



QUALITY ASSURANCE PLAN

Approved by: Tammy Courtney Date: 1/31/19
Tammy Courtney
Project Manager

Effective Date: _____

TABLE OF CONTENTS

LIST OF FIGURES.....	4
REVISION SUMMARY.....	5
ACRONYM LIST	6
1.0 INTRODUCTION.....	8
1.1 PURPOSE AND OBJECTIVE	8
1.2 SCOPE.....	8
1.3 SUMMARY OF KEY CHANGES	8
2.0 APPLICATION OF ISO 9001:2015	9
2.1 ISO 9001:2015.....	9
2.2 REQUIREMENTS	9
3.0 APPLICATION OF GRADED APPROACH	9
4.0 QUALITY PROGRAM CRITERIA.....	10
4.1 CRITERION 1 – PROGRAM.....	10
4.1.1 PROGRAM DEFINITION	10
4.1.2 ORGANIZATION, ROLES, AND RESPONSIBILITIES	11
4.1.3 MANAGEMENT PROCESSES	14
4.2 CRITERION 2 – PERSONNEL TRAINING AND QUALIFICATION	14
4.2.1 QUALIFICATION OF PERSONNEL.....	14
4.2.2 TRAINING.....	14
4.2.3 ORGANIZATIONAL KNOWLEDGE AND AWARENESS.....	15
4.2.4 QUALIFICATION OF AUDITORS	15
4.2.5 CERTIFICATION OF NQA-1 LEAD AUDITORS.....	15
4.2.6 MAINTENANCE OF PROFICIENCY OF NQA-1 LEAD AUDITORS	16
4.2.7 RECERTIFICATION OF NQA-1 AUDITORS/LEAD AUDITORS	16
4.2.8 CERTIFICATION OF NQA-1 AUDITORS	16
4.2.9 CERTIFICATION OF INSPECTION AND TEST PERSONNEL	17
4.2.10 CERTIFICATION OF TECHNICAL SPECIALIST.....	17
4.2.11 RECORDS.....	17
4.3 CRITERION 3 – QUALITY IMPROVEMENT.....	17
4.3.1 CONTINUOUS IMPROVEMENT	18
4.3.2 NONCONFORMANCE IDENTIFICATION AND CONTROL	18
4.3.3 CORRECTIVE ACTION PROGRAM.....	19
4.3.4 CORRECTIVE ACTION PLANS	20
4.4 CRITERION 4 – DOCUMENTS AND RECORDS	20

4.4.1	DOCUMENTS	21
4.4.2	PROCEDURES	21
4.4.3	RECORDS	22
4.4.4	RECORDS FACILITIES	23
4.5	CRITERION 5 – WORK PROCESSES	23
4.5.1	PERFORMANCE OF WORK	23
4.5.2	IDENTIFICATION AND CONTROL OF ITEMS	24
4.5.3	HANDLING, STORING, AND SHIPPING	25
4.5.4	MEASURING AND TEST EQUIPMENT	25
4.5.5	CONTROL OF COMPUTER SOFTWARE	26
4.5.6	SUSPECT/COUNTERFEIT ITEMS	26
4.6	CRITERION 6 – DESIGN	27
4.7	CRITERION 7 – PROCUREMENT	28
4.7.1	PROCUREMENT PROGRAM DEFINITION	28
4.7.2	SUPPLIER SELECTION AND EVALUATION	28
4.7.3	PROCUREMENT DOCUMENTS	29
4.7.4	ITEMS AND SERVICES ACCEPTANCE	30
4.8	CRITERION 8 – INSPECTION AND ACCEPTANCE TESTING	30
4.8.1	CONTRACT PERFORMANCE QUALITY ASSURANCE PLAN.....	30
4.8.2	INSPECTION	31
4.8.3	TEST CONTROL	31
4.8.4	MEASURING AND TEST EQUIPMENT	32
4.9	CRITERION 9 – MANAGEMENT ASSESSMENT	32
4.10	CRITERION 10 – INDEPENDENT ASSESSMENT	32
5.0	REFERENCES.....	33
6.0	QUALITY ASSURANCE GLOSSARY OF TERMS	34
7.0	ATTACHMENTS	42
	ATTACHMENT A – QUALITY ASSURANCE IMPLEMENTATION PLAN.....	43
	ATTACHMENT B – REQUIREMENTS CROSSWALK.....	56
	ATTACHMENT C – PROCUREMENT QUALITY LEVELS AND ASSOCIATED CONTROLS	68

LIST OF FIGURES

FIGURE 1. SWIFT & STALEY ORGANIZATION	13
---	----

REVISION SUMMARY

Rev. No.	Description of Change	Pages	Date
Revisions 0 through 15 from previous contracts.			
16	Annual review and revision. Incorporates comments from DOE provided with approval of Rev. 15 for incorporation in next revision. Updated directive, plan, and procedure references as necessary. Updated organization chart and roles and responsibilities to reflect management changes and additions. Addressed two corrective actions (IM-2016-183 for roles and responsibilities and IM-2016-128 to update training plan reference in Section 2). Updated description of relationship of QAP to the radiological program quality program for DOELAP accreditation. Deleted Figure 1 (DOE produced) since it has not been updated to reflect NQA-1-2008, as required by DOE O 414.1D. Described Swift & Staley Contract Performance Quality Assurance Plan. General changes to active voice throughout (not tracked). Page reorganization for flow of information following acceptance of changes (not tracked).	vii, 1, 3-5, 7-10, 12-17, 20-22, 25-30, 32, 40-41, 44-45, 49-50, Appendix A (all pages)	09/27/16
17	Revision to incorporate changes resulting from corrective actions developed in response to DOE assessment PADU-17-IS-101067; incorporation of TIDC changes made by the QA organization; and other general revisions. Significant changes include the addition of definitions of QA terms, several of which have changed as a result of PADU-17-IS-101067. Incorporation of ISO 9001-2015 consensus standard. Added a QA Glossary of Terms.	All	11/07/17
18	Formatted into new template, previous no. SST.QA-0001. Incorporate changes resulting from corrective actions developed in response to internal and external assessments; incorporation of document changes made by the QA organization; and other general revisions. Corrected Plan number from ISSC-QA-PL-004 TO ISSC-QA-PL-001.	8-10,13, 15-17, 19, 26, 29-31, 42, 43-71	1/31/19

ACRONYM LIST

ANSI	American National Standards Institute
AQL	Acceptable Quality Level
ASME	American Society of Mechanical Engineers
AU-1	DOE Office of Environment, Health, Safety, and Security
BOD	Board of Directors
CAP	corrective action plan
CAQ	condition adverse to quality
CAS	Contractor Assurance System
CFR	Code of Federal Regulations
CofC	Certificate of Conformance
COTS	Commercial off-the-shelf
CPQAP	Contract Performance Quality Assurance Plan
CTCS	Computing, Telecommunications, and Cyber Security
DOE	U.S. Department of Energy
DPM	Deputy Project Manager
E&AM	Engineering and Assets Manager
EEOICPA	Energy Employees Occupational Injury Compensation Act
EM	DOE Office of Environmental Management
EM-QA-001	EM Quality Assurance Program
EPO	Enforcement Program Overview
ES&H	Environment, Safety and Health
FM	Functional Manager
G	Guide
GFSI	Government Furnished Services and Items
HMR	Hazardous Materials Regulations
IEEE	Institute of Electrical and Electronics Engineers
IMS	Integrated Management System
ISMS	Integrated Safety Management System
ISO	Note: ISO is not an acronym but is used in the identifier for standards issued by the International Organization for Standardization
IT	Information Technology
ITS	Issues Tracking System
M&TE	measuring and test equipment
MBWA	management by walking around
NNSA	National Nuclear Security Administration
NQA-1a-2009	ANSI/ASME Standard <i>Quality Assurance Requirements for Nuclear Facility Applications</i>
NTS	Noncompliance Tracking System
O	Order
OM	Organizational Manager
O&M	Operations and Maintenance
OFI	Opportunity for improvement
OPEX	Operating Experience

ORPS	Occurrence Reporting and Processing System
OSHA	Occupational Safety and Health Administration
PDCA	Plan-Do-Check-Act
PGDP	Paducah Gaseous Diffusion Plant
PM	Project Manager
PPPO	Portsmouth/Paducah Project Office
QA	Quality Assurance
QAP	Quality Assurance Plan
QASP	Quality Assurance Surveillance Plan
QIP	Quality Assurance Implementation Plan
QL	Quality Level
S&S	Safeguards and Security
S/CI	suspect/counterfeit items
SCAQ	significant condition adverse to quality
SME	subject matter expert
SOW	scope of work
SQA	software quality assurance
SSC	structure, system, and component
SSI	Swift & Staley Inc.
SSIMS	Safeguards and Security Information Management System
SST	Swift & Staley Team
STOP	Safety Team of Paducah

1.0 INTRODUCTION

Swift & Staley Inc. (SSI) provides infrastructure support services to the U.S. Department of Energy (DOE) in accordance with the prime contract DE-EM0003733, *Infrastructure Support Services Contract* (the Contract). SSI provides the management; administration; environment, safety, and health (ES&H); quality assurance (QA); engineering; and project management functions necessary to accomplish the following scope elements.

- Radiological site services for others
- Safeguards and Security (S&S)
- Computing, telecommunication, and cyber security (CTCS)
- Operation and management of assets
- Records management and document control (including operation of the DOE Environmental Information Center)
- Mail services
- Training services
- On-site fueling service
- Energy Employees Occupational Injury Compensation Program Act (EEOICPA)

1.1 Purpose and Objective

This Quality Assurance Plan (QAP) describes how Swift & Staley Team (SST) meets the quality requirements as defined in the Contract; 10 Code of Federal Regulations (CFR) 830, Subpart A, *Quality Assurance Requirements* (the Rule); DOE Order (O) 414.1D, *Quality Assurance* (the Order); and DOE Office of Environmental Management (EM) *Quality Assurance Program* (EM-QA-001). The QAP includes a Quality Assurance Implementation Plan per EM-QA-001 as Attachment A, *Quality Assurance Implementation Plan* (QIP). References to the QAP throughout the remainder of the document include the QIP.

The QAP was written utilizing DOE Guide (G) 414.1-2B Admin. Chg. 2, *Quality Assurance Program Guide* (the Guide).

1.2 Scope

The SST QAP applies to employees and suppliers of SST (as specified in the procurement document) for work conducted at the Paducah site.

1.3 Summary of Key Changes

This revision of the QAP includes the following program changes. None of these changes reduce the overall quality program and are the results of corrective actions taken in response to DOE-identified and self-identified issues, as well as continuous improvement efforts.

- SST has added information related to auditor training for NQA-1 auditors.
- SST has added information related to procurement and acceptance of items and services.

2.0 APPLICATION OF ISO 9001:2015

2.1 ISO 9001:2015

SST has been granted a variance to use ISO 9001:2015 as the appropriate consensus standard for the Contract scope of work (SOW)¹. ISO 9001 is a globally recognized quality standard for industrial and service applications. SST uses ISSC-PM-PL-001, *Integrated Management System (IMS) Plan*, to integrate the requirements of ISO 9001:2015 and ISO 14001:2015 into a single management system, and document the context of the organization, which includes:

- Internal and external issues
- Relevant interested parties
- Identification of Key Processes and Objectives
- Mapping the interaction of the Key Processes
- Documenting the IMS Scope and Policy

In addition, SST uses ISSC-PM-PL-004, *Key Processes and Measurement Plans*, to document the details of each process plan, diagram their anatomy, and defines the measurement plans SST uses to track Key Performance Indicators.

SST will continue to adhere to American Society of Mechanical Engineers (ASME) NQA-1a-2009, *Quality Assurance Requirements for Nuclear Facility Applications*, as specified in EM-QA-001 for activities that meet the definitions applicable to nonreactor nuclear facilities, conducted on behalf of other DOE prime contractors as Government Furnished Services and Items (GFSI), as well as SST employees.

2.2 Requirements

SST presents a crosswalk of the ten quality criteria defined in the Order to the ISO 9001:2015 quality requirements in Attachment B. The crosswalk notes those areas where the ISO standard does not adequately address the Order requirements. This QAP ensures that those additional DOE requirements are acknowledged and addressed.

3.0 APPLICATION OF GRADED APPROACH

SST applies QA program requirements to items, services, processes, and activities in a graded manner. Consistent with EM-QA-001 and ISO 9001:2015, SST applies QA

¹ Letter from R. Edwards to T Courtney, "CONTRACT NO. DE-EM0003733: RESPONSE TO RESUBMITTAL OF THE ANNUAL REVIEW OF DELIVERABLE NO. 13, QUALITY ASSURANCE PROGRAM AND DELIVERABLE NO. 14 QUALITY ASSURANCE IMPLEMENTATION PLAN" (PPPO-02-4635445-18) received January 31, 2018.

controls according to the significance, impact, and probability and consequences of failure of the item or service (risk-based approach). Application of a graded approach process ensures that the level of analysis, documentation, and actions used to comply with requirements are commensurate with the following criteria as defined in the Order.

- The relative importance to safety, environment, and Safeguards & Security (S&S)
- The magnitude of any hazard involved
- The life-cycle stage of a facility or item
- The programmatic mission of an associated facility or activity
- The particular characteristics of a facility or item
- The relative importance of radiological and non-radiological hazards
- Other relevant factors (e.g., complexity, economic value)

The SST risk management process is defined in ISSC-PM-PL-002, *Risk Management Plan for the Infrastructure Services Contract at Paducah, Kentucky*. Section 2 of the risk management plan defines the risk methodology.

The graded approach is applied to the procurement process through the assignment of a quality level (QL). The type and rigor of vendor qualification and inspection of items and services are established based on the QL. Attachment C provides the SST QLs and associated levels of controls. SST applies (flows down) quality and safety requirements to subcontractors and suppliers consistent with the assigned QL and in conformance with the Order and EM-QA-001.

4.0 QUALITY PROGRAM CRITERIA

4.1 Criterion 1 – Program

-
- a. *Establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work.*
 - b. *Establish management processes, including planning, scheduling, and providing resources for the work.*
-

4.1.1 PROGRAM DEFINITION

The QA program is a management system that addresses the four major elements of the fundamental Plan-Do-Check-Act (PDCA) cycle: (1) planning activities, (2) performing work under controlled conditions, (3) assessing the adequacy of work, and (4) collecting feedback to incorporate in future work planning. The QA program utilizes PDCA to support continuous improvement.

This QAP provides the overall strategy for implementing the SST QA program in a tailored manner. Separate documents (e.g., procedures, training modules, work packages) provide specific controls for the achievement and verification of the quality of items or activities. SST supplements the QAP with QA program plans as required to provide specific quality guidance for projects and functions [e.g., SST *Dosimetry Quality*

Assurance Program Plan]. The QIP (Attachment A) provides a crosswalk of the ten QA Criteria from the Order with applicable SST processes and implementing documents.

SST applies quality controls appropriately to each work activity using a graded approach commensurate with the risk to workers, the public, and the environment (graded approach or risk-based approach). SST does not have operational responsibility for any nuclear or radiological facilities. Therefore, SST has adopted consensus standard ISO 9001:2015 for non-nuclear activities and NQA-1a-2009 requirements from Part I and Part II for nuclear activities as applicable to the scope of work (SOW). Examples of nuclear-related work within the SOW include the following activities.

- Working in nuclear facilities for the other DOE prime contractors (e.g., mowing in cylinder yards, maintenance in a Category 2 or 3, or radiological facility)
- Nuclear activity records management (e.g., quality records from nuclear facility activities that are generated by other prime contractors)
- Radiological control program administration and implementation when designated by other prime contractors for nuclear facilities (maintenance of radiological equipment or software applications designated as supporting the safety basis for other prime contractors' nuclear or radiological facilities)
- Training provided as GFSI to contractors with nuclear facilities that fulfills a requirement of the safety basis for other prime contractors (e.g., training tied to Technical Safety Requirements)

Where NQA-1a-2009 is applied, SST does not grade requirements to zero, but applies all Part I and Part II elements in a graded approach, in accordance with EM-QA-001. SST considers applicable Part III and Part IV guidance as specified in Attachment A.

All other work (e.g., mowing, maintenance, janitorial, non-nuclear training, snow removal, security, information technology support) is controlled under the requirements of the Rule, the Order, EM-QA-001, and ISO 9001:2015.

4.1.2 ORGANIZATION, ROLES, AND RESPONSIBILITIES

In the Contract (DE-EM0003733) project organization, line managers [including the Vice President and Project Manager (PM), Deputy Project Manager (DPM), Organizational Managers (OMs), Functional Managers (FMs), and Supervisors] have the responsibility and accountability for work execution and performance as they apply to their department, function, and the overall project. Line managers are responsible and accountable for:

- Flowing down and implementing the contract requirements as directed by the Corporate Board of Directors (BOD) and PM in compliance with directives, laws, and standards;
- Establishing and maintaining compliant programs and processes to execute the contract SOW and submitting associated deliverables;
- Planning, scheduling, and providing resources to perform the contract work; and

- Ensuring personnel have the competence to perform the work through establishment of qualifications and technical and safety training, direction, mentoring, and oversight.

All personnel have the responsibility and authority to immediately suspend/stop work if an activity or process seriously jeopardizes safety, health, the environment, security, or quality. The BOD reports to the respective parent companies and the DOE Portsmouth Paducah Project Office (PPPO). The PM reports to the BOD and DOE PPPO; the DPM and OMs report to the PM. The QA Manager has additional dotted line reporting to the President to ensure independence in the event of a conflict between quality and operations. FMs report to the OMs. Other organizational personnel report directly to FMs and Supervisors.

Selected personnel may be recognized as a Subject Matter Expert (SME) by their Line Manager, and listed in ISSC-QA-TD-002, *Subject Matter Expert Index*. An SME is defined as the employee most knowledgeable about the professional standards, requirements, and practices used within the discipline represented. The recognition of an SME is solely based on line manager discretion and recorded through concurrence with the SME Index. SMEs are points of contact for exchanging information, coordinating activities, answering questions, reviewing documents, screening lessons learned, etc.

The PM retains full responsibility for the successful implementation of the QA Program. Figure 1 shows the management structure.

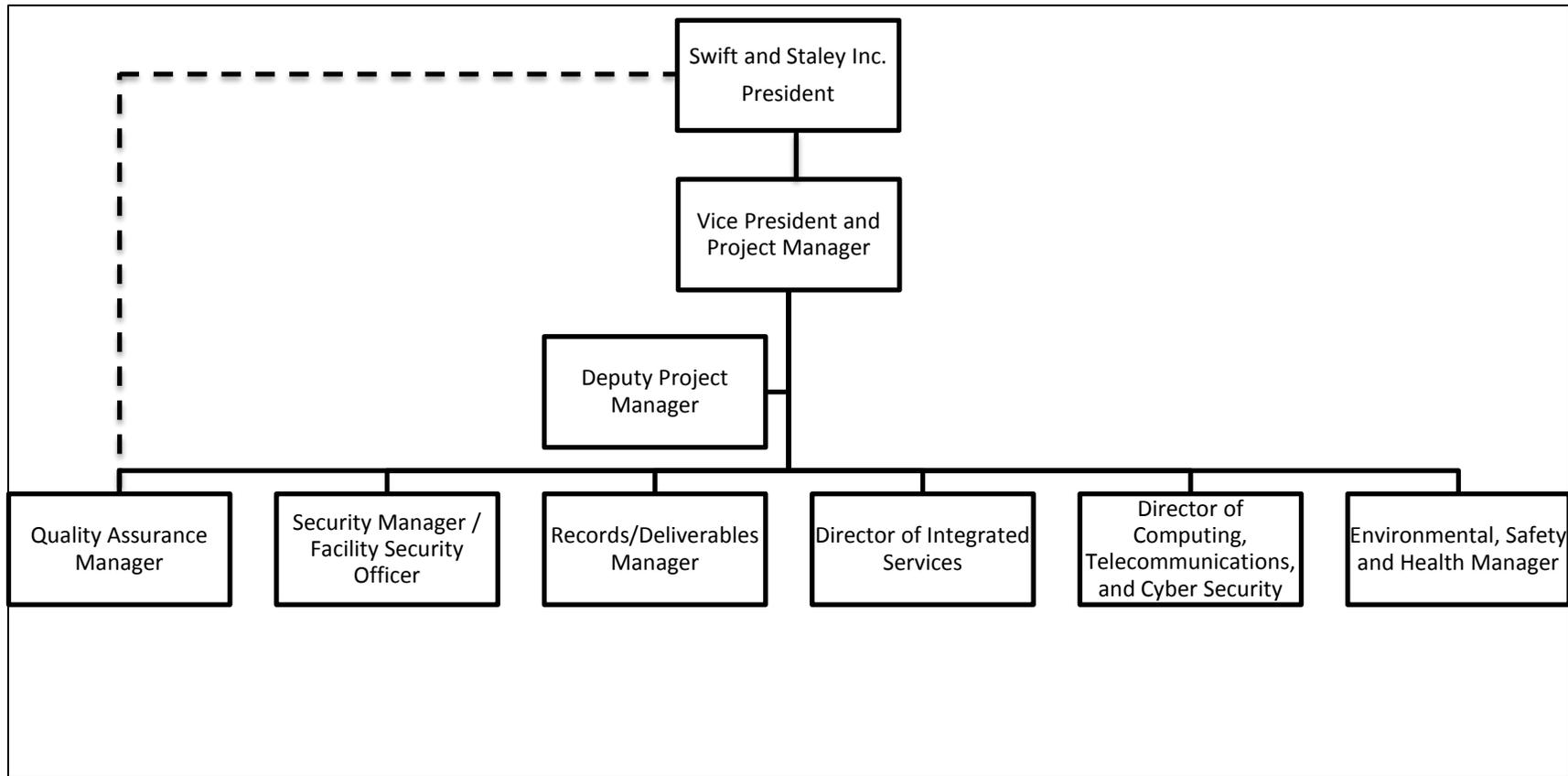


Figure 1. Swift and Staley Organization

The QAP describes the basic SST organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing work. Company procedures, organization charts, and internal memoranda provide further detail on responsibilities, authorities, and interfaces as necessary. ISSC-PM-PL-003, *Roles, Responsibilities, Authorities, and Lines of Communication*, provides descriptions of the roles, responsibilities, authorities, and lines of communications for the PM, DPM, managers, and other key positions integral to the performance of the contract scope.

4.1.3 MANAGEMENT PROCESSES

ISSC-QA-PL-004, *Contractor Assurance System (CAS)*, describes the key management processes that ensure successful performance of the contract SOW. These key processes are:

- Contract Management
- Special Projects
- Operations and Maintenance (O&M)
- Safeguards and Security (S&S)
- Information Technology (IT), Telecommunications and Cyber Security
- Radiological Control, Dosimetry and Training
- Records and Deliverables

The CAS further describes the objectives applicable to each key process and the key performance indicators used to monitor effectiveness.

4.2 Criterion 2 – Personnel Training and Qualification

-
- a. *Train and qualify personnel to be capable of performing their assigned work.*
 b. *Provide continuing training to personnel to maintain their job proficiency.*
-

4.2.1 QUALIFICATION OF PERSONNEL

SST qualifies and trains personnel commensurate with their responsibilities. Management establishes initial qualification requirements for specific job categories through job descriptions, and supplements these basic requirements with initial and continuing training documented in position assignment forms and performance plans. Qualified personnel include certain equipment operators, industrial hygiene personnel, and Radiological Control personnel. The certification process is similar to qualification, but includes testing and/or written designation by company officers. Certification is documented by the designated manager based on qualifications, training, experience and education (resume), and other factors as deemed appropriate.

4.2.2 TRAINING

The SST Training Program (ISSC-ESH-PL-001, *Training Program*) describes the processes for ensuring personnel competence commensurate with responsibilities. Training techniques include lectures, classroom presentations, seminars, computer-

based training, on-the-job training, and structured self-study activities. SST utilizes the learning management system, classroom attendance sheets, crew briefing sheets, or other means to document training. SST utilizes training from a variety of sources to meet employee needs, including internally developed and presented training, subcontracted training, DOE Training Institute classes, DOE National Training Center classes, free training through federal and state agencies, and vendor-provided training.

SST provides initial training programs for personnel to develop or enhance their knowledge and skills to perform job assignments, including an orientation to the SST QA Program. Training program content is commensurate with specific position needs including job responsibilities, authority, acceptable standards and regulations, and procedural requirements. SST utilizes examinations and/or operational evaluations on material included in the training programs as appropriate.

Continuing training programs maintain and enhance the knowledge and skills of designated personnel. Continuing training includes items such as regulatory or directive changes, training in significant facility system and component changes, procedure changes, industry operating experience, selected fundamentals with emphasis on knowledge and skills necessary to assure safety, and training to correct identified performance problems. Employees also receive annual review of the QA program.

4.2.3 ORGANIZATIONAL KNOWLEDGE AND AWARENESS

SST provides its employees with the knowledge necessary for the operation of its key processes and to achieve conformity of services. Selected personnel may be recognized as a SME by their Line Manager, and listed in ISSC-QA-TD-002, *Subject Matter Expert Index*. An SME is defined as the employee most knowledgeable about the professional standards, requirements, and practices used within the discipline represented.

SST has ensured that persons doing work are aware of the integrated management system policy, the relevant integrated management system objectives, their contribution to the effectiveness of the integrated management system, and the implications of not conforming to the integrated management system requirements.

4.2.4 QUALIFICATION OF AUDITORS

ISSC-QA-PR-006, *Qualification/Certification of Auditors*, applies to personnel conducting audits of activities for SST. Personnel conducting, leading or participating in audits are trained in the audit process. The QA Manager may alternately accept prior audit training, working knowledge of the audit process, and/or prior audit experience.

4.2.5 CERTIFICATION OF NQA-1 LEAD AUDITORS

ISSC-QA-PR-006, *Qualification/Certification of Auditors*, applies to personnel leading/conducting audits of nuclear program activities for SST. The Lead Auditor candidate submits the certification paperwork to serve as a NQA-1 Lead Auditor. The QA Manager evaluates Lead Auditor qualifications, and assigns additional training in

codes, standards, regulations, and QA Program elements, as deemed necessary. After successfully demonstrating written and oral skills through testing and participation in a combination of five audits within a three year period including one nuclear audit within the year prior to qualification, the QA Manager recommends the Lead Auditor to the PM for certification. Up to four of the audits can be substituted with other team assessment activities (consistent with NQA-1a-2009). The PM certifies Lead Auditors for the current contract SOW.

4.2.6 MAINTENANCE OF PROFICIENCY OF NQA-1 LEAD AUDITORS

ISSC-QA-PR-006, *Qualification/Certification of Auditors*, applies to personnel leading/conducting audits of nuclear program activities for SST. The candidate submits the proficiency paperwork to continue serving as a NQA-1 Lead Auditor. The QA Manager evaluates NQA-1 Lead Auditor qualifications, and assigns additional training in codes, standards, regulations, and QA Program elements, as deemed necessary. After participation in at least one nuclear quality assurance audit in the 12 months since certification or annual proficiency verification, or completion of training in an applicable subject matter area (codes, standards, and procedures), the QA Manager recommends the candidate as an NQA-1 Lead Auditor to the PM for certification. The PM certifies NQA-1 Lead Auditors for the current contract SOW.

4.2.7 RECERTIFICATION OF NQA-1 AUDITORS/LEAD AUDITORS

The candidate submits the requalification paperwork to serve as a NQA-1 Auditor/Lead Auditor. The QA Manager evaluates NQA-1 Auditor/Lead Auditor qualifications, and assigns additional training in codes, standards, regulations, and QA Program elements, as deemed necessary. After successfully demonstrating written and oral skills through testing and participation in a minimum of one nuclear quality assurance audit within the two year period, the QA Manager recommends the NQA-1 Auditor/Lead Auditor to the PM for certification. The PM certifies NQA-1 Auditors/Lead Auditors for the current contract SOW.

4.2.8 CERTIFICATION OF NQA-1 AUDITORS

ISSC-QA-PR-006, *Qualification/Certification of Auditors*, applies to personnel conducting audits of nuclear program activities for SSI. The candidate submits the paperwork to serve as a NQA-1 Auditor. The QA Manager evaluates NQA-1 Auditor qualifications, and assigns additional training in codes, standards, regulations, and QA Program elements, as deemed necessary. After successfully demonstrating written and oral skills through testing and participation in a combination of five audits within a three year period including one nuclear audit within the year prior to qualification, the QA Manager recommends the Lead Auditor to the PM for certification. The PM certifies NQA-1 Auditors for the current contract SOW.

4.2.9 CERTIFICATION OF INSPECTION AND TEST PERSONNEL

SST has no contractual scope which requires Inspection and Test Personnel. If Inspection and Test Personnel were required to meet new or additional scope, SST would evaluate and approve candidates by their education, experience, training and either test results or demonstration of capability. Qualifications, evidence of approval and related inspection and test activities would be documented and saved as records.

4.2.10 QUALIFICATION OF TECHNICAL SPECIALIST

There are no Technical Specialists currently involved in SST operations. However, if Technical Specialists were to be used, the auditing organization shall establish the qualifications and requirements for use of technical specialists to accomplish the auditing of the quality assurance programs, and document through a memo to file, in accordance with NQA-1a-2009.

4.2.11 RECORDS

The qualification of inspection, test, and applicable audit personnel shall be certified in writing and include the following information:

- (1) Employer's name
- (2) Identification of person being verified
- (3) Activities certified to perform
- (4) Basis of qualification
 - (a) Education, experience, indoctrination, and training
 - (b) Test results, where applicable
 - (c) Capability demonstration results
- (5) Results of periodic evaluation
- (6) Results of physical examinations, if applicable
- (7) Signature of employer's designated representative who is responsible for such certification
- (8) Date of certification or recertification and certification expiration

4.3 Criterion 3 – Quality Improvement

-
- a. *Establish and implement processes to detect and prevent quality problems.*
 - b. *Identify, control, and correct items, services, and processes that do not meet established requirements.*
 - c. *Identify the causes of problems, and include prevention of recurrence as a part of corrective action planning.*

- d. *Review item characteristics, process implementation, and other quality related information to identify items, services, and processes needing improvement.*
-

4.3.1 CONTINUOUS IMPROVEMENT

The SST QA program follows the PDCA method for continuous improvement. Methods used for problem prevention include self-checking, peer review, self-assessment, performance measures (metrics), internal and external customer surveys, performance analysis, management by walking around (MBWA), and trending.

SST fosters continuous improvement in the performance of activities by implementation of the management assessment program as described in Criterion 9 and audit program described in Criterion 10. The QA Program evaluations include review of quality program data from the management assessments and from audits to identify programmatic issues. Implementation of the operating experience and lessons learned programs also fosters continuous improvement.

Another objective of quality improvement is to reduce the variability of processes that directly or indirectly influence the quality of products and services. SST strives to meet problem prevention and continuous quality improvement objectives by measuring and evaluating performance against key performance indicators/standards. Quarterly trending analysis by the QA group looks at item characteristics, process implementation, and other quality-related information, and analyzes the data to identify items, services, and processes needing improvement. SST reviews the data for adverse trends that impact the quality of items and processes. Trends requiring action are tracked in the Issues Tracking System (ITS).

4.3.2 NONCONFORMANCE IDENTIFICATION AND CONTROL

SST expects personnel to report identified nonconforming items and processes (ISSC-QA-PR-004, *Control of Nonconforming Items and Services*), and ISSC-QA-PR-013, *Issues Management*. Procedures define the reporting system used to identify such items and processes, to correct deficiencies, to ensure adequate closure of issues, and to provide effectiveness reviews, when needed. Multiple procedures describe other mechanisms used for bringing events, conditions, employee concerns, and issues to management's attention:

- ISSC-PM-PR-007, *Shared Site Issues*
- ISSC-ESH-PR-008, *Accident-Incident Reporting*
- ISSC-QA-PR-011, *Nuclear Program Audits*
- ISSC-QA-PR-012, *Management Assessments*
- ISSC-QA-PR-010, *Audits*
- ISSC-HR-PR-002, *Employee Concerns*

Front-line supervisors and mid-level managers collect employee feedback and concerns during pre-job and post-job briefings as another means to communicate nonconformances. SST maintains a Hazard Tracking database to give employees and additional means to submit safety-related concerns, anonymously if desired.

Controls exist to prevent the inadvertent testing, installation, or use of nonconforming items and processes (ISSC-QA-PR-001, *Acceptance of Items and Services*). SSI uses established controls such as the identification and tagging of items, segregation of items (when possible), and conditional releases. The Engineering and Assets Manager (E&AM) approves nonconforming item dispositions such as rework or use-as-is, provides a technical justification that details the reasoning behind the disposition decision, and identifies any additional testing that may be required. Evaluation and disposition of nonconforming items are handled according to ISSC-QA-PR-004, *Control of Nonconforming Items and Services*. Control and disposition of supplier nonconformances are also handled in ISSC-QA-PR-004, *Control of Nonconforming Items and Services*. Responsible organizations review and approve nonconformities and disposition of items. QA Specialists inspect and/or test repaired nonconforming items against the original acceptance criteria. QA specialists also use original acceptance criteria for reworked or use-as-is items unless the E&AM specifies alternate acceptance criteria. QA completes such inspections or tests prior to the final acceptance of the item.

QA activities associated with nonconforming items and processes include validation of the nonconformance, review of dispositions, verification of completion of disposition actions, and closure of the reporting document.

4.3.3 CORRECTIVE ACTION PROGRAM

SST uses established processes to detect and prevent quality problems. Items, services, and processes that do not meet established requirements are identified and reported in a timely manner, then controlled and corrected according to the importance of the problem and the affected work. Correction addresses the immediate nonconformance. Corrective action includes identifying the causes of problems and taking action to prevent recurrence (ISSC-QA-PR-013, *Issues Management*). SST utilizes ITS to track issues and actions. ITS is a single, company-level problem identification and corrective action control system consistent with DOE G 414.1-2B Admin. Chg. 2, *Quality Assurance Program Guide*.

SST is subject to identification of issues through independent oversight (e.g., DOE, state, or federal regulators). SST controls and corrects quality problems identified through independent sources through the same processes used for internally-identified issues. SST supports independent assessment teams and provides feedback on final reports. Corrective action plans (CAPs) include compensatory actions as needed, and actions to prevent recurrence of the problem, for all program or performance deficiencies. Updates on corrective action status through closure of the action are provided to the independent oversight group as requested.

While the inputs to the corrective action process come from multiple, problem-identification sources, the tools used to resolve each type of problem have consistent process steps. The issue owner, assisted by the QA organization, assigns the significance category, causes, cause codes, Integrated Safety Management System (ISMS) codes, corrective actions, and completion dates to each nonconformance. The QA group enters the issues into the ITS. ITS sends an email to the issue owner and

their manager for acceptance of the corrective action assignment. The QA Manager or designee, with assistance from appropriate SMEs, conducts reviews for Occurrence Reporting and Processing System (ORPS) and Enforcement reportability. The QA group provides weekly reports from ITS to management and all personnel with assigned actions.

SST designates issues as nonconformances (nonconformities) or opportunities for improvement. Nonconformities require correction and/or corrective action by the responsible manager. Nonconformities that represent significant programmatic breakdowns (i.e., serious effect on safety or operability) are classified as Significant Conditions Adverse to Quality (SCAQs). Opportunities for improvement (OFIs) are areas that, when addressed, contribute to increased organizational effectiveness or efficiency and performance excellence (continuous improvement). Response to OFIs by the responsible manager is not mandatory, but do not require a justification for not addressing. External auditors have different definitions and SST responds to issues from external audits per those definitions.

All issues identified in a nuclear program area are considered nonconformances [conditions adverse to quality (CAQs)] and must be addressed by the responsible manager.

4.3.4 CORRECTIVE ACTION PLANS

CAPs are the collection of corrective actions necessary to address all the issues associated with a particular audit or assessment. A member of the QA team approves all CAPs, and the QA Manager and PM approve all CAPs for issues identified by external oversight. For each corrective action, SST will identify the following:

- Documentation of completion
- Responsible organizations and individuals
- Dates actions are planned to be completed (estimated completion dates)

SST schedules effectiveness reviews as required by ISSC-QA-PR-013, *Issues Management*. When performed, effectiveness reviews determine whether completed corrective actions have effectively resolved the initial issue and prevented recurrence of the same or similar issues, and identify any additional actions necessary.

Documentation associated with all quality improvement activities are QA records and are managed in accordance with Criterion 4, *Documents and Records*.

4.4 Criterion 4 – Documents and Records

-
- Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design.*
 - Specify, prepare, review, approve, and maintain records.*
-

4.4.1 DOCUMENTS

SST adopts the NQA-1 definition of a document, which is, “Any written, pictorial, or electronic information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results. A document is not considered to be a QA record until it satisfies the definition of a QA record” (Section 4.2). This definition is also consistent with the ISO 9000, *Quality Management Systems – Fundamentals and Vocabulary*, definition of document, which is; “Information (meaningful data) and the medium on which it is contained” (Section 3.8.5 et. al. of ISO 9000). SST prepares, reviews, approves, issues, uses, and revises documents to prescribe processes or specify requirements.

SST conducts quality-related activities in accordance with approved processes. Documented processes are controlled, maintained, stored, protected, and capable of being retrieved in a timely manner. The Records Management group retains the record copies of documents for their specified retention period (PGDP-RM-PR-001, *Records Management*). Documents provide the level of detail necessary to perform the task and knowledgeable individuals review documents prior to issuance. The level of detail is based on the work complexity, safety significance, work environment, and personnel safety, and worker competence. Each manager is responsible for developing, reviewing, approving, issuing, and revising documents associated with their work activities.

SST assigns “ownership” of documents to the organization primarily responsible for the conduct of the program or activity described. Organizational personnel and SMEs review and approve the original document and document revisions. Personnel from other functional organizations review and approve documents based on their technical competence and capability in the required functional areas as requested by the author. The revision process also provides for urgent changes to be processed expeditiously.

The Document Control and Procedure Coordinator, as part of the Records Management functional group, is responsible for issuance and maintenance of controlled documents (ISSC-RM-PR-001, *Controlled Documents*). The Document Control and Procedure Coordinator makes controlled copies of approved documents available to personnel electronically. When necessary, the Document Control and Procedure Coordinator also may distribute or make available hard copies of controlled documents. Document control activities include provisions for a master index and/or table of contents to identify the current revisions of controlled documents. Employees are instructed to utilize the current revision of controlled documents as issued by the Document Control and Procedure Coordinator.

4.4.2 PROCEDURES

Procedure refers to any document that is used to control work activities to ensure safety, quality, security, and consistent performance (e.g., procedures, work instructions, work packages, Activity Hazard Assessments, policies, charters, forms). The primary goal of controlling procedures is to maintain configuration control to ensure that the worker has the most current procedure that documents the best work practices.

The primary individual procedures that document the procedure controls are listed in Attachment A.

4.4.3 RECORDS

SST is responsible for the storage, protection, maintenance, and disposition of DOE records at Paducah Gaseous Diffusion Plant (PGDP). Approved procedures and work instructions describe the operations and responsibilities for Records Management, and include mechanisms for record revision, storage, retention, destruction, and personnel access. SST Records Management provides for the storage and disposition of special record media to include photographic film, magnetic media, and optical disc storage devices.

Practices and procedures exist that identify records and describe methods to prepare, review, approve, and maintain records. SST authenticates and controls records through the process described in PGDP-RM-PR-001, *Records Management*, and associated procedures and forms. Throughout this QAP, use of the term records is consistent with the NQA-1 definition of a quality assurance record, which is, "A completed document that furnishes evidence of the quality of items and/or activities affecting quality" and the ISO 9000 definition of record, which is, "Document stating results achieved or providing evidence of activities performed" (Section 3.8.10 et. al.). Types of record media may include paper, electronic (magnetic or optical), or specially processed media such as radiographs, photographs, negatives, and microforms. Electronic records also include electronic mail, electronic files, and information stored in databases or other programs. SST maintains the hardware and software needed to access records. SST uses "backwards compatible" record retrieval software to ensure that previous electronic records are not lost or rendered unusable. Originators of records must classify the record generated from nuclear activities as lifetime or non-permanent per NQA-1a-2009, Requirement 17, *Quality Assurance Records*, according to the following requirements:

- Lifetime records are those that meet one or more of the following criteria:
 - Those that would be of significant value in demonstrating capability for safe operation
 - Those that would be of significant value in maintaining, reworking, repairing, replacing, or modifying an item
 - Those that would be of significant value in determining the cause of an accident or malfunction of an item
 - Those that provide required baseline data for in-service inspections
- Lifetime records are required to be maintained for the life of the particular item while it is installed in the plant or stored for future use.
- Nonpermanent records are those required to show evidence that an activity was performed in accordance with the applicable requirements but need not be retained for the life of the item because they do not meet the criteria for lifetime records. Nonpermanent records are maintained for the identified retention period.

Records have sufficient content to provide objective evidence of the quality of an item or activity and are identified in implementing procedures. The Records Management organization maintains records in accordance with guidelines established by 44 United States Code Chapter 29, 36 CFR Chapter XII, ISO 9001:2015, NQA-1a-2009 (where applicable), and the National Archives and Records Administration requirements. The Senior Records Manager coordinates with DOE to ship records for long-term storage to an approved records storage facility. SST bases decision for the transfer or disposal of records created and maintained by and for DOE on the DOE Records Disposition Schedules, and obtains approval for transfers or destruction from the PPPO Records Management Field Officer.

4.4.4 RECORDS FACILITIES

SST requires originators of records to submit them to Records Management electronically. SST accepts and maintains paper copies only for records required by regulation to be issued as a hardcopy. SST manages the primary electronic records management system for long-term retention of records. SST converts historical records to electronic format as described in the contract SOW. SST also uses satellite areas for field operating records prior to their transfer to Records Management. The Senior Records Manager approves use of satellite areas to ensure they are equipped with fire detection, suppression devices (or other protective devices), and fire-rated cabinets, or duplicates of the records are stored in an alternate location. SST provides for the controlled access to, and the retention, traceability, accountability, and retrievability of records. Records storage facilities or mechanisms provide protection from natural disasters and environmental conditions that might negatively impact the quality of stored records.

4.5 Criterion 5 – Work Processes

-
- 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.*
 - b. *Identify and control items to ensure proper use.*
 - c. *Maintain items to prevent damage, loss, or deterioration.*
 - d. *Calibrate and maintain equipment used for process monitoring or data collection.*
-

4.5.1 PERFORMANCE OF WORK

Work control processes (primarily described in ISSC-PM-PR-003, *Work Planning and Control*, and ISSC-PM-PR-002, *Project Work Process*) describe how SST manages work; ensures compliance with applicable standards and technical requirements that are tailored to the work and hazards; and enhances worker safety. These processes require line organizations and personnel performing work to be responsible for the quality, safety, and security of their work. Working to established standards and controls is consistent with expectations of the ISMS and S&S core functions and guiding principles.

SST conducts work processes in accordance with appropriate conduct of operations as specified in ISSC-PM-TD-003, *Swift & Staley Team Conduct of Operations Applicability Matrix*. SST trains personnel in the concepts of conduct of operations.

SST develops requirements for work processes using a risk-based approach appropriate for the facility type, task difficulty, environmental and safety consequences, quality, security, and programmatic effects. The graded approach determines the extent of involvement of QA, support functions, safety, environment, and/or security functions in the review, approval, and monitoring of work control activities, and in the level of detail and control in the work document.

Work control programs require that personnel with work approval authority review the work requests and provide approval prior to work start and changes during work execution. Closed work packages become records.

SST utilizes predictive and preventive, as well as corrective, maintenance on selected equipment. Predictive maintenance preemptively addresses potential problems based on historical knowledge of operations. Preventive maintenance ensures significant equipment operates within design parameters. The corrective maintenance program includes criteria to test the item to verify it meets specified operational parameters.

Personnel responsible for work performance help prepare and review the work package for correctness and adequacy and to become familiar with contents. Appropriate safety, environmental, engineering, QA, and operations and maintenance (O&M) personnel review and approve work packages prior to commencement of work. Multidisciplinary teams review new, complex, infrequently performed, or more hazardous work. After completion, reviews verify that desired results have been attained and that the required documentation is completed. Worker feedback documented on the closed work packages is collected and reviewed for applicability for future work.

The SST maintenance management program is responsive to applicable requirements of DOE O 433.1B, Admin Change 1, *Maintenance Management Program for DOE Nuclear Facilities*, concerning personnel training, qualification, tools, metrics, and oversight for work conducted in nuclear activities.

Instructions accompanying work packages comply with the requirements of applicable technical standards, vendor manuals, safety codes, specifications, and/or other technical requirement documents. Monitoring of work activities may include self-checking, peer review, hold points, and independent oversight. Each of these monitoring activities evaluates the work against the criteria in the work documents or associated procedure(s).

4.5.2 IDENTIFICATION AND CONTROL OF ITEMS

Items are identified and controlled to ensure their proper use and maintained to prevent their damage, loss, or deterioration using a risk-based approach. SST controls measuring and test equipment (M&TE) per ISSC-PM-PR-005, *Control of Measuring and Test Equipment*.

SST utilizes an identification program for items or substances in construction, modification, waste management, environmental, and chemical work activities. When required, SST applies identification markings on items from initial receipt or fabrication up to and including installation or use. The identity for these items or substances is maintained either on the item packaging or in documentation traceable to the item. Shelf-life information is maintained on the original container and any subdivided containers.

SST processes include provisions for labeling and marking to replace damaged or aged label information. SST personnel review labeling and marking as part of routine checks (e.g., waste area inspections, chemical inventories, operational inspections, MBWA, daily equipment checks) and responsible managers correct deficiencies.

4.5.3 HANDLING, STORING, AND SHIPPING

ISSC-PM-PR-005, *Control of Measuring and Test Equipment*, provides instructions for the control, handling, storage, and shipping of certain items to prevent damage, loss, or deterioration (e.g., radiological survey instruments). The control levels established for handling and shipping are derived from technical documents, such as vendor manuals, and are specified where necessary, in procedures and/or procurement documents. SST has limited warehousing capability, instead relying primarily on pickup or delivery of items when needed. Upon receipt, SST considers most items “in-use” as opposed to “stored.” SST temporarily stores office equipment, IT equipment, and limited quantities of consumables.

SST complies with 49 CFR Parts 171-180, *Hazardous Materials Regulations (HMR)*, and 49 CFR Parts 350-399, *Federal Motor Carrier Safety Regulations*, for the onsite transfer of hazardous materials. SST manages hazardous waste and ships waste offsite in compliance with the HMR. SST flows down these requirements when waste management and/or shipment are subcontracted.

4.5.4 MEASURING AND TEST EQUIPMENT

The M&TE program is based on applicable requirements in ISO 9001-2015 and NQA-1a-2009, and for radiological M&TE Institute of Electrical and Electronic Engineers (IEEE) N323AB-2013, *American National Standard Radiation Protection Instrumentation Test and Calibration*, Portable Survey Instruments and American National Standards Institute (ANSI) N323D-2002, *Installed Radiation Protection Instrumentation*. Equipment used for inspections, tests, monitoring, and surveys is identified, calibrated, and maintained.

The M&TE Coordinator ensures calibration of M&TE at specified intervals and in-use checks as established by documented requirements. Calibration is performed against standards traceable to national measurement standards or to international measurement standards that have been verified against national standards.

SST follows the NQA-1a-2009 standard for accuracy of M&TE calibration standards for M&TE associated with nuclear activities to ensure that equipment will be calibrated within required tolerances. If no national standards exist, SST identifies alternative

standards. These standards have a minimum accuracy four times that of the equipment being calibrated, or documented and accepted technical justification for use of alternate standards. M&TE calibration frequencies are based on regulatory requirements, vendor recommendations, required accuracy, intended use, frequency of use, stability characteristics, and other conditions affecting performance. M&TE is labeled, tagged, or otherwise controlled to indicate calibration status. M&TE identification provides traceability to calibration and test data. M&TE found to be out of calibration is tagged and/or segregated to prevent use until dispositioned.

4.5.5 CONTROL OF COMPUTER SOFTWARE

SST adheres to and applies the applicable QA requirements listed in Attachment 2 of the Order to all software using a graded approach. SST managed facilities are non-nuclear; however SST invokes requirements in Attachment 4 of the Order using applicable NQA-1 Part I and Part II standard requirements to safety software supporting nuclear activities as defined in Section 4.1.1, Program Definition. SST adheres to EM-QA-001, *EM Quality Assurance Program (QAP)*, Attachment G – *Software Quality Requirements*, for validation and verification of developed software. Software requirements are flowed down to subcontractors, vendors, and consultants as applicable.

SST does not grade SQA requirements to zero; therefore all software is controlled. The ISSC-IT-PL-001, *Software Quality Assurance Program Plan* provides the software control methodology and programmatic structure that is flowed down to the ISSC-IT-PR-003, *Software Quality Assurance* implementing procedure.

ISSC-IT-TD-004, *SST Software Inventory Report*, ISSC-QA-TD-002, *Subject Matter Expert Index*, and SST.IT-0020, *Information Technology Subject Matter Expert List* identify key personnel responsible for software design, procurement, testing, management, control, and retirement. These individuals are designated by management dependent on demonstration of proficiency in software lifecycle management and through a combination of completed training and experience.

4.5.6 SUSPECT/COUNTERFEIT ITEMS

The QA Manager or designee is responsible for the suspect/counterfeit items (S/CI) program implementation and serves as the point of contact with the DOE Office of Environment, Health, Safety, and Security (AU-1) on S/CI issues. SST implements the S/CI Program in accordance with the Order and EM-QA-001, which flows down requirements of International Atomic Energy Agency TECDOC-1169, *Managing Suspect and Counterfeit Items in the Nuclear Industry* (August 2000). SST utilizes DOE-HDBK-1221-2016, *Suspect/Counterfeit Items Resource Handbook*, and DOE G 414.1-2B, Admin. Chg. 2, *Quality Assurance Program Guide*, in the implementation of the S/CI Program.

The extent to which S/CI controls are applied is commensurate with the importance of the item to safe and reliable operations (risk-based approach). S/CI program requirements are included in technical and QA specifications added to the appropriate

procurement mechanism (e.g., purchase order, subcontract, service agreement) to ensure purchase of new parts from reputable vendors and to provide the basis for receipt inspection and acceptance prior to use. When S/CI is identified, SST removes it to prevent use.

The work process controls used to prevent/detect S/CI include a combination of engineering and administrative controls that involve the SME, Procurement, QA, supervisors, and oversight. The extent to which these controls are applied is commensurate with the importance of the item to safe and reliable operations. These controls include the following:

- Developing procurement specifications and other types of supplier controls
- Receipt inspection
- Field assessment

The Operating Experience (OPEX) Coordinator reviews information resources regularly to keep abreast of the latest S/CI data. Resources include, but are not limited to, OPEXShare, ORPS, commercial recalls and bulletins, and the DOE S/CI Website.

The QA Manager or designee serves as the primary contact for S/CI information from AU-1 and is responsible for implementation of the S/CI Program to ensure the following.

- Obtaining the latest information on S/CI through the AU-1 website
- Reporting S/CI to DOE (PPPO and Headquarters, as appropriate)
- Evaluating and dispositioning potential S/CI
- Contacting the DOE Inspector General when required for counterfeit items
- Conducting tests using approved engineering test methods
- Performing trend analyses
- Issuing reports as required (e.g., ORPS, Lessons Learned)
- Providing S/CI training

4.6 Criterion 6 – Design

-
- a. *Design items and processes using sound engineering/scientific principles and appropriate standards.*
 - b. *Incorporate applicable requirements and design bases in design work and design changes.*
 - c. *Identify and control design interfaces.*
 - d. *Verify or validate the adequacy of design products using individuals or groups other than those who performed the work.*
 - e. *Verify or validate work before approval and implementation of the design.*
-

SST self-performs limited design work and subcontracts additional design work as needed. SST ensures that design work is conducted by the appropriate engineering discipline and by engineers with adequate education, experience, and certifications (e.g., professional engineers licensed by the state in which the work is done). Design control is applied to projects from planning, through implementation and documentation (ISSC-PE-PR-005, *Engineering*). Application of design criteria is established using a graded approach. The graded approach is based upon complexity and the potential

impact on facility safety, worker safety, and/or protection of the environment. The graded approach applies the following criteria in varying degrees:

- Design items and processes using sound engineering/scientific principles and appropriate standards
- Incorporate applicable requirements and design bases in design work and design changes
- Identify and control design interfaces
- Verify/validate the adequacy of design products using individuals or groups other than those who performed the work
- Verify/validate work before approval and implementation of the design
- Control design drawings and technical specification changes (configuration control)
- Control changes to design to the same level as original

4.7 Criterion 7 – Procurement

-
- Procure items and services that meet established requirements and perform as specified.*
 - Evaluate and select prospective suppliers on the basis of specified criteria.*
 - Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services.*
-

4.7.1 PROCUREMENT PROGRAM DEFINITION

Procurement procedures provide a detailed methodology for preparing, reviewing, and approving purchase requisitions, amendments to requisitions, procurement specifications, bid packages, and other procurement documents. The applicable SST procedures used to ensure procured items and services meet established requirements and perform as specified are listed in Attachment A.

Technical, administrative, and quality requirements are developed using a risk-based approach appropriate for the items or services being procured and are specified in procurement documents (ISSC-QA-PR-007, *Quality Level Determination for Procurement of Items and Services*). These requirements include appropriate codes, regulations, industry standards, tests and inspections, traceability, and any special instructions. SST conducts technical review of supplier offers for supplier assurance that the item or service provided meets the requirements of the procurement documents.

The SST SOW does not include facilities or equipment requiring Commercial Grade Dedication in the procurement process.

4.7.2 SUPPLIER SELECTION AND EVALUATION

Supplier selection and evaluation applies to the procurement of items and services. The SST management team evaluates and selects prospective suppliers on the basis of

specified criteria and under a graded approach, using one or more of the following:

- Supplier history
- DOE complex-wide supplier information
- Supplier records attesting to their ability to provide the appropriate quality
- Direct evaluation of the supplier's facility, program, and capability

Suppliers of items or services must demonstrate qualifications that satisfy the requirements of the procurement specifications. Based on the nature and application of items or services being procured, the QA group evaluates the supplier's quality program and capabilities for supplier selection. SST may pre-approve the quality program of suppliers of items or services deemed critical to safety, security, quality, or the protection of employee health or the environment. In addition, QA conducts requalification and supplemental audits on suppliers to verify compliance with the procurement requirements.

4.7.3 PROCUREMENT DOCUMENTS

Procurement documents contain the appropriate level of technical and quality requirements. Management team members, Business Management, SMEs, and QA review and approve procurement documents prior to award or purchase. Significant or intent changes to the documents require the same level of review and approval as the original. The request for proposal or other purchase documents (e.g., purchase order) issued to prospective suppliers include, as applicable, a SOW that clearly describes the work to be performed, requirements that flow down from the SST contract, requirements that specify the requirements for the Supplier's reporting of nonconformities, and a list of deliverables (drawings, data, manuals, etc.) that must be provided to SST, as applicable.

Quality assurance program requirements are defined in procurement documentation, for items or services related to the stated NQA-1a-2009 SOW. These requirements are applied in a graded approach consistent with importance and/or complexity of the item or service being procured.

- Documents shall require the Supplier to incorporate appropriate quality assurance program requirements in subtier procurement documents.
- Documents shall specify the technical requirements for the service or item.
- Documents shall identify the appropriate test, inspection, and acceptance criteria for determining acceptability of the item and/or service.
- Documents shall list the requirements for the Supplier's reporting of nonconformances.
- Documents shall also specify the Supplier's requirements to identify spare and replacement parts or assemblies and the related data required for ordering these parts or assemblies.

4.7.4 ITEMS AND SERVICES ACCEPTANCE

Purchased items or services are accepted by the method(s) specified by the requisitioning organization or supporting functions (e.g., ES&H, Security, QA, and Engineering). Items critical to safety or having significant operational risks are accepted by one or more of the following methods: certificate of conformance, source verification, receiving inspection, post-installation testing, and/or document review. The document review acceptance method may include a certificate of conformance (CofC) from the supplier attesting that the item or service meets or exceeds contract requirements. The CofCs identify the material, procurement document, and standards and are signed by the supplier's quality representative. Refer to procedure ISSC-QA-PR-001, *Acceptance of Items and Services*, for acceptance of items or services by certificate of conformance. Document review also may include the supplier's program description documents, manufacturing or processing procedures, certified material test reports, and others as deemed appropriate by the requisitioner and QA. These documents are controlled through their acceptance, evaluation, and disposition and are traceable through the contract to the item or service.

The QA organization performs source verification and receiving inspection activities utilizing procurement document criteria (SST Procedure ISSC-QA-PR-001, *Acceptance of Items and Services*). The QA group may conduct source verifications at supplier facilities using qualified personnel to verify compliance to bid or contract requirements. Procurement documents specify unrestricted access to supplier's facilities for the purpose of source verifications, inspections or audits (SST Work Instruction WI-QA-011, *Supplier Audit*). For acceptance of services only, vendor performance is another method to accept the services. Vendor performance could include technical verification of data produced, oversight of the activity or review of evidence for conformance to procurement requirements. Refer to procedure ISSC-QA-PR-001, *Acceptance of Items and Services*, for use of vendor performance as an acceptance method.

Procured items are put into service only when the acceptance requirements have been satisfied. If an item does not meet a specified requirement, the QA Manager or designee initiates a nonconformance report to document the deficiency according to the requirement in ISSC-QA-PR-004, *Control of Nonconforming Items and Services*.

4.8 Criterion 8 – Inspection and Acceptance Testing

-
- a. *Inspect and test specified items, services, and processes using established acceptance and performance criteria.*
 - b. *Calibrate and maintain equipment used for inspections and tests.*
-

4.8.1 CONTRACT PERFORMANCE QUALITY ASSURANCE PLAN

The SST QA Program ensures that services performed for our customers meet the defined quality criteria, or meet the requirements of the customer where criteria are not specifically defined. DOE has defined a specific set of Requirements, Performance Criteria, and Acceptable Quality Levels (AQLs) for work under the Contract via the DOE

QASP. SST uses an internal Contract Performance Quality Assurance Plan (CPQAP) to describe the processes for tracking performance to the DOE QASP. QA and management personnel provide independent oversight of work to check for compliance with customer requirements and to identify defects (i.e., inaccuracies or omissions in services or products) or emerging trends that may indicate needed corrections to avoid problems. Line managers conduct a monthly management assessment (i.e., QASP self-assessment) to compare work performance to the AQLs. This management assessment report is documented as part of the Invoice Performance Report submitted to DOE.

The CPQAP contains an appendix that clarifies key elements of the DOE QASP. The Customer Service Specialist serves as a primary point of contact for DOE, prime contractor, and internal customers. The Customer Service Specialist monitors SST services for compliance with requirements, monitors metrics to identify and address emerging issues, attends routine and special meetings with customers to gather customer requirements and concerns, and actively solicits customer feedback for incorporation in the overall SST QA Program continuous improvement process. The Customer Service Specialist works with the management team and front line supervisors to help them understand where they have performance deficiencies, or may have performance deficiencies developing, and helps identify appropriate corrective actions. In addition, the Customer Service Specialist actively looks for and seeks out program and process improvement opportunities that can be implemented to improve the quality of services and increase efficiency.

4.8.2 INSPECTION

The QA program includes the preparation and implementation of quality testing and inspection processes for ongoing work. SST uses established acceptance and performance criteria to conduct inspections of specified items, services, and processes.

When needed, SST uses certified personnel to conduct nondestructive examination and civil, electrical, and mechanical inspections and testing. SST may procure these services. Projects that detail performance standards (e.g., electrical divisions, concrete density) have those standards examined or tested by certified personnel based on specifications.

When sampling is necessary for inspection of items or processes, SST follows ANSI/American Society for Quality Z 1.4-2003 (R2013), *Sampling Procedures and Tables for Inspection by Attributes*, or other appropriate consensus standard.

4.8.3 TEST CONTROL

Depending upon the significance of the non-safety equipment, SST may employ testing in a graded approach to assure conformance to specified requirements. The design authority documents test parameters, specialized training, environmental conditions, and acceptance criteria in a test plan or work package, which is approved by the QA Manager or designee. Completed tests document the non-safety-related structure, system, or component performance against specified requirements and include the date, name of tester, observations, results, and action to correct deviations (if any). The

design authority, line manager, and QA Manager or designee review and accept completed test results. Completed test documents are maintained as records.

4.8.4 MEASURING AND TEST EQUIPMENT

Where necessary, SST calibrates and maintains equipment used for inspections and tests as M&TE, to ensure traceability and accountability. M&TE typically includes instruments, tools, gauges, reference and transfer standards, and nondestructive examination equipment. Refer to Section 4.5.4, Measuring and Test Equipment, for additional information on the M&TE Program.

4.9 Criterion 9 – Management Assessment

Ensure that managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives.

SST identifies issues through self-checking, peer checking, and management assessments as described in ISSC-QA-PR-012, *Management Assessments*. Self-assessment ensures the adequacy and effectiveness of SST work activities and management control systems to support continuous improvement. The program requires managers and designees to evaluate the performance of the activities assigned to their organization and to identify and correct problems that may hinder the organization's ability to perform. Managers select personnel to conduct these self-assessments and provide them the authority and access to information to effectively identify nonconformities and other issues. The QA group oversees the conduct of management assessments by reviewing assessment reports and assisting with the identification of issues, cause analysis, and development of clear, closeable actions.

4.10 Criterion 10 – Independent Assessment

-
- a. *Plan and conduct independent assessments to measure item and service quality, to measure the adequacy of work performance, and to promote improvement.*
 - b. *Establish sufficient authority and freedom from line management for independent assessment teams.*
 - c. *Ensure persons who perform independent assessments are technically qualified and knowledgeable in the areas to be assessed.*
-

SST conducts independent assessments (i.e., audits) as described in ISSC-QA-PR-010, *Audits*; WI-QA-011, *Supplier Audits*; and ISSC-QA-PR-011, *Nuclear Program Audits*.

SST meets the DOE requirement for independent assessment of programs through two primary means. First, SST utilizes audit services from outside the SST organization. ISO 9001 and ISO 14001 certification audits provide a review of the quality and environmental management programs completely independent of the SST organization. To ensure compliance with DOE requirements, SST supplements these independent program audits by calling on other DOE prime contractors to provide audit support

services, not only of the QA and environmental programs, but also other performance areas.

Second, the QA organization provides independent audits for other functions within the organization, or procures independent oversight services from outside agencies through corporate reach back or subcontracting. The audits are part of the ISMS and S&S feedback and improvement function, and are separate from and in addition to those identified in Criterion 9. The PM and QA Manager or designee develop the Fiscal Year Integrated Oversight Schedule to ensure the oversight program meets requirements and organizational needs.

Audit planning includes defining the scope, identifying the requirements, identifying the assessment team, describing the activities to be reviewed, and identifying persons to interview. SST auditors develop lines of inquiry or assessment criteria derived from source documents, and documents these in checklists used during the assessment. Audits are typically performed by teams of two or more; however, NQA-1a-2009 allows single auditor teams. The leader of the assessment team must be a trained auditor (for non-nuclear program audits) or a Certified Lead Auditor (Criterion 2) for audits of nuclear program areas.

The group performing audits has complete authority and freedom from the line organizations to carry out its responsibilities. Personnel performing audits do not have direct responsibilities in the area(s) they are assessing.

5.0 REFERENCES

- 10 CFR 830, Subpart A, *Quality Assurance Requirements*
- DOE G 414.1-1C, *Management and Independent Assessments Guide*
- DOE G 414.1-2B, Admin. Chg. 2, *Quality Assurance Program Guide*
- 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*
- DOE G 450.4-1C, *Integrated Safety Management System Guide*
- DOE-HDBK-1221-2016, *Suspect/Counterfeit Items Resource Handbook*
- DOE O 226.1B, *Implementation of Department of Energy Oversight Policy*
- DOE O 414.1D, Admin. Chg. 1, *Quality Assurance*
- DOE O 420.1C, *Facility Safety*
- DOE O 450.2, *Integrated Safety Management*
- DOE Policy 450.4A, *Integrated Safety Management Policy*
- EM-QA-001, Rev. 1, *Office of Environmental Management (EM) Quality Assurance Program*
- International Atomic Energy Agency TECDOC-1169, *Managing Suspect and Counterfeit Items in the Nuclear Industry*
- DOE Quality Assurance Surveillance Plan (Attachment J-11 of DE-EM0003733)
- ASME NQA-1a-2009, *Quality Assurance Requirements for Nuclear Facility Applications*
- ANSI/IEEE 498, *Standard Requirements for the Calibration and Control of Measuring and Test Equipment Used on Nuclear Facilities*

- ISO 9001:2015, *Quality management systems – Requirements*
- ISO 14001:2015, *Environmental management systems – Requirements with guidance for use*

6.0 QUALITY ASSURANCE GLOSSARY OF TERMS

Acceptance Testing (software) – The process of exercising or evaluating a system or system component by manual or automated means to ensure that it satisfies the specified requirements and to identify differences between expected and actual results in the operating environment. (ASME NQA-1a-2009; DOE O 414.1D Criterion 8)

Acquired Software – Software generally supplied through basic procurements, two-party agreements, or other contractual arrangements. Acquired software includes commercial off-the-shelf (COTS) software, such as operating systems, database management systems, compilers, software development tools, and commercial calculation software and spreadsheet tools (e.g., Mathsoft’s MathCad and Microsoft’s Excel). Downloadable software that is available at no cost to the user (referred to as freeware) is also considered acquired software. Firmware is acquired software. Firmware is usually provided by a hardware supplier through the procurement process and cannot be modified after receipt.

Application Programmer – The IT employee, subcontractor, or vendor assigned responsibility to develop or modify software code for software applications.

Assessment (Management) – A review, evaluation, inspection, test, check, surveillance, or audit performed by a manager or other person familiar with the work activity to determine and document whether items, processes, systems, or services meet specified requirements and perform effectively.

Audit – A planned and documented activity performed to determine by investigation, examination, or evaluation of objective evidence, the adequacy of and compliance with established procedures, instructions, drawings, and other applicable documents, and the effectiveness of implementation (NQA-1a-2009); or a systematic, independent and documented process for obtaining objective evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled (ISO 9000:2015).

Auditor – An individual qualified and trained to perform audits.

Calibrate/calibration – Comparison of two instruments or measuring devices, one of which is a standard of known accuracy traceable to national standards, to detect, correlate, report, or eliminate by adjustment any discrepancy or inaccuracy of the instrument or measuring device being compared with the standard. Field checks (e.g., zero the instrument) do not constitute calibration.

Cause – A factor that, if corrected, is expected to prevent recurrence of the issue.

Certification – The act of determining, verifying, and attesting in writing to the qualifications of an individual.

Competence – Ability to apply knowledge and skills to achieve intended results (ISO 9000:2015).

Compliance-Based Oversight – Oversight processes that focus on review of the regulatory, DOE directive or other requirements, and look for evidence of compliance with those requirements.

Condition² – Any as-found state, whether or not resulting from an event, that may have adverse safety, health, QA, operational or environmental implications. A condition is usually programmatic in nature. For example, errors in analysis or calculation; anomalies associated with design or performance; or items indicating a weakness in the management process are all conditions.

Condition Adverse to Quality (CAQ) (NQA-1) – An all-inclusive term used in reference to any of the following: failures, malfunctions, deficiencies, defective items, and nonconformances.

Configuration Management (Software) – The process of identifying and defining the configuration items in a system (i.e., software and hardware), controlling the release and change of these items throughout the system's life cycle, and recording and reporting the status of configuration items and change requests.

Correction – Action taken to eliminate a detected nonconformity (ISO 9000:2015).

Corrective Action – Measure taken to rectify conditions adverse to quality and, where necessary, to preclude repetition (NQA-1a-2009) or action to eliminate the cause of a nonconformity and to prevent recurrence (ISO 9000-2015).

Corrective Action Plan – The collection of corrections and/or corrective actions assigned for all issues from a single source (e.g., internal or external assessment, audit, walk down, Initial Event Report).

Effectiveness Review – An evaluation of a corrective action plan to determine whether the actions taken corrected the initial issues and will work to prevent recurrence of the issue, or a similar issue, from occurring.

Enforcement Coordinator – The designated person within SST that has the appropriate training to evaluate and report enforcement rule noncompliances.

Event³ – Something significant and real-time that happens (e.g., pipe break, valve failure, loss of power, environmental spill, earthquake, tornado, flood, injury).

Extent of Condition – A generic implication of a failure, malfunction, deficiency, defective item, weakness or issue (i.e., the actual or potential applicability for an event or condition to exist in other activities, projects, programs, facilities or organizations). A determination of whether any corrective actions should be implemented by organizations outside of the organization that experienced the issue.

Extent of Problem – A review to determine how many items or activities are impacted by the identified failure, malfunction, or weakness (e.g., if one piece of equipment failed, are there others that may be close to failure?).

² Definition from DOE O 232.2A, *Occurrence Reporting and Processing of Operations Information*.

³ Definition from DOE O 232.2A, *Occurrence Reporting and Processing of Operations Information*.

Finding – A type of condition adverse to quality, which represents a departure from a written requirement.

Hardware – Physical equipment that, when placed together in a certain configuration to support a software program, becomes part of the controlled operating environment for that software.

Hazard⁴ – Means a source of danger (i.e., material, energy source, or operation) with the potential to cause illness, injury, or death to a person or damage to a facility or to the environment (without regard to the likelihood or credibility of accident scenarios or consequence mitigation).

In-process surveillance – The act of evaluating a product during the fabrication stage.

Issue – A general term referring to significant conditions adverse to quality, conditions adverse to quality, nonconformances (nonconformities), findings, observations, etc.

Lead Auditor – The qualified and trained individual assigned to organize and direct audits, report audit results, and evaluate corrective actions in accordance with ISSC-QA-PR-006, *Qualification/Certification of Auditors*.

Lessons learned⁵ – A “good work practice” or innovative approach that is identified and shared, or an adverse work practice or experience that is captured and shared to avoid recurrence.

Life Cycle – The series of stages through which a software application passes during its lifetime.

Measuring Equipment – Measuring instrument, software, measurement standard, reference material or auxiliary apparatus or combination thereof necessary to realize a measurement process (i.e., set of operations to determine the value of a quantity) (ISO 9000:2015)

Measuring and Test Equipment – Devices or systems used to calibrate, measure, gage, test or inspect in order to control or acquire data to verify conformance to specified requirements (NQA-1a-2009).

Management By Walking Around – An informal periodic evaluation of field activities by the management team.

Nationally Recognized Testing Laboratory – An Occupational Safety and Health Administration (OSHA) designation given to testing facilities that provide product safety testing and certification to manufacturers.

Noncompliance Tracking System (NTS) – A centralized DOE database that allows DOE contractors to promptly report potential nuclear or worker safety and health enforcement rule noncompliances and associated corrective actions and enables contractors to take advantage of the mitigation provision of the DOE enforcement policy.

⁴ From 10 CFR 830, Subpart A, *Quality Assurance*.

⁵ Definition from DOE O 232.2A, *Occurrence Reporting and Processing of Operations Information*.

Nonconformity/Nonconformance – Non-fulfilment of a requirement (ISO 9000:2015). Or, a deficiency in characteristic, documentation, or procedure that render the quality of an item or activity unacceptable or indeterminate (NQA-1a-2009). See also Finding.

Nonreactor Nuclear Facility⁶ – Nonreactor nuclear facility means those facilities, activities or operations that involve, or will involve, radioactive and/or fissionable materials in such form and quantity that a nuclear or a nuclear explosive hazard potentially exists to workers, the public, or the environment, but does not include accelerators and their operations and does not include activities involving only incidental use and generation of radioactive materials or radiation such as check and calibration sources, use of radioactive sources in research and experimental and analytical laboratory activities, electron microscopes, and X-ray machines.

Nonreportable noncompliance – An enforcement rule noncompliance that does NOT exceed the Enforcement Program Overview (EPO) thresholds for reporting.

Noteworthy Practice – An activity or process that exceeds the minimum requirements and supports continuous improvement. This should be reserved for a novel methodology that exceeds requirements.

Notification report – The initial documented report to the Department of an event or condition that meets the reporting criteria defined in DOE O 232.2A.

Occurrences⁶ – Events or conditions that adversely affect, or may adversely affect, DOE (including National Nuclear Security Administration [NNSA]) or contractor personnel, the public, property, the environment, or the DOE mission.

Occurrence report⁶ – A documented evaluation of a reportable occurrence that is prepared in sufficient detail to enable the reader to assess its significance, consequences, or implications and to evaluate the actions being proposed or employed to correct the condition or to avoid recurrence.

Occurrence Reporting and Processing System – An unclassified, centralized DOE database containing occurrence reports from the DOE community.

Operating Experience – A generic term for numerous DOE and industry publications for communicating lessons learned (e.g., alerts, bulletins, OPEX reports, and summaries).

OPEX Program Coordinator – The person primarily responsible for collectively reviewing and disseminating OPEX and lessons learned from external and internal sources.

Opportunity for Improvement – A situation or condition of a management system that may be weak, cumbersome, redundant, overly complex, or in some other manner, may, in the opinion of the auditor, offer an opportunity for an organization to improve its current status. OFIs do not require any action on the part of the organization; however, the organization should give them serious consideration in view of the auditor's knowledge and exposure to similar systems.

⁶ From DOE O 232.2A, *Occurrence Reporting and Processing of Operations Information*.

Performance-Based Oversight – Oversight processes that focus on the performance of the work through review of activities in the field and checking for how well performance objectives (e.g., scope, cost, schedule, and defined processes) are being met.

Performance/Trend analysis – A quarterly analysis of events during the previous 12-month period to detect trends and recurrences.

Plan of Actions and Milestones – The corrective actions identified to respond to the issues identified by an assessment in the IT area. The Plan of Actions and Milestones serves the same function as a CAP and are entered into the ITS.

Procurement Package – The collection of documents used to successfully acquire items and services on behalf of DOE.

Procurement Representative – The Business Management organization employee who handles the procurement.

Product recalls – The act of a manufacturer requesting the return of a commercial product, because of a defect, safety concern, or efficiency problem.

Qualification, personnel – The characteristics or abilities gained through education, training, or experience, as measured against established requirements, such as standards or tests that qualify an individual to perform a required function (NQA-1a-2009) or demonstrated competence (ability to apply knowledge and skills to achieve intended results) (ISO 9000:2015).

Qualified Suppliers List – A compilation of suppliers who have successfully completed a QA review in accordance with WI-QA-0011, *Supplier Audits*, to provide services or items that meet the determined QL.

Quality Level – A determined value that reflects the graded approach to procurement quality in accordance with ISSC-QA-PR-007, *Quality Level Determination*. The QL is used to determine the appropriate controls and verifications based on the risk of failure.

Receipt inspection – A verification inspection performed items and services after product delivery and prior to being placed in service in accordance with ISSC-QA-PR-001, *Acceptance of Items and Services*. The inspection criteria are based on the procurement documents.

Reject – A disposition action taken to eliminate a nonconforming item or service from its specified use (e.g., scrap, return to supplier, etc.).

Repair – The disposition process of restoring a nonconforming item to reliable and safe function, even though that item may not conform to the original requirements (technical justification required).

Reportable noncompliance – An enforcement rule noncompliance that exceeds the EPO threshold for reporting.

Requisitioner – The individual initiating a procurement action (e.g., requisition or subcontract).

Review (Enforcement) – Process to determine which issues or problems constitute a potential noncompliance with enforcement regulations.

Rework – The disposition process by which an item or service is made to conform to original requirements by completing processing or correcting a deficiency. The disposition of reworked items shall specify the original design requirements and other acceptance criteria and by what means it will be verified (e.g., testing).

Reverse Traceability – The ability to trace a measurement standard from the M&TE to which it was applied.

Root cause – The causal factor(s) that, if corrected, would prevent recurrence of the occurrence. It is the most basic cause that explains why the event happened, that can responsibly be identified, that senior management has the control to fix, and for which effective corrective actions can be generated.

Safety Software⁷ – Includes the following:

- Safety System Software. Software for a nuclear facility that performs a safety function as part of an [structure, system, and component] SSC and is cited in either (a) a DOE-approved documented safety analysis; or, (b) an approved hazard analysis per DOE P 450.4A and 48 CFR 970-5223.1.
- Safety and Hazard Analysis Software and Design Software. Software that is used to classify, design, or analyze nuclear facilities. This software is not part of a structure, system, and component (SSC) but helps to ensure the proper accident or hazards analysis of nuclear facilities or an SSC that performs a safety function.
- Safety Management and Administrative Controls Software. Software that performs a hazard control function in support of nuclear facility or radiological safety management programs or technical safety requirements or other software that performs a control function necessary to provide adequate protection from nuclear facility or radiological hazards. This software supports eliminating, limiting, or mitigating nuclear hazards to workers, the public, or the environment as addressed in 10 CFR Parts 830 and 835, the U.S. Department of Energy Acquisition Regulations Integrated Safety Management System clause, and 48 CFR 970-5223.1.

Scope of work – Information that allows for translation of mission into work, sets expectations and prioritizes tasks and allocates resources (ISMS). Procurement documentation providing detailed instructions concerning the work activities and performance of a service contract (for subcontracts).

Screening (Enforcement) – Process to determine which noncompliances exceed the screening thresholds as described in the EPO for reporting in either NTS or the Safeguards and Security Information Management System (SSIMS).

Self-assessment (Management Assessment) – An audit by a manager (or designee) of work activities under their control.

Significant Condition Adverse to Quality (NQA-1a-2009) – An issue that if uncorrected could have a serious effect on safety or operability.

⁷ Copied from DOE O 414.1D Chg. 1, Section 6.0, *Definitions*.

Software – Computer programs and associated documentation and data pertaining to the operation of a computer system (NQA-1a-2009).

Software application – Any program, whether developed or acquired, used in the processing, gathering, or generation of information, where that information is relied upon to make design, analytical, operational, or compliance-related decisions.

Software Owner – The person assigned primary responsibility for the content and correct use of a computer application. This person must authorize access and changes to the application.

Software Quality Assurance (SQA) – A process of systematic development, testing, documentation, maintenance, and execution of software applications designed to ensure all products conform to operational, functional, and technical requirements.

Software Requirements – Services and/or outputs a software application must provide to the Data Owner and the constraints under which the software application must operate.

Software Validation (Acceptance Testing) – The process of testing a software application and evaluating the results to ensure compliance with specified requirements.

Specification – Procurement documentation providing details and performance characteristics for an item or service.

Supplier Evaluation – Any activity undertaken to determine a supplier's ability to meet procurement requirements, as described in SST Work Instruction WI-QA-011.

Subject Matter Expert – Personnel designated by their manager as the employee most knowledgeable about the professional standards, requirements, and practices used within the discipline represented. SMEs are listed in ISSC-QA-TD-002, *Subject Matter Expert Index*.

Suspect/Counterfeit Items⁸ – An item that is suspect when inspection or testing indicates that it may not conform to established Government or industry-accepted specifications or national consensus standards or whose documentation, appearance, performance, material, or other characteristics may have been misrepresented by the vendor, supplier, distributor, or manufacturer. A counterfeit item is one that has been copied or substituted without legal right or authority or whose material, performance, or characteristics have been misrepresented by the vendor, supplier, distributor, or manufacturer. Items that do not conform to established requirements are not normally considered S/CIs if non-conformity results from one or more of the following conditions (which must be controlled by site procedures as nonconforming items):

- (1) Defects resulting from inadequate design or production quality control;
- (2) Damage during shipping, handling, or storage;
- (3) Improper installation;
- (4) Deterioration during service;

⁸ Copied from DOE O 414.1D Chg. 1, Section 6.0, *Definitions*.

- (5) Degradation during removal;
- (6) Failure resulting from aging or misapplication; or,
- (7) Other controllable causes. (IAEA-TECDOC-1169)

Technical Justification – A statement from an design authority defining the basis for the proposed course of action. This basis is founded on statements of fact derived from calculations, evaluations, codes, standards, documented history, or other technical sources. Sufficient detail exists to allow a peer to confirm the validity of the statement. Technical justifications are used with Repair and Use-As-Is dispositions.

Test – Determination (activity to find out one or more characteristics and their characteristic values) according to requirements (need or expectation that is stated, generally implied or obligatory) for a specific intended use or application (ISO 9000:2015).

Test Plan – A document that describes the approach to be followed for testing a system or component. Typical contents identify the items to be tested, tasks to be performed, and responsibilities for the testing activities (NQA-1a-2009).

Third Party Oversight – Oversight conducted by an outside agency on SSI. Examples include financial (Defense Contract Audit Agency) audits, regulatory audits, and DOE audits and surveillances (e.g., property management, cyber security, S&S assessments, enforcement program reviews, DOE Facility Representative walk downs).

Traceability – The ability to trace the history, application, or location of an item and like items or activities by means of recorded identification (NQA-1a-2009). The ability to trace the history, application, or location of an object. When considering a product or services, traceability can related to the origin of materials and parts, the processing history, or the distribution and location of the product or services after delivery (ISO 9000:2015).

Trend – Accumulated data indicating a tendency or movement in a particular direction.

Use-As-Is – A disposition permitted for a nonconforming item when it has been established that the item is satisfactory for its intended use (technical justification required).

Validation – The process of: (a) evaluating a system or component during, or at the end of the development process to determine whether it satisfies specified requirements; or, (b) providing evidence that the software, and its associated products, satisfies system requirements allocated to software at the end of each life-cycle activity, solves the right problem (e.g., correctly models physical laws, implements business rules, uses the proper system assumptions), and satisfies the intended use and user needs. (IEEE Standard 1012-2004) The confirmation, through the provision of objective evidence that the requirements for a specific intended use or application have been fulfilled (ISO 9000:2015).

Verification – The process of: (a) evaluating a system or component to determine whether the products of a given development phase satisfy the conditions imposed at the start of that phase; or, (b) providing objective evidence that the software and its

associated products conforms to requirements (e.g., for correctness, completeness, consistency, accuracy) for all life-cycle activities during each life-cycle process (acquisition, supply, development, operation, and maintenance); satisfies standards, practices, and conventions during life-cycle processes; and, successfully completes each life-cycle activity and satisfies all the criteria for initiating succeeding life-cycle activities (e.g., building the software correctly) (IEEE Standard 1012-2004). The act of reviewing, inspecting, testing, checking, auditing, or otherwise determining and documenting whether items, processes, services, or documents conform to specified requirements (NQA-1a-2009). Confirmation, through the provision of objective evidence, which specified requirements have been fulfilled (ISO 9000:2015).

7.0 ATTACHMENTS

A, Quality Assurance Implementation Plan

B, Requirements Crosswalk

C, Procurement Quality Levels and Associated Controls

ATTACHMENT A – QUALITY ASSURANCE IMPLEMENTATION PLAN

DOE O 414.1D and EM-QA-001	Processes	Swift & Staley Implementing Documents
<p>Criterion #1 – Program</p> <p>1. Establish an organizational structure, functional responsibilities, level of authority, and interfaces for those managing, performing, and assessing the work.</p> <p>2. Establish management processes, including planning, scheduling, and providing resources for the work.</p>	<p>Business Management Project management Special Projects Operations and Maintenance</p>	<p>All Work</p> <ul style="list-style-type: none"> • SSI.CFO-0003, <i>Project Management Plan for the Paducah Infrastructure Support Services Contract at Paducah, Kentucky</i> • ISSC-PM-PL-002, <i>Risk Management Plan for the ISC at Paducah</i> ISSC-QA-PL-002, <i>Contract Performance Quality Assurance Plan</i> • ISSC-PM-PL-001, <i>Integrated Management System Plan</i> • PGDP-SS-PL-007, <i>Site Security Plan</i> PGDP ISSC-QA-PL-004, <i>Quality Assurance Plan</i> • ISSC-QA-TD-002, <i>Subject Matter Expert Index</i> • SST.QA-0035, <i>Dosimetry Quality Assurance Program Plan</i> • ISSC-PM-PR-001, <i>Management Review Board</i> ISSC-ESH-PL-004, <i>Worker Safety and Health Plan</i> • ISSC-ESH-PL-010, <i>Integrated Safety Management System Description</i> SST.POL-001, <i>Approval and Signature Authority</i> • SST.POL-004, <i>Subject Matter Expert Policy</i> • SST Organization Chart <p>Nuclear Work</p> <ul style="list-style-type: none"> • NQA-1a-2009 Part III, 1A-1, <i>Guidance on Organization</i> • NQA-1a-2009 Part III, 2A-1, <i>Guidance on the Qualifications of Inspection and Test Personnel</i>

ATTACHMENT A – QUALITY ASSURANCE IMPLEMENTATION PLAN (CONTINUED)

DOE O 414.1D and EM-QA-001	Processes	Swift & Staley Implementing Documents
<p>Criterion #2 – Personnel Training and Qualification</p> <p>1. Train and qualify personnel to be capable of performing their assigned work.</p> <p>2. Provide continuing training to personnel to maintain their job proficiency.</p>	<p>Hiring Radiological Control, Dosimetry and Training Quality Management System</p>	<p>All Work</p> <ul style="list-style-type: none"> • ISSC-ESH-PL-001, <i>Training Program</i>, ISSC-ESH-PL-007, <i>Training Implementation Matrix</i> • PGDP-SS-PL-007, <i>Site Security Plan</i>, ISSC-ESH-PL-004, <i>Worker Safety and Health Plan</i> • ISSC-ESH-PR-004, <i>Conduct of Training</i> • ISSC-ESH-PR-014, <i>Training Development</i> • ISSC-ESH-PR-015, <i>Respiratory Protection Program</i> • ISSC-RAD-PR-006, <i>Radiological Control Technician Training</i> • ISSC-ESH-PR-025, <i>Paducah Radiation Safety Training</i> • ISSC-QA-PR-006, <i>Qualification/Certification of Auditors</i> • ISSC-OM-PR-004, <i>Industrial Equipment Operator Qualification</i> • Position descriptions • Professional qualifications • Industrial Equipment Operator Qualification • Receipt Inspector Certification • Auditor certification and designation <p>Nuclear Work</p> <ul style="list-style-type: none"> • NQA-1a-2009 Part III, 2A-1, <i>Guidance on the Qualifications of Inspection and Test Personnel</i> • NQA-1a-2009 Part III, 2A-3, <i>Guidance on the Education and Experience of Lead Auditors</i>

ATTACHMENT A – QUALITY ASSURANCE IMPLEMENTATION PLAN (CONTINUED)

DOE O 414.1D and EM-QA-001	Processes	Swift & Staley Implementing Documents
<p>Criterion #3 – Quality Improvement</p> <p>1. Establish and implement processes to detect and prevent quality problems.</p> <p>2. Identify, control, and correct items, services, and processes that do not meet established requirements.</p> <p>3. Identify the causes of problems, and include prevention of recurrence as a part of Corrective Action planning.</p> <p>4. Review item characteristics, process implementation, and other quality related information to identify items, services, and processes needing improvement.</p>	<p>Quality Management System Self-Assessment Operations & Maintenance Management Review Board Corrective and Preventative Actions Work Control</p>	<p>All Work</p> <ul style="list-style-type: none"> • PGDP Procedure 01.02.01, Safety Team of Paducah (STOP) <i>Committee</i> • ISSC-ESH-PL-006, <i>Environmental Management System</i> • ISSC-QA-PL-004, Contractor Assurance System • ISSC-PM-PR-001, <i>Management Review Board</i> • ISSC-PM-PR-007, <i>Shared Site Issues</i> • ISSC-ESH-PR-008, <i>Accident/Incident Reporting</i> • ISSC-QA-PR-004, <i>Control of Nonconforming Items and Services</i> • ISSC-QA-PR-011, <i>Nuclear Program Audits</i> • ISSC-QA-PR-012, <i>Management Assessments</i> • ISSC-QA-PR-010, <i>Audits</i> • ISSC-QA-PR-008, <i>Occurrence Notification and Reporting</i> • ISSC-QA-PR-002, <i>Enforcement Noncompliance Determination and Reporting</i> • ISSC-QA-PR-013, <i>Issues Management Program</i> • ISSC-QA-PR-003, <i>Event Investigation</i> • ISSC-QA-PR-009, <i>Operating Experience Program</i> • ISSC-QA-PR-001, <i>Acceptance of Items and Services</i> • ISSC-HR-PR-002, <i>Employee Concerns</i> • ISSC-PE-PR-005, <i>Engineering</i> <p>Nuclear Work</p> <ul style="list-style-type: none"> • NQA-1a-2009 Part III, 2A-4, <i>Guidance on Surveillance for Use in Assessment of Processes and Activities</i>

ATTACHMENT A – QUALITY ASSURANCE IMPLEMENTATION PLAN (CONTINUED)

DOE O 414.1D and EM-QA-001	Processes	Swift & Staley Implementing Documents
		<ul style="list-style-type: none"> • NQA-1a-2009 Part III, 16A-1, <i>Guidance on Corrective Action</i> • NQA-1a-2009 Part IV, Subpart 4.5, <i>Application Guide on the Use of NQA-1–2000 for Compliance With Department of Energy Quality Assurance Requirements 10 CFR 830, Subpart A and DOE O 414.1</i>
<p>Criterion #4 – Documents and Records</p> <p>Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design.</p> <p>Specify, prepare, review, approve, and maintain records.</p>	<p>Records and Deliverables</p>	<p>All Work</p> <ul style="list-style-type: none"> • SSI.DC-1003, <i>Records Disposition Plan</i> • SSI.DC-1004, <i>Records Management Plan</i> • SSI.DC-1007, <i>Essential Records Plan</i> • SST Procedure ISSC-ESH-PL-006, <i>Environmental Management System</i> • PGDP Procedure PGDP-RM-PR-001, <i>Records Management</i> • PGDP Procedure PGDP-RM-PR-001, <i>Document Control</i> • PGDP Procedure 01.04.04, <i>Administrative Records</i> • ISSC-RM-PR-001 <i>Controlled Documents</i> ISSC-HR-PR-001, <i>Release of Medical Records Outside of Swift & Staley Team</i> • ISSC-RAD-PR-010, <i>Radiation Protection Program Records</i> • SST Procedure 08.06.01, <i>Processing Freedom of Information Act and Privacy Act Requests</i> • ISSC-PE-PR-005, <i>Engineering</i> <p>Nuclear Work</p> <ul style="list-style-type: none"> • NQA-1a-2009 Part III, 17A-1, <i>Guidance on Quality Assurance Records</i>

ATTACHMENT A – QUALITY ASSURANCE IMPLEMENTATION PLAN (CONTINUED)

DOE O 414.1D and EM-QA-001	Processes	Swift & Staley Implementing Documents
		<ul style="list-style-type: none"> • NQA-1a-2009 Part III, 17A-2, <i>Guidance for Electronic Records</i> • NQA-1a-2009 Part IV, Subpart 4.4, <i>Application Guide for Managing Electronic Information</i>
<p>Criterion #5 – Work Processes</p> <ol style="list-style-type: none"> 1. Perform work consistent with technical standards, administrative controls, and other hazard controls adopted to meet regulatory or contractual requirements using approved instructions, procedures, or other appropriate means. 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>Measuring and test equipment Information Technology, Telecommunications and Cyber Work Control Corrective and Preventative Actions Radiological Control, Dosimetry and Training</p>	<ul style="list-style-type: none"> • All Work • SSI.CFO-0003, <i>Project Management Plan for the Paducah Infrastructure Support Services Contract at Paducah, Kentucky</i> • ISSC-PM-PL-002, <i>Risk Management Plan for the ISC at Paducah</i> SSI.OM-0004, <i>Space Cleaning Plan</i> • ISSC-OM-PL-005, <i>Snow and Ice Removal Plan</i> • ISSC-OM-PL-002, <i>Mowing Plan</i> • SSI.OM-0007, <i>Pest Control Plan</i> • ISSC-OM-PL-001, <i>Preventive Maintenance Plan</i> • ISSC-PM-TD-003, <i>SST Conduct of Operations Applicability Matrix</i> • ISSC-QA-PL-004, <i>Contractor Assurance System</i> • ISSC-QA-PL-001, <i>Quality Assurance Plan</i> • ISSC-QA-TD-002, <i>Subject Matter Expert Index</i> • SST.IT-0020, <i>Information Technology Subject Matter Expert List</i> • ISSC-ESH-PL-004, <i>Worker Safety and Health Plan</i> • ISSC-ESH-PL-010, <i>Integrated Safety Management System Description</i> • ISSC-ESH-PL-006, <i>Environmental Management System</i> • ISSC-PM-PR-001, <i>Management Review Board</i> • SST.POL-004, <i>Subject Matter Expert Policy</i>

ATTACHMENT A – QUALITY ASSURANCE IMPLEMENTATION PLAN (CONTINUED)

DOE O 414.1D and EM-QA-001	Processes	Swift & Staley Implementing Documents
		<ul style="list-style-type: none"> • ISSC-RM-PR-001 <i>Controlled Documents</i> • ISSC-ESH-PR-009, <i>Suspension of Work (Safety-Related)</i> • ISSC-PM-PR-005, <i>Control of Measuring and Test Equipment</i> • SST Procedure 03.02.10, <i>Hoisting and Rigging</i> • SST Procedure 03.04.03, <i>Chemical Safety Management Program</i> • SST Procedure 03.08.01, <i>Emergency Operations Center Activities</i> • SST.QA-0035, <i>Dosimetry Quality Assurance Program Plan</i> • ISSC-RAD-PR-014, <i>Workplace Monitoring</i> • ISSC-IT-PR-002, <i>Software Quality Assurance</i> • ISSC-PM-PR-003, <i>Work Planning and Control</i> • ISSC-PM-PR-002, <i>Project Work Process</i> • ISSC-PM-PR-004, <i>Work Package Development</i> • ISSC-OM-PR-001, <i>Public Address System Maintenance</i> • ISSC-OM-PR-002, <i>Public Warning System Maintenance</i> • ISSC-PE-PR-03, <i>Fleet Operations</i> • ISSC-BM-PR-002, <i>Definition and Organization of Work Scope</i> • PGDP-SS-PL-001, <i>Information Security Plan,</i> • PGDP-IT-PR-002, <i>Information Technology Baseline Configuration Management</i> • PGDP-IT-PR-010, <i>Routine and Scheduled Maintenance of Information Systems</i> • PGDP-IT-PR-005, <i>Account Management for Information Systems</i>

ATTACHMENT A – QUALITY ASSURANCE IMPLEMENTATION PLAN (CONTINUED)

DOE O 414.1D and EM-QA-001	Processes	Swift & Staley Implementing Documents
		<ul style="list-style-type: none"> • PGDP Procedure 10.03.01, <i>Media Sanitization</i> • ISSC-IT-PR-004, <i>Information Systems Data Backup</i> • PGDP -IT-PR-011, <i>Contingency Plan Procedure for the Paducah, Kentucky, Project Information Systems</i> • ISSC-PE-PR-005, <i>Engineering</i> <p>Nuclear Work</p> <ul style="list-style-type: none"> • N/A
<p>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 or validate the adequacy of design products using individuals or groups other than those who performed the work. 5. Verify or validate work before approval and implementation of the design. 	<p>Special Projects Information Technology, Telecommunications and Cyber Work Control</p>	<p>All Work</p> <ul style="list-style-type: none"> • ISSC-QA-PR-004, <i>Control of Nonconforming Items and Services</i> • ISSC-IT-PR-002, <i>Software Quality Assurance</i> • ISSC-PE-PR-005, <i>Engineering</i> <p>Nuclear Work</p> <ul style="list-style-type: none"> • NQA-1a-2009 Part I, Requirement 3, <i>Design Control</i> • NQA-1a-2009 Part II, Subpart 2.7, <i>Quality Assurance Requirements for Computer Software for Nuclear Facility Applications</i>
<p>Criterion #7 – Procurement</p> <p>Procure items and services that meet established requirements and perform as specified. Evaluate and select prospective suppliers</p>	<p>Business Management Special Projects Operations and Maintenance</p>	<p>All Work</p> <ul style="list-style-type: none"> • ISSC-ESH-PL-005, <i>Pollution Prevention Plan for Swift & Staley Team Facilities at the Paducah Gaseous Diffusion Plant</i> • SSI.SSPP-0001, <i>Fiscal Year Site Sustainability</i>

ATTACHMENT A – QUALITY ASSURANCE IMPLEMENTATION PLAN (CONTINUED)

DOE O 414.1D and EM-QA-001	Processes	Swift & Staley Implementing Documents
<p>on the basis of specified criteria.</p> <p>Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services.</p>		<p><i>Plan, Paducah Gaseous Diffusion Plant</i></p> <ul style="list-style-type: none"> • ISSC-QA-PL-004, <i>Contractor Assurance System</i> • ISSC-ESH-PR-013, <i>ES&H Subcontractor Oversight Program</i> • ISSC-QA-PR-004, <i>Control of Nonconforming Items and Services</i> • ISSC-QA-PR-009, <i>Operating Experience Program</i> • ISSC-QA-PR-007, <i>Quality Level Determination for Procurement of Items and Services</i> • WI-QA-0011, <i>Supplier Audits</i> • ISSC-QA-PR-001, <i>Acceptance of Items and Services</i> • ISSC-BM-PR-004, <i>Unauthorized Procurement Commitments</i> • ISSC-BM-PR-003, <i>Procurement of Items and Services</i> • ISSC-BM-IN-002, <i>Price/Cost Analysis</i> • ISSC-PE-PR-005, <i>Engineering</i> • SST.QA-0016, <i>Qualified Suppliers List</i> <p>Nuclear Work</p> <ul style="list-style-type: none"> • NQA-1a-2009 Part III, 4A-1, <i>Guidance on Procurement Document Control</i> • NQA-1a-2009 Part III, 7A-1, <i>Guidance on Control of Purchased Items and Services</i>

ATTACHMENT A – QUALITY ASSURANCE IMPLEMENTATION PLAN (CONTINUED)

DOE O 414.1D and EM-QA-001	Processes	Swift & Staley Implementing Documents
<p>Criterion #8 – Inspection and Acceptance Testing</p> <p>Inspect and test specified items, services, and processes using established acceptance and performance criteria. Calibrate and maintain equipment used for inspections and tests.</p>	<p>Quality Management System Special Projects Operations and Maintenance</p>	<p>All Work</p> <ul style="list-style-type: none"> • ISSC-QA-PL-002, <i>Contract Performance Quality Assurance Plan</i> • ISSC-ESH-PR-017, <i>Defective Equipment Tags</i> • SST.QA-0035, <i>Dosimetry Quality Assurance Program Plan</i> • ISSC-PM-PR-005, <i>Control of Measuring and Test Equipment</i> • ISSC-QA-PR-001, <i>Acceptance of Items and Services</i> • ISSC-PE-PR-005, <i>Engineering</i> • ISSC-QA-PR-004, <i>Control of Nonconforming Items and Services</i> <p>Nuclear Work</p> <ul style="list-style-type: none"> • NQA-1a-2009 Part III, 10A-1, <i>Guidance on Inspection</i> • NQA-1a-2009 Part III, 11A-1, <i>Guidance on Test Control</i>
<p>Criterion #9 – Management Assessment</p> <p>Ensure that managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives.</p>	<p>Quality Management System Self-Assessment</p>	<p>All Work</p> <ul style="list-style-type: none"> • ISSC-PM-PR-001, <i>Management Review Board</i> • ISSC-PM-IN-001, <i>Carrying out MBWA</i> ISSC-ESH-PR-001, <i>Hazard Assessments</i> • ISSC-ESH-PR-008, <i>Accident/Incident Reporting</i> • ISSC-QA-PR-012, <i>Management Assessments</i> • ISSC-QA-PR-013, <i>Issues Management</i> <p>Nuclear Work</p> <ul style="list-style-type: none"> • NQA-1a-2009 Part III, 2A-1, <i>Guidance on the Qualifications of Inspection and Test Personnel</i>

ATTACHMENT A – QUALITY ASSURANCE IMPLEMENTATION PLAN (CONTINUED)

DOE O 414.1D and EM-QA-001	Processes	Swift & Staley Implementing Documents
		<ul style="list-style-type: none"> • NQA-1a-2009 Part III, 2A-3, <i>Guidance on the Education and Experience of Lead Auditors</i> • NQA-1a-2009 Part III, 2A-4, <i>Guidance on Surveillance for Use in Assessment of Processes and Activities</i> • NQA-1a-2009 Part III, 18A-1, <i>Guidance on Audits</i> • NQA-1a-2009 Part IV, Subpart 4.5, <i>Application Guide on the Use of NQA-1–2000 for Compliance With Department of Energy Quality Assurance Requirements 10 CFR 830, Subpart A and DOE O 414.1</i>

ATTACHMENT A – QUALITY ASSURANCE IMPLEMENTATION PLAN (CONTINUED)

DOE O 414.1D and EM-QA-001	Processes	Swift & Staley Implementing Documents
<p>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 persons who perform independent assessments are technically qualified and knowledgeable in the areas to be assessed.</p>	<p>Quality Management System Auditing</p>	<p>All Work</p> <ul style="list-style-type: none"> • ISSC-ESH-PR-001, <i>Hazard Assessments</i> • ISSC-ESH-PR-008, <i>Accident/Incident Reporting</i> • ISSC-QA-PR-011, <i>Nuclear Program Audits</i> • ISSC-QA-PR-010, <i>Audits</i> • ISSC-QA-PR-006, <i>Qualification/Certification of Auditors</i> • ISSC-QA-PR-013, <i>Issues Management</i> • ISSC-PM-PR-001, <i>Management Review Board</i> <p>Nuclear Work</p> <ul style="list-style-type: none"> • NQA-1a-2009 Part III, 2A-1, <i>Guidance on the Qualifications of Inspection and Test Personnel</i> • NQA-1a-2009 Part III, 2A-3, <i>Guidance on the Education and Experience of Lead Auditors</i> • NQA-1a-2009 Part III, 2A-4, <i>Guidance on Surveillance for Use in Assessment of Processes and Activities</i> • NQA-1a-2009 Part III, 10A-1, <i>Guidance on Inspection</i> • NQA-1a-2009 Part III, 11A-1, <i>Guidance on Test Control</i> • NQA-1a-2009 Part III, 16A-1, <i>Guidance on Corrective Action</i> • NQA-1a-2009 Part III, 18A-1, <i>Guidance on Audits</i>

ATTACHMENT A – QUALITY ASSURANCE IMPLEMENTATION PLAN (CONTINUED)

DOE O 414.1D and EM-QA-001	Processes	Swift & Staley Implementing Documents
<p>Attachment 3 – Suspect/Counterfeit Item Prevention</p>	<p>Quality Management System</p>	<p>All Work</p> <ul style="list-style-type: none"> • ISSC-ESH-PR-017, <i>Defective Equipment Tags</i> • SST.QA-0035, <i>Dosimetry Quality Assurance Program Plan</i> • ISSC-PM-PR-005, <i>Control of Measuring and Test Equipment</i> • ISSC-QA-PR-001, <i>Acceptance of Items and Services</i> • ISSC-BM-PR-004, <i>Unauthorized Procurement Commitments</i> • ISSC-BM-PR-003, <i>Procurement of Items and Services</i> • ISSC-BM-IN-002, <i>Price/Cost Analysis</i> • ISSC-PE-PR-005, <i>Engineering</i> • ISSC-QA-PR-004, <i>Control of Nonconforming Items and Services</i>
<p>Attachment 4 – Safety Software Quality Requirements for Nuclear Facilities</p>	<p>Information Technology, Telecommunications and Cyber Security Quality Management System Corrective and Preventive Action</p>	<p>All Work</p> <ul style="list-style-type: none"> • ISSC-IT-PR-002, <i>Software Quality Assurance</i> • ISSC-BM-PR-003, <i>Procurement of Items and Services</i> • PGDP-IT-PR-002, <i>Information Technology Baseline Configuration Management</i>
<p>Corrective Action Management Program</p>	<p>Quality Management System Self-Assessment Corrective and Preventive Action</p>	<p>All Work</p> <ul style="list-style-type: none"> • ISSC-PM-PR-001, <i>Management Review Board</i> • ISSC-QA-PR-002, <i>Enforcement Noncompliance Determination and Reporting</i> • ISSC-QA-PR-013, <i>Issues Management</i>

ATTACHMENT A – QUALITY ASSURANCE IMPLEMENTATION PLAN (CONTINUED)

DOE O 414.1D and EM-QA-001	Processes	Swift & Staley Implementing Documents
		<ul style="list-style-type: none">• ISSC-QA-PR-009, <i>Operating Experience Program</i>• ISSC-PM-PR-001, <i>Management Review Board</i>

ATTACHMENT B – REQUIREMENTS CROSSWALK

10 CFR 830.122/DOE O 414.1D	NQA-1a-2009 ⁹	ISO 9001-2015	ISO 14001-2015
Criterion 1 – Management/Program			
<p>a. Establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work.</p> <p>b. Establish management processes, including planning, scheduling, and providing resources for the work.</p>	<p>Requirement 1 – Organization 100 – Basic 200 – 202 Structure and Responsibility 300 – Interface Control</p> <p>Requirement 2 – Quality Assurance Program 100 – Basic 200 – 202 Indoctrination and Training 300 – 305 Qualification Requirements 400 – Records of Qualification 500 – Records</p>	<p>4 Context of the organization 5 Leadership 6.2 Quality objectives and planning to achieve them 7.1 Resources</p>	<p>4 Context of the organization 5 Leadership 6.2 Environmental objectives and planning to achieve them 7.1 Resources</p>
Criterion 2 – Management/Personnel Training and Qualification.			
<p>a. Train and qualify personnel to be capable of performing their assigned work.</p> <p>b. Provide continuing training to personnel to maintain their job proficiency.</p>	<p>Requirement 2 – Quality Assurance Program 100 – Basic 200 – 202 Indoctrination and Training 300 – 305 Qualification Requirements 400 – Records of Qualification 500 – Records</p>	<p>7.1.6 Organizational knowledge 7.2 Competence 7.3 Awareness</p>	<p>7.2 Competence 7.3 Awareness</p>

⁹ From U.S. Department of Energy Environmental Management EM-QA-001 Rev. 1, *EM Quality Assurance Program*.

ATTACHMENT B – REQUIREMENTS CROSSWALK (CONTINUED)

Criterion 3 – Management/Quality Improvement			
<p>a. Establish and implement processes to detect and 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 CA planning.</p>	<p>Requirement 2 – Quality Assurance Program 100 – Basic 200 – 202 Indoctrination and Training 300 – 305 Qualification Requirements 400 – Records of Qualification 500 – Records</p>	<p>6 Planning 7 Support 8.7 Control of nonconforming outputs 9 Performance evaluation 10 Improvement</p>	<p>9 Performance evaluation 10 Improvement</p>
10 CFR 830.122/DOE O 414.1D	NQA-1a-2009	ISO 9001-2015	ISO 14001-2015
<p>d. Review item characteristics, process implementation, and other quality related information to identify items, services, and processes needing improvement.</p>	<p>Requirement 15 – Control of Nonconforming Items 100 – Basic 200 – Identification 300 – Segregation 400 – 405 Disposition Requirement 16 – Corrective Action 100 – Basic Requirement 18 – Audits 100 – Basic</p>		

ATTACHMENT B – REQUIREMENTS CROSSWALK (CONTINUED)

Criterion 4 – Management/Documents and Records			
a. Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design. b. Specify, prepare, review, approve, and maintain records.	Requirement 5 – Instructions, Procedures, and Drawings 100 – Basic Requirement 6 – Document Control 100 – Basic 200 – Document Control 300 – 302 Document Changes Requirement 17 – Quality Assurance Records 100 – Basic 200 – Generation of Records 300 – Authentication of Records 400 – 402 Classification 500 – Receipt Control of Records 600 – 603 Storage 700 – Retention 800 – Maintenance of Records	7.5 Documented information	7.5 Documented information

ATTACHMENT B – REQUIREMENTS CROSSWALK (CONTINUED)

10 CFR 830.122/DOE O 414.1D	NQA-1a-2009 ¹⁰	ISO 9001-2015	ISO 14001-2015
Criterion 5 – Performance/Work Processes (Continued)			
	100 – Basic Requirement NQA-1 Part II, Subpart 2.7 – QA Requirements for Computer Software for Nuclear Facility Applications 100 – 102 General 200 – 204 General Requirements 300 – 302 Software Acquisition 400 – 407 Software Engineering Method 500 – Standards, Conventions, and Other Work Practices 600 – 602 Support Software 700 – References		

¹⁰ From U.S. Department of Energy Environmental Management EM-QA-001 Rev. 1, *EM Quality Assurance Program*.

ATTACHMENT B – REQUIREMENTS CROSSWALK (CONTINUED)

Criterion 6 – Performance/Design			
<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>Requirement 3 – Design Control 100 – Basic 200 – Design Input 300 – Design Process 400 – 402 Design Analyses 500 – 501.3 Design Verification 600 – 601.9 Change Control 700 – Interface Control 800 – 802.3 Software Design Control 900 – Documentation and Records</p> <p>Requirement NQA-1 Part II, Subpart 2.7 – QA Requirements for Computer Software for Nuclear Facility Applications 100 – 102 General 200 – 204 General Requirements 300 – 302 Software Acquisition 400 – 407 Software Engineering Method 500 – Standards, Conventions, and Other Work Practices 600 – 602 Support Software 700 – References</p>	<p>8.3 Design and development of products and services</p>	<p>6.1.3 Compliance obligations 8.1 Operational planning and control</p>

ATTACHMENT B – REQUIREMENTS CROSSWALK (CONTINUED)

Criterion 7 – Performance/Procurement			
<p>a. Procure items and services that meet established requirements and perform as specified. b. Evaluate and select prospective suppliers on the basis of specified criteria. c. Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services.</p>	<p>Requirement 4 – Procurement Document Control 100 – Basic 200 – 207 Content of Procurement Documents 300 – Procurement Document Review 400 – Procurement Document Changes Requirement 7 – Control of Purchased Items and Services 100 – Basic 200 – Supplier Evaluation and Selection 300 – Bid Evaluation 400 – Control of Supplier-Generated Documents 500 – 507 Acceptance of Item or Service 600 – Control of Supplier Nonconformances 700-705 Commercial Grade Items and Services 800 – Records Requirement NQA-1 Part II, Subpart 2.7 – QA Requirements for Computer Software for Nuclear Facility Applications 100 – 102 General 200 – 204 General Requirements 300 – 302 Software Acquisition 400 – 407 Software Engineering Method</p>	<p>8.2 Requirements for products and services 8.4 Control of externally provided processes, products and services</p>	<p>8.1 Operational planning and control</p>

ATTACHMENT B – REQUIREMENTS CROSSWALK (CONTINUED)

Criterion 7 – Performance/Procurement (continued)			
	500 – Standards, Conventions, and Other Work Practices 600 – 602 Support Software 700 – References Part II, Subpart 2.14 – QA Requirements for Commercial Grade Items and Services 100-101 – General 200 – CGI Definition Applications 300 – Utilization 400-403 – Technical Evaluation 500 – Critical Characteristics 600-606 – Methods of Accepting Commercial Grade Items and Services 700 – Commercial Grade Services 800 – Documentation 900 – References		
Criterion 8 – Performance/Inspection and Acceptance Testing			
a. Inspect and test specified items, services, and processes using established acceptance and performance criteria. b. Calibrate and maintain equipment used for inspections and tests.	Requirement 3 – Design Control 100 – Basic 200 – Design Input 300 – Design Process 400 – 402 Design Analysis 500 – 501.3 Design Verification 600 – 601.9 Change Control 700 – Interface Control 800 – 802.3 Software Design Control 900 – Documentation and Records	8 Operation 9 Performance Evaluation	8 Operation 9 Performance evaluation

ATTACHMENT B – REQUIREMENTS CROSSWALK (CONTINUED)

Criterion 8 – Performance/Inspection and Acceptance Testing (continued)			
	<p>Requirement 8 – Identification and Control of Items 100 – Basic</p> <p>Requirement NQA-1 Part II, Subpart 2.7 – QA Requirements for Computer Software for Nuclear Facility Applications 100 – 102 General; 200 – 204 General Requirements 300 – 302 Software Acquisition; 400 – 407 Software Engineering Method 500 – Standards, Conventions, and Other Work Practices 600 – 602 Support Software 700 – References</p> <p>200 – 202 Identification Methods 300 – 303 Specific Requirements</p> <p>Requirement 10 – Inspection 100 – Basic 200 – Inspection Requirements 300 – Inspection Hold Points 400 – 402 Inspection Planning 500 – In-Process Inspection 600 – 604 Final Inspections 700 – Inspections During Operations 800 – Records</p>		

ATTACHMENT B – REQUIREMENTS CROSSWALK (CONTINUED)

Criterion 8 – Performance/Inspection and Acceptance Testing (continued)			
	Requirement 11 – Test Control 100 – Basic 200 – Test Requirements 300 – Test Procedures (Other Than for Computer Programs) 400 – Computer Program Test Procedures 500 – Test Results 600 – 602 Test Records Requirement 12 – Control of Measuring and Test Equipment 100 – Basic 200 – Selection 300 – 304 Calibration and Control 400 – 402 Records Requirement 14 – Inspection, Test, and Operating Status 100 – Basic		

ATTACHMENT B – REQUIREMENTS CROSSWALK (CONTINUED)

Criterion 9 – Assessment/Management Assessment			
<p>Ensure that managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives.</p>	<p>Requirement 2 – Quality Assurance Program 100 – Basic 200 – 202 Indoctrination and Training; 300 – 305 Qualification Requirements; 400 – Records of Qualification 500 – Records Requirement 16 – Corrective Action 100 – Basic Requirement 18 – Audits 100 – Basic 200 – Scheduling 300 – 303 Preparation 400 – Performance 500 – Reporting 600 – Response 700 – Follow-up Action 800 – Records</p>	<p>9 Performance Evaluation</p>	<p>9 Performance evaluation</p>

ATTACHMENT B – REQUIREMENTS CROSSWALK (CONTINUED)

Criterion 10 – Assessment/Independent Assessment			
<p>a. Plan and conduct independent assessments to measure item and service quality, to measure the adequacy of work performance, and to promote improvement. b. Establish sufficient authority and freedom from line management for independent assessment teams. c. Ensure persons who perform independent assessments are technically qualified and knowledgeable in the areas to be assessed.</p>	<p>Requirement 1 – Organization 100 – Basic 200 – 202 Structure and Responsibility 300 – Interface Control</p> <p>Requirement 2 – Quality Assurance Program 100 – Basic 200 – 202 Indoctrination and Training 300 – 305 Qualification Requirements 400 – Records of Qualification 500 – Records</p> <p>Requirement 10 – Inspection 100 – Basic 200 – Inspection Requirements 300 – Inspection Hold Points 400 – 402 Inspection Planning 500 – In-Process Inspection 600 – 604 Final Inspections 700 – Inspections During Operations 800 – Records</p> <p>Requirement 11 – Test Control 100 – Basic 200 – Test Requirements 300 – Test Procedures (Other Than for Computer Programs) 400 – Computer Program Test Procedures 500 – Test Results 600 – 602 Test Records</p>	<p>9 Performance Evaluation</p>	<p>9 Performance evaluation</p>

ATTACHMENT B – REQUIREMENTS CROSSWALK (CONTINUED)

Criterion 10 – Assessment/Independent Assessment			
	Requirement 15 – Control of Nonconforming Items 100 – Basic 200 – Identification 300 – Segregation 400 – 405 Disposition Requirement 16 – Corrective Action 100 – Basic Requirement 18 – Audits 100 – Basic 200 – Scheduling 300 – 303 Preparation 400 – Performance 500 – Reporting 600 – Response 700 – Follow-up Action 800 – Records		
Additional DOE Programs			
Graded Approach	Not addressed	Not addressed	Not addressed
Suspect/Counterfeit Items	Not addressed	Not addressed	Not addressed
Safety Software Quality Assurance	Not addressed	Not addressed	Not addressed
Integrated Safety Management System	Not addressed	Not addressed	Not addressed

ATTACHMENT C – PROCUREMENT QUALITY LEVELS AND ASSOCIATED CONTROLS

EFCOG QL ¹¹	Swift & Staley QL	Risk Factor ¹¹	Procurement Controls	Examples of Procurements ¹²
4	3	Minimal, if any, safety or mission impact - level of controls for those items, services, or processes where no additional quality controls beyond the providers published or stated attributes of the item, service, activity, or process are required. General acceptance processes to ensure item, quantity, and other characteristics are met.	<ul style="list-style-type: none"> No special quality controls. Normal procurement processes and procedures are followed. Process implementation is checked through management assessment or audit. 	<ul style="list-style-type: none"> Office supplies. Materials and supplies for operations and maintenance (e.g., salt, gravel, mowing equipment, lease of construction equipment). Staff augmentation through consulting agreements. Purchase orders for lease/maintenance agreements for electronic equipment (e.g., copiers and printers).
3	2	Important to safety or mission, low to medium risk procurement where quality controls are needed to verify critical attributes.	<ul style="list-style-type: none"> Quality Assurance (QA) review of procurement document. Specification of quality requirements applicable to the work activity. Receipt inspection of materials, equipment, and supplies. Field oversight of work activities (not continuous). Confirmation of supplier certifications, qualifications, licenses, or other approvals from external agencies applicable to the scope of work or materials, equipment, or supplies. 	<ul style="list-style-type: none"> Items or equipment with potential suspect/counterfeit item concerns. Calibration and maintenance services for nonnuclear applications. Laboratory services for nonnuclear applications when the laboratory has a valid certification or qualification to a recognized quality standard such as ISO 9001 or ISO 17025. Measuring and test equipment purchase, calibration, or maintenance for nonnuclear applications.

¹¹ Adapted from Energy Facility Contractors Group *Office of Environmental Management And Energy Facility Contractors Group Quality Assurance Improvement Project Plan*. Swift & Staley has combined the Level 1 and Level 2 categories into a single category to retain the three QLS used since the beginning of the Contract.

¹² Not intended to be a comprehensive list of all work activities. This column is to provide general guidance for comparison purposes only.

ATTACHMENT C – PROCUREMENT QUALITY LEVELS AND ASSOCIATED CONTROLS (CONTINUED)

EFCOG QL¹¹	Swift & Staley QL	Risk Factor¹¹	Procurement Controls	Examples of Procurements¹²
1, 2	1	Important to safety or mission, medium to high risk procurement where quality controls are needed to verify critical attributes and a moderate to high level of assurance is needed to ensure expectations associated with additional quality controls are being met.	<ul style="list-style-type: none"> • QA review of procurement document. • Specification of quality requirements applicable to the work activity. • Receipt inspection of materials, equipment, and supplies. • Field oversight of work activities (continuous). • In-process oversight of fabrication of critical parts. • Pre-approval of vendor or supplier. • Evaluation of supplier quality program. 	<ul style="list-style-type: none"> • Calibration and maintenance services for nuclear applications. • Laboratory services for nuclear applications. • Laboratory services when the laboratory does not have a valid certification or qualification to a recognized quality standard such as ISO 9001 or ISO 17025. • Measuring and test equipment purchase, calibration, or maintenance, for nuclear applications.