SAVANNAH RIVER REMEDIATION LLC
[redacted]
Savannah River Site, Aiken, SC 29808

JUN 12 2009

SRR-2009-00007
RSM Track #: 10667

Mr. Jeffrey M. Allison, Manager
Savannah River Operations Office
P.O. Box A
Aiken, SC 29808

Dear Mr. Allison:

SAVANNAH RIVER REMEDIATION (SRR), LLC QUALITY ASSURANCE MANAGEMENT PLAN INCLUDING THE SRR CONTRACTOR ASSURANCE SYSTEM DESCRIPTION DOCUMENT (U)

Attached is the baseline Savannah River Remediation, LLC Quality Assurance Management Plan (QAMP) SRR-RP-2009-00764, revision 0. This baseline document meets the requirements of 10CFR 830 and DOE Order 414.1C.

The QAMP provides a detailed description of the SRR Quality Assurance Program and Contractor Assurance System. It also demonstrates the relationship between the Quality Assurance Program, the Integrated Safety Management System, and the Contractor Assurance System.

This document aligns the SRR QA Program with the requirements of 10 CFR 830 Subpart A, DOE O414.1C, and DOE O226.1A. This document and the related implementing procedures satisfy all applicable quality assurance requirements.

This document also serves as the SRR submittal to the Department for the following program descriptions:

- Quality Assurance Program
- Software Quality Assurance Program
- Graded Approach
- Contractor Assurance System Description Document

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The next annual submittal of this document will be in June 2010. Should you have any questions concerning this document, please contact R. N. Hinds at 208-7735.

Sincerely,

Jim French, President

vg

Attachment

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SRR-RP-2009-00764
Revision 0

SAVANNAH RIVER REMEDIATION LLC

(SRR)

QUALITY ASSURANCE

MANAGEMENT PLAN (U)

Effective July 1, 2009

Approval: _____

James French, SRR President

Reviewer: _____

Patricia Allen, SRR ESH&QA Manager

Reviewer: _____

Robert Hinds, SRR Quality Assurance Engineering Manager

Savannah River Remediation
Savannah River Site
Aiken, SC, 29808

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Foreword

The Savannah River Remediation (SRR) Quality Assurance (QA) Program is designed around three programmatic areas: Management, Performance, and Assessment. These three program areas are based on, incorporate, and meet the quality assurance requirements contained in the following:

- 10 CFR 830 Subpart A
- DOE Order 414.1C
- DOE Order 226.1A
- DOE/RW-0333P Revision 20
- NQA-1-2000

A brief summary of these key requirement documents is included in Attachment Fore-1 "Requirements Document Overview."

The SRR QA Program is described in this document, the Quality Assurance Management Plan (QAMP). The QAMP was developed in response to the Code of Federal Regulations (CFR), Department of Energy (DOE) Orders, National Standards, and other applicable requirements. SRR and DOE approved the original submittal and subsequent revisions are also reviewed and approved by DOE Savannah River Operations Office (DOE-SR), and other Offices or Agencies, as appropriate.

The QAMP is submitted annually to DOE Savannah River Operations Office (DOE-SR), and other offices or agencies, as appropriate, for review and approval. SRR may, at any time, make changes to the approved QAMP to address emerging issues or changes in requirements. Changes to the QAMP made during the year are provided to DOE-SR and other offices or agencies, as appropriate, for review and do not affect the annual QAMP submittal schedule. Revisions to the QAMP that are submitted for approval provide identification of the changes, the pages affected, the reason for the changes, and the basis for concluding that the revised QAMP continues to satisfy the requirements of 10 CFR 830 Subpart A and DOE Order 414.1C. Changes made to correct spelling, punctuation, or other editorial items do not require explanation. In accordance with 10 CFR 830 requirements, the QAMP shall be regarded as approved by DOE-SR 90 days after submittal for approval, unless approved or rejected within the 90 days.

Foreword (Continued)

The QAMP demonstrates the relationship between the QA Program, Integrated Safety Management System (ISMS), and the Contractor Assurance System (CAS). The QA Program, as described in this QAMP, implements 10 CFR 830 Subpart A, DOE Order 414.1C, DOE Order 226.1A, DOE/RW-0333P, and NQA-1-2000 in accordance with the Standards / Requirements Identification Document (S/RID) that is also approved by DOE-SR. (NOTE: As part of contract transition, SRR adopted the Washington Savannah River Company (WSRC) S/RID in it's entirety. As various sections of the S/RID are revised in the future, the corporate name will be changed from WSRC to SRR. From this point forward, the WSRC S/RID is the SRR S/RID and will be referred to as such.) DOE/RW-0333P is applicable to those systems, structures, and components identified in the Defense Waste Processing Facility (DWPF) Waste Acceptance Manual, WSRC-IM-93-45.

This revision is being made to accommodate the liquid waste contract transition from WSRC to SRR. The changes made since the last submittal are additive or minor and do not detract from the requirements.

The SRR QA Program is implemented through the Savannah River Site 1Q Quality Assurance Manual and other program level manuals and procedures. When conflicts occur between the SRR QAMP and the 1Q or other lower-tier documents, the requirements of the QAMP shall govern. Any conflicts involving interpretation of the QAMP requirements are resolved through the SRR QA Manager.

This revision incorporates and satisfies the requirements of 10 CFR 830 Subpart A, DOE O 414.1C, DOE O 226.1A, NQA-1-2000, and others as described. It partially satisfies the requirements of NQA-1-2004 through NQA-1-2007, with full incorporation targeted for 10/1/2009, pending receipt of a Contractor Administration Notice directing implementation of this requirements document.

Margin notations (bars) are included in this revision identifying areas of change.

Introduction

This QAMP describes a single, integrated, effective QA Program that has been appropriately tailored to apply to facilities operated, and activities conducted, under Contract DE-AC09SR22505.

The QAMP documents how SRR implements the contractual requirements as appropriate for work scope. The QAMP also serves as the annual submittal to DOE-SR describing the SRR QA program, graded approach, software quality assurance program, and suspect/counterfeit item programs. The QAMP and the QA Program are key elements of the safety management and contractor assurance programs. The Contractor Assurance System Description (CASD) is included in Appendix A "SRR Contractor Assurance System Description" to the QAMP. Both the QAMP and the CASD are revised and submitted to DOE-SR for review and approval annually. The annual updates reflect programmatic and organizational changes that have occurred over the previous year. The submittal document for the QAMP provides assurance that the changes continue to satisfy QA requirements.

QA is a broad management program that supports the Integrated Safety Management (ISM) core functions and guiding principles with a goal of producing products and / or providing services that meet or exceed the expectations of DOE-SR. As a management system, QA principles ensure that clear roles and responsibilities are established for the conduct of work performed by SRR and its subcontractors. The QA Program provides assurance that individuals have the competence commensurate with their work responsibilities. These QA principles speak to the effectiveness of the workforce and are broadly and horizontally integrated into all work. QA is also an integral part of the processes by which work is prioritized, facilities designed, hazards analyzed, standards and controls identified and applied, equipment procured, work performed, and performance evaluated and improved. Each section of this QAMP addresses specific areas of the QA Program's role in ISM.

The QAMP establishes QA requirements for conducting activities, including providing items or services that affect, or may affect, nuclear and conventional safety of facilities in a tailored manner to ensure that environmental, safety, and health risks and impacts are minimized and that safety, reliability, products, and performance are maximized by using effective management systems. The one exception to this is that the graded approach is not used in implementing the Unreviewed Safety Question (USQ) process or in implementing technical safety requirements.

Introduction (Continued)

The QAMP provides an outline using contemporary principles for managing, performing, and assessing operations in an integrated and cost-effective manner. The Contractor Assurance System description provides the road map to oversight and assurance activities for operations and business operations. The programmatic QA requirements are contained in S/RID Functional Area 2 "Quality Assurance." The programmatic oversight requirements are contained in S/RID Functional Area 1 "Management Systems" and Functional Area 2. The S/RID Functional Areas identify the source requirement document and a cross-reference to the implementing procedures. Key interfaces and specific reference documents are also identified in S/RID Functional Area 01 and 02. A complete listing of the S/RID functional areas is contained in Attachment Intro-1 "Functional Area Titles." As part of the SRR management system and structure, separate from contractual requirements, Source and Compliance Document (SCD) Organizational Functional Areas are used to manage similar Programs or Functions. These are also included in Attachment Intro-1. As a point of clarification, the S/RID and Organizational functional area numbers are similar for some functional areas but not for all. This is because they were established at different times for different reasons. As such, the numbering schemes have been incorporated and embedded into various safety basis documents as well as contractual documents. Revising and aligning the technical and business documents would require a major effort and considerable expense on the part of SRR, SRNS, and DOE.

The requirement documents used during QA Program development and maintenance are identified in Attachment Intro-2 "QA Program Basis Documents."

The QAMP is formatted in the following manner. There are twelve criteria similar to those in 10CFR 830 Subpart A and DOE Order 414.1C that address the various elements of the QA Program. Appendix A contains the Contractor Assurance System description. Following Appendix A are the supporting attachments providing enhanced details of specific portions of the SRR quality assurance program.

This document serves the purpose of the initial submittal of the following SRR information to DOE:

- Quality Assurance Program
- Software Quality Assurance Program
- Graded Approach
- Contractor Assurance System Description Document

Mission

The mission of SRR is to support the DOE Office of Environmental Management (EM) in the accelerated risk reduction and cleanup of the environmental legacy of the Nation's nuclear weapons program. The cleanup effort is one of the largest, most diverse, and technically challenging environmental cleanup programs in the world. DOE EM is responsible for the cleanup of over 100 sites across the country, including SRS. SRR is responsible for SRS cleanup activities as well as processing or providing expertise to other sites across the complex. The range of SRR activities includes the responsibility for:

- The safe disposition of nuclear wastes;
- Supporting deactivation and decommissioning of contaminated facilities no longer needed to support DOE missions

This is documented in the System Integration Management Plan (CBU-PIT-2005-00267 Revision 2) as follows:

> "The mission of the Liquid Waste program at Savannah River Site is to provide safe and efficient receipt, storage, and processing of radioactive liquid waste to support both site operations and the Department of Energy Savannah River plans for permanent disposal of radioactive waste and to close the storage, processing, and disposition facilities when they have completed their planned use.

ACRONYMS

ANSI	American National Standards Institute (ANSI)
ASME	American Society of Mechanical Engineers (ASME)
ALARA	As Low As Reasonably Achievable (ALARA)
BBS	Behavior-Based Safety (BBS)
CPIC	Capital Planning and Investment Control (CPIC)
C of C	Certificate of Conformance (C of C)
CFR	Code of Federal Regulations (CFR)
CQF	Cognizant Quality Function (CQF)
CTF	Cognizant Technical Function (CTF)
CGD	Commercial Grade Dedication (CGD)
COTS	Commercial Off-the-Shelf (COTS)
CAT	Continuing Annual Training (CAT)
CAS	Contractor Assurance System (CAS)
COTS	Corrected On The Spot (COTS)
CAS	Contractor Assurance System (CAS)
CASD	Contractor Assurance System Description (CASD)
CPL	Controlled Products List (CPL)
D&D	Deactivating and Decommissioning (D&D)
DNFSB	Defense Nuclear Facility Safety Board (DNFSB)
DOE	Department of Energy (DOE)
DEAR	Department of Energy Acquisition Regulation (DEAR)
DOE-SR	DOE Savannah River Operations Office (DOE-SR)
DSA	Documented Safety Analysis (DSA)
EOC	Emergency Operations Center (EOC)
ERPG	Emergency Response Planning Guideline (ERPG)
ESH&QA	Environment, Safety, Health, and Quality Assurance (ESH&QA)
EM	Environmental Management (EM)
E.O.	Executive Order (E.O.)
ESQB	Executive Safety and Quality Board (ESQB)
FEB	Facility Evaluation Board (FEB)
FOIA	Freedom of Information Act (FOIA)
FSA	Functional Service Agreement
GAO	Government Accountability Office (GAO)
GET	General Employee Training (GET)
GRS	General Records Schedule (GRS)
GS	General Services (GS)
GIDEP	Government-Industry Data Exchange Program (GIDEP)
HSS	Health, Safety and Security (HSS)
HEPA	High Efficiency Particulate Air (HEPA)
HPI	Human Performance Improvement (HPI)

ACRONYMS (Continued)

IPI	Installed Process Instrumentation (IPI)
INPO	Institute of Nuclear Power Operations (INPO)
IPMS	Integrated Procedure Management System (IPMS)
ISM	Integrated Safety Management (ISM)
ISMS	Integrated Safety Management System (ISMS)
ISO	International Organization for Standardization (ISO)
MDP	Material Delivery Point (MDP)
MOA	Memorandum of Agreement
MOU	Memorandum of Understanding
MSA	Management Self Assessment (MSA)
M&TE	Measuring and Test Equipment (M&TE)
ARA	National Archives and Records Administration (NARA)
NIST	National Institute of Standards and Technology (NIST)
NEPA	National Environmental Policy Act (NEPA)
NTS	Non-Compliance Tracking System (NTS)
ORPS	Occurrence Reporting and Processing System (ORPS)
OIG	Office of Inspector General (OIG)
OMB	Office of Management and Budget (OMB)
OCRWM	Office of Civilian Radioactive Waste Management (OCRWM)
ORR	Operational Readiness Reviews (ORR)
OOC	Out of Commission (OOC)
PA	Performance Analysis (PA)
POMC	Performance Objective, Measure, and Commitment (POMC)
PAAA	Price Anderson Amendment Act (PAAA)
PS	Production Support (PS)
PLC	Programmable Logic Controller (PLC)
P.L.	Public Law (P.L.)
QSL	Qualified Suppliers List (QSL)
QA	Quality Assurance (QA)
QAMP	Quality Assurance Management Plan (QAMP)
QARD	Quality Assurance Requirements and Description (QARD)
QAPC	Quality Assurance Policy Committee (QAPC)
QC	Quality Control (QC)
RME	Radiological Monitoring Equipment (RME)
RA	Readiness Assessment (RA)
R&D	Research and Development (R&D)
SC	Safety Class (SC)
SS	Safety Significant (SS)
SSIL	Safety Software Inventory List (SSIL)
SRNS	Savannah River Nuclear Solutions (SRNS)

ACRONYMS (Continued)

SRR	Savannah River Remediation (SRR) LLC
SIRIM	Site Item Reportability and Issue Management (SIRIM)
SPPC	Site Policy and Procedure Council (SPPC)
STAR	Site Tracking, Analysis, and Reporting (STAR)
SQAP	Software Quality Assurance Plan (SQAP)
SCD	Source and Compliance Document (SCD)
S/RID	Standards/Requirements Identification Document (S/RID)
SSC	Structure, System, or Component (SSC)
SME	Subject Matter Expert (SME)
S/CI	Suspect/Counterfeit Item (S/CI)
U.S.C.	United States Code (U.S.C.)
USQ	Unreviewed Safety Question (USQ)
WSRC	Washington Savannah River Company (WSRC)
WIPP	Waste Isolation Pilot Plant (WIPP)
WP&C	Work Planning and Control (WP&C)

Criterion 1 - Program

1.0 Requirements and Key Implementing Documents

A. Federal QA Requirements

- Establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work (10CFR830, DOE Order 414.1C)
- Establish management processes, including planning, scheduling, and providing resources for the work (10CFR830, DOE Order 414.1C)

B. National Code & Standard Requirements

- NQA-1 Part 1 Requirements "1-Organization" and "2-Quality Assurance Program"

C. Key Implementing Documents

- See Attachment 1-7 "Key Implementing Documents for Criterion 1 – Program"

1.1 Quality Policy

SRR performs activities in conducting its mission, using technical, quality, and administrative programs, procedures and policies. These control methods are integrated using management programs and safety management systems that ensure the safety and protection of workers, the public, and the environment while performing activities. The SRR President has the responsibility to work with DOE EM management to ensure activities are effectively planned, adequately budgeted, safely executed, and evaluated before, during, and after activities. This serves to ensure that the activity is done correctly and safely the first time. QA is a management system that is used to ensure that quality requirements for products, services, and activities are clearly defined before activities begin. The combination of the QA controls and oversight activities are used to ensure that work processes are continuously monitored, assessed, and improved to achieve a rising standard of excellence in the quality and safety of programs, projects, products, and services. QA is the responsibility of all workers and it is the role of management to ensure adequate QA implementation, including performance and application of QA principles.

The senior management commitment to a QA Program is documented in the management policy on QA. The policy is a collaborative effort with SRNS, who is responsible for maintaining the policy and SRR is responsible for implementation. As part of the implementation of the policy, senior SRR management has committed the company to implement and work with SRNS to manage and maintain a formal QA Program that is documented in the 1Q quality assurance manual. This is further refined in the Memorandum Of Agreement (MOA) G-MOA-G-00002, and Functional Service Agreements between the two companies.

1.1 Quality Policy (Continued)

Senior management responsibilities under the QA Program include planning, organizing, staffing, directing, and controlling. These are essential elements to ensure the effectiveness of the QA Program. The Quality Assurance Policy and subsequent QA Program are consistent with 10 CFR 830 Subpart A; DOE O 414.1C; special program documents; DOE Orders on environment, safety, and health protection; Environmental Protection Agency; and South Carolina Department of Health and Environmental Control (when that agency has primacy) guidance documents applying to environmental protection and remediation. The policy and program also currently meet the requirements of NQA-1-2000.

Key requirements documents used in development and maintenance of the QA Program are identified in Attachment Intro-2. Documents containing special QA program requirements used in development and maintenance of this QAMP are identified in Attachment 1-1 "Special QA Program Requirements Documents."

The policies and implementation-level manuals are owned by SRNS and managed jointly by SRR and SRNS through a Site Policy and Procedure Council (SPPC) that is controlled by procedure (MRP 3.26). These implementation-level manuals are created and managed by Functional Program Managers and integrated with various functional programs through the SPPC. The SPPC review and approval process is a tool of ISM that serves to ensure that quality program requirements are flowed into work performed under the contract, including items and services that are procured or subcontracted. QA and technical requirements are flowed down to subcontractors, using a graded approach, through procedures or procurement documents as part of the normal conduct of company business.

1.2 SRR QA Program Description

The SRR QA Program is a management system that addresses three major elements: managing, performing, and assessing the adequacy of work.

The QAMP provides the strategy for implementing the QA Program in a tailored manner. Additional QA plans may be required and developed to provide guidance for specific programs, projects, functions, and environmental regulations.

The QAMP requirements are flowed down and implemented through the QA Program. Attachment 1-2 "QA Requirements Flow Down Overview" provides an overview of the flow down process. The QA Program uses a compilation of policies, plans, manuals, and implementing procedures that are parsed into applicable functional program areas. The QA Program framework is detailed in the Savannah River Site (SRS) 1Q Quality Assurance manual. Where applicable, the 1Q manual procedures are implemented directly. Where this is not possible, additional implementing manuals, procedures, or

1.2 SRR QA Program Description (Continued)

documents are used. These are supplemented where applicable, to provide the detail necessary for proper implementation of QA requirements. Implementing procedures constitute a significant portion of the ISMS, which is intended to ensure that work is performed safely. A detailed listing of manuals containing QA requirements or procedures is contained in Attachment 1-3 "QA Requirements Implementing Manuals."

As manuals and procedures are revised, the SPPC ensures that the appropriate Subject Matter Expert (SME) and appropriate stakeholders from both SRNS and SRR have reviewed and approved changes. This ensures that contractual requirements are not compromised by proposed changes. Once approved, these changes are incorporated and alignment with source requirements is maintained.

The QA Program promotes the effective and efficient achievement of performance objectives by:

- Planning and documenting requirements for items, processes, and services
- Controlling activities affecting the quality of items, processes, and services
- Verifying the required quality for items, processes, and services

QA Program implementation and performance is verified through a combination of assessments, audits, surveillance, and performance analysis. The assessment program consists of organizational-level Management Assessments, comprised of self-assessments and performance analyses performed by appropriate facilities and organizations to determine compliance, promote continuous improvement, and enhance performance. The assessment program also consists of independent assessments performed by Facility Evaluation Board (FEB). QA audits are also used to provide oversight of the QA Program. Performance analysis is used to evaluate performance and promote continuous improvement.

Third-party QA Program assurance activities include corporate audits, third-party certifications, and external reviews that are performed as requested or required and provide additional improvement information.

1.3 Integrated Safety Management System

DOE has implemented ISM throughout the complex. DOE Policy 450.4, "Safety Management System Policy" and the SRR contract require an implemented ISM system that satisfies the policy objective "to do work safely" by adhering to the guiding principles and functions of ISM.

1.3 Integrated Safety Management System (Continued)

Overall safety management and performance is improved with both internal and external reviews, evaluations, and assessments. This includes management assessments, independent assessments, corporate evaluations, DOE evaluations, Government Accountability Office (GAO) reviews, and the Defense Nuclear Facilities Safety Board (DNFSB) oversight.

The QA program provides processes and tools for ensuring that ISM objectives are achieved. Attachment 1-4 "SRR ISMS/QAMP Cross Linkage" provides a cross linkage between the ISM core functions and the QAMP criteria. Policy Manual 1-01, MP 1.22, contains the policy that SRR will use to implement ISM. This QAMP is consistent with, and an integral part of, the SRR ISMS. A detailed description of the SRR ISMS is located in the front of the S/RID.

The SRR QA Program, in conjunction with other ISM activities ensures compliance with approved safety standards, so that the expectation for safe work within controls are met. This combination also ensures that workers, the environment, and the public are reasonably protected from harm.

Integration of quality, health, environment and safety requirements into work practices and work execution occurs at all levels. This integration helps to reduce ESH&QA risks and impacts while maximizing reliability and performance of work. Policy manuals and procedures define the principal mechanisms for implementing safety management. This plan is a part of the ISM implementing mechanisms and its contents are responsive to the regulatory requirements of the QA Program. For ISMS details, see WSRC-RP-94-1268, "Integrated Safety Management System Description."

1.4 SRR Organizational Structure and Responsibilities

The SRR President identifies the organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing work. Organizations may further identify or describe functional responsibilities and interfaces within implementing procedures or other controlled documents. See Attachment 1-5 "SRR Senior Management Structure" for the current organizational structure.

1.4 SRR Organizational Structure and Responsibilities (Continued)

The QA Program applies to all personnel, including those responsible for planning, scheduling, providing resources for work, operating, and conducting business operation activities. QA Program requirements, programs, procedures, etc., are also applicable to subcontractors and are flowed down through the procurement system, to the extent necessary, to ensure compliance with the requirements for the safe performance of work. The basic QA Program is presented annually to personnel using the Continuing Annual Training (CAT) forum. This forum is used to ensure that personnel have an understanding and ongoing refresher on the basic QA Program as part of the formal, documented indoctrination and training program. Additional, in-depth training is provided to meet job or facility-specific needs.

SRR Senior Management is responsible for establishing the performing organizations and their associated responsibilities. The QA Program describes the organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing work. Operational QA personnel report directly to the SRR QA Manager. Construction Quality Services personnel report to the ESH&QA&CA QA Manager. These are documented in the Savannah River Information Network Environment (ShRINE), procedures, charters, and/or organization charts. Organizational descriptions include those functions within the QA Program scope. Attachment 1-5 shows the SRR senior management structure. Although senior SRR management is responsible for the scope, planning, implementation, and maintenance of an effective QA Program, each individual employee is held directly responsible for achieving and maintaining the quality of their work, with line management having final responsibility. Senior management establishes overall expectations for effective implementation of the QA Program and is responsible for obtaining the desired end result.

All individuals have the responsibility to immediately stop their activities when work quality is unsatisfactory unless stopping would be detrimental to the safety or health of personnel or the environment, violate criticality rules, or unnecessarily result in damage to equipment. In such cases, work shall be stopped as soon as practicable. Individuals also have the responsibility to verbally request responsible management to stop work external to their activities to prevent a nonconforming item from further use, installation, or processing, or to prevent a nonconforming activity from proceeding. The authority to issue formal QA Stop Work Orders has been delegated to the Cognizant Quality Function (CQF) to ensure planning or scheduling considerations do not override safety or quality considerations. Prior to restart after a formal QA Stop Work Order due to safety or quality concerns, appropriate reviews or assessments are planned, performed, and documented to verify that conditions that warranted the Stop Work Order are resolved and corrective actions completed.

1.4 SRR Organizational Structure and Responsibilities (Continued)

The SRR Quality Assurance Manager is responsible for providing central leadership, direction, assessment, and implementation of the QA Program, and for ensuring that the QA Program is compatible and consistent with the ISMS. These responsibilities include, but are not limited to: ensuring preparation and maintenance of a QA Management Plan; implementing the established quality policy; defining QA Program direction; ensuring development and maintenance of a QA Manual; serving as the primary SRR interface with DOE-SR officials on QA matters; resolving conditions not in compliance with QA Program requirements; serving as the SRR member on the Quality Assurance Policy Committee (QAPC), ensuring that all organizations have an assigned CQF; ensuring that Quality Control and Lead Audit personnel maintain their certifications; and ensuring QA personnel complete their technical staff qualifications.

The Independent Assessment organization is a component of the Contractor Assurance System reporting to the Contractor Assurance organization under the Environment, Safety, Health, and Quality Assurance (ESH&QA) and Contractor Assurance Manager. The Independent Assessment organization evaluates the QA Program, Safety Management System, Contractor Assurance System, Worker Safety and Health Program, and as appropriate, selected site-wide programs as described in Criterion 10 “Independent Assessment.” These various systems and programs are evaluated and documented by periodically performing independent assessments of operational or support units. The frequency of the assessments is dependent upon such factors as the risk level, operating status, on-going facility performance, or at the request of SRR senior management.

1.4 SRR Organizational Structure and Responsibilities (Continued)

CQF personnel are responsible for assisting line management in implementing site-wide QA programs, and program-specific controls (e.g., DOE/RW-0333P) within their areas of responsibility. Activities include, but are not limited to:

- Assisting the line organization in problem identification and resolution
- Providing analytical support for production processes as related to the QA discipline in accordance with approved procedures
- Assessing the adequacy of the QA Program and identifying management problems that hinder the organization from achieving its objectives
- Preparing internal implementing procedures
- Reviewing and/or approving administrative and selected operating procedures, QA Project Plans, Task Technical Plans, and Task QA Plans
- Reviewing and approving Level 1 and Level 2 procurement and commercial grade dedication documents used for acceptance
- Reviewing design and technical work documents
- Supporting implementation of the nonconformance process and reviewing / approving associated documentation, segregation, and tagging
- Performing and documenting independent inspections and tests where applicable
- Participating in the DOE Occurrence Reporting and Processing System (ORPS) as requested
- Issuing Stop Work Orders when conditions adverse to quality require immediate corrective action
- Reviewing and/or approving Safety Class and Safety Significant Test procedures, Test procedure change requests, and Test Deficiency Reports
- Reviewing and approving calibration extension requests
- Performing and documenting assessments, audits and/or surveillances
- Assisting, reviewing, and/or performing QA evaluations of suppliers
- Implementing the Software QA program

1.5 Relationship Between QA and the FEB

The relationship between the QA Manager and the Independent Assessment organization is shown in Attachment 1-6 “QA and Oversight Relationship.” The FEB and QA organizations report through the same administrative organization but have different missions. The FEB focuses on Startup, Operational Readiness, Operations, and Project activities. The FEB is independent of facility and project management and is tasked with providing them performance-based information to support continuous improvement, direct leadership resources, adjust personnel and financial resources, and identify areas of excellence.

1.5 Relationship Between QA and the FEB (Continued)

The role of the QA organization is to develop and maintain the quality program elements that are key components of an effective management system. The role of the organizational CQF is to facilitate implementation of the quality program in their specific organization. All permanent FEB team members are independent of line management and their reports are issued through the Office of the President. The FEB primarily performs independent assessments. The QA organizations primary function is to provide support to the operating facilities and project management for the implementation of the quality program.

1.6 Management Processes

The QA Program describes management processes including planning, scheduling, resource considerations and processes to detect and prevent quality problems and facilitate work. In the planning process, the basis for initial identification of quality requirements and the controls necessary to ensure their performance are established. These processes directly support implementation of the ISM Core Function, "Define Scope of Work."

1.7 Interface Control

For work assigned to organizations outside SRR, management controls are established, responsibilities are assigned, and lines of communication are identified in accordance with the controls for procured items and services. Task and program responsibilities split with SRNS are outlined in the MOA and the Functional Service Agreements (FSA) and that can be found on ShRINE. These agreements are reviewed and approved by senior management of both SRR and SRNS. The approved agreements clearly define the associated responsibilities, interfaces, and authority of each organization.

Work not performed by SRR or the Management and Operating contractor is controlled through the procurement process. The procurement process includes key points of contact for contracts. In addition, the procurement process ensures that responsibilities, interfaces, and authority are clearly defined. Procurement provisions included in the procurement documents require subcontractors and suppliers to satisfy applicable quality criteria and provide SRR and SRNS access to their facilities for independent oversight of activities. SRR and SRNS maintain responsibility for flowing down the requirements to subcontractors and suppliers at any tier to the extent necessary to ensure compliance with requirements and the safe performance of work. These quality aspects support the tailored flow down of programmatic requirements to subcontractors and satisfy the ISM requirements of the SRR contract.

1.7 Interface Control (Continued)

The SRR president and senior management team has established protocols for interface with:

- DNFSB
- DOE EM Headquarters
- DOE Office of Health, Safety and Security (HSS)
- Office of Civilian Radioactive Waste Management

1.8 Graded Approach

SRR applies QA Program requirements to items, services, processes, and associated activities, which implement the requirements in a graded manner as defined in 10 CFR 830 Subpart A. However, the graded approach is not used in the USQ process or in implementing technical safety requirements.

Application of a graded approach process ensures that the level of analysis, documentation, and actions used to comply with a requirement is commensurate with:

- Relative importance to safety, safeguards, security, operations, and business operations
- Magnitude of any hazard involved
- Life cycle stage of a facility
- Programmatic mission of a facility
- Particular characteristics of a facility
- Relative importance of radiological and non-radiological hazards
- Any other relevant factors such as complexity, economic value, etc.

The graded approach process, as applied to safety, is synonymous with the concept of tailoring requirements to the work and hazards described in ISM. The term "safety" includes all aspects of environmental, safety, and health management including pollution control, waste management, radioactive waste minimization, transportation, and safeguards and security. A hazard analysis/categorization and safety analysis process is used to evaluate the magnitude and consequences of hazards, and impact on safety for existing facilities, modifications to existing facilities, and for new facilities. Early in the project/modification or proposed activity, a safety strategy is developed to guide the approach taken in establishing the safety basis for the process. This is a key mechanism for hazard control that supports the guiding principles and core functions of ISM.

Designation of a Structure, System, or Component (SSC) as Hazard Category 1, 2, 3 or a Radiological Facility is used as a basis for applying QA Program requirements commensurate with risk for radioactive/waste activities managed directly by SRR and by suppliers providing radioactive/waste management services.

1.8 Graded Approach (Continued)

The established functional classification for a facility-based SSC serves as a primary driver for the level and rigor of design, analysis, technical reviews, verification actions, administrative controls, documentation requirements, and specific actions to be taken. Initially, the functional classification is assigned as early as practical in the design phase. However, it is periodically reviewed and evaluated and can be changed when the nature of the hazard, the mission of the facility, or specific characteristics of the SSC change. For a given functional classification, established methods and practices are applied to ensure that safe and proper operation or use of the SSC for the protection of the public, the workers, and the environment is achieved in a cost-effective manner.

The four functional classifications in order of decreasing significance are: Safety Class (SC), Safety Significant (SS), Production Support (PS), and General Services (GS). A qualitative evaluation of risk, considering all SC, SS, and Non-SC/SS Defense-In-Depth controls is performed to support selected accident scenarios. Defense-In-Depth is the process of selecting SSC, and engineering/administrative controls to provide multiple layers of protection to prevent or to mitigate the release of hazardous material.

In addition to safety considerations, requirements are tailored according to cost and complexity of the item, impact on mission success, and programmatic effects. No facility or activity is exempt from meeting applicable safety requirements. The results of the graded approach, each requirement, and the facilities to which it applies are captured in the S/RID.

1.9 Special Program Requirements

Some programs or projects require unique QA requirements for their activities. Such special QA Program requirements are added to, and integrated where possible with, the basic QA Program requirements for the affected facilities and activities. Some of these QA requirements are defined and controlled by the program or project, because they only apply to specific organizations and facilities. Attachment 1-1 illustrates special QA Program requirements and the responsible/affected organizations. These special program requirements are also reflected in the S/RID.

1.10 Alternative Standards

The requirements of DOE Order 414.1C are designed to achieve quality assurance for all work based on a series of principles that are applicable to nuclear and non-nuclear facilities and activities. These requirements are the same as the requirements for QA programs described in 10 CFR 830 Subpart A. The application of the graded approach for these facilities and activities is described in this QAMP. Also, in relation to DOE Order 414.1C, and only with respect to non-nuclear activities, alternative QA standards may be applied to such activities when approved through formal processes, such as, the S/RID process described in the Procedure Manual 8B, "Compliance Assurance Manual." Alternate QA standards and their application are documented in the S/RID and are approved by the Quality Assurance Manager and DOE-SR Contracting Officers.

When alternative standards are used, they must provide requirements to maintain equivalent assurance and oversight activities. When additional standards are used to address unique or specific work activities, they must be consistent with contractual and regulatory requirements.

Criterion 2 - Personnel Training and Qualification

2.0 Requirements and Key Implementing Documents

A. Federal QA Requirements

- Train and qualify personnel to be capable of performing their assigned work (10CFR830, DOE Order 414.1C)
- Provide continuing training to personnel to maintain their job proficiency (10CFR830, DOE Order 414.1C)

B. National Code & Standard Requirements

- NQA-1 Part 1 Requirements "2-Quality Assurance Program" and "18-Audits"

C. Key Implementing Documents

- See Attachment 2-1 "Key Implementing Documents for Criterion 2 – Personnel Training and Qualification"

2.1 Indoctrination and Training

All employees receive General Employee Training (GET) when initially hired and Continuing Annual Training (CAT) in subsequent years. Subcontractor initial training is included as part of the procurement process. Initial training / briefings for visitors are required and controlled by procedure.

2.2 Qualification Requirements

Personnel are trained and qualified, commensurate with their responsibilities, to ensure they are capable of performing their assigned work. Management establishes initial and continuing training and qualification requirements with supporting processes for specific job categories. The qualification of personnel supports the QA Program, the ISM core functions and guiding principles to ensure personnel have the competence commensurate with their responsibilities.

The qualification of personnel is accomplished by consideration of experience, education, training, and by demonstration and testing to verify acquired skills. Training programs consist of a combination of classroom, on-the-job training, and simulator or laboratory training as it applies to the position. Classroom training includes lectures, seminars, computer-based training, and structured self-study activities.

The qualifications for independent assessment personnel are established commensurate with the assessment purpose and scope. Persons conducting independent assessments are technically qualified and knowledgeable in the areas assessed. Cognizant technical/operational personnel may be included as team members to provide specialized expertise and knowledge. The assessment team leader is responsible for determining the need for specialized expertise to perform the assessment.

2.2 Qualification Requirements (Continued)

The qualifications for QA audit and surveillance personnel are established and documented in the QA manual. The certification requirements and process for Lead Auditors and Quality Inspectors is also documented in the QA Manual. SRNS is the certification authority for Auditors/Lead Auditors and Operations Quality Inspectors at the request of SRR. The construction organization is the certification authority for construction inspectors.

All training and qualification programs for personnel are developed and implemented in a tailored manner consistent with the hazards and the risks associated with the operation of the facility or activity. Qualification and certification programs are reviewed by management and are maintained to reflect changes to the facility, operational procedures, QA requirements, and regulations as well as applicable industry operating experience. Programs are structured to be in compliance with DOE Order requirements for training and qualification of managers, operators, technicians, and maintenance personnel. All requirements are described in procedures and Training Program plans.

2.3 Training

Initial training programs are established for personnel performing activities affecting quality to develop or enhance their knowledge and skills to perform job assignments. These programs are structured for specific position needs. Examinations and/or operational evaluations on material included in the training programs are administered and documented as appropriate.

Continuing training programs maintain and enhance the knowledge and skills of personnel who perform functions associated with safety-related structures, systems, and components. DOE guidance is used to develop continuing training programs that maintain job proficiency as well as improve the knowledge and skills of personnel. These programs are structured for specific position needs.

Continuing training includes items such as training in significant facility system and component changes, applicable procedure changes, applicable industry operating experience, selected fundamentals with emphasis on knowledge and skills necessary to assure safety, and other training as needed to correct identified performance problems.

2.4 Training Plans

Training and qualification procedures are used to establish standards to conduct training, qualification, and certification programs. Training plans are used to identify the knowledge base required for individuals to technically and safely perform a job. The plan also contains any continuing or optional training necessary to maintain job performance. The training plan is a tool that can be used to identify improvement and developmental opportunities. Various sources of training are considered. The training and qualification requirements for QA and QC technical support positions and management positions, are defined and documented in the QA Training and Qualification Program Description.

2.5 Instructors

Instructors are trained in performance-based training and are appropriately qualified for the specific training tasks. Classroom instructors are trained in accordance with the Instructional Staff Training and Qualification Program Description. The instructor training is based, in part, on the results of instructor evaluations and the need for training on new methods and equipment. Instructors possess the technical knowledge, experience, developmental and instructional skills commensurate with the subject material and the level of instruction that is provided.

Criterion 3 - Quality Improvement

3.0 Requirements and Key Implementing Documents

A. Federal QA Requirements

- Establish and implement processes to detect and prevent quality problems (10CFR830, DOE Order 414.1C)
- Identify, control and correct items, services, and processes that do not meet established requirements (10CFR830, DOE Order 414.1C)
- Identify the causes of problems and work to prevent recurrence as a part of correcting the problem (10CFR830)
- Identify the causes of problems, and include prevention of recurrence as a part of corrective action planning (DOE Order 414.1C)
- Review item characteristics, process implementation, and other quality-related information to identify items, services, and processes needing improvement (10CFR830, DOE Order 414.1C)

B. National Code & Standard Requirements

- NQA-1 Part 1 Requirements "15-Control of Nonconforming Items" and "16-Corrective Action"

C. Key Implementing Documents

- See Attachment 3-2 "Key Implementing Documents for Criterion 3 – Quality Improvement"

3.1 Improvement Program

The QA Program integrates strategic plans, processes, and procedures to ensure compliance with legal, regulatory, contractual, and corporate requirements related to quality improvement. Methods used for problem prevention include peer reviews, design reviews, probabilistic risk assessments, and safety analysis reports. These activities comply with DOE Order requirements, and applicable industry standard requirements, for environmental protection and protection of the health and safety of employees and the public. Performance and quality improvement is the intended result of the feedback and improvement core function of ISM and the Contractor Assurance System.

3.1 Improvement Program (Continued)

The Management Assessment Program is used to provide continuous improvements in performance, quality, activities, products, and services. The Management Assessment Program includes self-assessment, with management leadership participation, and on-going performance analysis of event and review-based deficiencies. As part of the Management Assessment and Performance Analysis Programs, the QA functional area is evaluated using quality program data from the corrective action database, assessments, FEB independent assessments, and performance metrics. These evaluations review and analyze a broad spectrum of data to identify QA programmatic issues. The information is used to develop corrective actions and make improvements in the functional area program. Similar evaluations are performed for the other Organizational Functional Areas leading to improvements in those areas as well.

Independent assessments, conducted by the FEB, DOE, SRR corporate team, etc. also provide a source of continuous improvement information and opportunities.

Another improvement tool used by Organizational Functional Areas is the use of Functional Area Councils and Committees. The QA Functional Area uses the QAPC as an avenue to identify weaknesses and develop improvements in the QA Program. The QAPC meetings are designed to be a forum for crosscutting issues to be identified, discussed, and improvements developed.

Performance Analysis, Operating Experience (Lessons Learned), and Corrective Action Programs all provide information on program performance as well as identify areas in need of improvement.

The Quality improvement process is used to identify, control, and correct items, services, and processes that do not meet established requirements. Quality improvement also involves reducing the variability of processes, which influences the quality of products and services. It is the responsibility of the line organization to achieve quality in the products produced and services provided. The individual worker's role is to meet the quality requirements and to recommend process improvements to enhance the quality of applicable products and services.

3.1 Improvement Program (Continued)

Problem prevention and continuous quality improvement are addressed in various implementing procedures. Measuring and evaluating performance against key performance indicators and standards are used to meet these objectives. Item characteristics, process implementation, and other quality-related information are reviewed and the data analyzed to identify items, services, and processes needing improvement. This data is also used to identify adverse trends that impact the quality of items and processes. Examples of quality-related information used include:

- Process capability studies;
- Performance analysis results;
- Studies that define assignable and inherent causes of process variability;
- Deficiencies identified through the Corrective Action Program;
- Failure rates;
- Corrective maintenance performed and backlog analysis; and
- Preventive maintenance performance.

To assure that appropriate improvement opportunities are identified, information from internal and external sources (DOE, industry data, and various subcontractors/suppliers) is used.

Policies for managing and continuously improving how work is performed, in order to meet customer expectations for quality and to measure and produce results aligned with strategic objectives, involve all personnel in the respective organizations. Performance and quality improvements are obtained thorough rigorous assessment, performance analysis, management involvement, and corrective action programs.

3.2 Human Performance Improvement

As a part of continuous improvement, a Human Performance Improvement (HPI) process was designed and implemented to reduce human errors in the workplace. The HPI process is designed to reduce the frequency of events by anticipating, preventing, and catching errors at the job site. The HPI process supports the vision of being a recognized leader in human performance through sustainable improvement in event reduction. Senior Management, through the Site Human Performance Improvement Steering Team, drives the HPI process. The Site Human Performance Improvement Working Group facilitates HPI implementation.

3.3 Corrective Action System

Corrective action procedures require personnel to report nonconforming items, processes, or activities. The procedures define the reporting system to be used, provide a graded approach used to correct deficiencies, and the process to ensure adequate closure and effectiveness of corrective actions. All personnel are granted the freedom and authority to identify those items and processes determined to be nonconforming and to stop work or to request that work be stopped until effective corrective action is completed. Procedures for bringing events, conditions, employee concerns, and issues to management's attention have been established by senior management. These procedures are in compliance with DOE Orders for occurrence reporting and the processing of operations information. The identification and reporting of unsatisfactory conditions is encouraged and supported by management.

Processes to detect and prevent quality problems have been established and implemented. Items, services, and processes that do not meet established requirements are identified, controlled, and corrected according to the importance of the problem and the affected work. Correction includes identifying the causes of problems and taking action to prevent recurrence based on the significance of the problem. A formal documented Corrective Action Policy is used by SRR. The corrective action policy, SRS Manual 1-01 procedure 5.35, establishes the system for identifying and controlling problems. The implementing procedures are in 1B procedure 4.23 and 1Q procedure 16.3. The system is a single database used for problem identification and corrective action control. The corrective action database system used is the Site Tracking, Analysis and Reporting (STAR).

Although the inputs to the STAR database come from multiple problem identification sources, the tools used to resolve each type of problem have consistent process steps. The Corrective Action System forms a comprehensive process with site-wide applicability as defined in implementing procedures. Continuous improvement is achieved by integrating the Corrective Action System with feedback processes such as:

- Price Anderson Amendments Act (PAAA) noncompliance's;
- Occurrence Reporting;
- Management Assessments;
- Independent Assessments;
- Operating Experience (Lessons Learned) processes; and,
- Customer reviews.

3.3 Corrective Action System (Continued)

The Corrective Action System includes the following elements:

- Problem identification/extent of problem determinations;
- Problem significance determination;
- Problem evaluation;
- Operating Experience (Lessons Learned) evaluation;
- Corrective action development/extent of condition determination;
- Corrective action implementation;
- Corrective action closure; and,
- Effectiveness reviews of those corrective actions implemented to prevent recurrence.

The corrective action methodology yields quality improvements that are implemented in a tailored manner. The significance of identified problems is the basis for the tailored application of the requirements within the corrective action process. The extent of causal analysis (e.g., Apparent Cause, Root Cause) is commensurate with the importance or significance of the problem.

As part of the Corrective Action System, issues are evaluated and assigned to one of five Significance Categories based on the impact to operations. These Significance Categories, as detailed in procedures include:

- Significance Category 1 – Issues in this category have a significant impact on safe/secure facility operations, worker or public safety and health, regulatory compliance, or public/business interests
- Significance Category 2 – Issues in this category have a moderate impact on safe/secure facility operations, worker or public safety and health, regulatory compliance, or public/business interests
- Significance Category 3 – Issues in this category have a minor impact on safe/secure facility operations, worker or public safety and health, regulatory compliance, or public/business interests
- Significance Category 4 – Issues in this category have a minor impact on safe/secure facility operations, worker or public safety and health, regulatory compliance, or public/business interests but are limited to issues that are Corrected On The Spot (COTS) and errors that do not warrant further corrective action
- Significance Category T – Issues for tracking that are necessary and/or appropriate to address and manage, but do not require a causal determination or full application of corrective action program elements

3.3 Corrective Action System (Continued)

Issues are entered into STAR and analyzed in accordance with Corrective Action System requirements. Implementation of corrective actions for problems is performed and documented by the responsible organization and verified based on the Significance Category of the problem. The applicable components of the Corrective Action System and requirements are detailed in the corrective action procedures.

Controls are used to prevent the inadvertent testing, installation, or use of nonconforming items and processes. Controls include tagging of items, segregation when possible, and conditional release for post-installation testing. Non-conformances are reviewed and approved by the organizations that reviewed and approved the original items or processes unless another organization with qualified and knowledgeable personnel is designated. Justification for the disposition action is documented in accordance with procedures for those items or processes not returned to their original, as-designed conditions. Nonconforming items that are subsequently reworked, repaired, or replaced are inspected and/or tested to either the original requirements or to specified alternative requirements. Such inspections or tests are conducted prior to the final acceptance of the items or processes.

The Cognizant Technical Function (CTF), chartered with having an adequate technical understanding of the work and access to pertinent background information, is responsible for the analysis and disposition of non-conformances involving “Repair” or “Use-As-Is” dispositions.

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. Alternative reporting documents (for example, deficiency reports and condition reports) may be used depending on the consequence of failure or operational status. Alternative controls are reviewed and approved by the SRR Quality Assurance Manager in accordance with established procedure.

Criterion 4 - Documents and Records

4.0 Requirements and Key Implementing Documents

A. Federal QA Requirements

- Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design (10CFR830, DOE Order 414.1C)
- Specify, prepare, review, approve, and maintain records (10CFR830, DOE Order 414.1C)
- See Attachment 4-1 "DOE Order 243.1 Records Management Program Requirements" for Federal Records Management requirements
- See Attachment 4-2 "Standards, Schedules, and Regulations for a Records Management Program" for Federal standards, schedules, and regulations for implementing a records management program
- See Attachment 4-3 "DOE Order 243.2 Vital Records Requirements" for Federal requirements for Vital Records

B. National Code & Standard Requirements

- NQA-1 Part 1 Requirements "2-Quality Assurance Program," "3-Design Control," "5-Instructions, Procedures, and Drawings," "6-Document Control," "7-Control of Purchased Items and Services," "9-Control of Special Processes," "10-Test Control," "12-Control of Measuring and Test Equipment," "17-Quality Assurance Records," and "18-Audits"

C. Key Implementing Documents

- See Attachment 4-2 "Key Implementing Documents for Criterion 4 – Documents and Records"

4.1 Documents

Documents are written, recorded, electronic media, or pictorial information that describes, defines, specifies, reports, or certifies activities, requirements, procedures, results, data, or plant conditions. Documents are prepared, reviewed, approved, issued, used, and revised to prescribe processes, specify requirements, or establish design.

Procedures require documents to be controlled, maintained, stored, protected, and capable of being retrieved in a timely manner. Record copies of documents are retained for their specified retention period. Documents are prepared and reviewed by cognizant individuals or organizations. Individuals or groups responsible for developing, reviewing, approving, issuing, and revising documents are identified in procedures. Guidelines for the distribution and effective dates of new or revised documents are established.

4.1 Documents (Continued)

Revisions are reviewed and approved by the same organizations that reviewed and approved the original document. Alternative organizations may be designated to review and approve documents based on their technical competence and capability in the required functional areas. The revision process provides for minor editorial changes and urgent changes to be processed expeditiously. Measures are provided to assure that approved changes are included in documents prior to implementation.

Controlled copies of approved documents are distributed or made available through Document Control DCRNotes. Data from DCRNotes and Document Images are also available through the Savannah River Information Network Environment (ShRINE) network for validation and performing assigned tasks. Document control activities include provisions for a master index and/or table of contents to identify the current revisions of controlled documents. Superseded or cancelled documents are controlled to preclude their use and to ensure the use of correct revisions.

Company-level and program-specific procedure manuals are also available electronically on the ShRINE website. Controls ensure that the current revisions of approved procedures are identified and are available electronically.

4.2 Records

Records provide adequate and proper documentation of the conduct of Government business. A record is complete and accurate, to the extent required, documenting an organization or functions, policies, decisions, procedures, and essential transactions and is designed to furnish the information necessary to protect the legal and financial rights of the Government and of persons directly affected by Government activities. A record can be a document or any other form of media that provides objective evidence about an item, service, or process. The Records Management and Quality Assurance Records Programs are detailed in the 1B and 1Q manuals. These manuals identify the specific procedures, requirements, and responsibilities to ensure cost-effective records management. These records management procedures along with the Records Disaster Preparedness Recovery Plan (WSRC-RP-99-00850) meet the requirements for a records management program identified in DOE O 243.1, "Records Management Program" and DOE O 414.1C "Quality Assurance," as well as vital records identified in DOE O 243.2, "Vital Records."

Records are identified and retained for in-process and/or completed work activities and should be sufficient to provide objective evidence of the quality of an item or activity. Records are specified in documents affecting quality, and are prepared, reviewed, approved, and maintained. Record maintenance includes provisions for record retention, protection, preservation, traceability, accountability, and retrievability. The requirements for the maintenance and control of QA records are specified in various procedures governing the particular activity.

4.2 **Records** (Continued)

Quality Assurance Records are records that are created and retained as prescribed under the Quality Assurance program. These records are controlled under the provisions of an approved procedure and retained as prescribed by the DOE records disposition schedules. A QA record is complete, authenticated, and provides evidence of:

- The quality of an item and/or activity;
- Conformance to significant requirements;
- The quality of site characterization data and samples; and,
- Effective operation of a quality program.

QA records are stored as hard copy, microfilm, magnetic media, or on optical disks. Records requiring special processing and control, such as computer codes or information on high-density media or optical disks, are controlled to ensure their validity and usability. Hardware and software needed to maintain and access these records are also controlled.

Record storage facilities are used for long-term retention of QA records. SRR also uses staging areas for records. In these staging areas, records are indexed and prepared for transfer to the primary records storage facility. Staging facilities, as well as temporary satellite records storage buildings, are equipped with fire detection and/or suppression devices, or other protective devices, and include provisions for controlling access to the records. All of these facilities provide retention, protection, preservation, traceability, accountability, and retrievability of records.

The Records Retention Schedule Matrix conforms to the NARA guidelines, General Records Schedule (GRS), and applicable DOE schedules. For those records not identified in the GRS or DOE Order on records disposition, appropriate retention and disposition schedules are written by originating organizations and submitted for NARA approval. When requirements differ from NARA, a request is submitted to NARA requesting authorization to retain the affected records in accordance with other requirements.

Required documentation and records are specified in manuals and procedures that are created and maintained through the Integrated Procedure Management System and serve as the primary mechanisms for implementing ISM.

4.3 Vital Records

Vital records are those emergency operating records and legal and financial rights records required during and after an emergency or as part of the recovery from a disaster. Emergency operating records are that type of vital record essential to the continued functioning or reconstitution of an organization during and after an emergency. Included are emergency plans and directives, orders of succession, delegations of authority, staffing assignments, selected program records needed to continue the most critical operations, as well as related policy or procedural records that assist the staff in conducting operations under emergency conditions and for resuming normal operations after an emergency. Legal and financial rights records are that type of vital record essential to protect legal and financial rights of the Government and individuals directly affected by its activities (also known as rights and interests records). Examples include accounts receivable records, social security records, payroll records, retirement records, and insurance records. Vital records are selected based on emergency missions, functions, and plans of operation. These records are managed and controlled using the Records Management and QA Records Management programs discussed in the previous section. Because of their importance in an emergency or disaster, vital records and the vital records program should be assessed regularly and a complete review performed at least annually to ensure that changing conditions are addressed and records are up-to-date and immediately accessible.

The Emergency Management Program Manager is responsible for ensuring that emergency operating records are compiled, maintained, updated, protected, and retrievable. They are also responsible to ensure that all alternate emergency operating centers, alternate command centers, and relocation sites are identified. Working in conjunction with the Records Management staff, they are responsible to ensure that emergency operating records are identified, collected, marked, numbered, and forwarded to the off-site storage location. They are also responsible to provide training to appropriate personnel on the vital records program.

The Records Management Officer is responsible to manage the vital records inventory. They are also responsible to ensure that vital records assessments are being performed.

Criterion 5 - Work Processes

5.0 Requirements and Key Implementing Documents Documents

A. Federal QA Requirements

- 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 (10CFR830)
- Perform work consistent with technical standards, administrative controls, and hazard controls adopted to meet regulatory or contract requirements using approved instructions, procedures, etc. (DOE Order 414.1C)
- Identify and control items to ensure their proper use (10CFR830, DOE Order 414.1C)
- Maintain items to prevent their damage, loss, or deterioration (10CFR830, DOE Order 414.1C)
- Calibrate and maintain equipment used for process monitoring or data collection deterioration (10CFR830, DOE Order 414.1C)

B. National Code & Standard Requirements

- NQA-1 Part 1 Requirements "7-Control of Purchased Items and Services," "8-Identification and Control of Items," "9-Control of Special Processes," "12-Control of Measuring and Test Equipment," "13-Handling, Storage, and Shipping," and "14-Inspection, Test, and Operating Status"

C. Key Implementing Documents

- See Attachment 5-1 "Key Implementing Documents for Criterion 5 – Documents and Records"

5.1 Performance of Work

Work is performed using approved procedures, work packages, or other approved work authorizing documents that meet technical standards, regulatory, or contractual requirements within the boundaries of established administrative and hazard controls. This implements the ISMS objective to "Do Work Safely." As part of fostering an overarching safe work environment, work planning includes worker feedback as part of the hazard identification and analysis. This feedback is then used to tailor the hazard controls consistent with the work while still providing for the prevention or mitigation of the hazard. The work control process is implemented to manage work, ensure compliance with requirements, avoid hazards, and to enhance worker safety at all organizational levels.

5.1 Performance of Work (Continued)

The success of the work processes is dependent on personnel performing work to be responsible for the safety and quality of their work. This is achieved by providing people with the necessary skills, training, and qualifications to safely and responsibly complete the assigned task. Success also requires continuing training and skill refinement as part of their career development process. This ensures workers maintain their qualifications and possess the necessary competence to ensure they provide superior craftsmanship as a normal job responsibility. Continuing training provides new and refreshed knowledge for their use ranging from technical requirements to capabilities of the tools and processes they use. Working to established standards and controls is consistent with the expectations of ISMS core functions of "Develop/Implement Controls" and "Perform Work."

An important aspect of ISM is the concept that readiness to do work safely must be confirmed before work may commence. This concept, applied using a tailored approach, ranges from simple readiness checklists for a task to formal and extensive independent Operational Readiness Reviews (ORR) for complex and hazardous facility startup.

Line management ensures that trained and qualified people are assigned to perform work and that necessary resources to accomplish the work are provided. The Conduct of Operations, Conduct of Engineering, and Conduct of Maintenance programs require employees to have the necessary training and skill development to perform their assignments.

Work Control Programs require personnel with work approval authority to review the scope of work and provide approval prior to work commencement. Necessary engineering and/or administrative controls, including hazard assessment, tagging and lockout, radiological work permits, and quality inspections are specified. Work control programs provide for work and job planning functions that require preparation, review, and approval of work documents prior to initiation of work. Work documents consist of steps needed to perform work safely and successfully. Work documents also specify post-modification or functional acceptance tests and applicable acceptance criteria.

Conducting a multi-disciplinary team review, by workers and support personnel, of work documents and associated hazards, enhances work planning at the task or activity level. This review is one tool used to implement ISM at the task or activity level. Personnel responsible for performing the work help develop the work document while checking its accuracy, adequacy, and to become familiar with its contents.

5.1 Performance of Work (Continued)

Work documents and associated hazard controls are reviewed and approved by applicable line supervision, quality, engineering, construction, and/or operations personnel prior to commencement of work. Pre-work reviews facilitate compliance to technical standards, verification plans, and inspection acceptance criteria. Pre-work reviews also ensure adherence to worker safety criteria, correctness of quality hold points, planned inspections, and work document completeness. After completion, post-work reviews verify that desired results have been attained and that the required documentation is available.

Procedures and instructions accompanying work documents must comply with the requirements of applicable technical standards, vendor manuals, safety analysis codes, specifications, and other technical requirement documents. Procedures used to accomplish work are developed using technical, safety, and quality requirements as specified in various applicable documents. These procedures define the requirements for reviews by CTF, CQF, operations, maintenance, radiological control, safety, engineering, principal investigators/researchers, and other affected organizations prior to approval. Personnel reviewing these procedures are selected by their organization based on qualification, knowledge, experience, and competency in their area of responsibility.

A graded approach is used to apply QA and safety requirements to proposed work based on risk and hazard analysis. Hazard analysis is part of the work planning process, and includes, task complexity, environmental consequences, safety consequences, and programmatic effects (for example, mission and cost). The graded approach is used to determine the extent of involvement of the CQF, CTF, safety, environment, radiation control, etc. functions in the review, approval and monitoring of work control programs.

5.2 Work Planning and Control Process

In 2004, the DNFSB issued DNFSB recommendation 2004-1. As a result of that recommendation, DOE identified a deficiency in the scope of Work Planning and Control (WP&C) activities across the DOE complex. The issue involved a limited application of WP&C to primarily maintenance activities, rather than to all work activities. As a result of that weakness and in conjunction with other ISMS improvement initiatives, improvements were made in the SRS WP&C process. Functional areas that performed activity level work (Operations, Construction, Radiation Control, and Maintenance) developed work area specific WP&C flow charts of their procedures to ensure they met DOE requirements. The WP&C process is integrated into activity level work.

5.3 Identification and Control of Items

Items are identified and controlled to ensure their proper use. Material identification and traceability requirements are based on the specificity of the material identification, its end use, and the consequences of its failure. Identification of items is maintained either on the item or in documentation traceable to the item. When required, items are identified from initial receipt or fabrication up to and including installation or use. Procedures are established to ensure that, when items having identification or traceability requirements are subdivided or sampled, identification will be transferred to each part, container of parts, or sample at the time of subdividing or sampling.

Items are maintained to prevent their damage, loss, or deterioration. Items include materials, equipment, components, appurtenances, assemblies, modules, parts, structures, subsystem units, subassemblies, and systems. Controls are established and implemented to ensure that only correct and accepted items are used and installed. Where specified, items having limited shelf life, operating life or operating life cycle are controlled to preclude use when such limits have been exceeded.

5.4 Handling, Storing, and Shipping

Procedures are established and implemented to control the handling, storing, shipping, cleaning, and preservation of items to prevent damage, loss, or deterioration. The control levels established for storing and shipping are derived from national consensus standards, SRS standards, or technical documents if no standards exist.

Instructions for marking and labeling for packaging, shipment, handling, and storage of items are established, as necessary, to adequately identify, maintain, and preserve the items' integrity, including indication of the need for special environments or special controls. Procedures for offsite transportation are established and implemented.

The need for special protective measures is evaluated and documented. Measures include containers, shock absorbers, accelerometers, inert gas atmospheres, and specific temperature and moisture levels. Measures are also specified and provided to maintain acceptable quality during storage.

5.5 Calibration and Maintenance of Monitoring and Data Collection Equipment

Monitoring and data collection equipment is identified as Measuring and Test Equipment (M&TE), Installed Process Instrumentation (IPI), Radiological Monitoring Equipment (RME), or Measurement Systems and Equipment (MS&E).

M&TE can be portable or fixed equipment. M&TE is used for acceptance, calibration, measurement, gauging, testing, and/or inspection of equipment in order to control or acquire data to verify conformance to specified requirements or for reference only. M&TE is not used for process controls.

5.5 Calibration and Maintenance of Monitoring and Data Collection Equipment (Continued)

IPI is the installed equipment, devices, instrument loops, or systems used for monitoring, collecting data, or controlling a facility process, system, or component that is an integral part of the process, system, or component. A program describing IPI calibration and maintenance requirements and controls is established in 1Q QAP 12-2 and implemented through the 1Y manual. The CTF is responsible for defining what equipment is considered IPI. IPI calibration requirements are specified and documented in implementing procedures. Each piece of IPI is uniquely identified with the identification either on or near the individual instrument. The identification is used for traceability and accountability of the equipment.

IPI calibration is performed at specified intervals, commensurate with the application of the equipment. The calibration frequencies and accuracy requirements are based on the system monitoring requirements, stability characteristics, service conditions, and other factors determined by the CTF. M&TE is used to calibrate IPI.

Out of tolerance IPI is documented and reported to responsible facility management. An evaluation is required to determine the effect on the validity of previous data collected by the out of tolerance IPI and the impact on any previously accepted data. When the evaluation indicates there was an impact or the evaluation indicates a condition adverse to quality, it is documented and processed through the corrective action process.

RME is used to measure radioactive emissions from ionizing radiation fields, radioactive effluents, or radioactive surface contamination for radiological control purposes. A program describing RME calibration, maintenance, requirements, and controls is established in 1Q QAP 12-3 and implemented through Radiation Control procedures. The responsible CTF establishes the minimum technical requirements for repair, calibration, and source checking of RME. RME calibration and source check requirements are specified and documented in implementing procedures that comply with applicable National Standards and Procedures such as American National Standards Institute (ANSI) Standards, National Institute of Standards and Technology (NIST), International Organization for Standardization (ISO), and others as applicable. RME is uniquely identified with the identification either on or near the individual piece of equipment. The RME Technical Authority maintains a list of controlled RME instrument types. SRNS is the RME Technical Authority for the Savannah River Site in accordance with Functional Service Agreement G-MOA-F-00006.

5.5 Calibration and Maintenance of Monitoring and Data Collection Equipment (Continued)

All RME receives an initial calibration and a source check performed by qualified personnel using approved procedures prior to being placed into service. RME calibration frequencies are established by the CTF and documented. Out of tolerance RME is documented, tagged and/or segregated and not used until it has been recalibrated. An evaluation is required to determine if the use of the RME could have resulted in an adverse impact on the health or safety of personnel or impacted any previously accepted data. When the evaluation indicates there was an impact or the evaluation indicates a condition adverse to quality, it is documented and processed through the corrective action process.

MS&E is analytical measurement systems used in analytical laboratories and waste characterization. The analytical measurement system applies quality control techniques in addition to basic M&TE requirements to ensure the adequacy of measurements. The analytical measurement program describing this alternative approach to M&TE controls is established and implemented.

MS&E calibration requirements are specified and documented in implementing procedures and performed to prescribed intervals. Out-of-calibration or suspect MS&E is tagged, segregated, or controlled to prevent inadvertent use. MS&E that is lost or destroyed, not serviceable, or whose test calibration results are outside acceptable limits, must have the sample results reported since the last calibration evaluated and documented by the CTF. When the evaluation indicates there was an impact or the evaluation indicates a condition adverse to quality, it is documented and processed through the corrective action process.

5.6 Status Indicators

Managers of organizations that perform operating, support, or experimental functions are required to maintain physical status indicators and supporting documentation for those work processes under their control. Procedures specify the content, application, updating, or removal of physical status indicators.

5.7 Control of Computer Software

Computer software is controlled, using a graded approach based on intended use, risk, safety, facility life cycle, complexity, project quality requirements, and classification level. This is accomplished through implementation of the software quality assurance program. See Criterion 11 “Software Quality Assurance” for additional details on the Software QA Program.

Criterion 6 - Design

6.0 Requirements and Key Implementing Documents

A. Federal QA Requirements

- Design items and processes using sound engineering/scientific principles and appropriate standards (10CFR830, DOE Order 414.1C)
- Incorporate applicable requirements and design bases in design work and design changes (10CFR830, DOE Order 414.1C)
- Identify and control design interfaces (10CFR830, DOE Order 414.1C)
- Verify or validate the adequacy of design products using individuals or groups other than those who performed the work (10CFR830, DOE Order 414.1C)
- Verify or validate work before approval and implementation of the design (10CFR830, DOE Order 414.1C)

B. National Code & Standard Requirements

- NQA-1 Part 1 Requirements "1-Organization" and "3-Design Control"

C. Key Implementing Documents

- See Attachment 6-1 "Key Implementing Documents for Criterion 6 – Design"

6.1 Design Requirements

Items and processes are designed using sound engineering/scientific principles, and appropriate standards. The design of items and processes to accommodate a defined scope of work has features tailored to address the hazards associated with the work. Design considerations interface with nearly all ISM functions and principles, but focus on the first three core functions. Facilities and equipment are designed to help translate missions into work. Design bases are developed to address the identified and analyzed hazards, culminating in tailored hazard controls. Engineering practices and procedures have been established and implemented to perform and control design, including design requirements, inputs, processes, outputs, changes, records, and organizational interfaces. If software or experiments are part of the design process, and safety or mission risks are identified, then design controls apply. SSCs are designed using a graded approach that assigns functional classifications according to the level of hazards present. Various elements of the QA Program and administrative controls are applied in accordance with these functional classifications. Design control measures correctly translate appropriate codes, standards, and quality requirements to ensure SSCs meet their specified design requirements.

6.1 Design Requirements (Continued)

Design work, including design changes, incorporates applicable requirements and design bases. The design control program specifies a number of design basis elements that must be considered during development of design input documents. Requirements for determining design bases include basic function and performance requirements; computer systems and applicable software programs; design and environmental conditions; material requirements; interface requirements; operational, maintenance, constructability and redundancy requirements; fire protection, safety, quality, and reliability requirements. Requirements are typically contained in task requirements or system/facility design description documents.

Design control processes ensure that design input requirements are correctly translated into design output documents, such as drawings and design and procurement specifications. Design input and output alignment, including drawings, calculations and analyses, and supporting documentation, is an integral part of the design verification process performed during various phases of design development to ensure that the applicable requirements are properly incorporated throughout the design activities.

6.2 Design Change Control

Written procedures establish controls for changes to final design, field changes, modifications, and changes resulting from nonconforming items dispositioned as "Use-As-Is" or "Repair." Design change information is typically included on approved, controlled change documents. Procedures require technical justifications for design changes, including the use of acceptance criteria if different from that specified in original design. Design changes are subject to the same controls as the original design. These controls ensure that the design analyses for the system, structure or components are still valid or are re-performed, as applicable. Procedures provide for changes to be approved by an in-house design organization, or other technically qualified designee, assigned the responsibility for developing, reviewing and approving the design. Formal change control processes are used depending upon the impact of a change.

6.3 Temporary Modifications

Temporary modifications are controlled in a similar manner to the controls for permanent design modifications. They are initiated by a request to the appropriate technical organization responsible for the SSC. A technical evaluation is performed for acceptability and the request logged into a temporary modification log. Individuals qualified to evaluate the temporary modification conduct a formal technical review and obtain the necessary approvals. The modification is installed and tags are applied to identify the modification. While in place, the temporary modification is subject to periodic reviews by the organization responsible for the SSC. When the temporary modification is complete, the SSC is returned to its original configuration and the modification log entry is closed. In some cases, a temporary modification may become permanent through an approved, controlled design change process.

6.4 Design Interfaces

Design interfaces are identified and controlled using procedures, instructions and/or formal agreements to provide effective coordination of design effort between participating organizations. These controls describe the responsibilities of the affected organizations for initiation, development, review, approval, release, distribution, revision of design documents, and management of the tasks.

6.5 Design Records

Design control procedures provide for the collection, storage and maintenance of design documentation and records. Design records include final design output and revisions, such as drawings, specifications, and quality inspection plans. Also included are documents prepared during important design steps: calculations/design analyses, quality assessments, design verifications, formal design reviews, computer programs, and design change documents. Design input documents are maintained as records.

These design records provide evidence that the design and design verification processes were adequately performed.

6.6 Design Verification

Design output adequacy is verified prior to its release for use by other organizations or to support processes such as procurement, manufacture, construction, equipment operation, or experimentation. If any portion of the design cannot be verified prior to release, the unverified portion of the design is identified, tracked, and controlled. Verification and validation work is completed before approval and implementation of the design.

Design output adequacy is verified or validated by qualified individuals or groups other than those who performed the work. Design organizations assign design verification responsibility to individuals or groups knowledgeable in the application of the design and capable of performing similar design activities.

6.6 Design Verification (Continued)

Design verification is accomplished using one or more of the following methods: design review; alternate calculations; and/or qualification testing. Separate verification is not required for multiple uses of identical or previously proven/verified designs unless they are intended for different applications or performance criteria.

Formal design review processes have been established and implemented that independently verifies compliance of the design with applicable requirements specified in design input documents. These review processes include review of design inputs, processes, outputs, and changes. The extent of verification is commensurate with the hazard, complexity of design, degree of standardization, and uniqueness of the design.

Representatives from project-sponsoring organizations and other applicable organizations are included on design review teams. Design review processes consist of peer reviews, interdisciplinary reviews, and reviews within design agencies.

Qualification tests may be used to verify design adequacy or portions of it in conjunction with other verification methods. Programs have been implemented to control such tests. These tests are conducted using approved procedures and include acceptance criteria, which verify or validate acceptability of specific design features. Qualification tests are conducted on a timely basis under conditions that simulate the most adverse design conditions. Determination of the most adverse conditions takes into consideration operating modes and environmental conditions in which the item being tested is required to perform satisfactorily. Test results are documented, evaluated, approved, and retained. Structures, systems or components are put into operation only after successful completion of qualification tests. When only certain feature characteristics can be verified by qualification testing, the remaining features are verified by other appropriate methods (for example, run-ins or monitored operations). The portions of the design to be verified are identified and the extent of the verification is defined and documented.

Alternate calculations may be used to verify correctness of the original design calculations. The appropriateness of assumptions, input data used, and the computer program or other calculation method used are also reviewed for correctness.

Criterion 7 - Procurement

7.0 Requirements and Key Implementing Documents

A. Federal QA Requirements

- Procure items and services that meet established requirements and perform as specified (10CFR830, DOE Order 414.1C)
- Evaluate and select prospective suppliers on the basis of specified criteria (10CFR830, DOE Order 414.1C)
- Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services (10CFR830, DOE Order 414.1C)

B. National Code & Standard Requirements

- NQA-1 Part 1 Requirements "4-Procurement Document Control" and "7-Control of Purchased Items and Services"

C. Key Implementing Documents

- See Attachment 7-1 "Key Implementing Documents for Criterion 7 – Procurement"

7.1 Procurement Program Description

Procurement program procedures provide a detailed methodology for preparing, reviewing and approving purchase requisitions, amendments to requisitions, procurement specifications, bid packages, and other procurement documents. The procurement program is a tool to ensure that applicable requirements are flowed down to suppliers. The supplier QA program ensures that the supplier is meeting these requirements and the receipt inspection process ensures acceptance criteria is met. These programs and procedures work together to ensure procured items and services meet established requirements and perform as specified.

The procurement process incorporates a graded approach for controlling procurement actions commensurate with the functional, quality, and technical requirements associated with the intended use or application of the procured item or service.

7.1 Procurement Program Description (Continued)

The graded approach consists of following three levels of control:

- Procurement Level 1 provides the highest level of control. These procurements require potential suppliers to be audited by SRR/SRNS and be on the SRS Qualified Suppliers List (QSL). Procurement document(s) reviewed by the applicable SRR QA organization and receipt inspection performed by the SRNS QA receipt inspection organization and SRR personnel certified to perform receipt inspection.
- Procurement Level 2 is used for intermediate levels of control. These procurements may include a supplier audit, surveillance, documentation review, or enhanced receipt inspection. Procurement document(s) reviewed by the applicable SRR QA organization and receipt inspection performed by the SRR/SRNS QA receipt inspection organization.
- Procurement Level 3 has the lowest level of control. Receipt of materials by Asset Management personnel in accordance with receipt of material procedure.

Another aspect of the graded approach to procurement is the Commercial Grade Dedication (CGD) process. The CGD procedure controls the process for evaluating off-the-shelf commercial grade items and dedicating these items for safety-related applications. As part of the CGD process, the CTF defines the critical characteristics and the associated verification requirements. These verification requirements may include specific inspections, tests, and/or evaluations to ensure that they will perform properly in the safety-related application.

In the case of on-site subcontracted services, a graded approach is used to determine the extent to which worker safety-related procedural requirements must be imposed on the subcontractor and their visitors and vendors. That graded approach is based on the complexity of the work, the level of hazards associated with the work, the subcontractor's safety performance history, and the proximity of the work to other workers. This process is in direct support of contractual requirements to flow-down, in a tailored manner, applicable S/RID and contractual requirements to subcontractors. Subcontract Technical Representatives (STRs) are assigned to provide oversight of subcontractor activities and to assure compliance with safety, security, technical, quality and any other requirements specified in the subcontract.

Procedures provide specific requirements and guidelines to initiate purchase requisitions, procurement specifications, and other procurement documents. These procedures define appropriate controls for the selection, suitability determination, evaluation, and receipt of items or services being procured.

7.1 Procurement Program Description (Continued)

Applicable Technical, administrative, and quality requirements and the procurement level are identified and specified in procurement documents. These requirements include applicable codes, regulations and industry standards, tests and inspections, traceability and special procedures or instructions. The procurement documents identify acceptance methods and criteria for items or services. Procurement documents for items or services that are critical to safety or have significant operational risks are reviewed by the CQF and CTF.

The procurement and procurement QA activities support the ISM function to "develop and implement controls."

7.2 Supplier Selection and Evaluation

The supplier selection and evaluation process involves both the QA and procurement organizations. Both organizations have procedures applicable to their role in in the process. Supplier selection and evaluation applies to the procurement of items and services that are important to safety. Prospective suppliers are evaluated and selected through specified criteria, using a graded approach. Items or services are procured from suppliers whose qualification results satisfy the requirements of the procurement specifications. Review of the suppliers' documentation and in-plant assessment of the suppliers' capabilities are typically used for supplier selection based on the nature and application of items or services being procured. Suppliers on the QSL are monitored and re-audited every three years. In addition, re-qualification and supplemental audits are performed on selected suppliers to verify compliance with the procurement requirements. Any portion of the supplier QA program can be invoked based on determination by the CTF. Supplier performance monitoring is an implementation example of the ISM "feedback and improvement" function.

SRR working in conjunction with SRNS ensure that QA is appropriately implemented through the use of effective policy, oversight, technical support and assessments. SRR and SRNS maintain Functional Service Agreements that help to maintain a network of working relationships that ensure effective communication of QA issues and timely feedback on their contractors as well as QA performance data.

The SRNS supplier quality organization in conjunction with SRR personnel, provide independent oversight, audit, assessment, and surveillance of contractor QA programs. This arrangement provides an independent review of contractor policies and programs. This information provides an objective, unbiased evaluation of contractor operations, performance, and testing.

7.3 Product Acceptance

The quality of purchased items and services is verified at intervals during various phases of the procurement process. The frequency of verification is determined by requirements of the procurement documents, applicable specification, code and standard, uniqueness, complexity, application of the item, quantity and frequency of the procurement, and previous quality-related performance of the supplier. Programs have been established to monitor suppliers of on-site environmental services. Suppliers of off-site analytical services are evaluated to ensure compliance with QA and technical requirements.

Purchased items or services are accepted by the method(s) specified by the requisitioning organization. One or more of the following methods is used to accept items important to safety or having significant operational risks:

- Source verification
- Receiving inspection
- Post-delivery testing

In addition, a Certificate of Conformance (C of C) from a qualified supplier with the appropriate receipt inspection can be used for acceptance of certain procurements. The C of C is traceable to the item and satisfies the requirements of the procurement documents. Procured services may be accepted by any of the following:

- Review and technical verification of data / reports produced
- Supplier performance
- Surveillance / audit of the activity

Source verification and receiving inspection activities are performed using procurement documents reviewed by the CQF of the requisitioning organization. Receipt inspected items are routinely examined for potential suspect/counterfeit characteristics. If identified as a potential suspect/counterfeit item, they are processed through the nonconformance process and evaluated by engineering. (See Criterion 12 Suspect/Counterfeit Items (S/CI) Prevention for additional details).

Processes to ensure that approved suppliers continue to provide acceptable items and services have been established and implemented. When required by procurement documents, surveillances are conducted at supplier facilities by qualified personnel. These surveillances consist of inspections and tests, including witness and hold points, and document verification as specified in procurement documents. Surveillance of sub-tier suppliers may also be performed.

7.3 Product Acceptance (Continued)

Procured items are put into service only when the acceptance requirements of the procurement documents are met. If an item does not meet a specified requirement or there is a documentation deficiency, a nonconformance or alternative reporting document is initiated to document such deficiency. Identified deficiencies are evaluated and corrective action is taken and verified prior to the item's use. Information from these nonconformance/deficiency documents is placed in the corrective action program for analysis and trending.

Post-maintenance, functional, or pre-operational testing is performed after installation of procured items when specified. These tests verify actual performance against established criteria for the item and the system. Tests, in-service inspections, and preventive maintenance programs monitor the performance of the procured item against established criteria.

The combination of supplier evaluation and product acceptance combines to ensure that suppliers are approved and continue to provide acceptable items and services.

Criterion 8 - Inspection and Acceptance Testing

8.0 Requirements and Key Implementing Documents

A. Federal QA Requirements

- Inspect and test specified items, services, and processes using established acceptance and performance criteria (10CFR830, DOE Order 414.1C)
- Calibrate and maintain equipment used for inspections and tests (10CFR830, DOE Order 414.1C)

B. National Code & Standard Requirements

- NQA-1 Part 1 Requirements "10-Inspection" and "11-Test Control"

C. Key Implementing Documents

- See Attachment 8-1 "Key Implementing Documents for Criterion 8 – Inspection and Acceptance Testing"

8.1 Inspection

Inspection and testing of specified items, services, and processes are conducted using established acceptance and performance criteria. Examples of inspections include in-process, in-service, final, source, receiving, and, independent. Independent inspections are performed by qualified and certified quality inspectors that are not responsible for performing or directly supervising the item or activity inspected.

Inspections are performed in accordance with requirements established by the CTF and CQF. The CTF is responsible for establishing the level, extent, and acceptance criteria for inspections based on critical characteristics, functional classification, or procurement level. Functional classification and procurement level are also a basis for establishing who will perform designated inspections. Inspections are identified in work documents by hold or witness points.

The inspection planning process is used to ensure that the characteristics to be inspected, method of inspection, and acceptance criteria are provided, properly identified, and incorporated into inspection documents before an inspection is performed. The inspection planning process includes, as a minimum, item and process characteristics to be inspected; inspection techniques to be used; acceptance criteria (including tolerances); hold and witness points; and identification of the organization performing these inspections.

8.1 Inspection (Continued)

When acceptance criteria are not met, non-conforming items and processes being inspected are controlled in accordance with the Nonconformance Control System. After verification of corrective action implementation, the item or process is re-inspected to the original or approved alternative acceptance criteria prior to being used or returned to service.

Administrative controls, including the use of status indicators, are used to preclude inadvertent bypassing of required inspections and inadvertent operation of nonconforming or indeterminate items or processes.

8.2 Acceptance Testing

Acceptance testing of specified items, services, and processes are conducted using established acceptance and performance criteria. Establishment and implementation of the test program includes the use of testing methods to demonstrate that items and processes perform, as intended. Test programs include bench tests and proof tests before installation, pre-operational tests, post-maintenance tests, post-modification tests, and operational tests. These programs are structured to clearly distinguish between tests that verify design requirements and tests that verify operation within safety limits and requirements. Test programs are implemented by or for the organization performing the work to be tested, using a graded approach to determine independent organizational involvement.

Item and process test requirements, including specified acceptance criteria, are provided or approved by the organization responsible for design. The CTF has the primary responsibility for establishing and approving test requirements and associated acceptance criteria. Designated operations personnel review the test packages for impact on/interface with operating systems and confirm that proposed testing will provide adequate verification that the equipment being tested will perform its design functions. Administrative controls and status indicators are used to preclude inadvertent bypassing, incomplete required tests, or operation of untested items or processes.

Test program controls include the development, approval, and use of test procedures. These procedures include:

- Instructions and prerequisites to perform the test;
- Requirements to ensure completeness and accuracy of data;
- Use of test equipment;
- Acceptance criteria;
- Inspection hold points as required; and,
- Test article configuration.

8.2 Acceptance Testing (Continued)

When items and processes do not meet documented test acceptance criteria, these deficiencies are documented and evaluated using the Nonconformance Control System.

Corrective action control documents are included as a part of test documentation. When deficiencies have been corrected, retesting is performed to verify that acceptance criteria are met.

Inspection and acceptance testing processes are mechanisms to confirm readiness to perform work safely and ensure that items will perform their assigned function.

8.3 Measuring and Test Equipment

A program describing controls applicable to M&TE has been established in 1Q QAP 12-1 and implemented through the 1Y and SRNL procedures. Equipment used for inspections and tests is calibrated and maintained. Traceability and accountability of this equipment is also required. SRNS, through services provided by the Savannah River National Laboratory, is responsible for performing calibrations of M&TE.

M&TE program documents define what equipment is considered M&TE. Calibration and traceability requirements are defined based on use. M&TE typically includes instruments, tools, gauges, reference and transfer standards, and nondestructive examination equipment.

M&TE calibration is performed at specified intervals or just prior to and after use, as established by documented requirements. The CTF is responsible for defining M&TE calibration frequencies. Calibration frequencies are based on required accuracy, intended use, frequency of use, stability characteristics, and other conditions affecting M&TE performance.

M&TE is labeled, tagged, or otherwise controlled to indicate calibration status. M&TE identification provides traceability to calibration and test data.

Accuracy of M&TE calibration standards is established to ensure equipment being calibrated will be within required tolerances. Calibration standards are traceable to national standards. If no national standards exist, the program requires the CTF to identify alternative standards.

8.3 Measuring and Test Equipment (Continued)

M&TE found to be out of calibration or out of tolerance is tagged or segregated. Such M&TE is not used until it has been either successfully recalibrated or replaced. The M&TE control program requires formal documented review of the use of such equipment dating back to its last known in-calibration date (reverse traceability). This review determines if such use resulted in the acceptability of items or processes being either invalid or indeterminate. The basis for acceptance of these nonconforming or indeterminate items and processes is formally evaluated and documented.

Criterion 9 - Management Assessment

9.0 Requirements and Key Implementing Documents

A. Federal QA Requirements

- Ensure managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives (10CFR830, DOE Order 414.1C)

B. National Code & Standard Requirements

- NQA-1 Part 1 Requirement "18-Audits"

C. Key Implementing Documents

- See Attachment 9-1 "Key Implementing Documents for Criterion 9 – Management Assessment"

9.1 Management Assessment

The goal of both the Management Assessment and Independent Assessment programs is to ensure that problems are identified and corrected. This ensures that organizations and operations are performed effectively, efficiently, and objectives are achieved.

The management assessment program requires assessments to be planned. The performance of these assessments provides feedback that is used to measure quality, adequacy of work performance, and to promote improvement. The management assessment process incorporates two major program activities: self-assessment and performance analysis. These oversight activities ensure the adequacy and effectiveness of the management control system and contractor assurance system throughout the organization. While retaining overall responsibility for management assessment, senior management requires managers to assess performance of activities assigned to them and identify and correct problems that hinder their organization from achieving its objectives. The management assessment program is a major contributor to ISM and oversight activities that comprise contractor assurance activities.

Self-assessments are planned, scheduled, and performed to verify conformance to applicable requirements and identify opportunities to improve performance and cost effectiveness. Results and conclusions from these assessments are documented and evaluated. Issues identified during assessments are documented in the Corrective Action Program using the corrective action data base system "Site Tracking, Analysis, and Reporting (STAR)." These issues are managed to resolution as required by the Corrective Action Program.

9.1 Management Assessment (Continued)

Performance analysis of event-based and review-based data from various sources (i.e., the Corrective Action Program, Management and Independent Assessment Programs, DOE Occurrence Reporting and Processing System (ORPS), and contractor assurance activities) is performed periodically to identify recurring problems and potential areas of concern. Analysis is accomplished at two different levels. Corporate level performance analysis is performed quarterly under the leadership of the Contractor Assurance organization. The analysis is a proactive evolution that involves key senior management personnel during the analysis process. The results are used to identify recurring company-wide problems. Organizational-level performance analysis is performed annually as directed by procedure, or additionally as directed by senior management, and identifies recurring organizational problems. All problems identified as recurring are processed in accordance with the Corrective Action System and as applicable in the DOE ORPS and DOE Price Anderson Amendment Act (PAAA) Non-Compliance Tracking System (NTS). Results from performance analysis activities are documented, and issues managed through STAR.

Criterion 10 - Independent Assessment

10.0 Requirements and Key Implementing Documents

A. Federal QA Requirements

- Plan and conduct independent assessments to measure item and service quality, to measure the adequacy of work performance, and to promote improvement (10CFR830, DOE Order 414.1C)
- Establish sufficient authority, and freedom from line management, for the group performing independent assessments (10CFR830)
- Establish sufficient authority and freedom from line management for independent assessment teams (DOE Order 414.1C)
- Ensure persons who perform or conduct independent assessments are technically qualified and knowledgeable in the areas to be assessed (10CFR830, DOE Order 414.1C)
- Internal audits of the radiation protection program, including examination of program content and implementation, shall be conducted through a process that ensures that all functional elements are reviewed no less frequently than every 36 months (10CFR835.102)

B. National Code & Standard Requirements

- NQA-1 Part 1 Requirement "18-Audits"

C. Key Implementing Documents

- See Attachment 10-1 "Key Implementing Documents for Criterion 10 – Independent Assessment"

10.1 Independent Assessment

Independent assessments are planned, scheduled, and conducted by the FEB. These independent assessments are designed to:

- Measure quality
- Evaluate facility performance
- Evaluate support organization service and performance
- Determine the adequacy of work performance
- Promote improvement
- Provide feedback

The feedback from these independent assessments is part of the ISM feedback and improvement function. Independent assessments are separate from, and in addition to the management assessments.

10.1 Independent Assessment (Continued)

These documented assessments provide a factually accurate comparative evaluation of performance; evaluate facility and programmatic self-assessment programs; and verify conformance to established requirements and contractual obligations. The schedules and allocation of resources are based on the status, hazard, complexity, and prior performance of the activity or process being assessed.

The SRR President has organizational responsibility for the FEB through the Performance Assurance organization. The FEB is responsible for issuing their report to the facility manager. In turn, the evaluated organization responds with the corrective actions taken or planned in response to the feedback.

Assessment results are entered and managed using the Corrective Action System. Management responsibilities for identified issues and the manager responsible for resolution are clearly assigned. Follow-up review of areas found deficient during earlier assessments are determined by management and the assessment team leader.

Readiness requirements for the startup/restart of nuclear activities are determined in accordance with procedure manual 12Q, which implements the requirements of DOE Order 425.1C. A graded approach is utilized to determine the scope and depth of readiness determinations, the appropriate level of approval authority and the rigor and formality of process documentation. The methodologies range from use of routine restart procedures, to graded approach Readiness Assessments (RA), up to a complete ORR.

Independent audits, assessments, and surveillances are performed by designated organizations to address special program requirements as necessary.

10.2 Independent Assessment Qualifications

The minimum qualifications of independent assessment personnel are specified in Criterion 2. Personnel performing independent assessments are given sufficient authority and freedom from the line organization to carry out their assessment responsibilities. Personnel performing independent assessments do not have direct responsibilities in the areas they are assessing, but are technically qualified and knowledgeable in these areas.

10.3 Independent FEB Audit of Radiation Protection Program and Implementation

Independent assessment provides a mechanism to evaluate implementation of contractual and regulatory obligations for independent oversight. The FEB process is another assessment tool to assure implementation and compliance to applicable DOE directives and regulatory requirements. The FEB, as an independent, internal independent auditing body, led by a knowledgeable Lead Auditor, using qualified auditors, and knowledgeable SMEs, fulfills the responsibility for performing an audit of the radiation protection program. This includes examining radiation protection program content and implementation and is conducted using a process that ensures all functional elements are reviewed no less frequently than every 36 months.

Criterion 11 – Software Quality Assurance

11.0 Requirements and Key Implementing Documents

A. Federal QA Requirements

- Work processes involving safety software must be developed and implemented using national or international consensus standards and must include the following elements:
  - Facility design authority involvement in identifying software specification, acquisition, design, development, verification and validation (including inspection and test), configuration management, maintenance, and retirement (DOE Order 414.1C)
  - Identify, document, and maintain safety software inventory (DOE Order 414.1C)
  - Establish grading levels for safety software and document the grading levels in the QA Program (DOE Order 414.1C)
  - Using approved grading levels, select and implement the applicable software QA work activities from the following list to ensure that safety software performs its intended functions (DOE Order 414.1C):
    - Software project management and quality planning (DOE Order 414.1C)
    - Software risk management (DOE Order 414.1C)
    - Software configuration management (DOE Order 414.1C)
    - Procurement and supplier management (DOE Order 414.1C)
    - Software requirements identification and management (DOE Order 414.1C)
    - Software design and implementation (DOE Order 414.1C)
    - Software safety (DOE Order 414.1C)
    - Verification and validation (DOE Order 414.1C)
    - Problem reporting and corrective action (DOE Order 414.1C)
- Training of personnel in the design, development, use, and evaluation of safety software (DOE Order 414.1C)

B. National Code & Standard Requirements

- NQA-1 Part 1 Requirement "3-Design Control"

C. Key Implementing Documents

- See Attachment 11-6 "Key Implementing Documents for Criterion 11 – Software Quality Assurance"

11.1 Software QA Program

The goal of the software QA program is to provide requirements for the acquisition, development, operation, maintenance, and retirement of software. The software QA program is implemented through a series of policies, procedures, plans, specifications, and work practices that provide the framework for software engineering activities. Software typically used in DOE applications can be characterized into one of the five following types:

- Custom developed
- Configurable
- Acquired
- Utility calculation
- Commercial design and analysis

See Attachment 11-1 "Software Types" for additional details.

The software quality assurance program includes the following elements:

- Management ensures the program is established, documented, and implemented
- Facility design authority is involved in software: specification, acquisition, design, development, verification and validation (including inspection and test), configuration management, maintenance, and retirement
- Software is identified, documented, and maintained using a graded approach.
- A safety software inventory list is identified, developed, documented, and maintained
- Software is controlled throughout the life cycle, using a graded approach, based on classification

11.1 Software QA Program (Continued)

Using the graded approach, the following work activities are used to ensure safety software performs its intended functions:

- Software project management and quality planning
- Software risk management
- Software configuration management
- Procurement and supplier management
- Software requirements identification and management
- Software design and implementation
- Software safety
- Verification and Validation (Design Verification, Testing, Implementation, Installation and Acceptance)
- Problem reporting and corrective action
- Training in the design, development, use and evaluation of safety software.

11.2 Software Quality Assurance Definitions

Some key definitions used in the software engineering and software QA are included in Attachment 11-2 "Software Quality Assurance Definitions."

11.3 Software Engineering

The scope of software QA and software engineering activities include the following:

- Software acquisition method(s) for controlling the acquisition process for software and software services
- Software engineering method(s) used to manage software life-cycle activities
- Application of standards, conventions, and other work practices that support the software life cycle
- Controls for support software used to develop, operate, and maintain computer programs

11.4 Software Documentation Review

The rigor and degree of review of software documentation is dependent on the control points established through the software engineering activities. Reviews of software are performed to ensure compliance with design requirements. These reviews and the associated documentation are included in engineering and QA procedures. Key review points in the software development process are related to preparing for acceptance testing and assuring satisfactory completion of the software development cycle including acceptance testing.

11.5 Control of Computer Software

Computer software is controlled through procedures designed to ensure that computer programs used to develop or verify design, or establish safety envelopes (design analyses, models, or algorithms) are adequate for the software's intended use. These measures include previous use, validation, or simulation.

Computer software used for the control or support of work processes is controlled using a graded approach commensurate with the software classification based on the intended use of the software, risk, safety, hazard analysis, facility life cycle, complexity, and project quality requirements. Access to the computer software is limited to authorized individuals.

11.6 Graded Approach to Software Quality Assurance

The software quality assurance program identifies two different software types, SSC Software and Non SSC Software. SSC Software is software that is designated as part of a Structure, System, or Component with an assigned functional classification. Non SSC Software is software that is not part of a SSC.

A graded approach to Software Quality Assurance is applied to computer software using controls commensurate with the software classification based on intended use of the software, risk, safety, hazard analysis, facility life cycle, complexity, and project quality requirements. The graded approach to software quality assurance is based on DOE Orders, NQA-1, and other consensus standards as documented in the S/RID. The use of these standards is concurred with and approved by DOE through the S/RID approval process. The graded approach to Software Quality Assurance ensures that the level of analysis, documentation, and control actions are commensurate with the following:

- Relative importance of the software to safety, safeguards, and security
- Magnitude of any hazard involved with or controlled by the software application
- Life-cycle stage of the facility or item relative to the software's use
- Programmatic mission of a facility relative to the software's use
- Particular characteristics of a facility or item relative to the software's use
- Impact of the software relative to radiological and non-radiological hazards
- Impact the software may have on any other relevant factors

11.6 Graded Approach to Software Quality Assurance (Continued)

The Software grading level is obtained through the software Quality Assurance graded approach. The software QA graded approach is incorporated into the software classification process. The software classification process applies to software that is part of a SSC as well as to software that is not part of a SSC. While the implementing procedures for classification differ, the appropriate controls are applied based on the resulting specific software classification. SSC related software is classified and controlled in accordance with the requirements in the E7 and 1Q manuals. Software that is not part of a SSC is classified and controlled in accordance with the 1Q manual. The software classification levels are detailed in Attachment 11-3 "Software Quality Assurance Grading Levels - Software Classifications." The software classification process is detailed in Attachment 11-4 "Software Quality Assurance Classification Process."

11.7 Safety Software

Safety software includes safety system software, safety and hazard analysis software and design software, and safety management and administrative control software. See Attachment 11-5 "Safety Software" for additional details. The software QA program ensures that requirements are established to ensure that safety software performs its intended specific functions. It also ensures that the classification and associated documents are in place as required by procedure. These requirements are detailed in procedures that contain the specific details to perform work associated with safety software that is conducted in accordance with 10 CFR 830 and DOE Order 414.1C.

Work processes involving safety software are developed based on national or international consensus standards as identified in the S/RID.

A Software Quality Assurance Plan (SQAP) is required for all safety software per defined procedures. These procedures/plans may be prepared individually for each software project or may be a generic document applied to software prepared, procured, or used by an organization. Software QA procedures/plans are reviewed and approved by the responsible manager, CTF, and CQF. Based on the nature, complexity, hazard, risk, and intended uses of the software, software quality assurance procedures/plans are prepared using a graded approach.

11.7 Safety Software (Continued)

As part of the software classification process, the Software Owner / Design Authority determine if the software is safety software that should be included on the Safety Software Inventory List (SSIL). The SSIL is a combined SRR/SRNS list containing safety software that is managed jointly by SRR and SRNS QA organizations. The Design Agency / CTF recommend software classification level and ensure the software classification documentation is complete. Safety software determinations are made by the CTF / owner of the software based on procedural requirements that are equivalent to those identified in DOE Order 414.1C and the accompanying guide DOE G 414.1-4. Software that meets these requirements is added to the SSIL. Software Classification Documents are used by the QA organizations to manage the SSIL.

Criterion 12 – Suspect/Counterfeit Items (S/CI) Prevention

12.0 Requirements and Key Implementing Documents

A. Federal QA Requirements

- An S/CI prevention process must be developed and implemented as a part of the QA Program and must be commensurate with the facility/activity hazards and mission impact (DOE Order 414.1C)
- The QA Program must:
  - Be applied to identifying, analyzing, and removing S/CIs and preventing them from being used (DOE Order 414.1C)
  - Prevent the introduction and use of S/CIs through engineering involvement, design, procurement, testing, inspection, maintenance, evaluation, disposition, reporting, trend analysis, and lessons learned work process controls (DOE Order 414.1C)
  - Train and inform managers, supervisors, and workers on S/CI processes and controls (including prevention, detection, and disposition of S/CIs) (DOE Order 414.1C)
  - Provide for identifying and disposing of S/CIs (DOE Order 414.1C)
  - Restrict S/CI use to only those items that have been found acceptable through engineering analysis and formal disposition process (DOE Order 414.1C)
  - Provide for collecting, maintaining, disseminating, and using the most accurate, up-to-date information on S/CIs and associated suppliers using all available sources (DOE Order 414.1C)
  - Identify the management point of contact responsible for S/CI activities to ensure that the DOE Office of Environment, Safety and Health has a viable recipient for S/CI information notices (DOE Order 414.1C)
- Procurement processes should prevent introduction of S/CIs by:
  - Identifying technical and QA requirements in procurement specifications (DOE Order 414.1C)
  - Accepting only those items that comply with the procurement specifications consensus standards, and commonly accepted industry practices (DOE Order 414.1C)
  - Inspecting inventory and storage areas to identify, control, and disposition S/CIs (DOE Order 414.1C)
- Inspect, identify, evaluate, and disposition S/CIs installed in all safety applications and other applications that create potential hazards (DOE Order 414.1C)

12.0 Requirements and Key Implementing Documents (Continued)

- Engineering evaluates and dispositions S/CIs installed in safety applications/systems or in applications that create potential hazards. The evaluations must consider potential risks to the public and worker and cost/benefit impact, and include a schedule for replacement (if required) (DOE Order 414.1C)
- Ensure that S/CIs identified in nonsafety applications during routine maintenance and/or inspection are reported, evaluated, and dispositioned to prevent future use in safety applications (DOE Order 414.1C)
- Contact the DOE Inspector General (IG) before destroying or disposing of S/CIs and their documentation to determine whether to retain them for criminal investigation or litigation (DOE Order 414.1C)
- Test procured or installed S/CIs as necessary using approved engineering test methods (DOE Order 414.1C)
- Report S/CIs per DOE O 231.1A Change 1, Environment, Safety, and Health Reporting, dated 06-03-04, and DOE O 221.1, Reporting Fraud, Waste, and Abuse, dated 03-22-01 (DOE Order 414.1C)
- Conduct trend analysis and issue lessons learned reports for use in improving S/CI prevention (DOE Order 414.1C)
- Work processes must be developed and implemented using available S/CI information and must include engineering involvement in the development of procurement specifications; during inspection and testing; and when replacing, maintaining, or modifying equipment (DOE Order 414.1C)

B. National Code & Standard Requirements

- NQA-1 Part 1 Requirement "7-Control of Purchased Items and Services"

C. Key Implementing Documents

- See Attachment 12-1 "Key Implementing Documents for Criterion 12 – Suspect/Counterfeit Item Prevention"

12.1 S /CI Definition

An item is suspect when inspection or testing indicates that it may not conform to established Government or industry-accepted specifications or national consensus standards. The supplier or manufacturer may have misrepresented the documentation, appearance, performance, material, or other characteristics.

A counterfeit item is one that has been copied or substituted without legal right or authority. The supplier or manufacturer may have misrepresented the material, performance, or characteristics.

12.1 S /CI Definition (Continued)

Items that do not conform to established requirements are not normally considered an S/CI if nonconformity results from one or more of the following conditions (which are controlled by site procedures as nonconforming items):

- Defects resulting from inadequate design or production quality control
- Damage during shipping, handling, or storage
- Improper installation
- Deterioration during service
- Degradation during removal
- Failure resulting from aging or misapplication
- Other controllable causes.

12.2 S /CI Prevention

The S/CI process is used to identify, analyze, remove, and/or prevent a S/CI from being used or supplied in goods or services to DOE, SRR, or SRR customers. SRNS is responsible for performing the role and responsibility of the S/CI Program Manager for the Savannah River Site in accordance with Functional Service Agreement G-MOA-F-00011. The process prevents the introduction, and use, of a S/CI through a comprehensive process which involves multiple organizations including engineering, design, testing, inspection, procurement, maintenance, operations, construction, operating experience, and quality. This is accomplished through various detailed procedure, program, and process controls. These same prevention methods are flowed down into subcontracts through procurement clauses that are issued by the procurement organization.

Training is provided to managers, supervisors, and workers on the S/CI process and controls, including prevention, detection, nonconformance reporting, and disposition authority. Operating Experience Reports are distributed throughout the organization as required to effectively prevent and provide additional emphasis and training on the detection of potential S/CIs.

The control process for an S/CI is the same process as for non-conforming items; however, disposition of a potential S/CI is at the direction of the S/CI program manager in the Engineering organization. If a S/CI is determined, through engineering analysis, to be acceptable for use by the S/CI program manager, the S/CI is identified/tagged with any necessary restrictions.

12.2 S /CI Prevention (Continued)

The S/CI Program Manager is responsible for implementation of the S/CI Program and interfacing with the DOE Office of Health, Safety and Security on issues related to collecting, analyzing, maintaining, disseminating, and using the most accurate, up-to-date information on S/CIs and associated suppliers. Key sources of obtaining S/CI information include: Government-Industry Data Exchange Program (GIDEP), Institute of Nuclear Power Operations (INPO), DOE Occurrence Reporting and Processing System (ORPS), and the DOE S/CI web site.

The S/CI Program Manager determines specific actions required to investigate and resolve S/CI quality and safety issues and tracks/reports the status of corrective actions. The S/CI Program Manager works with the legal departments to notify local Office of Inspector General (OIG) on disposing of counterfeit items.

12.3 Work Process Controls to Prevent/Detect Suspect Counterfeit Items

The work process controls used to prevent or detect an S/CI include a combination of engineering, design, and administrative controls involving the CTF and CQF commensurate with the facility/activity hazards and mission impact. The S/CI Program relies on a number of organizations including engineering, quality, procurement, design, testing, and maintenance. These organizations can be involved in any of the work process controls from installation, detection, reporting, evaluation, disposition, trend analysis, or operating experience. The goal of all these organizations is to detect and prevent an S.CI from being received or used when replacing, maintaining, or modifying equipment. Training and informing managers, supervisors, and workers is a proactive effort to promote S/CI awareness. Inspection and nonconformance reporting further ensure potential S/CIs are identified, segregated, and sent to the S/CI program manager for evaluation and disposition.

Appendix A

SRR Contractor Assurance System Description

1.0 Contractor Assurance System (CAS) Overview

This appendix describes the SRR Contractor Assurance System. The requirements of DOE Policy 226.1A and DOE Order 226.1A are incorporated and integrated throughout the various programs and procedures used to control SRR operational oversight and assurance activities (see Table 1 "Operational Oversight and Assurance Activity Program Documents") and business oversight and assurance operations (see Table 2 "Business Oversight and Assurance Operation Program Documents"). Operational activities (Table 1) include, but are not limited to:

- Environmental
- Safety
- Health
- Safeguards
- Security
- Cyber Security
- Emergency Management
- Conduct of Operations
- Quality Assurance
- Training
- Engineering
- Maintenance
- Construction

Business operations activities (Table 2) include, but are not limited to:

- Maintenance
- Procurement
- Accounting
- Budget and Financial Management
- Personnel Administration and Labor Relations
- Property Management
- Legal
- Public Affairs
- Administrative
- Employee Concerns
- Equal Employment Opportunity.

1.0 Contractor Assurance System Overview (continued)

SRR assurance activities include, but are not limited to: assessment, monitoring, evaluation, audit, benchmarking, oversight, review, performance review, corporate sizing, data analysis, effectiveness review, extent of condition determination, extent of problem determination, peer review, verification, inspection, surveillance, investigation, observation, overview, physical survey, screening, and tracking. These assurance activities are integrated into the various SRS programs and procedures with applicability as detailed in Table 1 and Table 2. These requirements, programs, and procedures are also applicable to SRR subcontractors and are flowed down through the procurement system, to the extent necessary, to ensure compliance with the requirements for the safe performance of work.

The purpose of the CAS is to provide a comprehensive and integrated oversight and assurance system for all aspects of operations essential to contract and customer mission success. The CAS is a method to implement the corporate responsibility for the safety and health of workers and is complimentary to the "Worker Safety and Health Program" (see SRR-CAA-2009-00011). Implementation of the CAS is used to identify and address: program and performance deficiencies; opportunities for improvement; provide the means and requirements to report deficiencies to responsible managers and authorities; establish and effectively implement corrective and preventive actions; and share operating experience (lessons learned) across all aspects of operations. This responsibility is implemented by Functional Area Program Managers (see Attachment Intro-1 Functional Area Titles") who possess the experience, knowledge, skill, and ability in their particular area of expertise (1Q and 4B Manuals). These Functional Area Program Managers are charged with oversight of the effective implementation of SRR programs and procedures. The CAS also establishes the expectation for workers to implement procedures, comply with applicable requirements, and deliver effective and efficient performance essential to mission success. When procedures or requirements are unclear, workers are expected to take a Time Out (8Q Manual), reevaluate the activity, and submit a change request in accordance with the 1B Manual if applicable. When DOE directives or site-specific requirements are unclear, conflict, or are incomplete, SRR personnel are expected to work through management to identify and report the issue to the SRS Contracting Officer or Contracting Officer Representatives. Deficiencies are reported to responsible managers and authorities in accordance with Attachment 3-1 "Corrective Action System Elements Based on Significance Category" and 1-01 Manual requirements.

1.0 Contractor Assurance System Overview (continued)

Integral parts of the CAS are the Corrective Action, Issues Management, Assessment, and Operating Experience (Lessons Learned) programs. These programs provide the means to identify and address program or performance deficiencies and opportunities for improvement. Managers at all levels are directly involved in these processes or programs and are able to provide the necessary resources to establish and effectively implement corrective and preventive actions as well as effectively distribute required information across the organization.

The CAS is implemented throughout operational and business operations using a graded approach based on risk, hazard, experience, etc. The assurance activities previously identified are included in:

- Assessments
- Event reporting
- Worker feedback
- Issues management
- Operating Experience (Lessons Learned)
- Performance measures
- Operational oversight
- Accident investigations
- Corrective action system
- Trend analysis

These activities are performed by knowledgeable, trained, and qualified personnel. The reporting relationships are dependent on the particular assurance activity being performed. The overall organizational structure and functional responsibilities are determined by the SRR President, who has the responsibility to ensure that DOE and SRR assurance personnel have unfettered access to the appropriate information and facilities required to implement an effective oversight program, consistent with applicable laws and requirements. Another component of the assurance system includes having the SRR President issue an annual ISM Declaration, ensuring the various elements of the safety management system are in place and effectively implemented.

The information obtained from the various assurance system activities is documented, compiled, analyzed, and reported to management periodically. Various components of this information are regularly provided to DOE through Performance Objectives, Measures, and Commitments (POMCs), Business Meetings (DOE Directed and Manual 1-01), Performance Analysis reports (12Q Manual), or contract performance evaluations (Manual 1-01). In addition, this information is available on a real-time basis through the SRS Corrective Action Program (Manual 1-01) using the STAR database described in Manual 1B.

1.0 Contractor Assurance System Overview (continued)

SRR has a thorough oversight and assurance system in place. Third-party assurance activities include corporate audits and external reviews that are performed as required. The corporations comprising the SRR team provide additional contractor assurance functions. The prime partner, URS, has a standing corporate Nuclear Safety Council which provides corporate oversight for SRR and other URS sites around the complex with respect to nuclear safety issues. In addition, the ESH Council and QA Council provide a similar function across parts of the DOE Complex in which URS-Washington Group provides ESH and QA support, including SRR. The companies also provide ad hoc corporate and third party assist and oversight visits. Senior site management determines the need for such support and arranges visits through their corporate contacts. SRR has various processes in place to obtain these reviews on an as-needed basis. Other external review options available include: DOE Headquarters, a service contract with the Institute of Nuclear Power Operations (INPO) managed by SRNS; Voluntary Protection Program (VPP); URS reviews; benchmarking of SRR by other sites and societal organizations; and independent consultant reviews.

As part of the CAS, the procurement process ensures the flow down of applicable requirements using contract clauses to subcontractors performing work for SRR. Oversight and assurance of subcontracted work are accomplished through a number of methods, such as procurement management, supplier surveillance, supplier audit, assessment, and subcontract management, and implemented by the 7B, 11B, and 1Q manuals.

In the area of safeguards and security, vulnerabilities and threats are treated the same as safety hazards. The 7Q Security Manual is the primary procedural document for determining threat level and tailoring controls to the type and level of threat. In the area of Cyber Security, the Computer Security Program (10Q manual) serves to effectively protect the integrity, confidentiality, and availability of classified and unclassified information, networks, systems, and applications. In the area of emergency management, the 6Q Emergency Management Program Procedures Manual and the SRS Emergency Plan (SCD-7) are used to coordinate the emergency management aspects of fire protection, radiological control, environmental management, safeguards and security, and transportation safety. These emergency management documents also provide the required coordination with offsite emergency planning and response authorities.

Table 1 – Operational Oversight and Assurance Activity Program Documents
(OPERATIONAL ACTIVITIES Oversight and Assurance Implementation Documents)

	Operational Activities												
SRS Procedures	**Environment**	**Safety**	**Health**	**Safeguards**	**Security**	**Cyber Security**	**Emergency Management**	**Con Ops**	**QA**	**Training**	**Engineering**	**Maintenance**	**Construction**
1-01	X	X	X	X	X	X	X	X	X	X	X	X	X
1B	X	X	X	X			X	X	X	X	X	X	X
3B											X		
4B										X			
5B													
6B													
7B													
8B													
9B							X						
11B		X								X			
12B						X							
13B	X	X	X	X			X	X					
1C	X	X	X	X				X					
1D													
1E6									X		X		X
3E									X		X		
5E								X					
1Q	X	X	X	X			X	X	X	X	X	X	X
2Q	X	X					X	X		X	X		
3Q	X		X				X	X	X				
4Q	X	X	X					X		X			
5Q	X	X	X	X			X	X	X	X	X	X	
6Q		X					X						
7Q				X	X	X		X		X			
8Q	X	X	X					X	X	X	X	X	X
10Q				X	X	X	X						
11Q	X	X					X	X	X	X	X	X	X
12Q	X	X	X	X	X	X	X	X	X	X	X	X	X
14Q				X	X			X	X	X			
18Q		X	X					X		X		X	X
19Q	X						X	X	X	X			
21Q		X	X										
1S	X	X	X					X					X
2S							X	X	X	X			
1Y	X	X	X					X	X	X		X	
2Y	X	X	X								X		
E7									X	X	X		
SCD-1													
SCD-2													
SCD-3	X	X					X		X	X	X		
SCD-4	X	X	X	X	X	X	X	X	X	X	X	X	X
SCD-6	X	X	X										
SCD-7	X	X	X				X	X		X			
SCD-9									X	X			
SCD-10		X	X				X						
SCD-11		X									X		
SCD-12		X									X		
L1								X	X		X		

Table 2 – Business Oversight and Assurance Operation Program Documents
(BUSINESS OPERATIONS Oversight and Assurance Implementation Documents)

	Business Operations										
SRS Procedures	**Maintenance**	**Procurement**	**Accounting**	**Budget & Financial Mgt.**	**Personnel Adm. &Labor Relations**	**Property Mgt.**	**Legal**	**Public Affairs**	**Administrative**	**Employee Concerns**	**Equal Empl. Oppor.**
1-01	X	X	X	X	X	X	X	X	X	X	X
1B	X	X	X	X	X		X	X	X	X	X
3B		X	X	X		X			X		
4B									X		
5B			X	X	X		X	X	X	X	X
6B				X					X		
7B		X							X		
8B									X		
9B									X		
11B		X		X	X				X		
12B									X		
13B		X							X		
1C	X								X		
1D						X			X		
1E6		X							X		
3E		X							X		
5E									X		
1Q		X							X		
2Q									X		
3Q									X		
4Q									X		
5Q					X				X		
6Q									X		
7Q									X		
8Q	X								X		
10Q											
11Q											
12Q		X							X		
14Q			X								
18Q									X		
19Q		X							X		
21Q									X		
1S									X		
2S									X		
1Y	X	X							X		
2Y											
E7		X							X		
SCD-1									X		
SCD-2									X		
SCD-3									X		
SCD-4	X	X		X					X		
SCD-6									X		
SCD-7									X		
SCD-9									X		
SCD-10									X		
SCD-11									X		
SCD-12									X		
L1											

2.0 Assessment

2.1 Self-Assessment

The self-assessment process was enhanced in 2008 and 2009 to improve planning, execution and response. The Management Assessment process (Criterion 9), detailed in the 1Q and 12Q Manuals, consists of the Self-Assessment and Performance Analysis Programs. The self-assessment component uses subject matter experts to perform evaluation of performance, effectiveness, and implementation of programs, processes, and procedures. The self-assessment scope is based on facility, activity, hazard, risk, contract, previous performance, etc. These assessments generally involve workers, supervisors, professionals, and managers who are encouraged to identify issues, opportunities for improvement, and best practices. Issues and opportunities for improvement resulting from self-assessments are documented and entered into the STAR database.

2.2 Internal Independent Assessment

The SRR Independent Assessment process follows an established and mature approach that is used as a benchmark by other DOE sites. Internal independent assessment (Criterion 10) is accomplished using a FEB concept. The FEB process, detailed in the 12Q and Q11 Manuals, focuses on entire facilities, projects, programs, or processes. These assessments are performance-based and focus on observing work activities and process implementation. The FEB resides in the ESH&QA and Contractor Assurance organization. The Contractor Assurance Manager is responsible for ensuring that FEB assessors are independent of areas being assessed. When engaged in evaluations, the Contractor Assurance Manager and the FEB Team Manager reports directly to the SRR President on matters related to the FEB, a Readiness Assessment, or an ISME. The FEB assessment schedule is formally planned and is based on past performance, emerging issues, risk, hazards, presidential directives, and work activities. The FEB assessors are technically qualified and knowledgeable in the areas assessed. The FEB members are typically proven field professionals in their areas of expertise, who have served as managers/leads in facility positions prior to the FEB assignment as part of the site developmental or rotational process. The FEB Team Lead may use additional technical/operational personnel as team members to provide expert specialty knowledge as required.

2.3 Other Oversight Assurance Tools

In addition to management and independent assessment, SRR uses various programs to identify, gather, verify, analyze, trend, disseminate, and improve performance. These programs and tools include Behavior Based Safety and Human Performance Improvement (Manual 1-01), management observations (12Q and 2S Manuals), QA audits (1Q Manual), internal audits (1B and 1Q Manuals), contract audits (1Q and 11B Manuals), QA surveillance (1Q Manual), subcontractor focused observations (8Q Manual), and management field observations. These programs supplement the assessment program and provide additional feedback and improvement opportunities.

3.0 Event Reporting Overview

Formal programs and processes are utilized to identify, investigate, report, and respond to operational events, incidents, occupational injuries, and illnesses. These programs and processes are integrated with the SRS Corrective Action Program (Manual 1-01) to ensure identification, reporting, evaluation, tracking, closure, operating experience (lessons learned), and effectiveness evaluation using a graded approach based on significance.

3.1 Operational Events and Incidents

The requirements of DOE M231.1-2, “Occurrence Reporting and Processing of Operations Information” are implemented in the 9B Manual. The thresholds and DOE reporting guidelines for reportable occurrences are clearly defined. The associated corrective actions from both reportable and non-reportable events are documented, evaluated, and entered into the corrective action system (Manuals 1-01, 1B, and 1Q) for processing.

3.2 Occupational Injuries and Illnesses

Management, recordkeeping, and reporting of occupational injuries and illnesses, are required by 10 CFR851 "Worker Safety and Health Program" and DOE M 231.1-1A, “Environment, Safety, and Health Reporting Manual.” SRR has established the framework for an effective worker protection program designed to reduce or prevent injuries, illnesses, and accidental losses by providing workers with a safe and healthful workplace. This framework is detailed in the “Worker Safety and Health Program” (SRR-CAA-2009-00011) and implemented in accordance with the procedural controls specified in the 8B, 9B, and 8Q Manuals.

3.3 Activities Covered by the Price-Anderson Amendment Act

The procedural process outlined in the 8B Manual is followed to evaluate, using a graded approach, items reported in the corrective action database. Potential events and activities are screened and evaluated against established reporting thresholds. Items exceeding the thresholds are reported to SRR senior management and DOE using the DOE-wide Noncompliance Tracking System (NTS). The process also provides management with the option to self identify a noncompliance that does not trip established thresholds as NTS reportable. As part of the feedback and improvement process, events and activities occurring across the complex are reviewed and evaluated for applicability to SRR activities.

3.4 Safeguards, Security, and Cyber Security

The identification and reporting of safeguards, security, and cyber security events are detailed in the 7Q, 10Q, and 14Q Manuals. These events are also entered, tracked, and managed using the corrective action system.

3.5 Trending and Analysis

SRR uses several trending and analysis tools, such as the ISM Performance, Objectives, Measures, and Commitments and the 63 QA Program Health Indicators to monitor and improve processes and performance. These structured, formal processes are described in the 8B and 12Q Manuals and are utilized to capture, trend, and evaluate information. In order to achieve a goal of zero injuries, management conducts reviews of occupational injuries/illnesses as well as a periodic review of performance indicators. At the company level, a series of various corporate performance metrics is maintained, reported monthly, and used by senior management to monitor key site program and operating performance. Also at the company level, the requirement for quarterly reporting is implemented by the quarterly performance analysis review that is performed in accordance with the 12Q Manual. This review uses data from the corrective action system to identify precursor or repetitive events in order to prevent more serious events from occurring.

4.0 Worker Feedback

SRR uses a formal structured self-assessment program (12Q Manual) to obtain worker feedback on their work activities. Workers assess their processes and performance and feed this information back to management through assessment reports. Other mechanisms are available for workers to report on activities or identify any concerns they may have. These include such programs as the employee concerns program, work planning activities, safety-related events and activities (i.e., critiques, ORPS, etc.), round table meetings, and other business processes. At all levels, SRR Managers maintain an open door policy to encourage employee input.

4.1 Employee Concerns Program

The requirements of Title 10 CFR Part 708, "DOE Contractor Employee Protection Program" are implemented by the SRR Employee Concerns Program. This formal program (1B MRP 1.06) has a 24-hour hotline to report any employee concerns. Concerns are investigated by personnel with appropriate experience to investigate health and safety-related concerns in accordance with established guidelines based on severity. The SRR program performance is overseen by DOE through monthly evaluation reports, meetings, and performance metrics on quality of investigation and timeliness of closure. (For details, see S/RID FA 01)

4.2 Work Performance

Worker input is valued and provided before and after work is performed. This worker input is accomplished using the Assisted Hazard Analysis process (8Q Manual). This process incorporates pre-job briefings (2S Manual), walk-downs, worker feedback, and reviews as part of a computer-assisted safety assurance system.

4.3 Business Operations

SRR has defined business operations as those activities identified in Table 2 "Business Oversight and Assurance Operation Program Documents." The related assurance and oversight implementing documents are also identified in Table 2. Feedback on business processes is also valued and used to make process improvements or investigate concerns. Feedback on financial accounting practices is provided by the Internal Oversight organization in accordance with the 1-01 and Internal Oversight Manuals. Feedback on human resource issues (e.g., Equal Employment Opportunity, employee discrimination, sexual harassment) is obtained through a variety of sources and investigated in accordance with the 5B Manual. Feedback on procurement issues is obtained through the processes contained in the 7B Manual and where subcontractors are involved, the 11B Manual.

Management of resources for business operations is controlled in accordance with requirements contained in Manual 1-01.

Managers assure and obtain feedback on implementation of their programs for efficient operation in accordance with the various councils and committees identified in Manual 1-01, perform assessments in accordance with 12Q Manual requirements, and meet contractual requirements in accordance with the S/RID.

4.4 Safety

Worker feedback and involvement is enhanced by using the Behavior-Based Safety (BBS) initiative described in the Manual 1-01. BBS is used to augment the safety program's effectiveness by involving workers. BBS is focused on identifying and eliminating unsafe behaviors and directly involves individual workers in eliminating their own at-risk behaviors through the use of positive reinforcement techniques. BBS Observers log their observations into a database that is available to identify unsafe behaviors leading to improved safety performance. The process also utilizes local area safety improvement teams composed of volunteers to identify safety issues and help improve safety performance.

In addition, Human Performance Improvement (HPI) promotes behaviors that support safe and reliable execution of work through error-free performance. HPI focuses on reinforcing desired jobsite behaviors and promoting expected behaviors by utilizing HPI Error Reduction Tools. The Time Out process, as contained in the 8Q Manual, is intended for workers to stop any activity that they feel is unsafe or different than expected. This temporary pause allows investigation of the concern and the ability to make any necessary changes.

SRS conducts an annual safety conference/expo that is open to employees, family members, and the community. The goal of the safety conference/expo is to highlight safety in SRS processes as well as reinforce the safety concept in daily activities. The safety conference/expo is prepared by a team of SRS volunteers who develop the agenda and secure exhibits from SRS as well as the community. Monthly work group safety meetings are used to focus on worker and work group safety. The annual safety conference/expo and monthly safety meetings are also methods used to obtain feedback on safety or work related topics.

5.0 Issues Management

SRR has a comprehensive, structured Issues Management System in place that is integrated with the Corrective Action Program (1-01, 1Q, and 1B Manuals). The Issues Management System uses a single, site-wide database (STAR) that is detailed in the 1B Manual. The purpose of the system is to provide documented analysis, resolution, and tracking of program and performance deficiencies based on the requirements of the Corrective Action Program. The system is structured to provide for the timely and effective resolution of identified issues affecting personnel safety, operational safety, regulatory compliance, or business operations that are entered into the corrective action program.

5.0 Issues Management (continued)

The Issues Management System integrates the following structured processes:

1. Significance Determination (1B Manual). Risk is used to make the significance determination and management discretion and resource allocation is used to determine the prioritization of the corrective action (also see Attachment 3-1).
2. Scope and Extent of Condition or Deficiency (1B Manual). A graded approach, based on significance categorization, is used to determine the extent of the problem as well as the extent of condition of identified issues.
3. Reportability Determination (8B, 9B, 7Q, and 10Q Manuals). A graded approach, based on significance categorization, is used to evaluate identified issues, then various screening processes are used to determine if issues are to be reported under Price-Anderson, ORPS, etc.
4. Root Cause Determination (1B, 9B, and SCD-9 Manuals). A graded approach, based on significance categorization, is used to determine the extent and level of causal analysis to be applied to identified issues.
5. Corrective Actions to Prevent Recurrence (1-01, 1B, 1Q, and 12Q Manuals). Actions to prevent recurrence are identified and entered into the corrective action system. The performance data is evaluated and analyzed quarterly for any recurring events which are then identified and entered into the ORPS system as such.
6. Responsible Manager (1-01 and 1B Manuals). The corrective action system and issues management database require the identification of the responsible manager/individual with the action to implement the identified corrective action.
7. Corrective Action Milestones (1-01 and 1B Manuals). Issues identified in the corrective action system, using the graded approach, identify the various actions required to close the issue. These actions are based on responsible management evaluation and determination of the risk and significance of the issue.
8. Tracking Progress and Timely Completion (1B Manual). The issues management system efficiently provides individual weekly status reports of upcoming and overdue issues and actions. This information is also reported to management to ensure that issues are being worked and corrected.
9. Verification of Corrective Actions (1-01, 1B, and 1Q Manuals). A graded approach, based on significance categorization, is used to determine the extent of verification required for completed corrective actions.
10. Validating Effective Corrective Actions Implemented (1-01 and 1B Manuals). A graded approach, based on significance categorization, is used to determine the application of effectiveness reviews for completed corrective actions.
11. Individual and Organization Accountability (1-01 and 1B Manuals). The issues management system is designed so that individual accountability is assigned at the activity level. When activities are overdue, management is notified and responsible to ensure corrective actions are completed.

5.0 Issues Management (continued)

The Issues Management database (STAR) is a real-time system that provides for rapid identification of issues and an effective and efficient means for communicating issues to management. STAR facilitates assignment of actions to the appropriate organizations. By sending the issue through the system, the responsible manager is provided with all the information surrounding the issue and can make the appropriate decision based on hazard, technical basis, and risk. The Corrective Action system is the process that is used to determine the impact of identified issues and the subsequent immediate actions required. There are several methods to ensure that worker safety is maintained when unsafe conditions are identified. These include the Time Out process (8Q manual) and the Stop Work process (1Q Manual). The Time Out process allows workers to stop work when an unsafe or unexpected condition occurs, or to shut down activities when safety is a concern. The formal Stop Work process is used to stop work when none of the other methods are used and workers or managers fail to recognize unsafe conditions.

Processes to analyze deficiencies are established for both programmatic and systemic issues and are discussed under the event reporting section. Management uses the results of these analyses to optimize the efficient allocation, extent, and schedule of assessment resources.

In cases where there are differing professional opinions on a given issue, a process (1-01 Manual) is in place to resolve the issue. It allows for documenting the dissenting opinions and disputes and the process to resolve them. There are also provisions established for independent technical reviews of significant issues. Management Review Teams and/or Corrective Action Review Boards are established in each operations group to review causal analysis, concur with planned corrective actions and review closure documentation for significant issues.

6.0 Operating Experience

A formal Operating Experience Program (Manual 1B, MRP 4.14) communicates operating experiences during work activities, process reviews, event analyses, and post-job work histories for application to future activities. The Operating Experience Program promotes safe, effective operation and enhances the safety and health of employees and the public. The program is coordinated by SRNS to identify, review, apply, and exchange operating experience/lessons learned from events at SRS facilities, other DOE complex facilities, commercial nuclear facilities, and other external sources to prevent similar occurrences.

6.0 Operating Experience (continued)

Typical documents reviewed for application include: DOE Complex Occurrence Reports; Suspect/Counterfeit Items; DOE ESH Operating Experience; Special Reports; Safety Bulletins; Just-In-Time Reports; Advisories; Operating Experience Alerts; Office of Independent Oversight and Performance Assurance reviews; DOE Type A & B Investigation Reports; INPO Operating Experience Reports; PAAA items; Defense Nuclear Facility Safety Board information; OSHA Safety and Health Bulletins; etc.

Operating Experience Coordinators determine which organizations need to take action on identified issues, monitor progress of corrective actions, and report on the status via the Issues Management database (STAR).

7.0 Performance Measures Overview

SRR uses a combination of performance measures and other programs to evaluate and improve performance. These various performance improvement tools are used in conjunction with the budget process. Evaluation of the overall metrics allows senior management to determine organizational performance and progress against established milestones. The evaluation allows management to allocate resources, establish compensatory measures, or institute corrective action. The evaluation also provides information to use in determining the correct mixture of oversight activities to apply across various facilities or specific processes.

7.1 Corporate Metrics

SRR uses a series of performance indicators to measure the performance of facilities, programs, and organizations. These indicators track performance improvement or deterioration relative to established goals. These performance indicators are detailed in POMCs. The corporate metrics focus on measuring performance across the company in: safety, personal contamination, environmental compliance, safeguards and security, emergency services and ORPS. The metrics provide a view of emerging trends over the past 12 months. Senior management reviews the corporate metrics and holds the responsible managers accountable.

7.2 Performance Analysis

As part of the Management Assessment Program, performance analysis is used to analyze and correlate data to identify improvements, areas of potential future problems, and recurring problems. The performance analysis process which includes metrics for disciplined operations and trending of performance data is detailed in the 12Q Manual. An Executive Safety and Quality Board (ESQB) reviews performance measures and analysis to ensure compliance with requirements and promote continual improvement in all safety and quality related activities. The ESQB also reviews plans to improve adverse trends and corrective actions for significant issues.

Attachment Fore-1

Requirements Document Overview
(Page 1 of 2)

10 CFR 830 Subpart A "Quality Assurance Requirements"

Title 10 Code of Federal Regulations (CFR), Part 830 Subpart A, "Quality Assurance Requirements" (effective April 2001), was issued to govern the conduct of Department of Energy (DOE), DOE prime contractors, sub-contractors, and others conducting activities or providing items or services that affect, or may affect, the safety of DOE nuclear facilities. This document required the development and implementation of a formalized Quality Assurance (QA) Program. The QA Program is a management system that is implemented to assure adequate protection of workers, the public, and the environment from adverse consequences. The degree and level of rigor applied to program elements, items, or activities is based on a graded approach that takes into account the work to be performed and the associated risks and hazards.

DOE Order 414.1C, "Quality Assurance"

DOE Order 414.1C, "Quality Assurance" (approved June 2005), was issued to supplement the CFR requirements on QA and accomplish three prime objectives. The first objective is to ensure that products and services meet or exceed expectations. The second is achieve QA for all work based on the following five principles:

(1) Quality is assured and maintained through a single, integrated, effective QA program
(2) Management support for planning, organization, resources, direction, and control is essential to QA
(3) Performance and quality improvement require thorough, rigorous assessment and corrective action
(4) Workers are responsible for achieving and maintaining quality
(5) Environmental, safety, and health risks and impacts associated with work processes can be minimized while maximizing reliability and performance of work products.

The third and final objective of the Order is to establish quality requirements for the control of Suspect/Counterfeit Items (S/CIs), safety issue corrective actions, and safety software.

DOE Order 226.1A "Implementation of DOE Oversight Policy"

DOE Order 226.1A, "Implementation of DOE Oversight Policy" (approved July 2007), provides direction for implementing DOE Policy 226.1A "Department of Energy Oversight Policy" (approved May 2007), which establishes DOE policy for assurance systems and processes established by DOE contractors and oversight programs performed by independent oversight organizations. The objective of the Order is to ensure that contractor assurance systems and DOE oversight programs are comprehensive and integrated for key aspects of operations essential to mission success.

Attachment Fore-1

Requirements Document Overview
(Page 2 of 2)

DOE/RW-0333P "Quality Assurance Requirements and Description"
Office of Civilian Radioactive Waste Management (OCRWM) DOE/RW-0333P "Quality Assurance Requirements and Description" (QARD) revision 20 (effective October 2008) establishes the requirements for the OCRWM QA program. The document is designed to meet 10 CFR 63.142 and DOE Order 414.1C QA criteria and define the organizational responsibilities related to implementation and oversight of the QA program. The QARD provides the framework for the achievement and verification of quality. The document is intended to meet the standards of a Nuclear Regulatory Commission licensee of a nuclear facility, provide objective performance assessment against these standards, and foster prompt and aggressive corrective action when there is divergence.

ASME-NQA-1-2000 "QA Requirements for Nuclear Facility Applications"
The American Society of Mechanical Engineers (ASME) national standard ASME-NQA-1-2000 was developed to reflect industry experience and understanding of the quality assurance requirements necessary to achieve safe, reliable, and efficient utilization of nuclear energy, and management and processing of radioactive materials. The Standard focuses on the achievement of results, emphasizes the role of the individual and management in the achievement of quality, and the application of requirements in a manner consistent with the relative importance of the item or activity. The standard contains the requirements for the establishment and execution of quality assurance programs during siting, design, construction, operation, and decommissioning of nuclear facilities. The requirements apply to activities that could affect the quality of nuclear material applications, structures, systems, and components of nuclear facilities.

Attachment Intro-1

Functional Area Titles

Standards/Requirements Identification Document (S/RID)
(Contractual Program Requirements)

Integrated Safety Management System Description			
Foreword		FA 10	Maintenance
FA 00	S/RID Purpose and Development	FA 11	Radiation Protection
FA 01	Management Systems	FA 12	Fire Protection
FA 02	Quality Assurance	FA 13	Packaging and Transportation
FA 03	Configuration Management	FA 14	Environmental Restoration
FA 04	Training And Qualifications	FA 15	Facility Disposition
FA 05	Emergency Management	FA 16	Waste Management
FA 06	Safeguards and Security	FA 17	R & D Experimental Activities
FA 07	Engineering Program	FA 18	Nuclear and Process Safety
FA 08	Construction Program	FA 19	Occupational Safety and Health
FA 09	Conduct of Operations	FA 20	Environmental Protection

Source and Compliance Document (SCD)
SCD-4 Assessment Performance Objectives and Criteria
(SRR Functional Area Program Managers)

Foreword		FA 13	Emergency Preparedness
FA 01	Design	FA 14	Review, Assessment, and Oversight
FA 02	Construction	FA 15	Nuclear Criticality Safety
FA 03	Management Systems	FA 16	Testing
FA 04	Training And Qualification	FA 17	Occurrence Reporting (Combined into FA 03)
FA 05	Procedures (Combined into FA 22)	FA 18	Safeguards and Security
FA 06	Safety Documentation	FA 19	Packaging and Transportation
FA 07	Environmental Protection	FA 20	Occupational Safety And Health
FA 08	Quality Assurance	FA 21	Procurement
FA 09	Configuration Management	FA 22	Conduct of Operations
FA 10	Maintenance	FA 23	Project Management
FA 11	Radiation Protection	FA 24	Waste Management
FA 12	Fire Protection	FA 25	Chemical Safety and Life Cycle Management

Attachment Intro-2

QA Program Basis Documents

(Page 1 of 2)

- Title 10 CFR Part 63 Subpart G, "Quality Assurance"
- Title 10 CFR Part 71 Subpart H, "Quality Assurance"
- Title 10 CFR Part 708, "DOE Contractor Employee Protection Program"
- Title 10 CFR Part 830 Subpart A, "Quality Assurance Requirements"
- Title 10 CFR Part 830 Subpart B, "Safety Basis Requirements"
- Title 10 CFR Part 835 "Occupational Radiation Protection"
- Title 10 CFR Part 851, "Worker Safety and Health"
- Title 36 CFR Chapter 12, "National Archives and Records Administration"
- Title 48 CFR "Federal Acquisition Regulations", Chapter 9 DOE
- DOE O 200.1A, Information Management Program
- DOE Order 210.2, "DOE Corporate Operating Experience Program"
- DOE Order 221.1, "Reporting Fraud, Waste, and Abuse To The Office of Inspector General"
- DOE Policy 226.1A, "Department of Energy Oversight Policy"
- DOE Order 226.1A, "Implementation of Department of Energy Oversight Policy"
- DOE Order 231.1A "Environment, Safety and Health Reporting"
- DOE Manual 231.1-1A, "Environment, Safety, and Health Reporting Manual"
- DOE Order 243.1, "Records Management Program"
- DOE Order 243.2, "Vital Records"
- DOE Order 414.1C, "Quality Assurance"
- DOE Guide 414.1-1A, "Management Assessment and Independent Assessment Guide for Use with 10 CFR, Part 830, Subpart A, and DOE O 414.1A, Quality Assurance; DOE P 450.4, Safety Management System Policy; and DOE P 450.5, Line ES&H Oversight Policy"
- DOE Guide 414.1-2A, "Quality Assurance Management System Guide for Use with 10 CFR 830 Subpart A Quality Assurance Requirements and DOE O 414.1C, Quality Assurance"
- DOE Guide 414.1-3, "Suspect/Counterfeit Items Guide for Use with 10 CFR 830 Subpart A, Quality Assurance Requirements, and DOE O 414.1B, Quality Assurance"
- DOE Guide 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 Guide 414.1-5, "Corrective Action Program Guide"
- DOE Order 420.1B, "Facility Safety"

Attachment Intro-2
QA Program Basis Documents
(Page 2 of 2)

- DOE Order 442.1A, "Department of Energy Employee Concerns Program"
- DOE Policy 450.4, "Safety Management System Policy"
- DOE Manual 450.4-1, "Integrated Safety Management System Manual" DOE Order 470.4, "Safeguards and Security Program"
- DOE Order 471.1A, "Identification and Protection of Unclassified Controlled Nuclear Information"
- DOE Order 471.3, "Identifying and Protecting Official Use Only Information"
- DOE/RW-0333P, "Quality Assurance Requirements and Description for the Civilian Radioactive Waste Management Program"
- DOE-STD-4001-2000, "Design Criteria Standard for Electronic Records Management Software Applications"
- ASME NQA-1, "Quality Assurance Requirements for Nuclear Facility Applications" (including the 18 requirements of Part I and, selective application of Part II Subparts and the Non-Mandatory Appendices of Parts III & IV)

Attachment 1-1

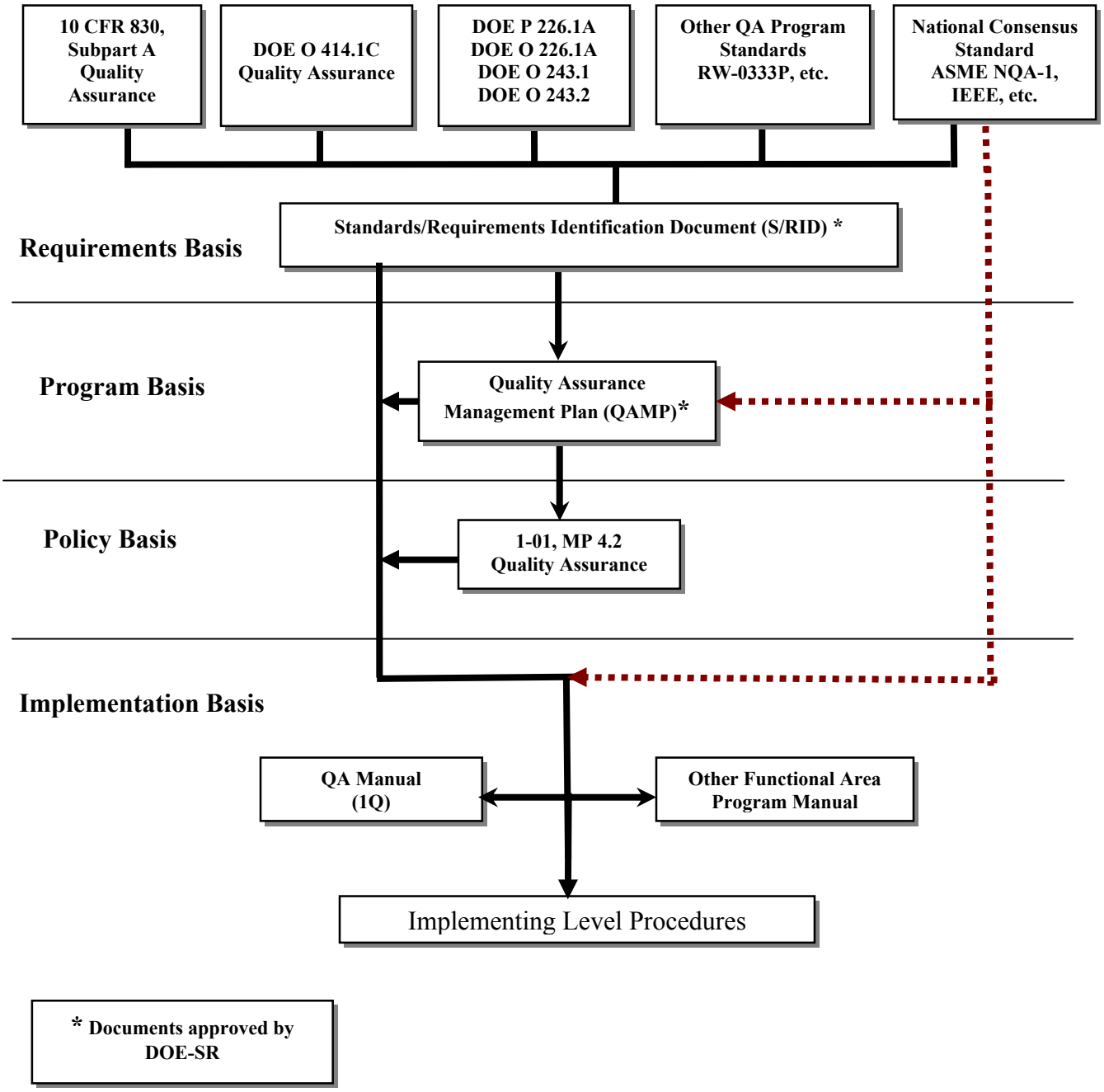
Special QA Program Requirements Documents

Requirement Document	Organizations Affected
10 CFR 63 Subpart G	Organizations providing products or services for the Office of Civilian Radioactive Waste Management
10 CFR 71, Subpart H, "Quality Assurance"	Organizations involved in the design, purchase, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, and modification of shipping packages for radioactive materials
10 CFR 851, Worker Safety and Health Program	All Organizations. Provides requirements for a worker safety and health program that reduces or prevents occupational injuries, illnesses, and accidental losses by providing workers with a safe and healthful workplace; and procedures for investigating whether a violation of requirements has occurred, nature and extent of violation, and appropriate remedy
DOE/RW-0333P, "Office of Civilian Radioactive Waste Management Quality Assurance Requirements and Description"	Organizations providing products or services for the Office of Civilian Radioactive Waste Management
DOE/CBFO-94-1012, "DOE Carlsbad Field Office Quality Assurance Program Document (QAPD)," (for the Waste Isolation Pilot Plant (WIPP) and related activities)	Solid Waste
DOE/NV-325, "Nevada Test Site Waste Acceptance Criteria"	Solid Waste

Attachment 1-2

QA Requirements Flow Down Overview

(Typical flow down of requirements for business, operations, etc.)



Attachment 1-3

QA Requirements Implementing Manuals

(Page 1 of 2)

1-01	Management Policies
1B	Management Requirements and Procedures
3B	Asset Management Manual
4B	Training and Qualification Program
5B	Human Resources Manual
6B	Program Management Manual
7B	Procurement Management Manual
8B	Compliance Assurance Manual
9B	Site Item Reportability and Issue Management (SIRIM)
11B	Subcontract Management Manual
12B	Information Management
13B	Chemical Management Manual
1C	Facility Disposition Manual
1D	Site Infrastructure and Services Manual
3E	Procurement Specification Procedure Manual
5E	Startup Test Manual
1Q	Quality Assurance Manual
2Q	Fire Protection Program
3Q	Environmental Compliance Manual
4Q	Industrial Hygiene Manual
5Q	Radiological Control Manual
6Q	SRS Emergency Plan/Emergency Management Program Procedures Manual
7Q	Security Manual
8Q	Employee Safety Manual
10Q	Computer Security Manual
11Q	Facility Safety Document Manual
12Q	Assessment Manual
14Q	Material Control and Accountability
18Q	Safe Electrical Practices and Procedures Manual
19Q	Transportation Safety
1S	SRS Waste Acceptance Criteria Manual
2S	Conduct of Operations Manual
1Y	Conduct of Maintenance
2Y	SRS HEPA Filter Program Manual

Attachment 1-3

QA Requirements Implementing Manuals

(Page 2 of 2)

E7	Conduct of Engineering and Technical Support
E11	Conduct of Project Management & Controls
SCD-1	Procedure Sourcebook
SCD-2	Procedure Writing
SCD-4	Assessment Performance Objectives and Criteria
SCD-6	SRS ALARA Manual
SCD-7	SRS Emergency Plan
SCD-9	Problem Analysis Manual
SCD-10	Management and Preparation of Fire Hazards Analyses
SCD-12	Safety Documentation Integrated Work Process
SCD-14	Maintenance Planning Guide
WSRC-RP-94-1268	Standards/Requirements Identification Document (S/RID)
MOA G-MOA-G-00002	Memorandum of Agreement between Savannah River Nuclear Solutions, LLC and Washington Savannah River Company LLC for the performance and payment of Support Services

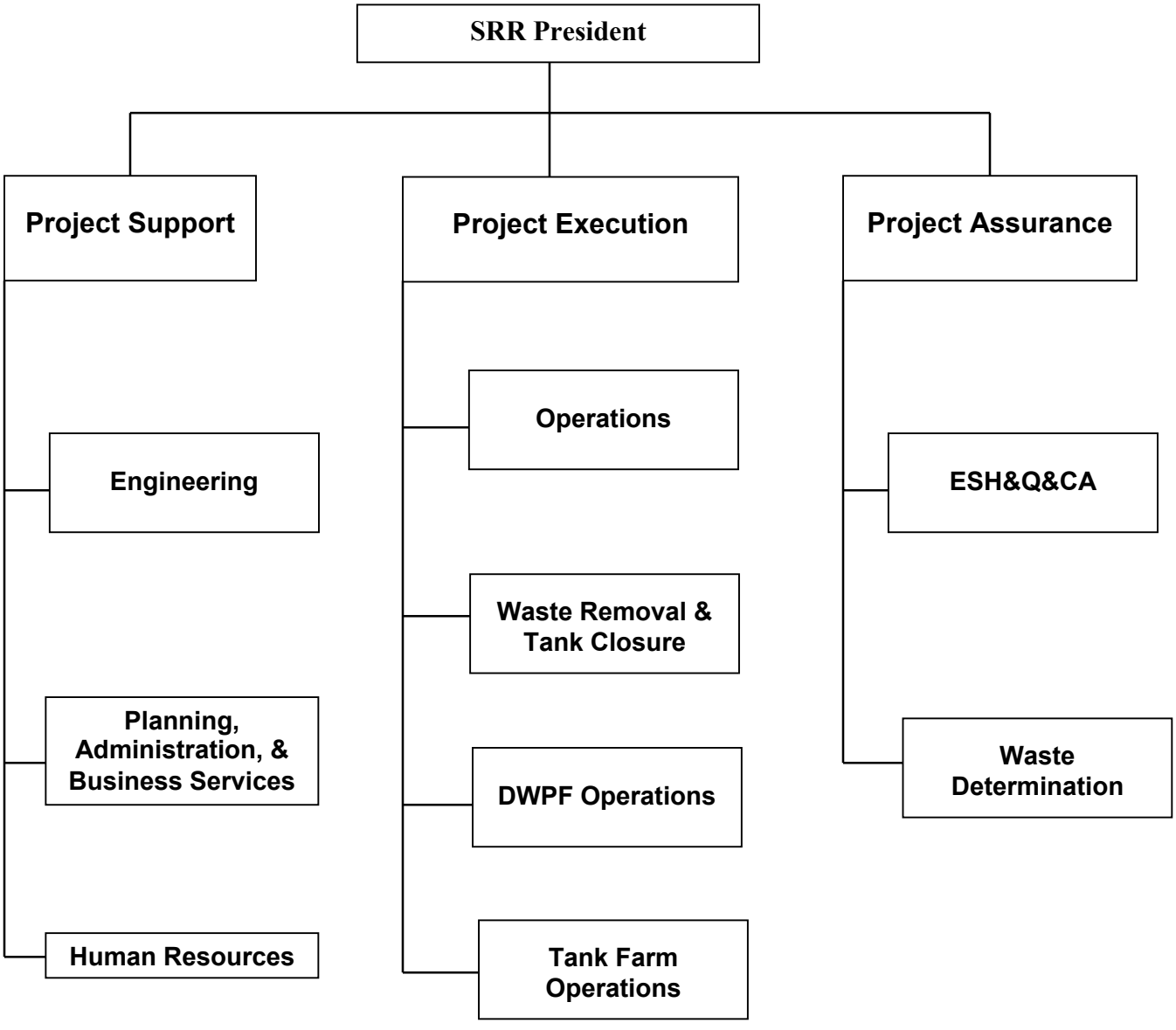
Attachment 1-4

SRR ISMS/QAMP Cross Linkage

	ISMS CORE FUNCTIONS				
QAMP Criterion	**Define Scope Of Work**	**Analyze Hazards**	**Develop / Implement Controls**	**Perform Work**	**Feedback / Improvement**
1. Program	**X**	**X**	**X**	**X**	**X**
2. Personnel Training and Qualification	**X**	**X**	**X**	**X**	**X**
3. Quality Improvement		**X**	**X**	**X**	**X**
4. Documents and Records	**X**	**X**	**X**	**X**	**X**
5. Work Processes	**X**		**X**	**X**	**X**
6. Design	**X**	**X**	**X**	**X**	**X**
7. Procurement	**X**		**X**		**X**
8. Inspection and Acceptance Testing					**X**
9. Management Assessment		**X**			**X**
10. Independent Assessment		**X**			**X**
11. Software Quality Assurance	**X**	**X**		**X**	**X**
12. Suspect / Counterfeit Item Prevention		**X**			**X**

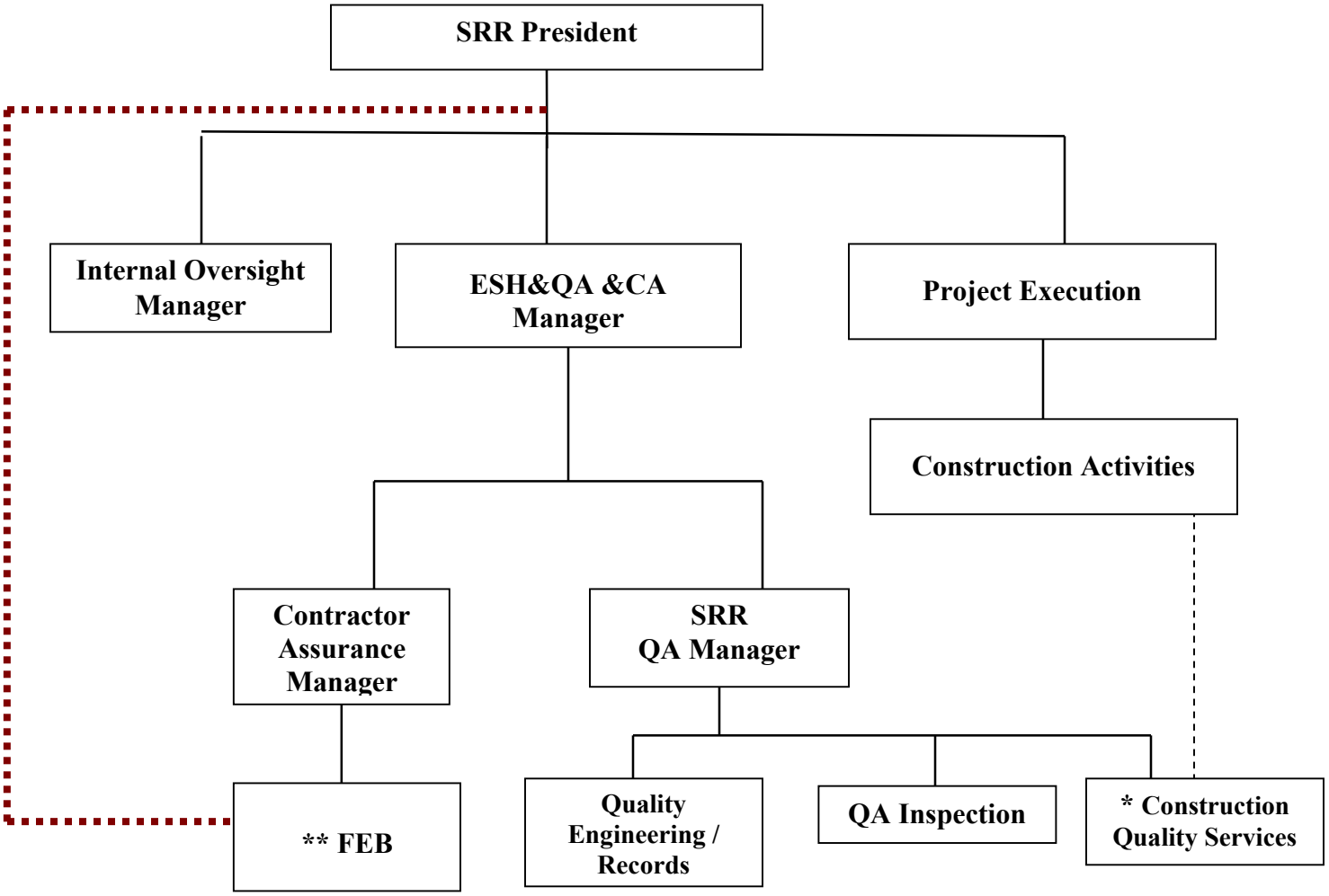
Attachment 1-5

SRR Senior Management Structure



Attachment 1-6

QA and Oversight Relationship



(Matrix Management Reporting Structure)

* Construction Quality Services reports on a matrix basis to the Project and direct report to the SRR QA manager for the purpose of centralized QA Program direction.
** The Contractor Assurance Manager is responsible for the FEB which implements the SRR Independent Assessment Program. The SRR President has organizational oversight of the FEB process.

Attachment 1-7

Key Implementing Documents for Criterion 1 – Program

(Page 1 of 2)

- 1-01 Management Policies
  - General and Administrative Management Procedures Section
  - ESH&QA Section
  - Technical and Operations Management Section
  - Charters – Committees Section
- 1B Management Requirements and Procedures
  - General and Administrative Management Procedures Section
  - Business and Financial Resources Section
  - ESH&QA Section
  - Technical Management Section
- 4B Training and Qualification Program Manual
- 5B Human Resources Manual
  - Employment Section
- 6B Program Management Manual
  - Organization and Responsibilities Section
- 8B Compliance Assurance Manual
- 9B Site Item Reportability and Issue Management (SIRIM)
- 1C Facility Disposition Manual
- 1Q Quality Assurance Manual
- 3Q Environmental Compliance Manual
- 4Q Industrial Hygiene Manual
  - Procedure 1202 “Indoor Environmental Quality Program”
- 8Q Employee Safety Manual
  - Procedure 1 “Safety Policy and Program Responsibilities”
- 12Q Assessment Manual

Attachment 1-7

Key Implementing Documents for Criterion 1 – Program

(Page 2 of 2)

- E7 Conduct of Engineering
  - Procedure 1.02 “Engineering Overview and Graded Approach”
  - Procedure 2.25 “Functional Classifications”
  - Procedure 3.10 “Determination of Quality Requirements for Procured Items”
  - Section 5 “Software Engineering & Control”
- 5E Startup Test Manual
- E11 Conduct of Project Management & Controls
  - Section 2.0 Project Management and Control Procedures
- G-MOA-F-00013 “Contractor Assurance Functional Service Agreement”
- G-MOA-F-00006 “ Environment, Safety, Health, and Quality Functional Service Agreement”

Attachment 2-1

Key Implementing Documents for Criterion 2 – Personnel Training and Qualification

(Page 1 of 2)

- Manual 1-01 Management Policies
  - MP 1.18 "Employee Training"
  - Human Resources Section
- 4B Training and Qualification Program Manual
  - Procedure 1 "WSRC Training Requirements"
  - Procedure 2 "Non-Qualification/Certification Training (Non-Qual/Cert Training)"
  - Procedure 3 "Qualification /Certification Training (Qual/Cert Training)"
  - Procedure 4 "Qualification and Certification Programs"
- 5B Human Resources Manual
  - Procedure 2-10 "Personal Assessment and Development Process"
  - Procedure 2-11 "Employee Performance and Documentation"
  - Procedure 2-16 "Consolidated Assessment Process"
- 11B Subcontract Management Manual
  - Section 3 Pre-Performance Activities Section
- 1Q Quality Assurance Manual
  - QAP 2-2 "Personnel Training and Qualification"
  - QAP 2-4 "Auditor/Lead Auditor Qualification and Certification"
  - QAP 2-5 "Training, Qualification and Certification of Inspection Personnel"
  - QAP 9-2 "Control of Nondestructive Examination"
  - QAP 10-1 "Inspection"
  - QAP 11-1 "Test Control"
- 2Q Fire Protection Manual
  - Procedure 2.13 "Fire Protection Training"
- 4Q Industrial Hygiene Manual
  - Section 1000 Training and Documentation
- 5Q Radiological Control Manual
  - Chapter 6 Training and Qualification

Attachment 2-1

Key Implementing Documents for Criterion 2 – Personnel Training and Qualification
(Page 2 of 2)

- 7Q Security Manual
  - Procedure 504 "Control of Visits – U.S. Citizens"
- 12Q Assessment Manual
  - SA-1 "Self-Assessment"
- 14Q Material Control and Accountability
  - Procedure 3.03 "Training and Qualification of Program Requirements for Accountability Measurement Personnel"
- 2S Conduct of Operations
  - Section 3 Training
- 1Y Conduct of Maintenance
  - Section 1 Part 3.0 Training and Qualification of Maintenance Personnel
- QATRNPLN.X0100 **"**QA Training and Qualification Program Description"

Attachment 3-1

Corrective Action System Elements Based on Significance Category

Required Corrective Action Elements (Based on Significance Category)	Sig Cat 1	Sig Cat 2	Sig Cat 3	Sig Cat 4	Sig Cat T
Issue Identification	X	X	X	X	X
Significance Category Determination	X	X	X	X	X
Apparent Cause Analysis			X		
Root Cause Analysis	X	X			
Corrective Actions to Remedy the Issue Identified	X	X	X	X*	
Corrective Actions to Prevent Recurrence of Specific Issue Identified	X	X			
Corrective Actions to Prevent Recurrence of Similar Issues Identified	X				
Corrective Action Implementation	X	X	X	X*	X*
Independent Verification on Corrective Actions to Prevent Recurrence of Specific and Similar Issues	X				
Independent Verification on Corrective Actions to Prevent Recurrence of Specific Issue		X			
Corrective Action Effectiveness Review	X	X			

* - See 1B Manual Procedure 4.23 “Corrective Action Program” for details / exceptions

Attachment 3-2

Key Implementing Documents for Criterion 3 – Quality Improvement

(Page 1 of 3)

- 1-01 Management Policies
  - MP 1.11 “Open Communication”
  - MP 4.2 “Quality Assurance”
  - MP 4.29 “Human Performance Improvement (HPI)”
  - MP 5.35 “Corrective Action Program”
  - MP Section 6 “Charters – Committees”
- 1B Management Requirements and Procedures
  - Section 1 General and Administrative Management
  - Section 4 ESH&QA
  - Section 5 Technical Management
- 5B Human Resources Manual
  - Compensation and Pay Practices Section
- 7B Procurement Management
  - Section A Procurement Requirements and Procedures5
- 8B Compliance Assurance Manual
  - Procedure 13 “Statistical Trending”
- 9B Site Item Reportability and Issue Management (SIRIM) Manual
- 11B Subcontract Management Manual
  - Section 5 Financial Aspects Section
  - Section 6 Post Performance Section
- 1C Facility Disposition Manual
  - Section 5 Decommissioning
- 3E Procurement Specification Procedure Manual
  - Procedure 1.7 “Supplier Deviation Disposition Request for Procurement Specifications”
- 5E Startup Test Manual
  - Procedure 10 “Test Review Board”

Attachment 3-2

Key Implementing Documents for Criterion 3 – Quality Improvement
(Page 2 of 3)

- 1Q Quality Assurance Manual
  - QAP 1-2 "Stop Work"
  - QAP 15-1 "Control of Nonconforming Items"
  - QAP 16-3 "Corrective Action Program"
  - QAP 19-2 "Quality Improvement"
- 2Q Fire Protection Program Manual
  - Procedure 2.12 "Evaluation and Resolution of Fire Protection Engineering Issues"
- 3Q Environmental Compliance Manual
  - ECM 2.3 "Best Management Practices"
- 5Q Radiological Control Manual
  - Chapter 1 Excellence in Radiological Control
  - Chapter 3 Conduct of Radiological Work
- 7Q Security Manual
  - Procedure 207 "Safeguards and Security Performance Assurance Program"
- 8Q Employee Safety Manual
  - Procedure 2 "WSRC Site Safety Committees"
  - Procedure 8 "Reporting Unsafe Conditions"
  - Procedure 18 "Reporting, Responding, Investigating, and Recording of Occupational Injury/Illness or Near Miss"
  - Procedure 122 "Hazard Analysis"
- 11Q Facility Safety Document Manual
  - Part 2 "Procedures"
- 12Q Assessment Manual
  - ORR-5 "WSRC ORR Finding/Corrective Action Management
  - FEB-2 "Facility Evaluation Board Annual Planning and Reporting"
  - PA-1 "Performance Analysis"
  - PA-2 "Functional Area Program Performance Analysis"

Attachment 3-2

Key Implementing Documents for Criterion 3 – Quality Improvement

(Page 3 of 3)

- 14Q Material Control and Accountability
  - Procedure 1.01 "Material Balance Area Custodian Appointment and Performance Evaluation"
  - Procedure 109 "Material Control and Accountability Anomaly Resolution"
- 2S Conduct of Operations Manual
  - Procedure 5.2 "Issue Investigations"
- 1Y Conduct of Maintenance
  - Procedure 5.05 "Predictive Maintenance"
  - Procedure 16.01 "Maintenance History and Trending"
  - Procedure ID-17.01 "Analysis of Maintenance Problems"
- E7 Conduct of Engineering
  - Procedure 2.33 "Notification of Discovered Technical Errors"
  - Procedure 3.04 "SSC Performance Monitoring"
- E11 Conduct of Project Management and Controls
  - Procedure 2.13 "Project Performance Analysis and Reporting"
  - Procedure 2.15 "Project Trend Program"

Attachment 4-1

DOE Order 243.1 Records Management Program Requirements

(Page 1 of 2)

- Implement a records management program in compliance with requirements for managing records in all formats, including early capture and control throughout their life cycles
    - Electronically formatted records will be maintained in an approved electronic records management application meeting the requirements of DOE-STD-4001-2000
    - E-mail records will be managed along with their metadata, including a listing of recipients and time of receipt, if available
    - Electronic systems that are not regularly backed up and controlled (e.g., instant messaging) should not be used for conducting official Departmental business
    - Until an electronic records management system is available and implemented, electronic records will be printed and retained as paper files
- Create and maintain current file plans/indexes that describe all categories of records created, received, and maintained by personnel in the course of their official duties
- Preserve and disposition records in the same manner as National Archives and Records Administration (NARA) approved records disposition schedules
- Preserve records placed under a destruction moratorium (freeze) as necessary to support audits, court cases, Freedom of Information Act appeals, or similar obligations
- Request disposition authority from NARA, through the Departmental Records Officer, for all unscheduled records
- Store records in a manner that meets the requirements of 36 CFR 1228, Subpart K. Unscheduled records are not to be sent offsite for storage at either NARA or commercial facilities.
- Review capital planning and investment control (CPIC) proposals and information architecture plans for electronic records management provisions
- Conduct internal evaluations of records management practices and programs, including the economy of the operation, at least every 3 years

Attachment 4-1

DOE Order 243.1 Records Management Program Requirements

(Page 2 of 2)

- Ensure that records management program training is provided for all personnel with records management responsibilities on a regular basis
- Identify vital records and preserve them in a manner that ensures they are maintained, kept current and where appropriate, available in the event of a continuity of operations or catastrophic event
- Ensure that the site exit process includes a requirement for the transfer of custodianship of Federal records to another employee or a records liaison officer when employees leave on a permanent or long-term basis
- Identify and confirm compliance with additional record keeping requirements placed on environmental, safety, health studies; quality assurance; emergency management; and other mission-related functions
- Manage the disposition of Federal records according to NARA-approved schedules and practices. Request disposition authority from NARA, through the records management field officer, the program records official, and the Departmental Records Officer, for all unscheduled records
- Use standards, schedules, and regulations to implement a records management program

Attachment 4-2

Standards, Schedules, and Regulations for a Records Management Program

- DOE N 150.1, Continuity of Operations
- DOE O 200.1A, Information Management Program
- DOE O 414.1C, Quality Assurance
- DOE P 450.4, Safety Management System Policy
- 36 CFR, Chapter 12, Subchapter B, Records Management
- Title 42 United States Code (U.S.C.) 7158, Naval Reactor and Military Application Programs
- 44 U.S.C., Chapters 21, 29, 31, 33, and 35
- Office of Management and Budget (OMB) Circular Number A-11, Preparation, Submission, and Execution of the Budget, Sections 31.8, 53 and Part 7
- OMB Circular Number A-130, Management of Federal Information Resources
- E-Government Act of 2002 [Public Law (P.L.) 107-347, 44 U.S.C. Ch 36]
- National Nuclear Security Administration Act (Title XXXII of P.L. 106-65)
- Paperwork Reduction Act, (P.L. 104-13, 5 U.S.C. 1320)
- Privacy Act [P.L 93-579, 5 U.S.C. 552 a (m)]
- Freedom of Information Act (FOIA) [P.L. 89-487, 5 U.S.C. 552 (g)]
- National Archives and Records Administration Publication, Guidance for Coordinating the Evaluation of Capital Planning and Investment Control Proposals for ERM Applications
- 48 CFR Federal Acquisition Regulations, Part 970 - DOE Management and Operating Contracts
    - 48 CFR 970.5204-3, Access to and Ownership of Records
    - 48 CFR 970.5232-3, Accounts, Records, and Inspection
    - 48 CFR 970.0404, Safeguarding Classified Information
    - 48 CFR 970.0407, Contractor Records Retention
- DOE Reference Book for Contract Administrators (Chapter 9)
- NARA-approved DOE administrative, programmatic, and site-specific records disposition schedules
- Records management section of the DOE Chief Information Officer Web site
- DOE-STD-4001-2000, Design Criteria Standard for Electronic Records Management Software Applications

Attachment 4-3

DOE Order 243.2 Vital Records Requirements

(Page 1 of 4)

- The Vital Records Program includes:
  - Legal and financial rights records (formerly known as rights and interests records)
  - Emergency operating records needed to ensure the continuity of operation and performance of essential functions during an emergency or disaster and resumption of normal business operations thereafter
- Identify and preserve vital records in support of DOE emergency preparedness responsibilities (as outlined in Executive Order (E.O.) 12656, Assignment of Emergency Preparedness Responsibilities)
- Vital records are selected based on emergency missions, functions, and plans of operation
- Implement vital record program that include the following:
  - Procedures for identifying, protecting, controlling access to, and ensuring availability of records and information systems that:
    - Specify how the organization will operate in case of an emergency and how it will support civil defense associated with disasters and attacks
    - Are needed for continued operations and mission delivery of the organization both during and after an emergency or disaster; and
    - Are essential to the preservation of the legal rights and interests of the Government and its citizens
  - Procedures for accessing records required to support critical activities the organization performs when operating under abnormal business conditions and/or in a location other than the normal place of business
  - Vital records inventory plans that include:
    - Requirements for proper labeling and handling of vital records
    - Security precautions
    - Frequency of updates
    - Media, hardware, software, and supporting service needs
    - Provisions for access from remote locations

Attachment 4-3

DOE Order 243.2 Vital Records Requirements
(Page 2 of 4)

- An inventory system that identifies hard copy and electronic records by:
  - Series or system title,
  - Description,
  - Type,
  - Name of office and individual responsible,
  - Physical location of records, and
  - Date of latest update.
- Provisions for protecting against or assessing damage to or loss of records and recovering records affected by an emergency or disaster must include:
  - Copies of the vital records and the inventory maintained at separate locations to ensure immediate access in any situation
  - Records maintained in media feasible for accessing and reviewing information during or immediately following and emergency
  - Evaluation of electronic records based on:
    - Volume
    - Frequency of updates
    - Electricity, computers, and software support services available to support records access and use, and
    - Accessibility from remote locations via virtual private networks or compact disks
- A process for selecting storage/backup protection methods that must include:
  - Evaluation of the effectiveness
  - Cost
  - Degree of risk or potential loss
  - Physical susceptibility to destruction
  - Need for special environmental conditions for transporting, storing, and updating records
  - Ability to retrieve records quickly during an emergency or disaster
- An ongoing appraisal of vital records and complete review at least annually to ensure that changing conditions are addressed and records are up-to-date and immediately accessible

Attachment 4-3

DOE Order 243.2 Vital Records Requirements
(Page 3 of 4)

  - A plan must be developed and maintained to recover records that are damaged in an emergency or disaster, regardless of media. This plan must include the priorities for restoring or recovering multiple damaged systems and the options for recovery and replacement. This plan must also include a resource list of local disaster recovery firms that can assist in restoration, along with employee contact lists and vital records inventories, which must be maintained at multiple off-site locations to facilitate their use

- Storage Considerations
  - Location - Establish locations where vital records will be stored, such as alternate Emergency Operations Center (EOC), command center, and relocation sites that will provide adequate protection and accessibility and meet the improved fire protection risk level required by DOE Order 420.1B, Facility Safety. Before classified documents can be stored at these locations, approval must be obtained in accordance with DOE Order 470.4, Safeguards and Security Program

- Manner of Storage
  - Records will be stored in a manner that ensures ease of access, retrieval, and control.
  - Storage systems must allow for access per the prioritized schedule. Classified and unclassified records must be handled in accordance with DOE Order 471.1A, Identification and Protection of Unclassified Controlled Nuclear Information, and DOE Order 471.3, Identifying and Protecting Official Use Only Information.

- Disposition of Records
  - Original vital records must be maintained for the period of time specified in the DOE records disposition schedules. The duplicate copy of vital records that is stored in the separate location should be deleted when obsolete or superseded and replaced with the updated revision

- Emergency Management Program Administrators
  - Ensure that emergency operating records are compiled, maintained, updated, and protected, and that they are retrievable
  - Ensure that all alternate emergency operating centers, alternate command centers, and relocation sites are identified

Attachment 4-3

DOE Order 243.2 Vital Records Requirements

(Page 4 of 4)

- Emergency Management Program Administrators and Records Management Program Staff ensure:
  - Emergency operating records are identified in accordance with established policies and procedures and that other information needs are addressed
  - Emergency operating records are collected, marked and numbered for control, forwarded to designated off-site storage locations, and updated as needed (updates shall be performed no less than annually)
  - Mechanisms are in place to provide records access and ease of retrieval during emergencies (through the Emergency Management Program)
  - Records storage facilities meet regulatory requirements
  - Training is provided to program personnel regarding the purpose and operations of the emergency operating records protection portion of the Vital Records Program. Maintain training records that can be made available for inspection
- Contractor Records Officers and Staff
  - Ensure that rights and interests records are compiled, maintained, updated, and protected and that they are retrievable for authorized review
  - Maintain inventory of vital records
  - Ensure that program personnel are trained in and knowledgeable of the purpose and operations for the rights and interests portion of the Vital Records Program
  - Include vital records identification and management in records program assessments

Attachment 4-4

Key Implementing Documents for Criterion 4 – Documents and Records

(Page 1 of 2)

- 1-01 Management Policies
  - General and Administrative Management Section
  - Business and Financial Resources Section
  - ESH&QA Section
- 1B Management Requirements and Procedures
  - MRP 1.05 "Release of Information"
  - MRP 3.01 "Integrated Procedure Management System (IPMS)"
  - MRP 3.11 "WSRC Document and Correspondence Numbering System"
  - MRP 3.18 "Management of SRS Forms"
  - MRP 3.25 "Capture, Management, and Disposition of Scientific and Technical Information and Software"
  - MRP 3.26 "Management of Company-Level Policies and Procedures"
  - MRP 3.27 "Management of Program-Specific Administrative Procedures"
  - MRP 3.31 "Records Management"
  - MRP 3.32 "Document Control"
  - MRP 3.65 "Printing and Duplicating Services"
- Manual 1-01 Policy MP 4.2 "Quality Assurance"
- 1Q Quality Assurance Manual
  - QAP 4-1 "Procurement Document Control"
  - QAP 5-1 "Instructions, Procedures and Drawings"
  - QAP 6-1 "Document Control"
  - QAP 17-1 "Quality Assurance Records Management"
- 3Q Environmental Compliance Manual
  - ECM 9.1 "Administrative Record File/Information Repository File Compilation"
- 4Q Industrial Hygiene Manual
  - Procedure 307 "Records and Reports of Alleged Significant Adverse Reaction to Health and Environment"
- 5Q Radiological Control Manual
  - Chapter 7 "Radiological Control Records"
- 7Q Security Manual
  - Procedure 201 "Facility Data and Approval Record"
  - Procedure 202 "Safeguards and Security Management Report"
  - Section 4.0 Information Security

Attachment 4-4

Key Implementing Documents for Criterion 4 – Documents and Records

(Page 2 of 2)

- 8Q Employee Safety Manual
  - Procedure 18 "Reporting, Responding, Investigating, and Recording of Occupational Injury/Illness or Near Miss"
- 14Q Material Control and Accountability
  - Procedure 1.05 "Required Material Balance Area Procedures and Plans"
  - Procedure 3.13 "Statistical Sampling Plans"
- 2S Conduct of Operations
  - Section 1.0 Procedures
  - Section 2.0 Communications
  - Procedure 5.4 "Round Sheet Preparation and Use"
  - Procedure 5.10 Operator Aid Postings"
- E7 Conduct of Engineering
  - Procedure 1.01 "Procedure Management"
  - Procedure 1.20 "Engineering Document Numbering System"
  - Procedure 1.40 "Engineering Certification of State and Federal Documents"
  - Procedure 1.53 "Commercial Drawings"
  - Procedure 1.54 "Commercial Engineering Calculations"
  - Procedure 1.55 "Field Change Request"
  - Procedure 2.30 "Drawings"
  - Procedure 2.31 "Engineering Calculations"
  - Procedure 2.37 "Design Change Form"
  - Procedure 2.38 "Design Change Package"
  - Procedure 2.60 "Technical Reviews"
  - Procedure 3.60 "Technical Reports"
  - Procedure 3.70 "Qualification of Existing Data"
  - Procedure 4.05 "Development of Safety Analysis Reports for Packaging"
- Records Disaster Preparedness Recovery Plan (WSRC-RP-99-00850)
- Functional Service Agreement
  - G-MOA-F-00016 "Records and Document Control"

Attachment 5-1

Key Implementing Documents for Criterion 5 – Documents and Records

(Page 1 of 3)

- 1-01 Management Policies
  - MP 3.6 “Transportation”
  - MP 4.25 “Behavior Based Safety (BBS)”
  - MP 5.20 “Maintenance Management”
  - MP 5.28 “Hoisting and Rigging Program”
  - MP 5.30 “Disposition of Contaminated Large Equipment”
- 1B Management Requirements and Procedures
  - MRP 3.64 “Davis-Bacon Act Applicability”
  - MRP 4.03 “Savannah River Remote Worker Notification”
  - MRP 4.19 “Requirements for Facility Operations Safety Committee”
  - MRP 4.22 Control of Radiation Monitoring Equipment”
  - MRP 5.0 “Off-Site Shipping”
- 11B Subcontract Management Manual
  - Section 4 Performance
- 13B Chemical Management Manual
  - Procedure 2.3 “SRS Hazard Communication Program”
- 1C Facility Disposition Manual
- 1Q Quality Assurance Manual
  - QAP 2-3 “Control of Research and Development Activities”
  - QAP 8-1 “Identification and Control of Items”
  - Section 9 Control of Processes
  - Section 12 Control of Measuring and Test Equipment
  - Section 13 Control of Packaging, Handling, Shipping, and Storage
  - Section 14 Inspection, Test, and Operating Status
  - Section 21 Environmental Quality Assurance
- 2Q Fire Protection Program Manual
  - Procedure 5.2 “Storage and Handling of Flammable/Combustible Liquids and Compressed Gases”
  - Procedure 5.3 “Fire Watch and Fire Patrol”
  - Procedure 5.4 “Control of Hot Work and Hot Work Permits”
  - Procedure 5.5 “Control of Transient Combustibles”

Attachment 5-1

Key Implementing Documents for Criterion 5 – Documents and Records
(Page 2 of 3)

- 3Q Environmental Compliance Manual
  - ECM 5.1 "National Environmental Policy Act (NEPA) Implementation and the Environmental Evaluation"
  - Section 21.0 Quality Control
- 4Q Industrial Hygiene Manual
  - Procedure 105 "Hazard Prevention and Control"
  - Procedure 110 "Industrial Hygiene Roles in Material Incidents"
  - Procedure 302 "Handling Materials that Pose a Potential Occupational Carcinogenic Hazard"
- 5Q Radiological Control Manual
  - Chapter 3 Control of Radiological Work
  - Chapter 4 Radioactive Materials
  - Chapter 5 Radiological Health Support Operations
- 8Q Employee Safety Manual
  - Procedure 8 "Reporting Unsafe Conditions"
  - Procedure 31 "Danger, Caution, and Warning Tags"
  - Procedure 32 "Hazardous Energy Control (Lockout/Tagout)"
  - Procedure 33 "Confined Space Entry Program"
  - Procedure 121 "Out of Commission Process (OOC)"
  - Procedure 122 "Hazard Analysis"
- 14Q Material Control and Accountability
  - Section 4.0 Material Transfers
- 18Q Safe Electrical Practices and Procedures
- 19Q Transportation Safety
  - Section 2.0 Routine Transfer/Shipment
  - Section 3.0 Non-Routine Transfer/Shipment
- 2S Conduct of Operations
  - Section 4.0 Shift Operations
  - Section 5.0 Facility Operations
- 1Y Conduct of Maintenance
  - Section 1.0 Maintenance Program Administrative Procedures

Attachment 5-1

Key Implementing Documents for Criterion 5 – Documents and Records

(Page 3 of 3)

- E7 Conduct of Engineering
  - Procedure 1.30 “Component Numbering System”
  - Procedure 1.31 “Master Equipment List”
  - Procedure 1.32 “Labeling of Configuration Controlled SSCs”
  - Section 2.0 Nuclear Process Technical Baseline Control
- Functional Service Agreement
  - Records and Document Control, Functional Service Agreement, G-MOA-F-00016

Attachment 6-1

Key Implementing Documents for Criterion 6 – Design

- 1-01 Management Policies
  - MP 5.7 “Configuration Management”
  - MP 5.10 “Value Engineering”
  - MP 5.14 “Technology Transfer”
- 1Q Quality Assurance Manual
  - QAP 3-1 “Design Control”
- 5Q Radiological Control Manual
  - Chapter 3 “Conduct of Radiological Work”
- 11Q Facility Safety Document Manual
  - Part II Procedures
- E7 Conduct of Engineering

Attachment 7-1

Key Implementing Documents for Criterion 7 – Procurement

- 1-01 Management Policies
  - MP 1.25 “Procurement and Technology Ombudsman Program”
  - MP 3.3 “Procurement and Materials Management”
  - MP 5.27 “Engineering and Construction Subcontracting”
  - MP 5.29 “Export Control”
- 1B Management Requirements and Procedures
  - MRP 1.13 “Work for Others”
  - MRP 1.14 “Memorandum Purchase Orders”
  - MRP 1.15 “Corporate Support Services”
  - MRP 3.58 “Material Delivery Point (MDP) Operation”
  - MRP 5.24 “WSRC Export Control”
  - MRP 5.28 “Controlled Products List”
- 3B Asset Management Manual
- 7B Procurement Management
- 11B Subcontract Management Manual
- 13B Chemical Management Manual
  - Section 2.0 Chemical Management Procedures
- 3E Procurement Specification Procedure Manual
- 1Q Quality Assurance Manual
  - QAP 4-1 “Procurement Document Control”
  - Section 7 Control of Purchased Items and Services
- 8Q Employee Safety Manual
  - Procedure 109 “Materials Handling, Storage, Use, and Disposal”
- 1Y Conduct of Maintenance
  - ID-10-01 “Procurement of Parts, Materials, and Services”
  - ID-11.01 “WSRC Maintenance Control of Material”
- E7 Conduct of Engineering
  - Procedure 3.10 “Determination of Quality Requirements for Procured Items”
  - Procedure 3.46 “Replacement Item Evaluation / Commercial Grade Dedication”

Attachment 8-1

Key Implementing Documents for Criterion 8 – Inspection and Acceptance Testing

- 5E Startup Test Manual
- 1Q Quality Assurance Manual
  - QAP 2-5 “Training, Qualification and Certification of Inspection Personnel”
  - QAP 10-1 “Inspection”
  - QAP 11-1 “Test Control”
- 2Q Fire Protection Program Manual
  - Procedure 5.1 “Facility Fire Prevention and Life-Safety Inspections”
  - Procedure 5.7 “Portable Fire Extinguisher Inspection”
  - Procedure 5.8 “Battery-Operated Emergency Lighting – Inspection and Test”
  - Procedure 5.9 “Exit Sign Inspection and Testing”
  - Procedure 5.10 “Passive Fire Protection Features Inspection and Functional Test”
  - Procedure 5.11 “Facility-Performed Inspection and Maintenance of Fire Protection System Components”
- 7Q Security Manual
  - Procedure 309 “Security System Testing and Maintenance”
- 8Q Employee Safety Manual
  - Procedure 51 “Final Acceptance Inspection of New, Altered, or Dispositioned Facilities or Equipment”
  - Procedure 53 “Safety Inspections and Inspection Color Code”
- 14Q Material Control and Accountability
  - Procedure 1.15 “Performance Testing of Material Control and Accountability Systems”
- 1Y Conduct of Maintenance
  - Procedure 9.01 “Post Maintenance Testing”
  - ID-14.01 “Facility Condition Inspection”
- Functional Service Agreement
  - G-MOA-F-00006, “Environment, Safety, Health Quality and Health Services Functional Service Agreement”

Attachment 9-1

Key Implementing Documents for Criterion 9 – Management Assessment

(Page 1 of 2)

- 1-01 Management Policies
  - MP 1.19 "Internal Audit"
- 8B Compliance Assurance Manual
  - CAP-05 "Conduct of WSRC Phase I Compliance Assessment – Source Documents within the S/RID"
  - CAP-06 "Conduct of WSRC Phase I Compliance Assessment – Non-ESH Source Documents"
- 1Q Quality Assurance Manual
  - QAP 18-2 "Surveillance"
  - QAP 18-4 "Management Assessment Program"
  - QAP18-6 "Quality Assurance Internal Audits"
  - QAP 18-7 "Quality Assurance Supplier Surveillance"
- 4Q Industrial Hygiene Manual
  - Procedure 103 "Role of Industrial Hygiene in the Assessment Process"
  - Procedure 104 "Integrated Exposure Assessment Program"
  - Procedure 109 "Occupational Medical Surveillance Program"
- 5Q Radiological Control Manual
  - Chapter 3 Conduct of Radiological Work
- 6Q Vol. II SRS Emergency Plan / Emergency Management Program Procedures Manual
  - EMPP 6Q-006 "Standards for the Development and Conduct of Facility Emergency Preparedness Drills"
  - EMPP 6Q-007 "Standards for Site Level Emergency Services Drill and Exercise Coordination and Conduct"
- 7Q Security Manual
  - Procedure 208 "Safeguards and Security Assessments"
- 8Q Employee Safety Manual
  - Procedure 6 "Safety and Housekeeping Audits"

Attachment 9-1

Key Implementing Documents for Criterion 9 – Management Assessment (Continued)
(Page 2 of 2)

- 12Q Assessment Manual
  - ORR-1 "WSRC Startup/Restart Planning"
  - ORR-2 "Management Self Assessment (MSA)"
  - SA-1 "Self-Assessment"
  - PA-1 "Performance Analysis"
  - PA-2 "Functional Area Program Performance Analysis"
- 2S Conduct of Operations
  - Procedure 5.7 "Independent Verification"
  - Procedure 5.13 "Facility Monitoring Program"
- 1Y Conduct of Maintenance
  - ID-15.01 "Management Involvement"

Attachment 10-1

Key Implementing Documents for Criterion 10 – Independent Assessment

- 1-01 Management Policies
  - MP 1.27 “Cooperation with Non-Westinghouse Audit Organizations”
- 1B Management Requirements and Procedures
  - Procedure 1.18 “Internal Audit Process and Follow Up”
- 1Q Quality Assurance Manual
  - QAP 2-4 “Auditor/Lead Auditor Qualification and Certification”
  - QAP 18-3 “Quality Assurance External Audits”
  - QAP 18-4 “Quality Assurance Internal Audits”
  - QAP 18-7 “Quality Assurance Supplier Surveillance”
- 7Q Security Manual
  - Procedure 210 “DOE HQ Inspections and Evaluations”
- 12Q Assessment Manual
  - ORR-4 “Conduct of the WSRC ORR”
  - ORR-8 “Readiness Assessment (RA)”
  - FEB-1 “Facility Evaluation Board”

Attachment 11-1

Software Types

(Page 1 of 2)

Software typically is either custom developed or acquired software. These two basic types can be further characterized five types of software commonly used in DOE applications: (1) custom developed, (2) configurable, (3) acquired, (4) utility calculation, and (5) commercial design and analysis.

1) Custom Developed Software

Custom Developed Software is built specifically for a DOE application or to support the same function for a related government organization. It may be developed by DOE or one of its contractors or contracted with a qualified software company through the procurement process. Examples of custom developed software include: material inventory and tracking database applications, accident consequence applications, control system applications, and embedded custom developed software that controls a hardware device.

2) Configurable Software

Configurable Software is commercially available software or firmware that allows the user to modify the structure and functioning of the software in a limited way to suit user needs. An example is software associated with a Programmable Logic Controller (PLC).

3) Acquired Software

Acquired Software is 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 calculatingly software and spreadsheet tools (e.g., MathCad and 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.

Attachment 11-1

Software Types
(Page 2 of 2)

4) Utility Calculation Software

Utility Calculation Software typically uses COTS spreadsheet applications as a foundation and user developed algorithms or data structures to create simple software products. The utility calculation software within the scope of this document is used frequently to perform calculations associated with the design of an SSC. Utility software that is used with high frequency may be labeled as custom software and may justify the same safety SQA work activities as custom developed software. With utility calculation software, it is important to recognize the difference between QA of the algorithms, macros, and logic that perform the calculations versus QA of the COTS software itself. Utility calculation software includes the associated data sets, configuration information, and test cases for validation and/or calibration.

5) Commercial Design and Analysis Software

Commercial Design and Analysis Software is used in conjunction with design and analysis services provided from a commercial contractor. An example would be where DOE or a contractor contracts for specified design services support. The design service provider uses its independently developed or acquired software without DOE involvement or support. DOE then receives a completed design.

Attachment 11-2

Software Quality Assurance Definitions

(Page 1 of 2)

- **Acceptance testing** - 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
- **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.
- **Control point** - A point in the software life cycle at which specified agreements or control (typically a test or review) are applied to the software configuration items being developed
- **Operating environment** - a collection of software, firmware, and hardware elements that provide for the execution of computer programs
- **Software design verification** - the process of determining if the product of the software design activity fulfills the software design requirements
- **Software development cycle** - The activities that begin with the decision to develop a software product and end when the software is delivered. The software development cycle typically includes the following activities: software design requirements, software design, implementation, test, and sometimes installation
- **Software engineering** - The application of a systematic, disciplined, quantifiable approach to the development, operation, and maintenance of software; that is, the application of engineering to software
- **Software life cycle** - the activities that comprise the evolution of software from conception to retirement. The software life cycle typically includes the software development cycle and the activities associated with operation, maintenance, and retirement
- **Software tool** - A computer program used in the development, testing, analysis, or maintenance of a program or its documentation
- **System software** - Software designed to enable the operation and maintenance of a computer system and its associated computer programs

Attachment 11-2

Software Quality Assurance Definitions (Continued)

(Page 2 of 2)

- **Testing** (software) - The process of:
  - (a) operating a system or system component under specified conditions
  - (b) observing and recording the results
  - (c) making an evaluation of some aspect of the system or system component in order to verify that it satisfies specified requirements and to identify errors
- **Test case** - A set of test inputs, execution conditions, and expected results developed for a particular objective, such as to exercise a particular program path or to verify compliance with a specific requirement.
- **Test plan** (procedure) - 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.

Attachment 11-3

Software Quality Assurance Grading Levels - Software Classifications

(Page 1 of 5)

1.0 Software Classifications and Requirement Overview for SSC Software

1.1 Safety Class (SC) Software

- Required to ensure that the consequences of any credible event will not challenge the radiological offsite evaluation guideline to an individual member of the public
- Required to provide a supporting function to ensure identified SC functions can be performed, or are not prevented from being performed in accordance with analyses
- Required to maintain operating parameters within the Technical Safety Requirements limits

Attachment 11-3

Software Quality Assurance Grading Levels - Software Classifications
(Page 2 of 5)

1.2 Safety Significant (SS) Software

- Required (for identified credible events) to protect all workers and provide applicable additional levels of control which provide a significant contribution to defense in depth for the public and/or workers
- Where failure is estimated to result in significant radiological or chemical exposure, a prompt fatality, or serious injury that would result in medical treatment for immediately life threatening or permanently disabling injuries (e.g., loss of eye, loss of limb) from other than hazards routinely encountered in general industry and construction, and for which codes or standards exist to guide safe design and operation
- Failure is estimated to result in either the exposure of a worker to a concentration of Hazardous Material in an occupied area inside a building that would challenge a concentration of Emergency Response Planning Guideline (ERPG-3), or the inventory released would exceed Hazard Category 3 thresholds for radionuclides
- Failure would result in a release that would, based on an informed qualitative approach, challenge the onsite hazardous material criteria
- Failure would result in a release that would exceed 29 CFR 1910.119 threshold quantities
- Required to ensure that any credible event shall not challenge the ERPG-2 chemical offsite evaluation criteria to an individual member of the public
- Provides a major contribution to defense in depth
- Required by a nuclear criticality safety program to prevent, monitor, or detect a nuclear criticality accident even if that accident would not directly impact worker safety
- Required to provide a supporting function to ensure identified SS functions can be performed or are not prevented from being performed
- Required to maintain operating parameters within the Technical Safety Requirements

Attachment 11-3

Software Quality Assurance Grading Levels - Software Classifications
(Page 3 of 5)

1.3 Production Support (PS) Software

- Failure would have an unacceptable impact on a Nuclear Production Facility by:
  - Causing a monetary loss in excess of $1,000,000 (1981 dollars) or $2,000,000 (2003 dollars) including cleanup, equipment damage, product value, etc.; or,
  - Causing a loss of primary program capabilities in excess of six months.

  Note: If a production time or monetary loss to a Nuclear Production Facility can be caused by the failure of software in a supporting facility, that software is classified PS
- Any on-line monitoring software required by an environmental permit or regulation that directly measures discharges to the atmosphere, to the ground water, or to the surface water
- Required by the SRS Emergency Plan for environmental monitoring or for communications with local, state, and Federal Governmental agencies

1.4 General Services (GS) Software

- All SSC related software is assigned a classification of GS unless otherwise determined and documented by the responsible engineer
- GS classification applies to both nuclear and non-nuclear facilities
- All SSC related software must fulfill the GS functions required to ensure the health and safety of the worker as identified in DOE Orders, selected National Codes and Standards, and Site Standards

2.0 Software Classifications and Requirement Overview for Non-SSC Software

2.1 "A" Classification Software

- Has a DIRECT effect on nuclear safety protection systems that keep exposure to the general public below the off-site regulatory or evaluation guidelines

Attachment 11-3

Software Quality Assurance Grading Levels - Software Classifications
(Page 4 of 5)

2.2 "B" Classification Software

- Failure to properly function may have an indirect effect on nuclear safety protection systems or toxic materials hazard systems that are used to keep nuclear or toxic material hazard exposure to the general public and workers below regulatory or evaluation guidelines
- Results are used to make decisions that could result in death or serious injury or are part of the evaluation in accident analyses

2.3 "C" Classification Software

- Failure to perform as expected would not affect nuclear safety but would have an unacceptable impact by causing loss of:
  - Greater than $2 Million Dollars production investment value and/or recovery cost
  - Primary program capabilities in excess of six months
- Important to continued operations of the business and used to support decisions regarding operating activities
- Used to comply with regulatory laws, environmental permits or regulations and/or commitments to compliance
- Required by the SRS Emergency Plan for environmental monitoring or for communications with Local, State and Federal Government agencies
  - Used in nuclear and non-nuclear facilities for trending and analysis of operational data; or to provide information to management in support of decisions regarding operating activities, causing an unacceptable impact
  - Output is used for defense-in-depth as determined by the safety analysis

Attachment 11-3

Software Quality Assurance Grading Levels - Software Classifications

(Page 5 of 5)

2.4 "D" Classification Software

- Important to the day-to-day administration of the business but whose failure to perform as intended will not adversely affect the safety or reliability of operations or will not result in losses exceeding $2 million dollars or result in a six month loss of program capabilities
  - Used to perform tasks related to hazards that are routinely encountered in general industry and construction and for which national consensus codes, standards or site programs exist to guide safe design and operation

2.5 "E" Classification Software

- Software that is within scope of the software quality assurance program but does not meet the A, B, C, or D classification levels specified above

Attachment 11-4

Software Quality Assurance Classification Process

(Page 1 of 3)

1.0 Determine Software Type (SSC or Non SSC)

1.1 SSC Functional Classification (SC, SS, PS, or GS)

- Software that is part of a SSC is classified using E7 procedure 2.25

Go to section 3.0 to finish classification process

1.2 Non SSC Classification (A, B, C, D, or E)

- Go to section 2.0 to determine Classification

2.0 Determine Classification (grading level) for Non SSC Software

2.1 "A" Classification (Non SSC Software)

- Software applications that have a DIRECT effect on nuclear safety protection systems that keep exposure to the general public below the off-site regulatory or evaluation guidelines
  - Include software running on hardware that has no direct output connections to an SSC, but whose output is used without further review or evaluation as a DIRECT input to the functioning of an SSC

If software meets "A" Classification, go to section 3.0 to finish classification process

2.2 "B" Classification (Non SSC Software)

- Software applications whose failure to properly function may have an indirect effect on nuclear safety protection systems or toxic materials hazard systems that are used to keep nuclear or toxic material hazard exposure to the general public and workers below regulatory or evaluation guidelines
- Software applications whose results are used to make decisions that could result in death or serious injury or are part of the evaluation in accident analyses.
- Use criteria in section 2.2.1 to determine if the software application meets criteria for lower classification

Attachment 11-4

Software Quality Assurance Classification Process
(Page 2 of 3)

2.2.1 If the software output is used for defense-in-depth as determined by the safety analysis:
- The Classification can be changed "C" Classification (Non SSC Software)

2.2.2 If the software is used to perform tasks related to hazards routinely encountered in general industry and construction and for which national consensus codes, standards or site programs exist to guide safe design and operation:
- The Classification can be changed to "D" Classification (Non SSC Software)

If software Classification is complete, go to section 3.0 to finish classification process

2.3 "C" Classification (Non SSC Software)

- Software applications whose failure to perform as expected would not affect nuclear safety but would have an unacceptable impact by causing a loss of:
  - Greater than $2 Million Dollars production investment value and/or recovery cost
  - Primary program capabilities in excess of six months
- Software applications important to continued operations of the business and used to support decisions regarding operating activities
- Software applications used to comply with regulatory laws, environmental permits or regulations and/or commitments to compliance
- Software applications required by the SRS Emergency Plan for environmental monitoring or for communications with Local, State and Federal Government agencies
  - Include software that is used in nuclear and non-nuclear facilities for trending and analysis of operational data; or to provide to operation or maintenance information to management in support of decisions regarding operating activities, causing an unacceptable impact
  - Include software whose output is used for defense-in-depth as determined by the safety analysis
- Use criteria in section 2.3.1 to determine if the software application meets criteria for lower classification

Attachment 11-4

Software Quality Assurance Classification Process
(Page 3 of 3)

2.3.1 If the software is used to perform tasks related to hazards routinely encountered in general industry and construction and for which national consensus codes, standards or site programs exist to guide safe design and operation:
- The Classification can be changed to "D"

If software Classification is complete, go to section 3.0 to finish classification process

2.4 "D" Classification (Non SSC Software)

- Software applications important to the day-to-day administration of the business but whose failure to perform as intended will not adversely affect the safety or reliability of operations or will not result in losses exceeding $2 Million Dollars or result in a six month loss of program capabilities
  - Include software used to perform tasks related to hazards that are routinely encountered in general industry and construction and for which national consensus codes, standards or site programs exist to guide safe design and operation

If software Classification is complete, go to section 3.0 to finish classification process

2.5 "E" Classification (Non SSC Software)

- Software that is within the scope of the software quality assurance program but does not meet any of the criteria specified for "A," "B," "C," or "D" Non SSC Software Classification Levels

3.0 Finish Classification Process

- Evaluate against criteria for Safety Software (see Attachment 12-4 "Safety Software") and determine if the software is Safety Software
- Document Classification and Safety Software determination
- Perform independent review of classification as required

Attachment 11-5

Safety Software

Safety Software
Safety Software includes safety system software, safety and hazard analysis software and design software, and safety management and administrative control software.

Safety System Software
Safety system software is software for a nuclear facility that performs a safety function as part of an SSC and is cited in either (1) a DOE approved Documented Safety Analysis (DSA) or (2) an approved hazard analysis per DOE Policy 450.4 Safety Management System Policy, and the Department of Energy Acquisition Regulation (DEAR) clause.

(Note: Per 10 CFR 830, quality assurance requirements apply to all DOE nuclear facilities including radiological facilities. See 10 CFR 830, DOE Standard 1120, and the DEAR clause for additional details)

Safety and Hazard Analysis Software and Design Software
Safety and Hazard Analysis Software and Design Software is software that is used to classify, design, or analyze nuclear facilities. This software is not part of an 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
Safety Management and Administrative Controls Software is 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 830, 10 CFR 835, and the DEAR ISMS clause.

Attachment 11-6

Key Implementing Documents for Criterion 11 – Software Quality Assurance

- 1-01 Management Policies
  - MP 3.8 “Data and Information Management”
  - MP 3.12 “Computing Coordination and Integration”
  - MP 3.33 “Computer Malware Control”
  - MP 3.34 “Cyber Security Configuration Management”
  - MP 4.10 “Computer and Technical Security”
- 1B Management Requirements and Procedures
  - MRP 1.07 “Inventions, Invention Disclosures, and Patents, Including Software Inventions”
  - MRP 3.25 “Capture, Management, and Disposition of Scientific and Technical Information and Software”
- 12B Information Management
- 1Q Quality Assurance Manual
  - QAP 20-1 “Software Quality Assurance”
- 2Q Fire Protection Program Manual
  - Procedure 2.0 “Fire Protection Database System Control Procedure”
- 10Q Computer Security Manual
- E7 Conduct of Engineering
  - Section 5.0 Software Engineering & Control

Attachment 12-1

Key Implementing Documents for Criterion 12 – Suspect/Counterfeit Item Prevention

1B Management Requirements and Procedures

- MRP 4.23 “Corrective Action Program”
- MRP 5.19 “Suspect and Counterfeit Item Program”

1Q Quality Assurance Manual

- QAP 15-1 “Control of Nonconforming Items”

Functional Service Agreement

- Engineering, Functional Service Agreement, G-MOA-F-00011