC-CH and SC-OR have each established their own program to implement the requirements of DOE O 440.1B *Worker*

## **7.0 PRODUCT REALIZATION**

### **7.1 Planning of Product Realization**

The products produced by the ISC include verbal advice and/or written documents. The SC ISC plans and develops the processes needed for product realization by:

- a. Establishing quality objectives and requirements for the product based on the customer's requests and specifications;
- b. Establishing appropriate written documents, and resources necessary for successful product development;
- c. With the customer's input and requirements, performing product verification, validation, monitoring and inspections specific to the product and by the customer; and
- d. Developing the records to provide evidence that the final ISC product is responsive to the customer's requirements.

### **7.2 Customer-Related Processes**

#### **7.2.1 Determination of Requirements Related to the Product**

SC-OR and SC-CH meet customer requirements for products and services as defined through various DOE requirements and SCMS. DOE requirements include orders, policies, notices, manuals, procurement specifications and agreements. Periodic phone calls, questionnaires and meetings are conducted to assure customer goals and needs are met in a timely and successful manner. New and revised customer requirements are received and reviewed in accordance with the SCMS Requirements Management System. This process also includes:

- 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 related to product and services; and
- d. Any additional requirements determined by SC-OR and SC-CH Managers to be necessary for successful product completion and use.

### **7.2.2 Review of Requirements Related to the Product**

When possible, prior to the commitment to provide the product/service, the cognizant ISC individual(s) reviews the request to help ensure:

- a. Product/service requirements are defined and mutually understood;
- b. Changing requirements are defined and effectively communicated; and
- c. The ISC has the capability to meet the requirements.

### **7.2.3 Customer Communication**

The cognizant ISC individual(s) determines and implements effective arrangements for determining customer satisfaction. As stated in [Section 7.2.1](#), above, various communication methods are used to assure effective interface and customer feedback/satisfaction. See [Section 8.2](#), below.

## **7.3 Design and Development**

See Section [3.4](#), Exclusions/Non-Applicability.

## **7.4 Purchasing**

See Section [3.4](#), Exclusions/Non-Applicability.

## **7.5 Production and Service Provision**

See Section [3.4](#), Exclusions/Non-Applicability.

## **7.6 Control of Monitoring and Measuring Devices**

See Section [3.4](#), Exclusions/Non-Applicability.

## **8.0 MEASUREMENT, ANALYSIS AND IMPROVEMENT**

### **8.1 General**

The ISC Managers plan and implement monitoring, measurement, analysis, and improvement process recommendations needed to demonstrate conformity of the product or service, ensure conformity of the QMS through internal audits/self-assessments, management reviews, and uses audit and management review feedback to continually improve the effectiveness of the QMS.

## **8.2 Monitoring and Measurement**

### **8.2.1 Customer Satisfaction**

ISC monitors information relating to customer perception as to whether the ISC has met customer requirements through customer feedback. ISC receives feedback by frequent contact with DOE-HQ and Site Office personnel, ISC management and staff, as well as through formal comments received on document reviews. ISC uses this information for measurement and evaluation of performance.

SCMS addresses customer satisfaction; ISC partners, SC-OR and SC-CH, have QA program descriptions that elaborate to some degree on customer satisfaction determinations.

### **8.2.2 Internal Audit – Self-Assessment**

Assessments and oversight of ISC activities are planned, performed, and documented in accordance with the SCMS Quality Assurance and Oversight Management System. Assessments are used to verify that business and process activities are effectively implemented and maintained, and comply with the applicable requirements. Assessments and oversight activities performed at customer requests are scheduled and described as discussed in Section 5 of the [ISC Service Plan](#).

Audits/self-assessments consist of verification of process requirements and assessments of ISC QMS processes; the ISC performs the internal evaluations annually. The frequency of audits factors the results of previous audits, the extent of ISC activities, and product quality indicators. The audit criteria, scope, frequency, and methods are defined in an audit/assessment plan.

SC-OR and SC-CH select internal auditors or assessors trained and/or experienced in audit processes, and may use Subject Matter Experts (SMEs), as deemed necessary. Internal auditors are assigned in a manner to assure objectivity and impartiality of the audit process. This is accomplished by assigning auditors from a different functional area than the area being audited. This method ensures that auditors do not audit their own work.

The responsibilities and requirements for planning and conducting audits, reporting results, and maintaining records are defined in SCMS. Site management and affected parties are notified of audit results.

The [SCMS Issues Management](#) Subject Area and inclusive procedure requirements are followed when corrective and/or preventive action is necessary. Follow-up verification activities are performed to record both completion and effectiveness review of implemented corrective actions.

### **8.2.3 Monitoring and Measurement of Processes**

The ISC Manager(s) applies suitable methods for monitoring and, where applicable, measuring QMS processes. The QMSD may be evaluated through a combination of management reviews, internal audits, external audits, self-assessments, independent assessments, customer feedback, and metrics. These methods demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, corrective and preventive actions are performed using the [SCMS Issues Management](#) Subject Area and inclusive procedure requirements for corrective and/or preventive action.

### **8.2.4 Monitoring and Measurement of Product**

The cognizant ISC Manager(s) monitor the quality of its products and services to verify that requirements have been met. Products and services are reviewed and documented records are maintained which provide evidence of product reviews. Product acceptance records identify the review authority responsible for the release of products or services.

## **8.3 Control of Nonconforming Product**

The products of the ISC are services and documents. These types of activities are considered unique in that they do not have to be usually, if ever, segregated from other work. The ISC maintains a continual dialog with its customers to ensure the final deliverable meets their requirements. Changes, modifications, revisions are worked directly between the ISC and the customer. Disposition of products needing changes, revisions, or corrections are addressed by taking direct action to eliminate the issue. Corrected or revised products are subject to re-review by the ISC before submittal to the customer. When a “nonconformance” or deficiency in a document or service is identified, either by the ISC or the customer, the ISC organization supporting the activity promptly works with the customer to remedy the identified situation and assures that no further work dependent on the variant product/service is performed until the condition is mutually resolved.

Any “nonconforming” process or product identified through an internal or external review/evaluation is documented in the computerized tracking system (either SMART in CH and/or ORION in OR), along with planned corrective/preventive actions, dates for completion, causes, area(s) of variance and person(s) responsible for corrective/preventive action(s). Objective evidence (usually with a copy of same electronically placed in the tracking system) is used to confirm action completeness/success.

#### **8.4 Analysis of Data**

To the extent practicable, common or specifically needed performance indicators are used within the ISC at both SC-OR and SC-CH. Data are selected, collected, and analyzed to demonstrate effectiveness and to continually improve the QMS. The analysis of data provides information relating to:

- a. Customer satisfaction;
- b. Conformity to product requirements; and
- c. Characteristics and trends of processes and products including opportunities for corrective/preventive action.

#### **8.5 Improvement**

##### **8.5.1 Continual Improvement**

The ISC is committed to continual improvement. The operating quality policy, quality objectives, assessment/audit results, analysis of data, corrective and preventive actions, and management reviews serve as a basis for the continual improvement of the QMSD.

Business and support organizations within SC-OR and SC-CH may also identify areas and processes which could benefit from corrective/preventive actions, which are focused to the individual organization.

##### **8.5.2 Corrective/Preventive Action**

ISC products are documents and services. Due to the nature of the preparation, review process, and continual communication with the customer, there is a minimized chance of a nonconforming product. Each document and service is reviewed, discussed between the provider and customer and revised until it meets all necessary and appropriate customer requirements. ISC takes action to eliminate the cause(s) of nonconformities to prevent recurrence. Corrective and preventive

action taken is appropriate to the degree and magnitude of the problem and risks encountered. Resulting corrective/preventive actions are documented by the ISC via internal tracking, e.g., ORION or SMART software tracking systems, as applicable, and as defined in SCMS.

The [SCMS Issues Management](#) Subject Area and implementing procedures provide direction and guidance in: (1) effectively managing issues or findings identified through oversight activities; (2) describing the processes required to ensure issues or findings are adequately analyzed to determine level of significance and underlying cause(s); (3) developing corrective/preventive actions and successfully implementing them in order to resolve the issue(s) or finding(s) in a timely manner and prevent recurrence; (4) requirements for tracking the status of issues or findings and corrective/preventive actions; and (5) requirements for the verification and closure of issues, findings, and corrective/preventative actions. Typically, these actions are confirmed as complete by review of objective evidence and generally included in subsequent or follow-up reviews to ascertain effectiveness.

Follow-up reviews to ensure actions are implemented and effective are performed under an internal effectiveness process or by the internal assessment process or both.

Using continual improvement tools and techniques, including ISMS considerations, corrective/preventive actions are steps that are taken to remove the cause(s) of identified or potential nonconformities or latent situations that are undesirable. The ISC corrective/preventive action process is designed to prevent the occurrence of nonconformities or situations that do not yet exist; it tries to prevent occurrence by eliminating base causes.

Collectively, the ISC uses the results of management reviews, customer feedback, lessons learned, corrective actions, data collection and evaluation, employee suggestions, and continual improvement techniques to identify potential opportunities for corrective/preventive action and mitigation of potential issues.

## **Appendix A – SCMS Management Systems**

**Office of Science Management System (SCMS)**  
**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**

**Appendix B – Crosswalk: ISO 9001:2008 x DOE Order 414.1D x SCMS**

DOE Order 414.1D Requirements	ISO 9001-2008 Criteria	Office of Science Management System (SCMS), Management System Description (MSD)/ Program Description (PD)/Subject Area (SA) and SCMS Procedure/SC Guidance
<p><b>4. Requirements</b></p> <p>a. <u>Quality Assurance Program Development and Implementation.</u> Each Departmental element and associated field element(s) must identify and assign a senior manager to have responsibility, authority, and accountability to ensure the development, implementation, assessment, maintenance, and improvement of the QAP. Using a graded approach, the organization must develop a QAP and implement the approved QAP. The QAP must do the following:</p>	<p><b>4.1 General requirements:</b> 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.</p> <p>5.4.2 Quality management system planning: Top management shall ensure that...</p> <p>b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.</p>	<ul style="list-style-type: none"> <li>• <b>MSD:</b> Office of Science Management System</li> <li>• <b>MSD:</b> Quality Assurance and Oversight               <ul style="list-style-type: none"> <li>– <b>PD:</b> SC-Wide Quality Assurance Program Description (entire document, specifically the following section: VI.A.4 Office of Science Quality Assurance Program Elements)</li> </ul> </li> </ul>
<p>4. a (1) Describe the graded approach used in the QAP.</p> <p>4. a (2) Implement QA criteria as defined in Attachment 2, as well as the requirements in Attachment 3 for all facilities, and for nuclear facilities, the requirements in Attachment 4. Note: This requires that all software meet applicable QA requirements in Attachment 2, using a graded approach.</p>	<p><b>4.1 General requirements:</b> 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.</p> <p>The organization shall</p> <p>a) determine the processes needed for the quality management system and their application throughout the organization (see ISO Standard Section 1.2),</p> <p>b) determine the sequence and interaction of these processes,</p> <p>c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective,</p> <p>d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes,</p> <p>e) monitor, measure where applicable, and analyze these processes, and</p>	<ul style="list-style-type: none"> <li>• <b>MSD:</b> Office of Science Management System</li> <li>• <b>MSD:</b> Quality Assurance and Oversight               <ul style="list-style-type: none"> <li>– <b>PD:</b> SC-Wide Quality Assurance Program Description (entire document, specifically the following sections: II Overview, III Quality Policy and Objectives, VI Performance Expectations and V Office of Science Line Management’s Responsibilities)</li> <li>– <b>SA:</b> Assessments                   <ul style="list-style-type: none"> <li>o Procedure 1. <i>Analyzing and Scheduling Assessment Needs</i></li> </ul> </li> <li>– <b>SA:</b> Office of Science (SC) Performing Planning and Evaluation                   <ul style="list-style-type: none"> <li>o Procedure 1. <i>Preparing and Reviewing the SC Annual Performance Plan</i></li> </ul> </li> </ul> </li> </ul>

DOE Order 414.1D Requirements	ISO 9001-2008 Criteria	Office of Science Management System (SCMS), Management System Description (MSD)/ Program Description (PD)/Subject Area (SA) and SCMS Procedure/SC Guidance
	<p>f) implement actions necessary to achieve planned results and continual improvement of these processes.</p> <p>These processes shall be managed by the organization in accordance with the requirements of this International Standard.</p> <p>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.</p> <p><b>5.3 Quality policy:</b> Top management shall ensure that the quality policy</p> <p>a) is appropriate to the purpose of the organization,</p> <p>b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system,</p> <p>c) provides a framework for establishing and reviewing quality objectives,</p> <p>d) is communicated and understood within the organization, and</p> <p>e) is reviewed for continuing suitability.</p>	<p>(APP)</p> <ul style="list-style-type: none"> <li>o Procedure 2. <i>Preparing and Reviewing the SC Annual Assessment Report (AAR)</i></li> </ul> <ul style="list-style-type: none"> <li>• <b>MSD:</b> Human Resources Services</li> <li>• <b>MSD:</b> Financial Assistance</li> <li>• <b>MSD:</b> Management and Operating (M&amp;O) Contracting</li> <li>• <b>MSD:</b> Non-Management and Operating (Non-M&amp;O) Contracting</li> <li>• <b>SC Guidance:</b> Annual Performance Plans and Assessment Reports</li> </ul>
<p>4. a (2) (c) Uses appropriate national or international consensus standards in whole or in part, consistent with regulatory requirements and Secretarial Officer direction. When standards do not fully address these requirements, the gaps must be addressed in the QAP. Example of currently acceptable standards include:</p> <p style="padding-left: 40px;">(1) ASME NQA-1-2008 with the NQA-1a-2009 addenda, <i>Quality Assurance</i></p>	<p>Reference: ISO 14001:2004/Cor.1:2009(E) 6 ISO 2009 – Annex A Table A.1 — Correspondence between ISO 9001:2008 and ISO 14001:2004</p> <p>Quality Management Systems — Requirements, Section <b>0.4 Compatibility with other management systems:</b> 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.</p> <p>This International Standard does not include</p>	

DOE Order 414.1D Requirements	ISO 9001-2008 Criteria	Office of Science Management System (SCMS), Management System Description (MSD)/ Program Description (PD)/Subject Area (SA) and SCMS Procedure/SC Guidance
<p><i>Requirements for Nuclear Facility Applications;</i></p> <p>(2) ANSI/ISO/ASQ Q 9001-2008, <i>Quality Management System-Requirements</i>; and,</p> <p>(3) ANSI/ASQ Z 1.13, <i>Quality Guidelines for Research.</i></p> <p>4. a (2) (d) Clearly identify which standards, or parts of the standards, are used.</p>	<p>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.</p>	
<p><b>Attachment 2: Quality Assurance Criteria</b></p> <p><b>Attachment 3: Suspect/Counterfeit Items Prevention</b></p> <p><b>Attachment 4: Safety Software Quality Assurance Requirements for Nuclear Facilities</b></p>	<p><b>7.2.1 Determination of requirements related to the product:</b> The organization shall determine</p> <p>a) requirements specified by the customer, including the requirements for delivery and post-delivery activities,</p> <p>b) requirements not stated by the customer but necessary for specified or intended use, where known,</p> <p>c) statutory and regulatory requirements applicable to the product, and</p> <p>d) any additional requirements considered necessary by the organization.</p>	<ul style="list-style-type: none"> <li>• <b>MSD:</b> Office of Science Management System (All Applicable SAs and Procedures)</li> <li>• <b>MSD:</b> Quality Assurance and Oversight <ul style="list-style-type: none"> <li>– <b>PD:</b> SC-Wide Quality Assurance Program Description</li> </ul> </li> <li>• <b>MSD:</b> Requirements Management <ul style="list-style-type: none"> <li>– <b>SA:</b> Requirements Management <ul style="list-style-type: none"> <li>○ Procedure 1. <i>Identifying and Proposing New or Revised Requirements</i></li> <li>○ Procedure 2. <i>Reviewing and Commenting on DOE Justification Memoranda, DOE Policies, and DOE Notices</i></li> <li>○ Procedure 3. <i>Reviewing and Commenting on Draft DOE Directives</i></li> <li>○ Procedure 4. <i>Processing Approved Requirements</i></li> </ul> </li> </ul> </li> </ul>
<p><b>Attachment 2: Quality Assurance Criteria</b></p> <p><b>Attachment 3: Suspect/Counterfeit Items</b></p>	<p><b>7.4.3 Verification of purchased product:</b> The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.</p>	<ul style="list-style-type: none"> <li>• <b>MSD:</b> Quality Assurance and Oversight <ul style="list-style-type: none"> <li>– <b>PD:</b> SC-Wide Quality Assurance Program Description (entire document, specifically the following</li> </ul> </li> </ul>

DOE Order 414.1D Requirements	ISO 9001-2008 Criteria	Office of Science Management System (SCMS), Management System Description (MSD)/ Program Description (PD)/Subject Area (SA) and SCMS Procedure/SC Guidance
<p><b>Prevention</b></p> <p><b>Attachment 4: Safety Software Quality Assurance Requirements for Nuclear Facilities</b></p>	<p>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.</p> <p><b>8.5.1 Continual improvement:</b> 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.</p> <p><b>8.5.2 Corrective action:</b> 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.</p> <p>A documented procedure shall be established to define requirements for...</p> <p><b>8.5.3 Preventive action:</b> 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...</p> <p><b>Note:</b> 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.</p>	<p>section: VI.B.7 DOE Criterion: Procurement)</p> <ul style="list-style-type: none"> <li>- <b>SA:</b> Issues Management <ul style="list-style-type: none"> <li>o Procedure 1. <i>Managing Issues Identified in Oversight Activities</i></li> <li>o Procedure 2. <i>Performing Causal Analysis</i></li> <li>o Procedure 3. <i>Developing, Approving, Implementing, and Verifying Preventive and Corrective Actions</i></li> <li>o Procedure 4. <i>Tracking Issues, and Preventive and Corrective Actions</i></li> <li>o Procedure 5. <i>Approving and Managing Issues and Corrective Actions Tracked in DOE Corrective Action Tracking System (CATS)</i></li> <li>o Exhibits</li> </ul> </li> <li>• <b>MSD:</b> Financial Assistance</li> <li>• <b>MSD:</b> Facilities and Infrastructure</li> <li>• <b>MSD:</b> Management and Operating (M&amp;O) Contracting</li> <li>• <b>MSD:</b> Non-Management and Operating (Non-M&amp;O) Contracting</li> </ul>
<p><b>Attachment 2: Quality Assurance Criteria</b></p> <p><b>Criterion 1 -Management/ Program.</b></p> <p>a. Establish an organizational</p>	<p><b>5.1 Management commitment:</b> 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</p>	<ul style="list-style-type: none"> <li>• <b>MSD:</b> Office of Science Management System (All applicable MSDs, SAs, and Procedures)</li> <li>• <b>MSD:</b> Quality Assurance and Oversight <ul style="list-style-type: none"> <li>- <b>PD:</b> SC-Wide Quality</li> </ul> </li> </ul>

DOE Order 414.1D Requirements	ISO 9001-2008 Criteria	Office of Science Management System (SCMS), Management System Description (MSD)/ Program Description (PD)/Subject Area (SA) and SCMS Procedure/SC Guidance
<p>structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing work.</p> <p>b. Establish management processes, including planning, scheduling, and providing resources for work.</p>	<p>resources.</p> <p><b>5.4.1 Quality objectives:</b> Top management shall ensure that quality 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.</p> <p><b>5.4.2 Quality management system planning:</b> Top management shall ensure that</p> <p>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</p> <p>b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.</p> <p><b>5.5.1 Responsibility and authority:</b> Top management shall ensure that responsibilities and authorities are defined and communicated within the organization.</p> <p><b>6.1 Provision of resources:</b> The organization shall determine and provide the resources needed</p> <p>a) to implement and maintain the quality management system and continually improve its effectiveness, and...</p>	<p>Assurance Program Description (entire document, specifically the following sections: III. Quality Policy and Objectives, VI.A.4 DOE Criterion: Documents and Records)</p> <ul style="list-style-type: none"> <li>- <b>SA:</b> Assessments <ul style="list-style-type: none"> <li>o Procedure 1. <i>Analyzing and Scheduling Assessment Needs</i></li> </ul> </li> <li>• <b>MSD:</b> Human Resources Services <ul style="list-style-type: none"> <li>- <b>SA:</b> Employee Development</li> </ul> </li> <li>• <i>Office of Science (SC) Environment, Safety and Health (ES&amp;H) Functions, Responsibilities and Authorities Manual (FRAM)</i></li> </ul>
<p><b>Attachment 2: Quality Assurance Criteria</b></p> <p><b>Criterion 2 - Management/Personnel Training and Qualification.</b></p> <p>a. Train and qualify personnel to be capable of performing assigned work.</p>	<p><b>6.2.1 General:</b> Personnel performing work affecting conformity to product requirements shall be competent on the basis of appropriate education, training, skills and experience.</p> <p><b>6.2.2 Competence, training and awareness:</b> The organization shall</p> <p>a) determine the necessary competence for personnel performing work affecting conformity to product requirements,</p>	<ul style="list-style-type: none"> <li>• <b>MSD:</b> Quality Assurance and Oversight <ul style="list-style-type: none"> <li>- <b>PD:</b> SC-Wide Quality Assurance Program Description</li> </ul> </li> <li>• <b>MSD:</b> Human Resources Services <ul style="list-style-type: none"> <li>- <b>SA:</b> Employee Development <ul style="list-style-type: none"> <li>o Procedure 1. <i>Preparing Individual Development Plans</i></li> </ul> </li> </ul> </li> </ul>

DOE Order 414.1D Requirements	ISO 9001-2008 Criteria	Office of Science Management System (SCMS), Management System Description (MSD)/ Program Description (PD)/Subject Area (SA) and SCMS Procedure/SC Guidance
<p><b>b.</b> Provide continuing training to personnel to maintain job proficiency.</p>	<p>b) where applicable, provide training or take other actions to achieve the necessary competence,</p> <p>c) evaluate the effectiveness of the actions taken,</p> <p>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</p> <p>e) maintain appropriate records of education, training, skills and experience (see ISO 9001-2008 Section 4.2.4).</p>	<ul style="list-style-type: none"> <li>o Procedure 2. <i>Processing Training Requests</i></li> <li>o Procedure 3. <i>Implementing Project Management Career Development Program Certification</i></li> <li>o Procedure 4. <i>Implementing Acquisition Career Management Program</i></li> <li>o Procedure 5. <i>Implementing Technical Qualification Program</i></li> <li>- <b>SA:</b> Organization Management – Implementation and Execution <ul style="list-style-type: none"> <li>o Procedure 1. <i>Merit Promotion</i></li> <li>o Procedure 2. <i>Developing Position Descriptions</i></li> </ul> </li> <li>- <b>SA:</b> Organization Management – Planning and Design <ul style="list-style-type: none"> <li>o Procedure 1. <i>Enter or View Information in the Department of Energy (DOE) Employee Self Service (ESS) Skills Assessment Tool</i></li> <li>o Procedure 2. <i>Complete Workforce Planning</i></li> <li>o Procedure 3. <i>Complete Staffing Plan</i></li> <li>o Procedure 4. <i>Restructure Organization</i></li> </ul> </li> </ul>
<p><b>Attachment 2: Quality Assurance Criteria</b></p> <p><b>Criterion 3 - Management/Quality Improvement.</b></p> <p>a. Establish and implement processes to detect and</p>	<p><b>5.6.1 General:</b> 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.</p>	<ul style="list-style-type: none"> <li>• <b>MSD:</b> Quality Assurance and Oversight <ul style="list-style-type: none"> <li>- <b>SA:</b> Assessments <ul style="list-style-type: none"> <li>o Procedure 1. <i>Analyzing and Scheduling Assessment Needs</i></li> <li>o Procedure 2. <i>Performing Assessments</i></li> </ul> </li> <li>- <b>SA:</b> Office of Science (SC)</li> </ul> </li> </ul>

DOE Order 414.1D Requirements	ISO 9001-2008 Criteria	Office of Science Management System (SCMS), Management System Description (MSD)/ Program Description (PD)/Subject Area (SA) and SCMS Procedure/SC Guidance
<p>prevent quality problems.</p> <p>b. Identify, control, and correct items, services, and processes that do not meet established requirements.</p> <p>c. Identify the causes of problems, and include prevention of recurrence as a part of correcting action planning.</p> <p>d. Review item characteristics, process implementation, and other quality related information to identify items, services, and processes needing improvement.</p>	<p>Records from management reviews shall be maintained (see ISO 9001-2008 Section 4.2.4).</p> <p><b>8.2.1 Customer satisfaction:</b> 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.</p> <p><b>8.2.2 Internal audit:</b> The organization shall conduct internal audits at planned intervals to determine whether the quality management system</p> <p>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</p> <p>b) is effectively implemented and maintained.</p> <p><b>8.3 Control of nonconforming product:</b> The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery...</p> <p><b>8.4 Analysis of data:</b> The organization shall determine, collect and analyze 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...</p> <p><b>8.5.1 Continual improvement:</b> The organization shall continually improve the effectiveness of the quality management system through the use of the quality policy,</p>	<p>Performing Planning and Evaluation</p> <ul style="list-style-type: none"> <li>o Procedure 1. <i>Preparing and Reviewing the SC Annual Performance Plan (APP)</i></li> <li>o Procedure 2. <i>Preparing and Reviewing the SC Annual Assessment Report (AAR)</i></li> </ul> <p>– <b>SA:</b> Performance Trending</p> <ul style="list-style-type: none"> <li>o Procedure 1. <i>Establishing and Implementing a Performance Trending Process</i></li> <li>o Procedure 2. <i>Analyzing, Charting, and Reviewing Performance Trends</i></li> </ul> <p>– <b>SA:</b> Issues Management</p> <ul style="list-style-type: none"> <li>o Procedure 1. <i>Managing Issues Identified in Oversight Activities</i></li> <li>o Procedure 2. <i>Performing Causal Analysis</i></li> <li>o Procedure 3. <i>Developing, Approving, Implementing, and Verifying Preventive and Corrective Actions</i></li> <li>o Procedure 4. <i>Tracking Issues, and Preventive and Corrective Actions</i></li> <li>o Procedure 5. <i>Approving and Managing Issues and Corrective Actions Tracked in DOE Corrective Action Tracking System (CATS)</i></li> </ul>

DOE Order 414.1D Requirements	ISO 9001-2008 Criteria	Office of Science Management System (SCMS), Management System Description (MSD)/ Program Description (PD)/Subject Area (SA) and SCMS Procedure/SC Guidance
	<p>quality objectives, audit results, analysis of data, corrective and preventive actions and management review.</p> <p><b>8.5.2 Corrective action:</b> 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...</p> <p><b>8.5.3 Preventive action:</b> 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...</p>	
<p><b>Attachment 2: Quality Assurance Criteria</b></p> <p><b>Criterion 4 - Management/Documents and Records.</b></p> <p>a. Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design.</p> <p>b. Specify, prepare, review, approve, and maintain records.</p>	<p><b>4.2.3 Control of documents:</b> 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...</p> <p><b>4.2.4 Control of records:</b> Records established to provide evidence of conformity to requirements and of the effective operation of the quality management system shall be controlled.</p> <p>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.</p>	<ul style="list-style-type: none"> <li>• <b>MSD:</b> Quality Assurance and Oversight <ul style="list-style-type: none"> <li>– <b>PD:</b> SC-Wide Quality Assurance Program Description (Section VI.A.4 DOE Criterion: Documents and Records)</li> </ul> </li> <li>• <b>MSD:</b> Requirements Management <ul style="list-style-type: none"> <li>– <b>SA:</b> Document Control Management <ul style="list-style-type: none"> <li>○ Procedure 1. <i>Identifying Controlled Documents</i></li> <li>○ Procedure 2. <i>Preparing and Submitting SCMS Documents</i></li> <li>○ Procedure 3. <i>Reviewing SCMS Documents</i></li> <li>○ Procedure 4. <i>Approving SCMS Documents</i></li> <li>○ Procedure 5. <i>Canceling an SCMS Document</i></li> <li>○ Procedure 6. <i>Annual Review of SCMS Management System Documents</i></li> <li>○ Procedure 7. <i>Control of</i></li> </ul> </li> </ul> </li> </ul>

DOE Order 414.1D Requirements	ISO 9001-2008 Criteria	Office of Science Management System (SCMS), Management System Description (MSD)/ Program Description (PD)/Subject Area (SA) and SCMS Procedure/SC Guidance
		<p><i>Non-SCMS Documents</i></p> <ul style="list-style-type: none"> <li>• <b>MSD:</b> Records Management <ul style="list-style-type: none"> <li>– <b>SA:</b> Records Management <ul style="list-style-type: none"> <li>○ Procedure 1. <i>Creating and Identifying Federal Records</i></li> <li>○ <u>Procedure 2. Ensuring the Adequacy of Documentation</u></li> <li>○ Procedure 3. <i>Conducting a Records Inventory</i></li> <li>○ <u>Procedure 4. Developing New Records Disposition Schedules</u></li> <li>○ Procedure 5. <i>Maintaining Records Efficiently</i></li> <li>○ <u>Procedure 6. Using Records</u></li> <li>○ <u>Procedure 7. Transferring and Destroying Records</u></li> <li>○ <u>Procedure 8. Managing Vital Records</u></li> <li>○ <u>Procedure 9. Coordinating Disaster Planning and Recovery</u></li> </ul> </li> </ul> </li> </ul>
<p><b>Attachment 2: Quality Assurance Criteria</b></p> <p><b>Criterion 5 - Performance/Work Processes.</b></p> <p>a. Perform work consistent with technical standards, administrative controls, and other hazard controls adopted to meet regulatory or contract requirements using approved instructions, procedures, or other appropriate means.</p> <p>b. Identify and control items to ensure their proper use.</p> <p>c. Maintain items to prevent damage, loss, or</p>	<p><b>4.2.3 Control of documents:</b> 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...</p> <p><b>4.2.4 Control of records:</b> Records established to provide evidence of conformity to requirements and of the effective operation of the quality management system shall be controlled.</p> <p>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.</p> <p><b>7.5.1 Control of production and service provision:</b> The organization shall plan and</p>	<ul style="list-style-type: none"> <li>• <b>MSD:</b> Records Management (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)</li> <li>• <b>MSD:</b> Office of SCience Management System</li> <li>• <b>MSD:</b> Quality Assurance and Oversight <ul style="list-style-type: none"> <li>– <b>PD:</b> SC-Wide Quality Assurance Program Description (Section VI.A. 4 DOE Criterion: Documents and Records)</li> <li>– <b>PD:</b> Line Management Oversight</li> </ul> </li> <li>• <b>MSD:</b> Management and Operating (M&amp;O) Contracting</li> <li>• <b>MSD:</b> Non-Management and</li> </ul>

DOE Order 414.1D Requirements	ISO 9001-2008 Criteria	Office of Science Management System (SCMS), Management System Description (MSD)/ Program Description (PD)/Subject Area (SA) and SCMS Procedure/SC Guidance
<p>deterioration.</p> <p>d. Calibrate and maintain equipment used for process monitoring or data collection.</p>	<p>carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable,</p> <p>a) the availability of information that describes the characteristics of the product,</p> <p>b) the availability of work instructions, as necessary,</p> <p>c) the use of suitable equipment,</p> <p>d) the availability and use of monitoring and measuring equipment,</p> <p>e) the implementation of monitoring and measurement, and</p> <p>f) the implementation of product release, delivery and post-delivery activities.</p> <p><b>7.5.3 Identification and traceability:</b> 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).</p> <p><b>7.5.5 Preservation of product:</b> 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.</p> <p><b>7.6 Control of monitoring and measuring equipment:</b> 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</p>	<p>Operating (Non-M&amp;O) Contracting</p> <ul style="list-style-type: none"> <li>• <b>MSD:</b> Project Management</li> <li>• Office of Science Strategic Plan</li> </ul>

DOE Order 414.1D Requirements	ISO 9001-2008 Criteria	Office of Science Management System (SCMS), Management System Description (MSD)/ Program Description (PD)/Subject Area (SA) and SCMS Procedure/SC Guidance
	<p>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.</p> <p>Where necessary to ensure valid results, measuring equipment shall</p> <ul style="list-style-type: none"> <li>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);</li> <li>b) be adjusted or readjusted as necessary;</li> <li>c) have identification in order to determine its calibration status;</li> <li>d) be safeguarded from adjustments that would invalidate the measurement result;</li> <li>e) be protected from damage and deterioration during handling, maintenance and storage.</li> </ul> <p>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.</p>	
<b>Attachment 2: Quality Assurance Criteria</b>	<b>7.2.1 Determination of requirements related to the product:</b> The organization shall determine	<ul style="list-style-type: none"> <li>• <b>MSD:</b> Office of Science Management System</li> <li>• <b>MSD:</b> Quality Assurance and</li> </ul>

DOE Order 414.1D Requirements	ISO 9001-2008 Criteria	Office of Science Management System (SCMS), Management System Description (MSD)/ Program Description (PD)/Subject Area (SA) and SCMS Procedure/SC Guidance
<p><b>Criterion 6 - Performance/Design.</b></p> <p>a. Design items and processes using sound engineering/scientific principles and appropriate standards.</p> <p>b. Incorporate applicable requirements and design bases in design work and design changes.</p> <p>c. Identify and control design interfaces.</p> <p>d. Verify or validate the adequacy of design products using individuals or groups other than those who performed the work.</p> <p>e. Verify or validate work before approval and implementation of the design.</p>	<p>a) requirements specified by the customer, including the requirements for delivery and post-delivery activities,</p> <p>b) requirements not stated by the customer but necessary for specified or intended use, where known,</p> <p>c) statutory and regulatory requirements applicable to the product, and</p> <p>d) any additional requirements considered necessary by the organization.</p> <p><b>7.3.1 Design and development planning:</b> The organization shall plan and control the design and development of product. During the design and development planning, the organization shall determine</p> <p>a) the design and development stages,</p> <p>b) the review, verification and validation that are appropriate to each design and development stage, and</p> <p>c) the responsibilities and authorities for design and development.</p> <p>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.</p> <p><b>7.3.2 Design and development inputs:</b> Inputs relating to product requirements shall be determined and records maintained (see ISO 9001-2008 Section 4.2.4). These inputs shall include</p> <p>a) functional and performance requirements,</p> <p>b) applicable statutory and regulatory requirements,</p> <p>c) where applicable, information derived from previous similar designs, and</p> <p>d) other requirements essential for design</p>	<p>Oversight</p> <ul style="list-style-type: none"> <li>- <b>PD:</b> SC-Wide Quality Assurance Program Description (Section VI.B.7 DOE Criterion: Procurement)</li> <li>• <b>MSD:</b> Requirements Management <ul style="list-style-type: none"> <li>- <b>SA:</b> Requirements Management <ul style="list-style-type: none"> <li>o Procedure 1. <i>Identifying and Proposing New or Revised Requirements</i></li> <li>o Procedure 2. <i>Reviewing and Commenting on DOE Justification Memoranda, DOE Policies, and DOE Notices</i></li> <li>o Procedure 3. <i>Reviewing and Commenting on Draft DOE Directives</i></li> <li>o Procedure 4. <i>Processing Approved Requirements</i></li> </ul> </li> </ul> </li> <li>• <b>MSD:</b> Financial Assistance</li> <li>• <b>MSD:</b> Facilities and Infrastructure</li> <li>• <b>MSD:</b> Management and Operating (M&amp;O) Contracting</li> <li>• <b>MSD:</b> Non-Management and Operating (Non-M&amp;O) Contracting</li> </ul>

DOE Order 414.1D Requirements	ISO 9001-2008 Criteria	Office of Science Management System (SCMS), Management System Description (MSD)/ Program Description (PD)/Subject Area (SA) and SCMS Procedure/SC Guidance
	<p>and development.</p> <p>The inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.</p> <p><b>7.3.6 Design and development validation:</b> 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 and any necessary actions shall be maintained (see ISO 9001-2008 Section 4.2.4).</p> <p><b>7.4.1 Purchasing process:</b> 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).</p> <p><b>7.4.1 Purchasing information:</b> Purchasing information shall describe the product to be purchased, including, where appropriate,</p> <ul style="list-style-type: none"> <li>a) requirements for approval of product, procedures, processes, and equipment,</li> <li>b) requirements for qualification of personnel, and</li> </ul>	

DOE Order 414.1D Requirements	ISO 9001-2008 Criteria	Office of Science Management System (SCMS), Management System Description (MSD)/ Program Description (PD)/Subject Area (SA) and SCMS Procedure/SC Guidance
	<p>c) quality management system requirements.</p> <p>The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.</p> <p><b>7.4.3 Verification of purchased product:</b> 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.</p>	
<p><b>Attachment 2: Quality Assurance Criteria</b></p> <p><b>Criterion 7 - Performance/Procurement.</b></p> <p>a. Procure items and services that meet established requirements and perform as specified.</p> <p>b. Evaluate and select prospective suppliers on the basis of specified criteria.</p> <p>c. Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services.</p>	<p><b>7.4.1 Purchasing process:</b> 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).</p> <p><b>7.4.2 Purchasing information:</b> Purchasing information shall describe the product to be purchased, including, where appropriate,</p> <p>a) requirements for approval of product, procedures, processes, and equipment,</p> <p>b) requirements for qualification of personnel, and</p> <p>c) quality management system</p>	<ul style="list-style-type: none"> <li>• <b>MSD:</b> Quality Assurance and Oversight <ul style="list-style-type: none"> <li>– <b>PD:</b> SC-Wide Quality Assurance Program Description (Section VI.B.7 DOE Criterion: Procurement)</li> </ul> </li> <li>• <b>MSD:</b> Financial Assistance (All Procedures)</li> <li>• <b>MSD:</b> Facilities and Infrastructure (All Procedures)</li> <li>• <b>MSD:</b> Management and Operating (M&amp;O) Contracting (All Procedures)</li> <li>• <b>MSD:</b> Non-Management and Operating (Non-M&amp;O) Contracting (All Procedures)</li> </ul>

DOE Order 414.1D Requirements	ISO 9001-2008 Criteria	Office of Science Management System (SCMS), Management System Description (MSD)/ Program Description (PD)/Subject Area (SA) and SCMS Procedure/SC Guidance
	<p>requirements.</p> <p>The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.</p> <p><b>7.4.3 Verification of purchased product:</b> 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.</p>	
<p><b>Attachment 2: Quality Assurance Criteria</b></p> <p><b>Criterion 8 - Performance/Inspection and Acceptance Testing.</b></p> <p>a. Inspect and test specified items, services, and processes using established acceptance and performance criteria.</p> <p>b. Calibrate and maintain equipment used for inspections and tests.</p>	<p><b>7.3.3 Design and development outputs:</b> 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...</p> <p>c) contain or reference product acceptance criteria, and</p> <p>d) specify the characteristics of the product that are essential for its safe and proper use.</p> <p><b>7.6 Control of monitoring and measuring equipment:</b> 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.</p> <p>Where necessary to ensure valid results, measuring equipment shall</p> <p>a) be calibrated or verified, or both, at</p>	<ul style="list-style-type: none"> <li>• <b>MSD:</b> Quality Assurance and Oversight <ul style="list-style-type: none"> <li>– <b>SA:</b> Assessments <ul style="list-style-type: none"> <li>○ Procedure 1. <i>Analyzing and Scheduling Assessment Needs</i></li> <li>○ Procedure 2. <i>Performing Assessments</i></li> </ul> </li> <li>– <b>SA:</b> Issues Management (All Procedures and Exhibits)</li> </ul> </li> </ul>

DOE Order 414.1D Requirements	ISO 9001-2008 Criteria	Office of Science Management System (SCMS), Management System Description (MSD)/ Program Description (PD)/Subject Area (SA) and SCMS Procedure/SC Guidance
	<p>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);</p> <ul style="list-style-type: none"> <li>b) be adjusted or readjusted as necessary;</li> <li>c) have identification in order to determine its calibration status;</li> <li>d) be safeguarded from adjustments that would invalidate the measurement result;</li> <li>e) be protected from damage and deterioration during handling, maintenance, and storage.</li> </ul> <p>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.</p> <p><b>8.1 General:</b> The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed</p> <ul style="list-style-type: none"> <li>a) to demonstrate conformity to product requirements,</li> <li>b) to ensure conformity of the quality management system, and</li> <li>c) to continually improve the effectiveness of the quality management system.</li> </ul> <p>This shall include determination of applicable methods, including statistical techniques, and</p>	

DOE Order 414.1D Requirements	ISO 9001-2008 Criteria	Office of Science Management System (SCMS), Management System Description (MSD)/ Program Description (PD)/Subject Area (SA) and SCMS Procedure/SC Guidance
	<p>the extent of their use.</p> <p><b>8.2.1 Customer satisfaction:</b> 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.</p> <p><b>8.2.3 Monitoring and measurement of processes:</b> The organization shall apply suitable methods for monitoring and, where applicable, 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, to ensure conformity of the product.</p> <p><b>8.2.4 Monitoring and measurement of product:</b> 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.</p>	
<p><b>Attachment 2: Quality Assurance Criteria</b></p> <p><b>Criterion 9 -</b></p>	<p><b>5.1 Management commitment:</b> Top management shall provide evidence of its commitment to the development and implementation of the quality management</p>	<ul style="list-style-type: none"> <li>• <b>MSD:</b> Office of Science Management System</li> <li>• <b>MSD:</b> Quality Assurance and Oversight</li> </ul>

DOE Order 414.1D Requirements	ISO 9001-2008 Criteria	Office of Science Management System (SCMS), Management System Description (MSD)/ Program Description (PD)/Subject Area (SA) and SCMS Procedure/SC Guidance
<p><b>Assessment/Management Assessment.</b></p> <p>Ensure that managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives.</p>	<p>system and continually improving its effectiveness by...</p> <p>e) ensuring the availability of resources.</p> <p><b>5.5.2 Management representative:</b> Top management shall appoint a member of the organization's management who, irrespective of other responsibilities, shall have responsibility and authority that includes...</p> <p>b) reporting to top management on the performance of the quality management system and any need for improvement, and...</p> <p><b>5.6.1 General:</b> 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...</p> <p><b>8.2.1 Customer satisfaction:</b> 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.</p> <p><b>8.4 Analysis of data:</b> The organization shall determine, collect and analyze 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.</p> <p>The analysis of data shall provide information relating to:</p> <p>a) customer satisfaction (see ISO 9001-2008</p>	<ul style="list-style-type: none"> <li>- <b>PD:</b> SC-Wide Quality Assurance Program Description (Section III Quality Policy and Objectives and V Office of Science Line Management's Responsibilities)</li> <li>- <b>SA:</b> Assessments (All Procedures and Exhibits)</li> <li>- <b>SA:</b> Performance Planning and Evaluation <ul style="list-style-type: none"> <li>o Procedure 1. <i>Preparing and Reviewing the SC Annual Performance Plan (APP)</i></li> <li>o Procedure 2. <i>Preparing and Reviewing the SC Annual Assessment Report (AAR)</i></li> </ul> </li> <li>- <b>SA:</b> Performance Trending <ul style="list-style-type: none"> <li>o Procedure 1. <i>Establishing and Implementing a Performance Trending Process</i></li> <li>o Procedure 2. <i>Analyzing, Charting, and Reviewing Performance Trends</i></li> </ul> </li> <li>- <b>SA:</b> Issues Management <ul style="list-style-type: none"> <li>o Procedure 1. <i>Managing Issues Identified in Oversight Activities</i></li> <li>o Procedure 2. <i>Performing Causal Analysis</i></li> <li>o Procedure 3. <i>Developing, Approving, Implementing, and Verifying Preventive and Corrective Actions</i></li> <li>o Procedure 4. <i>Tracking Issues, and Preventive and Corrective Actions</i></li> <li>o Procedure 5. <i>Approving and Managing Issues and Corrective Actions Tracked in DOE Corrective Action Tracking System (CATS)</i></li> </ul> </li> </ul>

DOE Order 414.1D Requirements	ISO 9001-2008 Criteria	Office of Science Management System (SCMS), Management System Description (MSD)/ Program Description (PD)/Subject Area (SA) and SCMS Procedure/SC Guidance
	<p>Section 8.2.1),</p> <p>b) conformity to product requirements (see ISO 9001-2008 Section 8.2.4),</p> <p>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</p> <p>d) suppliers (see ISO 9001-2008 Section 7.4).</p> <p><b>8.5.1 Continual improvement:</b> 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.</p> <p><b>8.5.2 Corrective action:</b> 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...</p> <p><b>8.5.3 Preventive action:</b> 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...</p>	<ul style="list-style-type: none"> <li>• <b>MSD:</b> Human Resources Services <ul style="list-style-type: none"> <li>– <b>SA:</b> Employee Development</li> </ul> </li> <li>• <i>Office of Science (SC) Environment, Safety and Health (ES&amp;H) Functions, Responsibilities and Authorities Manual (FRAM) Section 2.0 Responsibilities</i></li> </ul>
<p><b>Attachment 2: Quality Assurance Criteria</b></p> <p><b>Criterion 10 - Assessment/Independent Assessment.</b></p> <p>a. Plan and conduct independent assessments to measure item and service quality, to measure the</p>	<p><b>8.2.2 Internal audit:</b> The organization shall conduct internal audits at planned intervals to determine whether the quality management system</p> <p>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</p>	<ul style="list-style-type: none"> <li>• <b>MSD:</b> Office of SCience Management System</li> <li>• <b>MSD:</b> Quality Assurance and Oversight <ul style="list-style-type: none"> <li>– <b>PD:</b> SC-Wide Quality Assurance Program Description (Section VI.A. 2 Staff Training and Qualifications)</li> <li>– <b>SA:</b> Assessments (All Procedures and Exhibits)</li> </ul> </li> </ul>

DOE Order 414.1D Requirements	ISO 9001-2008 Criteria	Office of Science Management System (SCMS), Management System Description (MSD)/ Program Description (PD)/Subject Area (SA) and SCMS Procedure/SC Guidance
<p>adequacy of work performance, and to promote improvement.</p> <p>b. Establish sufficient authority and freedom from line management for independent assessment teams.</p> <p>c. Ensure persons who perform independent assessments are technically qualified and knowledgeable in the areas to be assessed.</p>	<p>b) is effectively implemented and maintained.</p> <p>An audit program 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).</p> <p>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.</p> <p>Follow-up activities shall include the verification of the actions taken and the reporting of verification results (see ISO 9001-2008 Section 8.5.2).</p> <p><b>6.2.2 Competence, training and awareness:</b> The organization shall</p> <p>a) determine the necessary competence for personnel performing work affecting conformity to product requirements,</p> <p>b) where applicable, provide training or take other actions to achieve the necessary competence,</p> <p>c) evaluate the effectiveness of the actions taken,</p> <p>d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the</p>	<ul style="list-style-type: none"> <li>-</li> <li>o Procedure 1. <i>Analyzing and Scheduling Assessment Needs</i></li> <li>o Procedure 2. <i>Performing Assessments</i></li> <li>- <b>SA:</b> Issues Management <ul style="list-style-type: none"> <li>o Procedure 3. <i>Developing, Approving, Implementing, and Verifying Preventive and Corrective Actions</i></li> <li>o Procedure 4. <i>Tracking Issues, and Preventive and Corrective Actions</i></li> <li>o Procedure 5. <i>Approving and Managing Issues and Corrective Actions Tracked in DOE Corrective Action Tracking System (CATS)</i></li> </ul> </li> <li>• <b>MSD:</b> Human Resources Services <ul style="list-style-type: none"> <li>- <b>SA:</b> Employee Development <ul style="list-style-type: none"> <li>o Procedure 1. <i>Preparing Individual Development Plans</i></li> <li>o Procedure 2. <i>Processing Training Requests</i></li> <li>o Procedure 3. <i>Implementing Project Management Career Development Program Certification</i></li> <li>o Procedure 4. <i>Implementing Acquisition Career Management Program</i></li> <li>o Procedure 5. <i>Implementing Technical Qualification Program</i></li> </ul> </li> <li>- <b>SA:</b> Organization Management – Implementation and Execution <ul style="list-style-type: none"> <li>o Procedure 1. <i>Merit Promotion</i></li> <li>o Procedure 2. <i>Developing Position Descriptions</i></li> </ul> </li> <li>- <b>SA:</b> Organization Management – Planning and</li> </ul> </li> </ul>

DOE Order 414.1D Requirements	ISO 9001-2008 Criteria	Office of Science Management System (SCMS), Management System Description (MSD)/ Program Description (PD)/Subject Area (SA) and SCMS Procedure/SC Guidance
	achievement of the quality objectives, and e) maintain appropriate records of education, training, skills and experience (see ISO 9001-2008 Section 4.2.4).	Design <ul style="list-style-type: none"> <li>○ Procedure 1. <i>Enter or View Information in the Department of Energy (DOE) Employee Self Service (ESS) Skills Assessment Tool</i></li> <li>○ Procedure 2. <i>Complete Workforce Planning</i></li> <li>○ Procedure 3. <i>Complete Staffing Plan</i></li> <li>○ Procedure 4. <i>Restructure Organization</i></li> </ul>
<b>Attachment 3: Suspect/Counterfeit Items Prevention</b>	<b>Note:</b> 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.	
<b>Attachment 4: Safety Software Quality Assurance Requirements for Nuclear Facilities</b>		<b>MSD:</b> Information Technology