



U.S. Department of Energy SLAC Site Office

Quality Assurance Program Description

Revision 1

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Quality Assurance Program Description

REVISION LOG

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ACRONYMS

ACMP	Acquisition Career Management Program
CATS	Corrective Action Tracking System
CBO	Contracts and Business Operations
DDFO	Deputy Director for Field Operations for the Office of Science
DEAR	Department of Energy Acquisition Regulation
DOE	U. S. Department of Energy
EFO	ES&H and Facility Operation
FAR	Federal Acquisition Regulation
HSS	DOE Office of Health, Safety and Security
ISEMS	Integrated Safety and Environmental Management
ISM	Integrated Safety Management
ISMS	Integrated Safety Management System
LL	Lessons Learned
MOU	Memorandums of Understanding
OPEX	Operating Experience
ORION	Oak Ridge Issues, Open Items, and Nonconformances System
PEMP	Performance Measurement and Evaluation Plan
QA	Quality Assurance
QAP	Quality Assurance Program
QAPD	Quality Assurance Program Description
SA	Service Agreements
SCMS	Office of SCience Management System
SLAC	SLAC National Accelerator Laboratory
SOP	Standard Operating Procedure
SSO	SLAC Site Office
STD	Standard

Quality Assurance Program Description

DEFINITIONS

APPARENT CAUSE(s) – The most probable cause(s) of an event or condition.

ASSESSMENT – [Also referred to as a “review,”] an assessment is the act of reviewing, evaluating, inspecting, testing, checking, performing surveillance, auditing, or otherwise determining and documenting whether items, processes, or systems meet specified requirements and are performing effectively. ([Department of Energy \[DOE\] O 414.1C](#))

DIRECTIVE – Written information originated by DOE Headquarters or SSO that assigns responsibilities or establishes requirements. The Headquarters directives include DOE Policies, Orders, Notices, Manuals, Guides, Technical Standards, and Secretary of Energy Notices. SSO directives include Orders, Chapters, Notices, Manuals, and Guides.

DOCUMENT – Any written or pictorial information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results. A document is not considered to be a quality assurance record as defined in this document.

DOE OVERSIGHT – “DOE Oversight” encompasses activities performed by DOE organizations to determine whether Federal and contractor programs and management systems, including assurance and oversight systems, are performing effectively and/or complying with DOE requirements. Oversight programs include operational awareness activities, on-site reviews, assessments, self-assessments, performance evaluations, and other activities that involve evaluation of contractor organizations and Federal organizations that manage or operate DOE sites, facilities, or operations. ([DOE O 226.1A](#))

EVIDENCE – Closure documentation demonstrates the issue has been completed or direct observation.

FINDING – A noncompliance with procedural, contractual or regulatory requirements identified during an assessment. Findings are used to indicate significant inadequacies or safety issues that warrant a high level of attention on the part of management. Findings 1 and 2 (see definitions) require resolution by management through a formal corrective action (CA) process. ([DOE O 470.2B](#))

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GRADED APPROACH – The process by which the levels of detail in an analysis or documentation and/or the actions necessary to comply with requirements are commensurate with all of the following:

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

INTEGRATED ASSESSMENT SCHEDULE – An annual schedule used by SSO management to plan assessment activity. The Annual Integrated Assessment Schedule flows from the Three-year Assessment Plan, is the detailed list of upcoming assessments for the FY, and provides more detail than the plan (i.e., the SSO Team owning the assessment, subject, assessment type, assessment category, Team lead, driver, and review dates). The Integrated Assessment Schedule is comprised of those assessments that meet the criteria established by senior management and assist in compliance with Criteria 9 and 10 of [DOE O 414.1C](#), *Quality Assurance*.
(*SSO Annual Performance Plan, SSO Assessment Planning, SSO Operational Awareness*)

ITEM – An all-inclusive term used in the place of any of the following: appurtenance, assembly, component, equipment, material, module, part, software, structure, subassembly, subsystem, system, unit, or support system.

ORION – ORION stands for “Oak Ridge Issues, Open Items, and Nonconformances System” database. The corrective action database utilized by the SSO to track assessments, findings, observations, concerns from surveillances and walkthroughs, corrective action plans, reports, issues, actions, quality assurance related items, and lessons learned.

PROCEDURE – A document that specifies or prescribes how an activity is to be performed.

PROCESS – A series of actions resulting in a product or service to meet a customer’s requirements.

PROCUREMENT DOCUMENT – A business instrument intended to formalize agreements between a purchaser and a seller. Purchase requisitions, purchase orders, drawings, contracts, specifications, or instructions are used to define the requirements for a purchase.

QUALIFICATION – The knowledge and skills gained through education, learning activities, and experience that, when measured against established qualification standards, ensure that an individual is competent to perform the required functions, duties, and responsibilities of his or her job position.

QUALITY – The condition achieved when an item, service, or process meets or exceeds the user’s requirements and expectations.

Quality Assurance Program Description

QUALITY ASSURANCE – All those actions that provide confidence that quality is achieved.

QUALITY ASSURANCE PROGRAM (QAP) – The overall program (management system) established to assign responsibilities and authorities, define policies and requirements, and provide for the performance and assessment of work.

QUALITY ASSURANCE RECORD – QA records furnish objective evidence of the quality of items, activities, and processes that affect quality. QA records are established based on regulatory and environmental requirements and the level of risk established for the item, activity, or process to which the records apply.

RECORD – A completed document or other media that provides objective evidence of a service or process.

ROOT CAUSE – The fundamental reason which, if corrected, will prevent recurrence of these and similar occurrences throughout the facility or organization. ([DOE G 225.1A-1](#))

ROOT CAUSE ANALYSIS – Analysis of a condition or event that results in an accurate description of how and why the condition or event was produced.

SERVICE – The performance of work such as design, construction, fabrication, inspection, nondestructive examination/testing, environmental qualification, equipment qualification, repair, installation, or the like.

SCIENCE MANAGEMENT ACTION AND RECORD TRACKING (SMART) – SSO's former database used to track assessments, walkthroughs, findings, actions, and closure evidence.

SOFTWARE – Computer programs and associated documentation and data pertaining to the operation of a computer system.

SUPPLIER – Any individual or organization that furnishes services in accordance with a procurement document. This is an all-inclusive term that is used in place of any of the following: vendor, seller, contractor, subcontractor, fabricator, consultant, and their sub-tier levels.

TRAINING – The process of providing for/making available to an employee and placing or enrolling the employee in a planned, prepared, and coordinated program, course, curriculum, subject, system, or routine of instruction or education in scientific, professional, technical, mechanical, trade, clerical, fiscal, administrative, or other field that will improve the individual's and organization's performance and assist in achieving DOE's missions and performance goals.

WORK – The process of performing a defined task or activity; for example, SSO work is primarily administration which includes: contracting, auditing, assessing, oversight, payment of invoices, budget execution, etc.

Quality Assurance Program Description

I. PURPOSE AND SCOPE

The purpose of this SLAC Site Office (SSO) Quality Assurance Program Description (QAPD) is to describe the management systems that SSO uses to ensure that SSO's missions, policies, and objectives are integrated into standard business practices and work processes for Federal operations, DOE oversight, and contractor oversight. The goal of the Quality Assurance Program (QAP) is to achieve continuous improvement while satisfying customer requirements in a cost-effective manner. The scope of SSO's QAPD includes the implementation requirements of DOE O 414.1C, *Quality Assurance*, 10 CFR 830 Subpart A, *Quality Assurance Requirements*, and incorporates the requirements of Office of Science Management System (SCMS) *Quality Assurance and Oversight, Review and Approval of DOE and Contractor Quality Assurance Program Descriptions (QAPDs) and Evaluation of QAPD Implementation Effectiveness, Procedure 1, Reviewing and Approving Quality Assessment Program Descriptions (QAPDs)*. SSO management has ultimate responsibility for implementing the QAP.

II. QUALITY ASSURANCE PROGRAM CRITERIA**A. PROGRAM****1. Requirements**

A written QAP must be developed, implemented, and maintained. The QAP must describe the organizational structure, functional responsibilities, levels of authority, and interfaces for those who are managing, performing, and assessing the work. The QAP must describe the management processes, including planning, scheduling, and resource considerations. The QAP integrates quality management system requirements and the suspect/counterfeit items prevention process as defined in this document with other quality or management system requirements in DOE directives and external requirements.

2. Description

- a. The SSO QAP is a broad-based management system which ensures that SSO's missions, policies, and objectives are integrated into standard work processes. The QAP applies to every SSO organization and employee.
- b. SSO's management system documents include the following:
 - SSO Annual Performance Plan
 - SSO Contract Management Plan
 - SSO Level III Functions, Responsibilities, and Authorities Manual
 - SSO Integrated Safety and Environmental Management System Description
 - SSO Environment, Safety and Health Program Plan
 - SSO Assessment Program
 - SSO Emergency Management Plan
 - SSO Continuity of Operations Plan

The levels of authority and interfaces are prescribed in these approved documents (e.g., SSO's implementing procedures).

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- c. SSO's missions and objectives are accomplished and its policies are implemented in a reasonable, practical, and cost-effective manner. Technical standards that are developed or adopted from commercial practice are used, wherever applicable, to implement the QAP. Employees are provided with the necessary information, tools, support, and encouragement to perform their tasks in a quality manner. In addition, employees are provided the authority to make decisions at the lowest effectual level where technical expertise is localized. By empowering employees with authority, they are encouraged to look for better, safer, and more efficient ways of accomplishing their work.
- d. Not all items, services, and processes have the same effect on safety and reliability. The rigor with which the QAP is applied is determined using a graded approach. The graded approach focuses on plans and schedules and considers cost impacts using the following criteria:
 - the relative importance to safety, safeguards, and security;
 - the magnitude of any hazard or risk involved;
 - the life-cycle stage of a facility or activity;
 - impact/consequences on the programmatic mission of a facility
 - the particular characteristics of a facility or activity;
 - the nuclear safety classification or hazard category of the item or activity;
 - adequacy of existing safety documentation;
 - the relative importance of radiological and non-radiological hazards;
 - complexity of products or services involved;
 - performance history of a facility or activity; and
 - any other relevant factors.
- e. Environment, safety, health, security, and quality requirements are integrated at all levels of activities.

3. Implementation

- a. **Organizational Structure** – SSO's organization is described in SSO Annual Performance Plan and the SSO Level III Functions, Responsibilities, and Authorities Manual.
- b. **Organizational Interfaces** – Interfaces between SSO and its main contractors are defined in the respective contracts. Interfaces with Office of Science and other DOE organizations and Site Offices are documented in Memorandums of Understanding (MOU), Service Arrangements (SA), etc., and SSO retains copies of these documents in central files. The Contract and Business Operations Team retains the official contract files and agreements signed by SSO Contracting Officer(s).

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- c. **Management Systems** – The SSO QAP integrates several management systems such as the Integrated Safety Management System (ISMS) and the Environmental Management System (EMS). The SSO QAP uses ANSI/ISO/ASQ Q9001-2000, *Quality Management System - Requirements*, and ANSI/ISO/ASQ E14001-2004, *Environmental Management Systems - Requirements*, as consensus standards. A crosswalk between DOE O 414.1C, *Quality Assurance*, and the ISO 9001-2000 with SSO Implementing Mechanisms is documented in Appendix A, “Crosswalk of DOE O 414.1C and ISO 9001-2000. A crosswalk of the DOE O 414.1C criteria and the Integrated Safety Management (ISM) guiding principles and core functions are found in Appendix B, “Crosswalk of Quality and Integrated Safety Management System Elements.” In addition, a crosswalk of the DOE O 414.1C criteria and the EMS elements is found in Appendix C, “Crosswalk of Quality and Environmental Management System Elements.”

Integrated Safety Management System – The ISMS provides requirements for SSO to implement DOE P 450.4, *Safety Management System Policy*, while supporting DOE P 450.7, *Environment, Safety and Health (ESH) Goals*, and DOE P 411.1, *Safety Management Functions, Responsibilities, and Authorities Policy*. DOE line management responsibilities for ISM are described in DOE M 411.1-1C, *Safety Management Functions, Responsibilities, and Authorities*. Consistent with DOE P 411.1, SSO’s safety management functions, responsibilities, and authorities for ensuring adequate protection and safe operations cannot be delegated to contractors. The SSO ISM Program is documented in the SSO Environment, Safety and Health Program Plan.

Quality Assurance – SSO’s quality assurance program (QAP) implements the requirements of DOE O 414.1C and ANSI ISO 9001 for Integrated Safety Management System Federal activities, and ANSI ISO 14001 for Environmental Management System elements, and the quality assurance requirements in Title 10, Code of Federal Regulations (CFR), Part 830, Subpart A. The adoption of the QAP is to ensure the Quality Assurance value proposition is integrated into the SSO daily activities; although, the contractor facilities that SSO provides federal oversight are not nuclear facilities. The SSO Site Manager has overall responsibility for development and implementation of the SSO QAP. The status, adequacy, effectiveness, and compliance aspects of the QAP are reviewed on a continuing basis. The Deputy Director for Field Operations (DDFO) for the Office of Science is the approval authority for the SSO QAP. The SSO QAP will be revised and updated annually, as needed.

SSO develops the Annual Performance Plan (APP) for the coming fiscal year. The APP follows the SCMS guidance and includes the review of management processes; including planning, scheduling, and providing resources for the work performed to support the mission of managing and administering the contract with Stanford University. The APP establishes clear performance objectives, measures, and targets for each SSO organization that are aligned with the DDFO’s organizational goals for the fiscal year, and communicates these organizational goals and expectations to DOE headquarters and employees to provide linkages to individual performance plans.

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The contractor established an Assurance Office within their Integrated Performance Management Office. This organization provides requisite internal oversight and positive reporting on Quality Assurance issues to the Site Office. The SSO Site Manager is the approval authority for the Management and Operating (M&O) contractor's QAP, which SLAC refers to as *SLAC Assurance Program Description*.

The contractors' QA programs are internally reviewed and revised periodically to accommodate changes in requirements, activities, organizations, and continuous improvement recommendations. Contractor QA programs require DOE approval. Reviews of the contractors' QA programs are accomplished through direct observation of contractor activities in the field during inspections, assessments and other operational awareness activities.

B. PERSONNEL TRAINING AND QUALIFICATION

1. Requirements

Per [DOE O 360.1B](#), *Federal Employee Training*, DOE Federal employees must be trained and qualified to ensure they are capable of performing their assigned work. Employees must be provided continuing training to ensure that job proficiency is maintained.

2. Description

The SSO Site Manager is responsible to ensure that:

- a. Planning, established requirements, and responsibilities are assigned for SSO employee's training, education, and development (hereafter referred to as "training.")
- b. Each employee has a current Individual Development Plan (IDP) and performs periodic reviews as well as holding Career Planning discussions with each employee. The objective is to ensure employees are not only competent for their current assignment but have access to professional development training to increase their skills portfolio and further strengthen the competencies and capabilities of all SSO employees. Where possible, the SSO Site Manager will identify complementary training opportunities that will broaden and deepen each employee's level of competency and afford them the opportunity to grow.
- c. An initial/continuing training and qualification requirement for each job position is established.
- d. Training is performed within a suitable time frame, provided per approved documents, and presented by individuals who are technically competent and qualified in the subject matter and instructional techniques.
- e. Specific training activities are planned and documented and are not limited to attainment of initial qualification, but are used to stimulate the professional development of each employee.

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- f. Employee qualification requirements are specified in various approved documents/ programs (e.g., Contracting Officer's Development, DOE Functional Area Qualification Standards, and the *SSO Technical Qualification Program Manual for Federal Personnel with Safety Oversight Responsibilities for Office of Science Facilities*) and Individual Development Plans. Employees are qualified based on satisfactory completion of required training courses and/or demonstrated proficiency.
- g. All SSO technical personnel are trained and qualified to perform their assignments. The SSO Training and Qualification Program (TQP) is structured to ensure that curricula address the specific needs of the technical employees. The TQP program is planned and carried out using clearly defined objectives, is continuously reviewed to determine when improvements are needed or other enhancements are identified, and is updated as needed.

3. Implementation

- a. **Training Process** – The SSO Site Manager, with the assistance of the SSO Team Leads, DOE HQ, and the DOE Oak Ridge Office (ORO) Human Resources Division, determines the need for training, and whether continuing training will be provided to SSO personnel to maintain their job proficiency. Objective evidence of completion of training requirements by each SSO employee is maintained by the ORO Human Resources Division.
- b. **Personnel Qualification** – Qualification for specific job categories is based on requirements established by SSO management. Management reviews job categories to determine the following:
 - Whether critical and unique job functions or tasks require highly technical, specialized skills
 - Whether competency must be demonstrated before performance
 - Whether a specialized certification may be required

Based on the review, qualification requirements are developed to ensure employee proficiency is established and documented within plans and procedures. The SSO Site Manager uses the services of the ORO Human Resources Division to maintain the documentation (objective evidence) that attests to the qualification, re-qualification, continuing education, or certification of proficiency of all assigned staff for which a formal qualification determination is made.

- c. **Training of Technical Personnel** – The SSO Site Manager will ensure that SSO's technical employees, whose duties and responsibilities require them to provide assistance, guidance, direction, oversight, or evaluation of contractor activities that could impact the safe operation of a contractor facility, are qualified per the DOE Technical Qualification Program (TQP) , which includes Subject Matter Experts, as defined in [DOE M 426.1-1A](#), *Federal Technical Capability Manual*. The *SSO Technical Qualification Program Manual for Federal Personnel with Safety Oversight Responsibilities for Office of Science Facilities* provides detailed information and guidance on the process used for qualification and re-qualification of technical employees.

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- d. **Training of Contracting Officer** – The SSO Site Manager will ensure that Contracting Officers are qualified per the Acquisition Career Management Program (ACMP), as defined in [DOE O 361.1B](#).
- e. **General Quality Training** – All SSO employees are required to read this QAP and complete the associated training.

C. QUALITY IMPROVEMENT**1. Requirements**

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

2. Description

- a. The SSO management approach to promoting continuous improvement is to maintain a culture in which every employee believes that he or she can make a difference in the quality of products and services. To ensure success, a “no fault” attitude is fostered that encourages employees to participate in solving problems and suggesting improvements.
- b. Processes that detect and prevent quality problems are contained in various programs, such as the following:
 - SSO Management and Independent Assessments
 - Performance Assurance Assessments
 - Occurrence Reporting and Processing System
 - Issues and Corrective Action Management
 - Effectiveness Reviews
 - Accident Investigations
 - Operational Experience/Lessons Learned Program
 - Performance Indicators
 - Safety Software
 - Suspect/Counterfeit Items Identification and Notification
 - Management-employee meetings and other communications
- c. Data resulting from the above programs is reviewed and analyzed to identify items and processes needing improvement.
- d. Quality improvement processes are documented and include guidance to identify problem causes and prevent their recurrence.

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3. Implementation

- a. **Identification of Quality Problems** – As part of SSO's Assessment Program in the *SSO Assessment Program* document, SSO has documented a process for identifying quality problems, reviewing item characteristics, process implementation, oversight of the contractor Suspect/Counterfeit (S/CI) material process, and other quality-related information to identify items, services, and processes needing improvement. Quality problems are identified during management and independent assessments, surveillances, and inspections, as well as audits by external organizations.
- b. **Corrective Action Management** – As part of SSO's Assessment Program, SSO has documented a process for corrective action management in the *SSO Assessment Program* document. Identified quality problems; including Suspect/Counterfeit (S/CI) material, are required to be analyzed, the causal factors identified, and effective corrective actions identified and implemented. Corrective actions are directed towards preventing recurrence and address the identified root cause(s) according to the importance of the problem and the work affected. Corrective actions should be effective alternatives and be within the capability of management to implement in a reasonable timeframe.
- c. **Tracking of Corrective Actions** – The assessed SSO organization (for Federal reviews) or line management (for contractor reviews) ensures that final assessment information which is not tracked by a formally recognized Headquarters corrective action system, such as the Corrective Action Tracking System (CATS) and the Departmental Audit Report Tracking System, is captured in the Oak Ridge Issues, Open Items, and Nonconformances System (ORION), the formal tracking system used by SSO.

SSO tracks findings against the contractor to closure in ORION.
- d. **Quality Trending** – To perform meaningful trend analysis, historical data is accumulated and made available. Historical data from periods of acceptable performance or industry benchmarks establishes the reference or performance baseline for determining the acceptability of current trends. SSO uses the SCMS Quality Assurance and Oversight, Performance Trending, Procedure 2: Analyzing, Charting, and Reviewing Performance Trends to conduct trending.
- e. **Operational Experience / Lessons Learned Program** – The SSO OPEX / Lessons Learned Program objective is to share information from the Federal and contractor workplace that may be useful to others. The generation of lessons learned within the SSO workplace and distribution of lessons learned generated outside SSO are necessary to satisfy the DOE requirements for feedback and improvement. Lessons learned are shared as widely as possible to promote positive recurrence or to avoid negative recurrence. Lessons learned are collected from all available sources, including DOE, its contractors and subcontractors, other government agencies, and private industry.

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The requirements for feedback and continuous improvement are found in 48 CFR 970.5223-1, *Integration of Environment, Safety, and Health into Work Planning and Execution*, and [DOE P 450.4](#), *Safety Management System Policy*. Additional guidance can be found in Chapters II and III of [DOE G 450.4-1B](#), *Integrated Safety Management System Guide*. The SSO Lessons Learned Program is based on the DOE Standard (STD) 7501-99, *The DOE Corporate Lessons Learned Program*, dated December 1999.

f. **Corrective Action Management Program for Headquarters-Managed Issues** – [DOE O 414.1C](#), *Corrective Action Management Program*, describes the process for resolving issues arising from:

- Findings identified by the Office of Health, Safety and Security (HSS) ([DOE O 470.2B](#), *Independent Oversight and Performance Assurance Program*, dated October 31, 2002)
- Judgments of Need identified by Type A accident investigations ([DOE O 225.1A](#), *Accident Investigations*, dated November 26, 1997)
- Other sources as directed by the Secretary or Deputy Secretary, including crosscutting safety issues.

SSO's role in this process from an ES&H perspective is described in SSO *Assessment Program document*.

D. DOCUMENTS AND RECORDS

1. Requirements

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

2. Documents Description

- a. The SSO document control system ensures that SSO's documents that specify requirements, establish policy, or prescribe work are properly prepared, reviewed, approved, issued, used, and revised. The document control system includes the following:
- Identification of documents to be controlled, their specified distribution, and the timeliness for distribution
 - Assignment of responsibility for preparing, reviewing, approving, revising, and issuing documents
 - Review of documents for adequacy, completeness, and correctness prior to approval and issuance. (Note: Individuals who were not involved in originating the document and who are technically competent in the subject matter perform the reviews.)
 - Physical protection of documents from misuse, loss, or compromise of information
 - A method of indicating the status of documents issued to ensure that only the correct documents are used
- b. SSO processes other documents (e.g., technical standards and notices) as required.

Quality Assurance Program Description

- c. SSO performs oversight of its contractor who prepares, reviews, approves, issues, uses, and revises documents to prescribe processes, specify requirements, or establish design as defined in the Contractor's Assurance System Description.
- d. SSO performs oversight of its contractor who specifies, prepares, reviews, approves, and maintains records as defined in the Contractor's Assurance System Description.

3. Records Description

The SSO records system ensures records are specified, prepared, reviewed, approved, and maintained to accurately reflect completed work and include the following features:

- Provisions for the retention and disposition of records to satisfy the requirements of [DOE O 200.1A](#), *Information Management Program*, and the National Archives and Records Administration's methods to preclude unauthorized access to SSO records
- Provisions for record storage areas that minimize the risk of damage from natural disasters and environmental conditions
- Methods for maintaining record accountability
- Provisions for the retrieval of SSO's records
- Provisions that ensure records are legible, accurate, complete, and traceable to the activities to which they apply

4. Implementation

- a. **Document Control** – SSO is in the process of developing the document control system (DOCS) to include procedures, letters, memoranda, forms, and reports. All external letters and business-related internal memoranda will be identified using correspondence numbers. Electronic mail and non business-related internal memoranda are not assigned correspondence numbers unless they are entered into the correspondence database.

SSO utilizes SCMS Requirement Management procedures to document and control SSO directives.

- b. **Records Management** – Management and staff must ensure that records are maintained per approved implementing procedures. Retention and disposition of records is referenced in [DOE O 243.1](#), *Information Management Program*.

E. WORK PROCESSES

1. Requirements

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

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2. Description

- a. SSO's work is planned, authorized, and performed by technically competent individuals who provide leadership, direction, and oversight. Work processes are performed using technical standards developed or adopted from commercial practice, policies, procedures, and other appropriate means and contain a level of detail commensurate with the complexity and importance of the work being performed (i.e., graded approach). Environment, safety, health, and security requirements are integrated into SSO's work processes.
- b. Work is reviewed to ensure the expected level of quality is achieved and to identify areas needing improvement.
- c. SSO does not utilize equipment used for process monitoring or data collection; however, SSO performs oversight on its contractors who calibrate and maintain equipment used for process monitoring or data collection.
- d. SSO performs property management oversight/walkthroughs to address how individuals and the contractor maintain items to prevent their damage, loss, or deterioration.

3. Implementation

- a. If the underlying DOE Order or SSO directive does not provide sufficient direction, SSO Deputy Site Manager and SSO Team Leads develop and implement organization-specific procedures, manuals, or desk instructions. The organization-specific procedures, manuals, or desk instructions should include sufficient detail to implement the Order or SSO directive requirements. The content and format of organization-specific procedures or desk instructions is at the discretion of the SSO Deputy Site Manager or SSO Team Leads. Organization-specific procedures, manuals, or desk instructions are reviewed and revised at the discretion of the Deputy Manager or cognizant Team Lead.
- b. The SSO Deputy Site Manager and SSO Team Leads are responsible for implementing this aspect of the QA program in their areas of responsibility as defined in the *SSO SCMS Desk Guide for Quality Assurance and Oversight*.
- c. Oversight of contractor work processes is performed through participation in formal design reviews, assessments, and deliverable reviews. SSO comments and findings are provided to the contractor through official correspondence.

F. DESIGN

1. Requirements

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

Quality Assurance Program Description

2. Description

- a. SSO does not design items; however, SSO performs oversight on its contractors who design items.
- b. SSO designs processes to meet customer requirements effectively and efficiently while complying with applicable laws and regulations and the ANSI ISO 9001 standard.

3. Implementation

- a. Oversight of contractors who design items is conducted using approved procedures. Line management develops and maintains processes and procedures needed for oversight of its contractor(s) design activities including design review and validation of designs of computer software. Support organizations develop and maintain processes and procedures to support line management as needed.
- b. SSO uses the graded approach to design processes to meet various requirements. Changes are incorporated based upon user requirements. Design interfaces are controlled and the adequacy of design is verified and validated prior to implementation.
- c. The contractor's design inputs, processes, outputs, and changes are to be reviewed by qualified individuals or groups other than those who performed the original design.

G. PROCUREMENT**1. Requirements**

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

2. Description

- a. SSO procures services per the DOE Acquisition Regulations (DEARs) and Federal Acquisition Regulation (FARs).
- b. SSO makes credit card purchases per FAR Subpart 3.104, FAR Part 8, FAR Part 12, and FAR Part 13.
- c. SSO provides oversight of the contractor's procurement system to ensure their performance meets procurement requirements and/or expectations and that the contractor continues to provide acceptable services and products.

3. Implementation

- a. Oral purchases for supplies or services may be accomplished using the DOE Purchase Card, provided the amount of the purchase is \$2,500 or less.
- b. SSO's Personal Property Manager attaches inventory control identification and updates personal property management records as soon as practicable following the purchase and the delivery of the personal property, as appropriate.

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- c. When SSO places a credit card order via telephone, the cardholder:
 - notifies vendors that purchases are tax exempt,
 - ensures quoted prices represent the Government's full obligation for the acquired item or service,
 - instructs vendors to include appropriate information on shipping documents or packing slips, if required.
- d. SSO purchase cardholder(s) execute and maintain appropriate records of each transaction.
 - Detailed bank statements from Bank of America are reviewed monthly and approved by both the SSO purchase card holder(s) and an approving official.
 - Each month, SSO transmits a signed Bank of America statement reconciliation to the ORO Finance Division.
- e. Additional services or supplies for SSO are provided by the Integrated Service Center at the Oak Ridge Office.
- f. SSO provides oversight of the contractor's procurement system. SSO performs contract administration duties as prescribed in the FAR Part 42 and in the SSO Contract Management Plan. The contract for SLAC National Accelerator Laboratory (SLAC) is a cost-plus performance-based M&O contract, subject to the appropriate provisions of the FAR and DEAR including Contract Clause I.025, *Contractor Purchasing System* (DEAR 970.5244-1, DEC 2000). Contract Clause H.011, *Administration of Subcontracts* allows the DOE to award any contracts that would normally be awarded by the contractor to obtain the Department's small business goals.
- g. SSO develops a Performance Measurement and Evaluation Plan (PEMP) that sets the standards for the contractor's performance through objectives, measures, and expectations. The measures are negotiated annually with the contractor and incorporated into the contract. SSO performs Contract Performance Oversight per the SSO Contract Management Plan.

H. INSPECTION AND ACCEPTANCE TESTING

1. Requirements

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

2. Description

- a. **Inspection and Acceptance Testing** – SSO performs limited inspection and acceptance testing of items, services, and processes as defined by [DOE O 414.1C](#). Examples include property management for personal equipment (e.g., office computers and cellular telephones), and reporting of inspections for suspect and counterfeit items.
- b. **Measuring and Test Equipment** – SSO may perform limited calibration or maintenance of equipment used for inspections and tests as defined by [DOE O 414.1C](#), but in general uses contractor-calibrated measuring and test equipment on an as-needed basis.

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3. Implementation

- a. SSO does not normally conduct inspection and acceptance testing of items or services; however, SSO performs contractor oversight to ensure the contractor's processes are conducted using established acceptance and performance criteria.
- b. On the rare occasion needing inspection and acceptance testing, the requirements should be specifically included in the Quality Assurance Surveillance Plan for the affected procurement.
- c. The requirements for SSO's personal equipment procurements are prescribed in [DOE O 580.1](#), *Department of Energy Personal Property Management Program*. SSO is supported by RS Information Systems (RSIS) through the Oak Ridge Office for Information Technology (IT) services.

I. **MANAGEMENT ASSESSMENT**

1. Requirements

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

2. Description

- a. SSO's management assessment process focuses on how well the QAP is working and identifies management problems that prevent effective implementation of quality, safety, and environmental requirements. This process not only assists SSO in achieving its objectives, but also allows SSO to evaluate customer and employee perceptions relative to the following key issues:
 - The organization's mission and strategic objectives
 - The employees' role in the organization
 - The customers' expectations and the degree to which those expectations are being met
 - Opportunities for improving quality and cost-effectiveness
 - Recognizing and enhancing human resource capabilities
- b. Problems that hinder SSO's quality, safety, and environmental goals and objectives are identified and corrected. Decisions and recommendations are promptly documented, acted upon, followed up on, and evaluated for effectiveness.

3. Implementation

SSO's Management Assessment Program is documented in SLAC Site Office Annual Performance Plan.

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J. INDEPENDENT ASSESSMENT**1. Requirements**

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

2. Description

- a. SSO's functions and activities (including those of the contractors as documented in the approved contractor's assurance system description) are independently assessed. These assessments expand on traditional auditing techniques and focus on implementation of the QAP, and they are intended to improve the quality and effectiveness of all of SSO's functions and activities.
- b. Independent assessments ensure consistent application of the QAP and are not intended to reinterpret or redefine the requirements of [DOE O 414.1C](#). Through defined assessment methodologies and techniques, which include the review and evaluation of organization-specific management assessments, independent assessments ensure that the following goals are achieved:
 - Problems preventing SSO from meeting its established goals, including potential or fundamental causes, are identified
 - Actions are taken to correct identified problems
 - Actions to prevent recurrence are identified and documented
 - Lessons learned are applied, where applicable
 - Actions are taken to improve the condition(s) causing the problem
- c. Independent assessment personnel (including contractor personnel) must meet the following criteria:
 - Are technically knowledgeable in the areas being assessed
 - Do not have direct responsibilities in the areas being assessed
 - Act in a management advisory function
 - Have sufficient authority and freedom from line management to identify problems
 - Monitor work performance
 - Identify abnormal performance and precursors of potential problems
 - Focus on improving the quality of the processes that lead to the end product
 - Document assessment results
 - Verify satisfactory resolution of problems
 - Perform follow-up reviews of deficient areas, as necessary

3. Implementation

SSO's Independent Assessment Program is documented in *SSO Assessment Program*.

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III. REFERENCES

1. [Office of Science Management System \(SCMS\) Quality Assurance and Oversight SCMS Revision: 2.5](#), dated April 14, 2009
2. 10 CFR 830, Subpart A, Quality Assurance Requirements, dated January 10, 2001
3. ANSI/ISO/ASQ Q9001-2000, American National Standard, Quality Management Systems – Requirements, dated December 13, 2000
4. ANSI/ISO/ASQ E14001-2004, Environmental Management Systems – Requirements, dated January 10, 2005
5. [DOE G 225.1A-1](#), Implementation Guide for use with DOE O 225.1 Accident Investigations, dated November 26, 1997
6. [DOE G 414.1-1B](#), Management and Independent Assessments Guide for Use with 10 CFR Part 830, Subpart A, and DOE O 414.1C, Quality Assurance; DOE M 450.4-1, Integrated Safety Management System Manual; and [DOE O 226.1A](#), Implementation of Department of Energy Oversight Policy, dated September 27, 2007
7. [DOE G 414.1-2A](#), Quality Assurance Management System Guide for Use with 10 CFR Part 830, Subpart A; and DOE O 414.1C, Quality Assurance, dated June 17, 2005
8. [DOE G 414.1-3](#), Suspect/Counterfeit Items Guide for Use with 10 CFR 830 Subpart A, Quality Assurance Requirements, and DOE O 414.1C, Quality Assurance, dated November 03, 2004
9. [DOE G 414.1-4](#), Safety Software Guide for Use with 10 CFR 830 Subpart A, Quality Assurance Requirements, and DOE O 414.1C, Quality Assurance, dated June 17, 2005
10. [DOE G 450.1-2](#), Implementation Guide for Integrating Environmental Management Systems into Integrated Safety Management Systems, dated August 20, 2004
11. [DOE G 450.4-1B Vol 1](#), Integrated Safety Management System Guide (Volume 1) for use with Safety Management System Policies (DOE P 450.4, DOE P 450.5, and DOE P 450.6); The Functions, Responsibilities, and Authorities Manual; and the DOE Acquisition Regulation, dated March 1, 2001
12. [DOE G 450.4-1B Vol 2](#), Integrated Safety Management System Guide (Volume 1) for use with Safety Management System Policies (DOE P 450.4, DOE P 450.5, and DOE P 450.6); The Functions, Responsibilities, and Authorities Manual; and the DOE Acquisition Regulation, dated March 1, 2001
13. [DOE M 140.1-1B](#), Interface with the Defense Nuclear Facilities Safety Board, dated March 30, 2001
14. [DOE M 360.1-1B](#), Federal Employee Training Manual, dated October 11, 2001
15. [DOE M 411.1-1C](#), Safety Management Functions, Responsibilities, and Authorities, dated December 31, 2003
16. [DOE M 426.1-1A](#), Federal Technical Capability Manual, dated May 18, 2004
17. [DOE O 200.1A](#), Information Management Program, dated December 23, 2009
18. [DOE O 210.2](#), DOE Corporate Operations (includes lessons learned), dated June 12, 2006
19. [DOE O 225.1A](#), Accident Investigations, dated November 26, 1997

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20. [DOE O 226.1A](#), *Implementation of Department of Energy Oversight Policy*, dated July 31, 2007
21. [DOE O 243.1](#), *Records Management Program*, dated February 03, 2006
22. [DOE O 360.1B](#), *Federal Employee Training*, dated October 11, 2001
23. [DOE O 361.1B](#), *Acquisition Career Development Program*, dated January 24, 2008
24. [DOE O 413.1B](#), *Management Control Program*, dated October 28, 2008
25. [DOE O 413.3A Chg 1](#), *Program and Project Management for the Acquisition of Capital Assets*, dated November 17, 2008
26. [DOE O 414.1C](#), *Quality Assurance*, dated June 17, 2005
27. [DOE O 450.1A](#), *Environmental Protection Program*, dated June 04, 2008
28. [DOE O 470.2B](#), *Independent Oversight and Performance Assurance Program*, dated October 31, 2002
29. [DOE O 580.1 Chg 1](#), *Department of Energy Personal Property Management Program*, dated May 08, 2008
30. [DOE P 226.1A](#), *Department of Energy Oversight Policy*, dated May 25, 2007
31. [DOE P 411.1](#), *Safety Management Functions, Responsibilities, and Authorities*, dated January 28, 1997
32. [DOE P 450.4](#), *Safety Management System Policy*, dated October 15, 1996
33. [DOE P 450.7](#), *Environment, Safety and Health (ESH) Goals*, dated August 2, 2004
34. [DOE-STD-7501-99](#), *The DOE Corporate Lessons Learned Program*, dated December 1999
35. *SSO Annual Performance Plan, for FY2009*
36. *SSO Assessment Program, dated September 25, 2008*
37. *SSO Level III Functions, Responsibilities, and Authorities Manual, dated December 12, 2008*
38. *SSO Environmental, Safety and Health (ES&H) Program Plan, dated March 31, 2009*
39. *SSO Environment, Safety and Health (ES&H) Operational Awareness Program for the Oversight of the SLAC National Accelerator Laboratory (SLAC), dated March 31, 2009*
40. *SSO Contract Management Plan, dated FY2009*
41. *SSO Training and Qualification Program, dated November 30, 2006*
42. *SSO Emergency Management Plan, dated July 30, 2009*
43. *SSO Standard Operating Procedure SSO-ADM-07, Oversight Activities for Emergency Planning and Response, dated August 26, 2005*
44. *SSO Continuity of Operations Plan, dated July 27, 2009*
45. *SSO Standard Operating Procedure SSO-OA-11, Review/Approval of Accelerator Safety Documentation, dated September 15, 2006*
46. *SSO Standard Operating Procedure SSO-PM-02, Project Management, dated July 13, 2006*
47. *SSO SCMS Quality Assurance and Oversight Desk Guide, dated July 08, 2009*
48. *SSO Standard Operating Procedure SSO-QA-05, Accident Investigations, dated March 15, 2007*

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Appendix A: Crosswalk of DOE O 414.1C and ISO 9001-2000 with SSO Implementing Mechanisms

Quality Assurance Criteria (DOE O 414.1C)	American National Standard for Quality Management Systems (ISO 9001-2000)	Implementing Mechanisms (Note: Current versions of SSO documents and procedures are not posted on a field office website)
<p>4.a Quality Assurance Program Requirements Each DOE organization must develop and implement a QAP.</p>	<p>4.2 Documentation Requirements 4.2.1 General The quality management system documentation shall include: documented statements of a quality policy and quality objectives; a quality manual; documented procedures required by this international standard; documents needed by the organization to ensure effective planning, operation and control of its processes; records required by this international standard 4.2.2 Quality Manual The organization shall establish and maintain a quality manual that includes the scope and justification for any exclusion, references to procedures, and description of interaction between the processes of the quality management system.</p>	<ul style="list-style-type: none"> • SSO QAPD • SSO SCMS QA Desk Guide

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Quality Assurance Criteria (DOE O 414.1C)	American National Standard for Quality Management Systems (ISO 9001-2000)	Implementing Mechanisms (Note: Current versions of SSO documents and procedures are not posted on a field office website)
<p>4.b(1) Management/Criterion 1— Program.</p> <p>(1) Establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing work.</p> <p>(2) Establish management processes, including planning, scheduling, and providing resources for work.</p>	<p>4 Quality management System</p> <p>4.1 General Requirements The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness.</p> <p>5.1 Management Commitment Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness.</p> <p>5.2 Customer Focus Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction.</p> <p>5.3 Quality Policy Top management shall ensure that the quality policy is appropriate to the purpose of the organization and includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system.</p> <p>5.4 Planning</p> <p>5.4.1 Quality Objectives Top management shall ensure that quality objectives, including those needed to meet requirements for product, are established at relevant functions and levels within the organization.</p> <p>5.4.2 Quality Management System Planning Top management shall ensure that the planning of the quality management system is carried out in order to meet the requirements and quality objectives and is maintained.</p> <p>5.5 Responsibility, Authority and Communication</p> <p>5.5.1 Responsibility and Authority Top management shall ensure that responsibilities and authorities are defined and communicated within the organization.</p> <p>6 Resource Management</p> <p>6.1 Provision of Resources The organization shall determine and provide the resources needed to implement and maintain the quality management system and continually improve its effectiveness, and enhance customer satisfaction.</p>	<ul style="list-style-type: none"> • SSO Annual Performance Plan • SSO QAPD • SSO SCMS QA Desk Guide • SSO Organizational Chart • SSO Level III FRAM • SSO-PM-02

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Quality Assurance Criteria (DOE O 414.1C)	American National Standard for Quality Management Systems (ISO 9001-2000)	Implementing Mechanisms (Note: Current versions of SSO documents and procedures are not posted on a field office website)
<p>4.b(2) Management/Criterion 2— Personnel Training and Qualification.</p> <p>(1) Train and qualify personnel to be capable of performing assigned work.</p> <p>(2) Provide continuing training to personnel to maintain job proficiency.</p>	<p>6.2 Human resources</p> <p>6.2.1 General Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills, and experience.</p> <p>6.2.2 Competence, awareness and training The organization shall determine the necessary competence for personnel performing work affecting product quality, provide training, evaluate the effectiveness, ensure that its personnel are aware of the relevance and importance of their activities, and maintain appropriate records of education, training, skills and experience.</p>	<ul style="list-style-type: none"> • SSO follows SCMS Employee Development • SSO follows DOE O 361.1B • SSO TQP Manual [for technical employees] • SSO Office/Facility-Specific Qualification Standard [for technical employees]

Quality Assurance Program Description

Quality Assurance Criteria (DOE O 414.1C)	American National Standard for Quality Management Systems (ISO 9001-2000)	Implementing Mechanisms (Note: Current versions of SSO documents and procedures are not posted on a field office website)
<p>4.b(3) Management/Criterion 3— Quality Improvement.</p> <ol style="list-style-type: none"> (1) Establish and implement processes to detect and prevent quality problems. (2) Identify, control and correct items, services, and processes that do not meet established requirements. (3) Identify the causes of problems, and include prevention of recurrence as a part of corrective action planning. (4) Review item characteristics, process implementation, and other quality-related information to identify items, services, and processes needing improvement. 	<p>5.5.2 Management representative Top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority.</p> <p>5.5.3 Internal communication Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.</p> <p>6.3 Infrastructure The organization shall determine, provide, and maintain the infrastructure needed to achieve conformity to product requirements.</p> <p>6.4 Work environment The organization shall determine and manage the work environment needed to achieve conformity to product requirements.</p> <p>8 Measurement, analysis and improvement</p> <p>8.1 General The organization shall plan and implement the monitoring, measurement, analysis, and improvement processes needed.</p> <p>8.2 Monitoring and measurement</p> <p>8.2.1 Customer satisfaction As one of the measurements of the performance of the quality management system, the organization shall monitor information relating to customer perception as to whether the organization has met customer requirements.</p> <p>8.2.4 Monitoring and measurement of product The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met.</p> <p>8.3 Control of nonconforming product The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery.</p> <p>8.4 Analysis of data 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.</p>	<ul style="list-style-type: none"> • SSO QAPD • SSO SCMS QA Desk Guide • SSO Assessment Program document • SSO-QA-05 • SSO <i>Three Year Assessment Plan</i> • SSO <i>Annual Integrated Assessment Schedule</i> and performance of assessments • ORION database and documentation • HSS CATS database and documentation • OPEX/Lessons Learned Program • Safety Attainment Board • Periodic ES&H Status Reports • SSO's Individual Performance Plans

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Quality Assurance Criteria (DOE O 414.1C)	American National Standard for Quality Management Systems (ISO 9001-2000)	Implementing Mechanisms (Note: Current versions of SSO documents and procedures are not posted on a field office website)
	<p>8.5 Improvement</p> <p>8.5.1 Continual improvement The organization shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions, and management review.</p> <p>8.5.2 Corrective action The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.</p> <p>8.5.3 Preventive action The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.</p>	
<p>4.b(4) Management/Criterion 4— Documents and Records.</p> <p>(1) Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design.</p> <p>(2) Specify, prepare, review, approve, and maintain records.</p>	<p>4.2.3 Control of documents Documents required by the quality management system shall be controlled.</p> <p>4.2.4 Control of Records Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system.</p> <p>5.6.1 Records from management reviews shall be maintained.</p>	<ul style="list-style-type: none"> • SSO follows DOE O 243.1 • DOCS System • SSO organizational File Rooms • SSO Records Management Program Document [forthcoming] • Each Contracting Officer or Business Team member oversees their documents and records management to ensure proper disposition of records

Quality Assurance Program Description

Quality Assurance Criteria (DOE O 414.1C)	American National Standard for Quality Management Systems (ISO 9001-2000)	Implementing Mechanisms (Note: Current versions of SSO documents and procedures are not posted on a field office website)
<p>4.b(5) Performance/Criterion 5— Work Processes.</p> <ul style="list-style-type: none"> (1) Perform work consistent with technical standards, administrative controls, and hazard controls adopted to meet regulatory or contract requirements using approved instructions, procedures, etc. (2) Identify and control items to ensure proper use. (3) Maintain items to prevent damage, loss, or deterioration. (4) Calibrate and maintain equipment used for process monitoring or data collection. 	<p>7 Product realization</p> <p>7.1 Planning of product realization The organization shall plan and develop the processes needed for product realization.</p> <p>7.2 Customer-related processes</p> <p>7.2.1 Determination of requirements related to the product The organization shall determine requirements specified by the customer, requirements not stated by the customer but necessary for specified or intended use, where known, statutory, and regulatory requirements related to the product, and any additional requirements determined by the organization.</p> <p>7.2.2 Review of requirements related to the product The organization shall review the requirements related to the product and the review shall be conducted prior to the organization's commitment to supply a product to the customer.</p> <p>7.2.3 Customer communication The organization shall determine and implement effective arrangements for communicating with customers.</p> <p>7.5 Production and service provision</p> <p>7.5.1 Control of production and service provision The organization shall plan and carry out production and service provision under controlled conditions.</p> <p>7.5.2 Validation of processes for production and service provision The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement.</p> <p>7.5.3 Identification and traceability Where appropriate, the organization shall identify the product by suitable means throughout product realization</p> <p>7.5.4 Customer property The organization shall exercise care with customer property while it is under the organization's control or being used by the organization.</p> <p>7.5.5 Preservation of product The organization shall preserve the conformity of product during internal processing and delivery to the intended destination.</p>	<ul style="list-style-type: none"> • SSO Environmental, Safety and Health (ES&H) Program Plan • SSO Operational Awareness Program • SSO organizational procedures • SSO staff follow contractor procedures and controls when on sites managed by contractors

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Quality Assurance Criteria (DOE O 414.1C)	American National Standard for Quality Management Systems (ISO 9001-2000)	Implementing Mechanisms (Note: Current versions of SSO documents and procedures are not posted on a field office website)
<p>4.b(6) Performance/Criterion 6— Design.</p> <ol style="list-style-type: none"> (1) Design items and processes using sound engineering/scientific principles and appropriate standards. (2) Incorporate applicable requirements and design bases in design work and design changes. (3) Identify and control design interfaces. (4) Verify/validate the adequacy of design products using individuals or groups other than those who performed the work. (5) Verify/validate work before approval and implementation of the design. 	<p>7.3 Design and development</p> <p>7.3.1 Design and development planning The organization shall plan and control the design and development of product.</p> <p>7.3.2 Design and development inputs Inputs relating to product requirements shall be determined and records maintained.</p> <p>7.3.3 Design and development outputs The outputs of design and development shall be provided in a form that enables verification against the design and development input and shall be approved prior to release.</p> <p>7.3.4 Design and development review At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements.</p> <p>7.3.5 Design and development verification Verification shall be performed in accordance with planned arrangements to ensure that the design and development outputs have met the design and development input requirements.</p> <p>7.3.6 Design and development validation Design and development validation shall be performed in accordance with planned arrangements to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known.</p> <p>7.3.7 Control of design and development changes Design and development changes shall be identified and records maintained.</p>	<ul style="list-style-type: none"> • Design calculations are performed by SSO's contractors and are covered by SSO's contractors' quality assurance programs and design control procedures. SSO exercises oversight and control through approval of the contractors' QAPs, contractual requirements, work authorization controls, assessments, and performance evaluations.

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Quality Assurance Criteria (DOE O 414.1C)	American National Standard for Quality Management Systems (ISO 9001-2000)	Implementing Mechanisms (Note: Current versions of SSO documents and procedures are not posted on a field office website)
<p>4.b(7) Performance/Criterion 7— Procurement.</p> <p>(1) Procure items and services that meet established requirements and perform as specified.</p> <p>(2) Evaluate and select prospective suppliers on the basis of specified criteria.</p> <p>(3) Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services.</p>	<p>7.4 Purchasing</p> <p>7.4.1 Purchasing process The organization shall ensure that purchased product conforms to specified purchase requirements.</p> <p>7.4.2 Purchasing information Purchasing information shall describe the product to be purchased, including where appropriate requirements for approval of product, procedures, processes and equipment, requirements for qualification of personnel, and quality management system requirements.</p>	<ul style="list-style-type: none"> • SSO follows the FARs • SSO follows DOE O 413.3A
<p>4.b(8) Performance/Criterion 8— Inspection and Acceptance Testing.</p> <p>(1) Inspect and test specified items, services, and processes using established acceptance and performance criteria.</p> <p>(2) Calibrate and maintain equipment used for inspections and tests.</p>	<p>7.4.3 Verification of purchased product The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.</p> <p>7.6 Control of monitoring and measuring devices The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements.</p> <p>Where necessary to ensure valid results, measuring equipment shall be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards.</p>	<ul style="list-style-type: none"> • SSO does not keep or maintain equipment used for inspections. SSO's contractors calibrate and maintain inspection and testing equipment.

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Quality Assurance Criteria (DOE O 414.1C)	American National Standard for Quality Management Systems (ISO 9001-2000)	Implementing Mechanisms (Note: Current versions of SSO documents and procedures are not posted on a field office website)
<p>4.b(9) Assessment/Criterion 9— Management Assessment. Ensure that managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives.</p>	<p>5.6 Management review 5.6.1 General Top Management shall review the organization’s quality management system, at planned intervals, to ensure its continuing suitability, adequacy, and effectiveness. 5.6.2 Review input The input to management review shall include information on results of audits, customer feedback, process performance and product conformity, status of preventive and corrective actions, follow-up actions from previous management reviews, changes that could affect the quality management system, and recommendations for improvement. 5.6.3 Review output The output from the management review shall include any decisions and actions related to improvement of the effectiveness of the quality management system and its processes, improvement of product related to customer requirements, and resource needs. 8.2.3 Monitoring and measurement of processes The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes.</p>	<ul style="list-style-type: none"> • SSO QAPD • SSO Assessment Planning • SSO SCMS QA Desk Guide • SSO organizational procedures • SSO assessments, including management assessments, are scheduled and tracked in ORION • SSO follows DOE P 226.1A

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Quality Assurance Criteria (DOE O 414.1C)	American National Standard for Quality Management Systems (ISO 9001-2000)	Implementing Mechanisms (Note: Current versions of SSO documents and procedures are not posted on a field office website)
<p>4.b(10) Assessment/Criterion 10— Independent Assessment.</p> <p>(1) Plan and conduct independent assessments to measure item and service quality, to measure the adequacy of work performance and to promote improvement.</p> <p>(2) Establish sufficient authority and freedom from line management for independent assessment teams.</p> <p>(3) Ensure that persons conducting independent assessments are technically qualified and knowledgeable in the areas to be assessed.</p>	<p>8.2.2 Internal audit</p> <p>The organization shall conduct internal audits at planned intervals to determine whether the quality management system conforms to the planned arrangements, to the requirements of this international standard and to the quality management system requirements established by the organization, and is effectively implemented and maintained.</p>	<ul style="list-style-type: none"> • SSO Assessment Planning • SSO organizational procedures. • Independent assessments are identified on the <i>Annual Integrated Assessment Schedule</i> and tracked in ORION. • The Office of Health, Safety and Security (HSS) also conducts independent assessments, which are tracked in HSS CATS. • Management selection of the review team leader and team leader selection of the team members ensures that persons conducting independent assessments are technically qualified and knowledgeable. • SSO follows DOE P 226.1A

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Appendix B: Crosswalk of Quality and Integrated Safety Management System Elements

<p style="text-align: center;">Quality Assurance Criteria</p> <p>ISM Principles and Functions (ISO 9001 Standard Requirements)</p>	Program	Training and Qualification	Quality Improvement	Documents and Records	Work Processes	Design	Procurement	Inspection/Acceptance Testing	Management Assessment	Independent Assessment
ISM Guiding Principles										
Line Management Responsibility for Safety	x			x					x	x
Clear Roles and Responsibilities	x			x					x	x
Competence Commensurate with Responsibilities		x		x					x	x
Balanced Priorities	x			x					x	x
Identification of ES&H Standards and Requirements			x	x	x	x	x	x	x	x
Hazard Controls Tailored to Work Being Performed				x	x	x	x	x	x	x
Operations Authorization				x	x	x	x	x	x	x
ISM Core Functions										
Define the Scope of Work				x	x	x	x	x	x	x
Analyze the Hazards				x	x	x	x	x	x	x
Develop and Implement Hazard Controls				x	x	x	x	x	x	x
Perform Work within Controls				x	x	x	x	x	x	x
Provide Feedback and Continuous Improvement			x	x	x			x	x	x
Supplemental High-Reliability Principles										
Highly-Reliable Operational Performance	x	x	x	x	x	x	x	x		
Individual Attitude and Responsibility	x	x	x	x	x	x	x	x		
Performance Assurance			x	x	x	x	x	x	x	x
Organizational Performance Improvement			x	x	x	x	x	x	x	x
<p>Note: Adapted from DOE G 414.1-2A and the Implementation Plan for Defense Nuclear Facilities Safety Board Recommendation 2004-1</p>										

Quality Assurance Program Description

Appendix C: Crosswalk of Quality and Environmental Management System Elements

Quality Assurance Criteria	Program	Training & Qualification	Quality Improvement	Documents & Records	Work Processes	Design	Procurement	Inspection/ Acceptance Testing	Management Assessment	Independent Assessment
Environmental Management System (ISO 14001 Standard Requirements)										
General Requirements	x									
Environmental Policy	x		x							
Planning										
Environmental aspects	x				x					
Legal and other requirements	x				x					
Objectives, targets and program(s)	x		x							
Implementation and Operation										
Resources, roles, responsibility and authority	x		x							
Competence, training and awareness		x								
Communication			x		x					
Documentation				x						
Control of documents				x						
Operational control					x	x	x	x		
Emergency preparedness and response			x							
Checking										
Monitoring and measurement			x					x	x	
Evaluation of compliance			x						x	
Nonconformity, corrective action and preventive action			x							
Control of records				x						
Internal audit										x
Management Review			x	x					x	
Environmental Protection Program (DOE O 450.1A)										
Environmentally and economically beneficial landscape practices	x									
Centralized procurement and distribution program for toxic and hazardous contents							x			
Pollution Prevention Program implementation and monitoring										x
Pollution Prevention Opportunity Assessments										x
Emergency Planning and Community Right-to-Know Act	x									
Planning and management requirements for historic property and environmental management	x									
Note: Adapted from DOE O 450.1A and Executive Order 13148, <i>Greening the Government Through Leadership in Environmental Management</i>										