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Acronyms and Abbreviations

ASL	Approved Suppliers List
BNI	Bechtel National, Inc.
CAMS	Corrective Action Management System
CFR	Code of Federal Regulations
DOE	US Department of Energy
DOE-RL	US Department of Energy, Richland Operations Office
IHLW	Immobilized High Level Waste
ILAW	Immobilized Low Active Waste
ITS	Important to Safety
LWA	Limited Work Authorization
OCRWM	Office of Civilian Radioactive Waste Management
PDC	Project Document Control
QA	Quality Assurance
QAP	Quality Assurance Program
QARD	Quality Assurance Requirements and Description
QC	Quality Control
QL	Quality Level
RCA	Root Cause Analysis
RPP-WTP	River Protection Project Waste Treatment Plant (formerly the Tank Waste Remediation System – Privatization Project)
R&T	Research and Technology
Project	Synonymous with RPP-WTP or WTP
SRD	Safety Requirements Document
SSCs	Structures, Systems, and Components
WTP	Waste Treatment Plant

Introduction

The US Department of Energy, Office of River Protection (DOE) has contracted Bechtel National, Inc. (BNI) to manage the workscope under the contract DE-AC27-01-RV14136, for the completion of design, performance of construction, and commissioning of the Hanford Waste Treatment and Immobilization Plant (WTP).

The WTP is comprised of four major elements, pretreatment, Low-Activity Waste (LAW) immobilization, High-Level Waste (HLW) immobilization, and balance of facilities.

To accomplish this mission and to ensure stakeholders expectations of product quality, BNI has developed this Quality Assurance Program. This program will govern all work performed at the WTP, including work performed by BNI WTP subcontractors. The Quality Assurance Program is supported by procedures, instructions, and guidance documents that implement the program.

Project Quality Policy

The fundamental aspect of any Quality Assurance (QA) Program is that the individuals performing the work determine the level of quality and are responsible for it being achieved. Though plans, procedures, and instructions are a basic part of any quality program, it should be recognized that people make quality happen. Each individual is responsible for the quality of his/her own work.

It is the policy of Bechtel National, Inc. to design, construct, commission, maintain, and operate the Waste Treatment and Immobilization Plant (WTP) in such a manner as to ensure the health and safety of the public and the personnel onsite and to protect the environment. One way to accomplish this critical objective is to have an aggressive and comprehensive quality assurance program in place, especially for those activities which can impact safety and quality.

As the Project Manager, I have directed the establishment of a formal and comprehensive quality assurance program at the WTP. This program places responsibility and accountability for quality on every person for the WTP. In addition, it emphasizes the creation of an atmosphere in the workplace where reporting and resolution of conditions adverse to quality is encouraged and expected at all levels.

The Quality Assurance Program is supported by the associated procedures and instructions which implement the Program requirements. The QA Program identifies those Quality Assurance Standards and Codes that shall be implemented to satisfy the contractual requirements.

Quality assurance objectives shall not be subordinate to cost or schedule objectives. To ensure compliance with the QA Program requirements, independent verifications and assessments shall be conducted to provide management a measure of the program's effectiveness and adequacy in meeting the requirements of the QA Program and its supporting procedures and instructions.

Conflicts involving implementation of the requirements of the Quality Assurance Program shall be resolved by the Quality Assurance Manager or, if deemed necessary, the BNI Corporate QA Manager. In those instances when Bechtel has delegated responsibility for implementation of parts of the Quality Assurance Program to suppliers and/or subcontractors, Bechtel retains responsibility for adequacy of the overall program.

R. Naventi
Project Manager

1. Quality Program

1.1. Objective

The objective of the QAP is to:

- (a) Establish the project organizational structure, management controls, functional responsibilities, levels of authority, and interfaces for managing, performing, and assessing the work; and
- (b) Ensure confidence in the safe completion of project work in full compliance with radiological, nuclear, process safety requirements, waste product acceptance quality requirements, and mission objectives.

For activities related to IHLW, a Quality Assurance Provisions Document shall be prepared and accepted by the Office of Civilian Radioactive Waste Management DOE/OCRWM Office of Quality Assurance or its delegated organization. This QA Provisions Document complements the QAP and provides an integrated quality assurance program for the project.

1.2. Purpose and Scope

The purpose of the Quality Assurance Program (QAP) is to:

- a) Describe the River Protection Project Waste Treatment Plant (RPP-WTP) commitment to quality;
- b) Establish quality policy; and
- c) Define the approach to the implementation of Quality Assurance (QA) requirements, and quality policy and principles on the Project.

The QAP reflects the quality requirements of 10 Code of Federal Regulations (CFR) Part 830.120, Top-Level Radiological Nuclear, and Process Safety-Standards and Principles for Tank Waste Remediation (TWRS) Privatization Contractors (DOE-RL-96-0006), Guidance for Review of TWRS Privatization Contractor Quality Assurance Program, RL/REG-96-01, RPP-WTP quality policies, and defines their applicability to project work.

The QAP defines the project organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work. To accomplish the work, the QAP defines the requirements for planning and performing work, as well as for checking and verifying the work to ensure that the applicable criteria, codes, standards, and regulations have been implemented effectively.

The QAP is applicable to work performed by or for the Project using a graded approach for the application of quality program elements to structures, systems, and components (SSCs). The graded approach is based on the safety classification determined by accident analysis that determines the safety class and quality level (QL) related to the safety class. The relationship between safety class and QL is defined in QAP Section 1.3.1.

The responsibility for the QAP resides with the Project Manager, with guidance from the WTP QA Manager. Additional support, guidance, and advice are provided by BNI Corporate Management, as required. The Project Manager is responsible for providing adequate resources to plan, assess

implementation, identify quality problems, and track corrective actions to completion. Implementation of the QAP is the responsibility of RPP-WTP personnel, through responsibility for the quality of their own work.

Selected QAP elements shall be applied to suppliers and subcontractors performing work for Project activities beginning early in the project with long lead procurements. A graded approach to application shall be used to flow down QAP requirements. The QAP provides direction for identifying the quality attributes necessary for planning, performing, and subcontracting work in a manner that will provide the maximum safety and optimum quality of tasks and deliverables.

The achievement, verification, control, and assurance of quality are accomplished through the clear delineation of quality policies in the QAP and the implementation procedures that specifically address the quality assurance criteria for the Project (Appendix A, Table A-1, QAP Implementation Procedures Matrix). Procedures to implement the QAP shall be developed and controlled through reviews, approvals, revision control, configuration control, and controlled distribution. Procedures and instructions shall address work performance and shall include the acceptance criteria necessary to verify performance. The approval of implementing procedures requires verification by the QA Manager that the procedures are in conformance with the QAP requirements.

The QAP provides for technical oversight and independent assessment of Project activities as specified in the scope of work for each phase of the Project.

The QAP further provides for the independent assessment and oversight of the implementation of management plans prepared for the management of work performance. Personnel performing assessments have direct access to the Project Manager when necessary to ensure that appropriate action can be effected. The assessment process is described in QAP Sections 9.0 and 10.0.

1.3. Requirements and Structure

The QAP is organized to meet the requirements of 10 CFR 830.120, principles stipulated in DOE/RL-96-0006, Project quality policy, specific contract requirements, and the intent of *Implementation Guide for Use with 10 CFR 830.120, Quality Assurance* (G-830.120, Rev. 0).

The implementation and maintenance of the QAP shall comply with 10 CFR 830.120 and the applicable elements of the following QA requirements:

- Quality Assurance Requirements for Nuclear Facility Applications (ASME NQA-1 1994)
- Quality Assurance Requirements and Description for the Civilian Radioactive Waste Management Program (QARD) (DOE/RW/0333P, Revision 8, 1998)

Table 1-1 provides a compliance matrix detailing the consistency of the QAP with NQA-1 and DOE/RW-0333P.

The content of other relevant industry standards and requirements for quality and safety were evaluated for application and were used as guidance during the development of the QAP.

Other Quality standards used as reference included the following:

- Quality Systems — Model for Quality Assurance in Design/Development, Production, Installation, and Servicing (ISO 9001 [ANSI/ASQC-Q9001])
- Establishing and Implementing a Quality Assurance Programme (IAEA 50-C-QA)
- Quality Systems Requirements for Environmental Programs (ANSI/ASQC E-4 1994)

A QARD requirements matrix shall be prepared for activities affecting IHLW product. The matrix identifies where the QARD requirements are directly addressed, where the QARD requirements are not applicable based on scope of work, and where exceptions to the QARD requirements have been taken, including justification. As changes are made to implementing documents, the QARD requirements matrix shall be revised if necessary.

Changes to the QARD requirements matrix shall be reviewed by the QA organization in accordance with paragraph 4.2.1.3 of this QAP.

The quality elements that form the content of the QAP are based on the three major areas of 10 CFR 830.120: Management, Performance, and Assessment, which are defined by the ten criteria of 830.120. The QAP elements are as follows:

- Section 1.0 Quality Program
- Section 2.0 Personnel training and qualification
- Section 3.0 Quality improvement
- Section 4.0 Documents and records
- Section 5.0 Work processes
- Section 6.0 Design
- Section 7.0 Procurement
- Section 8.0 Inspection and acceptance testing
- Section 9.0 Management assessment
- Section 10.0 Independent assessment

1.3.1. Classification of Items

The QAP shall be applied to SSCs, activities, and services that have been determined to be Important To Safety (ITS) or have attributes requiring quality criterion such as IHLW affecting requirements. The determination of QA Classification for SSCs and plant items shall be based on a safety and design process that considers and evaluates the following attributes as applicable to the SSCs: hazard and accident analysis, design reviews, safety reviews, reliability, maintainability, operability and availability.

The identification of important to safety SSCs is the product of a project's design and safety process for which hazards from radiological, non-radiological and chemical processes are analyzed. The Project's safety approach includes initial hazards identification, development of a Safety Requirements Document (SRD), Process Hazard Analysis, Accident Analysis, identification of safety functions, and the identification of SSCs that are important to safety.

Quality Levels (QLs) for SSCs are based on the safety classes determined through the above safety and design process. The QAP and applicable attributes of the Quality Assurance Provisions Document shall be applied to IHLW product affecting SSCs, items, and services. SSCs that serve to provide reasonable assurance that the facility can operate without undue risk to the health and safety of the workers and the public are considered important to safety. QLs for items and SSCs are based on the safety classes determined through accident analysis. The safety classes and their relationship to QLs are as follows:

Safety Design Class

SSCs that, by performing their specified safety function, prevent workers or the maximally exposed member of the public from receiving a radiological exposure that exceeds the exposure standards defined in the SRD. Safety Design Class also applies to those features that by functioning, prevent the worker or maximally exposed member of the public from receiving a chemical exposure that exceeds the Emergency Response Planning Guidelines (ERPG)-2 (AIHA 1988) chemical release standard. Those features credited for the prevention of a criticality event also are designated as Safety Design Class.

Quality Level 1 (QL-1)

Requirements are applied to Safety Design Class SSCs to provide added assurance that the SSCs can perform their specified safety function.

Safety Design Significant

SSCs needed to achieve compliance with the radiological or chemical exposure standards for the public and workers during normal operation; and SSCs that can, if they fail or malfunction, place frequent demands on, or adversely affect the function of, Safety Design Class SSCs.

Quality Level 2 (QL-2)

Requirements are applied to Safety Design Significant SSCs to provide adequate assurance that the SSCs can perform their specified function.

Other SSCs

Those SSCs that are neither Safety Design Class nor Safety Design Significant.

Quality Level 3 (QL-3)

Requirements consisting of basic and specifically applicable quality attributes, but essentially only sound commercial practices and compliance with industry codes and standards are applied to these SSCs.

Commercial Grade SSCs

Requirements, consisting of sound commercial practices and compliance with applicable industry codes and standards.

The graded approach process is described in the *Integrated Safety Management Plan, the Initial Safety Analysis Report*, and project procedures prepared for Project activities. During the design stage, a list of

Safety Design Class and Safety Design Significant SSCs will be developed. The list will be maintained throughout all project phases.

The provisions of the QARD shall be applied to QL-1 and QL-2 items and activities associated with IHLW services from product development through production, qualification, and acceptance.

1.3.2. Graded Approach

The QAP elements shall be applied using a graded approach based on the evaluated risk of the work process or item to the safety of the public and workers. The technical/design groups specify the quality elements, technical, inspection, and testing requirements in specifications, drawings, and procurement documents as necessary to meet the specific design, task, or operation based on the identified safety classes.

The graded approach shall be used through a process by which the level of analysis, verification/validation, documentation, and actions necessary for compliance with quality assurance requirements are commensurate with the importance of the equipment, processes, and facilities in order to ensure the following:

- Prevent or mitigate a release of radiological and hazardous material that could exceed exposure standards
- Prevent a nuclear criticality
- Meet exposure standards for normal operation

This is accomplished through the appropriate level of effort necessary to attain and document the accomplishment of the established requirements.

A graded approach to QA controls shall be applied. The rigor with which the quality program is applied to an activity is determined considering the following criteria and to the degree commensurate with the following risk management factors:

- Function or end use of the item
- Consequence of failure (risk) of the item
- Importance of the data being collected or analyzed
- Complexity of design or fabrication of the item or design or implementing of the activity
- Reliability of the process
- Reproducibility of the results
- Uniqueness of the item or service quality
- Necessity for special controls or processes
- Degree to which functional compliance can be demonstrated through inspection or test
- Any other relevant factors, including program risk

Appendix B represents a tabular summary of the application of QAP requirements for QL-1, QL-2, and QL-3 SSCs. Implementation of the graded approach shall be addressed in procedures or codes of practice to effectively meet the requirements.

The Quality Program consists of quality policy, program description, management documents, and implementing procedures delineated in Figure 1-1.

1.3.3. Quality Assurance Program Implementation

The control and assurance of quality shall be accomplished through the clear delineation of quality policies in the QAP and the implementing procedures that specifically address the quality assurance elements for the project.

The QAP defines management systems and controls for Project work activities as specified in the scope of work for each phase of the Project.

The development and implementation of clear and concise implementing procedures that accurately address the management controls and work processes are key to the effectiveness of the QAP. The QAP provides the structure and criteria for the project technical functions to develop the appropriate procedures controls and quality acceptance criteria for each work process. The procedures and management controls necessary to execute work shall address all phases of the project as defined by the Contract.

The QAP shall be implemented through project management documents using a tiered approach that includes the following:

- **Project Management plans** that define the management policies, goals, criteria, and responsibilities to perform the work
- **Project Management procedures** that define the management systems and controls that will be used to manage the execution of the project mission and goals
- **Implementing procedures and work instructions** that define the specific work tasks and operations

The QAP document hierarchy and relationship is depicted in Figure 1-2.

1.3.3.1. Integrated Application of Requirements

The QAP is applicable to project work performed by the functional groups and principal subcontractors performing work for the project, and is the single QA program for the Project. Subcontractors performing work for the project are required to work to the QAP. However, when subcontractors must perform work unique to their business, subcontractors are required to address the specific quality assurance program requirements specific to their work and specific procedures that will be used for the work, and submit their plan to the WTP QA Manager for approval before starting the work.

The QAP shall be integrated throughout and across project activities through close interdisciplinary interface and management involvement. The quality interface between design and construction is critical to ensure that design is accurately translated into plans, drawings, and specification requirements for site characterization and preparation, and SSCs. Design documents are evaluated by the construction organization to ensure efficiency and effectiveness of construction and equipment installation ensuring maintenance of configuration control. The quality interface between construction and operations is critical to ensure that the start-up testing is accomplished in accordance with the required and approved test plans and procedures.

A single QAP shall be implemented on the project to ensure appropriate QA/QC coverage across the project with the WTP QA Manager as the point of contact on quality assurance matters.

1.3.3.2. Planning for Quality

Quality is a key performance element that is built into work processes through specification of technical quality criteria and programmatic controls in project documents to support the overall project goal of safety. Determination of QA classification shall be based on the design safety classification through accident analysis, safety reviews, and reliability, availability, maintainability analysis.

To ensure the success of the QAP implementation, the project personnel performing quality-affecting activities shall receive an orientation on the QAP, and shall be advised of their individual roles in the program and responsibilities for the quality of their work. Orientation on the QAP shall be provided by the WTP QA Manager to ensure a complete understanding of QAP principles and policies, and the application of quality elements into the project work processes.

1.3.3.3. Design Quality

Design activities are controlled, and designs are verified and validated commensurate with the importance of the design to safety and the project mission as identified by safety and QL. Enhanced QA requirements are applied through the design to those items and activities that provide for the safety and protection of the public, workers, and the environment. Guidelines for determination of the appropriate QL and acceptance criteria are included in the QAP and project procedures that are responsive to the project design criteria. QLs for items and activities are identified on a list that is used across the project for design, procurement, construction, and operations activities. QA/QC reviews are performed of selected design documents to ensure that technical quality, QC inspection, and QA criteria are specified adequately.

Peer reviews shall be conducted, as determined by the Project Management, when the adequacy of information cannot be established through testing, alternate calculations, or reference to previously established standards and practices.

1.3.3.4. Procurement Quality

Quality in procurement is achieved through the requirements in procurement documents that provide for qualified bidders, through submittal of their quality plans for review and acceptance before award of a subcontract. Design documents define the technical quality requirements, and procurement documents define the contractual quality criteria required to ensure that the equipment or services meet specified project requirements. Procurement documents are reviewed by the WTP QA Manager for conformance to project quality criteria and to ensure that bidders are qualified to perform work of the quality required by the project.

1.3.4. Resolution of Quality Disputes

Differences of opinion involving QA program requirements shall be brought to the attention of the appropriate management and if not resolved shall be elevated progressively to successively higher levels of management until the dispute is resolved.

1.3.5. Organization

The Project Manager is responsible for the proper execution of the QAP and all work under the contract and is directly responsible for the performance of the work undertaken by both the Project and

subcontractors. BNI retains overall responsibility for the execution of the work under the contract and the overall implementation of the QAP. The project management organization for the project is shown in Figure 1-3.

The central point of Project control rests with each Area Manager. The Functional Managers provide the resources to accomplish the Project activities identified by the Area Managers. This is graphically displayed in Figure 1-3.

1.4. Responsibilities

Project Personnel

Are responsible for:

- The quality and the improvement of quality in his/her own work
- Implementation of the QAP as related to their work

The Project Manager

- 1 Has full authority to represent and commit the RPP-WTP Project Team on all matters related to the fulfillment of the contract obligations.
- 2 Is the senior manager responsible for development, implementation, and compliance with the Project's policies and implementing documents.
- 3 The relationship between the Project Manager and the WTP QA Manager is one of project coordination and QA support.

Is responsible for:

- Safety
- Overall implementation of the QAP
- Planning and completing an annual review of the overall effectiveness of the management assessments.
- Leading the RPP-WTP team in planning and implementing the contract and work scope
- Setting goals and objectives
- Providing necessary and sufficient program resources
- Providing a link to corporate policies and their application across the business
- Developing, authorizing, and releasing the Project Quality Policy statement
- All aspects of safety and environmental compliance, quality, and operations
- Project management, integration, direction, and performance based on the scope of work, agreed-on DOE top-level standards and principles, and project policies and procedures
- Establishing and maintaining external interface controls for the project
- Approval of the QAP and assigns each project team manager, and their assigned personnel, the responsibility and accountability for implementation of the QAP and the implementing procedures
- Providing the overall project and contract strategy

- Establishment and maintenance of the technical, cost, and schedule baseline
- Overall management of the Project
- Ensuring appropriate integration of the project activities with related safety and business functions
- The adequate provision and management of all project technical, engineering, and construction resources, systems, practices, procedures, standards, and quality control
- The provision and management of Project Control and Administration systems
- Deputy Chair of the Project Management Integrated Process/Product Team
- Providing adequate funds to ensure suitably qualified and experienced individuals are hired into all project departments
- Establishing and maintaining internal interface controls for the project
- Ensuring the adequacy of the arrangements implemented by the project team members regarding the design and supporting activities

The Engineering Manager

Is responsible for:

- Establishing the technical basis for the project and the technical integration of the overall project
- Providing leadership and guidance in the technical area to ensure satisfactory process design and the technical adequacy of the design documents
- Ensuring the compliance of project documents with applicable engineering codes and standards
- Providing direction to subcontractors and verifying that project deliverables satisfy the design requirements

The WTP QA Manager

- 1 Reports directly to the Corporate (BNI) QA Manager, and has direct access to the Project Manager. The WTP QA Manager has sufficient authority and organizational freedom to verify that the Project activities are performed in accordance with the requirements specified in applicable codes and standards
- 2 Is the single point of contact for project quality assurance matters and is the single point of contact on quality assurance program matters
- 3 Has the authority and responsibility to stop Project work when the work, if allowed to continue, would result in activities or documents being in noncompliance with stated requirements
- 4 The WTP QA Manager has no other assigned responsibilities unrelated to the QAP that would prevent full attention to QA matters. The WTP QA Manager has sufficient authority and organizational freedom to effectively communicate with other senior management positions and is sufficiently independent from cost and schedule considerations.

Is responsible for:

- Developing and maintaining the QAP in compliance with applicable regulatory QA requirements, and for approving the QAP for use on the Project

- Interfacing with the DOE and Project functional organizations on QA activities and for providing an overview of Project work activities
- Verifying the proper establishment and execution of the QA program
- Determining when appropriate corrective and preventative actions have been taken and for lifting the Stop Work Order to allow work to proceed
- Identifying QA requirements and maintaining the QA program matrices

The Environmental, Safety, and Health (ES&H) Manager

Is responsible for:

- The development and implementation of the regulatory, nuclear, and process safety project documents
- The interfaces among the DOE, State of Washington Department of Ecology, Federal Agencies, and project functional organizations for the preparation, control, and implementation of the documents required throughout the regulatory process.
- Development and maintenance of the nuclear and process safety case
- Development and maintenance of the environmental monitoring program
- Development and maintenance of a robust safety culture in the organization

The Business/Project Controls Manager

Is responsible for:

- Establishing a cost and schedule performance monitoring system, maintaining the project summary-level performance information, and preparing the required performance report
- On behalf of the Project Manager, monitoring and control of the project cost and schedule baseline
- The development and maintenance of the project budget and schedule baseline
- The development, monitoring, and reporting, both internal and external, of all project cost and schedule information
- Prime and subcontract management and administration
- Oversight and review of project team efforts in these areas
- Identification, maintenance, and control of contract scope changes via the baseline change control process
- Administration of prime contract request for equitable adjustment due to changes in law or regulation, client directed changes, or uncontrollable circumstances
- Subcontract management and performance within the overall contract strategy, including the negotiation, placement, and integration of subcontractors
- Contractual interfaces related to financial, quality, and legal matters
- Ensuring that procurement documents are issued only to qualified suppliers listed on the project approved suppliers list for purchase of items and services based on identified safety and QAs
- Providing subcontract administration

The Operations Manager

Is responsible for:

- Development and maintenance of a robust safety culture in the Operations organization
- Operations labor relations and development of labor agreements
- Research and Technology (R&T) activities

1.5. Management Processes

The Project Management approach has been established to ensure project continuity and success while assigning responsibility and accountability for specific scope to each Project team member. BNI provides the Project management oversight and integration of engineering, procurement, and construction, regulatory and nuclear safety management, operation management, and interface with DOE and regulatory agencies.

The Project Baseline is an integrated Precedence Diagramming Method schedule that is resource loaded to reflect increments of the project estimate and will be developed and maintained in conformance with the *Project Controls Procedures*. These project procedures establish the standards for the Project and its principal subcontractors to develop a cost and schedule plan, collect costs, forecast future requirements, and measure and report performance. The Business/Project Controls Manager is responsible for the development and maintenance of the Project budget and schedule baseline.

1.6. Program Reviews

The Project Manager and the WTP QA Manager shall perform an annual review of the Project QAP, project quality policies, and implementing project procedures for conformance with applicable regulatory and quality requirements. Changes resulting from the review shall be documented and controlled.

Changes to the QAP that affect commitments specified in a previously approved QAP made as part of on-going maintenance may be made at any time prior to the annual update. These changes shall be submitted to the DOE for review and approval 30 days before the implementation of subject changes and shall be regarded as approved 30 days after submittal, unless approved or rejected by the DOE at an earlier date.

Table 1-1 Compliance Table-ASME NQA-1 and DOE/RW-0333P vs. Quality Assurance Program

NQA-1*/DOE/RW-0333P	QAP
Organization	Section 1.3.5
Quality Program	Sections 1 and 2
Design Control	Section 6
Procurement Document Control	Section 7.2.2
Instruction, Procedures, and Drawings/Implementing Documents	Sections 4.2.1 and 5.3.2
Document Control	Section 4.2.1
Control of Purchased Items & Services	Section 7
Identification & Control of Items	Section 5.3.3
Control of Processes/Control of Special Processes	Section 5.3.4
Inspection	Section 8.2.1
Test Control	Section 8.2.2
Control of Measuring & Test Equipment	Sections 5.3.5 and 8.2.3
Handling, Storage, and Shipping	Section 5.3.6
Inspection, Test, & Operating Status	Section 8.2.4
Nonconforming Items	Section 3.2.1
Corrective Action	Section 3.2.2
QA Records	Section 4.2.2
Audits	Section 10

* Indicates the basic requirements of ASME NQA -1, Part I (1994). Supplementary requirements are to be addressed as required by specific project activities.

Figure 1-1 RPP-WTP Quality Program

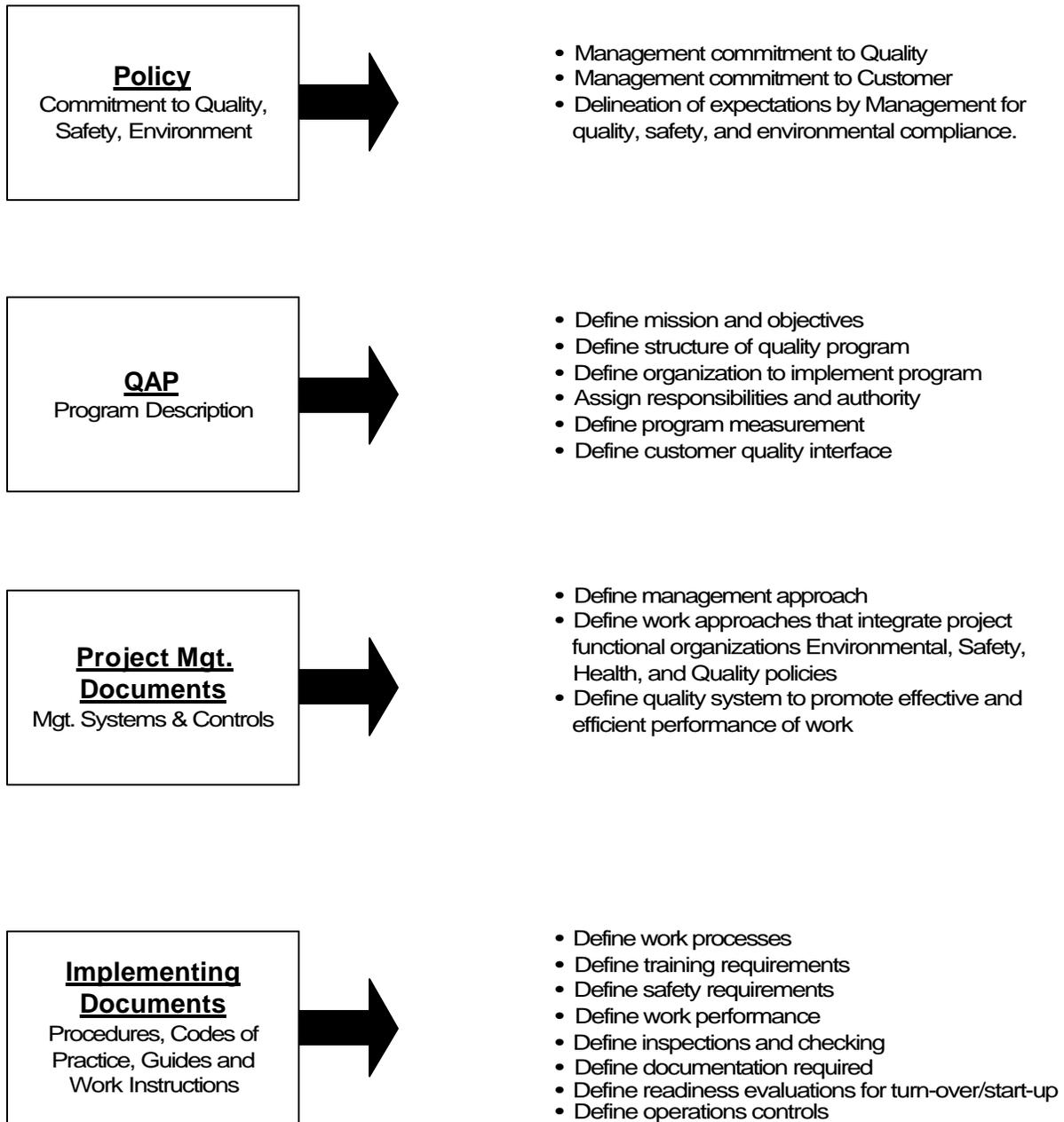


Figure 1-2 Quality Program Document Hierarchy and Relationship

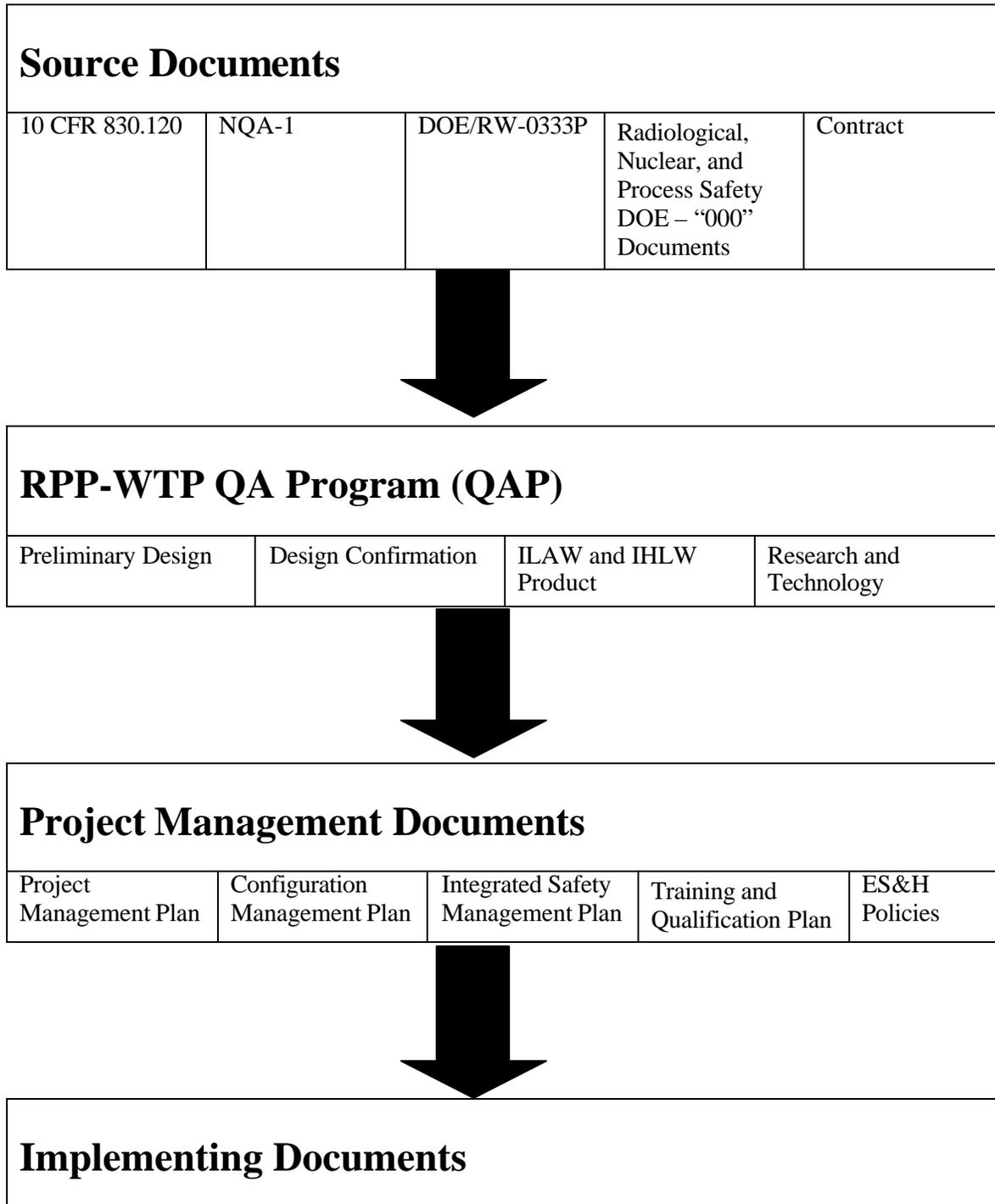
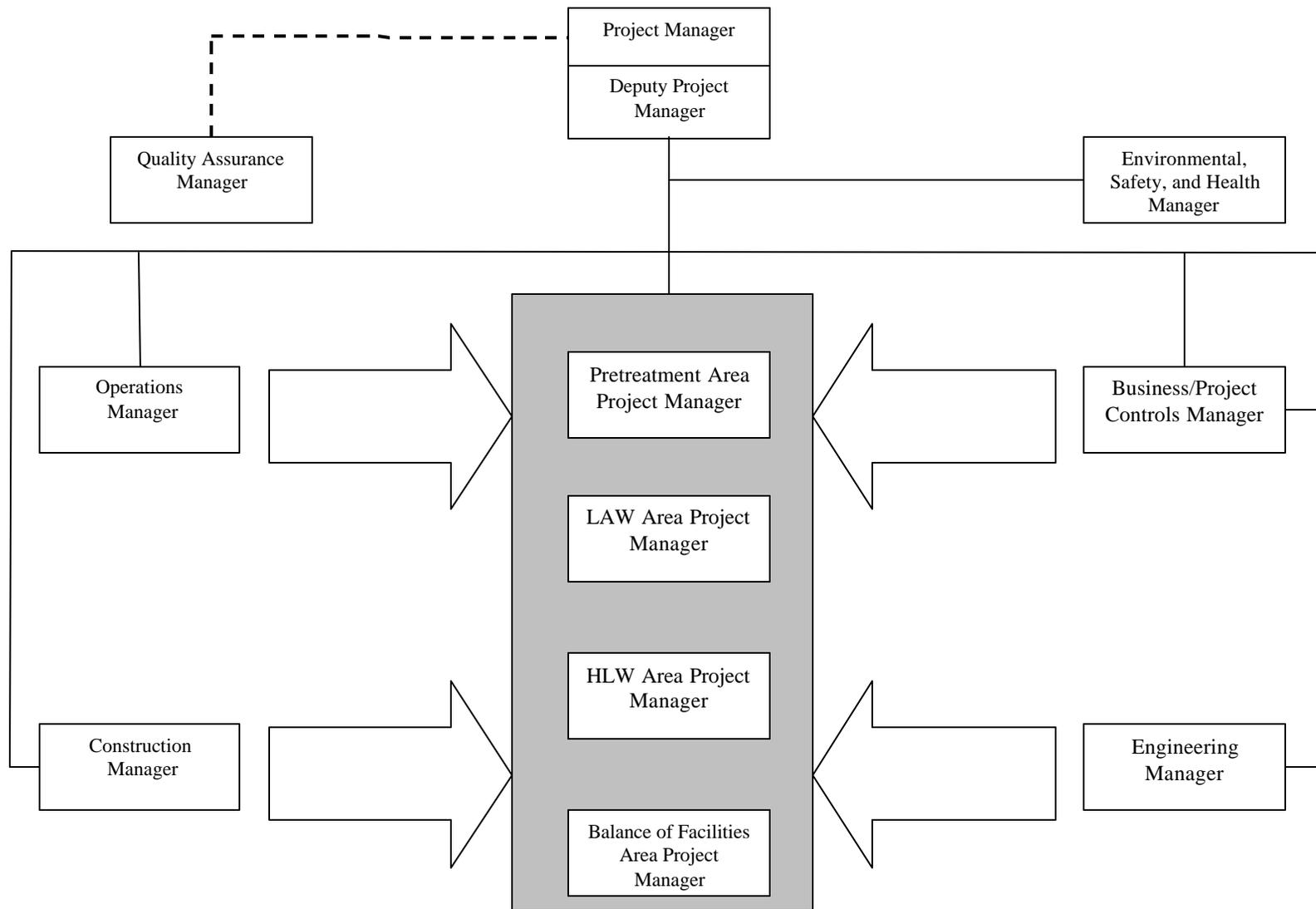


Figure 1-3 Overall Management Structure and Organization



2. Personnel Training and Qualification

2.1. Purpose

The purpose of this section is to define requirements and responsibilities to ensure that personnel are qualified and appropriately trained to perform their work in a quality manner including their initial proficiency; maintenance of proficiency; and adaptation to new technologies, methods, or responsibilities.

2.2. Requirements

A basic principle of RPP-WTP is that the project shall hire employees with the proper educational background (formal degrees, diplomas, and/or years of experience) to fit established positions. Minimum education and experience shall be verified, or, when minimum education and experience cannot be verified, documented justification shall be provided for the personnel assignment. Training and qualifications shall be commensurate with the scope, complexity, and nature of the activities performed. Indoctrination and training programs shall be established and implemented, as appropriate.

The WTP QA Manager or designee shall provide orientation to newly reporting Project personnel on the QAP. Project personnel performing activities affecting quality shall receive training consistent with the requirements to perform their assigned work. The orientation is to provide familiarization with key elements of the quality program principles and policies, application of quality elements into the Project work processes, the role of Project individuals in the program, and responsibilities of Project personnel for the quality of their work.

Specific safety, quality, and technical training shall be planned, scheduled, provided, and maintained for personnel in their respective disciplines as defined by position descriptions and specific work assignments. Training shall be defined in documents that describe scope of the training and subject, and shall be presented by a qualified instructor, documented with attendees names, and dates. Training developed using computer based training modules shall be approved by the training organization.

Personnel shall receive necessary and sufficient training before their start of work. Personnel reassigned or moved in the organization structure such that functions and responsibilities have changed significantly shall be retrained as necessary. Until full completion of training assignments, Project personnel are allowed to perform and complete on-the-job training and work, with their products being reviewed by their supervisors while they complete training. A nominal duration to complete training should be described. Personnel performing special processes (as defined by contract or regulation, such as: welding, nondestructive examination, heat treating, and chemical cleaning) or requiring special abilities shall complete training and qualification prior to commencing work requiring such skills. Examples of this type of position are hazardous material workers, radiological control technicians, welders, and NDE inspectors. Personnel selected to perform work shall have the experience and ability to provide the necessary quality performance as defined by position descriptions.

Worker performance shall be evaluated on an annual basis by project functional and line managers. When worker certification is necessary to comply with regulations or specific codes or standards, personnel shall be certified by qualified personnel or agency as required by the governing code or standard. The responsible manager shall track and verify that certifications are maintained. Training and certification records shall be maintained in the project records management system.

Training consists of on-the-job training, formal training sessions, reading assignments, refresher courses, technical seminars and conferences, and self-study. Formal training, when required, is provided by qualified instructors who possess the technical and instructional skills needed to accomplish instructional assignments in an effective manner.

When required by applicable codes and standards, qualified personnel shall be certified to perform specified activities. Periodic training, as required by applicable codes or standards, shall be conducted and documented to maintain certifications.

Personnel certification is required for performing the following:

- Independent assessments and audits – Required for Team Leader to meet NQA-1 requirements
- Nondestructive examination – Required for personnel performing nondestructive examination or reviewing nondestructive examination results. (American Society for Nondestructive Testing Standard SNT-TC-1A, 1980 Edition). In lieu of the three-year recertification interval specified in SN-TC-1A, 1980 Edition, Level III nondestructive examination personnel may be recertified on a five-year interval
- Construction inspections and tests – Level I, II, or III based on experience, test, and discipline (civil, electrical, mechanical, instrumentation)
- Site activities (e.g., equipment operation, fire protection, training for hazardous waste workers based on specific code, standard, and site requirements)
- Engineering activities requiring professional engineer licensing in the State of Washington

Certifications include identification of the person and specific activities, experience, previous training, capability demonstrations and test results (as required), signature of the designated person responsible for certification, certification date, and date of expiration.

When special processes (as defined by the contract or regulation) are subcontracted, the appropriate requirements for the activity are included in the procurement documents in accordance with Section 7.0, "Procurement".

2.3. Responsibilities

All Managers

Are responsible for:

- Committing resources and provide training to Project personnel performing activities that affect quality within their organizations
- Establishing training requirements for Project personnel based on the position descriptions
- Review job responsibilities and scope-of-work assignments to ensure that the training program is maintained current with work assignments and is updated to improve overall work performance
- Staff recruitment and training

The Project Manager

Is responsible for:

- Assigning qualified personnel to perform project tasks. Personnel selected to perform work shall have the experience and ability to provide the necessary quality performance as defined by position descriptions
- Establishing training requirements for project personnel and for instructors, based on the position descriptions
- Reviewing job responsibilities and scope-of-work assignments to ensure that the training program is maintained current with work assignments and is updated to improve overall work performance

The Operations Manager

Is responsible for:

- Training department activities and implementation, control, and maintenance of the training matrix for tracking training of personnel and for determining the status of the training program
- Processes for personnel training, qualification, and certification
- Establishing training requirements for project personnel and instructors based on the position descriptions
- Control and maintenance of training and certification records as required until turnover to the project records management system

The Business/Project Controls Manager

Is responsible for:

- Coordination of the hiring of qualified personnel to meet position requirements
- Assignment of qualified personnel to perform project tasks
- Maintaining position descriptions

The WTP QA Manager

Is responsible for:

- Periodically assessing the status and effectiveness of the indoctrination and training programs to ensure that they continue to reflect the current systems, procedures, and policies applicable to each position. Assessments of the training program conducted by the WTP QA Manager shall be coordinated with the Project Manager and shall be scheduled and conducted at least annually
- Control and maintenance of QA training and certification records as required until turnover to the project records management system
- When the evaluation of the indoctrination and training programs identifies deficiencies, the responsible manager is required to respond in writing within 30 days indicating the appropriate corrective action

The Engineering Manager

Is responsible for:

- Assigning trained and qualified technical personnel to the Project and providing for the necessary training of the Project technical personnel

3. Quality Improvement

3.1. Purpose

The purpose of this section is to define the RPP-WTP Project, requirements, and responsibilities to prevent conditions adverse to quality, control nonconforming conditions, take corrective action when appropriate, and continuously improve process and product quality.

3.2. Requirements

The improvement of quality and work processes used to achieve quality in BNI services is embedded in BNI Corporate policies. Continuous improvement is an integral part of the Project's activities. Work processes are embedded with elements to detect, correct, and prevent quality problems as part of performing the work. Continuous attention is given to the quality of work performed, procedural effectiveness, and customer satisfaction. The QAP is a management tool that provides structure to the quality process and directly supports Project management's achievement of applicable quality requirements.

The RPP-WTP is committed to building a culture that makes continuous improvement a normal part of doing business for the project team. It is management's policy that the responsibility for improvement belongs to each individual and organization, including those having responsibility for planning, scheduling, and cost control. Processes are established and implemented to detect and prevent quality problems, prevent recurrence, and to provide for quality improvement. Quality improvement is achieved through implementation of the following:

- Early identification of potential problems through structured surveillance, assessments, and audits
- Identification of conditions adverse to quality by any employee
- Review of key project documents to ensure conformance to quality requirements
- Review of contract and regulatory elements to identify those that have potential for impact on quality
- Corrective action management through tracking and trending of adverse conditions
- Interface with customer quality representatives to ensure expectations are addressed
- Employee recommendations
- Application of lessons learned from project reviews, DOE lessons learned system, and corporate/industry feedback information
- Quality improvement metrics based on audit and trending data from the Corrective Action Management System (CAMS) database

The RPP-WTP process for quality improvement provides a mechanism for any employee to identify quality concerns. The identification concerns extend to safety concerns as a part of the overall problem identification process. Management, in keeping with the Hanford Site safety policies, empowers employees to stop work when a concern presents an imminent danger to employee safety and health, the environment, facilities, or property. Concerns will be transmitted to the appropriate manager for action and disposition. All project personnel have an obligation to identify nonconforming conditions or services in the areas subject to the QAP. Project personnel shall be informed of this obligation as part of

their initial indoctrination and training. No adverse actions shall be taken against an employee for identifying a condition that the employee reasonably believes is adverse to quality or safety.

3.2.1. Control of Nonconforming Items, Services, and Processes

Nonconforming items, services, and processes may be identified through internal project audit findings, customer or external agency identified deficiencies, DOE's Representative findings, nonconformances identified during work activities, inspection or surveillance observations, or employee identified concerns.

The identification, tracking, analysis, resolution, and trending of program, process, or procedure deficiencies and nonconformances are managed through an active project-wide CAMS. The CAMS provides real-time information to project management and working-level personnel on the status of corrective actions project wide.

It is BNI policy to promote open communication for the identification of safety and quality issues. Adverse conditions or deficiencies may be identified at any time by any member of the Project and submitted to management for action and disposition.

Deficiencies identified by Corrective Action Requests, supplier/subcontractor audit finding reports, surveillance reports, nonconformance reports, inspection reports, or otherwise identified conditions that require corrective action, are entered into the Project CAMS database that records the condition, action planned to correct the condition/deficiency, responsible manager, date the condition was identified, date the condition is scheduled for completion, and completion date.

Conditions and deficiencies may be identified through different methods. The most common identification methods are through personnel performing work, management assessment, internal surveillance, inspection, or audit, or by external oversight of the project by DOE or other agencies. The system database provides the means to record and track all of the methods discussed, and provides a means to sort corrective actions based on Project needs. The system data provide a means for identifying recurring conditions and potential adverse trends that will be reported to management.

Corrective actions for identified deficiencies and conditions and the reporting of status are completed by the manager responsible for the area/activity where the deficiency occurred. On completion of corrective action, the completion status is reported for entry into the CAMS database. The follow-up verification of the effectiveness of corrective actions is performed by the WTP QA Manager through inspection, surveillance, assessment, and audit.

Management participation in the corrective action management process is through meetings to review the open action items and to establish priorities for completion of the necessary corrective actions. The meeting shall be chaired by the Project Manager, with direct support by the WTP QA Manager for input from the CAMS database. The purpose of the meeting would be to review the open corrective actions and prioritize actions to ensure prompt corrective action is or will be taken by the responsible manager to complete and close the open actions that pose the greatest risk to safety and Project mission. CAMS data will be distributed to the meeting attendees. The meeting is part of the Project Management Monthly Status Meeting attended by the Project Manager, the senior staff or designees, including the WTP QA Manager. The meetings should be on a monthly basis, then shifted to a quarterly basis unless conditions dictate more frequent meetings. Minutes shall be issued to ensure response to management requests for action.

For equipment and construction process nonconformances, documentation shall clearly identify and describe the characteristics that do not conform to specified criteria. Nonconformance documentation shall be reviewed, and recommended dispositions of nonconforming items shall be proposed. Justification for disposition shall be provided by the responsible technical organization and shall be fully documented. Nonconforming items, services, and processes shall be identified, controlled, and dispositioned to prevent inadvertent use.

Suspect/counterfeit items discovered at receipt inspection or as a result of surveillance shall be reported as nonconformances to the WTP QA Manager. The description of the occurrence shall be documented in sufficient detail to establish who, what, when, where, why, and how relative to the suspect/counterfeit items in question.

The methods for controlling nonconforming items, services, and processes that do not meet requirements or specifications include the following dispositions: reject, repair, re-work, or use-as-is. Technical justification is required for “use-as-is” or “repair”, and “as-built” records must reflect the change. Reworked items shall be inspected, tested, or reviewed in accordance with the original requirements. Repaired items shall be inspected, tested, or reviewed in accordance with alternate requirements approved by the original responsible organization. Replacement items, when used, must be of the same quality level as the original and shall be inspected, tested, or reviewed in accordance with the above dispositions. Nonconforming items or activities should be corrected or resolved prior to application or use of the item or activity.

Personnel responsible for analyzing and the disposition of nonconforming items, services, and processes shall have previously demonstrated adequate technical understanding of the area in which they are working, as well as access to pertinent background information concerning the nonconforming items, services, and processes.

3.2.2. Corrective Action

Nonconformances and deficiencies shall be evaluated to determine if a significant condition adverse to quality has been identified. Significant conditions adverse to quality shall be analyzed to determine the cause and corrective/preventive action that must be taken to eliminate the causes of nonconforming conditions to preclude recurrence. A condition adverse to quality shall be identified when a QAP requirement, including the QARD or an implementing document requirement, is not met. Criteria for determining the importance or significance of the problem and the extent of cause analysis shall be developed so that actions can be taken commensurate with the importance of the fault or nonconformance.

Two classifications of conditions adverse to quality shall be established: (a) conditions adverse to quality, and (b) significant conditions adverse to quality. Either condition adverse to quality shall be documented, entered into the CAMS, and managed to disposition and closure of the identified condition in a timely manner. All identified conditions adverse to quality shall be documented and reported to management responsible for the condition, their upper management, and to the quality assurance organization for tracking. Remedial actions for non-significant conditions adverse to quality and corrective actions shall be tracked on the CAMS database and the completion verified. Follow-up of completed corrective actions for effectiveness shall be through surveillance, assessment, or audit by the WTP QA Manager.

Managers evaluating and determining the causes and corrective actions for significant conditions adverse to quality shall use root cause analysis as a tool to complete the corrective action. A standard list of cause codes will be used to group and trend data identified by root cause analysis. Trend reports are issued to

Project management and working-level personnel for use as a tool in the identification of potential work process improvement opportunities. Project procedures shall describe responsibilities for determining when root cause analysis is used and who is responsible for performing the activity.

3.2.3. Process Improvement and Problem Prevention

The quality assurance organization shall establish criteria for determining adverse quality trends. Data from corrective action(s), assessments, nonconformance reports and other quality measurement processes shall be collected and analyzed for trends and improvement opportunities. Trend evaluation should be performed at least once every 60 days in a manner that provides for prompt identification of adverse quality process trends. When identified conditions or deficiencies are determined to warrant further analysis, a root cause analysis shall be performed. Personnel performing root cause analysis shall be qualified through training. Results of the analysis shall be documented and transmitted to the responsible manager for determination of corrective actions necessary to correct or prevent further problems.

3.2.4. Quality Assurance Program Status

Monthly reports shall be prepared by the WTP QA Manager for the Project management on the status and effectiveness of the Project QAP. These reports shall provide a status of the effectiveness of the QAP implementation, areas of concern, opportunities for quality improvement, and identify adverse quality trends. Reports shall be distributed to Project management, Project supervisors, and business management. The WTP QA Manager may schedule meetings with Project personnel to review program status when necessary to discuss specific QAP activities.

3.3. Responsibilities

Project Personnel

Are responsible for:

- Identifying nonconforming conditions or services
- Reporting to appropriate management those processes believed to be in nonconformance with applicable requirements, or that can result in improvements to safety, improvements to quality, or reduction in cost
- The quality and improvement of quality for his/her own work
- Identifying improvement opportunities for work products and processes and to identify nonconforming items, services, and processes

The Engineering Manager

Is responsible for:

- Providing direction to engineering personnel in the corrective action process and disposition of nonconforming conditions
- Identifying and documenting performance problems and conditions adverse to quality
- Identifying opportunities for quality improvement

- Taking prompt action to resolve problems that hinder achieving objectives, resolving deficiencies, and improving processes and quality
- Data Quality
- The development of test plans yielding technically defensible results

The Operations Manager

Is responsible for:

- The development of commissioning test plans
- Process technology

The Area Project Managers

Are responsible for:

- Identifying and documenting performance problems and conditions adverse to quality
- Identifying opportunities for quality improvement
- Taking prompt action to resolve problems that hinder achieving objectives, resolving deficiencies, and improving processes and quality
- Identifying quality problems, initiating, recommending, or providing potential solutions to quality problems

The WTP QA Manager

Is responsible for:

- Development and implementation of the CAMS database to track and trend corrective actions
- Reviewing significant conditions adverse to quality and concurring with proposed corrective actions and the dispositions of nonconforming conditions
- Verification of completion of identified corrective actions

4. Documents and Records

4.1. Purpose

The purpose of this section is to establish requirements for the following:

- Preparation, review, approval, revision, and control of documents that specify or prescribe activities that affect quality, including changes to ensure that correct information is used in performing work activities
- Collection, storage, maintenance, and disposition of documents through a records system that provides sufficient evidence of the quality of activities performed

4.2. Requirements

The document control and records management process shall be established and implemented to ensure that current documentation, including revisions, is distributed and used to perform work activities at prescribed locations. Sufficient records (for example, records of design, environmental conditions, applied research and development, procurement, construction, data acquisition, assessments, inspection, testing, maintenance, and modification) are identified, collected, stored, and maintained to prevent loss or damage. The maintenance of records includes provisions for retention, protection, preservation, traceability, accountability, and retrievability.

4.2.1. Documents

4.2.1.1. Document Preparation

Activities affecting quality are prescribed and performed in accordance with instructions, procedures, plans, and drawings of a type appropriate to the circumstances. When appropriate, these documents include or reference quantitative and/or qualitative acceptance criteria for determining that prescribed activities have been accomplished satisfactorily.

4.2.1.2. Document Control

Preparation, review, approval, distribution, use, and revision of documents that establish policies, prescribe work, specify requirements, or establish designs are controlled. A master list shall be established to identify the current revision of controlled documents to preclude the use of nonapplicable or superseded documents. The document control system includes the following:

- Identifying documents to be controlled and their specified distribution (including timeliness guidelines)
- Identifying responsibility for preparing, reviewing, approving, and issuing documents
- Providing for review of documents for adequacy, completeness, and correctness before approval for issue
- Defining methods for control for user access to documents
- Providing for maintenance of record copies of controlled documents
- Describing the conditions or limitations applicable to uncontrolled documents

4.2.1.3. Document Review and Approval

Documents prescribing quality-affecting activities including revisions (e.g., QAP, procedures, safety analysis, design documents) are reviewed for adequacy, conformance with technical requirements and quality system requirements, and approved for issuance by authorized personnel with expertise in the subject, before distribution for use. Project personnel who review and approve documents shall have access to pertinent background information on which to base their reviews.

Peer reviews of documents, when requested, are conducted for work that goes beyond the state of the art where potential uncertainty exists. Peer reviews are performed by one or more individuals who have technical expertise collectively at least equivalent to those who performed the original work. The peer review is an in-depth critique of assumptions, documents, calculations, extrapolations, alternate interpretations, methodology acceptance criteria, conclusions, and material or data that require interpretation or judgement to verify or validate them.

4.2.1.4. Document Change

Changes to documents prescribing quality-affecting activities are controlled, reviewed, and approved by the same organization that performed the original review and approval unless other organizations are designated specifically. Changes to documents, which include other-than-editorial corrections, are considered major changes and require review and approval by the originating organization. Editorial changes are considered minor changes and do not require the same level of review and approval. Authorization for minor changes is identified in project document control procedures.

The Project document control process provides for the controlled distribution of documents to ensure that current and correct information is used in performing work activities. This is accomplished through the identification of recipients and identification of administrative actions required when documents are revised, become obsolete, or are superseded. Project procedures include measures to ensure that only correct documents are in use, at the location where the work is being performed, and superseded or voided documents are maintained for a specified retention time to provide revision history.

The types of documents under controlled distribution include, but are not limited to, the following:

- QAP
- Radiological, Nuclear, and Process Safety Documents
- Project Plans
- Project Procedures
- Interface Control Documents
- Design Drawings
- Specifications
- Construction Drawings

4.2.2. Records

A record contains information that is retained for its expected future value. Records shall be sufficient to support technical requirements and regulatory compliance.

Records shall be specified, prepared, reviewed, approved, and maintained to reflect the achievement of required quality. Specific quality assurance records and retention periods shall be addressed in a records retention and turnover plan that will define the customer and Project retention requirements. Records shall be legible, accurate, dated (including revision date), paginated, identifiable to the product or service involved, complete, and maintained in an orderly manner. Records and documentation shall be stored via hard copy, electronically, or magnetically, for safekeeping and preservation, and shall be retrievable. A project records retention and turnover plan shall be prepared to meet the requirements of ASME NQA-1 Supplement 17S-1 "Supplementary Requirements for Quality Assurance Records", the QARD 10 CFR 830.120, and other applicable standards. The plan shall define specific documents and their retention as agreed on by BNI and the DOE.

Basic documents to be retained as quality assurance records include the following:

- Documents specifying quality requirements for SSCs important to safety, safeguards and security
- Documents specifying environmental protection
- Training records and qualification certifications
- Design documents (calculations, specifications, drawings) and design review documents
- Safety analysis reports, hazards analyses
- Quality assessment reports
- Inspection and test documentation
- Quality verification documents
- QAP
- Project procedures

4.2.2.1. Preparation

Records shall be prepared in accordance with policies and/or procedures governing the preparation of each specific document (i.e., calculations, specifications, safety analyses). Procedures for each document type define the steps necessary for interfacing with Project document control personnel to ensure appropriate processing of documents for records purposes. Individuals handling QA records shall protect them from damage or loss until the records are submitted to the records management system.

4.2.2.2. Validation

QA records are considered valid only when they have been authenticated. This may include handwritten signature, initials or stamping, and dating. When electronic media is used for authentication, a password protected and controlled process shall be used.

4.2.2.3. Identification and Collection

Records are identified in indices that include the document identity, retention time, storage type (single or duplicate, microform or hardcopy), and storage location. A close interface is maintained between document control and the functional groups, projects, and suppliers to ensure a timely and complete collection of records. Submittal periods for records are identified in Project document control procedures.

4.2.2.4. Retention

Records are identified as lifetime or nonpermanent in accordance with the requirements of ASME NQA-1, Supplement 17S-1 *Supplementary Requirements for Quality Assurance Records*. The retention period for lifetime records is considered to be the lifetime of the facility plus 75 years. Lifetime records are those that meet one or more of the following criteria:

- Significant value in demonstrating capability for safe operation
- Significant value in maintaining, reworking, repairing, replacing or modifying an item
- Significant value in determining the cause of an accident or malfunction
- Provide required baseline data for in service inspection
- Support or validate actions for items identified as QL-1 and QL-2
- Documents that provide evidence of the quality of the production process for the high-level waste form and acceptance of the high-level waste form
- Personnel training and qualification documents for individuals executing QA program requirements

Nonpermanent records are those required to show evidence that an activity was performed in accordance with applicable requirements but need not be retained for the life of the item/facility.

Some records associated with activities are not directly related to items to be installed in facilities. These records are not identified as lifetime or nonpermanent, and require special retention. Such records include personnel medical monitoring records, radiation and chemical exposure records, and data and reports obtained from scientific investigations. Retention requirements are established for such records as specified by BNI internal and applicable legal requirements.

4.2.2.5. Changes to Records

Records that contain errors or discrepancies shall be corrected. Corrections shall be identified and marked with a date, as well as the identification of the person authorized to correct the record and authenticate the correction. Corrections shall be reviewed and approved by the originating organization.

4.2.3. Storage and Maintenance

Maintenance of records in a secure records storage area shall be defined in project document and records management procedures prepared by the Business/Project Controls Manager to address contract requirements and Project-specific regulatory requirements for records management. A Records Inventory and Disposition Schedule system shall be used to set forth and describe mandatory disposition for disposal, or transfer to storage or the client after specified retention periods in the office.

QA records shall be stored in a container or facility with a fire rating of one-hour or dual storage will be provided. For QA record storage, containers or facilities shall bear an Underwriter Laboratory label (or equivalent) certifying one-hour fire protection, or be certified by a person competent in the technical field of fire protection.

Measures shall be established and documented in project procedures to preserve the integrity of storage facilities and media. The procedures shall provide the following:

- Description of the storage areas
- Filing system to be used
- Method for verifying the records received are legible and agree with the transmittal document
- Rules governing access to and control of the files
- List designating personnel with access to the files
- Disposition of superseded records
- Provisions to prevent damage from environmental conditions
- Storage and handling provisions for special processed records such as radiographs, computer disks, photographs, negatives, and microfilm to prevent damage from excessive light, humidity, pressure, and temperature
- Retrieval of information without undue delay
- Coordination with the DOE on records retention and turnover as specified by contract

4.3. Responsibilities

Project Personnel

Are responsible for:

- Updating their assigned documents by removing obsolete material and inserting current material, as copyholders of controlled documents
- Submitting completed documents/records to PDC for logging, distribution, and retention

The Project Manager

Is responsible for:

- Developing, authorizing, and releasing the RPP-WTP Quality Policy statement
- Approval of the QAP
- Assignment of approval authority for project procedures
- Approval of the controlled documents' distribution lists

The WTP QA Manager

Is responsible for:

- Approval of the QAP
- Preparation and revision of the QAP
- Developing, maintaining, controlling, and releasing the project QAP and procedures
- Ensuring that the document control and records management systems meet applicable contractual and regulatory requirements
- Ensuring the preparation, review, and approval of project procedures, codes of practice, design guides, and instructions

The Business/Project Controls Manager

Is responsible for:

- Establishing and maintaining a document control and records management system in accordance with written procedures

5. Work Processes

5.1. Purpose

The purpose of this section is to establish the Project requirements and responsibilities to control work processes, equipment, and conditions that affect the quality of services and products.

5.2. Requirements

Work activities shall be performed in accordance with established regulatory requirements, technical standards, and administrative controls. All activities affecting quality shall be prescribed by, and performed in accordance with, documented, management-approved procedures, codes of practice, instructions, and design documents. The procedures and instructions shall be prepared at a level of detail appropriate to describe and control the work based on the importance and complexity of the work process being performed. Such documents shall include or reference appropriate quantitative or qualitative acceptance criteria for determining that prescribed activities have been accomplished satisfactorily.

Project procedures, instructions and design documents shall be maintained current. When revised, revision indicators shall be provided to ensure that current requirements are identified to personnel using the document.

Examples of work processes include the following:

- Design procurement, construction, commission, start-up, and operations
- Control of materials and items including maintenance to ensure their proper use and to prevent their damage, loss, or deterioration
- Use and maintenance of calibrated measuring and test equipment
- Document control activities

5.3. Work Performance

5.3.1. Project Management and Planning

Project management for the RPP-WTP is through the Project Management Plan that describes the approach and objectives for managing the Project. Work planning is performed by functional managers and their groups, which include engineering, procurement, construction, administration, operations, and project controls.

Field activities during construction that include site preparation, construction, equipment installation, start up support, operations support, operations maintenance support, and construction deactivation are performed by the field organization under the direction of the Construction Manager. Special processes shall be performed in accordance with approved procedures prepared by the organization responsible for certifying/qualifying the process, equipment, and personnel. Field work is accomplished by the construction organization either directly or through subcontracts.

5.3.2. Procedures, Codes of Practice, and Instructions

Work performance shall be specified in management-approved work planning documents, controlled manuals and procedures, and approved operating and administrative procedures.

Processes that affect quality shall be conducted under controlled conditions using approved instructions, procedures, codes of practice, checklists, and other appropriate means. The procedures and instructions shall be prepared at a level of detail appropriate to describe and control the work based on the importance and complexity of the work process being performed. Such documents shall include or reference appropriate quantitative or qualitative acceptance criteria for determining that prescribed activities have been accomplished satisfactorily.

Project procedures, codes of practice, and instructions shall be maintained current. When revised, revision indicators shall be provided to ensure that current requirements are identified to personnel using the document.

5.3.3. Identification and Control of Items

5.3.3.1. Identification

Identification shall be maintained on items or in documents traceable to the items. Identification shall be indicated by one or more of the following methods:

- 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 to ensure positive identification
- Identification markings, when used, shall be applied using materials and methods that provide clear and legible identification and do not detrimentally affect the function or service life of the item
- Indication of inspection/test status of items shall be maintained as appropriate throughout fabrication, assembly, storage, shipping, installation, erection, and operation of the item
- Markings shall be transferred to each part of an identified item when subdivided and shall not be obliterated or hidden by surface treatment or coatings unless other means of identification are substituted
- Markings used to identify items shall be evaluated for compatibility with the environment to which they will be exposed (e.g., radiation, temperature, weather) as well as the chemical composition of the material to ensure that the function or service life of the item is not detrimentally affected, and to avoid contamination of samples
- Markings that become obliterated shall be restored immediately

5.3.3.2. Identification Methods

Items of normal production (e.g., batch, lot component, parts) requiring traceability shall be identified and physically segregated, as necessary, from initial receipt up to and including installation or consumption. This identification of an item shall relate to a specifying document (e.g., specification, procedure, test result) to provide objective evidence of compliance with requirements.

5.3.3.3. Traceability

Item identification or traceability provisions shall be provided when specified by codes, standards, or specification. Traceability requirements include, but are not limited to, identification or traceability of the item to applicable specification, material grade, heat, batch, lot, sample, part, or serial number. For items with traceability requirements, the traceability and identification markings shall be applied using materials and methods that provide clear and legible identification and are not detrimental to the function or service life of the item.

When items with established traceability requirements are subdivided, the identification necessary to retain traceability shall be transferred to each part, item, data, or sample at the time of subdivision (e.g., subdivision of samples, dividing contents of boxes of sample containers).

5.3.3.4. Control of Items with Limited Shelf Life

Items with limited calendar or operating life shall be physically identified with the shelf or operating life expiration date, and shall be stored and issued so that the oldest dated items are issued first, provided sufficient operating life remains so that early replacement will not be required. When the established shelf or operating life has expired, the item shall be marked prominently to preclude inadvertent use and shall be removed from the controlled storage area. The expired item shall be reported to the requesting organization, so that the item can be disposed of properly. Such items shall be discarded or identified for training purposes only.

5.3.3.5. Storage

Items not installed shall be stored in an area of controlled access. Access requirements, shall be specified by the person responsible for the item. Storage area inspections shall be scheduled and documented to ensure that the physical identification is legible, accessible, secure, and readily identifiable. Status indicators shall be changed or removed by the issuing organization only, or as described in procedures approved by that organization. Items that are stored for future use or archived for historical purposes shall be protected against physical damage or loss.

5.3.4. Control of Special Processes

Special processes such as: welding, nondestructive examination, heat treating, and chemical cleaning shall be controlled. Special processes (such as: welding, nondestructive examination, heat treating, and chemical cleaning) that control or verify quality shall be performed by qualified and certified personnel using qualified procedures in accordance with specified requirements.

Special process procedures or instructions shall contain the following:

- Codes, standards, and specifications applicable to the process
- Identification of the organizations responsible for development and qualification of the procedure for the process activity
- Acceptance criteria
- Ambient condition requirements as defined by the applicable procedures, specification, codes, and/or standards
- Qualification and/or certification requirements for procedures, equipment, and personnel

- Equipment and/or calibration requirements
- Parameters and attributes for which verification and/or documentation is required

Special process procedures shall be developed and qualified as required by the applicable code, standard, or specification for the process and approved by the appropriately designated specialists.

Personnel performing or controlling special processes shall be qualified. When required by the controlling code, standard, or specification, they also shall be certified.

Certification records for individuals who perform or control special processes shall include results of a written proficiency examination, and/or results of a practical examination in which the process was performed, which shall be evaluated by a qualified and certified examiner.

Equipment and instrumentation used in the performance of special processes shall be controlled and calibrated as necessary.

Special processes controlled by automatic equipment shall be qualified in accordance with approved procedures. The qualification shall provide objective evidence of acceptable process control and repeatability. Required documentation shall be described in implementing procedures.

Operators for automatically controlled special processes must be qualified. Certification is not necessary unless specifically required by the controlling specification, code, or standard. Operator qualification requirements shall be defined in the implementing procedure or instruction for the process.

Scientific investigations shall be planned and coordinated with organizations providing input to or using the results of the investigation. Scientific investigations shall be performed using scientific notebooks, implementing documents, or a combination of both.

Special process requirements unique to work conducted for the processing of high-level waste shall be implemented as described in the specific sections or supplements of the DOE/RW-0333P.

5.3.5. Control of Measuring and Test Equipment

Measuring and inspection tools, gauges, process instruments, and other measuring and testing devices shall be calibrated and adjusted at specific periods to maintain accuracy within specified limits. Calibration shall be performed using standards traceable to nationally or internationally recognized standards, or a method that gives the basis for the calibration.

QC procedures shall provide for controls that include the following:

- Controlling newly procured measuring equipment to ensure that the equipment is properly identified, calibrated, and a calibration frequency is established
- Identifying each device with a unique marking
- Segregating equipment found to be out of calibration until recalibration is performed
- Requiring that equipment is placed into controlled storage as necessary to maintain calibration accuracy
- Selecting or approving the selection of measuring equipment compatible with the type and accuracy requirements of the operations to be performed

- Verifying controlled issue of measuring and test equipment
- Recalling equipment for calibration before the expiration date of the current calibration
- Performing calibration in an environment appropriate to the type of equipment
- Application of calibration status indicators (labels) on equipment
- Maintaining calibration records including manufacture's calibration data
- Evaluating the services of calibration laboratories when used
- Dispositioning of items or materials that become suspect when the measuring and testing devices used are found to be out of calibration tolerance

Project procedures or instructions shall provide for the training of workers performing calibration. The training program includes training for personnel that maintain such equipment.

5.3.6. Handling, Storage, and Shipping

Handling, storage, and shipping of items shall be controlled to prevent damage or loss and to minimize deterioration. Handling, storage, and shipping of items shall be conducted in accordance with established work and inspection instructions, drawings, specifications, shipment instruction, or other pertinent documents specified for use in conducting the activity.

When requirements for special handling, storage, and shipping are outlined in specifications, these requirements shall be reflected in implementing procedures.

When required for particular items, special equipment (e.g., containers, radiographic equipment, survey instruments) and special protective environments (e.g., inert gas atmosphere, specific moisture content levels, temperature levels) shall be provided, and the conditions verified. Special protective environments shall be applied to items based on their sensitivity to environmental conditions, resistance to physical forces, relative irreplaceability, and importance to end use.

The following shall be considered in determining the handling, storage, and shipping requirements: blocking, bracing, choking, strapping, and orientation; cleaning, containment, and confinement; desiccants; environment (e.g., dust, dirt, water, sunlight, salt spray); in-storage inspection, maintenance, and testing; lifting points and methods; packaging; preservation; recording devices (e.g., temperature, pressure, humidity, loading); sealing and coatings; transportation methods; and inert blanketing.

5.3.6.1. Shipping

Shipping of items shall be conducted in accordance with established work instructions, drawings, and specifications by appropriately assigned project personnel. The responsible personnel shall ensure that appropriate documentation (e.g., forms, labels, property release forms) is prepared and, if required, signed by the appropriate person(s). The shipping documentation will accurately reflect specific traceability to the items being shipped.

5.3.6.2. Storage

Controlled access areas shall be established for storage of critical, sensitive, perishable, or high-value items before use or shipment. The project personnel shall document all movement of such items into or within the designated storage areas.

5.3.6.3. Packaging

Packaging requirements shall be specified for the protection of item(s) against corrosion, contamination, physical damage, or any effect that would lower the quality of an item or cause an item to deteriorate during the time it is handled, stored, and shipped.

5.3.7. Sample Control

As required by specific aspects or functions of the project, samples shall be controlled and identified in a manner consistent with their intended use. These controls shall identify responsibilities including interfaces between organizations for documenting and tracking sample possession from sample collection and identification through handling, preservation, shipment, transfer, analysis, storage, and final use. Controls shall include specifics on orientation relative to the location that was sampled, as appropriate. Additional requirements and criteria specifically addressing the IHLW requirements or other quality sampling requirements are described in implementing documents prepared for the sample requirements. Environmental sampling quality requirements are specified in environmental quality plans prepared for specific activities of the project.

Sample traceability shall ensure that the sample can be traced at all times from collection through final use.

5.4. Responsibilities

Project Personnel

Are responsible for:

- Following approved procedures and processes
- Reporting to appropriate management those processes believed to be in nonconformance with applicable requirements, or that can be improved to improve safety, improve quality, or reduce cost

The Project Manager

Is responsible for:

- Ensuring that personnel are provided with necessary training, suitable working environment, and administrative controls to accomplish work processes
- Reviewing and assessing work and related information to ensure that the required quality is being achieved and to identify processes that require improvement

The Engineering Manager

Is responsible for:

- Ensuring the preparation, review, and approval of work process instructions and procedures for the Technical and Engineering processes
- Assigning trained and qualified technical personnel to the project and provides qualified instructors to administer training to the project technical personnel

- Development and implementation of the project engineering process and systems, including documents and implementing procedures.
- Development and implementation of the project configuration management plan, including document control and commitment tracking systems
- Production and maintenance of the Engineering processes and engineering execution plan
- Development and application of Standardization principles
- Providing technical input and review of safety and environmental documentation by interfacing with ES&H personnel

The Operations Manager

Is responsible for:

- Developing and maintaining the facility functional specification
- Developing the operating and maintenance philosophies
- Preparing inactive and active startup strategies, and developing startup documentation and execution of startup
- Providing qualified instructors to administer training to the project technical personnel
- Providing technical input and review of safety and environmental documentation by interfacing with ES&H personnel
- Providing and managing experienced operational staff for input to safety activities and design
- Is the Chair of the Project Safety Committee

The WTP QA Manager

Is responsible for:

- Monitoring processes that affect quality to ensure that specified requirements are met and processes conform to documented procedures
- Ensuring, through assessment and surveillance, that work processes are performed according to specified requirements and implementing procedures and instructions, and work is in conformance to QAP requirements
- Reviewing and concurring with procedures for identification and control of items, maintenance and preservation of items, and calibration and maintenance of equipment for conformance to QAP requirements
- Ensuring through audit and surveillance that measuring and test equipment is maintained according to documented procedures, and that maintenance records are maintained, including records of any damage, malfunction, modification, or repair

The ES&H Manager

Is responsible for:

- Developing and maintaining of the safety related Authorization Basis documents

- Developing of safety philosophies
- Providing and management of experienced operational staff for input to safety activities and design
- Developing and maintaining of effective links with stakeholders
- Management of the hazardous operations (HAZOPS) process and safety issue tracking process
- Consequence analysis work and safety
- Oversight and review of project and operation efforts for compliance with ES&H standards

The Deputy Project Manager

Is responsible for:

- Ensuring that the WTP is designed, constructed, tested, commissioned, operated, and maintained in a safe, reliable, and efficient manner in accordance with policies and all applicable laws, regulations, authorization bases, and technical requirements
- Integrating nuclear and industrial safety, quality, and environmental protection into all work
- Managing the design transition, facility and process design, construction, acceptance testing, and commissioning
- Integrating the Area Project Managers and functional managers
- Creating an atmosphere in the workplace where reporting and resolution of conditions adverse to quality is encouraged at all levels
- Stopping activities within his area of responsibility, which are not accomplished in compliance with applicable authorization bases and/or regulatory requirements
- Giving full support to the Quality Assurance Program described herein, thereby assuring that all work performed under their cognizance will conform to and support the requirements of the Manual

The Business/Project Controls Manager

Is responsible for:

- Information Technology applications and control of software applications

The Construction Manager

Is responsible for:

- Quality of construction for the facilities
- Completion of constructability review
- Action to provide facility needs for construction
- Construction infrastructure development, including procedures and systems to be utilized

6. Design

6.1. Purpose

The purpose of this section is to define the Project requirements and responsibilities to plan, perform, control, and verify design activities including design inputs, design outputs, configuration and design changes, documentation, records, and technical interfaces consistent with the graded approach.

6.2. Requirements

The design process shall be established and implemented for design using sound engineering and scientific principles and appropriate standards. Designs shall be defined, controlled, and verified. Design input shall be specified, and translated into design documents at the optimum time in the design process. Design interfaces shall be identified and controlled. Design adequacy is to be verified, by persons other than those who performed the design. Design changes, including field changes, shall be controlled by measures commensurate with those applied to the original design.

Engineering procedures include the necessary design control elements for use by project engineering personnel in meeting the design control policies specified in this QAP. Preparation and issue of procedures and instructions precede the start of related design activities.

6.2.1. Design Principles

The design of SSCs shall be accomplished using sound engineering and scientific principles in full compliance with applicable requirements and the following design principles:

- QA and QC will be applied to quality affecting work activities to ensure that all items, services, and tasks meet required standards
- Well-proven and established techniques and procedures supported by QAP elements will be used to achieve high-quality deliverables
- Formal configuration management will be applied to all facility activities during the program's lifetime to ensure that programmatic design objectives, including safety, are fully achieved
- The facility will be designed for a set of events that include normal operations, anticipated operational occurrences, maintenance, and testing; external events; natural phenomena; and postulated accidents
- Hazard and accident analyses to evaluate the safety performance of the design and identify requirements for operations will be factored into the design

6.2.2. Design Process

Design activities are controlled, and designs are verified and validated commensurate with the importance of the design to safety and the project mission. Enhanced QA requirements are applied through the design to those SSCs and activities that provide for the safety and protection of the public, workers, and the environment. Guidelines for determination of the appropriate QL and acceptance criteria are included in QAP Section 1.3 and in project procedures that are responsive to the project design criteria. QLs for items and activities are identified on a project list that is used across the project for design, procurement, construction, and operations activities. QA reviews are performed of selected design documents to ensure

that appropriate quality requirements, QC inspection requirements, and QA criteria are adequately specified.

The design process includes the translation of the design criteria into calculations, specifications, drawings, reports, and procurement documents. The process includes documented design analyses and design verification. Design provisions shall be included to prevent the loss of safety functions due to damage to Important-to-Safety SSCs resulting from a common-cause or common-mode failure. Important-to-Safety SSCs shall be designed and qualified to function as intended in the environment associated with the events for which they are intended to respond.

Design control is the responsibility of the Engineering Manager who plans and carries out engineering activities in accordance with the project engineering procedures. These procedures shall be prepared by the engineering organization. These procedures provide for appropriate levels of review, checking, and approval for specified aspects of design and engineering work. These procedures identify design aspects that include the following:

- Preparation of design documents by qualified personnel
- Checking of engineering documents by personnel with technical qualifications comparable to the originator
- Review and approval of documents by supervision
- Independent design verification
- Design interface control
- Measures to preclude the use of unverified design data and ensure that appropriate verification or qualification testing is completed before design data are used
- Review, as required by applicable QL requirements, by independent specialists of design documents such as drawings, calculations, and safety analysis for Important-to-Safety SSCs
- Control of design changes through configuration management
- Identification of Important-to-Safety SSCs

6.2.3. Computer Software Control

The development, test, maintenance, control, and use of computer software to perform calculations, analyses, and modeling for Important-to-Safety SSCs is a controlled process. Software preparation includes documentation of physical or mathematical models used, in sufficient detail to allow reviewers to understand the preparation method. *Quality Assurance Requirements for Computer Software for Nuclear Facility Applications* (ASME NQA-1, Part II, Subpart 2.7, 1994b) is used as guidance for software quality requirements, as applicable.

Software verification and validation testing shall occur prior to software use in preparation of final design documents and includes comparison of program results with benchmark solutions. Software verifications and validations shall be documented in validation reports or test documentation.

Engineering procedures shall include the following software controls for project-developed software:

- Methods to be used for preparation, review, validation, testing, documentation, and control of software

- Requirements for content, preparation, approval, and maintenance of software documentation, user manuals, and validation reports
- Methodology for establishing software baselines and baseline updates
- The extent of software validation to be included in completed calculation package
- Controls to be implemented for use of software that is controlled by organizations external to the Project
- Controls for data transfers
- Protection of software from sources that can alter computer data
- Change control of computer programs
- Managing operating system changes
- Computer program error reporting and necessary remedial actions

When software development is subcontracted, quality program requirements shall be flowed down to subcontractors. Software QA requirements include the following:

- Software lifecycle phases
- Verification and validation
- Configuration control
- Documentation
- Verification reviews
- Problem reporting and corrective action
- Access control
- Procurement of software services
- Records

Computer software used during the design process for Important-to-Safety SSCs shall be verified and validated. Software verification and validation activities shall ensure the following.

- Software adequately and correctly performs all intended functions
- Software does not perform any unintended function that either by itself or in combination with other functions can degrade the entire system
- Computer software verification and validation activities shall be conducted in accordance with the approved procedure
- Software verification and validation activities shall be planned and performed for each system configuration that may impact the software. The results of software verification and validation activities shall be documented

6.2.4. Design Input

Design inputs shall be technically correct and complete. Essential design inputs shall be identified, reviewed, and approved by the responsible engineering group. Changes from specified design inputs, including the reasons for the changes, shall be identified, approved, documented, and controlled. When design inputs are another organization's design output, the responsible design organization shall obtain

evidence (e.g., design review reports, certification) that the originating organization has completed verification of its design output documents.

Design inputs shall be specified on a timely basis and to the level of detail necessary to permit the design activity to be carried out in a correct manner, and to provide a consistent basis for making decisions, accomplishing design verification measures, and evaluating design changes.

6.2.5. Configuration Management

Configuration management shall be introduced from the outset of design through engineering procedures that control the status and flow of engineering and design information. This process, supported by the project schedule logic, shall ensure that design activities do not commence until appropriate design criteria have been established.

Procedures shall define arrangements to ensure that ongoing design changes are formally stated and communicated throughout the design organization to ensure consistent system integration and configuration control. The procedures shall include allocation of specific responsibility for approval of design output documents and design change documents.

Configuration control, as a part of the overall configuration management plan, originates with the functional requirements and the design criteria established for the Project. SSCs shall be identified, designed, and related to the design criteria to become an integral part of the configuration management process. The specified design criteria and all changes to the design shall be controlled to ensure that changes to the design or design documents, created by design change notices, construction field changes (field change notices or field change requests), or procurement originated changes, are factored into the configuration control process. Changes that impact the design shall be reviewed for conformance with the design criteria and related project documents. Accurate as-built drawings for Important-to-Safety SSCs shall be maintained, under configuration control, during the life of the facility.

When it is necessary to transmit design information orally or by other informal means, the design information shall be promptly confirmed with formal documentation initiated in accordance with the approved project procedures.

6.2.6. Design Interfaces

Design interfaces shall be identified and controlled. The design effort shall be coordinated among participating organizations both internal and external to ensure integration of design and other technical requirements into the design documents.

Internal interface controls include the assignment of responsibilities and the establishment of procedures among project team members, functional organizations, and support groups. Internal interfaces include integrated project functional group such as project engineering, construction, startup, and other project groups.

External interfaces include the DOE, its contractors, and other organizations providing support to the project.

Engineering procedures or project plans provide for interface controls that include the following:

- Defining and documenting the interacting disciplines and organizations and their roles with respect to design reviews, design-basis exchange, deliverables among disciplines and organizations, and associated approvals
- Identifying lines of communication between interfacing organizations
- Methods for ensuring that design information between organizations is reviewed and incorporated into the design documents
- Methods to ensure that notifications to project engineering by construction, suppliers, and startup of discrepant items that require disposition
- Systems that avoid or identify and correct conflicts

6.2.7. Design Analyses

Design analysis shall be planned, controlled, and documented to assure that appropriate design methods and computer programs, when applicable, were used. Design analysis documents shall be legible and in a form suitable for reproduction, filing, and retrieval and the originator, reviewer, and approver shall be identified. Calculations shall be identifiable by subject (including structure, system, or component to which the calculation applies), originator, reviewer, and date or by other designators such that the calculations are traceable.

6.2.8. Design Output

The completed design shall be recorded in design output documents such as drawings, specifications, test/inspection plans, maintenance requirements, and reports. The administrative interface process shall clearly indicate responsibilities for design output document activities including as-built, mark-up, and updating during project construction, document control, and records management.

6.2.9. Design Checking

Checking of design documents before issuance is an essential element of QC during design. Checking is to be performed by an engineer of competence equivalent to the originator.

The purpose of checking is to ensure that the technical content of work is correct within itself and that all information used has been correctly taken from the reference quoted.

RPP-WTP engineering procedures provide for checking controls that include the following:

- Assignment of qualified personnel to perform checking
- Identification (initials/signature) on design document of personnel involved in document preparation, checking, and approval
- The extent and use of review checklists or other techniques

6.2.10. Design Verification

Design verification shall be performed before release of the design for use in another design, for procurement, licensing, manufacture, construction, operations, or release to another organization. When this timing cannot be achieved, the unverified portion of the design shall be identified and controlled. In all cases, the design shall be verified before it is approved and implemented.

Design verification shall be accomplished through checking of design documents, manufacturing tests, design reviews, and operational tests. It is the Project's practice, that design documents determined to require design verification be identified, reviewed, and the review documented to provide traceability to the individual or group who performed the review. Verification of computer programs includes appropriate testing (QAP Section 6.2 *Software Control*). Design verification will be performed commensurate with the QL requirements associated with a SSC.

Design verification methods include, but are not limited to, design reviews, alternate calculations, independent peer reviews, and qualification testing. Separate verification may not be needed for multiple uses of identical previously proven designs, unless they are intended for different applications or different performance requirements. Alternate calculations, peer review documentation, and qualification testing results become QA records to support the verification.

Design verification shall be performed for Important-to-Safety (SSCs) by qualified individuals or groups other than those who performed the original design; however, they may be from the same organization. Design verification may be performed by the originator's supervisor, provided that the supervisor:

- Did not specify a singular design approach
- Did not rule out certain design consideration
- Did not establish the design inputs used in the design
- Is the only individual in the organization competent to perform the verification

The decision to use the supervisor for performing design verification shall be documented and approved by the Engineering Manager, with concurrence by the WTP QA Manager.

Engineering procedures define and provide design verification controls for the following:

- Identification of design documents requiring design verification
- The methods used and the personnel responsible for performing design verification
- Controls to ensure accomplishment and documentation of design verification in a time frame appropriate for the design
- Measures to ensure that design verification comments are mutually resolved
- Criterion that specify when verification is performed by testing

6.2.11. Design Reviews

Design reviews shall be controlled and performed to ensure:

- The design inputs were correctly selected and incorporated
- Assumptions necessary to perform the design were adequately described, reasonable and where applicable, identified as requiring confirmation as the design proceeds
- Appropriate design methods, and computer programs when applicable, were used
- The design outputs are reasonable compared to design inputs
- The necessary design input(s) for interfacing organizations were specified in the design documents

6.2.12. Alternate Calculations

Where appropriate, alternate calculations may be used as a design verification method. These calculations or analyses are made with alternate methods to verify the correctness of the original calculations or analyses. The appropriateness of assumptions, input data, and the computer program or other calculation method shall be reviewed and the results checked to validate the original calculation or analyses.

6.2.13. Qualification Testing

Where the design is to be verified by qualification tests, the tests shall be identified. Section 8, "Inspections and Acceptance Testing", provides the requirements for this method of design verification.

6.2.14. Design Changes

All changes to final design, included those initiated by field changes, modifications, and nonconforming items that have a disposition of "use-as-is" or "repair" shall be justified and subject to controlled measures commensurate with those applied to the original design. If changes to previously verified designs have been made, design verification is required for the changes. This includes evaluation of the effects of those changes on the overall design and on any design analysis on which the design is based. This control shall include assurances that the design and safety analysis of the items remain valid. Temporary modifications shall receive the same levels of control as the permanent modifications.

6.3. Responsibilities

The Project Manager

Is responsible for:

- Ensuring the adequacy of the arrangements implemented by the project team members regarding the design and supporting activities

The Engineering Manager

Is responsible for:

- The overall design control process including the following:
 - Chair of the Technical Committee
 - Review and oversight of engineering efforts performed on project teams
 - Providing the interface to access historical design information for use on the project
 - The establishment and maintenance of the overall technical baseline on behalf of the Project Manager
 - Preparation of the DOE requested Trade Studies
 - Establishing interface controls for data collection activities
 - Establishing technical requirements with DOE
 - Control of engineering software applications

- Develop design criteria document
- Coordinating external contracted technical resources for resolution of design and technical issues
- Conduct or technical reviews
- Support external review and interface requirements.
- Ensure quality and performance of the operational plant is achieved with minimum lifetime costs.
- Provide the Basis of design and design philosophy documents including the establishment of design requirements and standards
- Coordinating external contractors to establish engineering/design standards for definitive design
- Chair of the Design Committee
- Establishing interface controls for design activities
- Ensure technical adequacy of design and design processes
- The establishment and enforcement of Standardization principles between the various facilities
- Coordinating information and technical issue resolution with Engineering Manager, supervisors, and engineers
- Preparation and updates of the applicable documents identified in Appendix B, "Application of Quality Assurance Program Requirements for QL-1, QL-2, and QL-3 Structures, Systems, and Components"
- Planning for verification that design criteria have been met
- Establishing a plan for independent verification of design products
- Documenting and approving design plans
- Reviewing progress of assigned engineering staff on their scope of work, design deliverables, budgets, and schedules
- Coordination of assigned engineering staff on project work to ensure an integrated project design is produced
- Defining project organization and assignment of work to assigned engineering staff
- Monitoring work progress to ensure that design is being carried out as required to satisfy technical, operational, quality, safety, and environmental commitments
- Supporting the implementation of cost effective standardization
- Preparation and update of all design documents
- Ensuring that design control procedures are implemented for the performance and control of design activities
- Performing design activities in accordance with approved project procedures
- Verifying that design and technical reviews are conducted in accordance with QAP requirements
- Establishing measures for controlling technical modifications to the IHLW form production process, including process control plans and other implementing documents

The Area Project Managers

Within their specific area, are responsible for:

- Defining the project scope of work, design deliverables, budgets and schedules
- All aspects including safety, quality, cost, and schedules performance

The WTP QA Manager

Is responsible for:

- Reviewing design plans (as applicable) before their approval to verify incorporation of appropriate QA provisions and compliance to procedures
- Assessing the design control process to ensure the adequacy and satisfactory implementation of the design procedures
- Participating in design reviews, as required
- Reviewing results of technical and design reviews for compliance with QAP requirements
- Evaluating subcontractors' design control programs

The Operations Manager

Is responsible for:

- Undertaking operability reviews of design
- Establishing measures for controlling technical modifications to the IHLW form production process. Technical modifications subject to control shall include waste form and waste acceptance product specification, waste form compliance plan, and waste form qualification reports.
- Development and maintenance of the applied Research and Technology (R&T) program including placement and management of R&T contract budgets and interfacing with design teams on technology development issues
- Ensuring that data collected during the technology development process which may be used as design inputs, is controlled

The ES&H Manager

Is responsible for:

- Control of safety and regulatory software applications.

The Construction Manager

Is responsible for:

- Completion of constructability review

7. Procurement

7.1. Purpose

The purpose of this section is to describe the Project requirements and responsibilities for ensuring that purchased items and services adhere to established requirements and perform as specified.

7.2. Requirements

The procurement of items and services is controlled to ensure conformance with specified requirements. Procurement activities are planned and documented to ensure provision of a systematic approach to the procurement process. The Business/Project Controls Manager establishes qualified and acceptable sources of materials, equipment, and services. The Business/Project Controls Manager arranges conferences with potential bidders, evaluates proposals, recommends awards, and issues purchase orders. The Business/Project Controls Manager expedites items, as necessary, to meet construction schedules, develops and administers logistical requirements, and provides supervision of field purchasing, material receiving, and site storage.

Surveillance and audits of suppliers and subcontractors for IHLW affecting, QL-1 and QL-2 SSCs, items, and services are performed by the WTP QA Manager through the following:

- Surveys of suppliers and subcontractors both pre-award and post-award as determined by the QL and technical requirements specified in the material requisition
- Surveillance or inspection either in shop or onsite during performance of work
- Audits at supplier and subcontractor facilities
- Audits of construction and site subcontractor quality program implementation

7.2.1. Technical Requirements

Technical requirements are specified and controlled in procurement documents by Project engineering. Design criteria and other design requirements necessary to ensure that adequate quality is achieved are specified and included in purchase requisitions prepared by engineering and transmitted to project procurement for inclusion in purchase orders and contracts. To the extent determined necessary by QL or specific engineering requirements, procurement documents define and provide requirements for suppliers/subcontractors to implement a QAP. QAP requirements are specific to the item or service procured, and may involve imposition of special requirements based on Project requirements.

Project engineering procedures provide for technical and quality requirements and controls that include the following:

- A clear statement of work
- Performance of bid evaluations
- Preparation, review, and approval of material requisitions
- Appropriate references in procurement document to required codes and standards
- Identification of tests, inspections, and acceptance criteria

- Interface requirements
- Specification of quality program elements based on identified QLs
- Requirements for control and calibration of measuring and test equipment
- Quality verification submittal requirements
- Special process requirements
- Quality assurance records retention requirements
- Requirements for use of supplier deviation disposition requests for deviation from procurement document requirements
- Identification of witness and hold points and release for shipment documentation
- Criteria for resolution/disposition of supplier/subcontractor nonconformances
- Receipt inspection requirements

Quality in procurement is achieved through the requirements in procurement documents that provide for qualified bidders, through submittal of their quality plans for review and acceptance before award of subcontract. Design documents define the technical quality requirements, and procurement documents define the contractual quality criteria required to ensure that the equipment or services meet specified project requirements. Procurement documents are reviewed by QA for conformance to the QAP and project-specified quality criteria, and to ensure that bidders are qualified to perform the quality of work.

A QL shall be assigned to each procurement by the individual responsible for processing the procurement documents in accordance with this QAP. All procurement documents for designated IHLW affecting, QL-1 or QL-2 SSCs and related services shall be reviewed by the QA staff before issuance for procurement.

Suppliers of IHLW affecting, QL-1/QL-2 items and services shall be evaluated to determine whether the supplier has the requisite QAP to support the procurement. This evaluation may be performed by reviewing the suppliers' quality documentation, facilities, history, and/or by using reports of other recognized industry organizations. Suppliers of IHLW affecting, QL-1/QL-2 items and services shall be re-audited at least every 3 years to confirm their continuing capabilities.

7.2.2. Procurement Documents

Design criteria, and other design requirements necessary to ensure requisite quality is achieved, shall be included in procurement documents. To the extent determined necessary by the project and the assigned QL of the item or services being procured, procurement documents define and provide requirements for suppliers/ subcontractors to implement a QAP. The QAP implemented by suppliers/subcontractors shall be reviewed and audited to ensure that applicable requirements of 10 CFR 830.120 and other applicable quality system requirements have been implemented, as specified by engineering for the procurement. The QAP requirements shall be specific to the item or service procured, and may involve imposition of special requirements.

Project engineering documents are transmitted to project procurement, for inclusion in purchase orders and contracts as procurement documents. The procurement documents shall specify the methods to be used for acceptance of the item or service. Procurement document changes shall be subject to the same review and approval process as required for the preparation of the original document.

Typical acceptance methods include the following:

- Reviewing manufacturing process controls
- Shop inspections
- Source verifications
- Receipt inspection
- Pre- and post-installation tests
- Certificates of conformance

The item or service shall not be used or placed into service until acceptance criteria have been satisfied.

7.2.3. Supplier Qualification

Qualified suppliers shall be identified early in the design and procurement process. The prospective suppliers shall be evaluated by the Business/Project Controls Manager, with assistance from the Engineering Manager and the WTP QA Manager, to verify capability to meet quality requirements. The suppliers shall be qualified on the basis of one or more of the following criteria:

- Past performance for identical or similar items/services
- Demonstrated capability or documented experience of users
- Objective evidence of quality supplied by vendors
- Onsite audits and surveillance

The QA organization shall establish and maintain an Approved Suppliers List (ASL) for the Project. Follow up evaluation of project suppliers and subcontractors shall be by surveillance and audits performed by the QA organization.

7.2.4. Supplier Monitoring

Audits of suppliers and subcontractors shall be conducted based on the complexity and importance of an item or service and/or results of performance analyses such as assessments and reliability, availability, and maintainability studies. QIs shall be used to determine scope of the audits and audit checklist content. Audits shall be conducted to evaluate the effectiveness of a supplier's/subcontractor's QAP implementation and to provide confidence that the supplier is adhering to specifications and applicable QA requirements.

7.3. Commercial Grade Items

Where the facility design specifies the use of commercial grade items, the following requirements are an acceptable alternative to other requirements of this section.

- The commercial grade item shall be identified in an approved design output document
- Supplier evaluation and selection, when determined necessary by the purchaser based on the complexity and importance to safety, shall be in accordance with the requirements for supplier qualification

- Commercial grade items shall be identified in the procurement document by the manufacturer's published product description

Receipt inspection of a commercial grade item, shall verify that damage was not sustained during shipment and that the item received was the item ordered. The receipt inspection shall also verify that inspection and/or testing is (or has been) accomplished to the extent determined by the project, that conformance with the manufacturers published requirements has been attained, and that documentation, as applicable to the item, was received and is acceptable.

7.4. Responsibilities

The Project Manager

Is responsible for:

- Ensuring through procurement planning that the statement of work is prepared, the scope of work defines the work to be accomplished, and related technical, administrative, and QA requirements are specified

The Engineering Manager

Is responsible for:

- Ensuring QL designation is specified on procurement documents
- The procurement of materials, equipment, and supplies necessary for facility construction
- Ensuring that technical requirements are specified in procurement documents
- Establishing the extent of control determined necessary by the quality levels of SSCs

The Construction Manager

Is responsible for:

- Ensuring QL designation is specified on procurement documents
- The procurement of materials, equipment, and supplies necessary for facility construction
- Ensuring that technical requirements are specified in procurement documents
- Establishing the extent of control determined necessary by the quality levels of SSCs.

The Business/Project Controls Manager

Is responsible for:

- Contractual interfaces related to financial, quality, and legal matters
- The preparation of the final procurement documents package and for ensuring that suppliers are identified on the approved suppliers list
- Development of Purchase Requisitions, Requests for Proposals, and Purchase Orders for all equipment, materials, and supplies for the capital project

- As related to contract cost and schedule performance, completion of:
 - Vendor shop inspection
 - Field receipt inspection
- Requisition of special service subcontractors as necessary to support the capital project efforts
- Establishing qualified and acceptable sources of materials, equipment, and services
- Tracking procurement documentation from suppliers
- Preparing the formal procurement documents package
- Ensuring that suppliers are identified on the approved suppliers list before the award of the contract
- Evaluating proposals, recommending awards, and issuing purchase orders
- Acting as source selection official

The WTP QA Manager

Is responsible for:

- Planning and performing audits and surveillance of suppliers and subcontractors
- Reviewing procurement documents related to Important-to-Safety or IHLW affecting SSCs, items or services for conformance to QAP requirements
- Performing and/or assisting in supplier/subcontractor bid evaluations for determination of QAP capability and qualifications
- Maintaining records of supplier reviews, audits, and assessments conducted by Project QA and technical personnel
- Maintaining the Approved Suppliers List (ASL)
- Ensuring that quality requirements are specified in procurement documents

As related to quality assurance performance, completion of:

- Vendor shop inspection
- Field receipt inspection

8. Inspection and Acceptance Testing

8.1. Purpose

This section describes the requirements and responsibilities for the control of inspection and test activities to verify conformance of items, services, and processes to specified requirements. The controls include provisions for calibration programs to ensure that design requirements are met for SSCs, and that equipment used for inspections and tests are calibrated, controlled, and maintained.

8.2. Requirements

Inspection and acceptance activities will be conducted in accordance with the principles stipulated by the US Department of Energy, Richland Operations Office (DOE-RL) top-level safety standards and principles, as follows:

“Structures, systems, and components Important-to-Safety should be the subject of appropriate, regular preventive maintenance, inspection, and testing and servicing when needed, to ensure that they remain capable of meeting their design requirements throughout the life of the facility. Such activities should be carried out in accordance with written procedures supported by quality assurance measures” (DOE-RL-96-0006, Section 4.3.5.1).

8.2.1. Inspection

Inspections required to verify conformance of items, services, and processes to specified requirements shall be planned and the results documented on inspection reports. Characteristics to be inspected, acceptance criteria, and inspection methods to be employed shall be specified. Inspection results shall be documented in inspection reports and in Nonconformance Reports, as needed. Inspection for acceptance shall be performed by inspection personnel qualified to the code or standard required for the work. Inspections shall be performed by persons other than those who performed or supervised the work being inspected.

Through procurement documents and implementing procedures, inspections and tests shall be planned in order to verify conformance of products, items, processes, designs, and computer programs or to demonstrate satisfactory performance of a service received.

Inspection procedures, instructions, or checklists shall provide for the following:

- Identification of characteristics and activities to be inspected
- A description of the method of inspection
- Identification of the individuals or groups responsible for performing the inspection
- Acceptance and rejection criteria
- Identification of required procedures, drawings, specifications, and revisions
- Recording inspector or data recorder and the results of the inspection
- Specification of the necessary measuring and test equipment, including accuracy requirements

8.2.1.1. Inspection Methods

QC instructions shall be prepared to describe the items and characteristics to be inspected, the acceptance criteria, and the method to be used for performing and documenting the inspection.

The basis for preparing the QC instructions includes the design documents and applicable national codes and standards specified in the design. Inspection witness and hold points shall be established by engineering, construction, or QA as needed to verify quality of work. The type and extent of inspection and testing shall depend on QLs and on the type of process, product, or service, and where appropriate, on the record of a supplier's previously demonstrated performance.

8.2.1.2. Receiving Inspection

Quality-affecting process items, products, and services shall be verified according to procurement documents and/or inspection and test plans to ensure conformance to specified requirements. Incoming products or services shall not be used until they have been verified as conforming with specified requirements through receipt inspection. Incoming products that require inspection, laboratory, or physical testing shall be segregated until the inspection and testing results confirm the acceptance criteria has been met, or dispositioned if found to be nonconforming. Items and products pending inspection or acceptance testing shall be identified with "HOLD" tags, or other equivalent means.

8.2.1.3. In-Process Measurement, Inspection, and Verification

Procedures or work instructions shall specify the quality characteristics to be measured, inspected, or verified during all phases of the project, as appropriate. These procedures and instructions shall identify any mandatory hold points requiring verification of quality characteristics of an item or process.

8.2.1.4. Qualification and Certification of Inspection Personnel

Personnel performing inspections, examinations, and tests for quality verification activities shall be qualified, and when specified by code, certified. These individuals shall have the freedom and responsibility to report nonconforming items, services, products, and processes.

Personnel performing, evaluating, and supervising nondestructive examinations shall be qualified and certified in accordance with applicable codes and standards. Certifications shall be documented and maintained current. Training and certification is discussed in QAP Section 2.0.

8.2.1.5. Final Inspection

Final inspection shall be performed at the completion of work or any increment thereof to ensure that the completed activity conforms to specified requirements. When required by codes and standards, certified inspection personnel shall be used for quality verification and when necessary, subcontractors who perform QC inspection and nondestructive examination shall be evaluated. Items that do not conform to approved design documents shall be documented on nonconformance reports.

8.2.2. Test Control

Tests required to demonstrate that items will perform satisfactorily in service shall be planned and executed in accordance with approved test plans or procedures. Characteristics to be tested, test methods

to be employed, and acceptance criteria shall be specified. Test results shall be documented and their conformance with acceptance criteria shall be evaluated and nonconformances documented.

8.2.2.1. Test Requirements

Test requirements and acceptance criteria shall be provided or approved by the organization responsible for the design of the item to be tested unless otherwise designated. Test requirements and acceptance criteria shall be documented in test plans or procedures and shall be based on specified requirements contained in applicable design or other pertinent technical documents. Identified nonconformances against test items or criteria should be corrected or resolved before the initiation of a design verification, pre-operational, or post-maintenance test of an item. When design verification is completed by test, those test conditions specified shall simulate the most adverse design conditions as determined by analysis.

8.2.2.2. Test Procedures

Test procedures shall include or reference test objectives and make provisions for ensuring that prerequisites for the given test have been met, adequate instrumentation is available and used, necessary monitoring is performed, and suitable environmental conditions are maintained. Test prerequisites include: instrumentation calibration, use of appropriate equipment, qualification of personnel and training if needed, acceptable condition of test equipment and item to be tested, and suitable environmental conditions. Test procedures shall be reviewed and approved by the Engineering Manager or designee.

In lieu of specifically prepared written test procedures, appropriate sections of related documents, such as American Society for Testing and Materials methods, supplier manuals, or equipment maintenance instructions may be used. Such documents shall include adequate instructions to ensure the required quality of work.

Test parameters affected by potential sources of uncertainty and error shall be identified and controlled, as applicable.

Test procedures and other implementing documents shall include provision for determining when a test is required, describing how tests are performed, and ensuring that testing is conducted by trained and appropriately qualified personnel.

If qualification testing indicates that modifications to the item are necessary to obtain acceptable performance, the modification shall be documented and the item modified and re-tested or otherwise verified to assure satisfactory performance. When tests are being performed on models or mock-ups, 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 final design work.

8.2.2.3. Test Results

Test and inspection results shall be documented and evaluated by responsible and qualified personnel to ensure that test requirements have been met.

8.2.3. Control of Measuring and Test Equipment

Tools, gauges, instruments, and other measuring and test equipment used to determine acceptance of items, products, or processes shall be controlled and, at specified periods, calibrated and adjusted to maintain accuracy within necessary limits. Routine preventive maintenance schedules shall be developed

for the measuring and test equipment. Measuring and test equipment shall be uniquely identified and the calibration standards shall be traceable to nationally recognized standards. Where such standards do not exist, the basis used for calibration shall be documented.

8.2.4. Identification of Inspection and Test Status

The status of inspection and test activities shall be identified either on the items or in documents traceable to the items where it is necessary to ensure that required inspections and tests are performed and to ensure that items that have not passed the required inspections and tests are not inadvertently installed, used, or operated.

Status shall be maintained through indicators, such as physical location and tags, markings, shop travelers, stamps, inspection records, or other suitable means.

Procedures shall be established to indicate, by the use of markings, the status of inspections and tests on individual items.

Status indicators also shall provide for indication of the operating status of systems and components of the facility to prevent inadvertent operation.

The application and removal of tags, markings, labels, and stamps shall be strictly controlled to ensure that only authorized personnel remove status indicators. Authority for removal of status indicators shall be specified clearly in approved program implementing procedures.

When it is necessary to alter the sequence of required inspection or test activities, the responsible organization shall ensure that either waivers are obtained and approved for deviation from the sequence specified in approved instructions, procedures, and drawings, or that a new procedure is established and approved to control the alteration of the sequence.

8.2.5. Records

Inspection and test records shall contain the following:

- A description of the type of observation
- The date and results of the inspection or test
- Information on conditions adverse to quality
- Identification of the inspector or data recorder
- Evidence as to the acceptability of the results
- Action taken to resolve any conditions adverse to quality

8.3. Responsibilities

The Engineering Manager

Is responsible for:

- Establishing required inspection and test activities including approval of inspection and test plans, inspection checklists and test procedures, and ensuring that inspection and test results fulfill specified requirements

The WTP QA Manager

Is responsible for:

- Verifying that inspections and tests are planned, performed, controlled, and documented in accordance with approved procedures and that inspections and tests are performed by qualified personnel
- Ensuring that the organization responsible for performing inspection and acceptance testing activities has the adequate independence from undue pressure, such as schedule and/or operational needs

9. Management Assessment

9.1. Purpose

To define requirements and responsibilities for conducting assessments of management processes to identify problems that hinder the organizations from achieving their objectives.

9.2. Requirements

QA criteria specified in 10 CFR 830.120, as well as the top level safety standards and principles stipulated by the DOE-RL shall be taken into consideration in conducting management assessments.

9.3. Management Assessments

Assessments are an important step in the Plan-Do-Check-Act cycle. As such, they can add value to products and services by linking management and the conduct of work to meaningful improvement actions.

Managers at every level shall periodically assess the performance of their organization to determine how well leadership is being provided to enable the organization to continuously meet project requirements, customer requirements and expectations.

Management assessments focus on the identification and resolution of both systematic and cultural management issues and problems. Strengths and weaknesses affecting the achievement of organizational objectives are identified so that meaningful action can be taken to improve quality.

Management assessments shall be conducted using a graded approach based on risk, using both the assessment of the probability of failure and the assessment of the consequence of failure. Specific methodologies shall be tailored to the activities being assessed.

Management assessments must be planned in a systematic manner by the individual managers to address activities under their responsibility, and to focus on those areas presenting the greatest risk for failure, potential for improvement, or areas that have not been covered by an independent assessment. Senior management shall retain overall responsibility for the planning and performance of management assessments. Planning of individual assessments should consider the following:

- Descriptive title or name of the assessment area
- Brief description of the area or activity to be evaluated
- Identification of the team leader and team members
- Schedule for the start and completion of the assessment, including issuance of the assessment report
- Other information related to the assessment evaluation (e.g., performance objectives, management systems, resource availability, efficiency measures, effectiveness measures)

Management assessments shall be performed and documented in accordance with written procedures. Results of management assessments shall be documented and reported to the assessed organization's management and senior management.

The emphasis of management assessment is on management issues that affect performance processes such as: adequacy of the QAP, effectiveness of the QAP implementation, strategic planning, project interfaces, cost controls, use of performance indicators, staff training and qualification, and supervisory oversight and support. Management assessment also includes the evaluation of the adequacy of resources and personnel provided to achieve and ensure quality. Review criteria are established for each management assessment element.

Assessment methods include direct observation of work in process, personnel interviews, and review of documentation. Documentation reviews may include specific deliverables, results of independent assessments, results of project reviews and readiness reviews, functional oversight reports prepared and issued by BNI management, and assessment reports issued by the DOE-RL. Management assessment reports are prepared detailing the review methods and results. For findings, observations, and recommendations for improvement, responsible personnel and completion dates shall be identified, and actions shall be tracked to completion. The results of the management assessments are used in the organizations continuous improvement process.

Managers shall conduct and document follow-up evaluation of actions taken to determine the effectiveness of the respective action. Management assessments shall be conducted periodically based on project schedule. The maximum period between management assessments shall not exceed 12 months. The responsibility to conduct assessments shall not be delegated, and the direct participation of each manager is required.

9.4. Responsibilities

All Managers

Are responsible for:

- Scheduling, performing and documenting management assessments
- Identifying and documenting performance problems and conditions adverse to quality, as well as opportunities for quality improvement, and shall take prompt action to resolve problems, deficiencies, and improve processes and quality

The Project Manager

Is responsible for:

- Planning and completion of an annual review of the overall effectiveness of the management assessments for the entire Project

The ES&H Manager

Is responsible for:

- Providing direction on the development of the regulatory framework and for identifying deficiencies in the implementation of regulatory-related project documents.

The WTP QA Manager

Is responsible for:

- Evaluating the effectiveness of management assessments and establish the emphasis of future management assessments
- Providing reports to Project management pertaining to the status of management assessment activities, including the correction of deficiencies and application of lessons learned to the project quality management system

10. Independent Assessment

10.1. Purpose

This section describes the responsibilities and requirements for planning and conducting independent assessments to measure item and service quality, measure the adequacy of work performance, and promote quality improvement.

10.2. Requirements

Independent assessments shall be based on QA criteria specified in 10 CFR 830.120, as well as the top-level safety standards and principles stipulated by the DOE-RL.

10.2.1. Independent Assessment

Independent assessments are a management tool used to advise and inform management of the implementation and adequacy of the quality system. Assessments determine if planned quality systems are implemented, the effectiveness of the quality systems, and if those systems are producing processes, products, and services that meet specified requirements.

The scheduling of independent assessments and allocation of resources shall be based on work scope, work status, relative importance to safety, and the complexity of the activity being assessed.

Independent assessments include performance of technical and QA audits, inspections, surveillances, and laboratory performance evaluation audits.

Audits, assessments, and surveillances are as follows:

- Regularly scheduled on the basis of the status and the safety significance of the activities being audited and/or assessed
- Initiated early enough to ensure the implementation of an effective QAP
- Objectively evaluate the effectiveness and proper implementation of the QAP for activities affecting quality of Important to Safety SSCs or IHLW affecting activities
- Independent assessment shall be performed to evaluate the quality of selected work subject to the QAP and QARD requirements
- Address the technical adequacy of the activities being conducted
- Performed in all areas where the requirements of the QAP are applicable
- Led by appropriately qualified and certified audit personnel when audits are conducted from the QA organization
- Conducted to identify conditions adverse to quality; to ensure that prompt corrective action is taken by management responsible for performing the work; and to verify the timely implementation, adequacy, and effectiveness of corrective action
- Conducted in accordance with approved procedures and documented in a report to appropriate management

Technical and QA programmatic audits, assessments and surveillances are performed to provide a comprehensive independent verification and evaluation of procedures and activities affecting the quality of SSCs, and to verify and evaluate principal subcontractors' QAP, procedures, and activities.

Inspections include activities as described in QAP Section 8.0.

Surveillances of specific project activities shall be used to determine compliance of activities to program requirements. Independent assessments shall be documented in reports and include the reference documents used, activities reviewed, results of the reviews, and items requiring corrective action. The QA personnel shall conduct and document independent assessments of project activities, report results, provide recommendations for corrective action and improvements, and perform follow-up and verification of actions taken.

Laboratory performance evaluation audits shall include periodic evaluations to measure the performance of laboratories conducting analytical and experimental work in support of the Project.

10.2.2. Assessment Personnel

Personnel that conduct assessments shall not be directly responsible for the work processes and systems being assessed, but shall be qualified and technically knowledgeable in the subject matter assessed. The qualifications of personnel conducting assessments shall be documented. Personnel that conduct assessments shall have sufficient authority and freedom from line organizations to carry out their responsibilities and shall focus on process effectiveness and quality improvement. Personnel that conduct audits shall meet the requirements described in paragraphs 3.1 through 3.4 of NQA-1, Supplement 2S-3 (1994).

10.2.3. Assessment Performance

Assessments shall be planned, scheduled, and conducted in accordance with established procedures or checklists. Checklists or redlined procedures can be prepared and used to guide the performance of assessments. The types and frequency of independent assessments shall be based on the status, complexity, and importance of the activities or processes being assessed. The maximum period between independent assessments shall not exceed 12 months, and at least one assessment shall be conducted during the preliminary design phase of the project. Objective evidence shall be examined to verify that quality requirements are being implemented effectively.

10.2.4. Assessment Results and Reports

The results of assessments shall be documented and reported to appropriate levels of management within the project organization. Adequate information shall be documented so that meaningful actions can be taken.

10.2.5. Management Responses and Actions

Management shall take appropriate action commensurate with the importance and severity of identified problems. Management responses to identified problems may include the following:

- Immediate action to correct a deficiency
- Root cause identification

- Actions taken to prevent recurrence
- Lessons learned shared with others in the organization
- Action taken to improve process or product quality
- Extent and proposed date for completion of action identified

Management must respond to assessment results within 30 days from receiving the report. Management responses to assessment results shall be documented.

10.3. Responsibilities

The Project Manager

Is responsible for:

- Reviewing assessment, surveillance, and audit reports as appropriate, investigating adverse findings, and taking timely, appropriate action
- Providing the support resources needed for the assessment process

The WTP QA Manager

Is responsible for:

- Planning and performing assessments
- Communicating the results of assessments to Corporate QA management, as applicable
- Evaluating the adequacy of management responses to assessment deficiencies and conducting follow-up evaluations to verify that corrective actions have been accomplished as scheduled
- Tracking identified deficiencies to completion of corrective actions

11. Glossary

Note: Many of the terms listed in this glossary have been taken from DOE/RL-96-0006.

Activity – An all-inclusive term describing a specific set of operations or work to be performed (e.g., research and development, environmental restoration, field sampling, analytical operations, equipment fabrication).

Activities Affecting Quality – All activities associated with IHLW affecting or Important-to-Safety structures, systems, and components, including but not limited to design, procurement, inspection, testing, and installation.

Administrative Controls – Provisions relating to organization and management, procedures, record keeping, assessment, and reporting necessary to ensure safe operation of a facility.

Approval – The documented determination by a responsible organization that work is suitable for the intended purpose and shall be used as required.

Assessment/Verification – The act of reviewing, inspecting, testing, conducting surveillance, auditing, or otherwise determining and documenting whether items, processes, or services meet specified requirements.

Audit – A planned and documented activity performed to determine by investigation, examination, or evaluation of objective evidence the adequacy of and compliance with requirements established in regulations, standards, procedures, drawings, contracts, QA documents, and other enforceable documents, and the effectiveness of implementation. An audit/appraisal should not be confused with surveillance or inspection activities performed for the sole purpose of process control or product acceptance.

Authentication – Process of attesting to the fact that a document is accurate, complete, and satisfies the definition of a record by the person who completes and approves the document.

Client – An entity who engages the professional services of another. DOE is the client of BNI regarding RPP-WTP activities. Other stakeholders may have a vested interest in the client but the client engages the services.

Collocated Worker – An individual within the Hanford Site, beyond the Contractor-controlled area, performing work for or in conjunction with the US Department of Energy or utilizing other Hanford Site facilities.

Commitment (QA) – A required practice that is mandatory in programs intended to comply with a standard.

Corrective Action – Measures taken to rectify conditions adverse to quality and, where necessary, to preclude recurrence.

Deactivation – The process of permanently ceasing active operation at a facility in a planned and controlled manner to support follow-on decontamination and decommissioning activities. A process whereby nonessential systems and/or equipment in a shut down facility are de-energized, drained and flushed, isolated, or removed to minimize the long-term cost of maintaining the facility in a physically safe and environmentally secure condition. Includes the removal of stored radioactive and/or hazardous waste from the facility and implementation of appropriate facility safety requirements.

Deficiency – A condition of an activity, attribute, documentation, or procedure that renders that activity, attribute, documentation, or procedure unacceptable or indeterminate.

Document – Recorded information that describes, specifies, reports, certifies, requires, or provides data or results. A document is not considered a quality assurance record until it meets the definition of a quality assurance record.

Facility – Those buildings and equipment directed to a common purpose and those activities and supporting elements occurring at a single location.

Facility Worker – An individual within the Contractor-controlled area, performing work for or in conjunction with the RPP-WTP Facility.

Graded Approach – A process by which the level of analysis, documentation, and actions necessary to comply with a requirement are commensurate with the following:

- Relative importance to safety, safeguards, and security and of the data being collected or analyzed
- Magnitude of any hazard involved and consequence of failure (risk)
- Life cycle stage of a facility
- Programmatic mission of a facility
- Particular characteristics of a facility and necessity for special controls or processes
- Function or end use of the item
- Complexity of design or fabrication of the item or design or implementing of the activity
- Reliability of the process
- Reproducibility of the results
- Uniqueness of the item or service quality
- Degree to which functional compliance can be demonstrated through inspection or test
- Any other relevant factor

Guidance – A suggested practice that is not mandatory in programs intended to comply with a standard or requirement. The word “should” denotes a guideline.

Important to Safety – Structures, systems, and components that serve to provide reasonable assurance that the facility can be operated without undue risk to the health and safety of the workers and the public. It encompasses the broad class of facility features addressed (not necessarily explicitly) in the top-level radiological, nuclear, and process safety standards and principles that contribute to the safe operation and protection of workers and the public during all phases and aspects of facility operations (i.e., normal operation as well as accident mitigation).

This definition includes not only those structures, systems, and components that perform safety functions and traditionally have been classified as safety class, safety-related or safety-grade, but also those that place frequent demands on or adversely affect the performance of safety functions if they fail or malfunction, i.e., support systems, subsystems, or components. Thus, these latter structures, systems, and components would be subject to applicable top-level radiological, nuclear, and process safety standards and principles to a degree commensurate with their contribution to risk. In applying this definition, it is recognized that during the early stages of the design effort all significant systems interactions may not be identified and only the traditional interpretation of important to safety, i.e., safety-related may be practical. However, as the design matures and results from risk assessments identify vulnerabilities resulting from non-safety-related equipment, additional structures, systems, and components should be considered for inclusion within this definition.

Independent Assessment – Assessments carried out by technically knowledgeable personnel in the area of assessment and who are free from direct responsibilities in the area they are assessing. Independent assessments should focus on improving items and processes by emphasizing line organization's achievement of quality.

Independent Personnel – A condition characterizing an individual or group of individuals qualified to analyze, review, inspect, test, or otherwise evaluate activities and work results because:

- a) They had no direct responsibility or involvement in performing the activity or the work

- b) They are not accountable for the activity or work result
- c) They do not report directly to the immediate supervisors who are responsible for performing the activity or work being evaluated

Inspection – Examination or measurement of an item or activity to verify conformance to specified requirements.

Integrated Safety Management Program – A set of integrated activities that is directed toward the management or control of radiological, nuclear, and process hazards such that adequate protection is provided to workers, the public, and the environment.

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

Lifetime records – Lifetime records are those records that meet one or more of the criteria specified in Section 4.2.2.4, “Retention”.

Management Assessment – Assessment performed by individuals, groups, or organizations directly responsible for overseeing and/or performing the work that focuses on how well the integrated QAP is working. Such assessments are conducted to identify management problems that hinder the organization from achieving its objectives in accordance with safety, quality, environmental protection, contract, or business requirements.

Nonpermanent records – 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.

Nuclear Facility – Reactor and nonreactor nuclear facilities; the RPP-WTP Facility is a nonreactor nuclear facility.

Orientation or Indoctrination – The act of instructing in fundamentals so as to provide an understanding of principles involved. The understanding of the principles will vary with topic, but should familiarize the individuals involved to the activity.

Process – A series of actions that achieves an end or result, **or**

Process – (chemical or radiochemical) Any activity involving a highly hazardous chemical including use, storage, manufacturing, handling, or the on-site movement of such chemicals, or a combination of these activities.

Process Safety – The operation of facilities that handle, use, process, or store hazardous materials in a manner free of episodic or catastrophic incidents. However, the handling, use, processing, and storage of materials with inherent hazardous properties can never be done in the total absence of risk. Process safety is an ideal condition toward which to strive.

Public – Individuals who are not occupationally engaged at the Hanford Site. The term “public” is considered synonymous with “offsite receptor” when evaluating the consequences of accidents.

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

Quality Assurance – All those actions that provide confidence that quality is achieved.

QA Classification – That process which determines an SSC, process or activity to require the application of a specified quality level (QL). The QL determined is based on the project defined process. The classification (assignment of a QL) is followed by the applicable QA grading process.

Quality Assurance Program – The overall program established to assign responsibilities and authorities, define policies and requirements, and provide for the performance and assessment of work, as required by 10 CFR 830.120, “Quality Assurance Requirements”.

Quality Assurance Record – A completed document that furnishes evidence of the quality of items and/or activities affecting quality.

Quality Improvement – A management program for improving the quality of operations or activities. This management program includes a mechanism for encouraging employee or team member recommendations with timely management evaluation and feedback or implementation.

Record – A completed document or other media that provides objective evidence of an item or process.

Repair – A nonconforming item fixed per the approved original requirement.

Requirements – Standards that are mandated by an authority through statute, regulation, or contract.

Rework – A nonconforming item fixed per alternate requirements (i.e., different than those originally specified).

Root Cause – The most fundamental circumstances that are manifested by an observed deficiency (i.e., where the deficiency is but a symptom of a more basic problem).

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

Standards – The expressed expectation for the performance of work.

Surveillance – The act of observing real-time activities and/or reviewing documentation to verify conformance with specified requirements and to evaluate their adequacy and effectiveness.

Worker – An individual within the controlled area of the facility performing work for or in conjunction with the Contractor or using Contractor facilities.

12. References

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A

Appendix A

Quality Assurance Program Implementation Matrix

QA Criteria	Implementing Documents/Procedures	Project Activity (Phase)									
		Preliminary Design	Design Confirmation	Detailed Design	Equipment Procurement	Site Preparation	Construction	Start-up	Operation		
I Quality Program	Project Management Plan	3	3	3	3	3	3	3	3		
	Safety Classification of SSC	3	3	3	3	3	3	3	3		
	Designation of QL and QAP Requirements	3	3	3	3	3	3	3	3		
	QA Authority to Stop Work	3	3	3	3	3	3	3	3		
	Preparation, Review, and Approval of QAP	3	3	3	3	3	3	3	3		
II Personnel Training and Qualification	Indoctrination and Training of Project Personnel	3	3	3	3	3	3	3	3		
	Training and Qualification Plan (Design & Construction)	3	3	3	3	3	3				
	Training and Qualification Plan (Operations)						3	3	3		
	Qualification of Personnel (e.g., ASME, WAC)			3	3	3	3	3	3		
III Quality Improvement	Nonconformance Reporting	3	3	3	3	3	3	3	3		
	Corrective Action	3	3	3	3	3	3	3	3		
	Corrective Action Tracking System	3	3	3	3	3	3	3	3		
	RCA			3	3	3	3	3	3		
	Identification, Tracking, and Reporting of PAAA Noncompliance	3	3	3	3	3	3	3	3		
IV Documents and Records	Document Control	3	3	3	3	3	3	3	3		
	Records Management	3	3	3	3	3	3	3	3		
	Project Filing System	3	3	3	3	3	3	3	3		

QA Criteria	Implementing Documents/Procedures	Project Activity (Phase)									
		Preliminary Design	Design Confirmation	Detailed Design	Equipment Procurement	Site Preparation	Construction	Start-up	Operation		
V Work Processes	Preparation, Review, and Approval of Project Procedures	3	3	3	3	3	3	3	3		
	Design Process	3	3	3	3	3	3	3	3		
	Identification and Control of Items				3	3	3	3	3		
	Control of Special Processes					3	3	3	3		
	Control of M&TE					3	3	3	3		
	Handling, Storage, and Shipping				3	3	3	3	3		
VI Design	Design Process	3	3	3	3	3	3	3	3		
	Project Design Criteria	3	3	3	3	3	3	3	3		
	Engineering Standards and Guides	3	3	3	3	3	3	3	3		
	V&V of Computer Programs; Error Reporting	3	3	3	3	3	3	3	3		
	Project Interface Control	3	3	3	3	3	3	3	3		
	Basis of Design	3	3	3	3	3	3	3	3		

QA Criteria	Implementing Documents/Procedures	Project Activity (Phase)									
		Preliminary Design	Design Confirmation	Detailed Design	Equipment Procurement	Site Preparation	Construction	Start-up	Operation		
	Engineering Drawings	3	3	3	3	3	3	3	3		
	Engineering Calculations	3	3	3	3	3	3	3	3		
	Procurement and Installation Specifications	3	3	3	3	3	3	3	3		
	Design Review	3	3	3	3	3	3	3	3		
	Design Verification	3	3	3	3	3	3	3	3		
	Design Change Control	3	3	3	3	3	3	3	3		
	Configuration Management	3	3	3	3	3	3	3	3		
VII Procurement	Content of Procurement Documents	3	3	3	3	3	3	3	3		
	Review of Procurement Documents	3	3	3	3	3	3	3	3		
	Supplier Qualification	3	3	3	3	3	3	3	3		
	Supplier Monitoring	3	3	3	3	3	3	3	3		
VIII Inspection and Acceptance Testing	Receiving Inspection				3	3	3	3	3		
	Site and Construction Inspection					3	3	3	3		
	In-process Inspection				3	3	3	3	3		
	Test Control				3	3	3	3	3		
	Control of M&TE					3	3	3	3		
	Identification of Testing Status						3	3	3		
IX Management Assessment	Management Self-Assessment	3	3	3	3	3	3	3	3		
	Management Review	3	3	3	3	3	3	3	3		

QA Criteria	Implementing Documents/Procedures	Project Activity (Phase)									
		Preliminary Design	Design Confirmation	Detailed Design	Equipment Procurement	Site Preparation	Construction	Start-up	Operation		
X Independent Assessment	QA Audit and Assessments	3	3	3	3	3	3	3	3		
	QA Surveillance	3	3	3	3	3	3	3	3		
	Project Safety Committee	3	3	3	3	3	3	3	3		

3 = Indicates the implementing documents/procedures in place.

ASME = American Society of Mechanical Engineers

M&TE = measuring and test equipment

PAAA = Price-Anderson Amendments Act

QA = quality assurance

QAP = Quality Assurance Program

QL = quality level

RCA = root cause analysis

SSC = structure, system, component

V&V = verification and validation

WAC = *Washington Administrative Code*

B

Appendix B

Application of Quality Assurance Program Requirements for QL-1, QL-2, and QL-3 Structures, Systems, and Components

QAP Requirement	QA Classification				Remarks
	QL-1	QL-2	QL-3	COM	
1. Program					
A written QAP shall be developed, implemented, and maintained.	X	3	3		A QAP describing selected criteria (as applicable) of 10 CFR 830.120 is acceptable for QL-3.
The QAP shall describe the organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work.	X	3			
QAP shall describe management processes, including planning, scheduling, and resource considerations.	X	3			
2. Personnel Training and Qualification					
Qualification of personnel: policies and procedures that describe personnel selection requirements shall be established for each position.	X	3	3		
Training shall provide knowledge of the correct processes and methods to accomplish assigned tasks.	X	3			
Training goals, lesson plans, and other training materials shall be developed, reviewed by subject matter experts, and approved by management.	X	3			No formal training programs required for QL-3.
Training effectiveness shall be monitored. Worker performance shall be evaluated to ensure that the training program conveys all required knowledge and skills.	X	3			
3. Quality Improvement					
Process to detect and prevent quality problems shall be established and implemented.	X	3			Commercial practices for QL-3.
Items, services, and processes that do not meet established requirements shall be identified, controlled, and corrected according to the importance of the problem and the work affected.	X	3			Commercial practices for QL-3.
Correction shall include identifying the causes of problems and working to prevent recurrence.	3	3			Commercial practices for QL-3.

QAP Requirement	QA Classification				Remarks
	QL-1	QL-2	QL-3	COM	
Item characteristics, process implementation, and other quality-related information shall be reviewed and the data analyzed to identify items, services, and processes needing improvement.	3	3			Commercial practices for QL-3.
4. Documents and Records					
Documents shall be prepared, reviewed, approved, issued, used, and revised to prescribe processes, specify requirements, or establish design.	X	3			Commercial practices for QL-3.
Records shall be specified, prepared, reviewed, approved, and maintained.	X	3			Commercial practices for QL-3.
5. Work Processes					
Work shall be performed to established technical standards and administrative controls using approved instructions, procedures, or other appropriate means.	3	3			Commercial practices for QL-3.
Items shall be identified and controlled to ensure their proper use.	3	3			Commercial practices for QL-3.
Items shall be maintained to prevent their damage, loss, or deterioration.	3	3			Commercial practices for QL-3.
Equipment used for process monitoring or data collection shall be calibrated and maintained.	3	3			Commercial practices for QL-3.
6. Design					
Design inputs shall be technically correct and complete. These inputs may include such information as design bases, health and safety considerations, performance parameters, codes and standards requirements, and reliability requirements.	3	3			Commercial design practices for QL-3.
Technical design interfaces shall be identified in the input documents and methods shall be established for their control.	3	3			Commercial design practices for QL-3.
The design process shall translate design input into design output documents that are technically correct and meet the end-user's requirements.	3	3			Commercial design practices for QL-3.
Aspects critical to the safety or reliability of the designed system, structure, or component shall be identified during the design phase.	3	3			Commercial design practices for QL-3.
Computer software verification and validation.	3	3			Computer software validation and verification is not required for QL-3.

QAP Requirement	QA Classification				Remarks
	QL-1	QL-2	QL-3	COM	
The completed design shall be recorded in design output documents such as: drawings, specifications, test/inspection plans, maintenance requirements, and reports.	3	3	3	3	QL-3: drawings, specifications, and calculations only. See QAP text for quality Commercial application.
Design verification is a formal documented process to establish that the resulting system, structure, or component will be fit for the intended use. Design verification methods include, but are not limited to, technical reviews, peer reviews, alternate calculations, and qualification testing.	3	3			Commercial design practices for QL-3
The adequacy of design products shall be verified or validated by individual or groups other than those who performed the work.	3	3			Commercial design practices for QL-3.
Design changes, including field changes and nonconforming items dispositioned “use-as-is” or “repair”, shall be controlled by measures commensurate with those applied to the original design.	3	3			Commercial design practices for QL-3.
Temporary modifications shall receive the same levels of control as the designs of permanent modifications.	3	3			Commercial design practices for QL-3.
7. Procurement					
Prospective suppliers shall be evaluated and selected on the basis of specified criteria.	X	3		3	Commercial practices for QL-3. See QAP text for quality Commercial application
Procurement documents shall clearly state test/inspection requirements and acceptance criteria for purchased items and service.	3	3		3	Commercial practices for QL-3.
Supplier Monitoring.	3	3		3	See QAP text for quality Commercial application
Receipt Inspection.	X	3	3	3	See QAP text for quality Commercial application
Reporting Nonconformances.	X	3	3		
Product Documentation: Supplier generated documents that are important to the product quality shall be accepted through the procurement system and controlled; these documents may include certificates of conformance, drawings, analysis, test reports, maintenance data, nonconformances, corrective actions, approved changes, waivers, and deviations.	X	3	3		

QAP Requirement	QA Classification				Remarks
	QL-1	QL-2	QL-3	COM	
8. Inspection and Acceptance Testing					
Inspection and testing of specified items, services, and processes shall be conducted using established acceptance and performance criteria.	3	3	3		
Equipment used for inspections and test shall be calibrated and maintained.	3	3	3		
9. Management Assessment					
Managers shall assess their management processes. Planned and periodic management assessments shall be established and implemented. Problems that hinder the organization from achieving its objectives shall be identified and corrected.	3	3			Commercial practices for QL-3.
10. Independent Assessment					
Independent assessments shall be planned to measure item and service quality.	3	3			Commercial practices for QL-3.
The group performing independent assessment shall have sufficient authority and freedom from the line organization to carry out its responsibilities.	3	3			
Persons conducting independent assessments shall be technically qualified and knowledgeable in the areas assessed.	3	3			

X = Application of the QAP Requirements correlated to work scope and requirement. The applicable requirement element shall be addressed, but the rigor at which the element is put into practice may be through a graded application.

3= Graded application of QAP requirements correlated to work scope and requirement (Criteria will be included based on a Graded Approach as provided in Section 1.3.2)

Graded application of QA controls shall be used. The rigor with which the quality program is applied to an activity is determined considering the following criteria and to the degree commensurate with the:

- Function or end use of the item
- Consequence of failure (risk) of the item
- Importance of the data being collected or analyzed
- Complexity of design or fabrication of the item or design or implementing of the activity
- Reliability of the process
- Reproducibility of the results
- Uniqueness of the item or service quality
- Necessity for special controls or processes
- Degree to which functional compliance can be demonstrated through inspection or test
- Any other relevant factor