SIGNATURE PAGE

Thomas Helms
SWPF QA Manager/QMS Management Representative

7/24/2018
Date

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7/24/2018
Date

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DOE SWPF Federal Project Director

7/30/2018
Date

Thomas Johnson, Jr.
Acting Deputy Manager, Savannah River Operations Office

8/8/2018
Date
### SUMMARY OF CHANGES

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<td>07/26/04</td>
<td>Initial issuance (Contract deliverable)</td>
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<td>Incorporates the applicable requirements of ASME NQA-1-2004. Complete rewrite, no revision bars shown.</td>
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<td>Update for annual review for DOE Compliance.</td>
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<td>08/02/10</td>
<td>Revised per DMR-1215, update to enhance compliance with NQA-1-2004 and DOE O414.1C; particularly software quality assurance. General update of titles, implementing documents. Complete Rewrite, no revision bars shown.</td>
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<td>Revised Per DMR-4348, update the QAP to reflect needed changes/revisions prior to Operations (MSA-3) by the transition date as dictated in the SWPF Implementation Plan for NQA-1-2008 with the NQA-1a-2009 Addenda (00-700-23883). This is a complete rewrite. No revision bars shown.</td>
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<tr>
<td>PAAA</td>
<td>Price-Anderson Amendments Act</td>
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<td>PCAR</td>
<td>Programmatic Compliance Assessment Report</td>
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<td>PIC</td>
<td>Person-in-Charge</td>
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<td>PP</td>
<td>Project Procedure</td>
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<td>QA</td>
<td>Quality Assurance</td>
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<td>QAP</td>
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<td>QC</td>
<td>Quality Control</td>
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<td>QMS</td>
<td>Quality Management System</td>
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<tr>
<td>QSPP</td>
<td>Quality System Program Plan</td>
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## LIST OF ACRONYMS AND ABBREVIATIONS (cont.)

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
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<tr>
<td>RFI</td>
<td>Request for Information</td>
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<tr>
<td>S/CI</td>
<td>Suspect/Counterfeit Item</td>
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<tr>
<td>S/RID</td>
<td>Standards/Requirements Identification Document</td>
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<td>SALT PCP</td>
<td>Project Collaboration Portal</td>
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<td>SAP</td>
<td>Supplier Assessment Plan</td>
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<td>SC</td>
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<td>SQA</td>
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<td>SS</td>
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<td>SSC</td>
<td>Structure, System, and Component</td>
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<td>SWPF</td>
<td>Salt Waste Processing Facility</td>
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<td>WSH</td>
<td>Worker Safety and Health</td>
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EXECUTIVE SUMMARY

QUALITY ASSURANCE PLAN FOR
THE SALT WASTE PROCESSING FACILITY PROJECT

Purpose

The purpose is to establish and implement a Quality Assurance Plan (QAP) specific to the Salt Waste Processing Facility (SWPF). This QAP establishes the quality assurance (QA) program requirements for the quality management system (QMS) and ensures risks and environmental impacts are minimized, and safety, reliability, and performance are maximized which is accomplished through the application of management systems using a graded approach commensurate with the risks.

The quality of items and services shall be controlled and evaluated to an extent consistent with their potential risk. The graded application of management controls for SWPF shall be applied based on the degree of confidence necessary to ensure end-product quality.

Applicability

The U.S. Department of Energy (DOE) intends to remove and treat sludge and “salt” wastes currently stored in the Savannah River Site (SRS) tanks in the F- and H-Area Tank Farms. SWPF is an essential and integrated part of the Liquid Waste Treatment System. This QAP documents the established QMS for SWPF through the transition from Commissioning to Operations. Management shall maintain the QMS and shall assess opportunities to continually improve its effectiveness. The implementation of and compliance with this QAP shall include major team subcontractors services.

The applicability of specific quality standards and their editions is defined through the DOE Contract (DE-AC09-02SR22210, Design, Construction, and Commissioning of a Salt Waste Processing Facility [SWPF]) modifications for specific phases of the SWPF Project. Part I and Subpart 2.7 of Part II of American Society of Mechanical Engineers (ASME) NQA-1-2004, Quality Assurance Requirements for Nuclear Facility Applications applied to the Design, Construction, and Testing, remains applicable to items designed, procured, and installed in SWPF and services subcontracted for design, installation, and testing. Part I and Part II of ASME NQA-1-2008/09a, Quality Assurance Requirements for Nuclear Facility Applications is applicable to the Operations phase for programmatic activities unrelated to design.

In specific relation to procurements and associated processes, ASME NQA-1-2008/09a only applies to new procurements of items and services for major changes/modifications to SWPF. ASME NQA-1-2004 applies to items already procured and currently in storage, items/services for which the procurement process was initiated prior to transitioning from Commissioning to Operations, or procurements of like for like spares or replacement of items. The ASME NQA-1-2004 Code of Record is retained for these items and the existing versions of Project Specifications remain in effect as long as necessary for these items. Additional
strategy/conditions associated with shipping and handling of procured items and procured software are discussed in implementing procedures and reflected in this document.

Appendix A provides a roadmap depicting the sections of the QAP that cover individual parts of the ASME NQA-1-2008/09a requirements, DOE O 414.1D, Quality Assurance criteria, and QMS program elements per American National Standards Institute/International Organization for Standardization/American Society for Quality (ANSI/ISO/ASQ) Q9001-2000, Quality Management System – Requirements. Criteria addressed under the DOE O 414.1D and Subpart A of 10 Code of Federal Regulations (CFR) 830, Nuclear Safety Management, mirror each other in intent and are identified in this QAP revision as DOE O 414.1D /Section 120 of 10 CFR 830. Additionally, this QAP implements the requirements of Parsons’ Quality Manual, which is compliant with ISO 9001:2015, Quality management systems - Requirements.

SWPF Project Procedures (PPs) that describe the means and methods for implementation of this QAP are available in the SWPF Project Procedures Manual, with electronic copies located on the SWPF Project Collaboration Portal (SALT PCP) website. The PPs and Department Procedures (DPs) describe the means and methods for implementation of the QAP. The PPs and applicable DPs are cross-referenced against the contractually invoked standards as part of the Programmatic Compliance Assessment Report (PCAR) generated per PP-AS-1200, SWPF S/RID Maintenance and Compliance as part of S-RCP-J-00001, SWPF Standards/Requirements Identification Document (S/RID). PCARs are maintained electronically on SALT PCP. Programmatic compliance is mandatory for all S/RID requirements.

Integration of Safety Management

This QAP describes the QMS for SWPF. This QAP also supports implementation of DOE P 450.4, Safety Management System Policy, by addressing SWPF Integrated Safety Management System (ISMS) requirements for the development of hazard controls, process and product quality, and safe performance of work within controls established by approved procedures and work instructions. The QMS provides tools for ensuring that ISMS objectives are achieved. DOE P 450.4 expresses a fundamental expectation that all work meets established requirements. In this regard, the QMS ensures compliance with the approved safety standards, so the expectation for safe work within controls is met. This also provides reasonable assurance that workers, the environment, and the public are protected from harm.

Graded Application of Quality Assurance Requirements

A graded approach that does not compromise public, employee, or facility safety or adversely impact the environment and complies with requirements, rules, and regulations is used to implement this QAP. The graded application of requirements is dependent on the hazards and/or risks associated with the service or other activities related to structures, systems, and components (SSCs) under consideration. The scope, depth, and rigor of the QMS application are determined by use of a grading process before performing the activity.
The purpose of grading is to select the controls and verifications to be applied to various items and services consistent with their importance to safety, cost, schedule, and success of the program. The grading process is not used to obtain exemptions from requirements of this QAP; however, it will be used to establish varying degrees of control and verification for items and services to ensure compliance with requirements.

The graded approach is defined in Appendix D.

**Quality Assurance Standards’ Application**

**NOTE:** See Appendix B: “Terms and Definitions” (e.g., functional classification, Safety Class [SC], safety function, Safety Significant [SS], General Service [GS], procurement level, commercial grade items [CGIs] and services, engineered items, etc.).

This QAP describes the QMS requirements for the SWPF, utilizing two quality standards to fully meet the DOE O 414.1D and 10 CFR 830.120 objectives:

1. ASME NQA-1-2008/09a³ Part I and Part II requirements:
   a) ASME NQA-1-2008/09a³ Part I focuses on the achievement of results, emphasizes the role of the individual and line management in the achievement of quality, and fosters the application of these requirements in a manner consistent with the relative importance of the item or activity;
   b) ASME NQA-1-2008/09a³ Part II supplements the requirements of Part I for the planning and execution of identified tasks; and

2. ANSI/ISO/ASQ Q9001-2000⁵ emphasizes management responsibilities for continual improvement and customer satisfaction and seeks to achieve quality by promoting the adoption of a process approach when developing, implementing, and improving the effectiveness of a QMS.

The program requirements of ANSI/ISO/ASQ Q9001-2000⁵ that are not relatable to ASME NQA-1-2008/09a³ (see Appendix A) shall be executed by using a graded approach.

Management shall establish and implement instructions, procedures, drawings, specifications, and/or other design output documents used to define technical and quality requirements of SSCs and computer programs, to address those described by this QAP, which includes a description of the SSC functional classification methodology as defined in PP-NS-5501, *Functional Classification Methodology*⁹, and SSC procurement levels as defined in PP-PR-6013, *Procurement Pre-Planning Process*⁹, as well as service procurement levels that are based on the risks associated with a service. These procedures shall be applied in a graded application with emphasis on quality requirements for items and services that could affect the safety function of SSCs.

The applicable ASME NQA-1-2008/09a³ requirements shall be fully implemented for SSCs that are functionally classified as SC or SS, and to those activities that may affect the safety function
of the SC or SS SSCs. The applicable ASME NQA-1-2008/09a\(^3\) requirements shall be flowed down to suppliers that are involved with SC or SS items or services.

ASME NQA-1-2008/09a\(^3\) requirements shall be applied by using a graded application for engineered items and their associated activities that are functionally classified as GS. The graded application shall consider the QMS program element requirements for GS engineered items and their activities and may flow down ASME NQA-1-2008/09a\(^3\) general requirements (Section 100 as a minimum) to its suppliers of items and services functionally classified as GS. If ASME NQA-1-2008/09a\(^3\) is not the appropriate quality standard for flow down, a commercially accepted standard may be chosen for items and services functionally classified as GS with the approval of the QA Manager.

Suppliers providing CGIIs that are functionally classified as GS shall provide items that are of standard commercial quality (see Appendix B), as a minimum requirement.

**Terms and Definitions**

Definitions provided in Appendix B are derived from 10 CFR 830\(^6\), DOE O 414.1D\(^4\), ASME NQA-1-2008/09a\(^3\), and ANSI/ISO/ASQ Q9001-2000\(^5\). When a difference in definition is noted, ASME NQA-1-2008/09a\(^3\) is the selected source for the definition.

**Quality Assurance Plan Review and Acceptance**

The QAP shall be submitted to DOE for review and approval. All QAP changes shall be approved by the Project Manager, and the revised QAP shall be resubmitted to DOE for approval at least annually, when QAP revision is required. The QMS Management Representative (MR) (see Section 1.3.4 of this QAP) has the authority and responsibility to revise the QAP.

Changes to the QAP shall be reviewed and approved by management.

**QAP Sections**

The requirements of 10 CFR 830\(^6\), DOE O 414.1D\(^4\), ASME NQA-1-2008/09a\(^3\), and ANSI/ISO/ASQ Q9001-2000\(^5\) have been incorporated in the QAP, with those deemed applicable identified by the individual QAP sections.

Personnel assigned to establish PPs and DPs for the implementation of requirements identified by this QAP shall review the referenced section(s) of documents listed under the “Program Basis” of each QAP section to ensure the applicable requirements are addressed by PPs and DPs.
1.0 ORGANIZATION

1.1 Program Basis

This QAP section identifies requirements for QMS implementation that are described by:

1. Part I, Requirement 1 of ASME NQA-1-2008/09a;
2. Criterion 1 and Criterion 10 of DOE O 414.1D/10 CFR 830.120; and
3. QMS Program Elements 4.0, 4.1, 5.0, 5.1, 5.5.1, and 5.5.2 of ANSI/ISO/ASQ Q9001-2000.

1.2 General

The roles and responsibilities for establishment and implementation of the QA program shall be defined, with the organizational structure, functional responsibilities, levels of authority, lines of communication for activities affecting quality, and interfaces for those managing, performing, and assessing work shall be documented.

1.3 Structure and Responsibility

The organizational roles and responsibilities of management personnel, line management, and other key personnel are defined in V-IM-J-00001, SWPF Organization, Roles, and Responsibilities Manual, as well as in other personnel position description documents. Specific responsibilities for positions identified in this QAP are summarized below.

1.3.1 Executive Management

Executive management takes a leading and visible role in defining, implementing, administering, and improving the QMS, with the goal of meeting all customer requirements. Executive management establishes the overall expectations for effective implementation of the QA program and is responsible for obtaining the desired end result. Executive management will ensure that quality is achieved and maintained by those assigned responsibility for performing work and those responsible for verifying quality achievement have sufficient authority, direct access to management, organizational freedom, and access to work to perform their function. The individuals responsible for establishing and executing a QA program may delegate any or all of the work to others but shall retain responsibility.

1.3.2 Project Manager

The Project Manager is responsible for controlling processes affecting safety, quality, schedule, cost, and environmental compliance. This responsibility includes directing implementation of this QAP.
1.3.3 Line Managers and Supervisors

Line managers and supervisors are responsible for meeting requirements, achieving quality of the work, and implementing this QAP.

1.3.4 QA Manager/Management Representative

The Project Manager has appointed the QA Manager as the QMS MR to establish and maintain the QAP and assess its implementation. The MR shall verify that instructions, DPs, PPs, and drawings required by the QAP are developed and implemented for the QMS.

The QA Manager reports to the Project Manager and has sufficient authority for the QMS, access to work areas, organizational freedom, and independence to accomplish the following, while verifying quality achievement:

- Identify quality problems and initiate, recommend, or provide solutions;
- Verify implementation of solutions;
- Reporting on the performance of the QMS and identifying needed improvements;
- Ensuring awareness of customer requirements by the organization;
- Verify that nonconforming or indeterminate conditions are being controlled in accordance with written procedures to preclude inadvertent use until disposition actions are implemented as prescribed and satisfactorily accomplished; and
- Access levels of management required to resolve identified problems.

The QA organizational structure includes the QA Manager who has a direct reporting relationship to the Parsons Vice President of QA and the Project Manager. The QA Manager’s direct reports include the Quality Control (QC) Manager and other managers, leads, and/or supervisory personnel assigned to Quality Department functions. The Quality Department includes a combination of QC Inspectors, Quality Engineers, and subcontract personnel. All Quality Department personnel, including subcontractors, have direct access to the QA Manager which enables the organization the ability to remain independent from cost and schedule considerations.

1.3.5 SWPF Personnel

Personnel are responsible for their work while achieving quality results and shall confirm that activities affecting quality have been correctly performed. Individuals who produce an item or perform an activity and their immediate management have direct and final responsibility for the quality of the item or activity.

All personnel have the authority to stop work in accordance with procedures when an item or activity is nonconforming with applicable requirements, or in instances where environmental protection, human health, or safety are in jeopardy.
1.3.6 Quality Assurance Personnel

QA personnel performing audits or independent assessment activities shall not be directly responsible for producing the item or completing the activity, but shall be responsible for the verification of quality achievement.

1.4 Organizational Structure and Quality Assurance Functions

QA is an interdisciplinary function involving many organizational components and should not, therefore, be regarded as the sole domain of a single QA Group. The QA Group is, however, designated to describe, integrate, and monitor the QMS activities of various disciplines and functions. The achievement of quality in all activities is the responsibility of all employees and is led by management.

The QAP provides for a systematic approach at various levels for oversight and assessment to ensure the adequacy and effectiveness of implementation of the QAP and all implementing procedures. A tiered approach to verification and assessment includes self-checking by the individuals performing the work, supervision and review by leaders, independent inspection, surveillance, and verification to confirm adequacy and effectiveness of results. Managers are required to assess the effectiveness of their own operations, implementation of their portion of the QAP, and regulatory programs. QA personnel perform audits and independent assessments to review, evaluate, and verify effectiveness of the QAP implementation.

1.5 Interface Control

The SWPF team is an integrated organization. The Project Manager is the primary interface with the DOE-Savannah River (DOE-SR) Federal Project Director and the DOE-SR Contracting Officer for all programmatic and Contract (DE-AC09-02SR222101) performance matters. The Director of Engineering is the primary interface with DOE-SR for design issues, and interfaces with the DOE-SWPF Chief Engineer concerning design/technical matters. The Director of Construction is the primary interface with DOE-SR for construction work execution issues, and interfaces with the DOE-SWPF Construction Manager on construction work execution matters. The Project Controls Manager shall interface with the DOE-SR Project Controls Specialist in matters related to cost and schedule performance. Other team management personnel are responsible for maintaining routine communication interfaces with designated DOE representatives. Responsibilities for clear and complete communications and coordination with DOE rest with all personnel.

Since more than one organization is involved in the execution of project activities, the responsibilities, interfaces, and authority of each organization are clearly defined and documented. SWPF interfaces are described in V-ESR-J-00025, SWPF Interface Management Plan13, including those for management, performance, and assessment of work.

The SWPF external interfaces between organizations and the internal interfaces between organizational units, and changes thereto, are also documented.
1.5.1  Request for Information

DOE-SR shall manage the SWPF interface with the SRS contractors. Executive management shall identify and document information or support requirements that need to be provided to or by the SRS contractor to the DOE-SR staff. DOE-SR is responsible for ensuring that the exchange of information between the SRS contractor and SWPF is consistent with the Contract (DE-AC09-02SR22210) and DOE policy.

Requests for Information (RFI) are processed in accordance with SWPF procedures. RFIs, once developed, are forwarded through Engineering, Procurement, and Construction Document Control and to DOE Document Control, where they are tracked to completion by DOE.

2.0  QUALITY ASSURANCE PROGRAM

2.1  Program Basis

This QAP section identifies requirements for QMS implementation that are described by:

1. Part I, Requirement 2 of ASME NQA-1-2008/09a;
2. Criterion 1, 2, 3, 9, and 10 of DOE O 414.1D; and
3. QMS Program Elements 4.1, 4.2.1, 4.2.2, 5.2, 5.4, 5.5.3, 5.6, 6.1, 6.2, 6.3, 6.4, 7.1, 7.2, 8.2.1, 8.2.3, 8.4, and 8.5.1 of ANSI/ISO/ASQ Q9001-2000.

2.1.1  General

The QA Program consists of those planned and systematic actions necessary to ensure that activities will be conducted in a satisfactory manner and systems and components will perform satisfactorily in service. The QA Program was established at the earliest time consistent with the schedule for accomplishing SWPF activities and applies to the operations of the SWPF. This QAP provides control over activities affecting quality to an extent consistent with their importance, including monitoring activities against acceptance criteria in a manner sufficient to provide assurance that the activities affecting quality are performed satisfactorily.

The QMS is based on the concept that work performance is a process that can be planned, performed, assessed, and improved. Executive management is responsible for these ongoing activities. Because all work is accomplished by using the resources of people, equipment, and procedures as directed by management, management is responsible for fostering an attitude of support and encouraging personnel to complete their work in a quality manner. All employees are responsible for identifying and reporting noncompliant work or areas for improvement. Management is responsible for identifying (both internal and external) customer needs and expectations. Meeting these needs and expectations is a measure of quality and success with the aim of enhancing customer satisfaction.
2.2 Resource Management

The Project Manager shall make certain that adequate physical and human resources are available to meet all requirements for achieving the quality of the work and implementing the QMS. Management shall provide for the planning and accomplishment of activities affecting quality under suitably controlled conditions. Controlled conditions include the use of appropriate equipment, suitable environmental conditions for accomplishing the activity, and assurance that prerequisites for the given activity have been satisfied. Management shall provide for any special controls, processes, test equipment, tools, and skills to attain the required quality of activities and items, and for verification of that quality, including establishing and implementing processes to detect and correct quality problems.

Indoctrination, training, and qualification as necessary of personnel performing or managing activities affecting quality to ensure that suitable proficiency is achieved and maintained shall be provided. Indoctrination and training shall be commensurate with the scope, complexity, importance of the activities, and the education, experience, and proficiency of the person. Management shall establish and document the competencies of its personnel performing activities affecting quality in accordance with PL-TR-1801, SWPF Personnel Selection, Training, and Qualification Plan\textsuperscript{14}.

Personnel performing quality functions shall have sufficient competence, qualifications, authority, and organizational freedom to identify quality problems, and initiate and recommend solutions.

2.2.1 Competence, Awareness, and Training

Management is responsible for committing resources to facilitate training and qualification processes for personnel in their organizations and ensuring that personnel hired or transferred into positions meet the established requirements. Each level of the organization shall adequately describe its training and qualification needs. Management shall:

- Determine the necessary competence for personnel performing work affecting product or process quality,
- Where applicable, provide training or take other actions to satisfy these needs,
- Evaluate the effectiveness of the actions taken,
- Ensure personnel are aware of the relevance and importance of their activities, including how they contribute to achievement of the quality objectives, and
- Maintain appropriate records of education, training, skills, and experience.

Professional personnel shall meet the requirements defined by position descriptions.
2.3 Training and Qualification

SWPF personnel performing or managing activities affecting quality shall receive indoctrination in their job responsibilities and authority, general criteria, technical objectives, including applicable codes and standards, regulatory commitments, company procedures, and QA program requirements.

The definition of work requirements, individual work tasks, and their collection into a work process shall be used to determine the individual and collective training and qualification needs. The need for a formal training program for personnel performing or managing activities affecting quality shall be determined. Training shall be provided, if needed, to achieve initial proficiency, maintain proficiency, and adapt to changes in technology, methods, or job responsibilities.

The accumulation of knowledge and skills through experience is an effective way of becoming proficient in a work activity. On-the-job training (including mentoring) is an effective training method and shall be documented, as is classroom training. On-the-job training shall be used if direct hands-on applications or experience is needed to achieve and maintain proficiency.

Demonstrated proficiency and consistent performance are two primary measures of good training and qualification practices. Controlling process variability may be a good indication that the training and qualification practices are adequate to reach performance objectives.

2.3.1 Training/SWPF Orientation

Training programs shall be developed to provide personnel with an understanding of the processes and tools required to effectively perform tasks. Training shall emphasize the correct performance of work. Training shall also provide an understanding of the importance of the work and why the quality requirements exist. Training shall focus attention on error prevention and doing work right the first time, and also address the potential consequences of improper work. Assigned personnel shall receive SWPF orientation and shall be trained to the requirements and how these requirements contribute to achievement of the quality objectives specified for the QMS.

2.3.2 Training/Qualification Requirements

Management shall designate those activities that require qualification of personnel and the minimum requirements for such personnel. The responsible organization shall establish written procedures for the qualification of personnel, and for the assurance that only those personnel who meet the requirements are permitted to perform these activities.

SWPF personnel performing work shall be capable of performing assigned tasks. Training requirements shall be developed and implemented for personnel and for specific job categories, as appropriate to the scope of work (SOW) to which they shall be assigned. Qualification requirements are established for specific job categories such as designers, engineers, technical support personnel, inspectors, procurement specialists, welders, nondestructive examination
(NDE) specialists, test engineers, operators, maintenance technicians, auditors, and QA personnel.

Training shall be presented by qualified trainers or instructors. The training program shall provide for initial training, continuing training, and maintaining job proficiency of personnel. This training may include the SWPF training programs, company-sponsored continuing education, professional society/institutional training, conference attendance, personal mentoring programs, and SRS-specific training.

Training related to access to SRS and specific Site areas and buildings may be conducted by the SRS contractor and will be coordinated with DOE-SR. Training may include (as appropriate to the individual):

- General employee training,
- Facility indoctrination training,
- Consolidated annual training, and/or
- Radiation worker training.

SWPF-specific training shall include, as appropriate to the individual’s responsibilities, indoctrination, and training covering SWPF documents, including procedures and other documents as determined by management. For personnel performing work requiring special skills or abilities, personnel shall be qualified and, when required, certified prior to performing that work.

2.3.3 Nondestructive Examination

All personnel performing NDE shall be qualified and certified in accordance with the American Society of Nondestructive Testing (ASNT) Recommended Practice No. SNT-TC-1A Nondestructive Testing\textsuperscript{15}, and its applicable supplements. Each candidate shall be evaluated based on education, experience, training, capability demonstration, and test results. The details of this process are defined in PL-QA-4701, *SWPF NDT Training, Examination, and Certification Plan*\textsuperscript{16}.

2.3.4 Inspection and Test

Qualified personnel that are to be certified as QC Inspectors per PL-QC-4800, *SWPF Quality Control Inspector Qualification/Certification Plan*\textsuperscript{17}, or Test personnel shall meet the qualification requirements established by procedures for certification, including considerations for:

- Past or current certification,
- Visual acuity, and
- Education and related experience.
The initial capabilities of a candidate shall be determined by an evaluation of the candidate’s education, experience, training, and either test results or capability demonstration. The job performance of inspection and test personnel shall be reevaluated and documented at periodic intervals not to exceed 3 years. Reevaluation shall be by evidence of continued satisfactory performance or redetermination of capability. If during this evaluation or at any other time it is determined that the capabilities of an individual are not in accordance with the qualification requirements specified for the job, that person shall be removed from that activity until such time as the required capability has been demonstrated. Any person who has not performed inspection or testing activities in the qualified area for a period of 1 year shall be reevaluated prior to performing these duties.

2.3.5 Lead Auditor

The prospective Lead Auditor shall meet the qualification and certification requirements established by procedures prior to designation as a Lead Auditor, in addition to organizing and directing audits, reporting audit findings, and evaluating corrective actions.

The prospective Lead Auditor shall be capable of communicating effectively, both in writing and orally. These skills shall be attested to in writing by the Lead Auditor’s employer.

Prospective Lead Auditors shall receive training to the extent necessary to assure auditing competence including:

- Knowledge and understanding of this QAP and other nuclear-related codes, standards, regulations, and regulatory guides, as applicable.
- General structure of QA programs and its applicable elements as defined in this QAP.
- Auditing techniques of examining, questioning, evaluating, and reporting; methods of identifying and following up on corrective action items; and closing out audit findings.
- Planning audits of activities affecting quality.
- On-the-job training to include applicable elements of the audit program.

Prospective Lead Auditors shall participate in a minimum of five QA audits within a period of time not to exceed 3 years prior to the date of qualification, one audit of which shall be a nuclear QA audit within the year prior to qualification.

Participation in independent assessments including team assessment activities such as operations readiness reviews and regulatory inspections/surveys may be used to satisfy up to four of the five required QA audits, provided that the activities can demonstrate the following:

- Independence from the functional areas being assessed.
- Planning that establishes the scope of the activities and associated evaluation criteria.
- Performance by technically qualified and experienced personnel.
• Results that are documented and reported to management.
• Appropriate corrective action initiated and tracked to resolution.

Such participation shall be subject to review and acceptance by the organization responsible for QA audits and/or the certifying authority prior to their use for qualification.

Prospective Lead Auditors shall pass an examination which shall evaluate comprehension of and ability to apply the body of knowledge identified above. The examination may be oral, written, practical, or any combination thereof.

Lead Auditors shall maintain their proficiency through one or more of the following:

• Regular and active participation in the audit process.
• Review and study of codes, standards, procedures, instructions, and other documents related to QA program and program auditing.
• Participation in training program(s).

Based on annual assessment, management may extend the qualification, require retraining, or require requalification.

Lead Auditors who fail to maintain their proficiency for a period of 2 years or more shall require requalification. Requalification shall include retraining, reexamination, and participation as an Auditor in at least one nuclear QA audit.

2.3.6 Auditor

Auditors are participants in an audit. Auditors shall have, or be given, appropriate training or orientation to develop their competence for performing audits. Competence of personnel for performance of the various auditing functions shall be developed by one or more of the following methods:

• Orientation to provide a working knowledge and understanding of the QAP and the auditing organization’s procedures for implementing audits and reporting results.

• General and specialized training in audit performance where the general training shall include fundamentals, objectives, characteristics, organization, performance, and results of quality auditing and the specialized training shall include methods of examining, questioning, evaluating, and documenting specific audit items and methods of closing audit findings.

• On-the-job training, guidance, and counseling under the direct supervision of a Lead Auditor. Such training shall include planning, performing, reporting, and follow-up action involved in conducting audits.
2.3.7 Technical Specialists

The responsible auditing organization shall establish the qualifications and requirements for use of technical specialists to accomplish the auditing of QA programs.

2.3.8 Certification

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

- Employer’s name;
- Identification of person being certified;
- Activities certified to perform;
- Basis of qualification;
  - Education, experience, indoctrination, and training;
  - Test results, where applicable; and
  - Capability demonstration results.
- Results of periodic evaluation;
- Results of physical examinations, when required;
- Signature of employer’s designated representative who is responsible for such certification; and
- Date of certification or recertification and certification expiration.

The responsible organization shall identify any special physical characteristics needed in the performance of each activity, including the need for initial and subsequent physical examination.

The employer may delegate qualification examination activities to an independent certifying agency, or teaming partner, but shall retain responsibility for conformance of the examination and its administration. Integrity of the examination shall be maintained by the employer or certifying agency through appropriate confidentiality of files and, where applicable, proctoring of examinations. Copies of the objective evidence regarding the type(s) and content of the examination(s) shall be retained as QA records.

2.3.9 Records

Records of implementation for indoctrination and training may take the form of attendance sheets, training logs, or personnel training records. Records of indoctrination and training shall include one or more of the following: a) attendance sheets; b) training logs; c) personnel training records. Records for indoctrination and training; Auditor and Lead Auditor qualification and
requalification; and inspection and test personnel qualification and requalification shall be established and maintained in accordance with Section 17.0 of this QAP.

2.4 Infrastructure and Work Environment

The Project Manager shall identify the necessary infrastructure and work environment such as buildings, workspace, utilities, process equipment (both hardware and software), and supporting devices (such as transport or communication) to achieve conformity of products and services.

2.5 Management Review

Management shall regularly assess the adequacy and effective implementation of the QA program. The Project Manager shall ensure that, at planned intervals, management reviews (assessments) of the QMS are performed to ensure its continued suitability, adequacy, and effectiveness. These reviews shall focus on how well the QMS accomplishes its quality objectives and how effective it is in identifying any management problems that hinder achieving these objectives.

Managers shall monitor and perform assessments of processes within their areas of responsibility to ensure that problems, which could hinder the organization from achieving its objectives, are identified and corrected without delay and address improvements to management systems. A review shall include, as appropriate, audit and other independent assessment results since the last review, customer feedback, process performance data, product conformity, status of preventive and corrective actions, follow-up actions from the previous management review, recommendations provided for improvements, and changes that could affect the QMS. All QAP change recommendations that are a result of management review shall be forwarded to the QMS MR.

These reviews shall be of sufficient detail to cover relevant activities and shall include any decisions and actions relating to improvements in the effectiveness of the QMS and its processes, improvement of products relating to DOE requirements, and resource needs. Records of these reviews shall be maintained as part of the Project record files in accordance with Section 17.0 of this QAP.

2.5.1 Assessment of Performance

Work task objectives should be clearly established with in-process and final acceptance criteria. Progress toward meeting objectives should be measured against parameters that are meaningful to the work process. If work tasks, performance objectives, and work responsibilities have been defined, performance measurement should automatically follow.

Those doing work should have first-line responsibility for the acceptability of their work and managers should regularly assess work performance.

Management assessments can be continuous measurements of performance or periodic efforts, depending on the SOW and process complexity, as well as risk management considerations.
A clear understanding of hazards and risks of achieving or not achieving work objectives should be used as the basis for establishing a management assessment process, and the nature of that process.

Frequently, a well-developed (and well-coordinated) management assessment process can be linked to customer reporting needs to avoid duplicate performance measurement programs.

Management may choose to use individuals who have no direct responsibility for accomplishing work tasks or objectives to assist in the management assessment process. Assessments can have a process or technical focus, depending on the nature and scope of the assessment. In either case, the individual performing the assessment should have assessment skills, as well as work process and product/customer understanding, to conduct an effective assessment.

2.6 Independent Assessment

Independent assessments shall be planned in accordance with PL-AS-1001, *SWPF Integrated Assessment Program Plan*\(^\text{18}\), and conducted to measure item and service quality and the adequacy of work performance and to promote improvement, taking into consideration the status and importance of the processes and areas to be assessed, as well as the results of previous assessments. The assessment criteria, scope, frequency, and methods shall be defined, conducted at planned intervals, and include assessment of self-performed work and activities of suppliers participating in the work.

Selection of assessors and conduct of assessments shall ensure objectivity and impartiality of the assessment process. Assessors shall not assess their own work. Assessors shall be technically qualified and knowledgeable in the areas to be assessed. Assessment teams shall have sufficient authority and freedom from line management.

Management shall establish and implement procedures for defining the responsibilities and requirements for planning and conducting assessments, and for reporting results and maintaining records. The manager responsible for the subject matter area being assessed shall ensure that actions are taken without undue delay to eliminate any detected nonconformance and its cause. Follow-up activities shall include the verification of the action(s) taken and the reporting of verification results.

Records of the results of the assessments and any necessary actions shall be retained as records, in accordance with Section 17.0 of this QAP.

3.0 DESIGN CONTROL

3.1 Program Basis

This QAP section identifies requirements for QMS implementation that are described by:

1. Part I, Requirement 3 of ASME NQA-1-2008/09a\(^3\),
2. Criterion 6 of DOE O 414.1D⁴, and
3. QMS Program Element 7.3 of ANSI/ISO/ASQ Q9001-2000⁵.

3.1.1 General

The design shall be defined, controlled, and verified. Design inputs shall be specified on a timely basis and translated into design documents. Design interfaces shall be identified and controlled. Design adequacy shall be verified by individuals other than those who designed the item or computer program. Design changes shall be governed by control measures commensurate with those applied to the original design.

Designed processes and items shall use sound engineering/scientific principles, as well as appropriate codes, standards, and applicable design basis. The design basis will be identified and controlled to accurately reflect the functional design characteristics and margins.

3.2 Design Input

Applicable design inputs shall be identified and documented, and their selection reviewed and approved. The design input shall be specified to the level of detail necessary to permit the design activities to be carried out in a correct manner and to provide a consistent basis for making design decisions, accomplishing design verification measures, and evaluating design changes. Design input shall include the following based on the type of work:

- Functional and performance requirements;
- Applicable statutory and regulatory requirements;
- Where applicable, information derived from previous similar designs; and
- Other requirements essential for design and development.

Requirements shall be complete, unambiguous, and not in conflict with each other.

3.3 Design Process

The responsible design organization shall prescribe and document the design activities to the level of detail necessary to permit the design process to be carried out in a correct manner, and to permit verification that the design meets requirements. Design documents shall support facility design, construction, and operation.

The design methods, materials, parts, equipment, and processes that are essential to the function of the items shall be selected and reviewed for suitability of application. Applicable information derived from experience, as set forth in reports or other documentation, shall be made available to cognizant design personnel. The final design shall be relatable to the design input by documentation in sufficient detail to permit design verification; specify required inspections and tests and include or reference appropriate acceptance criteria; and identify assemblies and/or components that are part of the item being designed. When such an assembly or component part
is a CGI that will perform a safety function, the critical characteristics of the item to be verified for acceptance and the acceptance criteria for those characteristics shall be documented and shall meet the requirements of Part II, Subpart 2.14 of ASME NQA-1-2008/09a\(^3\).

Critical characteristics to be verified are those which provide reasonable assurance that the item will perform its intended function. If a CGI, prior to its installation, is modified or selected by special inspection and/or testing to requirements that are more restrictive than the Supplier’s published product description, the component part shall be represented as different from the CGI in a manner traceable to a documented definition of the difference.

The design process shall make certain that the products produced meet specified design requirements. Management shall establish and implement instructions, procedures, and drawings that describe the design process, and define the installation, inspection, and testing requirements for SSCs.

### 3.4 Design Output

Design methods, materials, parts, equipment, and processes shall be selected for the preparation, release, and revision of design outputs. Design outputs (e.g., drawings, specifications, design analyses, equipment lists, data sheets, calculations, Computer Aided Design models) shall be provided in a form that enables verification against the design input and shall be approved prior to release. Design outputs shall:

- Meet input requirements for design and development;
- Provide appropriate information for purchasing, production, and service provisions;
- Contain or reference product acceptance criteria; and
- Specify characteristics of the product that are essential for its safe and proper use.

### 3.5 Design Analyses

Design analyses shall be sufficiently detailed such that a person technically qualified in the subject can review and understand the analyses and verify the adequacy of the results without recourse to the originator.

To the extent required, computer program acceptability shall be pre-verified or the results verified with the design analysis for each application. Pre-verified computer programs shall be controlled in accordance with the requirements of this QAP. The computer program shall be verified to show that it produces correct solutions for the encoded mathematical model within defined limits for each parameter employed. Also, the encoded mathematical model shall be shown to produce a valid solution to the physical problem associated with the particular application.
3.5.1 Documentation of Design Analyses

Design analyses shall be documented as described by SWPF procedures. Documentation of design analyses shall include the objective of the analyses; design inputs and their sources; results of literature searches or other applicable background data; assumptions and indication of those assumptions that must be verified as the design proceeds; identification of any computer calculation, including identification of the computer type, computer program name, and revision, inputs, outputs, evidence of or reference to computer program verification, and the bases (of reference thereto) supporting application of the computer program to the specific physical problem; and review and approval.

3.6 Design Verification

The responsible design organization shall identify and document the particular design verification method(s) used. The results of design verification shall be documented with the identification of the verifier clearly indicated. Design verification shall be performed by any competent individual(s) or group(s) other than those who performed the original design but who may be from the same organization, and shall have access to pertinent background information or data to base its approval. This verification may be performed by the originator’s supervisor, provided the supervisor did not specify a singular design approach or rule out certain design considerations and did not establish the design inputs used in the design; or the supervisor is the only individual in the organization competent to perform the verification. Cursory supervisory reviews do not satisfy the intent of this QAP.

Design verification shall be performed prior to releasing the design for procurement, manufacture, construction, or use by another design organization, except where this timing cannot be met, such as when insufficient data exist. In those cases, the unverified portion of the design shall be identified and controlled. In all cases the design verification shall be completed prior to relying upon the SSC, or computer program to perform its function. If the design is modified to resolve verification findings, the modified design shall be verified prior to release or use.

The extent of the design verification shall be a function of the importance to safety, the complexity of the design, the degree of standardization, the state of the art, and the similarity with previously proved designs. Where the design has been subjected to a verification process in accordance with this QAP, the verification process need not be duplicated for identical designs. However, the applicability of standardized or previously proven designs, with respect to meeting pertinent design inputs, shall be verified for each application. Known problems affecting the standard or previously proved designs and their effects on other features shall be considered. The original design and associated verification documentation shall be referenced in records of subsequent application of the design.

Acceptable verification methods include, but are not limited to, any one or a combination of the following:

- Design reviews,
• Alternate calculations, and
• Qualification testing.

3.6.1 Design Reviews

Design reviews shall provide assurance that the final design is correct and satisfactory, in accordance with the following, where applicable:

• Were the design inputs correctly selected?
• Are assumptions necessary to perform the design activity adequately described and reasonable? Where necessary, are the assumptions identified for subsequent reverifications when the detailed design activities are completed?
• Were appropriate design methods and computer programs used?
• Were the design inputs correctly incorporated into the design?
• Is the design output reasonable compared to design inputs?
• Are the necessary design inputs for interfacing organizations specified in the design documents or in supporting procedures or instructions?
• Have suitable materials, parts, processes, and inspection and testing criteria been specified?

At suitable stages, systematic reviews of the design shall be performed in accordance with Intradiscipline Check and Interdiscipline Review guidelines established by Engineering, Procurement, and Construction Contractor procedures to:

• Evaluate the ability of design results to meet requirements,
• Identify any problems, and
• Propose necessary actions.

Participants in Interdiscipline Reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. A record of design reviews shall be maintained to document the results of review.

3.6.2 Alternate Calculations

Alternate calculations shall use alternate methods to verify correctness of the original calculations or analyses. The appropriateness of assumptions; input data used; and the computer program, its associated computer hardware and system software, or other calculation method used shall also be reviewed.

3.6.3 Qualification Tests

Testing shall demonstrate adequacy of performance under conditions that simulate the most adverse design conditions. Where the test is intended to verify only specific design features, the
other features of the design shall be verified by other means. When tests are being performed on models or mockups, scaling laws shall be established and verified. The results of model test work shall be subject to error analysis, where applicable, prior to use in the final design.

3.7 Design Validation

Design and development validation shall be performed to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use. Wherever practicable, validation shall be completed prior to the delivery or implementation of the product. Records of validation results and any necessary actions shall be maintained.

3.8 Change Control

Changes to design inputs, final designs, field changes, and temporary and permanent modifications to the SWPF during operations shall be justified and subject to design control measures commensurate with those applied to the original design. These measures shall include evaluation of effects of those changes on the overall design and on any analysis upon which the design is based. The evaluation shall include facility configurations that occur during operation, maintenance, test, surveillance, and inspection activities. The design organization approving the change shall have demonstrated competence in the specific design area of interest and have an adequate understanding of the requirements and intent of the original design.

When a design change is approved other than by revision to the affected design documents, measures shall be established to incorporate the change into these documents, where such incorporation is appropriate.

Where a significant design change is necessary because of an incorrect design, the design process and verification procedure shall be reviewed and modified as necessary.

3.9 Configuration Management for SWPF Operations

Procedures implementing configuration management requirements shall be established and documented at the earliest practical time prior to facility operation. These procedures shall include the responsibilities and authority of the organizations whose functions affect the configuration of the facility including activities such as operations, design, maintenance, construction, licensing, and procurement. The SWPF configuration management requirements are detailed in P-CDM-J-00001, SWPF Configuration Management Plan19.

1. Configuration management requirements shall include measures to ensure changes that may affect the approved configuration are recognized and processed.
2. The configuration shall be established and approved at the earliest practical time prior to initial operation of the facility, and maintained for the life of the facility.
3. The configuration shall include, as applicable, characteristics derived from regulatory requirements and commitments, calculations and analyses, design inputs, installation and test
requirements, supplier manuals and instructions, operating and maintenance requirements, and other applicable sources.

4. Interface controls shall include the integration of activities of organizations that can affect the approved configuration.

5. Documentation shall identify the design bases and the approved configuration for the approved modes of operation.

6. Measures shall be established and implemented to ensure that proposed changes to the configuration are evaluated for their conformance to the design bases.

7. The implementation sequence for approved configuration changes shall be reviewed to determine that the configuration conforms to the design bases.

8. Approval by the design authority shall be required prior to implementation of a change to the design bases.

9. The configuration of the facility shall be documented in drawings, specifications, procedures, and other documents that reflect the operational status of the facility. The process used to control the current revision and issuance of these documents shall take into account the use of the document and the need for revision in support of operation.

3.10 Interface Control

The interfaces among different groups involved in the design to ensure effective communication and clear assignment of responsibility shall be managed via V-ESR-J-00001, SWPF Interface Control Document List, and V-ESR-J-00025.

Design information transmitted across interfaces shall identify the status of the design information or document provided, and will identify incomplete items that require further evaluation, review, or approval. Where it is necessary to initially transmit design information orally or by other informal means, the transmittal shall be confirmed promptly by a controlled document.

3.11 Software Design Control

The software design process shall be documented, approved by the responsible design organization, and controlled. Part II, Subpart 2.7 of ASME NQA-1-2008/09 provides work practice requirements to aid in the implementation of this section.

3.11.1 Identification of Software Design Requirements

Software design requirements shall be identified and documented and their selection reviewed and approved. The software requirements shall identify the operating system, function, interfaces, performance requirements, installation considerations, design inputs, and any design constraints of the computer program.
3.11.2 Software Design

The software design shall be documented and shall define the computational sequence necessary to meet the software requirements. The documentation shall include, as applicable, numerical methods, mathematical models, physical models, control flow, control logic, data flow, process flow, data structures, process structures, and the applicable relationships between data structures and process structures. This documentation may be combined with the documentation of the software design requirements, or the computer program listings resulting from implementation of the software design.

3.11.3 Implementation of Software Design

The software design shall be translated into computer program(s) using the programming organization’s or design organization’s programming standards and conventions.

3.11.4 Software Design Verification

Software design verification shall be performed by a competent individual(s) or group(s) other than those who developed and documented the original design, but who may be from the same organization. This verification may be performed by the originator’s supervisor, provided:

- The supervisor did not specify a singular design approach or rule out certain design considerations and did not establish the design inputs used in the design, or
- The supervisor is the only individual in the organization competent to perform the verification. Cursory supervisory reviews do not satisfy the intent of this QAP.

The results of verification shall be documented with the identification of the verifier indicated. Software verification methods shall include any one or a combination of design reviews, alternate calculations, and tests performed during computer program development. The extent of verification and the methods chosen are a function of the complexity of the software, the degree of standardization, the similarity with previously proved software, and the importance to safety.

3.11.5 Computer Program Testing

Computer program testing shall be performed in accordance with Section 11.0 of this QAP.

3.12 Software Configuration Management

Software configuration management includes, but is not limited to: configuration identification, change control, and status control. Configuration items shall be maintained under configuration management until the software is retired. The SWPF software configuration management requirements are identified in P-CDM-J-00001\textsuperscript{19} and PL-QA-4704, \textit{SWPF Software Quality Assurance Program Description}\textsuperscript{21}. 

\textsuperscript{19} SWPF Software Quality Assurance Program Description

\textsuperscript{21} SWPF Software Quality Assurance Program Description
3.12.1 Configuration Identification

A software baseline shall be established at the completion of each activity of the software design process. Approved changes created subsequent to a baseline shall be added to the baseline. A baseline shall define the most recently approved software configuration. A labeling system for configuration items shall be implemented that uniquely identifies each configuration item; identifies changes to configuration items by revision; and provides the ability to uniquely identify each configuration of the revised software available for use.

3.12.2 Configuration Change Control

Changes to software shall be formally documented. The documentation shall include:

- A description of the change,
- The rationale for the change, and
- The identification of affected software baselines.

The change shall be formally evaluated and approved by the organization responsible for the original design, unless an alternate organization has been given the authority to approve the changes. Only authorized changes shall be made to software baselines. Appropriate verification activities shall be performed for the change. The change shall be appropriately reflected in documentation, and traceability of the change to the software design requirement shall be maintained. Appropriate acceptance testing shall be performed for the change.

3.12.3 Configuration Status Control

The status of configuration items resulting from software design shall be maintained current. Configuration item changes shall be controlled until they are incorporated into the approved product baseline. The controls shall include a process for maintaining the status of changes that are proposed and approved, but not implemented. The controls shall also provide for notification of this information to affected organizations.

3.13 Documentation and Records

Design documentation and records shall include not only final design documents, such as drawings and specifications, and revisions to those documents, but also documentation that identifies the important steps in the design process, including sources of design inputs that support the final design.

4.0 PROCUREMENT DOCUMENT CONTROL

4.1 Program Basis

This QAP section identifies requirements for QMS implementation that are described by:
1. Part I, Requirement 4 of ASME NQA-1-2008/09; 
2. Criterion 7 of DOE O 414.1D; and 

4.2  Procurement Document Control Process

Procurement document control process shall be established for procured items and services in approved programs and procedures as delineated in PL-PR-6001, SWPF Acquisition Process System Description. Applicable design bases and other requirements necessary to assure adequate quality shall be included or referenced in items and services procurement documents. To the extent necessary, procurement documents require suppliers to adequately implement a Quality Program consistent with the requirements of this QAP applicable to the type and use of the item or service being purchased. Procurement documents shall be reviewed to ensure inclusion of appropriate requirements.

4.3  Content of the Procurement Documents

Procurement documents issued at all tiers of procurement shall include provisions for the following, as deemed necessary.

4.3.1  Scope of Work

Procurement documents shall include a statement of the scope of the work to be performed by the Supplier.

4.3.2  Technical Requirements

Technical requirements shall be specified in the procurement documents. These requirements shall be specified, as appropriate by reference to specific drawings, specifications, codes, standards, regulations, procedures, or instructions, including revisions thereto that describe the items or services to be furnished. The procurement documents shall identify appropriate test, inspection, and acceptance criteria for determining acceptability of the item or service. In addition, requirements will address appropriate security and health and safety criteria.

4.3.3  Quality Assurance Program Requirements

QA program requirements shall be specified in the procurement documents. These requirements shall be consistent with importance and/or complexity of the item or service being procured. The procurement documents shall require the Supplier to incorporate appropriate QA program requirements in sub tier procurement documents.
4.3.4 Right of Access

The procurement documents shall provide for access to the Supplier’s and sub tier Supplier’s facilities and records for surveillance, inspection, or audit by the Buyer’s designated representative and others authorized by the Buyer.

4.3.5 Documentation Requirements

The procurement documents shall identify the documentation required to be submitted for information, review, or approval. The time of submittal shall also be established. When the Supplier is required to maintain specific records, the retention times and disposition requirements shall be prescribed.

4.3.6 Nonconformances

The procurement documents shall specify the requirements for the Supplier’s reporting of nonconformances.

4.3.7 Spare and Replacement Parts

The procurement documents shall specify the Supplier’s requirements to identify spare and replacement parts or assemblies and the related data required for ordering these parts or assemblies.

4.4 Procurement Document Review

A review of the procurement documents, and changes thereto, shall be made and documented prior to award to assure that documents transmitted to prospective Supplier(s) include appropriate provisions to assure that items or services will meet the specified requirements.

Technical or QA program changes made as a result of bid evaluations or negotiations shall be incorporated into the procurement documents prior to their issuance to the Supplier.

Procurement document review shall be performed by personnel who have access to pertinent information and who have an adequate understanding of the requirements and intent of the procurement documents.

4.5 Procurement Document Changes

Procurement document changes affecting the technical or QA program requirements shall be subject to the same degree of control as utilized in the preparation of the original documents.

5.0 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

5.1 Program Basis

This QAP section identifies requirements for QMS implementation that are described by:
1. Part I, Requirement 5 of ASME NQA-1-2008/09a and
2. Criterion 4 and Criterion 5 of DOE O 414.1D.

5.1.1 General

Management shall ensure that activities affecting quality and services are prescribed by and performed in accordance with documented instructions, procedures, or drawings that include or reference appropriate quantitative or qualitative acceptance criteria for determining that prescribed results have been satisfactorily attained. The activity shall be described to a level of detail commensurate with the complexity of the activity and the need to assure consistent and acceptable results. The need for, and level of detail in, written procedures or instructions shall be determined based upon complexity of the task, the significance of the item or activity, work environment, and worker proficiency and capability (education, training, experience).

Instructions, procedures, and drawings shall be consistent with the technical, quality, administrative, and regulatory requirements and be formally approved for use.

Management is responsible for maintaining these documents current to reflect actual work practices. Instructions, procedures, and drawings shall be prepared, reviewed, issued, and controlled in accordance with approved procedures. Major changes to these documents receive the same levels of review as the original document (see Section 6.3 of this QAP for the definition of major change).

5.2 Management System

Managers shall ensure that required management system processes are planned and developed. Process planning shall determine the following, as appropriate:

- Quality objectives and requirements of the product;
- Need to establish processes, documents, and resources required for product realization;
- Required verification, validation, monitoring, inspection, and test activities specific to the product and acceptance criteria; and
- Records necessary to provide evidence of process implementation and compliance of the product.

The processes required to execute the SOW shall be identified (by instructions, procedures, drawings, etc.) for the following elements:

- Design transition,
- Facility and process design,
- Construction management and procurement,
- Acceptance testing,
• Facility pilot testing,
• Commissioning/Operations, and
• Maintenance of SSCs.

5.3 Process Control

A process control checklist, PP, and/or report may be used to record evidence of process implementation (such as demolition, grading, concrete placement, trenching and backfilling, cutting, welding, bolting, rigging, finishing, painting, operations, maintenance, etc.). The process control document shall address the following, as appropriate:

• Unique identification of product throughout the process;
• Detailed sequence of work to be performed or, when this is not possible, the protocols providing necessary management, engineering, quality, safety, and operational controls;
• Sequence, type, and extent of QC hold points or inspections and tests for each stage of the work cycle, as appropriate;
• Acceptance criteria for each process or function, as required;
• Use of appropriate equipment and a suitable working environment;
• Compliance with acceptance criteria, standards/codes, regulations, permits, vendor manuals, and procedures;
• Control and monitoring of process parameters and features (to include verification and validation of associated calculations and formulas);
• Suitable equipment maintenance to ensure process capability; and
• Personnel qualifications.

6.0 DOCUMENT CONTROL

6.1 Program Basis

This QAP section identifies requirements for QMS implementation that are described by:

1. Part I, Requirement 6 of ASME NQA-1-2008/09a;
2. Criterion 4 of DOE O 414.1D; and
6.2 Document Control Process

The preparation, issue, and change of documents that specify quality requirements or prescribe activities affecting quality such as instructions, procedures, and drawings shall be controlled to ensure that correct documents are being employed. Such documents, including changes thereto, shall be reviewed for adequacy and approved for release by authorized personnel.

Management shall establish and implement procedures for the control of documents used for implementing the QMS and for controlling the work. The following controls shall be applied to documents and changes thereto:

- Identification of controlled documents;
- Specified distribution of controlled documents for use at the appropriate location;
- Identification of individuals responsible for the preparation, review, approval, and distribution of controlled documents;
- Review of controlled documents for adequacy, completeness, and approval, prior to distribution;
- Method to ensure that correct documents are being used;
- Method to ensure that documents of external origin are identified and their distribution is controlled; and
- Unintended use of obsolete documents is prevented, and suitable identification is applied to obsolete documents if they are retained for any purpose.

6.3 Document Changes

6.3.1 Major Changes

Changes to documents, other than those defined as minor changes, are considered major changes and shall be reviewed and approved by the same organizations that performed the original review and approval unless other organizations are specifically designated. The reviewing organization shall have access to pertinent background data or information upon which to base their approval.

6.3.2 Minor Changes

Minor changes to documents, such as inconsequential editorial corrections, shall not require that the revised documents receive the same review and approval as the original documents. To avoid a possible omission of a required review, the type of minor changes that do not require such a review and approval and the persons who can authorize such a decision shall be clearly delineated.
7.0 CONTROL OF PURCHASED ITEMS AND SERVICES

7.1 Program Basis

This QAP section identifies requirements for QMS implementation that are described by:

1. Part I, Requirement 7 of ASME NQA-1-2008/09a;
2. Part II, Subpart 2.14 of ASME NQA-1-2008/09a;
3. Criterion 7 of DOE O 414.1D; and
4. QMS Program Elements 7.4.1 and 7.4.3 of ANSI/ISO/ASQ Q9001-2000.

7.2 Process Control

The procurement of items and services shall be controlled to ensure conformance with specified requirements. Such control shall provide for the following as appropriate: source evaluation and selection, evaluation of objective evidence of quality furnished by the Supplier, source inspection, audit, and examination of items or services upon delivery or completion.

CGIs may be procured and dedicated for safety-related applications. This process shall identify the critical characteristics and method(s) (e.g., special tests and inspections, commercial supplier survey, source verification, and/or acceptable supplier/item performance record) to be used to dedicate CGIs. Dedication of CGIs shall be accomplished in accordance with written procedures.

7.3 Procurement/Subcontract Process Control

A graded approach shall be used (see “Graded Application of Quality Assurance Requirements” in the Executive Summary of this QAP) to ensure that a purchased item or service conforms to specified requirements. The type and extent of controls applied to the supplier and the item or service shall be dependent upon the effect of the item or service on subsequent SWPF operations.

Management shall flow down to its suppliers the applicable requirements of this QAP and other SWPF requirements, as applicable to the supplier SOW.

The requirements for flow down include flow down to all participants in the work, including supplier-outsourced work to sub-tier suppliers.

7.4 Supplier Evaluation and Selection

Prior to award of a purchase order or subcontract, the supplier’s capability to provide items or services in accordance with the requirements of the procurement documents shall be evaluated. Supplier evaluation and selection results shall be documented and shall include one or more of the following:

- Supplier’s history of providing an identical or similar product that performs satisfactorily in actual use (the supplier’s history shall reflect current capability);
• Supplier’s current quality records supported by documented qualitative and quantitative information that can be objectively evaluated; and/or

• Supplier’s technical and quality capability as determined by a direct evaluation of the facilities, personnel, and implementation of the supplier’s QA program.

7.5 Bid Evaluation

Cognizant SWPF personnel shall perform a bid evaluation to determine the supplier’s capability to conform to quality, technical, process, and commercial requirements. Prior to the award of the contract, the Buyer shall resolve or obtain commitments to resolve unacceptable technical and QA conditions resulting from the bid evaluation.

7.6 Control of Supplier-Generated Documents

Document Control shall administer and implement controls for the review of supplier-generated documents, in accordance with Section 4.0 of this QAP. These controls shall provide for the acquisition, processing, and recorded evaluation of the QA, technical, inspection, and test documentation or data against acceptance criteria.

7.7 Acceptance of Item or Service

The supplier shall furnish documentary evidence that the item or service conforms to the procurement requirements. Management shall identify in the purchasing documents, either by statement or by reference (e.g., applicable specification), the acceptance method(s) necessary to accept the item or service for use. The extent of verification by SWPF shall be a function of the relative importance, complexity, and quantity of the item or services procured and the quality performance of the supplier. The method(s) of acceptance shall be based on a supplier certificate of conformance, source verification, receiving inspection, post-installation testing, or a combination of these methods.

Documentary evidence that items or services conform to procurement requirements shall be available at SWPF prior to installation or use.

7.7.1 Certificate of Conformance

When a Certificate of Conformance is used, the minimum criteria of (1) through (6) shall be met.

1. The certificate shall identify the purchased material or equipment, such as by the purchase order number.

2. The certificate shall identify the specific procurement requirements met by the purchased material or equipment, such as codes, standards, and other specifications. This may be accomplished by including a list of the specific requirements or by providing, on-site, a copy of the purchase order and the procurement specifications or drawings, together with a suitable certificate. The procurement requirements identified shall include any approved changes, waivers, or deviations applicable to the subject material or equipment.
3. The certificate shall identify any procurement requirements that have not been met, together with an explanation and the means for resolving the nonconformances.

4. The certificate shall be signed or otherwise authenticated by a person who is responsible for this QA function and whose function and position are described in the Buyer’s or Supplier’s QA program.

5. The certification system, including the procedures to be followed in filling out a certificate and the administrative procedures for review and approval of the certificates, shall be described in the Buyer’s or Supplier’s QA program.

6. Means shall be provided to verify the validity of Supplier certificates and the effectiveness of the certification system, such as during the performance of audits of the Supplier or independent inspection or test of the items. Such verification shall be conducted at intervals commensurate with the Supplier’s past quality performance.

7.7.2 Source Verification

When source verification is used, it shall be performed at intervals consistent with the importance and complexity of the item or service, and shall include monitoring, witnessing, or observing selected activities. Source verification shall be implemented in accordance with plans to perform inspections, examinations, or tests at predetermined points. Upon acceptance of source verification, documented evidence of acceptance shall be furnished to the receiving destination of the item, to the Buyer, and to the Supplier.

7.7.3 Receiving Inspection

When receiving inspection is used, purchased items shall be inspected as necessary to verify conformance to specified requirements, taking into account source verification and audit activities and the demonstrated quality performance of the Supplier. Receiving inspection shall verify by objective evidence such features as:

- Configuration;
- Identification;
- Dimensional, physical, and other characteristics;
- Freedom from shipping damage; and
- Cleanliness.

Receiving inspection shall be coordinated with review of Supplier documentation when procurement documents require such documentation to be furnished prior to receiving inspection.
7.7.4 Post-Installation Testing

When Post-Installation Testing is used, Post-Installation Test requirements and acceptance documentation shall be mutually established by SWPF and Supplier.

7.7.5 Acceptance of Services Only

In cases involving procurement of services only, such as third-party inspection; engineering and consulting services; auditing; and installation, repair, overhaul, or maintenance work, the service shall be accepted by any or all of the following methods:

- Technical verification of data produced,
- Surveillance and/or audit of the activity, and
- Review of objective evidence for conformance to the procurement document requirements.

7.8 Control of Supplier Nonconformances

Methods for control and disposition of Supplier nonconformances for items and services that do not meet procurement document requirements shall include (1) through (5):

1. Evaluation of nonconforming items.

2. Submittal of nonconformance notice to the Buyer by Supplier as directed. These submittals shall include Supplier-recommended disposition (e.g., use-as-is or repair) and technical justification. Nonconformances to the procurement requirements or Buyer-approved documents, which consist of one or more of the following, shall be submitted to the Buyer for approval of the recommended disposition:

   a) Technical or material requirement is violated.
   b) Requirement in Supplier documents, which has been approved by Buyer, is violated.
   c) Nonconformance cannot be corrected by continuation of the original manufacturing process or by rework.
   d) The item does not conform to the original requirement even though the item can be restored to a condition such that the capability of the item to function is unimpaired.

3. Buyer approval of Supplier recommendation for use-as-is or repair dispositions.

4. Verification of the implementation of the disposition.

5. Maintenance of records of Supplier-submitted nonconformances.

7.9 Supplier Assessment

The QA Manager will develop a Supplier Assessment Plan (SAP), using a graded approach, to be included in requisitions for the purpose of assessing supplier activities. The assessment process shall be based on the QMS manual or plan submitted by the supplier and keyed to the
major milestones, critical stages in design, or manufacturing sequence. The SAP shall establish requirements, as applicable, for:

- Review of supplier processes and procedures,
- SWPF representative’s witness (hold) points for inspections and tests,
- Verification of product conformance,
- Review of as-built information,
- Supplier’s packaging and item(s) preservation, and
- Buyer authorization for shipment.

SWPF’s representative shall verify at the supplier’s location that the item or service complies with the specified requirements and, after satisfactory verification of the specified requirements, shall authorize item’s release for shipment. The representative performing the assessment shall be responsible for issuing a Supplier Assessment Report to management.

### 7.10 Commercial Grade Items and Services

When CGIs or services are utilized, the requirements of Part II, Subpart 2.14 of ASME NQA-1-2008/09a shall apply and are an acceptable alternative to Section 7.7 of this QAP, except that Supplier evaluation and selection, where determined necessary, shall be in accordance with Section 7.4 of this QAP. The applicable requirements of this QAP shall apply to dedication activities for acceptance, which are detailed in PP-EN-5023, \textit{Replacement Item Evaluation/Commercial Grade Item Dedication}.

#### 7.10.1 Documentation

Documentation of the CGI or service dedication process shall be traceable to the item, group of items, or services and shall contain the following types of documents, depending on the applicable dedication method:

1. Dedication plans or procedures including the essential elements of the dedication process;
2. CGI or service procurement documents;
3. Technical evaluations;
4. Critical characteristic identification and acceptance criteria;
5. Test reports or results, inspection reports, analysis reports;
6. Commercial grade survey reports;
7. Source verification reports;
8. Historical performance information; and
9. Dedication report containing sufficient data to accept the item or service.
7.11 Records

Records shall be established and maintained in accordance with Section 17.0 of this QAP to indicate performance of the following functions:

- Supplier evaluation and selection;
- Acceptance of items or services; and
- Supplier nonconformances to procurement document requirements, including their evaluation and disposition.

8.0 IDENTIFICATION AND CONTROL OF ITEMS

8.1 Program Basis

This QAP section identifies requirements for QMS implementation that are described by:

1. Part I, Requirement 8 of ASME NQA-1-2008/09a³;
2. Criterion 5 and Criterion 8 of DOE O 414.1D⁴; and
3. QMS Program Element 7.5.3 of ANSI/ISO/ASQ Q9001-2000⁵.

8.2 Control of Items

Controls to ensure that only correct and accepted items are used or installed shall be established. SWPF shall implement inspections, tests, or other activities necessary for ensuring that purchased items meet specified requirements. Management shall ensure that suspect/counterfeit items (S/CIs) (see Section 22.0 of this QAP) are prevented from being installed in the SWPF.

8.3 Identification and Traceability of Items

Items shall be identified by suitable means throughout product realization. Items of production (batch, lot, component, part) shall be identified from the initial receipt and fabrication of items up to and including installation and use. This identification shall relate an item to an applicable design or other pertinent specifying document. Identification shall be maintained on the items or in documents traceable to the items, or in a manner that ensures identification is established and maintained.

Physical identification shall be used to the maximum extent possible. Where physical identification on the item is either impractical or insufficient, physical separation, procedural control, or other appropriate means shall be employed. When codes, standards, or specifications include specific identification or traceability requirements (such as identification or traceability of the item to applicable specification and grade of material; heat, batch, lot, part, or serial number; or specified inspection, test, or other records), the program shall provide such identification and traceability control.
8.3.1 Markings
Identification markings are applied by using materials and methods that are clear, legible, and do not detrimentally affect the function or service life of the item. Markings are transferred to each part of an identified item when subdivided. Markings are not obliterated or hidden by surface treatments or coatings unless other identification methods are established.

8.3.2 Limited-Life Items
Items having limited calendar or operating life or cycles shall be identified and controlled to preclude use of items whose shelf life or operating life has expired.

8.3.3 Maintaining Identification of Stored Items
Provisions shall be made for the control of item identification, consistent with the planned duration and conditions of storage, such as:

- Provisions for maintenance or replacement of markings and identification records due to damage during handling or aging,
- Protection of identification on items subject to excessive deterioration due to environmental exposure, and
- Provisions for updating existing plant records.

9.0 CONTROL OF SPECIAL PROCESSES

9.1 Program Basis
This QAP section identifies requirements for QMS implementation that are described by:

1. Part I, Requirement 9 of ASME NQA-1-2008/09a³;
2. Criterion 5 of DOE O 414.1D⁴; and
3. QMS Program Elements 7.5.1 and 7.5.2 of ANSI/ISO/ASQ Q9001-2000⁵.

9.2 Special Process Control
This section defines minimum requirements for control of special processes not described in other sections of the QAP. Special processes that control or verify quality, such as those used in welding, heat treating, and NDE, shall be performed by qualified personnel using qualified procedures in accordance with specified requirements. Special process control procedures shall prescribe or establish the requirements for planning and developing special processes, establishing special process objectives, and providing tools for measuring those objectives to ensure that special processes and resulting product meet the requirements. It is the responsibility of the organization performing the special process to adhere to the approved procedures and processes.
Special processes shall be controlled by instructions, procedures, drawings, checklists, travelers, or other appropriate means. Special process instructions shall include or reference procedure, personnel, and equipment qualification requirements. Conditions necessary for accomplishment of the process shall be included. These conditions shall include proper equipment, controlled parameters of the process, specified environment, and calibration requirements. The requirements of applicable codes and standards, including acceptance criteria for the process, shall be specified or referenced in procedures or instructions. Controlled conditions shall include as applicable information available that describes product characteristics; work instructions if necessary; use of suitable equipment; availability and use of measuring and test equipment (M&TE); implementation of monitoring and measurement; and release, delivery, and post-delivery activities.

For special processes not covered by existing codes and standards or where quality requirements specified exceed those of existing codes or standards, the necessary requirements for qualifications of personnel, procedures, or equipment shall be specified or referenced in procedures or instructions.

### 9.3 Records

Records shall be maintained in accordance with Section 17.0 of this QAP, as appropriate for the currently qualified personnel, processes, and equipment of each special process.

### 10.0 INSPECTION

#### 10.1 Program Basis

This QAP section identifies requirements for QMS implementation that are described by:

1. Part I, Requirement 10 of ASME NQA-1-2008/09a;
2. Criterion 8 and Criterion 10 of DOE O 414.1D; and

#### 10.1.1 General

QA/QC, Engineering, and technical support representatives are responsible for ensuring that inspections required for verifying conformance of an item or activity to specified requirements or continued acceptability of items in service are planned and executed in accordance with approved procedures. Characteristics subject to inspection and inspection methods shall be specified and results documented. Inspection for acceptance shall be performed by qualified persons other than those who performed or directly supervised the work being inspected.

Inspection requirements and acceptance criteria shall include specified requirements contained in the applicable design documents or other pertinent technical documents approved by the responsible design organization. Equipment modifications, repairs, and replacement are
inspected in accordance with the original design and inspection requirements, unless an approved alternate exists.

10.2 Inspection and Process Monitoring

Inspection of items under construction or otherwise in process shall be performed as necessary to verify quality. If inspection of processed items is impossible or disadvantageous, indirect control by monitoring of processing methods, equipment, and personnel shall be provided. Process monitoring shall be performed by qualified personnel or qualified automated means. Both inspection and process monitoring shall be provided when control is inadequate without both. When inspection and process monitoring are used, they should be performed in a systematic manner to ensure that the specified requirements for control of the process and quality of the item are being achieved throughout the duration of the process.

Process monitoring may be advantageous when acceptance inspection may introduce significant delays or process interruptions or inhibit effective material control. When process monitoring is performed by personnel responsible for performing the process operation, results of monitoring shall be verified by sampling inspection or surveillance.

Controls, where required, shall be established and documented for the control and sequencing of these activities at established inspection points during successive stages of the conducted process or construction. If mandatory inspection hold points are required beyond which work shall not proceed without the specific consent of the designated representative, the specific hold points shall be indicated in appropriate documents. Consent to waive specified hold points shall be recorded prior to continuation of work beyond the designated hold point.

10.2.1 In-Service Inspection

Required in-service inspection (e.g., periodic inspections) or surveillance of SSCs shall be planned and executed by or for the organization responsible for the operation and continued during operations to assure the conformity of the performance of their required functions.

Inspection methods shall be established and executed to verify that the characteristics of an item continue to remain within specified limits. Inspection methods should include evaluations of performance capability of essential emergency and safety systems and equipment, verification of calibration and integrity of instruments and instrument systems, and verification of maintenance, as appropriate.

10.3 Inspection of Work

Controls shall be established to ensure conformance with requirements at each product stage in accordance with planned arrangements, identify nonconformance at the earliest possible time, and facilitate corrective action and continual improvement. Suitable methods for monitoring and, where applicable, measurement of the QMS processes shall apply. Methods shall demonstrate the ability of the processes to achieve planned results. Management shall monitor and measure the characteristics of the product to verify requirements have been met. Evidence of conformity
with the acceptance criteria shall be maintained and indicate the person authorizing release. Release shall not proceed until the planned arrangements have been satisfactorily completed, unless approved by an authorized representative and if applicable, the customer. When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product.

Furnished items shall be subjected to inspection by qualified personnel other than those who performed or directly supervised the work being inspected. Personnel performing QC functions, reporting to the QC Manager, shall be assigned as needed to support the work. The QC Manager shall have no supervisory or managerial responsibility over the work force responsible for the performance or supervision of the work being inspected. The QC Manager or designee shall be onsite as necessary to verify and document that work is being performed properly and observe work in progress, as required.

10.4 Inspection Procedures

Inspection procedures shall be established and implemented for the control of inspections, to include the following instructions for:

- Designating witness (hold) points during the inspection process;
- Observing work in process and comparing this work with the requirements;
- Recording observations and requirements for demonstrating through the reports that the work observed was in compliance, or a deficiency was noted and action to be taken;
- Calibration, maintenance, and control of M&TE;
- Precluding the covering of deficient or rejected work;
- Rejecting work;
- Verification and control of inspections;
- Providing for location maps for inspections performed, or location of work covered by the inspection;
- Use of valid statistical methods when using sampling procedures;
- Maintenance and retention of inspection reports; and
- Ensuring that follow-up inspections are properly taken and documented, as applicable.

10.5 Inspection and Test Planning

Characteristics to be inspected, methods of inspection, and acceptance criteria shall be identified during the inspection planning process. Inspection and test planning shall establish suitable methods for monitoring and measuring the characteristics of an item or activity to ensure that requirements have been met. The process owners shall develop inspection and acceptance
criteria based on the requirements contained in the design documents, environmental requirements, and applicable operations and maintenance (O&M) manuals.

The inspection and acceptance criteria shall include the following, as applicable, to the identified inspection or test method:

- Product characteristics and inspection acceptance criteria identified by the responsible design organization, methods of inspection or test, frequency of inspection or test (e.g., in-process, final), and the report format for documenting the results of inspection and test;
- Sampling procedures, when used, shall be based upon standard statistical methods with engineering approval;
- Appropriate environmental conditions and temporary changes necessary to an approved configuration for inspection and test purposes;
- Mandatory witness (hold) points beyond which work shall not proceed without specific recorded consent of the authorized representative; and
- Requirements for qualifications of the performer to conduct the inspection or test.

Inspection and test results shall be documented and evaluated by qualified personnel to ensure that requirements have been satisfied. The item shall not be released for service prior to completion of all activities specified and associated documentation is available and authorized. Completed items shall be inspected for completeness, markings, calibration, adjustments, protection from damage, or other characteristics as required to verify the quality and conformance of the item to specified requirements. Final inspections shall include a records review of the results and resolution of nonconformances identified by prior inspections. The acceptance of the item shall be approved by authorized personnel.

If an unverified item must be released for immediate use prior to acceptance, the item shall be identified in accordance with Section 14.0 of this QAP, allowing recall and replacement if a nonconformance is identified. If a nonconforming item is identified, it shall be controlled in a manner specified in Section 15.0 of this QAP. When a nonconforming activity is identified, Section 16.0 of this QAP describes an alternate method of documenting action(s) requiring correction. Any modifications, repairs, or replacements of items performed subsequent to final inspection shall require re-inspection or retest, as appropriate, to verify acceptability.

### 10.6 Records

Results of inspections, process monitoring, and in-service inspections shall be documented on established records and shall include the following information:

- Identity of the process or item inspected;
- Date of inspection;
- Identity of inspector;
• Type of observation;
• Identification of M&TE used and status of calibration, as applicable;
• Results or acceptability; and
• Reference to information on action taken in connection with nonconformances.

The records providing evidence that items have been inspected shall be maintained as specified in Section 17.0 of this QAP.

11.0 TEST CONTROL

11.1 Program Basis

This QAP section identifies requirements for QMS implementation that are described by:

1. Part I, Requirement 11 of ASME NQA-I-2008/09a and
2. Criterion 8 and Criterion 10 of DOE O 414.1D.

11.2 Test Requirements

Tests required for the collection of data, to verify conformance of an item or computer program to specified requirements, or to demonstrate satisfactory performance for service shall be planned and executed. Characteristics to be tested and test methods to be employed shall be specified by the design organization. Test results shall be documented and their conformance with test requirements and acceptance criteria shall be evaluated.

Test requirements and acceptance criteria shall be provided or approved by the responsible design organization. Required tests, including, as appropriate, prototype qualification tests, production tests, proof tests prior to installation, construction tests, preoperational tests, operational tests, and computer program tests (such as software design verification, factory acceptance, site acceptance, and in-use tests) shall be controlled under appropriate environmental conditions using the tools and equipment necessary to conduct the test in a manner to fulfill test requirements and acceptance criteria. The tests performed shall obtain the necessary data with sufficient accuracy for evaluation and acceptance.

Test requirements and acceptance criteria shall be based upon specified requirements contained in applicable design documents, or other pertinent technical documents that provide approved requirements.

If temporary changes to the approved configuration of a facility are required for testing purposes, approval by design authority is required prior to performing the test.
11.2.1 Test Requirements for Computer Programs

Test requirements and acceptance criteria for computer programs shall be provided by the organization responsible for the use of the computer program and shall include the following, as applicable:

1. Software design verification testing shall demonstrate the capability of the computer program(s) to provide valid results for test problems encompassing the range of documented permitted usage.

2. Computer program acceptance testing shall consist of the process of exercising or evaluating a system or system component by manual or automated means to ensure it satisfies the specified requirements and identifies differences between the expected and actual results in the operating environment.

3. In-use computer programs testing shall demonstrate required performance over the range of operation of the controlled function or process.

11.3 Test Procedures (Other than for Computer Programs)

NOTE: As an alternative to the following instruction, appropriate sections of related documents, such as American Society for Testing and Materials (ASTM) methods, supplier manuals, equipment maintenance instructions, O&M manuals, or approved drawings or travelers with acceptance criteria, can be used. These documents shall include or be supplemented with appropriate criteria to assure adequate procedures for the test are used.

Test procedures shall include or reference the test configuration and test objectives. Test procedures shall also include provisions for assuring that prerequisites and suitable environmental conditions are met, adequate instrumentation is available and used, appropriate tests and equipment are used, and necessary monitoring is performed.

NOTE: Testing procedures may identify QA hold points; however, the QA Manager has the discretion to waive the hold points, and documents the waiver and basis on the applicable document.

Management shall establish and implement procedures for the control of tests to include the following:

- Designating witness (hold) points during the test process;
- Instructions for recording observations during monitoring for demonstrating through the reports that the test observed was in compliance, or a deficiency was noted and action to be taken;
- Test configuration and test objective(s);
- Identity of other prerequisites, as applicable:
Calibrated instrumentation,
- Appropriate equipment,
- Trained personnel,
- Condition of test equipment and the item to be tested,
- Suitable environmental conditions, and
- Provisions for data acquisition.

- Instructions for rejecting work;
- Instructions for maintenance and retention of test reports; and
- Instructions to ensure that a follow-up retest is performed, when required.

11.3.1 Inspection and Test Planning

Refer to Section 10.5 of this QAP for inspection and acceptance criteria.

11.3.2 Test Records

Results of tests shall be documented and evaluated by a responsible authority to ensure that test requirements have been satisfied, and include the following information:

- Identity of the process or item;
- Date of test;
- Tester or data recorder;
- Identity of person(s) evaluating test results;
- Type of observation;
- Identification of M&TE used and status of calibration, as applicable;
- Results or acceptability; and
- Reference to information on action taken in connection with nonconformance.

Test results for design qualification tests and software design verification shall be evaluated by the responsible design organization.

The records providing evidence that items have been tested and indicating the ability of the item to satisfactorily perform its intended function or to meet its documented requirements shall be established and maintained as specified in Section 17.0 of this QAP.
11.4 Computer Program Test Procedures

The requirements of this section apply to testing of computer programs, and as appropriate, the computer hardware and operating system.

Computer program test procedures shall provide for demonstrating the adherence of the computer program to documented requirements. For those used in design activities, computer program test procedures shall provide assurance that the correct results are produced. For those used for operational control, computer program test procedures shall provide for demonstrating the required performance over the range of operation of the controlled function or process. The procedures shall also provide the evaluation of technical adequacy through comparing test results from alternative methods, such as hand calculations, calculations using comparable proven programs, or empirical data and information from technical literature.

Test procedures or plans shall specify the following, as applicable:

1. Required tests and test sequence,
2. Required ranges of input parameters,
3. Identification of the required testing stages,
4. Criteria for test cases,
5. Requirements for testing logic branches,
6. Requirements for hardware integration,
7. Anticipated output values,
8. Acceptance criteria, and
9. Reports, records, standard formatting, and conventions.

11.4.1 In-Use Test Procedures

In-use test procedures shall be developed and documented to permit confirmation of acceptable performance of the computer program in the operating system. Performance of in-use test procedures shall occur after the computer program is installed on a different computer, or when there are significant operating system changes. Periodic in-use manual or automatic self-check in-use tests shall be prescribed and performed for those computer programs in which computer program errors, data errors, computer hardware failures, or instrument drift can affect the required performance.

11.4.2 Computer Program Test Records

Computer Program test records shall be documented and evaluated by responsible authority to ensure that test requirements have been satisfied, established, and maintained in accordance with Section 17.0 of this QAP, to indicate the ability of the computer program to satisfactorily
perform its intended function or to meet documented requirements. Computer program test records shall contain the following information, as a minimum:

1. Computer program tested including system software used;
2. Computer hardware used;
3. Test equipment and calibrations, where applicable;
4. Date of test;
5. Tester or data recorder;
6. Simulation models used, where applicable;
7. Test problems;
8. Results and applicability;
9. Action taken in connections with any deviations noted;
10. Person evaluating test results; and
11. Acceptability.

12.0 CONTROL OF MEASURING AND TEST EQUIPMENT

12.1 Program Basis

This QAP section identifies requirements for QMS implementation that are described by:

1. Part I, Requirement 12 of ASME NQA-1-2008/09a³;
2. Criterion 5 and Criterion 8 of DOE O 414.1D⁴; and
3. QMS Program Elements 7.5.3 and 7.6 of ANSI/ISO/ASQ Q9001-2000⁵.

12.2 Calibration and Control

Tools, gages, instruments, and other M&TE used for activities affecting quality shall be controlled, calibrated at specific periods, adjusted, and maintained to required accuracy limits as delineated in PP-QA-4711, Controlling Measuring and Test Equipment. Selection of M&TE shall be based on the type, range, accuracy, and tolerance needed to accomplish the required measurements for determining conformance to specified requirements. Management shall determine the monitoring and measurement to be undertaken and shall calibrate and maintain equipment for process monitoring, data collections, inspections, and testing, as determined appropriate to provide evidence of conformity of product with determined requirements.

Where necessary to ensure valid results, M&TE shall be:

- Calibrated or verified at specified intervals (or prior to use) and whenever the accuracy of the M&TE is suspect;
• Calibrated or verified against and traceable to certified equipment or measurement standards having known valid relationships to nationally recognized standards, or to international standards known to be equivalent to and verified against corresponding nationally recognized standards; where no such standards exist, the basis used for calibration or verification shall be recorded;

• Adjusted or re-adjusted as necessary;

• Identified to enable the calibration status to be determined;

• Safeguarded from adjustments that would invalidate the measurement result; and

• Protected from damage and deterioration during handling, maintenance, and storage.

M&TE shall be used in a manner that ensures the measurement uncertainty is known and is consistent with the required measurement capability.

M&TE shall be selected to provide the proper range and accuracy for its intended use. Precision and accuracy tolerances shall be identified and documented.

12.2.1 Reference Standards

Reference standards shall have a minimum accuracy four times greater than that of the M&TE being calibrated to ensure that the reference standards contribute no more than one-fourth of the allowable calibration tolerance. Where this 4:1 ratio cannot be maintained, the basis for selection of the standard in question shall be technically justified.

12.2.2 Calibration Procedures

Calibration procedures shall identify or reference required accuracy and shall define methods and frequency of checking accuracy. The calibration method and interval of calibration shall be based on the type of equipment, stability characteristics, required accuracy, intended use, and other conditions affecting performance. M&TE, which is overdue for calibration or found to be out-of-calibration, shall be tagged and/or segregated, or removed from service, and not used until it has been recalibrated. M&TE consistently found to be out-of-calibration shall be repaired or replaced. M&TE and reference standards submitted for calibration shall be checked and the results recorded before any required adjustments or repairs are made.

12.2.3 Application

M&TE shall be traceable to its application and use.

12.2.4 Corrective Action

When M&TE is lost, damaged, or found to be out of calibration, the validity of previous measurement, inspection, or test results and the acceptability of items previously inspected or tested shall be evaluated. The evaluation shall be from at least the last acceptable calibration. The evaluation and resulting actions shall be commensurate with the significance of the condition.
Corrective action for the M&TE evaluation results shall be documented in accordance with Section 15.0 of this QAP.

12.2.5 Handling, Storage, and Environmental Controls

M&TE shall be properly handled and stored to maintain accuracy, and used and calibrated in environments that are controlled to the extent necessary to ensure that the required accuracy and precision are maintained.

12.2.6 Status Indication

M&TE shall be suitably marked, tagged, labeled, or otherwise identified to indicate calibration status and to establish traceability to calibration records.

12.2.7 Commercial Devices

Calibration and control measures are not required for commercial devices such as rulers, tape measures, levels, etc., if such equipment provides the required accuracy.

12.3 Records

Records shall be established and maintained to indicate calibration status and the capability of M&TE to satisfactorily perform its intended function.

Calibration reports and certificates reporting the results of calibrations shall include the information and data necessary for interpretation of the calibration results and verification of conformance to applicable requirements.

Calibration records for M&TE shall be maintained in accordance with Section 17.0 of this QAP.

13.0 HANDLING, STORAGE, AND SHIPPING

13.1 Program Basis

This QAP section identifies requirements for QMS implementation that are described by:

1. Part I, Requirement 13 of ASME NQA-1-2008/09a³;
2. Criterion 5 of DOE O 414.1D⁴; and
3. QMS Program Element 7.5.4 and 7.5.5 of ANSI/ISO/ASQ Q9001-2000⁵.

13.2 Item Preservation

Handling, storage, cleaning, packaging, shipping, and preservation of items shall be controlled to prevent damage or loss and to minimize deterioration. The conformity of product, and its constituent parts, during internal processing and delivery to the intended destination shall be preserved. These activities shall be conducted in accordance with established work and
inspection instructions, drawings, specifications, shipment instructions, or other pertinent documents or procedures specified for use in conducting the activity. Requirements for item handling, storage, and shipping shall be implemented by SWPF or, when identified by procurement documents, SWPF suppliers.

13.2.1 Marking or Labeling

Marking or labeling shall be utilized as necessary to adequately maintain and preserve items, including indication of the presence of special environments or the need for special controls.

13.3 Special Requirements

When required, special equipment and special protective environments shall be specified and provided and their existence verified.

13.4 Specific Procedures

When required for critical, sensitive, perishable, or high-value items, specific procedures for handling, storage, packaging, shipping, and preservation shall be used.

13.5 Tools and Equipment

Special handling tools and equipment shall be utilized and controlled where necessary to ensure safe and adequate handling. Special handling tools and equipment shall be inspected and tested in accordance with procedures at specified time intervals or prior to use.

13.5.1 Operators

Operators of special handling and lifting equipment shall be experienced or trained in the use of the equipment.

14.0 INSPECTION, TEST, AND OPERATING STATUS

14.1 Program Basis

This QAP section identifies requirements for QMS implementation that are described by:

1. Part I, Requirement 14 of ASME NQA-1-2008/09a³ and
2. Criterion 5 of DOE O 414.1D⁴.

14.2 Status Controls

Management shall identify controls to status inspections and tests and to indicate the operating status of systems and components. The status of inspection and test activities shall be identified on the items or in documents traceable to the items. Status shall be maintained through indicators, such as physical location and tags, markings, shop travelers, stamps, inspection
records, or other suitable means to ensure that items which have not passed the required inspections and tests are not inadvertently installed, used, or operated.

Management is responsible for ensuring that the status of items can be determined at any point throughout an operational process to prevent inadvertent use, installation, or operation of nonconforming or defective items. Status indicators are required to the extent possible to prevent operation of items removed from service for test, calibration, maintenance, or repair and to ensure that required inspections and tests have been performed. Operating procedures shall include reporting requirements that establish the equipment status at key events.

Status is identified by the use of tags, markings, stamps, or travelers. The authority for application and removal of status indicators is identified in approved procedures. QA/QC personnel routinely monitor activities to ensure that status indicators are used and removed, as appropriate, in accordance with procedures. The operating status of systems and components is controlled through use of lockout tags secured to appropriate valves and switches to prevent inadvertent operation.

15.0 CONTROL OF NONCONFORMING ITEMS

15.1 Program Basis

This QAP section identifies requirements for QMS implementation that are described by:

1. Part I, Requirement 15 of ASME NQA-1-2008/09a;
2. Criterion 3 and Criterion 10 of DOE O 414.1D; and

15.2 Process Control

Management shall ensure items that do not conform to specified requirements are controlled to prevent inadvertent installation or use. Controls shall provide for identification, documentation, evaluation, segregation when practical, and disposition of nonconforming items, and for notification to affected organizations.

Management shall establish and implement a PP for identifying and controlling nonconforming items. The PP shall require that nonconforming items be identified by legible marking, tagging, or other methods not detrimental to the item, either on the item, the container, or the package containing the item. Also, nonconforming items shall be segregated, when practical, by placing them in a clearly identified and designated hold area until properly dispositioned. When segregation is impractical or impossible due to physical conditions such as size, weight, or access limitations, other precautions shall be employed to preclude inadvertent use of a nonconforming item.
Additionally, the PP shall address:

- Responsibility and authority for the evaluation and disposition of nonconforming items;
- Responsibility for the control of further processing, delivery, installation, or use of nonconforming items pending the evaluation and an approved disposition by authorized personnel designated in writing;
- Personnel and process utilized for tracking (logging) deficient and nonconforming items; and
- The documentation closure process.

Nonconforming items shall be dispositioned by one or more of the following methods:

- Take action to eliminate the detected nonconformity (e.g., “rework” to restore to approved configuration);
- Take action to preclude its original intended use or application (“scrap or replace”, “reject”); or
- Provide technical justification for its use, release, or acceptance under concession (“use-as-is” or “repair”) for review and acceptance by the approval authority prior to implementing the disposition and use or delivery of the work.

Disposition of nonconformances shall be addressed in a timely manner by management. Personnel performing evaluations to determine a disposition shall have demonstrated competence in the specific area they are evaluating, an adequate understanding of the requirements, and access to pertinent background information. Dispositions of nonconformances are evaluated and approved by QA/QC personnel; however, the technical adequacy of the dispositions are determined and reviewed by the appropriate Engineering discipline.

A disposition, such as use-as-is, reject, scrap, repair, or rework of nonconforming items shall be made and documented. Technical justification for the acceptability of a nonconforming item dispositioned repair or use-as-is shall be documented. Nonconformances to design requirements dispositioned use-as-is or repair shall be subject to design control measures commensurate with those applied to the original design. Required as-built records shall reflect the use-as-is or repair condition. Reworked items shall be reexamined in accordance with applicable procedures and with the original acceptance criteria. Repaired items shall be reexamined in accordance with applicable procedures and with the original acceptance criteria unless the disposition has established alternate acceptance criteria.

When nonconforming items are corrected, they shall be subject to re-verification (such as by inspection and/or testing) to demonstrate conformity to the requirements.

When nonconforming items are detected after delivery or use has started, Management shall take action appropriate to the effects, or potential effects, of the nonconformity.
15.3 Identification of Nonconformance and Documentation of Status

All Project personnel are responsible, as a part of their normal work duties, for promptly identifying and reporting conditions adverse to quality.

An item that does not conform to prescribed technical and/or quality requirements is tagged or otherwise identified, documented, and reported as nonconforming. The report of nonconformance shall include the following information, as applicable:

- Identification of the nonconforming item;
- Identification of the technical and quality requirement(s) with which the item is not in compliance;
- Identification of the current status of the item (e.g., hold, conditional release);
- Name and date of the individual identifying the nonconformance;
- Identification of the individual or organization responsible for resolution;
- Indication of the type and extent of action required to resolve the nonconformance; and
- Indication regarding the continuance or stoppage of work (or of the item’s use) associated with each nonconforming item.

Management may conditionally release the nonconforming item for limited use or to allow further processing, installation, or testing, when it is deemed necessary or appropriate. A nonconforming item may be conditionally released, provided the ability to correct the nonconformance or inspect and test the released item is not compromised. In such cases, a status indicator (e.g., hold tag) will be used to clearly identify the item as nonconforming.

The status of the nonconforming item and the progress of resolution is documented and reviewed routinely to ensure prompt attention to resolution.

Management is responsible for establishing an environment for identifying potential conditions adverse to quality. Management shall conduct analysis, as appropriate, to systematically determine the significance of these conditions and actions appropriate to the conditions.

Reports of conditions that are adverse to quality are analyzed to identify trends in quality performance. Significant conditions adverse to quality and significant trends are reported to executive management.

15.4 Evaluation of Nonconformance for Reportability

Occurrence reports inform DOE, on a timely basis, of occurrences that could adversely affect national security, health and safety of the public or workers, the environment, the intended purpose of DOE facilities, or the credibility of DOE.
Management shall establish and implement a PP to implement the requirements of DOE O 232.2A, *Occurrence Reporting and Processing of Operations Information*. The PP shall address the following, as a minimum requirement:

- Categorizing occurrences related to safety, environment, health, or operations (reportable occurrences);
- Notifying DOE of these occurrences; and
- Developing and submitting documented follow-up reports.

### 15.5 Records

Records of the nature of nonconformances and any subsequent actions taken, including concessions obtained, shall be maintained. The records shall be retained in accordance with Section 17.0 of this QAP.

### 16.0 CORRECTIVE ACTION

#### 16.1 Program Basis

This QAP section identifies requirements for QMS implementation that are described by:

1. Part I, Requirement 16 of ASME NQA-1-2008/09a;
2. Criterion 3 and Criterion 10 of DOE O 414.1D; and

#### 16.2 Requirement for Corrective Action

Management shall establish and implement a PP for corrective action. Conditions adverse to quality shall be promptly identified and reported to the QA Manager, with a copy of the corrective action report submitted to the appropriate management. Corrective action shall be promptly initiated when it is determined that a condition adverse to quality exists. In cases where it is not possible to accomplish a corrective action immediately, the appropriate management provides a written response, describing the cause of the deficiency and proposed corrective action to be completed within a specified time. For significant conditions adverse to quality, procedures provide for the: identification of conditions; assignment of responsibility for corrective action; documentation of the cause and corrective action taken; implementation, evaluation, verification of corrective action to prevent recurrence; and reporting to the appropriate levels of management.

The procedures for condition reporting, corrective action, and action tracking will include processes for correcting conditions, continual improvement, and lessons learned. Causal analysis, extent of condition, effectiveness review, and action tracking methods are all part of the corrective action process used, as applicable, to continuously improve performance, especially
for those deemed significant conditions adverse to quality. The Continual Improvement process is described in Section 21.0 of this QAP.

QA ensures follow-up on corrective actions to verify that they are complete and implemented. QA, with assistance from the Assurance organization, shall trend adverse conditions to determine quality tendency for management review. The Assurance organization is responsible for performing compliance assessments, verifying and documenting compliance with environmental, safety, health, and QA requirements, and capturing information to support performance analysis processes.

The QA Manager is responsible for verifying the effectiveness and closure of corrective actions. The QA Manager is responsible for reporting significant conditions adverse to quality to the Project Manager.

16.3 Evaluation of Reported Conditions for Reportability

Occurrence Reports inform DOE, on a timely basis, of occurrences that could adversely affect national security, health and safety of the public or workers, the environment, the intended purpose of DOE facilities, or the credibility of DOE.

Management shall establish and implement a PP to implement the requirements of DOE O 232.2A. The PP shall address the following, as a minimum requirement:

- Categorizing occurrences related to safety, environment, health, or operations (reportable occurrences);
- Notifying DOE of these occurrences; and
- Developing and submitting documented follow-up reports.

Positive incentives are available to contractors in relation to the DOE Price-Anderson Amendments Act (PAAA) and Worker Safety and Health (WSH) enforcement policies and philosophies. Aspects of the positive incentives are elective by DOE contractors. However, prompt contractor identification, reporting to DOE and the timely correction of PAAA/WSH non-compliances provides DOE with a basis to exercise enforcement discretion, in whole or in part, to mitigate penalties. Therefore, SWPF shall maintain and implement a PP that affords an opportunity to receive PAAA/WSH enforcement discretion/mitigation.

16.4 Records

Documentation of corrective actions may include root cause analysis, logs, formal reports, and objective evidence of satisfactory implementation. This documentation is maintained in accordance with approved procedures.
17.0 QUALITY ASSURANCE RECORDS

17.1 Program Basis

This QAP section identifies requirements for QMS implementation that are described by:

1. Part I, Requirement 17 of ASME NQA-1-2008/09a³;
2. Criterion 4 of DOE O 414.1D⁴; and
3. QMS Program Element 4.2.4 of ANSI/ISO/ASQ Q9001-2000⁵.

17.1.1 General

The control of QA records shall be established consistently with the schedule for accomplishing work activities. QA records shall furnish documentary evidence that items and activities meet specified quality requirements. QA records shall be identified, generated, authenticated, and maintained, and their final disposition specified. Procedures providing direction on QA records shall document responsibilities for records generation and maintenance.

17.2 Generation of QA Records

QA records shall remain legible and uniquely identifiable for ready access and retrieval. The records shall be traceable to associated items and activities and accurately reflect the work accomplished or information required. Records generated, supplied or maintained shall be specified in applicable documents. Management shall:

- Establish and implement procedures to define the controls needed for identification, storage, protection, retrieval, retention time, disposition of records, and record change controls;
- Establish and maintain records to provide evidence of conformity to requirements and effective operation of the QMS. The records shall be protected from deterioration, damage, and destruction; and
- Maintain a Master List that identifies the specific records generated and maintained in conjunction with the work.

17.3 Authentication of QA Records

Documents shall be considered valid records only if stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated. Corrections to documents shall be reviewed and approved by the responsible individual from the originating or authorized organization. Electronic documents shall be authenticated with comparable information, as appropriate:

- With identification on the media or
- With authentication information contained within or linked to the document itself.
17.4 Classification of QA Records

QA records will be classified as lifetime or nonpermanent (see Appendix B). The records will be maintained by the Owner, or authorized agent, and consistent with applicable regulatory requirements.

Lifetime records are those that meet one or more of the following criteria:

1. Those which would be of significant value in demonstrating capability for safe operation.
2. Those which would be of significant value in maintaining, reworking, repairing, replacing, or modifying an item.
3. Those which would be of significant value in determining the cause of an accident or malfunction of an item.
4. Those which provide required baseline data for in-service inspections.

Nonpermanent records are those required to show evidence that an activity was performed in accordance with the applicable requirements but need not be retained for the life of the item because they do not meet the criteria for lifetime records. Nonpermanent records shall be maintained for the identified retention period.

Records shall be retained until completion of the Contract (DE-AC09-02SR222101) period and shall turn over the lifetime records to DOE at the end of the Contract (DE-AC09-02SR222101), or as directed by DOE. The retention period of nonpermanent records shall be established by the Project Manager, in consultation with DOE.

17.5 QA Records Processing and Retention

SWPF staff originating records shall submit to Document Control all records specified by the QAP, SWPF plans, and procedures. Document Control shall organize and implement a system for logging and storing these records, customer-furnished information, and correspondence (internal, incoming, and outgoing) in a retrievable manner within retrieval times specified. Receipt controls shall provide a method for identifying the records received, receipt and inspection of the records, and submittal of records to storage. Retention periods shall be documented and the records maintained per the established retention time. Records shall be protected from damage or loss. The records shall be retained in a records facility providing protection from deterioration, theft, and damage, including implementation of measures in consideration of wind, flood, fire, temperature, humidity, dust or airborne particles, moisture, pressure, erasure, exposure to light, or injurious insects, mold, and rodents. Provisions shall be made to prevent damage from harmful conditions, (such as excessive light, stacking, electromagnetic fields, temperature, and humidity), as applicable to the specific media utilized for record storage. Activities detrimental to the records shall be prohibited in the storage area and access shall be limited to authorized personnel.
17.6 Storage Facility Types

Two equally satisfactory methods of providing storage under ASME NQA-1-2008/09a\textsuperscript{3} are single or dual.

Single storage consists of a storage facility, vault, room, or container. Per DOE contract (DE-AC09-02SR22210\textsuperscript{1}) requirements, Parsons SWPF is permitted to continue use of 1-hour fire rated cabinets and 1-1/2 hour fire-rated rooms for single storage of records. The design and construction shall be reviewed for adequacy by a person competent in fire protection or certification/rating from an accredited organization.

Dual facilities for records storage are required by DOE. Electronic and paper documents or electronic back-ups are considered an acceptable practice for the dual storage of records. Provisions shall be established to ensure that no unacceptable degradation of the electronic record media occurs during the established retention period. Also, provisions shall be made to ensure that the records remain retrievable after hardware, software, or technology changes.

Dual storage facilities shall be sufficiently remote from each other to reduce the chance of a simultaneous hazard. When temporary storage of records is required, the storage facility or container shall provide a one-hour fire rating unless dual storage requirements are met. Finally, provisions shall be established to ensure the following when records are duplicated or transferred to the same media or to a different media for the purposes of maintenance or storage:

- Duplication or transfer is appropriately authorized and
- Record content, legibility, and retrievability are maintained.

18.0 AUDITS

18.1 Program Basis

This QAP section identifies requirements for QMS implementation that are described by:

1. Part I, Requirement 18 of ASME NQA-1-2008/09a\textsuperscript{3};
2. Criterion 9 and Criterion 10 of DOE O 414.1D\textsuperscript{1}; and
3. QMS Program Element 8.2.2 of ANSI/ISO/ASQ Q9001-2000\textsuperscript{5}.

18.1.1 General

Audits shall be performed to verify compliance to QA program requirements, to verify that performance criteria are met, and to determine the effectiveness of the QMS. Audits shall be performed in accordance with written procedures or checklists by personnel who do not have direct responsibility for performing the activities being audited. Audit results shall be documented and reported to and reviewed by management responsible for the work activities being audited. Follow-up action shall be taken where indicated.
Management shall establish and implement a PP that describes the audit process, to include provisions for the following:

- An audit plan for each audit. This plan shall identify the audit scope, requirements, audit personnel, activities to be audited, organizations to be notified, applicable documents, schedule, and written procedures or checklists.

- Audit personnel shall have sufficient authority and organizational freedom to make the audit process meaningful and effective.

- An audit team shall be identified prior to the beginning of each audit. This team shall contain one or more Auditors, one being designated Lead Auditor who organizes and directs the audit. The audit team shall have experience or training commensurate with the scope, complexity, or special nature of the audited activities.

- Elements selected for audit shall be evaluated against specified requirements. Objective evidence shall be examined to the depth necessary to determine if these elements are being implemented effectively. Conditions requiring prompt corrective action shall be reported immediately to management of the audited organization.

- The audit report shall be signed or otherwise endorsed by the Lead Auditor and issued to the audited organization. The contents of the report shall:
  - Describe the audit scope;
  - Identify auditors and persons contacted;
  - Summarize audit results, including a statement on the effectiveness of the elements audited; and
  - Describe each reported adverse audit finding.

Audits and other assessment techniques, such as independent assessments (including surveillance), will be used to monitor and confirm that the QAP is being effectively implemented. These other assessment techniques, as described in Section 2.0 of this QAP, should be used as complementary methods and not redundantly applied.

Where surveillance is more practical for assessment of ongoing activity, the surveillance may be used in support of audits to cover the necessary scope of the entire QAP. Adequate demonstration of the areas covered by surveillance is a requirement to be considered as part of an effective audit program. Surveillance must be documented in sufficient detail to identify the activity covered, identify individuals doing surveillance, and document results and any necessary corrective measures.

### 18.2 Scheduling

Audits shall be scheduled in a manner to provide coverage and coordination with ongoing activities, based on the status and importance of the activity. Scheduled audits shall be supplemented by additional audits of specific subjects when necessary to provide adequate
coverage. Internal audits and external evaluations are scheduled based on the status and importance of an activity, and schedules are updated, as necessary, to ensure that adequate coverage is maintained.

18.3 Performance

The team uses an audit checklist or the procedure steps being audited, which contain the elements of the activity being covered and the requirements to evaluate them. The audit team uses objective evidence to make its evaluations.

Key elements for effectively implementing the audit program include:

- Scheduling and notifying management of scope and nature of audit;
- Team selection, orientation, and planning;
- Entrance conference;
- Exit conference;
- Reporting and response; and
- Follow-up action.

18.4 Reporting and Follow-up

Reports documenting results are prepared upon completion of the audit, distributed to appropriate management for review, and posted on SALT PCP for information. Audit reports require management of the audited organization or activity to investigate adverse audit findings, schedule corrective action, including measures to prevent recurrence of significant conditions adverse to quality, and notify the appropriate organization in writing of action taken or planned.

The adequacy of responses is evaluated by the auditing organization. Follow-up action shall be taken to verify that corrective action is accomplished as scheduled. It is the responsibility of QA to verify that effective corrective actions are in place before closing the audit.

18.5 Audit Personnel Qualification

Audit personnel qualification requirements are addressed in Sections 2.3.5, 2.3.6, and 2.3.7 of this QAP.

18.6 Audit Records

Audit records shall include audit plans, audit reports, checklists, written replies, and the record of completion of corrective action. Audit records shall be retained in accordance with Section 17.0 of this QAP.
19.0 COMPUTER SOFTWARE MANAGEMENT

19.1 Program Basis

This QAP section identifies requirements for QMS implementation that are described by DOE 414.1D.

19.2 Requirements for Computer Software Management

This section identifies requirements for computer software management that includes both safety and non-safety software used by SWPF. Management shall ensure that software, when used, performs its intended specific functions.

Management shall establish and implement a program for defining and controlling work activities involving software. Details of this program are described in PL-QA-4704. Work processes shall be addressed using ASME NQA-1-2004 and ASME NQA-1-2008/09a including Subpart 2.7.

19.3 Definition of Safety and Non-Safety Software

Safety software, as defined in the DOE O 414.1D, includes the following:

- Safety System Software – Software for a nuclear facility that performs a safety function as part of an SSC and is cited in either (a) a DOE-approved documented safety analysis, or (b) an approved hazard analysis per DOE P 450.4 and the DOE O 414.1D;

- Safety and Hazard Analyses Software and Design Software – 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; and

- Safety Management and Administrative Controls Software – Software that performs a hazard control function in support of nuclear facility or radiological safety management programs or technical safety requirements, or other software that performs a control function necessary to provide adequate protection from nuclear facility or radiological hazards. This software supports eliminating, limiting, or mitigating nuclear hazards to workers, the public, or the environment as addressed in 10 CFR 830, 10 CFR 835, Occupational Radiation Protection, and the DOE O 414.1D.
Non-safety Software:

Software used in GS (non-safety) applications where software failure or application error could result in the potential for high, medium, or low project risk; or where results are the sole source of quality related information that is provided to external customers.

19.4 Graded Application of QA for Software

SWPF shall use a graded application of QA for software. Appropriate QA controls (Software QA [SQA] work activities) are identified and implemented by grading software, based on its application. Software grading levels are described in terms of consequence and regulatory compliance. The grading levels are defined as follows:

**Level A:** This grading level includes safety software applications that meet one or more of the following criteria.

1. Software failure that could compromise a limiting condition for operation;
2. Software failure that could cause a reduction in the safety margin for a safety SSC that is cited in DOE approved documented safety analysis;
3. Software failure that could cause a reduction in the safety margin for other systems such as toxic or chemical protection systems that are cited in either (a) a DOE approved documented safety analysis or (b) an approved hazard analysis per DOE P 450.4\textsuperscript{11} and the U.S. Department of Energy Acquisition Regulation (DEAR) ISMS clause, DEAR 970.5223-1, *Integration of Environment, Safety, and Health into Work Planning and Execution*\textsuperscript{25}; and
4. Software failure that could result in nonconservative safety analysis, design, or misclassification of facilities or SSCs.

**Level B:** This grading level includes safety software applications that do not meet Level A criteria but meet one or more of the following criteria.

1. Safety management databases used to aid in decision making whose failure could impact safety SSC operation.
2. Software failure that could result in incorrect analysis, design, monitoring, alarming, or recording of hazardous exposures to workers or the public.
3. Software failure that could comprise the defense in depth capability for the nuclear facility.

**Level C:** This grading level includes software applications that do not meet Level B criteria but meet one or more of the following criteria.

1. Software failure that could cause a potential violation of regulatory permitting requirements.
2. Software failure that could affect environment, safety, health monitoring, or alarming systems.
3. Software failure that could affect the safe operation of an SSC.
**Level D**: This grading level includes software used in GS (non-safety) applications that meet one or more of the following **high project risk** criteria:

1. Software failure could result in operating and/or recovery costs in excess of $2 million dollars or primary program capability losses in excess of six months;
2. Software failure could impact emergency communications with local, state, and federal government agencies;
3. Software failure could adversely disrupt vital GS systems (e.g., ventilation systems, radiological protection systems, fire detection and suppression systems, facility security systems, etc.) important to continued facility operations;
4. Software failure could have a legal, regulatory, or external milestone impact; or
5. Where software results are the sole source of quality-related information that is provided to external customers.

**Level E**: Software used in GS (non-safety) applications where software failure or application error could result in the potential for medium to low project risk, but where results are not the sole source of quality-related information that is provided to external customers.

### 19.5 Safety Software Requirements

In addition to using ASME NQA-1-2008/09a³ including Subpart 2.7 to address work processes, additional requirements are imposed by DOE O 414.1D⁴ for the management of safety software, as follows:

1. The facility design authority will be involved, as applicable, in: identifying software specification, acquisition, design, development, verification and validation (including inspection and test), configuration management, maintenance, and retirement of safety software.
2. A software registry will be used to identify, document, and maintain the software inventory for safety software. The software registry includes: software description; software name; version identifier; safety software designation (e.g., safety system software, safety and hazard analysis software and design software, safety management and administrative controls software); grade level designation; specific nuclear facility application used; and the responsible individual.
3. Using ASME NQA-1-2008/09a³ or equivalent consensus standard and the grading level described in this QAP, select and implement the applicable SQA work activities from the list below:
   a) Software project management and quality planning,
   b) Software risk management,
   c) Software configuration management,
   d) Procurement and supplier management,
e) Software requirements identification and management,
f) Software design and implementation,
g) Software safety analysis and safety design methods,
h) Software verification and validation,
i) Problem reporting and corrective action, and
j) Training of personnel in the design, development, use, and evaluation of safety software.

19.6 Software Work Activities

Several work activities cross all or multiple phases of the software life cycle. Other work activities are performed within software life cycle phases. The relationship of work activities to software lifecycle phases is presented in Figure 19-1.

![Figure 19-1. Work Activity and Life Cycle Phase Relationship](image)

An in-depth analysis of the implementation of the work activities within the software life cycles and the applicability of the grading levels defined in Section 19.4 is documented in PL-QA-4704 and further defined in PP-QA-4714, Software Management.

19.7 Graded Approach for SQA Work Activities

The SQA work activities shall be implemented using a graded approach based on the software classification and applicable software type. Grading matrices are developed that identify whether implementation can be graded for a classification level and software type, which are further defined in PL-QA-4704.
For each software type and classification level, implementation of a work activity is defined as Full (F), Graded (G), or Not Applicable (N/A). The following information is provided as a guide in determining actions required for each grading approach.

- “Full” (F) implementation of a particular SQA work activity requires that all essential documentation is completed to the degree necessary to ensure that the life cycle work activity is performed in a traceable, planned, and orderly manner. The intended method for demonstrating required implementation of the SQA activity must be documented in software project plans.

- “Graded” (G) implementation of a particular SQA work activity adapts the software life cycle to the extent necessary to provide reasonable assurance that the software performs its intended function. Less formality is required in documentation and implementation of the work activity. The intended graded implementation of the SQA activity must be documented in software project plans.

- “Not Applicable” (N/A) applies to work activities that are not required. For example, certain SQA activities are not required when performed by a service supplier. In this case, control of SQA activities of the software is achieved through procurement contracts and specifications.

19.8 Records

Computer software management process records identified shall be retained in accordance with Section 17.0 of this QAP.

20.0 GOVERNMENT PROPERTY

20.1 Program Basis

This QAP section identifies requirements for QMS implementation that are described by:

1. Criterion 5 of DOE O 414.1D\textsuperscript{4} and
2. QMS Program Element 7.5.4 of ANSI/ISO/ASQ Q9001-2000\textsuperscript{5}.

20.2 Government Property Control

Management shall exercise care with Government property while it is under the control of, or is being used by, SWPF personnel. Procedures for verification, storage, and maintenance of Government property shall be established and implemented to make certain the property is incorporated into the SWPF. The procedures shall ensure that items have been accepted and are properly used and installed. If any government property is lost, damaged, or otherwise unsuitable for use, it shall be reported to DOE and records maintained.
20.3 Government-Furnished Information

Government-furnished information issued by DOE shall be controlled in the manner specified in S-SRI-J-00001, SWPF J-Area and Parsons Offsite Facilities Site Security Plan. All other information shall be controlled as incoming correspondence, in the manner specified in Section 6.0 of this QAP.

21.0 CONTINUAL IMPROVEMENT

21.1 Program Basis

This QAP section identifies requirements for QMS implementation that are described by:
1. Criterion 3 of DOE O 414.1D and
2. QMS Program Elements 5.2, 8.1, 8.4, 8.5.1, and 8.5.3 of ANSI/ISO/ASQ Q9001-2000.

21.2 Quality Improvement

Quality improvement is a disciplined management process based on the premise that all work can be planned, performed, measured, and improved. Management should ensure that the focus is on improving the quality of products, processes, and services by establishing priorities, promulgating policy, promoting cultural aspects, allocating resources, communicating lessons learned, and resolving significant management issues and problems that hinder the organization in achieving its objectives. Management should balance safety and mission priorities when considering improvement actions.

Management should encourage employees to plan, develop, explore, and implement new ideas for improving products, processes, and services. Improvement processes are most effective when each employee participates and should not be delegated to a particular person or group. Management commitment can be demonstrated by empowering and encouraging employees to:

- Identify problems;
- Identify opportunities for improvement;
- Identify “best management practices”;
- Develop alternative approaches for addressing problems and recommend improvements (e.g., reducing process variability or cycle time);
- Implement the approved solution;
- Evaluate the improvement; and
- Provide lessons learned to other organizations.
21.3 Continuous improvement

Management shall determine, collect, and analyze data to demonstrate the suitability and effectiveness of the quality program and evaluate where continuous improvements can be made to enhance the program’s effectiveness. Data information sources can include customer satisfaction results, conformance with requirements, characteristics and trends including opportunities for preventive action, and suppliers. Continuous improvement of the program’s effectiveness will stem from use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions, and management reviews.

21.4 Lessons Learned

Management shall establish and implement a PP to address a Lessons Learned program for the SWPF to enable the following objectives:

- No repetitive failures;
- Repeat successes;
- Improve performance (e.g., safety, quality, cost, schedule, etc.); and
- Improve culture.

21.5 Analyses of Data

Management shall determine, collect, and analyze appropriate data to demonstrate the suitability and effectiveness of the QMS, and to evaluate where continual improvement of the QMS can be made. This shall include data generated as a result of assessments and from other relevant sources. Analyses of data provide information relating to:

- Customer satisfaction;
- Conformity to product requirements;
- Characteristics and trends of processes and products, including opportunities for preventive action; and
- Suppliers of items and services.

A trend analysis report will be developed periodically (when sufficient information and data are available to ensure that the analysis is meaningful). The trend analysis report, including results from management reviews, will provide an analysis of the data reviewed, trends noted, and recommendations for QMS improvements, as applicable. As a minimum, the report will be distributed to executive management.

21.6 Management Considerations for Improvement

The management quality policy is to implement and maintain the QMS, continually improve its effectiveness, and enhance customer satisfaction by meeting customer requirements.
Management is responsible for the work to be performed safely and in conformance with requirements.

The process characteristics and product conformity measurements, feedback (includes audit, other independent assessment results, management reviews, etc.) received from management, trend analyses of nonconformance, corrective action, preventive action, inspection and test results, and lessons learned shall be analyzed to identify improvement opportunities in the QMS. Implemented improvement shall be monitored during management reviews (see Section 2.5), audits (see Section 18.0) and other independent assessments (see Section 2.6) to verify the effectiveness through subsequent measurements.

21.6.1 SWPF Goals and Objectives

The Project Manager shall review requirements and identify the processes and activities needed for execution, sequence, and interaction of these processes, as well as criteria and methods needed to ensure that operation and control of these processes are effective.

The Project Manager shall identify appropriate measurable goals for the QMS for the processes performed by the relevant functions and levels within the organization, along with the frequency for monitoring, analyzing, and measurement. When planned goals are not achieved, the Project Manager shall direct action(s) to reach those goals.

Project management shall develop appropriate measurable objectives to meet the goals established, to include performance indicators for processes such as cost, schedule, engineering, item and service procurement, safety, environmental, QA, construction, commissioning, and operations. The performance indicators shall be developed by using the corporate performance criteria for guidance and used to measure process owners’ success in achieving objectives as part of the continual improvement process.

21.7 Preventive Action

Management shall determine preventive action to eliminate the cause of potential nonconformances, in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.

A preventive action process shall be established and implemented and define the methods for:

- Determining potential nonconformances and their causes,
- Evaluating the need for action to prevent occurrence of nonconformances,
- Determining and implementing action needed,
- Providing records of results of action taken, and
- Reviewing preventive action taken.
22.0 SUSPECT/COUNTERFEIT ITEMS

22.1 Program Basis

This QAP section identifies requirements for QMS implementation that are described by DOE O 414.1D.

22.2 SWPF Project Suspect/Counterfeit Items Program

Management shall establish and implement a PP to document the SWPF S/CI program. The PP shall include the requirements identified under “Program Basis”, while considering the additional guidance provided by the following document:


The QA Manager shall designate the S/CI Coordinator as the position responsible for S/CI activities and for serving as a point of contact with the Office of Health, Safety, and Security.

22.3 Suspect/Counterfeit Items

S/CI is defined as follows:

- An item is suspect when inspection or testing activities indicate that it may not conform to established Government- or industry-accepted specifications or national consensus standards or whose documentation, appearance, performance, material, or other characteristics may have been misrepresented by the supplier or manufacturer and

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

22.4 Related Processes and Personnel Familiarization with S/CI Program

The subject of S/CI is a consideration during the development of procedures for various processes (e.g., procurement, supplier evaluation, item receipt, inspection, etc.). SWPF staff involved with the development and implementation of management processes shall be required to be familiar with S/CI program requirements described in PL-QA-4703, SWPF Suspect/Counterfeit Item Prevention Plan.

S/CI program requirements include processes for S/CI prevention including:

- Preventing the introduction and use of S/CIs through engineering involvement:
  - In the development of procurement documents, including specifications;
  - During inspection and testing; and
  - When maintaining, replacing, or modifying equipment.
• Identifying and placing technical and QA requirements in procurement documents (specifications);
• Accepting only those items that comply with procurement specifications, consensus standards, and commonly accepted industry practices;
• Inspecting inventory and storage areas to identify, control, and disposition for S/CIs;
• Training and informing managers, supervisors, and workers on S/CI processes and controls (including prevention, detection, and disposition of S/CIs);
• Identifying and disposing of S/CIs on site;
• Restricting the use of an S/CI to only those items that have been found acceptable through engineering analysis and formal disposition process;
• Performing inspection, identification, evaluation, and disposition of S/CIs that have been installed in safety applications and other applications that create potential hazards through engineering supported evaluations for acceptance of installed S/CI as well as marking to prevent future reuse;
• Conducting engineering evaluations used in the disposition of identified S/CIs installed in safety applications/systems or in applications that create potential hazards, which takes into consideration the potential risks to the environment, the public and workers along with a cost/benefit impact, and a schedule for replacement (if required);
• Performing evaluations to determine whether S/CIs installed in non-safety applications pose potential safety hazards or may remain in place and dispositioning S/CIs identified during routine maintenance and/or inspections to prevent future use;
• Reviewing existing lessons learned reports and submittal of new lessons learned reports for use in improving the S/CI prevention process;
• Conducting trend analyses for use in improving the S/CI prevention process as determined by the QA Manager; and
• Collecting, maintaining, disseminating, and using the most accurate, up-to-date information on S/CIs and suppliers using all available sources.

22.5 Control of S/CI

The identification (finding) of any S/CI in conjunction with the work shall be documented in accordance with Section 15.0 of this QAP and shall be immediately reported to SWPF local DOE and the DOE Inspector General.

The S/CI Coordinator shall retain the S/CI until disposition or otherwise directed by SWPF local DOE and the DOE Inspector General.
23.0 PART II SUBPARTS OF ASME NQA-1-2008/09A

This QAP section identifies requirements for QMS implementation that are described by Part II of ASME NQA-1-2008/09a. Each Subpart will be addressed individually.

23.1 SUBPART 2.1, Quality Assurance Requirements for Cleaning of Fluid Systems and Associated Components for Nuclear Power Plants

The requirements of this Subpart will be applied on a forward fit basis to SWPF Operations per procedure PP-EN-5045, SWPF Pipe Cleaning. This procedure specifies appropriate cleanliness requirements, including system cleanliness levels. The procedure contains supplemental requirements for application under an ASME B31.3-2002, Process Piping29 piping program (or per client approved Code of Record year edition).

SWPF-specific requirements are defined in the referenced procedure for cleaning and cleanliness control of all ASME B31.3-2002 piping systems during fabrication, installation, maintenance, repairs, and modifications as applicable. These requirements ensure cleaning of piping systems including removing harmful contaminants, minimizing recontamination of cleaned surfaces, and minimizing the cleaning required after installation, repair, or modification. Piping systems require assurance of cleanliness to ensure proper function. The methodology provided in this PP can be applied to non ASME B31.3-2002 fluid systems and associated components at the discretion of the Design Authority.

23.1.1 General

The work and quality assurance requirements for the cleaning of components and systems and for the control of their cleanliness shall be established in order to:

1. Ensure the removal of deleterious contaminants,
2. Minimize recontamination of cleaned surfaces, and
3. Minimize the cleaning required after installation, repair, or modification.

The cleanliness classification of each item shall be specified.

23.1.2 Planning

Cleaning and cleanliness control activities for each phase (manufacturing, construction, modification, repair, etc.) shall be planned in accordance with the requirements. The plan(s) shall define the cleaning and inspection operations to be used, the system, the responsibilities of the parties concerned for each operation, and the measures to be employed to preserve the cleanliness of cleaned surfaces. In addition, planning shall consider the following factors, as appropriate, recognizing that this list may neither be complete nor applicable to each phase:

1. Adequacy of vents, drains, inspection access points, and bypass or recirculation lines;
2. Facilities for filters and flushing and drain connections in locations where dead legs are unavoidable;
3. Design and installation of piping in a manner that minimizes the necessity for installing temporary piping during the cleaning operations, such as dividing the system into a number of separate cleaning circuits to facilitate cleanability;
4. Sequencing of installation operations to provide for visual inspection of inside surfaces of large diameter piping;
5. Control of installation operations so that piping and components that have already been installed are not subject to contamination when subsequent installation operations are performed;
6. Adequacy of pumping and heating capacities when these are important factors in the cleaning operations;
7. Disposal of cleaning solutions and waste water; and
8. Safety, fire protection, and other hazards.

23.1.3 Procedures and instructions

Written procedures and instructions for cleaning, cleanliness control, inspections, and tests to verify cleanliness of items shall be prepared in accordance with requirements.

Preparation of the actual cleaning procedures or instructions shall consider the following:

1. Work practices, housekeeping, access control, and prevention of contamination and recontamination;
2. Effectiveness of cleaning methods for removal of the contaminants;
3. Effects of residual quantities of cutting fluids, liquid penetrants, weld fluxes, precleaning solutions, engineering test fluids, and other process compounds that may have been intentionally or advertently applied to the surface of the item during prior steps of manufacture, installation, or use;
4. Corrosiveness of cleaning solutions in contact with the material of an item, particularly in the case of dissimilar metals and entrapment of cleaning solutions;
5. Chemical composition, concentration, and temperature limits of cleaning solutions to avoid deleterious effects;
6. Solution and metal temperatures, solution concentrations, velocity, and contact times during cleaning;
7. Methods for monitoring cleaning solution concentration, temperatures, and velocities during cleaning operations;
8. Identification of the items for which the procedures are to be used;
9. Sequence of operations and methods of filling system circulation, draining, and flushing; see below:
   a) Equipment isolation;
   b) Location of:
      i) temporary piping and valves;
      ii) strainers;
      iii) temporary equipment; and
      iv) connections for filling, flushing, rinsing, and draining equipment.

10. Activities to be prohibited or constrained before, during, and after cleaning operations;

11. Methods for rinsing and neutralizing, including estimated number of rinses;

12. Methods for verifying cleanness;

13. Methods for drying and layup;

14. Methods for protecting installed items that are not involved in the cleaning operation; and

15. Method of disposal of cleaning solution.

23.1.4 Rectification of Unacceptable Cleanness

If indications of contamination in excess of specified limits are observed at the end of a cleaning operation or at any subsequent inspections for cleanness, the item shall be re-cleaned using an approved procedure. If such indications are observed at the anticipated end of a cleaning operation, continued cleaning shall be performed to reduce the level to the specified limit. If necessary, an evaluation shall be made to determine the cause of the unacceptable cleanness and the actions required to preclude recurrence.

23.1.5 Control of Cleaning Solutions

Cleaning solutions shall be prepared in accordance with the applicable cleaning procedure and shall be checked for proper chemical composition and effectiveness of inhibitors, if used. Solution temperatures shall be maintained and controlled to ensure adequate cleaning and to prevent cleaning agent decomposition and possible damage to the item.

23.1.6 Cleanness criteria

23.1.6.1 Cleanness Classification

The level of cleanness required for any particular application is a function of the particular item under consideration. The assignment of a cleanness classification shall consider the following:

1. The function of the item to be cleaned;
2. The susceptibility of its materials of construction to various forms of corrosion, including intergranular cracking, or stress corrosion cracking under fabrication, installation, or operating conditions;

3. The consequences of malfunction or failure of the item; and

4. The possibility of contaminants (introduced during fabrication, storage, installation, repairs, or service) contributing to or causing such malfunction or failure.

Four classes of surface cleanliness (Classes A, B, C, and D) with criteria for each are provided. The cleanliness class or classes applicable to the item or specific parts of the item shall be established and specified in the applicable drawings, specifications, or other appropriate documents. Different cleanliness classes may be assigned to internal and external surfaces, or to different parts of the same item based on the cleanliness needs of the specific item.

23.1.7 Cleanliness Class Criteria

23.1.7.1 Class A

A very high level of cleanliness as evidenced by the freedom from all types of surface contamination, according to the acceptance criteria of the inspection methods specified in the required procedures. If close control of particulate contamination is required, a clean room, in accordance with paragraph 8.5.5 of ASTM A380-78, Standard Practice for Cleaning, Descaling, and Passivation of Stainless Steel Parts, Equipment, and Systems, shall be employed during the manufacturing, assembly, and installation operations when particulate contamination could occur. Gross and precision inspection methods applicable to Class A are described in paragraphs 7.2 and 7.3 of ASTM A380-78; other special tests shall be specified as necessary. Where the cleanliness of internal surfaces is evaluated by flushing, criteria shall be specified in the cleaning procedure.

23.1.7.2 Class B

A high level of cleanliness as evidenced by the following characteristics:

1. Corrosion-Resistant Alloys
   a) The surface shall appear metal clean and free of organic films and contaminants when examined in accordance with para. 7.2.1 of ASTM A380-78, Practice for Cleaning and Descaling Stainless Steel Parts, Equipment, and Systems, except light deposits of atmospheric dust are permissible and shall show no evidence of deleterious contamination when subjected to the wipe test of para. 7.2.2 of ASTM A380-78. When visual inspection is impossible but surfaces are accessible for wipe tests, sufficient wipe tests in different areas of the item shall be made to evaluate the general cleanliness level of the surface. Scattered areas of rust are permissible, provided the aggregate area does not exceed 2 square inch (in.\(^2\)) in any 1 square foot (ft\(^2\)) area (14 square centimeter [cm\(^2\)] per 1,000 cm\(^2\)). Temper films and discolorations resulting from welding are acceptable.
b) If flushing is the only practical means for evaluating the cleanliness of internal surfaces, a 20-mesh (850 μm, ASTM E11, Standard Specification for Woven Wire Test Sieve Cloth and Test Sieves\(^3\)) or finer filter (or the equivalent) shall be installed and the item flushed with water or other fluid meeting the requirements of this Subpart. The item shall be flushed at the design velocity (or other flow velocity if specified in the procedure) until the screen shows no more than slight speckling (as specified in the procedure in qualitative or quantitative terms, such as the number of particles per unit surface of the screen) and no more than slight rust staining. There shall be no particles larger than 1/32 in. × 1/16 in. long (0.8 mm × 1.6 mm). In water-flushed systems there shall be no visual evidence of contamination (e.g., oil, discoloration) of the effluent flush water or screen.

2. Carbon and Low-Alloy Steels

   a) The surface shall appear metal clean when examined in accordance with para. 7.2.1 of ASTM A380-78\(^3\), except light deposits of atmospheric dust are permissible, and shall show no deleterious contamination when subjected to the wipe test of para. 7.2.2 of ASTM A380-78\(^3\). Wipe tests shall be made prior to the application of any preservative film (some type of protective film may be required in order to maintain a clean carbon or low-alloy steel surface at Class B level). When visual inspection is impossible, but surfaces are accessible for a wipe test, sufficient wipes of different areas of the item shall be made to evaluate the general cleanliness of the surface. Scattered areas of rust are permissible, provided the aggregate area does not exceed 2 in.\(^2\) in any 1 ft\(^2\) area (14 centimeter [cm] per 1,000 cm\(^2\)).

   b) If flushing is the only practical means for evaluating the cleanliness of internal surfaces, a 20-mesh (850 μm, ASTM E11\(^3\)) or finer filter (or the equivalent) shall be installed and the item flushed with water or other fluid meeting the requirements of this Subpart. The item shall be flushed at the design velocity (or other flow velocity if specified in the procedure) until the screen shows no more than slight speckling (as specified in the procedure in qualitative or quantitative terms, such as the number of particles per unit area of the screen) and no more than slight rust staining. There shall be no particles larger than 1/32 in. × 1/16 in. long (0.8 mm × 1.6 mm). In water-flushed systems there shall be no visual evidence of contamination (e.g., oil, discoloration) of the effluent flush water or screen.

23.1.7.3 Class C.

An intermediate level of cleanliness in which the surfaces meet the requirements for Class B, except:

1. **Corrosion-Resistant Alloys.** Scattered areas of rust are permissible, provided the aggregate area does not exceed 15 in.\(^2\) per 1 ft\(^2\) area (100 cm per 1,000 cm\(^2\)).

2. **Carbon and Low-Alloy Steels.** A uniform light rust bloom that can be removed by brushing or wiping is acceptable.
3. **Corrosion-Resistant Alloys and Carbon and Low-Alloy Steels.** Screens installed for evaluation of internal surfaces by flushing may exhibit considerable particle speckling (as specified in the procedures in qualitative or quantitative terms, such as the number of particles per unit area of the screen) and considerable rust staining.

### 23.1.7.4 Class D

A nominal level of cleanliness in which the following are acceptable:

1. Rust films on both corrosion-resistant alloys and carbon and low-alloy steel surfaces;
2. Tightly adherent mill scale on non-machined carbon and low-alloy steel surfaces that resist removal by hand scrubbing with a stiff wire brush;
3. Paint or preservative coatings on carbon or low alloy steel surfaces that will not peel or flake when subjected to cold water flushing; and
4. Particles no larger than 1/16 in. x 1/8 in. long (1.6 mm x 3.2 mm) on a 14-mesh (1.4 μm, ASTM E1131) or finer filter (or the equivalent).

### 23.1.8 Hydraulic, Instrument Controls, and Lubrication Lines and Systems

The preceding cleanliness classifications and criteria are primarily applicable to relatively large items that are generally amenable to visual inspection of internal surfaces at some time during manufacture and installation operations. Interior surfaces of hydraulic, instrument control, and lubrication systems are generally not accessible for visual inspection during manufacture and installation, and may have much more stringent requirements on particulate contamination than those specified in the preceding cleanliness classes. Where special characteristics and specific requirements are needed for such systems; they shall be specified.

### 23.1.9 Cleaning and Flushing Fluid Quality Requirements

#### 23.1.9.1 Water

The water quality for mixing cleaning solutions, rinsing, and flushing shall be specified by the organization responsible for cleaning unless otherwise stipulated in procurement documents or approved procedures. Water quality requirements commonly used for such purposes in nuclear cleaning operations shall be specified. The water quality for final flushes of fluid systems and associated components shall be at least equivalent to the quality of the operating system water. To minimize the possible adverse effects of halogens, the chemical requirements for water including the use of halogen stress-cracking inhibitors used on components or systems containing austenitic stainless steel or corrosion-resistant alloy shall be as determined by technical evaluation.
23.1.9.2 Gaseous Fluids

The requirements for gaseous fluids used for flushing are dependent upon the particular item being flushed. The requirements for any given item shall incorporate restrictions on particulate contaminants, organic contaminants, water-soluble contaminants, and water content as appropriate for the item.

23.1.9.3 Organic Fluids

Requirements for organic fluids used for flushing are dependent upon the particular item being flushed. The requirements for any given item shall incorporate restrictions on particulate contaminants, water-soluble contaminants, and water content as appropriate for the item.

23.1.9.4 Fluids for Hydraulic, Instrument Control, and Lubrication Systems

In addition to the requirements above, as applicable for the system being flushed, fluids used for final flushing or rinsing of components and installed systems covered by this paragraph shall meet the particulate contamination limits for the system class specified.

If acid cleaning is used, particular attention shall be given to:

1. Avoidance of entrapment of acids in crevices;
2. Effects on either welded or sensitized corrosion resistant alloys and nonferrous materials;
3. Complete removal of any residual acid solution from the item; and
4. Neutralizing treatment followed by thorough rinsing or flushing.

The use of contaminated tools shall be avoided. Tools that contain, or that may become contaminated with, materials that could contribute to stress corrosion or inter-granular cracking shall not be used on corrosion-resistant alloys.

23.1.9.5 Cleanliness During Installation

The installation process represents an opportunity for the introduction of contaminants into a cleaned item, and care shall be taken to minimize contamination. Operations that generate particulate matter, such as grinding and welding, shall be controlled. Cleanup of locally contaminated areas as installation progresses is recommended (rather than one cleanup operation when installation is completed). Consideration shall be given to sequencing of installation and erection operations to facilitate cleaning, cleanliness control, and inspection.

Insofar as practicable, internal surfaces of a portion of a system that can be blocked or obscured by subsequent operations shall be visually inspected and verified as being clean before the access points are closed. Openings and pipe ends shall be sealed at all times except when they must be unsealed to carry out necessary operations. Precautions shall be taken to avoid contamination of crevices, blind holes, dead legs, undrainable cavities, and inaccessible areas. When grinding,
sanding, chipping, or wire brushing, the item shall be so oriented that chips fall away from the openings, or covers shall be provided for the openings.

The use of cleaning methods and materials, cutting fluids, lubricants, liquid penetrants, marking materials, pre-cleaning solutions, engineering test fluids, tools, and other materials and process compounds used during installation of items made from austenitic stainless steel or other corrosion-resistant alloys shall be subject to the limitations specified on such methods and materials.

Surfaces shall be visually inspected upon completion of work, and obvious contamination removed before proceeding to the next installation or construction step. The use of mineral acids and organic acids to clean austenitic stainless steel and nickel alloys shall be evaluated and approved prior to use. Pre-cleaning and post cleaning of weld joint areas and welds shall be performed by wire brushing and scrubbing with a solvent-moistened clean cloth unless otherwise specified. Large openings shall be protected against falling and windblown contaminants.

23.1.9.6  Maintenance of Installation Cleanliness

After any isolable item has been installed in a clean condition, cleanliness control measures and access control shall be established to minimize the introduction of contaminants between the time of system isolation and preoperational testing. Where environmental contamination could cause degradation of quality, seals shall be installed to prevent contamination of interior surfaces. Materials used for sealing items made from austenitic stainless steel or other corrosion-resistant alloys shall be subject to the limitations specified. Seals shall be installed in a manner to prevent accidental removal. Removal shall be only with proper authorization. If access to such sealed items is required, precautions shall be taken to prevent introduction of contaminants. Such precautions include masking and tenting of surrounding areas with plastic film or tape, cleanup of the immediate surroundings to remove particulate matter that can be introduced into the opening, requiring personnel to wear clean outer clothing and shoe covers, etc. Control of tools, loose items, and access shall be maintained in accordance with applicable requirements. When the necessary work is completed, the interior surface shall be locally cleaned, if necessary, to its original condition and the item resealed.

23.1.10  Preoperational Cleaning

23.1.10.1  Preparations

Insofar as practicable, cleaning and flushing operations shall be scheduled so as to minimize interference from other plant operations. Areas in which cleaning operations are being performed shall be isolated and marked to the extent that personnel are aware that the cleaning operations are being conducted.

Personnel shall be familiarized with the intended procedure and associated hazards. Means for communicating shall be provided between the local areas in which the cleaning is performed and any remote areas (e.g., control rooms) that may be related to the cleaning operations. Tools and other loose items shall be controlled as specified.
The actual circulating flow path shall be checked for agreement with specified requirements with regard to location, position, and status of all components. Critical valves, controls, and switches shall be tagged to prevent inadvertent actuation during the cleaning operation. The interior of all accessible components (e.g., tanks) and large diameter piping shall be inspected for cleanliness. All debris and contamination shall be removed. Demineralizers, filters, instruments, valve internals, and other items that may be damaged by the cleaning process shall be blanked off, bypassed, or removed. Protective screens shall be installed on the suction side of all pumps and other components that may be subject to damage during the cleaning operations. Instrumentation (e.g., pressure, differential pressure temperature, and flow) shall be used as necessary to monitor flushing and circulatory cleaning operations. Instrumentation installed in the system but not used to monitor the cleaning operations shall be isolated where necessary. Cleaning shall be completed before process chemicals are introduced. Provisions shall be made to collect liquid leakage and to prevent wetting of insulation.

Where the use of installed plant components such as pumps may be affected by the cleaning operations, recommendations shall be obtained from the component manufacturers regarding precautions to be taken for the use of their components. Procedures shall be established to protect or isolate installed components that could be adversely affected by cleaning or flushing operations.

23.1.11 Flushing and Cleaning Methods

23.1.11.1 Flushing

If the intended level of cleanliness has been maintained during erection of the plant, only flushing or rinsing will normally be required. The system shall be filled with fluid of the type and quality specified and flushed in accordance with approved procedures. Completion of flushing shall be determined by filter, turbidimetric or chemical analysis, or any combination of these, as applicable. If flushes are directed toward the large components, provisions shall be made to prevent contaminants from collecting in areas where they cannot be removed in subsequent cleaning operations. Provisions shall be made to ensure that organics do not remain on the surfaces.

After system flushing is completed, but before draining, all pockets and dead legs shall be thoroughly flushed. Where conditioned water is used, particular attention should be given to ensure that large volumes of solvent do not remain trapped in the system.

After cleaning, the item shall be sealed where appropriate to prevent the subsequent entry of contaminants. If no further cleaning is required, system layup shall be performed if specified.

23.1.11.2 Alkaline Cleaning

Although it is the intent of those involved in erecting the nuclear plant to install piping systems and components in a clean condition, this may not be fully achieved. Common sources of organic contamination in items are lubrication oils from air tools, preservative films, and valve lubricants. When immediate local cleanup is not performed, full item cleaning to remove such
organic contaminants may be necessary. Such cleaning shall be performed according to the cleaning procedures established for the operation, and the procedure shall ensure that quantities of organic contaminants do not remain on the surfaces.

Alkaline cleaning consists of the circulation of an appropriately heated solution until a selected area represented by the worst contamination or a coupon contaminated with the expected contamination is cleaned by the cleaning solution to the specified cleanness level. After item cleaning is completed, the item shall be flushed with water of the specified quality in accordance with paragraph 304.1 of Subpart 2.1 of ASME NQA-1-2008/09a to remove the cleaning agents. In particular, all pockets and dead legs shall be flushed and attention given to ensure that large volumes of solution do not remain.

Where appropriate, the item shall be sealed to prevent subsequent contamination. If no further cleaning is required, system layup shall be performed, if specified.

Alkaline cleaning compounds that contain free caustic shall not be used on components or systems in which cleaning solutions may be entrapped. Cleaners based on compounds that produce alkaline solutions by hydrolysis, such as phosphate compounds, are acceptable. If heavy organic contaminants are present, the addition of an emulsifier and a wetting agent is required.

**23.1.11.3 Chelate Cleaning**

If chelate cleaning is used, attention shall be given to all pockets and dead legs to ensure that large volumes of solution do not remain in the item. Unless it is considered desirable to leave a film of chelating agent on the surfaces as a protective film, the item shall be flushed with water to remove residual chelating agents. Where appropriate, items shall be sealed to prevent subsequent contamination. If no further cleaning is required, layup shall be performed, if specified. Acid-chelating agent shall not be used on welded or furnace-sensitized stainless steels and nickel-based alloys.

**23.1.12 Layup and Post Layup Cleaning**

Upon completion of preoperational cleaning, unless the item is to be released for the next series of operations or tests, the item shall be placed in layup condition by filling with dry, contaminant-free inert gas or air; the process fluid that will be used in the system during operation; fluid of purity equivalent to that used to make up the system; chemically conditioned fluid; or other specified method. Prior to the next series of operations or tests, residual cleaning solutions or layup media shall be removed, if required, from the item by flushing or by draining and filling until the effluent fluid from the item meets the preoperational test fluid quality requirements for the system.

**23.1.13 Post Operational Repairs and Modifications**

Subpart 2.1 does not address radioactive decontamination operations that may be required prior to post operational repairs or system modifications, although some of its requirements may be applicable to such decontamination operations. For the purposes of maintenance of cleanliness,
post operational repairs or system modifications shall be considered identical to preoperational installation procedures and treated in accordance with the specified requirements.

If system cleaning following repair or modification operations is deemed necessary, such cleaning shall be performed until expected contamination is removed and the specified water quality level is achieved. If layup is deemed necessary, it shall be performed.

23.1.14 Records

The following shall be prepared:

1. Record copies of procedures,
2. Reports,
3. Test equipment calibration records,
4. Test deviation or exception records,
5. Inspection or examination records, and
6. Other records necessary to document the cleaning and cleanness history of the items during manufacture, shipment, storage, installation, preoperational cleaning, modifications, and repairs.

These records shall be retained with other project records as required by code, standard, specification, or project procedures.

23.2 SUBPART 2.2 Quality Assurance Requirements for Packaging, Shipping, Receiving, Storage, and Handling of Items for Nuclear Power Plants

The requirements of this Subpart will be applied on a forward fit basis to new procurements of items. This does not include items already procured and in storage, items for which the procurement process has been initiated prior to the effective date of this revision, or procurements for like for like spares or replacements of items. The ASME NQA-1-2004 Code of Record is retained for these items and the existing version of Specification 01610, SWPF Packaging, Shipping, and Storage of Items remains in effect as long as necessary for these items.

Specification 01620, Packaging, Shipping, and Storage of Items (Operations) was developed to align with this Subpart and is available for use with any new procurement on a forward fit basis (except those excluded above).

23.2.1 General Requirements

Measures shall be established and implemented for the packaging, shipping, receiving, storage, and handling of specified items to be incorporated in the nuclear facilities, and for the inspection, testing, and documentation to verify conformance to specified requirements.
23.2.2 Classification of Items

Requirements are divided into four levels with respect to protective measures to prevent damage, deterioration, or contamination of the items based upon the important physical characteristics, and not upon the important functional characteristics of the item with respect to safety, reliability, and operation. It should be recognized, however, that within the scope of each level there may be a range of controls, and that the detailed requirements for an item are dependent on the importance of the item to safety reliability. Each of the specific items shall be classified into one of these four levels by the buyer or the contractor. The manufacturer’s documented standard or minimum requirements shall be considered when classifying the items. Items, once classified at a level, shall be restricted to that level or a higher level for each of the packaging, shipping, receiving, storage, and handling operations. Any package unit or assembly made up of items of different levels shall be classified to the highest level designated for any of the respective items. If the unit is disassembled, a level shall be indicated for each part.

Items shall be categorized under the following levels:

**Level A:** Items classified to Level A are those that are exceptionally sensitive to environmental conditions and require special measures for protection from one or more of the following effects: temperatures outside required limits; sudden temperature changes; humidity and vapors; accelerating forces; physical damage; airborne contamination (e.g., rain, snow, dust, dirt, salt spray, fumes).

Types of items to be categorized under this classification level are:

1. Special electronic equipment and instrumentation;
2. Special materials, such as chemicals, that are sensitive to environmental conditions; and
3. Special nuclear material and sources.

**Level B:** Items classified to Level B are those that are sensitive to environmental conditions and require measures for protection from the effects of temperature extremes, humidity and vapors, accelerating forces, physical damage, and airborne contamination, and do not require special protection required for Level A items.

Types of items to be categorized under this classification level are:

1. Electronic equipment and instrumentation;
2. Electrical equipment;
3. Batteries;
4. Welding electrode and wire (welding electrodes hermetically sealed in metal containers may be stored under conditions described for Level C, unless other storage requirements are specified by the manufacturers);
5. Motor control centers, switchgear, and control panels;
6. Motors and generators;
7. Precision machine parts;
8. Spares, such as gaskets, O-rings;
9. Air-handling filters; and

**Level C:** Items classified to Level C are those that require protection from exposure to the environment, airborne contamination, acceleration forces, and physical damage. Protection from water vapor and condensation is not as important as for Level B items.

Types of items to be categorized under this classification level are:

1. Pumps,
2. Valves,
3. Fluid filters,
4. Compressors,
5. Instrument cable (unjacketed),
6. Thermal insulation,
7. Fans and blowers, and
8. Cement.

**Level D:** Items classified to Level D are those that are less sensitive to the environment than those for Level C. These items require protection against the weather, acceleration forces, airborne contamination, and physical damage.

Types of items to be categorized under this classification level are:

1. Tanks,
2. Heat exchangers and parts,
3. Piping,
4. Electrical cable (jacketed),
5. Structural items,
6. Reinforcing steel, and
7. Aggregates.
23.2.3 Packaging

23.2.3.1 General

Packaging of items for protection against corrosion, contamination, physical damage, or any effect that would lower the quality or cause the items to deteriorate during the time they are shipped, handled, and stored shall be specified. The degree of protection specified will vary according to conditions and duration of storage, shipping environment, and handling conditions.

Implementation of the specified requirements is accomplished by identifying the item and the appropriate packaging level, and then applying the appropriate criteria concerning cleaning, preservatives, desiccants, inert gas blankets, cushioning, caps and plugs, barrier and wrapping materials, tapes, blocking and bracing, containers, marking, other QA provisions, and documentation.

23.2.3.2 Packaging

The packaging requirements shall be based on the protection that is necessary during shipping, handling, and storage of the item to satisfy Levels A, B, C, and D protection requirements. The requirements are intended to be in addition to industry classifications or tariff rules for rail, truck, air, and water shipments and regulatory agency rules already established in the transportation industry; and in no way are they intended to reduce the minimum standards established by these regulatory agency rules.

The following packaging criteria are divided into four levels corresponding to the classification categories.

**Level A Items:** Level A items require the highest degree of protection and shall conform to the following criteria:

1. Package design requirements shall be for extraordinary environmental protection to avoid the deleterious effects of shock and vibration, to control temperature or humidity within specified limits, or for any other special requirements.

2. Items shall have been inspected for cleanliness immediately before packaging. Dirt, oil residue, metal chips, or other forms of contamination shall have been removed by approved cleaning methods. Any entrapped water shall have been removed.

3. Items that are not immediately packaged shall be protected from contamination.

4. Items requiring protection from water vapor, salt air, dust, dirt, and other forms of contamination penetrating the package shall be packaged with a barrier.

5. Items that require protection from damage during shipping and handling shall be packaged in containers or crates.
6. Items that can be damaged by condensation trapped within the package shall be packaged with approved desiccant inside the sealed waterproof and vapor-proof barrier or by an equivalent method.

7. All openings into items shall be capped, plugged, or sealed. Weld end preparations shall be protected against corrosion and physical damage.

8. Items packed in containers shall be blocked, anchored, braced, or cushioned to prevent physical damage to the item or barrier.

9. Items and their container shall be identified by marking.

**Level B Items:** Level B items require a high degree of protection, and the package shall be designed to avoid the deleterious effects of shock, vibration, physical damage, water vapor, salt spray, condensation, and weather during shipping, handling, and storage. This packaging shall be equivalent to that for Level A, except that the package design requirements need not be equivalent to satisfy the level of extraordinary environmental protection indicated where such protection is not justified. Shipment of Level B items in fully enclosed vehicles or equivalent protective enclosure or packaging is acceptable, provided the above-stated high degree of protection for Level B items is maintained throughout shipment, and the shipment goes through to destination in the original vehicle and Level B storage facilities are available on site. If transfer becomes necessary to transit, transfer procedures shall be subject to purchaser acceptance.

**Level C Items:** Protection is required from exposure to salt spray, rain, dust, dirt, and other contaminants. Protection from water vapor and condensation is less important than for Level B items. The following criteria shall apply:

1. Criteria (2), (3), (5), (7), (8), and (9) for Level A items shall apply to Level C items.
2. Items shall be packaged with a waterproof barrier so that water, salt spray, dust, dirt, and other forms of contamination do not penetrate the item.
3. Items subject to detrimental corrosion, either internal or external, shall be suitably protected.

**Level D Items:** Protection is required from physical and mechanical damage. The following criteria shall apply:

1. Items, just before packaging, shall have been inspected for cleanliness according to the requirements specified in the purchasing document. Dirt, oil residue, metal chips, or other forms of contamination shall have been removed by approved cleaning methods. Any entrapped water shall have been removed.
2. All openings into items shall be capped, plugged, and sealed. Weld end preparations shall be protected from corrosion and physical damage.
3. Items subject to detrimental contamination or corrosion, either internal or external, shall be suitably protected.
4. Items packed in containers shall be blocked, braced, or cushioned to prevent damage.
5. The identity of the item shall be maintained by marking or other appropriate means.

23.2.3.3 Cleaning

Cleaning includes the preparation of items for preservation or packaging, or both, to minimize the requirements for site cleaning. Items shall be inspected for cleanliness immediately before packaging according to the cleaning requirements specified in the procurement documents. Any dirt, oil residue, metal chips, or other forms of contamination shall be removed by documented cleaning methods. Any entrapped water shall be removed.

The following general criteria shall apply as part of the manufacturing specifications specific cleaning procedures:

1. The cleaning process, including cleaning compounds chosen, shall in no way damage the item during cleaning or subsequent service when considering the composition, surface finish, complexity, or other inherent features, or other interface equipment after installation.

2. The cleaning process or processes chosen shall remove loose mill and heat scale, oil, rust, grease, paint, welding fluxes, chalk, abrasives, carbon deposits, coatings used for nondestructive testing processes, and other contaminants that would render ineffective the method or preservation and packaging or other specified requirements.

3. Item surfaces after cleaning shall be free of cleaning media, such as aluminum oxide, silica, grit, cleaning cloth residual, chemical cleaning residue, and petroleum solvent residue, etc.

4. After cleaning, the item shall be protected from contamination until preservation or packaging is complete.

23.2.3.4 Methods of Preservation

Items subject to deleterious corrosion shall be protected by using either contact preservatives, inert gas blankets, or vapor-proof barriers with desiccants.

1. Contact Preservations. Contact preservatives are compounds applied to bare metal surfaces to prevent surface corrosion during shipping and storage and generally require removal prior to installation.

The following criteria shall be used when considering the type of contact preservative to be used:

a) The contact preservative shall be compatible with the material on which it is applied.

b) Contact preservatives that are nondrying shall require a neutral greaseproof protective wrap when packaged.

c) The procedure for applying contact preservatives shall not require disassembly of the item nor shall it be necessary to disassemble the item at the site for complete removal. An exception would be for long-term storage protection to be agreed upon by the Owner, buyer, and manufacturer.
d) The method of contact preservative removal shall be accomplished with approved solvents and wiping cloths, or by flushing internal cavities with solvents that are not deleterious to the item or other interconnecting material. However, preservatives for inaccessible inside surfaces of pumps, valves, and piping shall be the water-flushable type.

e) The name of the preservative used shall be provided to facilitate touch-up.

f) When motors, pumps, turbines, etc., are shipped with oil reservoirs and bearing cavities filled with preservative oil, the item shall be so tagged and instructions for draining, flushing, refilling, and periodic rotation shall be included with the item.

g) When it is anticipated that the item might require an extended storage period (6 months or longer), a preservative needed for the long-term protection of the item shall be applied or arrangements shall be made to periodically reapply the preservatives.

2. **Inert Gas Blankets.** Purging and pressurizing the interior of an item or its container, or both, with a dry inert gas provides a means of preventing moisture or corrosive atmospheres from acting on sensitive, bare metal surfaces or other materials. The item or its container shall be either evacuated prior to filling with the inert gas or adequately purged with the same gas prior to applying the gas blanket.

When inert gas blankets are used, the following criteria shall apply:

a) Inert gas blankets shall be used only when the exterior shell of the item or its container can be tightly sealed or an inert gas blanket can otherwise be maintained.

b) Only dry, oil free, inert gas shall be used.

c) Provisions shall be made for measuring and maintaining the blanket pressure within the required range and within each pressurized purged item or container. Closures and seals, when used to maintain a static pressure, shall be tightly secured so that the absolute pressure (by mass) after final seal is maintained for 24 hours, without adding gas, prior to shipping the item from the manufacturer’s plant.

d) The item or container shall be marked in bold letters cautioning that an inert gas blanket has been used. The required pressure range also shall be marked on the item or container.

### 23.2.3.5 Caps, Plugs, Tapes, and Adhesives

These items shall be of materials that enable them to perform their intended function adequately, without causing deleterious effects on the items or system operation.

1. **Caps and Plugs.** Caps and plugs shall be used to seal openings in items having sensitive internal surfaces and to protect threads and weld end preparations.

Caps and plugs shall conform to the following criteria:

a) Nonmetallic plugs and caps shall be brightly or contrasting color. Clear plastic closures are not to be used except when specified for a special purpose, e.g., as a window.
for humidity indicator cards. Special attention shall be given in the control of these closures.

b) Metallic plugs and caps contacting metal surfaces shall not cause galvanic corrosion at the contact areas. Gasketing or other nonmetallic materials used in conjunction with metallic caps or plugs shall exhibit no corrosive effect on the material.

c) Simplicity of installation, inspection, and removal without damage to the item shall be considered.

d) Provisions shall be made to preclude the plug or cap from falling into or being pushed into the opening after its installation.

e) Plugs or caps shall be secured with tape or other means as necessary to prevent accidental removal.

f) All plugs and caps shall be clean and free of visible contamination such as, but not limited to, dust, dirt, stains, rust, discoloration, or scale.

g) Plugs and caps used in contact with austenitic stainless steel or nickel alloys shall be made from nonhalogenated materials or stainless steel.

2. **Tapes and Adhesives.** Pressure-sensitive, removable tape shall be used in lieu of adhesives in contact with bare metal surfaces. Tapes or adhesives that could have damaging effects on the item or system shall not be used. Tapes near a weld shall be removed completely, immediately prior to performing a weld. Tapes used for identification rather than sealing that are not near a welding operation may remain until system testing is complete, but shall be removed before facility operations unless qualified for operating conditions.

Tapes and adhesives shall conform to the following criteria:

a) When contacting austenitic stainless steel and nickel alloy surfaces:

   i) Tapes shall not be compounded from, or treated with chemical compounds containing elements in such quantities that harmful concentrations are leachable, or that they could be released by breakdown under expected environmental conditions and could contribute to intergranular cracking or stress corrosion cracking, such as those containing fluorides, chlorides, sulfur, lead, zinc, copper, and mercury (paperbacked [masking] tape shall not be used).

   ii) Upon removal of tape, all residual adhesive shall be removed by wiping with a nonhalogenated solvent (acetone, alcohol, or equal).

   iii) Starch, silicone, and epoxy tape material may be used for tape adhesive.

b) When contacting other surfaces and containers:

   i) Tapes and adhesives used to seal nonaustenitic materials, nickel alloys, or containers are not subject to the above restrictions.

   ii) Tape shall be impervious to water and not subject to cracking or drying out if exposed to sunlight, heat, or cold.
When used on surfaces of items, tapes shall be visibly distinguishable from the materials on which they are used.

23.2.3.6 Barrier and Wrap Materials and Desiccants

Material thickness shall be selected on the basis of type, size, and weight of equipment or item to be protected, such that the barrier or wrap will not easily be damaged by puncture, abrasion, weathering, cracking, temperature extremes, wind conditions, and the like. Barrier and wrap materials shall be noncorrosive and shall not be otherwise harmful to the item packaged. When barrier and wrap materials are used in direct contact with austenitic stainless steels, the total and water leachable content of halogen shall not be harmful to the item packaged. Also, barrier and wrap materials shall not readily support combustion. Vapor-proof barrier materials used with desiccants constitute another preservation system that protects against potential damage by water vapor condensate.

1. **Waterproof Barrier Material.** Waterproof barrier material shall be resistant to grease and water; it shall protect items from airborne and windblown soils.

2. **Vapor-proof Barrier Material.** Vapor-proof barrier materials shall be sealable, and the edge of the barrier that normally will be opened at destination shall be of sufficient area to permit at least two subsequent sealing operations. When maximum vapor protection is required, barrier material shall meet the maximum water vapor transmission rate of 0.05 grams/100 in.² per 24 hours required by Procedure E, of ASTM E 96, *Standard Test Methods for Water Vapor Transmission of Materials*[^34], and shall be packaged with an approved desiccant. Vapor-proof barrier material should be colored to contrast with the material on which it is used.

3. **Desiccants.** Desiccants shall be used within a vapor-proof barrier when condensation or high humidity could damage an item by corrosion, mold, or mildew.

Desiccants shall consist of nondeliquescent, nondusting, chemically inert, dehydrating agents. The following criteria shall apply:

a) The desiccant bag shall be made of puncture-, tear-, and burst-resistant material.

b) When used with austenitic stainless steel and nickel alloy materials, tapes, desiccants, and the materials for the desiccant bag shall not be compounded from or treated with chemical compounds containing elements in such quantities that harmful concentrations are leachable, or they could be released by breakdown under expected environmental conditions and could contribute to intergranular cracking or stress corrosion cracking, such as those containing fluorides, chlorides, sulfur, lead, zinc, copper, and mercury.

c) The reactivation temperature and time shall be marked on the desiccant container.

d) Canisters used to contain desiccants shall be placed so as to cause no deleterious effects such as galvanic corrosion, even when the desiccant has reached its absorptive capacity for water vapor.
e) Desiccant bags and canisters, when used, shall be secured to prevent movement, rupture of the bags, or damage to the item being protected.

f) Waterproof and vapor-proof barriers shall be used to seal items containing desiccants. The included air volume within the barrier shall be kept to a minimum.

g) Items that contain desiccants shall have all openings securely sealed. When flange connections are a part of the barriers, O-rings or gaskets shall be used with all bolts in place and tightened sufficiently to ensure a waterproof and vapor-proof seal. Weld end preparations, after capping, shall be covered with a waterproof and vapor-proof seal.

h) Packages and items containing desiccants shall be marked. The total number of separate bags or containers of desiccants in the package shall be indicated.

i) The minimum quantity of desiccant for use in each package shall be determined in accordance with Formula I or Formula II, as applicable.

   i) Formula I: to determine minimum units of desiccant for use with other than sealed rigid metal barrier:

   \[ U = 1.6A + XD \]  

   (Eq. 1)

   ii) Formula II: to determine minimum units of desiccant for use with sealed rigid metal barrier:

   \[ U = KV + XD \]  

   (Eq. 2)

where

- \( A \) = area of barrier, ft\(^2\) (square meters X 0.0929)
- \( D \) = dunnage (other than metal) within barrier, pound (lb) (kilogram [kg] X 2.2)
- \( K \) = 0.0007 when volume is given in cubic inches
  - = 1.2 when volume is given in cubic feet (ft\(^3\))
  - = 0.0000425 when volume is given in cubic centimeters (cm\(^3\)) (42.5 in cubic meters)
- \( U \) = number of units of desiccant to be used (see Note)
- \( V \) = volume within barrier in cubic inches or ft\(^3\) (cm\(^3\) or cubic meters)
- \( X \) = 8 for hair felt, cellulosic material (including wood), and other material not categorized below
  - = 6 for bound fibers (animal hair, synthetic fiber, or vegetable fiber bound with rubber)
  - = 2 for glass fiber
  - = 0.5 for synthetic foams and rubber

NOTE: A desiccant unit is that quantity of desiccant, as received, that will absorb at equilibrium with air at 78 degrees Fahrenheit (°F) (25 degrees Celsius [°C]) at
least the following quantities of water vapor: 3.00 grams at 20 percent (%) relative humidity and 6.00 grams at 40% relative humidity.

j) A humidity indicator shall be included in every waterproof and vapor-proof envelope containing desiccant. As applicable, the indicator shall be located behind inspection windows or immediately within the closing edge, face, or cover of the barrier and, as far as practical, from the nearest unit of desiccant.

23.2.3.7 Containers, Crating, and Skids

1. Containers. Containers shall be used when maximum protection for the item or its barrier is required. Container types shall include, but not be limited to, the following:
   a) Cleated, sheathed boxes (500 lb [227 kg] maximum net weight);
   b) Nailed, screwed, or bolted wood boxes;
   c) Wood-cleated solid fiberboard boxes;
   d) Metal or fiber drums;
   e) Crates;
   f) Wire-bound boxes [200 lb (91 kg) maximum net weight];
   g) Other specially designed containers for special equipment; and
   h) Fiberboard boxes [120 lb (54.5 kg) maximum net weight]. The following criteria shall apply for fiberboard boxes used as exterior containers:
      i) Boxes shall be weather-resistant fiberboard preferably from the grade types (or compliance symbol): V2 s, V3 s, or V3 c (Federal Specification PPP-B-636).
      ii) Box style shall be Regular Slotted Container regular slotted box (outer flaps meet, inner flaps and outer flaps are of equal length).
      iii) Fiberboard boxes shall be securely closed with a water-resistant adhesive applied to the entire area of contact between the flaps. All seams and joints shall be further sealed with not less than 2 inch (5 cm) wide, water-resistant tape.
      iv) Boxes shall be strapped with pressure-sensitive reinforced tape, lengthwise (top, bottom, and ends), girthwise (top, bottom, and sides), and horizontal sides and ends.
      v) Wood cleating on fiberboard boxes shall be fabricated from structurally sound, seasoned or treated lumber. Cleated boxes in excess of 50 lb (22.7 kg) shall be bound with steel strapping, or equivalent, around the container at not less than two places.

2. Crates and Skids. Crates and skids shall be used for equipment in excess of 500 lb (227 kg). Skids or runners shall be used on crates with a gross weight of 100 lb (45.5 kg) or more, allowing a minimum floor clearance for forklift tines as provided by 4 inches (10 cm) lumber.
23.2.3.8 Cushioning, Blocking, Bracing, and Anchoring

1. **Cushioning.** Cushioning shall be used where protection from shock and vibration is required. The cushioning materials shall have sufficient strength to perform this function.

   Selection of cushioning material shall be based on the following:
   a) It shall exhibit no corrosive effect when in contact with the item being cushioned.
   b) It shall have low moisture content and exhibit low moisture absorption properties, or if the cushioning material has some moisture-absorbing capacity, the item shall be protected with a water-vapor proof barrier.
   c) It shall have negligible dusting characteristics.
   d) It shall not readily support combustion.

2. **Blocking and Bracing.** Blocking and bracing used for protection of the load to be supported shall be compatible with the size, shape, and strength of bearing areas of the shipment. The blocking and bracing used to prevent item movement shall withstand thrust and impact applied in any direction. Blocking and bracing used in direct contact with the item being blocked shall not have a corrosive effect on the item.

3. **Anchoring.** Anchoring of the item within a crate or on a skid shall adequately fasten the item during shipment and protect the item from potential damage due to rough handling.

   When bolts are used for anchoring, the following criteria shall apply:
   a) If precision bolt holes in the item are used for anchoring, precaution shall be taken to ensure that properly fitting bolts of the correct dimension and characteristics are used to prevent marring or elongation of the holes.
   b) Holes bored through containers or mounting bases shall provide a snug fit.
   c) When mounting items to container bases equipped with skids, bolts shall be extended through the skids whenever practical. In such instances, countersinking of the bolts in the sliding surface of the skid shall be done.
   d) Washers shall be used under the nuts to decrease the possibility of the bolt pulling through the wood.
   e) Nuts shall be properly tightened. To prevent their loosening during shipment, locknuts, lock washers, cotter pins, or staking shall be employed.

   Temporary cushioning, blocking, bracing, or anchoring placed on an item for shipping protection that needs to be removed prior to operation of the item shall be identified by warnings placed in a conspicuous manner to affect proper removal of the packing material.

23.2.3.9 Marking

To maintain proper identification and instructions, or both, during shipping, receiving, and storage and to provide for identification after the outside of the container has been removed, the item and the outside of the containers shall be marked. If equipment does not lend itself to
marking, records shall be maintained that are uniquely identifiable to the item. Items shall be marked to preserve identity in accordance with the following criteria:

1. The specified identification shall be stamped, etched, stenciled, or otherwise marked on the item or on tags to be affixed securely to the item in plain, unobstructed view. When metal stamps are employed, low stress stamps shall be used when the item proper is marked. When vibrating marking tools are used, they shall be fitted with carbide marking tip or its equivalent, and shall be designed to provide a rounded impression not to exceed 0.010 in. (0.25 mm) in depth. Etching shall not be used on nickel alloys, weld areas, or sensitized areas of stainless steel. Electric-arc marking pencils shall not be used.

2. The marking shall neither be deleterious to the material nor violate any other specified requirements.

3. (When tags are employed, they shall be of a material that will retain the marking, withstand weathering deterioration, and other normal shipping and handling effects, and shall not be detrimental to the item.

4. The English language shall be used. Duplicate marking may be made in other languages.

5. References to weights shall be in avoirdupois units. Duplicate markings in other systems may also be indicated.

Markings on the outside container shall be in accordance with the following criteria:

1. Container markings shall appear on a minimum of two sides of a container, preferably on one side and one end.

2. The English language shall be used. Duplicate marking may be made in other languages or in pictorial marking according to ISO Recommendation R780, *Pictorial Markings for Handling of Goods (General Symbols)* or ANSI MH6.1, *Pictorial Markings for Handling of Goods*.

3. References to weights shall be in avoirdupois or System International units. Duplicate markings in other systems may also be indicated.

4. Container markings shall be applied with waterproof ink or paint in characters that are legible. When information relative to handling and special instructions is required, such information shall be preceded by the word CAUTION in letters that are at least 1/2 inch (12.7 mm), as permitted by container size.

5. Where tags or labels are used, they shall be affixed to the container using a waterproof adhesive, tacks where practical, or a corrosion-resistant wire.

6. Container markings shall include the following information:
   a) Destination;
   b) Return address;
   c) Package numbers showing the purchase order number, followed by the package number and the total number of packages;
d) Material identification number;

e) Handling instructions (e.g., fragile, center of gravity, keep dry, this side up, sling here, do not freeze) and stacking limitations, as appropriate;

f) Weight of package [in excess of 100 lb (45.5 kg)]; and

g) Special instructions (desiccant inside, special inspection, storage, unpacking restrictions, etc.) as appropriate.

Marking of items not within a container, such as pipe, tanks, and heat exchangers, shall exhibit specified information in a location that is in plain unobstructed view. Marking may be applied directly to bare metal surfaces, provided it has been established that the marking material is not deleterious to the item.

23.2.3.10 Shipping

The general requirements for loading and shipment of items are defined. The mode of transportation used shall be consistent with the protection classification of the item and the packaging methods employed. Special shipping instructions from the manufacturer, approved alternatives should be addressed while meeting the specified requirements.

23.2.3.10.1 Transportation Requirements

1. Open Carriers. For shipment on open carriers where items may be exposed to adverse environmental conditions, the following shall apply:

   a) Levels A, B, and C items shall be covered for protection from environmental conditions. Tarpaulins, when used, shall be fire retardant, and they shall be installed in a manner to provide drainage and to ensure air circulation to prevent condensation.

   b) Barrier and wrapped materials subject to transportation damage shall be covered with waterproof shrouds, such as tarpaulins, so that they are not exposed directly to the environment.

2. Closed Carriers. For shipment on closed carriers, when Levels A, B, and C items cannot be adequately protected from weather or environment on open carriers, closed carriers or fully enclosed vehicles shall be used.

3. Special Shipments. Items that exceed established weight or size limitations for railroads or highways or require special handling shall be given additional consideration in the following areas:

   a) The type of bracing and tie-down methods to be used with the mode of transportation selected for special shipments shall be specified.

   b) No humping shall be specified on rail shipments of these items, and no humping signs shall be prominently displayed.

   c) Use of impact recording meters shall be specified on shipments of heavy or relatively large items incorporating delicate factory-installed instrumentation. Devices, when
specified, shall be installed prior to loading (to record any rough handling during loading). Procedures shall be established to interpret recorded data and to thoroughly check the integrity of an item when there is evidence of rough handling. A notice that impact recording devices are being used shall be prominently displayed. Special recording devices with operating time limits greater than the expected transit time shall be specified or, if the expected transit time exceeds the operating time limit of the recorders being used, provisions shall be made to service the devices during transit.

d) For special shipments, the conveyance used for transport shall be certified to be structurally adequate to take the loads imposed during loading, while en route, and during unloading. Prior to shipment, the route shall have been investigated to ensure safe transit.

**23.2.3.10.2 Precautions During Loading and Transit**

1. **Loading.** The weight, lifting points, or center of gravity indicated by the shipper on the crate, skid, or package by the shipper shall be utilized to ensure proper handling during loading, transfer between carriers, and unloading.

2. **Rigging.** Carbon steel rigging equipment shall not come in direct contact with stainless steel, except when attached to lifting lugs, eyes, or pads in order to avoid surface damage.

3. **Handling Precautions.** All austenitic stainless steel and nickel-base alloy materials shall be handled in such a manner that they are not in contact with lead, zinc, copper, mercury, or other low melting point elements, carbon steel, alloys, or halogenated material having a water-leachable content harmful to the material.

4. **Package and Preservative Coatings.** Package or preservative coatings shall be visually inspected after loading and damaged areas repaired prior to shipment. Items shipped with desiccants shall be inspected after loading to ensure that sealed areas are intact.

5. **Sealed Openings.** Sealed openings shall be visually inspected after loading to ensure closures are intact. Materials used for resealing shall be in accordance with specified requirements.

6. **Stacking.** Where special care is deemed necessary to avert damage, written instructions concerning the location or stacking limits for crates or boxes shall be marked on the containers.

7. **Theft and Vandalism.** Precautions shall be taken to minimize the possibility of theft and vandalism during shipment of items.

8. **Identification and Markings.** Identification and markings on the outside of all packages, skids, or protective covering shall be maintained.

**23.2.3.10.3 Shipments from Countries Outside the United States**

When overseas shipments are involved, use of deck cargo facilities shall be avoided unless necessary due to physical dimensions. Shipments using approved watertight containers may be carried on deck. Items shall be inspected to ensure integrity of packaging or protective enclosures after being loaded aboard ship and when off-loaded at the point of entry.
Identification and markings shall follow approved procedures. Requirements for transportation shall be followed where applicable.

23.2.3.11 Receiving

Receiving requirements shall be fulfilled by the organization(s) responsible for the receiving of items. Receiving starts when the items arrive at a storage facility or construction site before unloading or unpacking.

23.2.3.11.1 Receiving Inspection Requirements

1. **Shipping Damage Inspection.** Preliminary visual inspection shall be performed prior to or immediately after unloading to determine if any damage occurred during shipping. Observations for unusual conditions shall include the following:
   a) Fire: Charred paper, wood, or paint, indicating exposure to fire or high temperature.
   b) Excessive exposure: Weather-beaten, frayed, rusted, or stained containers, indicating prolonged exposure during transit.
   c) Environmental damage: Water or oil marks, damp conditions, dirty areas, or salt film, indicating exposure to sea water or winter road salt chemicals.
   d) Tie-down failure: Shifted, broken, loose, or twisted shipping ties, and worn material under ties indicating improper blocking and tie down during shipment.
   e) Rough handling: Splintered, torn, or crushed containers, indicating improper handling.
   f) Review of impact recording device readings against established criteria.
   g) Review of humidity recording data against established criteria.

2. **Item Inspection.**
   a) Unless the package marking prohibits unpacking, the contents of all shipments shall be visually inspected to verify that the specified packaging and shipping requirements have been maintained. When items are contained in transparent, separate, moisture proof bags or envelopes, visual inspection without unpacking the contents shall be acceptable. Where specific inspection requirements can be achieved, statistical sampling methods may be used for groups of similar items. Care shall be taken to avoid contamination of the items during inspection. The inspection shall be performed in an area equivalent to the level of storage requirement for the item. If an appropriate area is not available, the inspection shall be performed in a manner and environment that does not endanger the required quality of the item. These inspections and examinations shall include the following, as appropriate:
      i) Identification and marking: Verification that identification and markings are in accordance with applicable codes, specifications, purchase orders, and drawings, and any specified requirements.
ii) Manufacturing documentations: Assurance that the item received was fabricated, tested, and inspected prior to shipment in accordance with applicable code, specification, purchase order, or drawings.

iii) Protective covers and seals: Visual inspection to ensure that covers and seals meet their intended function.

iv) Coatings and preservatives: Verification that coatings and preservatives are applied in accordance with specifications, purchase orders, or manufacturer’s instructions.

v) Inert gas blanket: Verification that the inert gas blanket pressure is within the acceptable limits.

vi) Desiccant: Verification that the desiccant is not saturated, as indicated, through the use of humidity indicators. Desiccants shall be regenerated or replaced as necessary in accordance with special instructions.

vii) Physical damage: Visual inspection to ensure that parts of items are not broken, cracked, missing, deformed, or misaligned, and that rotating parts turn without binding. Accessible internal and external areas shall be free of detrimental gouges, dents, scratches, and burrs.

viii) Cleanness: Visual inspection to ensure that accessible internal and external areas are within the specification requirements for dirt, soil, mill scale, weld splatter, oil, grease, or stains. If inspection for cleanness was performed prior to sealing and shipping, and inspection upon receipt indicates that there has been no penetration of the sealed boundary, then inspection for internal cleanness is optional.

b) Unless the completed item was inspected at the source, it shall be inspected at the point of receiving to verify that the following characteristics conform to the specified requirements. These inspections shall include such items as:

i) Physical properties: Assurance that physical properties conform to the specified requirements and that chemical and physical test reports, if required, meet the requirements.

ii) Dimensions: Random visual inspection to ensure that important dimensions conform with drawings and specifications, i.e., base plate mounting holes, overall external size, and configuration and orientation of parts.

iii) Weld preparations: Random verification that weld preparations are in accordance with applicable drawings and specifications.

iv) Workmanship: Visual inspection of accessible areas to ensure that the workmanship is satisfactory to meet the intent of the requirements.

v) Lubricants and oils: Verification of presence of proper lubricants and oils, if required, by either specification, purchase order, or manufacturer’s instructions.
vi) Electrical insulation: Performance of insulation resistance tests for motors, generators, and control and power cable to ensure conformance with specifications.

3. **Special Inspection.** Where receiving inspection in addition to that described above is required, the special inspection procedure, complete with documentation instructions, shall be attached to the item or container. This is in addition to the copy sent through normal channels. The special inspection shall be performed, and the results of the inspection shall be documented.

**23.2.3.11.2 Disposition of Received Items**

Containers and items inspected and found in conformance with specified requirements shall be identified as acceptable and placed in a storage area for acceptable items, or moved to the final location for installation and use. Items that do not conform to the specified requirements shall be controlled in accordance with nonconforming items procedures. If the nonconformance that caused the item to be classified unacceptable can be corrected after installation, the item may be released for installation on a conditional release basis. A statement documenting the authority and technical justification for the Conditional Release of the item for installation shall be prepared and made part of the documentation.

**23.2.3.11.3 Status-Indicating System, Marking, and Documentation**

A status-indicating system is a system or method for identifying the status of items (e.g., an inventory management system, tagging, labeling, color coding, etc.) that clearly indicates whether items are acceptable or unacceptable for installation. A controlled physical separation is an acceptable equivalent method. The system shall provide for indication of the date the item was placed in the acceptable or unacceptable installation status and the conditional release of the items for installation pending the subsequent correction of the nonconformance. When tags are used, the stock shall be made from material that will not deteriorate during storage. The stock used shall not be deleterious to the item. Tags shall be securely affixed to the items and displayed in an area that is readily accessible. Changing, correcting, or any other marking on nameplates shall be prohibited, unless authorized by the manufacturer of the item. A written record of the receiving inspection, package identification, tagging, corrective actions, and justification for conditional acceptance shall be prepared.

**23.2.3.12 Storage**

The requirements that shall be fulfilled by the organization responsible for performing the storage of items shall be defined. Levels and methods of storage are defined to minimize the possibility of damage or lowering of quality due to corrosion, contamination, deterioration, or physical damage from the time an item is stored upon receipt until the time the item is removed from storage and placed in its final location. Special storage instructions from the manufacturer, if specified, shall be addressed as part of the storage process for both short- and long-term storage of items.
23.2.3.12.1 Levels of Storage

Environmental conditions for items classified as Levels A, B, C, and D shall meet the requirements as described in the following paragraphs:

1. Level A items shall be stored under special conditions similar to those described for Level B items but with additional requirements such as temperature and humidity control within specified limits, a ventilation system with filters to provide an atmosphere free of dust and harmful vapors, and any other appropriate requirements.

2. Level B items shall be stored within a fire-resistant, tear-resistant, weather-tight, and well-ventilated building or equivalent enclosure. Precautions shall be taken against vandalism. This area shall be situated and constructed so that it will not be subject to flooding; the floor shall be paved or equal, and well drained. Items shall be placed on pallets or shoring to permit air circulation. The area shall be provided with uniform heating and temperature control or its equivalent to prevent condensation and corrosion. The minimum temperature shall be 40°F (5°C), and the maximum temperature shall be 140°F (60°C) or less if so stipulated by the manufacturer.

3. Level C items shall be stored indoors or in an equivalent environment with all provisions and requirements as set forth for Level B items, except that heat and temperature control is not required.

4. Level D items may be stored outdoors in an area marked and designated for storage that is well drained, preferably gravel covered or paved, and reasonably removed from high traffic areas so that the possibility of damage from equipment is minimized. Items shall be stored on cribbing or equivalent to allow for air circulation and to avoid trapping water.

23.2.3.12.2 Storage Areas

Periodic inspections shall be performed to ensure that storage areas are being maintained in accordance with applicable requirements.

1. Access to Storage Areas. Access to storage areas for Levels A, B, and C items shall be controlled and limited only to personnel designated by the responsible organization. Access to storage areas involving Level D items shall be controlled as designated by the responsible organization.

2. Cleanliness and Housekeeping Practices. Cleanliness and good housekeeping practices shall be enforced at all times in the storage areas. The storage areas shall be cleaned as required to avoid the accumulation of trash, discarded packaging materials, and other detrimental soil.

3. Fire Protection. Fire protection commensurate with the type of storage area and the material involved shall be provided and maintained.

4. Storage of Food and Associated Items. The use or storage of food, drinks, and salt tablet dispensers in controlled storage areas shall not be permitted.
5. **Measures to Prevent Entrance of Animals.** Measures shall be taken to prevent the entrance of rodents and other animals into indoor storage areas or equipment to minimize possible contamination and mechanical damage to stored material.

### 23.2.3.12.3 Storage Methods

Storage methods and procedures shall comply with the requirements described in 1 through 6 below.

1. **Ready Access to Stored Items.** All items shall be stored in such a manner as to permit ready access for inspection or maintenance without excessive handling to minimize risk of damage.

2. **Arrangement of Items.** Items stacked for storage shall be arranged so that racks, cribbing, or crates are bearing the full weight without distortion of the item.

3. **Storage of Hazardous Material.** Hazardous chemicals, paints, solvents, and other materials of a like nature shall be stored in well-ventilated areas and not in close proximity to important nuclear facility items.

4. **Identification.** Items and their containers shall be plainly marked so that they are easily identified without excessive handling or unnecessary opening of crates and boxes.

5. **Coverings.** Weatherproof coverings, when used for outdoor storage, shall be the flame-resistant type of sheeting or tarpaulins. They shall be placed so as to provide drainage and to ensure air circulation to minimize condensation. They shall be tied down to prevent moisture from entering laps and to protect the coverings from wind damage.

6. **Outdoor Storage.** Items stored outdoors shall be positioned or covered to avoid trapping moisture in pockets or internally.

### 23.2.3.12.4 Control of Items in Storage

1. **Inspections.** Inspections shall be performed and documented on a periodic basis to ensure that the integrity of the item and its container is being maintained. Deficiencies noted shall be corrected and documented. The characteristics verified during this inspection shall include such items as:
   a) Identification and marking,
   b) Protective covers and seals,
   c) Coatings and preservatives,
   d) Desiccants and inert gas blankets,
   e) Physical damage, and
   f) Cleanness.

2. **Care of Items.** Requirements for proper maintenance during storage shall be documented. Care of items in storage (includes storage in place) shall be exercised in accordance with the following:
a) Items in storage shall have all covers, caps, plugs, or other closures intact. Methods used to seal openings shall be defined. Covers removed for internal access shall be immediately replaced and resealed after completion of the purpose for removal.

b) Temporary preservatives shall be left intact during storage. Should reapplication of preservatives be required at the site, only those previously approved shall be used.

c) Items pressurized with inert gas shall be monitored at such a frequency as to ensure that the gas pressure is maintained within specified limits during storage. Desiccant humidity indicators shall also be monitored, and desiccants shall be changed or reprocessed when specified.

d) Instrumentation racks shall be energized as specified by the manufacturer.

e) Space heaters enclosed in electrical items shall be energized.

f) Rotating electrical equipment shall be given insulation resistance tests on a scheduled basis.

g) The shafts of rotating equipment shall be rotated on a periodic basis. The degree of turn shall be established so that the parts receive a coating of lubrication, where applicable, and so that the shaft does not come to rest in a previous position (90 degree and 450 degree rotations are examples).

h) Other maintenance requirements specified by the manufacturer’s instructions for the item shall be performed.

3. **Post-fire Evaluation.** In the event that a fire should occur in the storage area at any time, each item known to have been heated to an ambient temperature of over 150°F (65°C) or subjected to smoke contamination shall be withheld from installation or use until it has been thoroughly examined, and the item has been verified to be in conformance with specified requirements.

**23.2.3.12.5 Removal of Items from Storage and Handling**

Only items that have been inspected and are considered acceptable for installation or use in accordance with the receiving inspection procedure shall be removed from storage for installation or use. Items released from storage and placed in their final locations and items stored in place within the nuclear facility shall be inspected and cared for in accordance with specified requirements and other standards, as applicable. The requirements that shall be fulfilled by the organizations responsible for handling items shall be defined.

**23.2.3.12.6 Records**

Written records shall be prepared that include such pertinent information as storage location, results of inspections, results of in-storage maintenance to include the results of configuration control activities for the item while in storage, protection requirements, changes in item ownership including (if applicable) certificates of conformance, and personnel authorized access to the storage location(s).
Record copies of procedures, reports, personnel qualification records, test equipment calibration records, test deviation or exception records, storage and maintenance records, and inspection records shall be prepared as required. These records shall be retained with other project records as required by code, standard, specification, or PPs.

23.3 SUBPART 2.3, Quality Assurance Requirements for Housekeeping for Nuclear Power Plants

This Subpart is specifically directed at construction activities and is, therefore, only applicable on a forward fit basis to Major Modifications involving such activities (as defined in 10 CFR 830) to the SWPF. Specific revisions to processes and procedures to implement this Subpart will only be pursued at the time of (and as necessary to support) a Major Modification and its associated contract modification(s).

23.4 SUBPART 2.4, Installation, Inspection, and Testing Requirements for Power, Instrumentation, and Control Equipment at Nuclear Facilities

This Subpart is only applicable on a forward fit basis to Major Modifications (as defined in 10 CFR 830) to the SWPF. Specific revisions to processes and procedures to implement this Subpart will only be pursued at the time of (and as necessary to support) a Major Modification and its associated contract modification(s).

23.5 SUBPART 2.5, Quality Assurance Requirements for Installation, Inspection, and Testing of Structural Concrete, Structural Steel, Soils, and Foundations for Nuclear Power Plants

This Subpart is only applicable on a forward fit basis to Major Modifications (as defined in 10 CFR 830) to the SWPF. Specific revisions to processes and procedures to implement this Subpart will only be pursued at the time of (and as necessary to support) a Major Modification and its associated contract modification(s).

23.6 SUBPART 2.7, Quality Assurance Requirements for Computer Software for Nuclear Facility Applications

Per the Executive Summary Applicability section of this QAP, implementation of Part II Subpart 2.7 of ASME NQA-1-2004 and the computer program requirements of Requirements 3 and 11 will remain as the stated Code of Record for all life cycle phases associated with software already acquired/developed or where the procurement process was initiated prior to the transition from Commissioning to Operations.

The new requirements of NQA-1-2008/09a included in this revision will be applied to new acquisitions of software and new development of software that is applicable to the Operations phase for programmatic activities unrelated to design. This does not include any future acquisitions of revisions to existing acquired/developed software.
23.6.1 General

The requirements for the acquisition, development, operation, maintenance, and retirement of software are defined. The appropriate requirements shall be implemented through the policies, procedures, plans, specifications, or work practices, etc., that provide the framework for software engineering activities.

23.6.2 Software Engineering

The scope of software engineering activities include the following elements, as appropriate:

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

23.6.3 Documentation

The appropriate software engineering elements, shall define the baseline documents that are to be maintained as records. Although multiple documentation requirements are specified, they can be provided as separate or as combined documents.

23.6.4 Review

The appropriate software engineering elements shall define the control points and associated reviews. Reviews of software shall ensure compliance with the approved software design requirements. Although multiple review requirements are specified, the reviews may be performed and documented separately or combined, as appropriate, to the defined software engineering method. The following two reviews are required:

1. One review shall consider the requirements related to the activities of preparing the computer program for acceptance testing. This review can be combined with or be part of the software design verification.
2. The other review shall provide assurance of the satisfactory completion of the software development cycle including acceptance testing. This review can be combined with or be part of software design verification.

Individual(s) familiar with the design detail and the intended use of the computer program shall be included in the review. Reviews shall identify the participants and their specific review responsibilities. Documentation of review comments and their disposition shall be retained until they are incorporated into the updated software. Comments not incorporated and their disposition shall be retained until the software is approved for use. When review alone is not adequate to
determine if requirements are met, alternate calculations shall be used, or tests shall be developed and integrated into the appropriate activities of the software development cycle.

Tests performed in support of a review can be used to complement acceptance testing. The tests and test results shall be included in the acceptance testing documentation. Such tests shall be subjected to the same criteria as the acceptance tests. These tests do not substitute for performing the comprehensive, end of development, acceptance test.

23.6.5  Software Configuration Management

In addition to the requirements of Part I, Requirement 3, software configuration management activities shall include the following:

1. The appropriate software engineering elements shall identify when configuration baselines are to be established. Configuration items to be controlled shall include, as appropriate:
   a) Documentation (e.g., software design requirements, instructions for computer program use, test plans, and results);
   b) Computer program(s) (e.g., source, object, backup files); and
   c) Support software.

2. The software configuration change control process shall include:
   a) Initiation, evaluation, and disposition of a change request;
   b) Control and approval of changes prior to implementation; and
   c) Requirements for retesting (e.g., regression testing) and acceptance of the test results.

23.6.6  Problem Reporting and Corrective Action

1. Method(s) for documenting, evaluating, and correcting software problems shall:
   a) Describe the evaluation process for determining whether a reported problem is an error or other type of problem (e.g., user mistake) and
   b) Define the responsibilities for disposition of the problem reports, including notification to the originator of the results of the evaluation.

2. When the problem is determined to be an error, the method shall provide, as appropriate, for:
   a) How the error relates to appropriate software engineering elements;
   b) How the error impacts past and present use of the computer program;
   c) How the corrective action impacts previous development activities; and
   d) How the users are notified of the identified error, its impact; and how to avoid the error, pending implementation of corrective actions.

The problem reporting and corrective action process shall address the appropriate requirements.
23.6.7 Software Acquisition

Software acquisition includes software or software services procured or otherwise acquired for use.

23.6.7.1 Procured Software and Software Services

Requirements for items and services shall be applied to the procurement of software and software services. The Purchaser shall be responsible for the appropriate requirements upon acceptance of the software or related item (e.g., programmable device). Procurement documents shall identify requirements for Supplier's reporting of software errors to the Purchaser and, as appropriate, the Purchaser's reporting of software errors to the Supplier.

23.6.7.2 Otherwise Acquired Software

In specific relation to procurements and associated processes, ASME NQA-1-2008/09a only applies to new procurements of items and services for major changes/modifications to SWPF.

Part II, Subpart 2.14 of ASME NQA-1-2008/09a, shall be applied to the acquisition software that has not been previously approved under a quality program for use in its intended application (e.g., freeware, shareware, procured commercial off-the-shelf, or otherwise acquired software). The acquired software shall be identified and controlled during the dedication process. The dedication process shall be documented and include the following:

1. Identification of the capabilities and limitations for intended use as critical characteristics;
2. Utilization of test plans and test cases as the method of acceptance to demonstrate the capabilities within the limitations; and
3. Instructions for use (e.g., user manual) within the limits of the dedicated capabilities.

The dedication process shall be documented and the performance of the actions necessary to accept the software shall be reviewed and approved. The resulting documentation and associated computer program(s) shall establish the current baseline. Subsequent revisions of accepted software received from organizations not required to follow this Subpart shall be dedicated in accordance with this section.

23.6.8 Software Engineering Method

Software engineering method(s) shall be documented. The selected software engineering method shall ensure that software life cycle activities are planned and performed in a traceable and orderly manner. The appropriate requirements shall be met.

23.6.8.1 Software Design Requirements

Software design requirements shall specify technical and software engineering requirements, including security features (e.g., vulnerability protection, and cyber-security). Identify applicable
reference drawings, specifications, codes, standards, regulations, procedures, or instructions that establish software design requirement test, inspection, and acceptance criteria. Security requirements shall be specified commensurate with the risk from unauthorized access or use. Software design requirements shall be traceable throughout the software life cycle.

23.6.8.2 Software Design

An integral part of software design is the design of a computer program that is part of an overall system. Thus, the software design shall consider the computer program's operating environment. Measures to mitigate the consequences of problems, as identified through analysis, shall be an integral part of the design. These potential problems include external and internal abnormal conditions and events that can affect the computer program.

23.6.8.2.1 Software Design Verification

Software design verification shall evaluate the technical adequacy of the design approach and ensure internal completeness, consistency, clarity, and correctness of the software design and shall verify that software design is traceable to the software design requirements. Software design verification shall include review of test results. The software design verification shall be completed prior to approval of the computer program for use. The requirements for the software design verification activity shall be documented in the software engineering method.

23.6.8.3 Implementation

The implementation process shall result in software products such as computer program listings and instructions for computer program use. A review shall be performed.

23.6.8.4 Acceptance Testing

The acceptance testing activity shall demonstrate that the computer program adequately and correctly performs all intended functions (i.e., specified software design requirements). Acceptance testing shall demonstrate, as appropriate, that the computer program.

1. Properly handles abnormal conditions and events as well as credible failures;
2. Does not perform adverse unintended functions; and
3. Does not degrade the system either by itself, or in combination with other functions or configuration items.

Acceptance testing shall be performed prior to approval of the computer program for use. Configuration items shall be under configuration change control prior to starting acceptance testing. Acceptance testing shall be planned and performed for all software design requirements. Acceptance testing ranges from a single test of all software design requirements to a series of tests performed during computer program development. Performance of a series of tests provides assurance of correct translation between activities and proper function of individual modules.
Testing shall include a comprehensive acceptance test performed in the operating environment prior to use. The test plans, test cases, and test results shall be documented, reviewed, and approved prior to use of the computer program. Observations of unexpected or unintended results shall be documented and dispositioned prior to test result approval.

The acceptance testing of changes to the computer program shall be subjected to selective retesting to detect unintended adverse effects introduced during the change. Such testing shall provide assurance that the changes have not caused unintended adverse effects in the computer program, and to verify that a modified system(s) or system component(s) still meets specified software design requirements.

23.6.8.5 Operation

After the software is approved for use and installed in the operating environment, the use of the software shall be controlled in accordance with approved procedures and instructions. These include, as appropriate:

1. Application documentation (e.g., application log);
2. Access control specifications;
3. Computer system vulnerability protections;
4. Problem reporting and corrective action;
5. In-use tests; and
6. The configuration change control process.

23.6.8.6 Maintenance

The appropriate software engineering elements shall identify how changes to the software are controlled. Typically, changes are in response to any of the following:

1. Enhancement requests from the user community;
2. Revisions to software based on software design requirements,
3. Changes to the operating environment and changes to computer system vulnerability protections, and
4. Reported software problems that must be corrected.

23.6.8.7 Retirement

During retirement, support for the software product is terminated, and the routine use of the software shall be prevented.
23.6.9 Standards, Conventions, and other Work Practices

As appropriate, the software engineering method, software acquisition method, or both shall establish the need for standards, conventions, and other required work practices to facilitate software life cycle activities (e.g., software design and implementation activities). Standards, conventions, and other required work practices shall be documented.

23.6.10 Support Software

Support software includes software tools and system software. As appropriate, the software engineering method, software acquisition method, or both shall establish the need for software tools.

23.6.10.1 Software Tools

Software tools shall be evaluated, reviewed, tested, and accepted for use, and placed under configuration control as part of the software development cycle of a new or revised software product. Software tools that do not affect the performance of the software need not be placed under configuration control.

In cases involving modifications of software products using the software tools, the configuration of the support software associated with that modification shall be managed. Changes to the software tool shall be evaluated for impact on the software product to determine the level of reviews and retesting that will be required.

23.6.10.2 System Software

System software consists of the on-line computer programs used to provide basic or general functionality and facilitate the operation and maintenance of the application computer program. Examples include lower level software layers, assemblers, interpreters, diagnostics, and utilities. System software shall be evaluated, reviewed, tested, and accepted for use as part of the software development cycle of a new or revised software product. System software shall be placed under configuration change control. Changes to the system software shall be evaluated for impact on the software product to determine the level of reviews and retesting that will be required.

23.7 SUBPART 2.8, Quality Assurance Requirements for Installation, Inspection, and Testing of Mechanical Equipment and Systems for Nuclear Power Plants

This Subpart is only applicable on a forward fit basis to Major Modifications (as defined in 10 CFR 830) to the SWPF. Specific revisions to processes and procedures to implement this Subpart will only be pursued at the time of (and as necessary to support) a Major Modification and its associated contract modification(s).
23.8 SUBPART 2.14, Quality Assurance Requirements for Commercial Grade Items and Services

The existing process for CGIs and services specified through PP-EN-50239 (and associated forms) meets the requirements of this Subpart.

23.8.1 Utilization

To utilize a CGI or service, controls shall be implemented to provide reasonable assurance that the item or service will perform its intended safety function. These controls shall include the following:

1. Determination that the item or service performs a safety function,
2. Confirmation that the item or service meets the applicable CGI definitions,
3. Identification and documentation of the critical characteristics, including acceptance criteria,
4. Selection, performance, acceptance, and documentation of the dedication method(s) for determining compliance with the critical characteristic acceptance criteria.

Only items or services that perform a safety function and meet the commercial grade definitions shall be considered for commercial grade dedication. A dedication plan shall be developed for the item or service that identifies the critical characteristics and dedication methods, including acceptance criteria. Dedication plans may be developed for a specific item, service, or for a generic group of items or services. Dedication requirements shall be included in applicable procurement and technical documents as necessary to support the dedication. Items or services that successfully complete the dedication process are subsequently subject to the specified controls.

23.8.2 Technical Evaluation

23.8.2.1 General

The technical evaluation(s) shall be performed by the responsible engineering organization to:

1. Determine the safety function(s) of the item or service;
2. Identify performance requirements, the component/part functional classification, and applicable service conditions;
3. Confirm that the item or service meets the commercial grade definition criteria;
4. Identify the critical characteristics, including acceptance criteria;
5. Identify the dedication method(s) for verification of the acceptance criteria; and
6. Determine if a replacement item is a like-for-like or equivalent item.
The requirements of this Subpart are only applicable to CGIs or services that perform a safety function. Design output documents, supplier technical information, and other relevant industry technical and operating experience information, as appropriate, shall be utilized to prepare the technical evaluation.

Components that perform a safety function can contain items that do not perform a safety function. Replacement items shall be evaluated to determine their individual safety function in relation to the component or equipment.

The credible failure modes of an item in its operating environment and the effects of these failure modes on the safety function shall be considered in the technical evaluation for the selection of the critical characteristics. Services shall be evaluated to determine if the failure or improper performance of the service could have an adverse impact on the safety function of equipment, materials, or the facility operations.

If the design criteria for the CGI are known by the dedicating entity, then the item may be dedicated to these criteria in lieu of defining a specific safety function. In this case, consideration of failure modes is not required and the item's design parameters and allowables become the critical characteristics and acceptance criteria.

If the design criteria or safety function of the original item have changed, the replacement item must meet the new design criteria and safety function. Like-for-like and equivalent items are not a design change subject to Change Control under Requirement 3 of ASME NQA-1-2008/09a.

23.8.2.2 Like-for-like Items

Items may be considered identical or like-for-like if one of the following applies:

1. The item is provided from the original equipment manufacturer (successor companies that maintain equivalent QCIs are acceptable), and has not been subject to design, materials, manufacturing, or nomenclature changes.

2. The item was purchased at the same time and from the same supplier, as determined by the purchase date, shipping date, date code, or batch/lot identification.

3. Evaluation of the item confirms that no changes in the design, materials, or manufacturing process have occurred since the procurement of the original item.

A like-for-like determination shall not be based solely on the selection of a commercial-grade vendor with items manufactured to meet the same industry standards of the original item. Meeting the same industry standards may be a necessary condition, but is not a sufficient condition for a like-for-like determination.

If the dedicating entity can demonstrate that the replacement item is identical, then the safety function, design requirements, and critical characteristics need not be re-determined. However, verification of the identified critical characteristics by an appropriate dedication method(s) is required to verify the acceptability of the replacement item.
23.8.2.3 Equivalent Items

When difference(s) exist from the original item, an equivalency evaluation is required to determine if any changes in design, material, manufacturing process, form, fit, or function could prevent the replacement item from being interchangeable under the design condition of the original items and performing its required safety function.

The equivalency evaluation shall be documented and include the following:

1. Identification of the change(s) in design, material, manufacturing process, configuration, form, fit, or function of the replacement item that is different from the original item;
2. Evaluation of the change(s); and
3. Confirmation that the change(s) does not adversely affect the current design or safety function of the item.

If the change(s) adversely affects or is not bounded by the current approved design bases, the replacement item is not equivalent and must be rejected or processed as a design change.

Equivalency evaluations can determine the acceptability of the difference in the item to perform its safety function and identify critical characteristics for acceptance for the replacement item. Equivalency evaluations are not to be used as the sole basis to accept a CGI. Selection and verification of the identified critical characteristics by an appropriate dedication method(s) is required to verify the acceptability of the replacement item.

23.8.3 Critical Characteristics

Critical characteristics selected for acceptance shall be identifiable and measurable attributes based on the complexity, application, function, and performance of the item or service for its intended safety function. Critical characteristics of an item for acceptance shall include the part number, physical characteristics, identification markings, and performance characteristics, as appropriate. The critical characteristic acceptance criteria shall include tolerances, when appropriate. An item's part or catalog number shall be considered a critical characteristic if it provides a method to link the item with the manufacturer's product description and published data. The dedication process shall not rely on the part number alone as the only critical characteristic to be verified. CGIs or services can have numerous characteristics that are related to the composition, identification, or performance of the item or service. However, for acceptance, not all of these characteristics need to be verified to provide reasonable assurance that the item or service will perform its intended safety function.

The manufacturer's published product description or additional technical information typically identifies technical criteria or performance characteristics inherent in the design and manufacturing of the item. The manufacturer can employ standard tests or inspections as part of the manufacturing process and utilize a quality program to assure that appropriate controls are applied. This type of information is an example to be considered in the selection of critical characteristics and the related acceptance criteria.
In cases where the critical characteristics and acceptance criteria cannot be determined from the manufacturer's documentation or other documentation, the dedicating entity may perform an engineering evaluation, examination, or test (or any combination thereof) of the original item to develop the critical characteristics and acceptance criteria.

Critical characteristics selected for acceptance shall include criteria related to the location/design basis conditions (or manufacturing design limits) of the item in the facility or criteria addressing the most severe location criteria/design basis conditions (or manufacturing design limits) of the item in the facility, unless controls are in place to prevent usage in undesignated locations.

CGIs designated for installation or installed in seismically or environmentally qualified equipment or in locations which require such qualification shall include the selection of appropriate critical characteristics required to maintain the qualification of the component or equipment.

**23.8.4 Methods of Accepting Commercial Grade Items and Services**

**23.8.4.1 Dedication**

1. To provide reasonable assurance that a CGI or service will perform its intended safety function, the dedicating entity shall verify that the CGI or service meets the acceptance criteria for the identified critical characteristics by one or more of the following dedication methods:
   a) Method 1: inspections, tests, or analyses performed after delivery,
   b) Method 2: commercial grade survey of the supplier,
   c) Method 3: source verification of the item or service, and
   d) Method 4: acceptable supplier/item performance record.

2. Prior to classifying the item or service as acceptable to perform its safety function, the dedicating entity shall determine that the following have been successfully performed, as applicable:
   a) Damage was not sustained during shipment.
   b) The item or service has satisfied the specified acceptance criteria for the identified critical characteristics.
   c) Specified documentation was received and is acceptable.

3. The dedication method(s) described shall provide a means to assure that the CGI or service meets the acceptance criteria for the selected critical characteristics. The selection of acceptance method(s) shall be planned and based on the type of critical characteristics to be verified, available supplier information, quality history, and degree of standardization. If a critical characteristic cannot be verified by the selected dedication method, the dedicating entity may select another or combination of dedication methods to verify the critical characteristic.
4. The organization that performs or directs the dedication activity and determines the item or service has satisfactorily met the acceptance criteria for the selected critical characteristics is the dedicating entity. The dedicating entity can be the manufacturer, a third-party organization, the purchaser, or the nuclear facility organization.

23.8.4.1.1 Method 1: Special Test(s), Inspection(s), and/or Analyses

Special test(s), inspection(s), or analyses either individually or in combination shall be conducted upon or after receipt of an item to verify conformance with the acceptance criteria for the identified critical characteristics. The special test(s), inspection(s), and/or analyses may include post-installation testing and may be performed utilizing a sampling plan, when appropriate.

Special inspections may include receipt inspection activities to verify adequate criteria associated with procurement activities. The receipt inspection activities may be included in the dedication plan.

Sampling plans utilized to select items for special test(s), inspection(s) and/or analyses shall be based upon standard statistical methods with supporting engineering justification and shall consider lot/batch traceability, homogeneity, and the complexity of the item.

When post-installation test(s) are used to verify acceptance criteria for the critical characteristics, the CGI or service shall be identified and controlled to preclude inadvertent use prior to satisfactory completion of the dedication activities.

When critical characteristics acceptance criteria is based on certified material test reports or certificates of conformance, the criteria of Section 503, Requirement 7 of ASME NQA-1-2008/09a shall be met.

Services can result in a deliverable product that can be evaluated upon receipt or result in an activity that can be evaluated during or at the conclusion of its performance.

23.8.4.1.2 Method 2: Commercial Grade Survey of the Supplier

1. A commercial grade survey is a method to verify critical characteristics by evaluating the adequacy and effectiveness of the supplier's commercial QCs. A commercial grade survey is performed in accordance with a checklist or plan at the supplier's facility and includes or addresses the following:
   a) Identification of the item(s), or product line, or service included within the scope of the survey;
   b) Identification of the critical characteristics to be controlled by the supplier;
   c) Verification that the supplier's processes and quality program controls are effectively implemented for control of the critical characteristics;
   d) Identification of the survey methods or verification activities performed with results obtained; and
e) Documentation of the adequacy of the supplier's processes and controls.

2. A commercial grade survey shall not be employed as a method for accepting CGIs or services from suppliers with undocumented quality programs or with programs that do not effectively implement the supplier's own specified processes and controls. After a supplier's processes and controls have been determined to be adequate, the dedicating entity shall invoke or reference the verified processes and controls including revision level as a part of the purchase order or control requirements for the CGI or service and require the supplier to provide a Certificate of Conformance attesting to the implementation of the identified processes and controls.

3. When critical characteristics acceptance criteria is based on certified material test reports or certificates of conformance, the criteria of Section 503, Requirement 7 of ASME NQA-1-2008/09a³ shall be met.

4. Surveys shall not be employed as a method for accepting items from distributors unless the survey includes the manufacturer and the survey confirms adequate processes and controls by both the distributor and the manufacturer. A survey of the distributor may not be necessary if:

a) The distributor acts only as a broker and does not warehouse or repackage the items and

b) In cases where traceability can be established by other means such as verification of the manufacturer's markings or shipping records.

5. Surveys performed by organizations other than the dedicating entity may be used as a basis for acceptance if the survey results of the critical characteristics, survey scope, supplier's processes and controls, and acceptance criteria are evaluated by the dedicating entity to be acceptable and consistent with the dedicating entity's dedication requirements.

6. The scope of the survey shall be determined by the dedicating entity based upon the item or service and critical characteristics to be verified. The survey shall be specific to the scope of the CGI or service being procured. When several items or services are purchased from a supplier, a survey of representative groups of CGIs or services can be sufficient to demonstrate that adequate processes and controls exist. The survey report shall provide objective evidence that the critical characteristics are verified and controlled by the supplier.

7. If the scope of the survey cannot verify a designated critical characteristic due to controls by the supplier's subsupplier(s), the dedicating entity shall extend the survey to the subsupplier(s) or select another dedication method(s) to verify the critical characteristic.

8. Organizations performing surveys shall develop criteria for the personnel qualifications and processes used to perform surveys. The survey documentation shall provide objective evidence that the processes and controls for the identified critical characteristics were observed and evaluated for acceptance. Deficiencies identified in the supplier's process or controls shall be corrected, if the survey is used for acceptance of the identified critical characteristic(s).

9. The dedicating entity shall establish a survey frequency to ensure that process controls applicable to the critical characteristics of the item or service procured continue to be effectively implemented. Factors to be considered in determining the frequency of
commercial grade surveys include the complexity of the item or service, frequency of procurement, receipt inspection, performance history, and knowledge of changes in the supplier's process and controls. The survey frequency interval may be the same used for supplier audits, but shall not exceed the frequency interval for supplier audits.

23.8.4.1.3 Method 3: Source Verification

Source verification is a method of acceptance conducted at the supplier's facility or other applicable location to verify conformance with the identified critical characteristics and acceptance criteria. The scope of the source verifications shall include activities such as witnessing the fabrication and assembly processes, NDEs, performance tests, or final inspections, as applicable. It shall also include verification of the supplier's design, procurement, calibration, and material process and control methods employed for the particular CGI or service being purchased, as applicable to the identified critical characteristics.

Organizations performing source verification shall develop criteria for the personnel qualifications and processes used to perform source verification. Source verification documentation shall provide objective evidence that the supplier's activities for the identified characteristics were observed and evaluated for acceptance.

Source verification is only applicable to the actual item(s) or service(s) that are verified at the supplier's facility or other applicable location. Source verification shall be performed in accordance with a checklist or plan with the documented evidence of the source verification furnished to the dedicating entity and shall include or address the following:

1. Identification of the item(s) or service(s) included within the scope of the source verification;
2. Identification of the critical characteristics, including acceptance criteria, being controlled by the supplier;
3. Verification that the supplier's processes and controls are effectively implemented for the identified critical characteristics;
4. Identification of the activities witnessed during the source verification and the results obtained;
5. Identification of mandatory hold points to verify critical characteristics during manufacture and/ or testing for those characteristics that cannot be verified by evaluation of the completed item; and
6. Documentation of the adequacy of the supplier's processes and controls associated with the critical characteristics and acceptance criteria.

23.8.4.1.4 Method 4: Acceptable Supplier Item or Service Performance Record

A documented supplier item or service performance record is a method of acceptance to verify conformance with the identified critical characteristics and acceptance criteria of a CGI or service against the supplier's performance record for identical or similar services. This allows the
dedicating entity to have reasonable assurance of the item's or service's performance based upon historical performance gained from the successful utilization of other acceptance methods, and/or pertinent industry-wide performance data.

Acceptable data for historical performance may be compiled utilizing monitored performance of the item, industry product tests, certification to national codes and standards (non-nuclear specific), and other industry records or databases. The supplier item or service performance record or data shall be from the condition of service, environmental condition, failure mode, maintenance program, testing, or other conditions equivalent to the intended application of the CGI or service.

1. An acceptable supplier item or service performance record shall include the following:
   a) Identification of the supplier item or service being evaluated,
   b) Identification of previously established critical characteristics specific to the supplier item or service,
   c) Identification of data examined to evaluate the supplier item or service,
   d) Identification of basis for determining that performance data substantiates acceptability of the supplier item or service, and
   e) Documentation of the adequacy and acceptance of the supplier/item/service performance record.

2. An acceptable item or service performance record shall not be employed alone as a method of acceptance unless:
   a) The established historical record is based on industry-wide performance data that is directly applicable to the critical characteristics and the intended facility application, i.e., single sources of information are not adequate to demonstrate satisfactory performance.
   b) The manufacturer's/supplier's measures for the control of applicable design, process, and material change have been accepted by the dedicating entity, as verified by survey.

Continued application of an acceptable supplier/item/service performance record as a method of acceptance shall include a documented periodic update and review to assure the supplier/item/service maintains an acceptable performance record.

23.8.4.2 Supplier Deficiency Correction

Deficiencies with the supplier's processes and controls identified by the acceptance method(s) shall be corrected by the supplier if it affects the acceptance criteria for critical characteristic(s) utilized for commercial grade dedication. Corrective actions shall be evaluated for acceptability by the dedicating entity. Uncorrected deficiencies in processes or controls may result in the selection of another dedication method for determining acceptance.
23.8.5   Commercial Grade Services

Some examples of services that may be provided as commercial grade include training, calibration, testing, engineering, computer software support, and other technical support activities. Services on equipment or items, including installation, repair, cleaning, or maintenance, that do not physically alter an item's critical characteristics are additional examples. Personnel qualification, activity controls, independent certifications, and documents are typical examples of critical characteristic for dedication of services.

Section 507, Requirement 7 of ASME NQA-1-2008/09a\(^3\) shall be reviewed to determine if this requirement is applicable before considering the dedication of a service. As an alternative to commercial grade dedication, services may be performed under the dedicating entity's or other organization's quality program and procedures that meet the specified requirements.

Physical, mechanical, or other service activities that alter or create new critical characteristics of an item that can be used to determine the acceptability of the service that produced the critical characteristic shall not be considered a commercial grade service. For example, if a plate is rolled to a defined radius, the new critical characteristic produced is the radius of the rolled plate and not the rolling process or service that produced the curvature. Original critical characteristics of the plate material and the plate thickness can remain unchanged or be specified by the design organization for the rolled plate. Another example of a commercial grade service is the repair or calibration of an installed instrument by the manufacturer's service representative. The instrument could have been previously dedicated, but now requires service using special tools from the manufacturer that does not have a QA program that meets the specified requirements. The successful results of the calibration service to return the item to the original performance characteristics can be verified by the dedicating entity for acceptance of the commercial grade service.

23.8.6   Documentation

Documentation of the CGI or service dedication process shall be traceable to the item, group of items, or services and shall contain the following types of documents, depending on the applicable dedication method:

1. Dedication plans or procedures including the essential elements of the dedication process;
2. CGI or service procurement documents;
3. Technical evaluations;
4. Critical characteristic identification and acceptance criteria;
5. Test reports or results, inspection reports, analysis reports;
6. Commercial grade survey reports;
7. Source verification reports;
8. Historical performance information; and
9. Dedication report containing sufficient data to accept the item or service.

23.9 Subpart 2.15, Quality Assurance Requirements for Hoisting, Rigging, and Transporting of Items for Nuclear Power Plants

The requirements of this Subpart will be applied on a forward fit basis to SWPF Operations consistent with the following strategy:

1. SWPF does not have any Category A and Category B items as defined in this Subpart. SWPF Category C items are managed in accordance with standard commercial rigging practices. Since there are no Category A or B components in the SWPF, defining and addressing these items per Part II, Subpart 2.15 of ASME NQA-1-2008/09a\textsuperscript{3} requirements for lifting are not necessary.

2. Requirements in this Subpart associated with Special Design Equipment only apply on a forward fit basis to Major Modifications (as defined in 10 CFR 830\textsuperscript{6}) that involve such equipment. Specific revisions to processes and procedures to implement these Subpart requirements will only be pursued at the time of (and as necessary to support) a Major Modification and its associated contract modification(s).

23.9.1 General Requirements

Requirements are provided for the design, manufacture, acceptance, testing, and use of hoisting, rigging, and transporting equipment to maintain the quality of items that require special handling. These requirements apply to any organization or individual participating in work relating to hoisting, rigging, and transporting. Hoisting equipment used for handling shall be certified by the manufacturer. The certification shall indicate the various parameters for the maximum load to be handled. Measures shall be established and implemented to perform handling activities for facility items and to perform the inspections, examinations, testing, and documentation to verify conformance to specified requirements. These measures are applicable to items that require special handling because of weight, size, susceptibility to shock damage, high nil-ductility transition temperatures, or any other conditions that warrant special instructions to preserve the quality of items and container. Where this Subpart references the use of consensus standards, these measures shall include the applicable requirements of ASME/ANSI B30 series, Safety Standards for Cableways, Cranes, Derricks, Hoists, Hooks, Jacks, and Slings\textsuperscript{37}, and of ANSI A10.5, Safety Requirements for Material Hoists\textsuperscript{38}. Subpart 2.15 of ASME NQA-1-2008/09a\textsuperscript{3} applies from the time these items are ready for delivery.

Use of permanent plant handling equipment during the construction phase is prohibited unless specifically authorized by the plant Owner and conducted in accordance with the plant Owner’s QA program. If such equipment is to be used during the construction phase, it shall be reviewed to ensure that such use conforms to additional specified requirements, as applicable, in addition to the other requirements of this section. After construction use and prior to release to the Owner, the permanent handling equipment shall be restored to its design configuration, and it shall be inspected and tested as specified by procedure. During subsequent use, the testing, inspection, and maintenance shall be performed as specified by applicable standards. The requirements may
also be extended to other appropriate parts of the facility when specified in contract documents, or to modifications involving operating plants.

23.9.2 Planning and Procedures

Planning and procedure preparation shall be in accordance with specified requirements. Procedures and instructions shall contain sufficient detail, such as center of gravity, weights, sling locations, balance points, methods of attachment, maximum hoist line speeds, ground loading, and other pertinent features considered necessary for safe handling, to govern handling operations, inspection thereof, and documentation. Planning shall provide for compliance with applicable federal, state, and local regulations.

23.9.3 Classification of Items Handled

The requirements for activities are based on classifying the items according to their important physical characteristics. It is recognized that within the scope of Category C there may be a range of controls, and that the need for, and extent of, detailed handling requirements for an item is dependent on the importance of the item to safe, reliable operation of the plant and the complexity of the operation. Pertinent manufacturer’s requirements shall be considered when classifying the items. Handling activities for SWPF are classified as Category C. An item shall not be reclassified without approval by the responsible organization that assigned the original category.

Category C. Items classified in Category C are those that may be handled with conventional equipment using sound rigging practice.

23.9.4 Types of Handling Equipment

23.9.4.1 Standard Manufactured Component

Handling equipment classed as a standard manufactured component is equipment that is available from several sources. This equipment is normally a catalog item, generally kept in stock, and normally used as a component of a handling system. Examples of standard manufactured components are:

1. Chains and chain accessories such as hooks, shackles, and links;
2. Fiber ropes and accessories;
3. Hooks such as link or eye type, single, sister, and miscellaneous;
4. Transporting devices such as casters, rollers, shoes, and wheels;
5. Wire rope and wire rope accessories such as blocks, clamps, sockets, thimbles, and turnbuckles; and
6. Miscellaneous items such as cribbing, eyebolts, pads, swivel devices, links, shackles, and sheaves.
23.9.4.2 Commercial Standard Design Equipment

Commercial standard design equipment for handling is equipment that is available as an item of standard design and manufacture. Examples of commercial standard design equipment are:

1. Gantry, mobile, overhead, and jib cranes;
2. Guys and stiffleg derricks;
3. Hoists, winches, and trolleys;
4. Jacks and jacking systems;
5. Transporting devices such as forklift trucks, rail cars, tractors, trailers, and transporters;
6. Elements of commercial standard design equipment such as booms, masts, and struts; and
7. Other optional standard accessories and adaptations available from the equipment manufacturer.

23.9.4.3 Special Design Equipment

Special design equipment for handling is equipment that is not available from a commercial source as a catalog or standard designed item, or equipment for which no generally accepted consensus standard exists. This type of equipment may be designated and fabricated by using standard manufactured components and commercial standard designed equipment, or by using a combination of nonstandard and standard equipment. Examples of special designed equipment are:

1. Special gin poles, derricks, and jacking towers;
2. Special crane supports such as runways, columns, and frames;
3. Rigging devices such as spreader beams, strongbacks, up end and down end devices, bolsters, and yokes; and
4. Transporting systems such as dollies, special rail cars, and transporters.

23.9.4.4 Permanent Plant Handling Equipment

Permanent plant handling equipment employed for handling items is equipment that is intended primarily for maintenance and operation of the plant, but which may also be used for construction. It may consist of standard manufactured components, commercial standard design equipment, or special designed equipment.

23.9.5 Design Requirements

Due to the wide range of equipment normally used in the handling of items, it is appropriate that different criteria be used for designing different types of handling equipment. Specific design criteria that are appropriate for most applications and that are recommended for general use are defined. If it can be shown that these criteria are not appropriate for a specific application, the
engineer responsible shall select compatible criteria and document the justification. It is recognized that some items are also covered by other standards, which may be more stringent, and items must meet requirements of both. Hoisting, rigging, and transporting equipment that is to be used exclusively during the construction phase shall be designed in accordance with specified requirements. Permanent plant handling equipment is designed and selected in accordance with other standards. The organization responsible for the design shall establish a program for ensuring that the handling equipment conforms to the design requirements.

1. **Standard Manufactured Components.** Standard manufactured components shall be selected to safely perform the intended operations structurally, mechanically, and electrically. They shall have been designed to conform to accepted industry standards.

2. **Commercial Standard Design.** Commercial standard design equipment shall be selected to perform the intended operations structurally, mechanically, and electrically. They shall have been designed to conform to consensus standards or, when a consensus standard is not totally adequate, to accepted standards.

3. **Special Design Equipment.** Special design equipment shall be designed to safely perform the intended operations structurally, mechanically, and electrically. Standard manufactured components or commercial standard design equipment, or elements thereof, incorporated into the total system, shall meet the respective requirements with safety factors as recommended by the manufacturer of the components and equipment.

a) **Structural.**

i) Structural design of the equipment shall be in accordance, as applicable, with the nationally accepted consensus standards specified in the Contract (DE-AC09-02SR222101) code of record, specifications, design documents, etc.

   (1) Equipment components shall be designed for the appropriate combination of vertical and horizontal loads.

   (2) The effects of seismic activity need not be included in combination with lifting or transporting operations during construction.

   (3) Winds in excess of 50 miles per hour (mph) (80.5 kilometers per hour [km/hr]) normally need not be considered in combination with lifting or transporting operations as these operations are normally suspended before winds exceed 50 mph (80.5 km/hr). If historical wind data indicate the likelihood of operations occurring during winds greater than 50 mph (80.5 km/hr), such data shall be used as the basis of design. ANSI A58.1, *Minimum Design Loads for Buildings and Other Structures*[^39], shall be used to determine appropriate wind loads. If these forces have not been considered in design, lifting and transporting activities shall be suspended before winds reach 50 mph (80.5 km/hr).

   (4) Special designed equipment normally is designed for a limited number of operations. Fatigue factors shall be included where applicable.
(5) Vertical impact shall be considered in the design, and selection of loads shall be supported by analysis. In no case shall vertical impact load be less than 10% of maximum handled load, excluding test load.

(6) Longitudinal and transverse horizontal forces shall be determined by the maximum acceleration or deceleration that can be delivered by the complete hoisting or transporting system, the maximum grades or slide slopes encountered, maximum out-of-plumb lift, wind, and similar loads. In no case shall longitudinal or transverse horizontal forces be less than 2% of maximum handled load.

(7) For the entire system considered as a whole, the ratio of failure stress to calculated stress shall be no less than 1.67. This minimum ratio shall exist after considering such factors as unequal load distribution, stability, slenderness ratios, and joint efficiencies.

(8) Calculated stress developed by handling the combination of dynamic test load and vertical impact, plus longitudinal or transverse horizontal loads, if applicable, shall not exceed 133% of allowable stress.

(9) NDEs to be performed during manufacture and the acceptance criteria for these examinations shall be specified by the responsible design organization. Particular attention shall be given to lamellar tearing, highly restrained connections, and welds joining load-carrying members.

(10) Guys and guyed systems, such as column-supported girders with traveling hoists, gallows, frames, guyed derricks, and similar equipment, shall be designed to provide system stability and restraint by:

   (a) Maintenance columns, poles, or masts in the desired position and within desired tolerances and

   (b) Providing capability to resist forces caused by handling operations, impact, wind, opposing guys, eccentricity, and similar causes.

   ii) The design shall consider the following as a minimum:

   (1) Handled load;
   (2) Height of column and column capability;
   (3) Slope of the guys;
   (4) Load sharing of multiple guyed systems;
   (5) Pretension requirements;
   (6) Physical characteristics or wire rope, such as area, modulus of elasticity, and spring constant;
   (7) Footing and anchorage adequacy;
   (8) Secondary loads caused by stretch of guys;
(9) Safety factors;
(10) End connections; and
(11) Nil-ductility transition temperatures. Design criteria shall be selected by the organization responsible for the design.

b) **Mechanical.**

The following special conditions apply to the mechanical design:

i) Special designed equipment normally is designed for a single operation, or for a limited number of operations. Life, durability, and fatigue factors shall be included where applicable.

ii) Gearing shall be designed by use of American Gear Manufacturers Association formulas, or equivalent formulas, for strength only.

iii) Each independent wire rope or chain and sprocket hoisting unit shall have at least one holding brake. At the place where the brake is applied, the minimum static torque rating shall be 150% of the torque required to hold the maximum load to be handled, excluding the test load.

iv) Engines, gear boxes, torque converters, couplings, hydraulic jacks, pumps, valves, fittings, lines, and similar components used for hoisting operations shall be designed in conformance with the consensus standard and shall be sized to:
   (1) Handle load, excluding test load, within the manufacturer’s rated capacity;
   (2) Operate continuously during the specified duty cycle; and
   (3) Safely resist maximum loads imposed by emergency braking.

v) Hydraulic circuit design shall take into consideration the need for design features that minimize possibilities of unexpected lowering of loads.

vi) Engines, electric motors, brakes, gear boxes, cylinders, bearing housings, and similar components that support any part of the load shall be secured to the main structure in such a way that the entire system, including components, meets structural requirements to adequately support the load.

vii) Rigidity of machinery base, shafts, and similar components shall be adequate to permit proper functioning of the equipment under operating conditions.

c) **Electrical.**

The following special conditions apply to the electrical design:

i) Electrical components and wiring used for hoisting operations shall be designed in conformance with consensus standards and shall be sized to:
   (1) Lift the handled load, excluding test load, within the manufacturer’s rated capacity;
   (2) Operate continuously during the specified duty cycle; and
(3) Be compatible with mechanical requirements for brakes.

   ii) Electrical circuits shall contain provisions for proper grounding and shall incorporate
design features to minimize possibilities of unexpected lowering of load.

23.9.6 Acceptance Criteria for Manufactured Handling Equipment

The requirements for manufacture and acceptance of manufactured equipment, structures, and
accessories used in the handling of items are defined.

23.9.6.1 Standard Manufactured Components

Standard manufactured components shall be manufactured and accepted in accordance with
accepted industry standards.

23.9.6.2 Commercial Standard Design

Commercial standard design equipment shall be manufactured and accepted in accordance with
applicable consensus standards.

23.9.6.3 Special Design Equipment

Special design equipment shall be based upon one of the following criteria.

23.9.6.3.1 Acceptance of Existing Equipment

Acceptance of existing equipment shall be based upon one of the following criteria:

1. Historical data that show satisfactory performance in handling loads within the design
capability, which are equal to or greater than the intended loads. This history would include
records of test, inspections, and maintenance performed on the equipment, along with the
record of actual handling operations.

2. A load test in accordance with specified requirements.

3. Recognition of capability by an engineer or other qualified materials handling
individual when the equipment is handling Category C items only.

23.9.6.3.2 Acceptance Criteria for New Equipment and Modifications to Existing
Equipment

Acceptance criteria for new equipment and modifications to existing equipment shall conform to
the following requirements:

1. The design shall have been performed in accordance with specified requirements.

2. Standard manufactured components or commercial standard design equipment incorporated
in the total system shall meet the specified requirements.

The following additional items shall be required:

a) Principal load-carrying members shall be designated by the design organization responsible for either or both the design and application of the equipment. Materials of principal load-carrying members shall meet any one of the following three qualifications:

   i) Record of meeting the minimum mechanical properties as documented by certified material test reports;

   ii) Mechanical test report of a sample of the material showing adequate mechanical properties (this may be made by the manufacturer or a testing laboratory); and

   iii) Conservatism of design, documented by engineer’s calculations [this option is acceptable only in emergency situations, when last-minute changes have proved necessary by field conditions, and when options specified are not available].

b) Structural welds shall be made by qualified welders using qualified procedures in accordance with the applicable requirements of the AWS D1.1, *Structural Welding Code-Steel*.

c) Welds joining principal load-carrying members shall be inspected as described.

d) Structural elements of material other than steel shall be constructed in accordance with applicable consensus or accepted industry standards.

4. Operational tests of the entire system shall be conducted.

5. Recognition of capability by an engineer or other qualified materials-handling individual will suffice in when the equipment is handling Category C items only.

### 23.9.7 Testing, Inspection, and Maintenance

The requirements for testing, inspection, and maintenance to ensure that the equipment will perform as required for the safe handling of items are defined.

#### 23.9.7.1 Testing

A test program shall be established to demonstrate that the handling component or equipment will perform satisfactorily in service. Testing may involve either operational or load-type tests, or a combination of the two. Operational-type tests ensure structural and mechanical capability. Test loads shall normally be handled at the same speeds and rates of acceleration (deceleration) as planned for the intended item. When dynamic test loads greater than 100% are designated, the rates of acceleration (deceleration) may be adjusted as long as the impact load does not exceed the maximum designed impact load. The combination of load and rate of acceleration (deceleration) shall not be lower than 100% dynamic load test. In addition, requirements specified in the following sections shall apply as applicable.
1. **Standard Manufacturing Components.** One of the following will satisfy the requirements for testing of these components:
   a) Tests as required by applicable accepted industry standards,
   b) Actual proof load tests by the manufacturer, and
   c) Dynamic load tests as part of the system being tested to 110% of the maximum load to be handled.

2. **Commercial Standard Design Equipment.** One of the following will satisfy the requirements for testing of this equipment:
   a) Tests as required by applicable consensus standard and
   b) A dynamic load test equal to 110% of the maximum load to be handled.

3. **Special Design Equipment.** Requirements for testing of this equipment shall be as follows:
   a) An operational test shall be performed. This test shall be over the portion of the motions applicable to the handling system tested.
   b) A dynamic load test equal to 110% of the maximum load to be handled by the complete system shall be performed, except that documented proof of equivalent handling ability as described may be substituted. Transport equipment tests shall demonstrate adequacy of braking, drawbar pull, stability, and other similar factors. Testing shall take place with equipment in the location where it will be used for actual handling of the item, except that in cases in which the test would interfere with, or needlessly endanger an existing item or the item to be lifted, testing may be conducted at another location, on or near the site. Where practical and useful, load tests shall be applied over the entire range of motions required for the actual handling of the item, with the following exceptions:
      i) Spreaders, bars, jacks, slings, or similar items whose loading is independent of travel may be tested in test fixtures at locations other than the site.
      ii) Transporting vehicles need not be tested over the entire length of travel.
   During subsequent use, the testing, inspection, and maintenance shall be performed as specified by other standards.

4. **Rerated equipment.** For special lifts, hoisting equipment may be rerated, or modified and rerated, upon approval by the manufacturer or, if the manufacturer’s specifications are not available, the limitations assigned to the equipment shall be based on the determinations of a qualified engineer competent in this field and such determination shall be documented and recorded appropriately.

   Rerated equipment shall be given a dynamic load test over the full range of the lift using a test weight at least equal to 110% of the lift weight. A dynamic test includes raising, lowering, and traversing the load, in contrast to a static test, in which the test weight may be increased incrementally with no movement.
23.9.7.2 Inspection

Handling equipment in use shall be subjected to inspection. Inspections as detailed herein include three types: frequent, periodic, and major. Evidence of inspections and the results of periodic and major inspections shall be documented.

1. Frequent Inspections. Frequent inspections are those performed on a day-to-day or similarly frequent basis. The inspections shall conform to the consensus standards and federal, state, and local health and safety regulations. The inspection coverage shall include parts essential to safe operation plus those parts recommended by the manufacturer. A checklist shall be used to perform the inspections. These inspections shall be performed by the individual responsible for the operation of the particular equipment or by another competent individual.

2. Periodic Inspections. Periodic inspections are those performed on a preset interval. The inspections shall conform to the consensus standards and federal, state, and local safety regulations. The inspection coverage shall include parts essential to safe operation plus those parts recommended by the manufacturer. If a system or component is not included in established codes or standards, it shall be included in a planned, scheduled inspection program developed by the organization responsible for its use and operation. Personnel qualified by experience or special training, as determined by the organization responsible for the inspection, shall perform such inspections. Results of periodic inspections shall be documented.

3. Major Inspections. Major inspections are those performed on an as-specified basis and shall conform to a procedure prepared by the responsible organization. The procedure shall also state when the inspections are to be performed. Inspection coverage shall include recommendations of the manufacturer or designer. Visual examinations or NDEs shall be used for these inspections as deemed necessary by the designer of the component or system and by the organization responsible for its use and operation. Particular attention shall be paid to the following as applicable:
   a) Welds at joints between highly stressed members,
   b) Welds at joints in principal load-carrying members and highly restrained members,
   c) Excessive deformation in principal load-carrying members or parts,
   d) Adequacy of brakes under both static and dynamic loadings,
   e) Response and positiveness of controls,
   f) Accuracy and response of load indicators, and
   g) Overheating of power supply.

Welds to be inspected shall be inspected in accordance with the applicable requirements of AWS D1.1[41]. NDE performed during these inspections shall be performed by a certified individual. Other parts of these inspections shall be performed by personnel qualified by experience or special training, as determined by the organization responsible for the inspections. Results of major inspections shall be documented.
23.9.7.3 Maintenance

A maintenance program shall be established to ensure that the handling equipment is maintained in good operating condition. The program shall provide for adequate protection of equipment that is used in an environment other than the environment for which it is designed. Those responsible for operation of equipment shall be responsible for maintenance.

Equipment shall be serviced at specified intervals in accordance with the manufacturer’s recommendations, severity of service, and environment. Items damaged or worn sufficiently to affect operation of equipment shall be repaired or replaced before continuing operations. Replacement parts shall meet or exceed the specifications of the part being replaced.

Maintenance shall be documented and the records kept current. These records shall show lubrication, servicing, adjustments, repairs, and replacement of the equipment.

23.9.8 Control of the Use of Handling Equipment

The requirements to be fulfilled by the organizations that will have operational control of the handling equipment in use are defined. These organizations shall appoint a person-in-charge (PIC). The PIC shall ensure that procedures are provided as required, and shall provide surveillance over the activities of personnel associated with the handling operations to ensure that the procedures are being followed, that specified QA requirements are being met, and that good handling practices are being followed.

23.9.8.1 Handling Category C Items

23.9.8.1.1 Prerequisites

Evidence of maintenance shall be verified.

23.9.8.1.2 Procedures

Written detailed procedures are not required. Category C items shall be handled by experienced personnel in accordance with good rigging and handling practices as described in safety handbooks, consensus standards, and corporate or contractor standards designated for the job, and in compliance with regulations. Manufacturer’s load charts and general safe rigging manuals shall be available to personnel.

23.9.9 Qualifications of Personnel

The minimum qualifications for certain key personnel involved in ensuring safe handling of items are defined. Qualifications of these personnel shall be verified by objective evidence and documented.
23.9.9.1 Person-in-Charge

The PIC of handling operations shall be designated by management. The PIC shall have demonstrated supervisory experience in the hoisting, rigging, and transporting activities to the satisfaction of the cognizant management.

23.9.9.2 Engineer

The engineer responsible for the design, selection, or application of special equipment, or a combination of these, shall have demonstrated capability in the technical aspects of similar work. This capability shall be achieved through education and experience and the individual shall be an engineering graduate of an accredited college or university, or a Professional Engineer registered to practice in an applicable discipline.

23.9.9.3 Inspector

The inspector of hoisting, rigging, and transporting equipment shall have demonstrated experience in the activity. Nondestructive examiners shall meet the qualifications as defined.

23.10 Records

Record copies of procedures, reports, personnel qualification records, test equipment calibration records, test deviation or exception records, and inspection and examination records shall be prepared. These records shall be retained with other project records as required by code, standard, specification, or PPs.

23.10 Subpart 2.16, Requirements for the Calibration and Control of Measuring and Test Equipment Used in Nuclear Facilities

As indicated in ASME NQA-1-2008/09a³, this Subpart has been cancelled. No further consideration is necessary for the Project.

23.11 Subpart 2.18, Quality Assurance Requirements for Maintenance of Nuclear Facilities

The requirements of this Subpart will be applied on a forward fit basis to SWPF Operations consistent with the application of Subpart 2.1 of ASME NQA-1-2008/09a³ as specified in Paragraph 203 of Subpart 2.18 of ASME NQA-1-2008/09a³ and in accordance with the strategy outlined for Subpart 2.1 of ASME NQA-1-2008/09a³.

Paragraph 208 (Updating of Maintenance Procedures from Vendor Technical Manuals and Industry Bulletins) will be implemented to the extent that such information is communicated through the DOE Corporate Operating Experience Program and associated DOE Corporate Lessons Learned Database under DOE O 210.2A, DEO Corporate Operating Experience Program®2. Separate Project activities to pursue contractual relationships with suppliers for ongoing receipt of document issuances after closure of the associated procurements or continuous
searching of numerous industry web sites (already reviewed by DOE Headquarters) will not be pursued.


### 23.11.1 General Requirements

These amplified requirements for the maintenance of nuclear facility components and systems are defined. Maintenance consists of actions necessary to maintain or restore an item to acceptable conditions. This does not apply to controlling modifications that may be determined to be needed during the performance of maintenance. Design or modification information shall be available to the operating organization so that it can review the adequacy of provisions for the maintenance program.

### 23.11.2 Responsibilities

Responsibilities shall be assigned for establishing and implementing the maintenance program. These responsibilities shall include:

1. The review of the maintenance program to ensure that changes to plant design or modifications are taken into consideration;
2. The development and updating of appropriate maintenance plans, procedures, and schedules;
3. The review of planned maintenance activities to ensure that radiation exposures to personnel will be as low as reasonably achievable;
4. The conduct of the program of maintenance activities and other inspections and tests as necessary to verify satisfactory performance;
5. The assurance that activities are performed by qualified personnel, using approved processes and calibrated test equipment and tools;
6. The assurance that properly controlled and identified materials are used;
7. The assurance that environmental or seismic qualification requirements of equipment are not compromised;
8. The development of provisions for installation and removal of temporary conditions (e.g., jumpers, transferring of control switch position) and returning equipment and systems to service;
9. The recording of all maintenance examination and test results including corrective actions required and actions taken;
10. The assessment and evaluation of the results of maintenance, examinations, post-maintenance tests, and equipment history;
11. The development and trending of performance indicators; and
12. The retention of records.

23.11.3 Procedures

1. Procedures and/or written instructions shall be established for performance of maintenance activities. Requirements for procedure format and content shall be established. Additional guidance regarding procedural requirements are contained in ANSI/ANS 3.2, Managerial, Administrative, and Quality Assurance Controls for Operational Phase of Nuclear Power Plants.

2. Checks shall be made to verify that:
   a) Procedures and/or written instructions with an appropriate level of detail have been provided and
   b) Procedures include applicable format and content elements.

3. All changes, including temporary changes, shall be controlled;

4. Provisions shall be made for documenting data to assist in ensuring satisfactory completion of the work. Such data shall include, as applicable:
   a) Parts used (e.g., serial number, part number, lot number);
   b) Identification number of M&TE used;
   c) “as found” condition;
   d) “as left” condition;
   e) Adjustments, repairs, replacements made;
   f) Post-maintenance clean-up and final inspection; and
   g) Post-maintenance testing and acceptance results.

Recorded data shall be reviewed for completeness and acceptability. The review shall be conducted by personnel who are familiar with the design and operation of the equipment, including acceptance criteria for its design features and operating characteristics. Administrative procedures shall require documentation of the acceptance of results.

23.11.4 Cleanness Control

1. Controls to minimize the introduction of foreign materials and to maintain cleanness during maintenance shall be in accordance with specified requirements. Verification methods shall be established to ensure that these requirements are met.

2. Immediately prior to closure of equipment, the absence of foreign materials shall be verified. The results of the verification shall be documented.
23.11.5 Environmental and Seismic Qualifications

Procedures shall be established to ensure that environmental and/or seismic qualification of equipment is not voided in performing maintenance. Such procedures shall include identification of the qualified items, methods for reestablishing qualifications, and verification of qualification status.

23.11.6 Work Authorization

1. Procedures shall be established for the authorization of maintenance work. The work authorization shall be documented and serve as the identification of authorized work for the purposes of work planning, scheduling, and control.

2. The work authorization shall contain the following information as a minimum:
   a) Unique work authorization identifier or number;
   b) Description of work, including identification and quality designation of the specific equipment on which the work is to be performed;
   c) Identification of performing organizations and their specific roles; and
   d) Approval by authorized personnel.

3. Interface concerns such as plant operations, health physics/as low as reasonably achievable, security, industrial safety, effluent control, fire protection and QC requirements shall be considered for applicability by authorized individuals prior to approval of the work authorization document.

4. The description of work shall reference the applicable maintenance procedure(s). If a separate procedure is not required, the work authorization shall contain or reference necessary and sufficient information (design drawings, equipment manuals, etc.) to perform the work.

5. Provision shall be made for verifying the completeness of work authorization documents prior to starting the maintenance work.

6. The work authorization approval process shall provide for approving substantive changes in the work requirements commensurate with the original SOW.

23.11.7 Equipment History

A system shall be established to identify equipment for which equipment history files shall be maintained. Files shall be established as early in the life of equipment as possible to maintain the history of maintenance activities on each specific item. Information to be entered in the files shall be specifically identified and mechanisms established for their incorporation into the files. The files shall be organized to facilitate information retrieval.
23.11.8 Verification of Maintenance Work

Verification shall be performed, as appropriate, to ensure that equipment on which maintenance has been performed conforms to specified requirements. This verification shall include inspection, testing, or document review as necessary. Verification activities shall be documented. When maintenance involves installation, inspection shall be conducted.

23.11.9 Updating of Maintenance Procedures from Vendor Technical Manuals and Industry Bulletins

Controls shall ensure that updated information (vendor technical manuals, industry bulletins, etc.) is received, reviewed, and incorporated where appropriate into maintenance procedures.

23.11.10 Preventive Maintenance

Preventive maintenance includes all those activities performed on designated equipment needed to maintain it within specified design limits.

23.11.10.1 Plans and Procedures

Plans and procedures shall be developed to identify the equipment that requires preventive maintenance, to establish the frequency and kind of preventive maintenance to be performed on the equipment, and to document those actions.

1. **Equipment.** Equipment shall be evaluated to determine its preventive maintenance requirements. That evaluation shall include the vendor recommendations as delineated in their technical manual and bulletins, applicable industry standards and operational experience, and maintenance experience and equipment history files. Equipment shall be monitored and evaluated for degradation of performance because of age, as appropriate. Equipment that is purchased for future installation or spares shall be evaluated to determine the preventive maintenance requirements associated with its storage.

2. **Frequency.** A preventive maintenance schedule shall be established to uniquely identify the equipment, frequency, and preventive maintenance to be performed.

3. **Evaluation.** The effectiveness of preventive maintenance actions on equipment shall be evaluated.

4. **Corrective Action.** When discrepancies or failures are identified as part of preventive maintenance activities, they shall be corrected in accordance with procedure requirements.

23.11.11 Corrective Maintenance

The following requirements apply to maintenance performed to restore an item to an intended condition following failure of the item. The term “failure”, as used herein, applies to any condition in which an item is determined to be unable to perform within its specified limits.
23.11.11.1 **Identification, Reporting, and Documenting of Equipment or Systems Requiring Corrective Maintenance**

Procedures shall be established for

1. Promptly identifying (e.g., tagging or other physical marking) the failed item and controlling it to preclude its inadvertent use.
2. Documenting and reporting of failures, in accordance with pre-established criteria, to:
   a) Designated levels of management responsible for failure analyses, authorization of corrective action, and performance of corrective action and
   b) Supplier and/or regulatory authority, as required.
3. Entering the failure and the attributed cause in equipment history records.
4. Verifying that failures are appropriately identified and reported as prescribed above to the extent necessary to ensure appropriate attention.

23.11.11.2 **Assessments and Evaluations**

An assessment of failure cause and required maintenance shall be made consistent with the type of item failure and the importance of the item. The assessment shall also include, as appropriate, the possibility of similar failure in other items. Assessments shall be performed in accordance with documented procedures and shall be appropriately reviewed.

For failures identified that could have serious effect on safety or operability, an engineering evaluation shall be performed and documented to substantiate or revise the failure assessment and corrective action planning.

23.11.11.3 **Implementing Corrective Maintenance**

Corrective maintenance shall be performed using work procedures. Provisions shall be made for emergency maintenance work, e.g., work that must be performed immediately to eliminate a threat to the safety of personnel or facilities. These provisions shall be documented to identify:

1. The minimum controls applicable to the authorization, planning, and performance of the work and
2. Requirements to ensure effective accomplishment of the work.

Emergency work shall be reviewed and evaluated immediately after work accomplishment for adequacy.

23.11.12 **Records**

1. Maintenance records shall be maintained to establish an equipment history and assist in performance evaluation and trend analysis. Maintenance records shall include work
authorization documents and shall identify the equipment, type of maintenance performed, tools, M&TE, parts and material, date of performance, observation, failure cause, post-maintenance testing results, and the person who performed the maintenance.

2. Records shall be maintained.

23.12 Subpart 2.20, Quality Assurance Requirements for Subsurface Investigations for Nuclear Power Plants

This Subpart is only applicable on a forward fit basis to Major Modifications (as defined in 10 CFR 8306) to the SWPF. Specific revisions to Project processes and procedures to implement this Subpart will only be pursued at the time of (and as necessary to support) a Major Modification and its associated contract modification(s).
Appendix A. SWPF Project Quality Assurance Program/Quality Management System Requirements Matrix
### Appendix A. SWPF Project Quality Assurance Program/Quality Management System Requirements Matrix

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<tr>
<th>SWPF PROJECT QAP REQUIREMENTS</th>
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<th>ANSI/ISO/ASQ Q9001-2000⁵</th>
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<td>*SUBCLAUSE 5.3 (Quality Policy)</td>
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<td>iv. Graded Application of QA</td>
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<td>1.0 ORGANIZATION</td>
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<td>1 2 3</td>
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<tr>
<td>2.0 QUALITY ASSURANCE PROGRAM</td>
<td>1 2 3 4 5 6 7 8 9 10</td>
<td>1 2 3</td>
<td>1 2 3 4</td>
</tr>
<tr>
<td>3.0 DESIGN CONTROL</td>
<td>1 2 3 4 5 6 7 8 9 10</td>
<td>1 2 3</td>
<td>1 2 3 4</td>
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<tr>
<td>4.0 PROCUREMENT DOCUMENT CONTROL</td>
<td>1 2 3 4 5 6 7 8 9 10</td>
<td>1 2 3</td>
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</tr>
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<td>5.0 INSTRUCTIONS, PROCEDURES, AND DRAWINGS</td>
<td>1 2 3 4 5 6 7 8 9 10</td>
<td>1 2 3</td>
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<tr>
<td>6.0 DOCUMENT CONTROL</td>
<td>1 2 3 4 5 6 7 8 9 10</td>
<td>1 2 3</td>
<td>1 2 3 4</td>
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<td>7.0 CONTROL OF PURCHASED ITEMS AND SERVICES</td>
<td>1 2 3 4 5 6 7 8 9 10</td>
<td>1 2 3</td>
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<tr>
<td>8.0 IDENTIFICATION AND CONTROL OF ITEMS</td>
<td>1 2 3 4 5 6 7 8 9 10</td>
<td>1 2 3</td>
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<tr>
<td>9.0 CONTROL OF SPECIAL PROCESSES</td>
<td>1 2 3 4 5 6 7 8 9 10</td>
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<td>10.0 INSPECTION</td>
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<td>11.0 TEST CONTROL</td>
<td>1 2 3 4 5 6 7 8 9 10</td>
<td>1 2 3</td>
<td>1 2 3 4</td>
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<tr>
<td>12.0 CONTROL OF MEASURING AND TEST EQUIPMENT</td>
<td>1 2 3 4 5 6 7 8 9 10</td>
<td>1 2 3</td>
<td>1 2 3 4</td>
</tr>
</tbody>
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# Appendix A. SWPF Project Quality Assurance Program/Quality Management System Requirements Matrix

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<tbody>
<tr>
<td>QAP SECTIONS</td>
<td>PART I REQUIREMENTS ¹</td>
<td>CRITERIA</td>
<td>QMS PROGRAM ELEMENTS</td>
</tr>
<tr>
<td>13.0 HANDLING, STORAGE, AND SHIPING</td>
<td>¹ ² ³ ⁴ ⁵ ⁶ ⁷ ⁸ ⁹ ¹⁰ ¹¹ ¹² ¹³ ¹⁴ ¹⁵ ¹⁶ ¹⁷ ¹⁸</td>
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<td>14.0 INSPECTION, TEST, AND OPERATING STATUS</td>
<td>¹ ² ³ ⁴ ⁵ ⁶ ⁷ ⁸ ⁹ ¹⁰ ¹¹ ¹² ¹³ ¹⁴ ¹⁵ ¹⁶ ¹⁷ ¹⁸</td>
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<td>15.0 CONTROL OF NONCONFORMING ITEMS</td>
<td>¹ ² ³ ⁴ ⁵ ⁶ ⁷ ⁸ ⁹ ¹⁰ ¹¹ ¹² ¹³ ¹⁴ ¹⁵ ¹⁶ ¹⁷ ¹⁸</td>
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<td>16.0 CORRECTIVE ACTION</td>
<td>¹ ² ³ ⁴ ⁵ ⁶ ⁷ ⁸ ⁹ ¹⁰ ¹¹ ¹² ¹³ ¹⁴ ¹⁵ ¹⁶ ¹⁷ ¹⁸</td>
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<td>17.0 QUALITY ASSURANCE RECORDS</td>
<td>¹ ² ³ ⁴ ⁵ ⁶ ⁷ ⁸ ⁹ ¹⁰ ¹¹ ¹² ¹³ ¹⁴ ¹⁵ ¹⁶ ¹⁷ ¹⁸</td>
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<td>18.0 AUDITS</td>
<td>¹ ² ³ ⁴ ⁵ ⁶ ⁷ ⁸ ⁹ ¹⁰ ¹¹ ¹² ¹³ ¹⁴ ¹⁵ ¹⁶ ¹⁷ ¹⁸</td>
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<tr>
<td>19.0 SOFTWARE MANAGEMENT</td>
<td>¹ ² ³ ⁴ ⁵ ⁶ ⁷ ⁸ ⁹ ¹⁰ ¹¹ ¹² ¹³ ¹⁴ ¹⁵ ¹⁶ ¹⁷ ¹⁸</td>
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<tr>
<td>20.0 GOVERNMENT PROPERTY</td>
<td>¹ ² ³ ⁴ ⁵ ⁶ ⁷ ⁸ ⁹ ¹⁰ ¹¹ ¹² ¹³ ¹⁴ ¹⁵ ¹⁶ ¹⁷ ¹⁸</td>
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<tr>
<td>21.0 CONTINUAL IMPROVEMENT</td>
<td>¹ ² ³ ⁴ ⁵ ⁶ ⁷ ⁸ ⁹ ¹⁰ ¹¹ ¹² ¹³ ¹⁴ ¹⁵ ¹⁶ ¹⁷ ¹⁸</td>
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<tr>
<td>22.0 SUSPECT/COUNTERFEIT ITEMS</td>
<td>¹ ² ³ ⁴ ⁵ ⁶ ⁷ ⁸ ⁹ ¹⁰ ¹¹ ¹² ¹³ ¹⁴ ¹⁵ ¹⁶ ¹⁷ ¹⁸</td>
<td></td>
<td></td>
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<tr>
<td>0 REFERENCES</td>
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</tbody>
</table>

### Note
1. Shaded areas (e.g., requirements, criteria) are addressed by the aligned QAP Section.
2. Capital letters represent clarifications provided under Legend (see below).
3. Numbers used under ANSI/ISO/ASQ Q9001-2000² columns represent paragraphs under a SUBCLAUSE (e.g., 1 under 5.5 is paragraph 5.5.1).
4. ANSI/ISO/ASQ Q9001-2000² paragraphs to be addressed in the following QAP Sections are not addressed by ASME NQA-1-2008/09a³:
   a) QAP Section 1 – Section 5.5.2 of ANSI/ISO/ASQ Q9001-2000²;
   b) QAP Section 9 – Section 7.5.1 of ANSI/ISO/ASQ Q9001-2000²;
   c) QAP Section 13 – Section 7.5.5 of ANSI/ISO/ASQ Q9001-2000²; and
   d) QAP Section 16 – Section 8.2.4 of ANSI/ISO/ASQ Q9001-2000².
5. The SWPF QAP implements the requirements of the Parsons’ *Quality Manual*² by addressing the QMS program elements identified above for ANSI/ISO/ASQ Q9001-2000².

### Legend
- **A**: Part I, Requirements 3 and 11, and Part II, Subpart 2.7 of ASME NQA-1-2008/09a³; Criterion 6 and CRD Attachment 4 of DOE O 414.1D²; and Sections 7.3.5 and 7.3.6 of ANSI/ISO/ASQ Q9001-2000².
- **B**: Criterion 5 of DOE O 414.1D², and Section 7.5.4 of ANSI/ISO/ASQ Q9001-2000².
- **C**: Criterion 3 of DOE O 414.1D², and Sections 8.1 and 8.5 of ANSI/ISO/ASQ Q9001-2000².
- **D**: Criterion 5 and CRD Attachment 3 of DOE O 414.1D².
Appendix B. Terms and Definitions
# Appendix B. Terms and Definitions

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<th>NO.</th>
<th>TERM</th>
<th>DEFINITION</th>
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</thead>
<tbody>
<tr>
<td>1.</td>
<td>Acceptance Criteria</td>
<td>Specified limits placed on the performance, results, or other characteristics of an item, process, or service defined in codes, standards, or other requirement documents.</td>
</tr>
<tr>
<td>2.</td>
<td>Assessment</td>
<td>A review, evaluation, inspection, test, check, surveillance, or audit to determine and document whether items, processes, systems, or services meet specified requirements and perform effectively. (DOE O 414.1D³)</td>
</tr>
<tr>
<td>3.</td>
<td>Audit</td>
<td>A planned and documented activity performed to determine by investigation, examination, or evaluation of objective evidence the adequacy of and compliance with established procedures, instructions, drawings, and other applicable documents, and the effectiveness of implementation. An audit should not be confused with surveillance or inspection activities performed for the sole purpose of process control or product acceptance.</td>
</tr>
<tr>
<td>4.</td>
<td>Certificate of Conformance</td>
<td>A document signed or otherwise authenticated by an authorized individual certifying the degree to which items or services meet specified requirements.</td>
</tr>
<tr>
<td>5.</td>
<td>Certification</td>
<td>The act of determining, verifying, and attesting in writing to the qualifications of personnel, processes, procedures, or items in accordance with specified requirements.</td>
</tr>
<tr>
<td>6.</td>
<td>Characteristic</td>
<td>Any property or attribute of an item, process, or service that is distinct, desirable, and measurable.</td>
</tr>
</tbody>
</table>
| 7.  | Commercial Grade Item (CGI)       | 1. An item satisfying the following:  
   a) Not subject to design or specification requirements that are unique to nuclear facilities or activities;  
   b) Used in applications other than nuclear facilities or activities; and  
   c) To be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer’s published product description (e.g., a catalog).  
   2. An SSC, or part thereof, that affects its safety function; that was not designed and manufactured in accordance with the requirements of ASME NQA-1-2008/09a³. |
| 8.  | Commercial Grade Service          | A service that was not provided in accordance with the requirements of ASME NQA-1-2008/09a³.                                                                                                               |
| 9.  | Computer Program                  | A combination of computer instructions and data definitions that enables computer hardware to perform computational or control functions.                                                                        |
| 10. | Condition Adverse to Quality      | An all-inclusive term used in reference to any of the following: failures, malfunctions, deficiencies, defective items, and nonconformances. A significant condition adverse to quality is one that, if uncorrected, could have a serious effect on safety or operability. |
## Appendix B. Terms and Definitions

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</thead>
<tbody>
<tr>
<td>11.</td>
<td>Configuration</td>
<td>The physical, functional, and operational characteristics of the structures, systems, components, or parts of the existing facility.</td>
</tr>
<tr>
<td>12.</td>
<td>Configuration Item (Software)</td>
<td>A collection of hardware or software elements treated as a unit for the purpose of configuration control.</td>
</tr>
<tr>
<td>13.</td>
<td>Configuration Management</td>
<td>The process that controls the activities, and interfaces, among design, construction, procurement, training, licensing, operations, and maintenance to ensure that the configuration of the facility is established, approved, and maintained.</td>
</tr>
<tr>
<td>14.</td>
<td>Continual Improvement</td>
<td>A set of recurring activities that are carried out in order to enhance performance.</td>
</tr>
<tr>
<td>15.</td>
<td>Correction</td>
<td>Any action that is taken to eliminate a nonconformity.</td>
</tr>
<tr>
<td>16.</td>
<td>Corrective Action</td>
<td>Measures taken to rectify conditions adverse to quality and, where necessary, to preclude repetition.</td>
</tr>
<tr>
<td>17.</td>
<td>Critical Characteristics</td>
<td>Important design, material, and performance characteristics of a CGI or service that, once verified, will provide reasonable assurance that the item or service will perform its intended safety function.</td>
</tr>
<tr>
<td>18.</td>
<td>Customer</td>
<td>Anyone who receives products or services (outputs) from a supplier.</td>
</tr>
<tr>
<td>19.</td>
<td>Customer Satisfaction</td>
<td>Customer’s perception of the degree to which the customer’s requirements have been fulfilled.</td>
</tr>
<tr>
<td>20.</td>
<td>Dedication</td>
<td>An acceptance process performed in accordance with ASME NQA-1-2008/09a(^3) to provide reasonable assurance that a CGI or service will successfully perform its intended safety function and, in this respect, is deemed equivalent to an item or services provided under the requirements of ASME NQA-1-2008/09a(^3).</td>
</tr>
<tr>
<td>21.</td>
<td>Dedicating Entity</td>
<td>The organization that performs the dedication process.</td>
</tr>
<tr>
<td>22.</td>
<td>Design and Development</td>
<td>A process (or set of processes) that uses resources to transform general input requirements for an object into specific output requirements.</td>
</tr>
<tr>
<td>23.</td>
<td>Design, Final</td>
<td>Approved design output documents and approved changes thereto.</td>
</tr>
<tr>
<td>24.</td>
<td>Design Authority</td>
<td>The organization having the responsibility and authority for approving the design bases, the configuration, and changes thereto.</td>
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</tbody>
</table>
# Appendix B. Terms and Definitions

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| 25. | Design Bases          | That information which identifies the specific functions to be performed by an SSC of a facility, and the specific values or ranges of values chosen for controlling parameters as reference bounds for design. These values may be:  
  - Restraints derived from generally accepted “state-of-the-art” practices for achieving functional goals; or  
  - Requirements derived from analysis (based on calculations and/or experiments) of the effects of a postulated accident for which an SSC must meet its functional goals. |
| 26. | Design Change         | Any revision or alteration of the technical requirements defined by approved and issued design output documents and approved and issued changes thereto. |
| 27. | Design Input          | Those criteria, performance requirements, codes and standards, design bases, regulatory requirements, or other design requirements upon which detailed final design is based. |
| 28. | Design Output         | Drawings, specifications, and other documents used to define technical requirements of SSCs, and computer programs. |
| 29. | Design Process        | Technical and management processes that commence with identification of design input and that lead to and include the issuance of design output documents. |
| 30. | Design Review         | A critical review to provide assurance that the final design is correct and satisfactory. |
| 31. | Deviation             | A departure from specified requirements. |
| 32. | Document              | Any written, pictorial, or electronic information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results. A document is not considered to be a QA record until it satisfies the definition of a QA record as defined by ASME NQA-1-2008/09a. |
| 33. | Document Control      | The act of assuring that documents are reviewed for adequacy, approved for release by authorized personnel, and distributed to and used at the location where the prescribed activity is performed. |
| 34. | Effectiveness         | Refers to the degree to which a planned effect is achieved. |
| 35. | Electronic Document   | A document stored in a form (i.e., magnetic or optical media) that is typically accessible only by a computer. |
| 36. | Engineered Item       | Any procured item that does not satisfy the criteria for CGI. |
| 37. | Executive Management  | Person or group of people who direct and control an organization at the highest level. Typically, direct reports to the Project Manager. |
# Appendix B. Terms and Definitions

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<tr>
<td>38.</td>
<td>Functional Classification</td>
<td>A graded classification system used to determine minimum quality and configuration management requirements for SSCs (i.e., design, procurement, operation, and maintenance requirements). The five functional classifications are SC, SS, GS-1, GS-1 [Specialty Equipment (SE)], and GS-2. GS classifications are based on information that is typically independent of the Safety Analysis status.</td>
</tr>
<tr>
<td>39.</td>
<td>General Service (GS)</td>
<td>The functional classification assigned to all SSCs not required to provide a SC or SS function. All SSCs are classified as GS, at a minimum, to ensure that proper design, operations, and maintenance requirements are assigned to provide for the health and safety of the workers and the environment, and to ensure compliance with other SRS requirements. GS SSCs are subdivided into three categories: GS-1, GS-1 SE, and GS-2.</td>
</tr>
<tr>
<td>40.</td>
<td>Grade</td>
<td>Category or rank given to different quality requirements for products, processes or systems having the same functional use.</td>
</tr>
<tr>
<td>41.</td>
<td>Guidance</td>
<td>A suggested practice that is not mandatory in programs intended to comply with ASME NQA-1-2008/09a³. The word <em>should</em> denotes guidance; the word <em>shall</em> denotes a requirement.</td>
</tr>
<tr>
<td>42.</td>
<td>Inspection</td>
<td>Examination or measurement to verify whether an item or activity conforms to specified requirements.</td>
</tr>
<tr>
<td>43.</td>
<td>Inspector</td>
<td>A person who performs inspection activities to verify conformance to specific requirements.</td>
</tr>
<tr>
<td>44.</td>
<td>Item</td>
<td>An all-inclusive term used in place of any of the following: appurtenance, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, or unit.</td>
</tr>
</tbody>
</table>
| 45. | Lifetime Records            | Lifetime records are those that meet one or more of the following criteria:  
  - Those which would be of significant value in demonstrating capability for safe operation;  
  - Those which would be of significant value in maintaining, reworking, repairing, replacing, or modifying an item;  
  - Those which would be of significant value in determining the cause of an accident or malfunction of an item; and  
  - Those which provide required baseline data for in-service inspections. |
## Appendix B. Terms and Definitions

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<tr>
<th>NO.</th>
<th>TERM</th>
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<tr>
<td>47.</td>
<td>Measuring Equipment</td>
<td>All things needed to carry out a measurement process.</td>
</tr>
<tr>
<td>48.</td>
<td>Measuring and Test Equipment (M&amp;TE)</td>
<td>Devices or systems used to calibrate, measure, gage, test, or inspect in order to control or acquire data to verify conformance to specified requirements.</td>
</tr>
<tr>
<td>49.</td>
<td>Nonconformance</td>
<td>A deficiency in characteristic, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate.</td>
</tr>
<tr>
<td>50.</td>
<td>Nonconformity</td>
<td>Nonfulfillment or failure to meet a requirement.</td>
</tr>
<tr>
<td>51.</td>
<td>Nonpermanent Records</td>
<td>Nonpermanent records are those required to show evidence that an activity was performed in accordance with the applicable requirements but need not be retained for the life of the item because they do not meet the criteria for lifetime records. Nonpermanent records shall be maintained for the identified retention period.</td>
</tr>
<tr>
<td>52.</td>
<td>Objective Evidence</td>
<td>Any documented statement of fact, other information, or record, either quantitative or qualitative, pertaining to the quality of an item or activity, based on observations, measurements, or tests that can be verified.</td>
</tr>
<tr>
<td>53.</td>
<td>Owner</td>
<td>The organization legally responsible for the construction and/or operation of a nuclear facility including but not limited to one who has applied for, or who has been granted, a construction permit or operating license by the regulatory authority having lawful jurisdiction.</td>
</tr>
<tr>
<td>54.</td>
<td>Preventive Action</td>
<td>Action to eliminate the cause of a potential nonconformity or other undesirable situation.</td>
</tr>
<tr>
<td>55.</td>
<td>Procedure</td>
<td>A document that specifies or describes how an activity is to be performed.</td>
</tr>
<tr>
<td>56.</td>
<td>Process</td>
<td>A series of actions that achieves an end or result. (DOE 414.1D)</td>
</tr>
<tr>
<td>57.</td>
<td>Procurement Document</td>
<td>Purchase requisitions, purchase orders, drawings, contracts, specifications, or instructions used to define requirements for purchase.</td>
</tr>
<tr>
<td>58.</td>
<td>Procurement Level</td>
<td>An alpha-numerical designation (i.e., PL-1, PL-2, PL-3, and PL-4) assigned for the procurement of services or items using a graded approach.</td>
</tr>
<tr>
<td>59.</td>
<td>Product</td>
<td>A tangible or intangible output that is the result of a process that does not include activities that are performed at the interface between the supplier (provider) and the customer.</td>
</tr>
<tr>
<td>60.</td>
<td>Purchaser</td>
<td>The organization responsible for establishment of procurement requirements and for issuance or administration, or both, of procurement documents.</td>
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<tbody>
<tr>
<td>61.</td>
<td>Qualification, Personnel</td>
<td>The characteristics or abilities gained through education, training, or experience, as measured against established requirements, such as standards or tests, that qualify an individual to perform a required function.</td>
</tr>
<tr>
<td>62.</td>
<td>Qualified Automated Means</td>
<td>Automated methods of controlling or monitoring processes that have been demonstrated to produce required quality within controlled limits.</td>
</tr>
<tr>
<td>63.</td>
<td>Qualified Procedure</td>
<td>An approved procedure that has been demonstrated to meet the specified requirements for its intended purpose.</td>
</tr>
<tr>
<td>64.</td>
<td>Quality Assurance (QA)</td>
<td>All those planned and systematic actions necessary to provide adequate confidence that an SSC will perform satisfactorily in service.</td>
</tr>
<tr>
<td>65.</td>
<td>Quality Assurance Record</td>
<td>A completed document that furnishes evidence of the quality of items and/or activities affecting quality. Types of record media may include paper, electronic (magnetic or optical), or specially processed media such as radiographs, photographs, negatives, and microforms. The term record, as used throughout NQA-1-2008/09a, is to be interpreted as QA record.</td>
</tr>
<tr>
<td>66.</td>
<td>Quality Management System (QMS)</td>
<td>A set of interrelated or interacting elements that organizations use to formulate policies and objectives and to establish the processes that are needed to ensure that policies are followed and objectives achieved.</td>
</tr>
<tr>
<td>67.</td>
<td>Quality Objective</td>
<td>A quality result that you intend to achieve.</td>
</tr>
<tr>
<td>68.</td>
<td>Quality Policy</td>
<td>Expresses top management’s commitment to the quality management system (QMS) and should allow manager’s to set quality objectives.</td>
</tr>
<tr>
<td>69.</td>
<td>Quality Standard</td>
<td>A code or standard that provides design inputs, acceptance criteria, or other criteria necessary to assure the quality of the designated item.</td>
</tr>
<tr>
<td>70.</td>
<td>Receiving</td>
<td>Taking delivery of an item at a designated location.</td>
</tr>
<tr>
<td>71.</td>
<td>Release</td>
<td>Grant permission to proceed to the next stage of a process.</td>
</tr>
<tr>
<td>72.</td>
<td>Repair</td>
<td>The process of restoring a nonconforming characteristic to a condition such that the capability of an item to function reliably and safely is unimpaired, even though that item still does not conform to the original requirement.</td>
</tr>
<tr>
<td>73.</td>
<td>Review</td>
<td>Activity undertaken to figure out how well the thing being reviewed is capable of achieving established objectives.</td>
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<tr>
<td>74.</td>
<td>Rework</td>
<td>The process by which an item is made to conform to original requirements by completion or correction.</td>
</tr>
<tr>
<td>75.</td>
<td>Right of Access</td>
<td>The right of a Purchaser or designated representative to enter the premises of a Supplier for the purpose of inspection, surveillance, or QA audit.</td>
</tr>
<tr>
<td>76.</td>
<td>Safety Class (SC) Function</td>
<td>A preventive or mitigative function that is performed to keep radiological exposure to the public from challenging the offsite Evaluation Guidelines.</td>
</tr>
<tr>
<td>77.</td>
<td>Safety Class (SC) Structures, Systems, and Components (SSCs)</td>
<td>SSCs whose preventive or mitigative functions are performed to limit radioactive hazardous material exposure to the public, as determined from Safety Analysis.</td>
</tr>
<tr>
<td>78.</td>
<td>Safety Function</td>
<td>The performance of an item or service necessary to achieve safe, reliable, and effective utilization of nuclear energy and nuclear material processing.</td>
</tr>
<tr>
<td>79.</td>
<td>Safety Significant (SS) Function</td>
<td>A preventive or mitigative function that is a major contributor to Defense-in-Depth (e.g., prevention of uncontrolled material releases) and worker safety, as determined from a hazard analysis.</td>
</tr>
<tr>
<td>80.</td>
<td>Safety Significant (SS) Structures, Systems, and Components (SSCs)</td>
<td>SSCs that perform SS functions.</td>
</tr>
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Appendix B. Terms and Definitions

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</table>
| 81. | Safety Software            | Safety Software, as defined in DOE O 414.1D³, includes the following:  
  - Safety System Software – Software for a nuclear facility that performs a safety function as part of an SSC and is cited in either (a) a DOE-approved documented safety analysis, or (b) an approved hazard analysis per DOE P 450.4¹¹ and the DOE O 414.1D⁴;  
  - Safety and Hazard Analyses Software and Design Software – 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; and  
  - Safety Management and Administrative Controls Software – Software that performs a hazard control function in support of nuclear facility or radiological safety management programs or technical safety requirements, or other software that performs a control function necessary to provide adequate protection from nuclear facility or radiological hazards. This software supports eliminating, limiting, or mitigating nuclear hazards to workers, the public, or the environment as addressed in Subpart A of 10 CFR 830⁶, 10 CFR 835²⁴, and the DOE O 414.1D⁴. |
| 82. | Scrap                      | Action on a nonconforming product to preclude its originally intended use.                                                                                                                                                                                                                                                                |
| 83. | Service                    | The performance of activities such as design, fabrication, inspection, NDE, repair, or installation.                                                                                                                                                                                                                                      |
| 84. | Software                   | Computer programs and associated documentation and data pertaining to the operation of a computer system.                                                                                                                                                                                                                              |
| 85. | Special Process            | A process, the results of which are highly dependent on the control of the process or the skill of the operators, or both, and in which the specified quality cannot be readily determined by inspection or test of the product.                                                                                                      |
| 86. | Standard Commercial Quality| Quality requirements specified by codes, standards, etc., for the design and manufacturing of CGIs (see definition) that may differ from those that are usually imposed for nuclear facility applications.                                                                                                                                    |
| 87. | Supplier                   | Any individual or organization who furnishes items or services in accordance with a procurement document. An all-inclusive term used in place of any of the following: vendor, seller, contractor, subcontractor, fabricator, consultant, and their sub-tier levels.                                                                 |
## Appendix B. Terms and Definitions

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<tr>
<td>88.</td>
<td>Surveillance</td>
<td>The act of monitoring or observing to verify whether an item or activity conforms to specified requirements.</td>
</tr>
<tr>
<td>89.</td>
<td>Testing</td>
<td>An element of verification for the determination of the capability of an item to meet specified requirements by subjecting the item to a set of physical, chemical, environmental, or operating conditions.</td>
</tr>
<tr>
<td>90.</td>
<td>Traceability</td>
<td>The ability to trace the history, application, or location of an item and like items or activities by means of recorded identification.</td>
</tr>
<tr>
<td>91.</td>
<td>Use-as-is</td>
<td>A disposition permitted for a nonconforming item when it has been established that the item is satisfactory for its intended use.</td>
</tr>
<tr>
<td>92.</td>
<td>Validation</td>
<td>The process of: (a) evaluating a system or component during, or at the end of the development process to determine whether it satisfies specified requirements; or, (b) providing evidence that the software, and its associated products, satisfies system requirements allocated to software at the end of each life-cycle activity, solves the right problem (e.g., correctly models physical laws, implements business rules, uses the proper system assumptions), and satisfies the intended use and user needs.</td>
</tr>
<tr>
<td>93.</td>
<td>Verification</td>
<td>The act of reviewing, inspecting, testing, checking, auditing, or otherwise determining and documenting whether items, processes, services, or documents conform to specified requirements. (ASME NQA-1-2008/09a³)</td>
</tr>
<tr>
<td>94.</td>
<td>Waiver</td>
<td>Documented authorization to depart from specified requirements.</td>
</tr>
</tbody>
</table>

Sources:
ASME NQA-1-2008/09a³,
DOE O 414.1D⁴,
DOE P 450.4¹¹,
10 CFR 830⁶, 10 CFR 835²⁴.
Appendix C. Quality Management System ISO Requirements
Appendix C. Quality Management System ISO Requirements

PROCESS PLANNING

SWPF Management is responsible for planning and developing the quality processes needed for operations consistent with the requirements of the QAP. Operations planning shall determine the following as appropriate:

- Quality objectives and requirements;
- Specific processes, documents, and resources needed;
- Specific verification, validation, monitoring, inspection, and test activities, as well as the acceptance criteria; and
- Records which provide evidence that the processes and end result meet requirements.

Management shall determine the requirements specified by the DOE and whether there are other requirements not stated but necessary for the specified or intended use of the operation, where known. The determination shall also include any statutory and regulatory requirements related to the facility’s operations, including any additional requirements SWPF Management deems necessary. Once determined, management reviews to ensure that the requirements are defined, differing requirements are resolved, and its ability to meet the defined requirements is verified. Records of the reviews and any associated actions are documented and maintained. If the requirements are subsequently changed, SWPF management will ensure that applicable documents are amended and the changes are communicated to operations personnel.

CUSTOMER COMMUNICATION

SWPF management has determined and implemented protocols for communicating with the customer concerning process information, contract inquiries including amendments, and customer feedback. As part of this communication management monitors information related to DOE’s perception of whether their requirements are being met. Management will establish the methods for gathering and using this information appropriately.

CONTINUOUS IMPROVEMENT

Management shall determine, collect, and analyze data to demonstrate the suitability and effectiveness of the quality program and evaluate where continuous improvements can be made to enhance the program’s effectiveness. Data information sources can include customer satisfaction results, conformance with requirements, characteristics and trends including opportunities for preventive action, and suppliers. Continuous improvement of the program’s effectiveness will stem from use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions, and management reviews.
Appendix D. Basis of the SWPF Graded Approach
Appendix D. Basis of the SWPF Graded Approach

10 CFR 830\(^6\), requires contractor’s to use a graded approach in implementing this regulation, where appropriate, and document the basis of their graded approach for submittal to DOE. DOE further clarified in their “Response to Comments on the Interim Final Rule” that although requirements for when and how such documentation should be submitted are not prescribed, it is expected that the documentation and justification for grading be submitted in the document in which it is used. Therefore, this Appendix to the SWPF QAP is provided to document the basis for the SWPF graded approach for QA implementation.

The objective of implementing a graded approach is to prudently manage available resources by aligning the level of rigor and effort expended in evaluating and confirming that an item or activity conforms to applicable requirements with the relative importance to safety and/or mission achievement of that item or activity. Items or activities with a high importance to safety and/or mission achievement would receive a more rigorous level of evaluation and confirmatory scrutiny whereas items with little importance to safety and/or mission would receive lower levels of evaluation and confirmatory scrutiny typically consistent with standard commercial practices.

The graded approach definition in 10 CFR 830\(^6\), includes seven factors to be considered in establishing how the varying levels of implementation rigor are to be applied to specific items and activities:

1. The relative importance to safety, safeguards, and security;
2. The magnitude of any hazard involved;
3. The life cycle stage of a facility;
4. The programmatic mission of a facility;
5. The particular characteristics of a facility;
6. The relative importance of radiological and non-radiological hazard; and
7. Any other relevant factor.

The SWPF is a new facility and it does not contain accountable quantities of special nuclear material. Therefore, life cycle stage and safeguards and security are not relevant factors in the SWPF graded approach.

The SWPF is a DOE hazard category 2 non-reactor nuclear facility, and as such the factors of safety, magnitude of hazard, and relative importance of radiological hazards and non-radiological hazards are of primary relevance to the SWPF graded approach. The importance of specific items and activities in relation to these safety-related factors is synthesized and determined through the safety basis development process and captured via the functional classification process. SWPF functional classification has four levels, which are in order of decreasing rigor:

1. SS,
Appendix D. Basis of the SWPF Graded Approach

2. GS-1 SE,
3. GS-1, and
4. GS-2.

The items functionally classified as SS have the highest priority within the SWPF graded approach framework. SS items and activities are those that ensure nuclear safety requirements for protection of the public and workers are met and receive the highest level of rigor with regard to evaluation and requirements confirmation.

As a keystone to the overall clean-up mission at SRS, the factor of programmatic mission is also relevant to the SWPF graded approach although this factor is of lower priority than those related to nuclear safety. Items that are not safety-related but are determined to be of a relatively higher importance to achieving the overall SWPF programmatic mission are typically functionally classified as GS-1. GS-1 items and activities receive an elevated level of rigor with regard to evaluation and requirements confirmation that exceeds typical commercial practices, but is less than that for nuclear safety-related items and activities. Items or activities that are not nuclear safety related but have importance to permit compliance and/or occupational safety, may also be upgraded to GS-1 SE to provide a slightly elevated level of rigor beyond GS-1.

The factors of particular facility characteristics and any other factors are addressed on a case-by-case basis and may result in an item or activity having its functional classification elevated to GS-1. An example of specific considerations associated with these factors could be equipment location and accessibility relative to potential rework or repair.

All other items and activities that are not safety-related, are not determined to be of significant importance to programmatic mission, permitting, or protection from occupational hazards, and are not elevated in functional classification based on a particular facility characteristic or other factor are considered to be general industrial support items and activities and they are functionally classified as GS-2. GS-2 items and activities receive a level of rigor with regard to evaluation and requirements confirmation that is consistent with typical commercial practices.

The SWPF graded approach is implemented through our project procedures consistent with the basis outlined above. Specifically, the individual project procedures stipulate required protocols for relevant project activities including analysis, design, procurement, construction, inspection, testing, maintenance, and operations that are tailored in rigor in accordance with the functional classification of the item or associated activity. The SWPF graded approach basis and implementation is considered to be fully compliant with 10 CFR 830, and ensures that project resources are prudently applied in accordance with appropriate considerations and priorities to ensure safe and cost-effective project execution.
REFERENCES


6. 10 CFR 830, Nuclear Safety Management.


17. PL-QC-4800, SWPF Quality Control Inspector Qualification/Certification Plan. Parsons, Aiken, South Carolina.


22. PL-PR-6001, SWPF Acquisition Process System Description. Parsons, Aiken, South Carolina.


24. 10 CFR 835, Occupational Radiation Protection.


32. 01610, SWPF Packaging, Shipping, and Storage of Items, Revision 0. Parsons, Aiken, South Carolina.

33. 01620, Packaging, Shipping, and Storage of Items (Operations), Revision 0. Parsons, Aiken, South Carolina.


