



Fluor-BWXT Portsmouth LLC

**ON-SITE WASTE DISPOSAL FACILITY (OSWDF)  
PROJECT QUALITY ASSURANCE PLAN  
PIKETON, OHIO**

**Fluor-BWXT Portsmouth LLC**

Date Issued – 01/30/24

**Prepared by**  
Fluor-BWXT Portsmouth LLC  
Managing  
Environmental Management Activities at the  
Portsmouth Gaseous Diffusion Plant  
Under contract DE-AC30-10CC40017  
for the  
U. S. Department of Energy  
Portsmouth Gaseous Diffusion Plant  
Piketon, Ohio

1 Year Periodic Review Date: 01/23/25

This document contains 45 pages.

## APPROVALS

**ON-SITE WASTE DISPOSAL FACILITY (OSWDF)  
PROJECT QUALITY ASSURANCE PLAN**

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## REVISION LOG

Revision Number	Revision Date	Description of Changes	Pages Affected
0	09/15/16	Initial Issue	All
1	05/30/17	Minor Revision/Periodic Review to update template, logos, titles, and references	All
2	05/17/18	Revision/Periodic Review: Updated titles and subcontractor qualifications and quality improvements. Added MTE tagging requirements and QA qualifications.	All
3	05/09/19	Revision/Periodic Review: Updated titles and references, added Subsection 1.1.7 and 7.2.8. Deleted Subsection 1.2.10.	1, 5, 6, 19, 20, 30
4	04/30/20	Revision/Periodic Review: Updated responsibilities and org chart. Added Appendix A, <i>Regulatory Requirements Flow Down</i> , and associated reference in introduction. Added 4.1.6, and updated the introduction, 2.1.3, 4.1.1, 4.1.4, 4.2.2, 7.2.6, and 12.1.H.	v, 1- 8, 10-14, 21, 28, 29, 31 & 33
5	07/20/21	Revision/Periodic Review: Revised Reference List and Acronym List; Added Step 1.2.13, 7.2.9, 1.2.4 bulleted item; 8.2.2 bulleted item; edited Section 11.0 and added subsections 11.3 through 11.12 to Section 11.0; edited Steps 9.1.1, 9.2.2, 9.3.1A, 10.1.2.	All

Revision Number	Revision Date	Description of Changes	Pages Affected
6	07/20/22	Revision/Periodic Review: update document format; change OSWDF Design Engineering Manager to OSWDF Design Manager; insert Figure 1 OSWDF Project Organization Chart; revise word “Subsection” to “Step” in 9.3.2B and cross-reference Step number; separate Reference FBP-ER-PDD-00003 from Reference FBP-ER-PRO-00299.	4, 8, 26, and 37
7	08/01/23	Revision/Periodic Review: update OSWDF Project Director and OSWDF Deputy Director names; make Description of Changes log dates consistent; correct titles of DOE O 413.3B (change “Manage” to “Management”), FBP-NSE-PRO-00083 (change “&” to “and”), FBP-QA-PDD-00002 (change “Suspect Counterfeit” to “Suspect/Counterfeit”), FBP-QA-PRO-00070 (change “NQA” to “Nuclear Quality Assurance (NQA)”), and FBP-SMPO-PL-00001 (add word “Software” at beginning); update “OSWF” to “OSWDF” in Step 5.6.1; update Figure 1 OSWDF Project Organization Chart; add document to Appendix A, <i>Regulatory Requirements Flow Down</i> .	ii, iii, vi, 4, 8, 19, and 37-39
8	01/23/24	Revision/Periodic Review: Update Steps 1.2.8, 1.3.2, 2.1.3, 2.2.3, 5.1.2, 5.3.5, 5.4.2, and 5.4.3 to clarify QA information; update Step 4.1.6 to align with definition of non-applicability for Immediate Procedure Changes (IPCs); update Step 10.1.4 to reference FBP-QP-PRO-00014 instead of FBP-QP-PRO-00020 to address FBP-PR-FY23-2157; update titles as needed throughout, including in Section 13.0, <i>References</i> , and Appendix A, <i>Regulatory Requirements Flow Down</i> ; update Subsection 12.2, <i>Acronyms</i> ; grammatical/editorial changes as needed.	All

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## INTRODUCTION

This Project Quality Assurance Plan (PQAP) provides the primary requirements for the integration of quality functions during the design, construction, and operational phases of the On-Site Waste Disposal Facility (OSWDF) located in Piketon, Ohio, for the U.S. Department of Energy (DOE) Portsmouth Paducah Project Office (PPPO), under prime contract DE-AC30-10CC40017.

This PQAP was written to meet the contractor Quality Assurance (QA) requirements of DOE Order (O) 413.3B, *Program and Project Management for Acquisition of Capital Assets*, which requires the development and implementation of a QA program in accordance with DOE O 414.1D, *Quality Assurance*; Title 10 Code of Federal Regulations (CFR) Part 830 Subpart A, *Quality Assurance Requirements*; and American Society of Mechanical Engineers (ASME) Nuclear Quality Assurance (NQA-1), *Quality Assurance Requirements for Nuclear Facility Applications* (2008 edition, with addenda through 2009).

This PQAP incorporates the requirement of Fluor-BWXT Portsmouth LLC (FBP) FBP-QA-PDD-00001, *Quality Assurance Program Description (QAPD)*, which allows the development of additional quality assurance plans to provide supplemental project specific guidance. This document is a flow-down of quality requirements from the QAPD. If a specific requirement is not clearly stated in this PQAP, refer to the FBP QAPD for further guidance. If a conflict arises between this PQAP and the FBP QAPD, the requirements of the FBP QAPD will take precedence.

FBP policies, plans, and procedures used to implement the requirements of this document are referenced in the applicable sections of this PQAP.

The requirements within FBP-PM-PDD-00001, *Integrated Safety Management System*, will be implemented on the project.

This PQAP will be reviewed annually and revised as necessary, to incorporate changes in QA requirements, project scope, or entering a new phase of the project relative to design, construction, waste placement, or operations.

This document implements applicable regulatory requirements. They are listed in Appendix A, *Regulatory Requirements Flow Down*.

## 1.0 OSWDF PROJECT

### 1.1 PROJECT DEFINITION

- 1.1.1** This PQAP is developed to flow down requirements from the FBP QAPD and is a quality management system consisting of three elements: managing, performing, and assessing the quality and adequacy of work performed within the scope of the OSWDF project.
- 1.1.2** The management element includes programs that establish organizational structures and responsibilities, as well as management processes including planning, scheduling, and resource considerations. This element also includes personnel training and qualifications, quality improvement, and management of documents and records.
- 1.1.3** The performance element includes work processes, design activities, procurement, and inspection and acceptance testing required to plan and perform work in a manner that meets the scope and requirements of the OSWDF Project.
- 1.1.4** The assessment element includes independent and management assessments, surveillances, and inspections.
- 1.1.5** This PQAP flows down the managing, performing, and assessing the quality and adequacy of work elements, during the design, construction, and operation of the OSWDF, placement of impacted materials in the OSWDF, and construction and operation of the Interim Leachate Treatment System/Modular Leachate Treatment System (ILTS/MLTS).
- 1.1.6** The OSWDF will be designed and constructed using site-controlled procedures; certified-for-construction design documents and technical specifications; and operated in accordance with approved operating plans, construction work packages, and procedures. All OSWDF work activities will comply with the FBP QAPD, OSWDF PQAP, Construction Quality Assurance Project Plan (CQAPP), and applicable QA requirements mandated by law and contractual requirements.
- 1.1.7** FBP-ER-PRO-00299, *Unreviewed Disposal Question Evaluation (UDQE), Unreviewed Composite Analysis Question Evaluation (UCAQE), and Special Analysis (SA) Process*, provides a process for evaluating proposed changes in the OSWDF design or operations that affect the inputs, assumptions, and data used in the Performance Assessment and Composite Analysis (PA/CA) (DOE 2015). Proposed changes require screening to determine if the Unreviewed Disposal Question Evaluation (UDQE), Unreviewed Composite Analysis Question Evaluation (UCAQE), or Special Analysis (SA) must be executed.
- 1.1.8** Environmental sampling and analysis will be performed in accordance to the requirements in FBP-ER-PRO-WD-PL-0006, *Sample Analysis Data Quality Assurance Project Plan (SADQ) at the Portsmouth Gaseous Diffusion Plant, Piketon, Ohio*. The SADQ was developed to satisfy sampling and data quality requirements for Decontamination and Decommissioning (D&D) under the April 13, 2010 *Director's Final Findings and Orders for Removal Action and Remedial Investigation and Feasibility Study and Remedial Design and Remedial Action*, including the July 16, 2012 Modification thereto (referred to as the D&D DFF&O) (Ohio Environmental Protection Agency [Ohio EPA] 2012), and for environmental cleanup under the Ohio Consent Decree and U.S. Environmental Protection Agency (EPA) Administrative Consent Order.

- 1.1.9** FBP OSWDF Project Management may delegate to others, such as contractors, agents, or consultants the work of establishing or executing the requirements of this PQAP, or any part thereof, but the OSWDF Project Management shall retain responsibility for all work activities governed by this PQAP.
- 1.1.10** Throughout the design, construction, and operations of the OSWDF; many organizations both FBP and subcontracted will be involved with execution of work activities. The responsibilities, interfaces, lines of communication, and authority of each organization shall be clearly defined through plans, procedures, construction work packages, and contract documents.
- 1.1.11** This PQAP shall be reviewed annually and revised as required to maintain compliance with regulations, DOE Orders and Directives, and any contractual requirements directing such change. The OSWDF Project Director shall be ultimately responsible for ensuring the annual review. The OSWDF Project QA Manager shall facilitate the review and approval of the OSWDF PQAP.
- 1.1.12** The requirements of this PQAP apply to all OSWDF project personnel and its subcontractors.

## **1.2 ORGANIZATION AND RESPONSIBILITIES**

### **1.2.1 OSWDF PROJECT ORGANIZATION AND KEY PERSONNEL ROLES & RESPONSIBILITIES**

- The OSWDF Project organization is shown in Figure 1, *OSWDF Project Organization Chart*, with the OSWDF Project Director having overall responsibility for execution of the project. The OSWDF project is executed through the appointment of a project management team supported by personnel matrixed from FBP program support organizations, including but not limited to; Business Services; Construction; Engineering; Environmental, Safety, Health, and Quality (ESH&Q); Operations; Project Controls; and subcontractors.
- This section will define the key roles and responsibilities for those who will have day to day responsibilities during the design, construction, and operation of the OSWDF. Not all roles and responsibilities identified in individual Roles, Responsibilities, Authorities, and Accountability (R2A2) are included in this document. A complete list of R2A2s for a particular position can be found in individual R2A2s. Responsibilities for those not included in this section will be defined in other OSWDF related plans, procedures, or work documents.

### **1.2.2 OSWDF PROJECT DIRECTOR**

Has overall administrative responsibility for the successful completion of the OSWDF through cost effective integration of construction, engineering, management, and ESH&Q. Key project responsibilities include the following:

- Staffs and organizes FBP OSWDF Division.
- Requests and integrates matrixed resources from other functional areas into OSWDF organization.
- Recruits, qualifies, and assigns subordinate OSWDF managers and administrative personnel.



- Administers compensation, performance management, and personnel development program for assigned staff (institutional and matrixed personnel).
- Ensures development & execution of training and qualification programs for OSWDF personnel.
- Prepares, executes, and conforms to OSWDF Control Account budgets.
- Implements the DFF&O and Consent Decree requirements relevant to OSWDF work scope to support D&D.
- Accountable for safety and quality of OSWDF staff performance.

### **1.2.3 OSWDF Deputy Project Director**

- Approves OSWDF documents/reports and delegates their approval to subordinate managers.
- Approves OSWDF plans and procedures.
- Qualifies/disqualifies/appoints/assigns/dismisses OSWDF management and staff personnel.
- Approves OSWDF work breakdown structure/budgets/baseline.
- Suspends any and all activities that may be considered unsafe, pose a risk to personnel, the public, the environment, or be in violation of approved policies, procedures, or contract requirements.
- Controls and manages project activities in order to execute the responsibilities outlined in the responsibilities section.
- Holds project team members accountable for performance and compliance to policies and procedures.
- Takes actions necessary to safely meet project cost, technical, schedule, quality, and baselines.
- Other authorities as delegated by Environmental Remediation Director, or OSWDF Project Director and as defined in approved FBP policies, program, and procedures.

### **1.2.4 OSWDF CONSTRUCTION MANAGER**

Has overall responsibility for construction of the OSWDF. Key project responsibilities include:

- Ensures all work on the project is performed safely - activities are planned and performed in compliance with Integrated Safety Management System (ISMS) principles and core functions.
- Ensures all activities are conducted to protect human health and the environment, champion's good environmental stewardship, and implements responsibilities as identified in the FBP-EP-PDD-00008, *Environmental Management System Description*.
- Manages and coordinates project assignments to superintendents, construction engineers and coordinators.
- Plays an active role in the development of the safety culture on the project.

- Remains knowledgeable of safety policies and procedures and performs assigned duties in a safe manner and, while supervising others, has responsibility for their safety; and ensures that they comply with established safety policies and procedures and practice safe work habits.
- Provides leadership and motivation to the project and organizational team as well as subcontractors and subordinate personnel.
- Follows Conduct of Operations requirements, prime contract terms, and company policies and procedures.
- Ensures qualification, training, and job proficiency has been met by all construction personnel.

### **1.2.5 OSWDF DESIGN MANAGER**

Is responsible for providing engineering design support to the OSWDF project. Key project responsibilities include:

- Planning, developing, and analyzing the design of the OSWDF.
- Performs and checks most types of civil engineering calculations and design using both computer-aided and manual design techniques on environmental remediation projects.
- Develops and prepares various technical documents, including proposals, specifications, work plans, technical evaluations, alternate analysis, and technical reports.
- Organizes, and plans work activities, develops and monitors estimates, assigns work, works with project team, client, field, and other organizations working on the project.
- Prepares estimates, scope of work, material, and service requisitions.
- Provides technical input during implementation of engineering studies, sampling and analysis plans, and other construction activities.
- Ensures that OSWDF design engineers are adequately trained and qualified.

### **1.2.6 OSWDF FIELD ENGINEERING MANAGER**

Is responsible for providing field engineering support to the OSWDF. Key project responsibilities include the following:

- Evaluates Request for Information (RFI) for compliance with approved design documents.
- Provides value engineering during construction.
- Coordinates field engineering personnel assignments.
- Manages project files and records in accordance with procedures.
- Prepares and submits construction certification documentation to DOE for regulatory approval.
- Reviews/approves construction materials (aggregate, liner materials, pipe, etc.) to verify that they meet plans and specifications.
- Initiates and processes Engineering Change Requests (ECR).

- Ensures OSWDF field engineers are adequately trained and qualified.

#### **1.2.7 OSWDF OPERATIONS MANAGER**

Has overall responsibility for OSWDF operation of the OSWDF. Key project responsibilities include:

- Ensures compliant operations of waste transportation (placement) in the OSWDF.
- Ensures compliant operations of routine monitoring and maintenance of the OSWDF.
- Ensures all work is performed safely – activities are planned and performed in compliance with ISMS principles and core functions.
- Provides leadership and motivation to the project and organizational team as well as subcontractors and subordinate personnel.
- Follows Conduct of Operations, prime contract terms, company policies and procedures.

#### **1.2.8 OSWDF PROJECT QA MANAGER**

Has overall responsibility for Quality Assurance/Quality Control (QA/QC) activities during construction and operations of the OSWDF. Key project responsibilities include:

- Ensure compliance to QAPD/PQAP in a graded approach, ensuring ISMS safety is flowed into all aspects of the project, protecting the worker, site, environment, and public.
- Manages the Construction Quality Control (CQC) contractor and Fluor-BWXT Portsmouth LLC QA/QC resources required to support the OSWDF project.
- Prepares and maintains OSWDF Project Quality Assurance Plan (PQAP).
- Develops annual OSWDF Project Surveillance and Assessment Schedule.
- Responsible for QA/QC technical and administrative functions for the OSWDF project, e.g., planning resources, interpretation of QA requirements, and coordination of project coverage and assignment.
- Interfaces with DOE and other external entities as necessary on OSWDF QA issues and interpretations.
- Assists with the development of corrective actions and the performance of follow-up to verify effectiveness of completed corrective actions.
- Serves as primary point of contact for the coordination of DOE QA OSWDF Assessments and Surveillances.
- Coordinates OSWDF supplier audits and assessments.

#### **1.2.9 CQC CONTRACTOR**

Under the direction of a Construction Quality Assurance (CQA) Officer, is responsible for conformance testing, monitoring, and performance testing in accordance with the OSWDF CQAPP and technical specifications.

Provides QC oversight during the placement of impacted materials in the cell during the operational phase of the OSWDF in accordance with CQAPP Section 15, *Impacted Material Placement*, and other related OSWDF Operations documents, as applicable.

A CQC will utilize a CQA Officer to oversee the site activities. Key project responsibilities for the CQA Officer and CQC Contractor include:

- Obtains and tests construction materials.
- Collects soil samples for testing.
- Ships samples to off-site laboratory for testing.
- Provides oversight of QC of off-site and on-site testing laboratory.
- CQA Officer prepares, signs, and seals yearly OSWDF CQA Construction Certification Report.
- Provides oversight and monitoring of CQC activities during construction ensuring the CQAPP has been successfully carried out and the OSWDF has been constructed to the design documents.
- Certifies, at project completion, that the OSWDF has been constructed in accordance with the design documents.
- Confirms acceptance, filling, and compaction of impacted material placement in the OSWDF are in compliance with the requirements established in the Impacted Material Placement Plan (IMPP), Technical Specifications, and this CQAPP.

#### **1.2.10 OSWDF ENVIRONMENTAL SAFETY & HEALTH (ES&H) FIELD REPRESENTATIVE(s)**

Is responsible for the safe performance of work during the construction and operation of the OSWDF. Key responsibilities include:

- Ensures implementation of regulatory ES&H/Radiological requirements applicable to the project.
- Ensures ES&H and Radiological personnel matrixed to the project are trained and qualified to perform their duties.
- Observes work activities during construction and operations for unsafe/noncompliant practices.
- Interfaces with the DOE and other external entities as necessary on ES&H/Radiological issues.
- Evaluates future work activities from an ES&H and Radiological perspective to ensure processes, documentation, training, and certifications needed are implemented.
- Ensures ES&H and Radiological permits are complete, properly executed, and adhered to.
- Assists with development and review of Project Health and Safety Plans, Job Hazard Analysis (JHA), Radiological Work Permits, as low as reasonably achievable reviews, and associated hazard mitigation controls.

**1.2.11 DESIGN ARCHITECT-ENGINEER (A-E)**

Responsible for the design of the OSWDF and the ILTS/MLTS in accordance with contractual requirements and may include Title III engineering services.

**1.2.12 CONSTRUCTION CONTRACTOR(s)**

Responsible for the construction of the OSWDF and ILTS/MLTS in accordance with contractual requirements and Certified for Construction design documents. The potentially clean Select Layer will be sub-contracted, but all waste/impacted material placement will be performed by FBP building trades.

**1.2.13 SOFTWARE OWNERS**

Responsible for the planning, design, maintenance, and procurement of OSWDF software in accordance with the requirements in FBP-SMPO-PDD-00005, *Software Management*.

**1.3 PROJECT QA RESPONSIBILITIES**

**1.3.1** It is the OSWDF Project Director's responsibility to establish policy and cultivate principles that integrate quality requirements into daily work. It is also the OSWDF Project Director's responsibility to ensure implementation and adequate resources are allocated to implement the QA requirements in this PQAP.

**1.3.2** It is the responsibility of all OSWDF project personnel to safely comply with the requirements of this PQAP and its implementing documents, to ensure conformance to approved design drawings and technical specifications, and to identify and report nonconforming items or problematic issues, ensuring ISMS flow down for protection of the worker, site, environment, and public.

**1.3.3** OSWDF personnel assigned the responsibility for verifying that activities affecting quality have been performed correctly, shall be independent of the work performed, have direct access to all levels of management, have access to all work areas, have independence from cost and schedule, and have sufficient authority to:

- Identify quality problems.
- Recommend solutions to quality problems.
- Verify implementation of solutions.
- Ensure that further processing, delivery, installation, or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred.

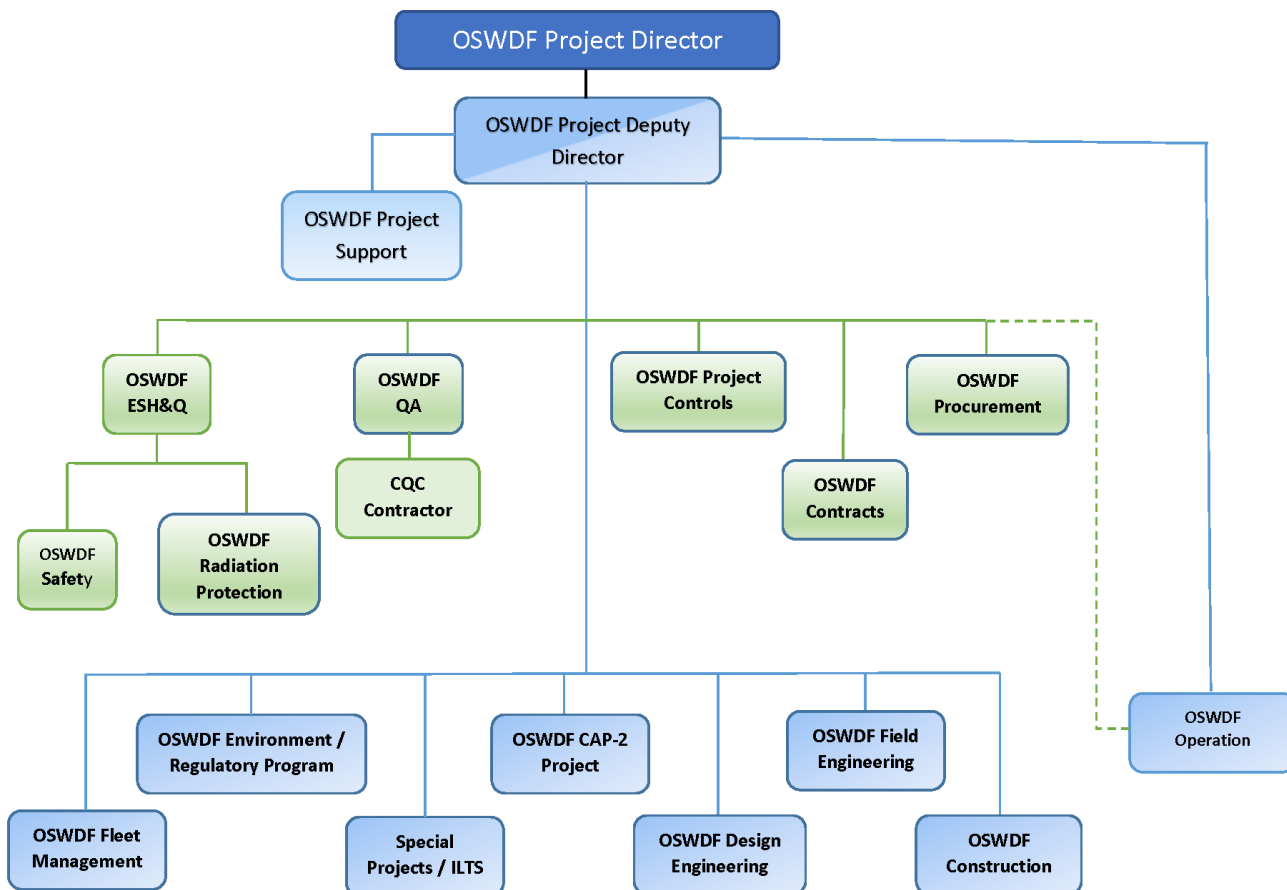


Figure 1. OSWDF Project Organization Chart

## 1.4 STOP WORK AUTHORITY

- 1.4.1** FBP stop work authority extends to all FBP personnel and subcontractors to prevent any work, activity, or process that jeopardizes personnel safety and health, quality, or has the potential to cause significant environmental impact.
- 1.4.2** This stop work authority is applicable to OSWDF project personnel and OSWDF subcontractor and is one of the mechanisms used to ensure that planning and scheduling considerations do not degrade safety, quality, or environmental performance.
- 1.4.3** Prior to restart of OSWDF related work after a work stoppage due to safety, quality, or environmental concerns; appropriate reviews, critiques, and/or assessments are planned, performed, and documented. Conditions warranting the work stoppage are understood and resolved and remedial/corrective/preventative actions are completed.
- 1.4.4** The stop work authority requirement shall flow down to OSWDF sub-contractors through procurement documents, such as the Statement of Work, and Attachment J-13, *Environmental, Health, and Safety Requirements for On-Site Work*, documents and reinforced through project team meetings, construction meetings, and during pre-job briefs.

## 1.5 MANAGEMENT PROCESSES

- 1.5.1** The successful execution of the OSWDF project requires careful planning, scheduling, and allocation of qualified and trained resources necessary to ensure the OSWDF is designed, constructed, and operated in accordance with applicable or relevant and appropriate requirements (ARARs).
- 1.5.2** Management processes to ensure successful project execution have been established and are defined in this PQAP which include training and qualification of personnel, quality improvement, records management, work processes, and project management guidelines that prescribe best management practices to effectively plan, execute, monitor, report, and close projects.
- 1.5.3** Management controls, lines of communication, and responsibilities are established in plans, procedures, and procurement documents to ensure adequate oversight of subcontracted work.

## 1.6 GRADED APPROACH

- 1.6.1** FBP site procedure FBP-QA-PRO-00008, *Graded Approach*, was developed to implement the requirements of 10 CFR 830.7, *Graded Approach*. Quality Levels (QLs) 1-4 were developed to aid in the implementation of quality requirements by application of the graded approach to Structures, Systems, and Components (SSCs); work activities; and subcontracted services affecting quality, with QL-1 having the highest consequence, and risk down to QL-4 having the lowest consequence and risk.
- 1.6.2** Factors to be considered in determining appropriate levels of control required to verify compliance with QA requirements include:
- The hazards associated with doing the work or using the results of the work.
  - The consequences of malfunction or failure of the item or inappropriate use of the results of services provided.
  - The probability of the occurrence of the postulated consequences.
  - The design and fabrication complexity or uniqueness of the item, or difficulty to perform services.
  - The need for special controls and oversight of processes, equipment, and performance.
  - The degree to which functional compliance can be demonstrated by inspection, test, or performance verification.
  - The quality history and degree of standardization of items and services.
  - The difficulty of repair, replacement, or replication.
- 1.6.3** The OSWDF project will utilize the graded approach during the design, construction, and operation of the OSWDF in accordance with the requirements prescribed in FBP-QA-PRO-00008, *Graded Approach*.

## **2.0 PERSONNEL TRAINING AND QUALIFICATION**

The FBP Training Program consists of classroom, computer-based training, laboratory training, and on-the-job training necessary to provide an understanding of the fundamentals, basic principles, systems, procedures, and emergency responses involved in an employee's work assignments. This enables efficient appropriate indoctrination, training, qualification, and, where applicable, certification of personnel performing or managing activities affecting quality. FBP's training program is tailored to ensure employees and subcontractors are trained, qualified, and certified (when required) commensurate with the scope, complexity, importance of their work activities, and job assignments.

### **2.1 QUALIFICATION AND TRAINING OF PERSONNEL**

- 2.1.1** The OSWDF Project Director, during the initial scoping and planning phase of the project, determines the required number of personnel and their qualification and experience needed to successfully execute the project. The program support organization(s) provide qualified and trained personnel to support the project execution team. The program support organizations are responsible to ensure personnel matrixed to the project are current with their required training in order to maintain job proficiency.
- 2.1.2** Project Contract Technical Representatives (CTRs) flow-down the project personnel qualification and experience requirements to subcontractors through procurement documents including, but not limited to, Statement of Work, J-13 Appendix 1, Training Matrix, *Project Work Plan, and Health and Safety Plans*. The CTR provides oversight verifying subcontractors complete required training prior to commencement of project work activities and complete continuing training required to maintain job proficiency.
- 2.1.3** Personnel who perform testing activities that are not QC shall achieve and maintain proficiency in the performance of quality-affecting activities. Specific activities that require special qualifications or certifications include construction riggers, crane operators, welders, and laboratory analysts. Qualification, training, and job proficiency for construction personnel shall be the responsibility of OSWDF Construction Management and, for operations personnel, shall be the responsibility of the Operations Manager with oversight performed by QA, when deemed necessary by the OSWDF Project QA Manager.
- 2.1.4** Personnel involved in the design, development, testing, or evaluating of software must be appropriately trained according to ASME NQA-1 (2008/Addendum 2009) to minimize the consequences of software failure. Training should be commensurate with the scope, complexity, and importance of the task and the education, experience, and proficiency of the individual. Software owners are responsible for defining and documenting Software training requirements in accordance with FBP-SMPO-PL-00002, *Software Management Program Qualifications and Training*.
- 2.1.5** All FBP personnel will be required to complete a Computer Based training Module on Software Management Program (SMP) overview.
- 2.1.6** All personnel involved in the design, development, testing, or evaluation of software will be required to complete classroom training on the FBP SMP.



## 2.2 QUALIFICATION OF INSPECTION AND TEST PERSONNEL

- 2.2.1** OSWDF project QC personnel who perform inspections and tests for the purpose of verifying that material, equipment, components, or processes meet the specified requirements shall be qualified and certified to ASME NQA-1 (2008/Addendum 2009), or an approved equivalent.
- 2.2.2** The FBP QA Program is responsible for ensuring FBP QC personnel supporting the project are qualified and certified in accordance with site QA procedures and the following requirements:
- Initial capabilities of a candidate shall be determined by an evaluation of the candidate's education, experience, training, and either test results or capability demonstration.
  - The job performance of inspection and test personnel shall be reevaluated at periodic intervals not to exceed three years. Reevaluation shall be by evidence of continued satisfactory performance or redetermination of initial capability, and satisfactory indoctrination and training requirements.
  - If during this evaluation, or at any other time, it is determined by the FBP QA program support organization that the capabilities of an individual are not in accordance with the qualification requirements specified for the job, that person shall be removed from the activity until such time as the required capability has been demonstrated.
  - Any person who has not performed inspection or testing for a period of one year shall be reevaluated.
- 2.2.3** Subcontract Inspection and Test Personnel:
- Shall meet the same requirements as FBP personnel. The flow-down of FBP QC qualification and certification requirements shall be included in procurement documents and approved by FBP Project QA Manager.
  - Personnel performing verification testing in nuclear facilities shall be qualified in accordance with ASME NQA-1 (2008/Addendum 2009) Non-Mandatory Appendix 2A-1, *Guidance on the Qualifications of Inspection and Test Personnel*.
  - Other special activities that require special qualification or certification include riggers, crane operators, welders, and laboratory analysts.
  - Nationally recognized qualification standards and boards such as the American Welding Society (AWS), Certified Welding Inspector Program, and State Department of Health Asbestos Inspectors are utilized, if applicable.
- 2.2.4** QC Non-Destructive Examination (NDE) personnel shall be qualified and certified in accordance with site QC procedures and the American Society of Nondestructive Testing (ASNT)-TC-1A.

### 3.0 QUALITY IMPROVEMENT

#### 3.1 QUALITY IMPROVEMENT PROCESS

- 3.1.1** FBP procedure FBP-QP-PRO-00020, *Problem Reporting and Issues Management*, is used to detect and prevent quality problems during the design, construction, and operation of the OSWDF. Items, materials, services, and processes that do not meet established requirements are promptly identified, documented on a problem report, controlled (segregated where practical), and corrected, with measures taken to minimize the reoccurrence of the identified non-conforming condition.
- 3.1.2** OSWDF problem reports are screened and categorized according to their significance, e.g., deficiency or significant deficiency. Based on the results of the screening, OSWDF problem reports may require casual analysis, extent of condition; but all problem reports require corrective actions to correct the nonconforming condition.
- 3.1.3** OSWDF problem reports are tracked through closure using the FBP Integrated Tracking System (ITS). The ITS is used to screen, categorize, document assignment of corrective and preventative actions, and to track the status of problem reports through closure.
- 3.1.4** Methods that may be used on the OSWDF project to identify quality issues include, but are not limited to, inspections, surveillances, testing, document reviews, walk-downs, and independent and management assessments.
- 3.1.5** OSWDF subcontractors manage issues and their associated remedial, corrective, and preventative actions within their own program which is reviewed and approved by FBP.
- 3.1.6** OSWDF subcontractors shall flow-down the quality improvement requirements of this section to their subcontractors, vendors, and suppliers.

#### 3.2 NONCONFORMING ITEMS

- 3.2.1** FBP-QA-PRO-00128, *Control of Nonconforming Items*, shall be used to document OSWDF nonconforming conditions on a nonconformance report (NCR) when an item or material:
- Fails to satisfy technical or contract requirements.
  - Fails to comply with predetermined engineering specifications.
  - Fails to function as specified.
  - Appears to be suspect or counterfeit item (SC/I).
  - Documentation deficiencies.
  - Lacks required testing or qualification with a nationally recognized testing laboratory unless evaluated and accepted by the FBP authority having jurisdiction.
- 3.2.2** A tagging or segregation system consistent with the requirements of FBP-QA-PRO-00128, *Control of Nonconforming Items*, shall be used for indeterminate or nonconforming items or materials to ensure those items or materials are not used until the disposition has been approved and documented on the NCR.

**3.2.3** Subcontractor nonconforming items or materials shall be documented and processed in accordance with their own program which is reviewed and approved by FBP and submitted to the cognizant OSWDF CTR for FBP review and approval.

### **3.3 CONTINUOUS FEEDBACK AND IMPROVEMENT**

Several methods are available to OSWDF project team members to participate in the continuous feedback and improvement process, (ISMS Principle 5) during the life cycle of the OSWDF project including project meetings, hazard identification, and pre- and post-job briefings. OSWDF project involvement in the continuous feedback and improvement process is encouraged.

## **4.0 DOCUMENTS AND RECORDS**

### **4.1 DOCUMENTS**

**4.1.1** Approved FBP work documents including plans, procedures, policies, design drawings, construction work packages, and specifications are employed by the OSWDF project team to manage and control work during the design, construction, and operation of the OSWDF. OSWDF subcontractors are procured to assist in the design, fabrication, and construction of the OSWDF using approved design documents, FBP work documents, or subcontractor documents approved by FBP.

**4.1.2** Work documents establish requirements and define how work is to be performed. They shall be prepared, reviewed, approved, issued, used, and revised in a controlled manner in accordance with approved procedures.

**4.1.3** Specific controls to be applied to work documents include:

- Identification of controlled work documents.
- Establishing controlled work document distribution list.
- Identification of individuals responsible for the preparation, review, approval, and distribution of controlled work documents.
- Reviewing and approving of controlled work documents prior to distribution.
- Establishing processes to ensure correct revision of controlled work documents are being used.
- Identifying minor revisions to controlled work documents.

**4.1.4** OSWDF work documents (FBP or subcontractor) shall be controlled. It is the responsibility of the person performing the work to ensure that the latest version of the work document is available at the work area.

**4.1.5** Revisions to work documents shall be reviewed and approved by the same organization that reviewed and approved the original document, unless it is a minor revision, as defined in FBP-BS-PRO-00024, *Developing and Maintaining Performance Documents*.

**4.1.6** FBP uses an Immediate Procedure Change (IPC) process, documented in FBP-BS-PRO-00135, *Immediate Procedure Change (IPC) Process*, to make immediate changes to a procedure. It is not applicable to forms in procedures; taking a procedure off Hold; change of Purpose, Scope, or Applicability; revision of Plans, Program Description Documents, Program Requirement Documents, Guides, Stand-Alone Forms, Emergency Operating Procedures, Alarm Response Procedures, Off-Normal Procedures, or Emergency Planning Implementing Procedures; or to reset a periodic review date.

## **4.2 RECORDS**

**4.2.1** Records furnish documentary evidence that the items or activities meet specified requirements. The term records as used throughout this section are considered QA Records. Records are classified as either lifetime or nonpermanent which will be further defined.

**4.2.2** Records generated as a result of the design, construction, maintenance, and operation of the OSWDF shall meet the record generation, authentication, classification, receipt, storage, maintenance, and retention requirements prescribed in FBP-BS-PRO-00062, *Records Management Process*, which include the following:

- Shall be accurate, legible, reproducible, retrievable, authenticated, and complete.
- As a best management practice, lines and spaces which are not applicable to the activity or task conducted should contain an N/A. If logs or sheets have multiple unused lines remaining, a single diagonal line should be drawn through the blank lines with the words “no further entries” along with an initial and date of the recorder.
- Record generator shall be responsible to ensure records are validated and/or authenticated by authorized personnel.
- Records that create or reiterate design data, technical data, or process controls, as a minimum, shall contain signatures of the preparer and of an independent reviewer, checker, and approver.
- Electronic documents are authenticated similarly to paper records with authorization indicated on the media or contained within or linked to the document itself.
- Access controls are established to prevent unauthorized use, disclosure, theft, or destruction of records. Lists are posted designating personnel approved for access to the records.
- In-process document corrections will be made with a single lineout through the incorrect entry without obscuring it and writing the correct entry in a nearby space, with date and initials of the authorizing person making the correction.

**4.2.3** Temporary storage of QA records (such as for processing, review, and use) is required; the single storage facility or container shall provide a one-hour fire rating unless dual storage requirements are met.

**4.2.4** FBP records management requirements shall flow down to OSWDF subcontractors through the procurement process. Subcontractor Quality Assurance Plans (QAPs), if required, shall include FBP record management requirements. Subcontractor QAPs shall be submitted to FBP for review and approval.

- 4.2.5** QA records are considered a federal record. FBP records management does not distinguish QA Records as such for special handling other than NQA-1, identification, classification control, storage, and maintenance requirements. Under the FBP records management system, QA Records can be identified as Classified Records, Essential Records, Controlled Unclassified Information (CUI) Records, Unclassified Controlled Nuclear Information (UCNI) Records, etc. QA Records are classified as lifetime or nonpermanent. FBP record custodians utilize approved File Plans to identify, classify, organize, maintain, and protect records.

## **5.0 WORK PROCESSES**

### **5.1 INSTRUCTIONS, PROCEDURES, AND DRAWINGS**

- 5.1.1.** The work associated with the design, construction, and operation of the OSWDF will be a combination of self-performed and subcontracted, but in both cases the work will be performed in accordance with approved instructions, procedures, drawings, specifications, or other approved documents.
- 5.1.2.** A graded approach, as previously discussed, and prescribed in FBP-QA-PRO-00008, *Graded Approach*, is used in the development of work control documents and implementation of QA requirements ensuring that the level of analysis, documentation, and actions used to comply are commensurate ISMS and with:
- Relative importance of safety, safeguards, and security
  - Magnitude of any hazard involved
  - Life-cycle stage of a facility or item
  - Programmatic mission of a facility
  - Relative importance to radiological and non-radiological hazards
  - Other relevant factors
- 5.1.3.** Documents used to define and perform work must comply with the requirements of applicable technical standards, vendor manuals, safety basis documents, codes, specifications, drawings, subcontract terms and conditions, and other applicable technical documents. These documents are developed using technical, health, safety, environmental, and quality requirements; and reviewed by qualified and knowledgeable personnel to ensure applicable and appropriate requirements are incorporated into the documents.
- 5.1.4.** OSWDF work performed by subcontractors are required to work to a QAP developed to include these requirements by the subcontractor, and approved by FBP. Programmatic requirements imposed on the subcontractor are defined by the terms and conditions of the subcontract; including the requirement to work to FBP work control documents, or to develop the necessary documents, plans, or procedures to perform their work scope.

## **5.2 IDENTIFICATION AND CONTROL OF ITEMS**

- 5.2.1** Procedures shall be used to assure only correct and accepted items are used during the construction and operation of the OSWDF. Items include materials, equipment, components, appurtenances, assemblies, modules, parts, structures, subsystem units, subassemblies, and systems.
- 5.2.2** 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.
- 5.2.3** Item identification shall be maintained on the item or in documentation traceable to the item from initial receipt or fabrication up to and including installation or use. When items are subdivided, identification shall be transferred to each part of the item prior to subdivision, and the identification shall not be obliterated or hidden by subsequent surface treatment or coating unless other means of identification are employed.
- 5.2.4** Provisions shall be made to ensure traceability of items are not lost due to degradation or weathering. Items having a limited shelf life or operating life shall be managed to ensure inadvertent use after expiration.

## **5.3 CONTROL OF SPECIAL PROCESSES**

- 5.3.1** Special processes that control or verify quality, such as welding, heat treating, brazing, soldering, and NDE, shall be performed by qualified personnel in accordance with approved and controlled procedures developed from applicable codes, standards, specifications, and other requirements.
- 5.3.2** Special processes shall be controlled by instructions, procedures, drawings, checklists, or other appropriate means; and shall include or reference procedure, personnel, and equipment qualifications requirements. Conditions necessary for accomplishment of the process shall include proper equipment, controlled parameters of the process, specified environment, and calibration requirements.
- 5.3.3** In addition to special processes previously listed, unique to the OSWDF project will be fusion and extrusion welding of the geomembrane liner and cap seams. The subcontractor shall submit procedures that will be used to control the fusion and extrusion welding of the geomembrane liner and cap seams to FBP for review and approval prior to commencement of the work activity.
- 5.3.4** For special processes not covered by existing codes and standards, requirements for qualification of personnel, procedures, or equipment shall be specified or referenced in procedures or instructions and submitted to FBP for approval.
- 5.3.5** Acceptance criteria for each special process shall be specified or referenced in procedures or instructions. The organization responsible for developing the special process (e.g., FBP) qualifies, approves, and verifies the special process. If subcontracted work, the subcontractor develops and submits the special process to FBP for review and approval in the form of a submittal. Records shall be maintained for qualified personnel, processes, and equipment for each special process.

## **5.4 CONTROL OF MEASURING AND TEST EQUIPMENT**

- 5.4.1.** Tools gauges, instruments, and other measuring devices used during the construction and operation of the OSWDF by FBP personnel or subcontractors shall be controlled, calibrated, and maintained to required accuracy limits. Procedures shall be developed to ensure Measuring and Test Equipment (M&TE) is of the proper type, range, accuracy, and calibration frequency needed to accomplish the required measurements for determining conformance to specified requirements.
- 5.4.2.** Calibration shall be against and traceable (per National Institute of Standards Technology [NIST]) to certified equipment or reference standards having known valid relationships to nationally recognized standards. Where no standards exist, the basis for calibration shall be defined. Reference standards shall have a minimum four times greater than that of the M&TE being calibrated. Where the 4:1 ratio cannot be maintained, the basis for selection of the standard shall be technically justified.
- 5.4.3.** When M&TE is lost, damaged, or found to be out of calibration; initiate a PR and the extent of condition shall determine the validity of previous measurements, inspection, or test results shall be re-evaluated for acceptability from at least the last acceptable calibration of the suspect M&TE.
- 5.4.4.** M&TE shall be:
- Traceable to its application and use.
  - Marked or labeled to indicate calibration status and traceability to calibration records.
  - Properly handled and stored to maintain accuracy, including environmental controls.
  - Submitted for calibration check and results recorded before any adjustments or repairs are made.
  - Tagged or segregated to prevent its use if found to be damaged, past calibration due date, or out of tolerance.
- 5.4.5.** Records shall be maintained to indicate calibration status. Calibration reports and certificates shall include the information and data necessary for interpretation of the calibration results and verification of conformance to applicable requirements.

## **5.5 HANDLING, STORAGE, AND SHIPPING**

- 5.5.1.** The requirements for handling, storing, shipping, cleaning, and preservation of items that will be used on the OSWDF project shall be defined in FBP procedures for self-performed work and in subcontractor work documents and procedures for subcontracted work.
- 5.5.2.** Included in the work documents and procedures shall be instructions for marking and labeling items for packaging, shipping, handling, and storing to adequately identify, maintain, and preserve the items' integrity, including indication of the presence of special environments, controls, and safe handling requirements.

## 5.6 INSPECTION, TEST, AND OPERATING STATUS

- 5.6.1** Indicators shall be used by OSWDF Project and subcontract personnel to identify the status of inspections and tests to ensure required inspections and tests are performed and 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 locations and tags, markings, inspection records, work travelers, stamps, or other suitable means. The process for using status indicators shall be proceduralized and include responsibilities and authority for removal.
- 5.6.2** Procedures shall also include a method for indicating the operating status of systems and components of a facility, such as the ILTS/MLTS, by tagging valves and switches to prevent inadvertent operation.

## 6.0 DESIGN CONTROL

### 6.1 BASIC

- 6.1.1** Controls are established to ensure that items and processes are designed using sound engineering and scientific principles and the selection of appropriate standards using the graded approach. Procedures are developed that define the design process from initial conception through final design approval. Design changes shall be governed by control measures commensurate with those applied to the original design.
- 6.1.2** Design may be self-performed by OSWDF or performed by organizations external to FBP commonly referred to as architect-engineer (A-E) firms. Regardless of who develops the design, the FBP Engineering Manager is the design authority and ultimately responsible for approving all designs developed for the OSWDF project.
- 6.1.3** When a design is to be developed by an A-E or another organization external to FBP, the requirements with the appropriate level of rigor shall be contractually flowed down to the subcontractor through the subcontract language.
- 6.1.4** The OSWDF project will use FBP approved design control procedures, or if the design is subcontracted to an A-E firm, the A-E firm will submit their design control procedures to FBP for approval prior to commencement of the design.
- 6.1.5** The following design process sections are standard requirements from FBP-QA-PDD-00001, *Quality Assurance Program Description (QAPD)*, and shall apply to OSWDF self-performed design; or if the design is subcontracted, the FBP design requirements shall flow down to the subcontractor(s) performing design activities.

### 6.2 DESIGN INPUT

- 6.2.1** Design inputs are identified and documented, and their selection reviewed and approved. The design input shall be specified to the level of detail necessary to permit the design activities to be carried out in a correct manner and to provide a consistent basis for making design decisions, accomplishing design verification measures, and evaluating design changes.



**6.2.2** Requirements for determining the design basis may include:

- Basic function and performance requirements
- Safety basis requirements
- Environmental conditions
- Material requirements
- Safety, quality, and fire protection requirements
- Reliability requirements
- Applicable code, standards, and other quality requirements

### **6.3 DESIGN PROCESS**

**6.3.1** The responsible design organization prescribes and documents the design activities in specifications, calculations, drawings, test plans, etc., in accordance with approved procedures, to the level of detail necessary to permit the design process to be carried out in a correct manner and to permit verification that the design meets all requirements. Design documents support OSWDF design, construction, and operation.

**6.3.2** The design methods, materials, parts, equipment, and processes that are essential to the function of the items are selected and reviewed for suitability of application. Applicable information derived from experience, as set forth in reports or other documentation, is made available to applicable design personnel.

**6.3.3** OSWDF engineering ensures that each final design:

- Is traceable to the design input by documentation in sufficient detail to permit design verification.
- Specifies required inspections and tests and includes and references appropriate acceptance criteria.
- Identifies assemblies and/or components that are a part of the item being designed. When such assembly or component part is a Commercial Grade Item (CGI), the critical characteristics of the item to be verified for acceptance and the acceptance criteria for those characteristics shall be documented.
- Ensures Commercial Grade Dedication (CGD) shall be performed in accordance with approved FBP procedures, or procedures approved by FBP if CGD is performed by a subcontractor.

**6.3.4** The design control processes correctly translate appropriate codes, standards, and quality requirements to ensure SSCs meet their specified design requirements, and their selection reviewed and approved. The modification team is required to ensure a multi-discipline review is performed which identifies interface requirements, identifies design input requirements, performs design input/output reconciliation, and approves design implementation requirements. The design control process is performed in accordance with approved FBP design control procedures, or procedures approved by FBP procedures if performed by a subcontractor.

## 6.4 DESIGN ANALYSIS

The design analysis process shall be sufficiently detailed in drawings, specifications, calculation, etc., that such a person technically qualified in the subject can review and understand the analyses and verify the adequacy of the results without recourse to the originator.

## 6.5 DESIGN VERIFICATION

**6.5.1** The OSWDF project identifies and documents the particular design verification method(s) to be used. The methods shall be compliant with FBP site design control procedures.

**6.5.2** Results of the design shall be documented with the identification of the verifier's clearly indicated. Design verification is performed by any competent individual(s) other than those who performed the original design, but who may be from the same organization. The verification may be performed by the originator's supervisor, provided the supervisor did not specify a singular design approach or rule out certain design considerations and did not establish the design inputs used in the design; or the supervisor is the only individual in the organization competent to perform the verification.

## 6.6 CHANGE CONTROL

**6.6.1** Configuration Management (CM) (FBP-NSE-PDD-00002, *Configuration Management Program Description*) is applicable to the OSWDF project. CM procedure implementation of operating facilities, e.g., OSWDF and the ILTS/MLTS, shall be established and documented at the earliest practical time prior to operation and CM shall be maintained for the life of the facility. CM procedures shall include the responsibilities and authorities of the organizations whose function affect the configuration of the OSWDF and ILTS/MLTS including activities such as operators, designs, maintenance, construction, licensing, and procurements. The design change process per FBP-NSE-PRO-00081, *Design Control*, applies to all facility changes.

**6.6.2** The configuration of a facility shall be documented in drawings, specifications, procedures, and other documents that reflect the operation of the facility. The configuration includes, as applicable, characteristics derived from regulatory requirements and commitments, calculations and analyses, design inputs, installation and test requirements, supplier manuals and instructions, operating and maintenance agreements, and other applicable sources.

## 6.7 INTERFACE CONTROL

Design interfaces shall be identified/established during the design phase and controlled using subcontract language, procedures, instructions, and/or formal agreements to provide effective coordination of design effort among and within participating organizations. This interface control is provided by the CM Program FBP-NSE-PDD-00002, *Configuration Management Program Description*, and the design change procedure FBP-NSE-PRO-00081, *Design Control*. These controls include a description of the responsibilities of the affected organizations for initiation, development review, approval, release, distribution, revision of design documents, and management of the overall design tasks.

## 6.8 CONTROL OF ENGINEERING SOFTWARE

Refer to Section 11, *Software QA*, for the development, verification, validation, and use of engineering software in support of the OSWDF project.

## 7.0 PROCUREMENT

### 7.1 PROCUREMENT DOCUMENT CONTROL

- 7.1.1 To ensure procured items and services meet established requirements and perform as specified, the OSWDF project shall use approved FBP procedures for preparing, reviewing, and approving purchase requisitions, procurement specifications, bid packages, and other procurement documents.
- 7.1.2 Procurement documents shall incorporate supplier QA program requirements as necessary for the type of procurement. The type of requisition will include the assigned Quality Level (QL). Quality Levels are directly related to the general quality levels described in Subsection 1.6, *Graded Approach*.
- 7.1.3 Purchase requisitions shall include reviewers with the knowledge, expertise, and information necessary to ensure appropriate requirements have been identified in the requisition.
- 7.1.4 Any technical and/or QA changes to procurement documents after approval shall be processed with the same controls as the original document. All required reviews and approvals, including budget approvals and issue requisitions or revisions, are the responsibility of the origination organization and are documented prior to award.

### 7.2 CONTROL OF PURCHASED ITEMS AND SERVICES

- 7.2.1 The procurement of items and services for the OSWDF project shall be controlled to ensure conformance to specified requirements. Controls include, as appropriate, supplier evaluation and selection based on their QA program meeting the requirement of the applicable subcontract QA program, review of objective evidence provided by the supplier to demonstrate that the item/service meets requirements, source verification, assessments, surveillances, and receipt inspection of items.
- 7.2.2 FBP QA maintains a Qualified Suppliers List (QSL) for certain QL-1 and QL-2 procurement and selected QL-3 when requested by the project. While the supplier program is based on ASME NQA-1 (2008/Addendum 2009), certain procurement activities may invoke other nationally recognized consensus standards such as International Organization for Standardization (ISO) and The NELAC Institute (TNI) Standards Volume 1, (September 2009), Quality Systems Manual (QSM) for Environmental Laboratories, American Association for Accreditation (A2LA), or National Voluntary Accreditation Program (NVLAP).
- 7.2.3 FBP approved procedures are used for supplier selection, suitability determination, evaluation, and receipt of items; or acceptance of services. Project management, engineering, procurement, and quality determine the need to procure a qualified supplier.

- 7.2.4** Prospective suppliers are evaluated to ensure the quality programs meet the required quality standard. The review is documented on FBP-QA-PRO-00016-F02, *Supplier Desktop Assessment*, included in procedure FBP-QA-PRO-00016, *Procurement Quality*.
- 7.2.5** Reviewers of suppliers' documentation and in-plant assessment of the supplier's capabilities may be used for supplier qualification based on the nature and application of items or services being procured. Post-award assessments may be performed on selected suppliers to verify compliance with the procurement requirements.
- 7.2.6** All approved QL-1, QL-2 and QL-3 suppliers are evaluated annually to ensure the quality documentation is current and the performance history is acceptable. These reviews are documented on FBP-QA-PRO-00016-F03, *Supplier Performance Review*. QL-1 and QL-2 suppliers receive a triennial supplier assessment to evaluate effectiveness, implementation, and adequacy of their programs.
- 7.2.7** QL-4 suppliers are selected based on the ability to produce a product or service that will meet the technical, safety, and business requirements established for the product or service. These items and services do not require to be approved per the FBP QA organization and are not maintained on the QSL.
- 7.2.8** Approved suppliers are added to the FBP QSL. Subcontractor-approved suppliers are added to the FBP QSL when subcontractor procurement quality programs and other applicable program requirements have been accepted by FBP.
- 7.2.9** Procured software and software services shall be purchased in accordance with the requirements in FBP-BS-PRO-00039, *Request for Purchase*; FBP-SMPO-AG-002, *Software Procurement Administrative Guide*; and FBP-QA-PRO-00016, *Procurement Quality*, including requirements for software supplier audit.

### **7.3 CONTROL OF SUPPLIER GENERATED DOCUMENTS**

The controls for identifying supplier technical and quality verification document requirements (submittals/deliverables) for items and/or services to be included in the Subcontractor Submittal Register and guidelines for the technical review of these documents by FBP are identified in FBP-implementing procedures. Supplier submittals and deliverables are processed according to approved FBP procedures.

### **7.4 ACCEPTANCE OF ITEM OR SERVICE**

- 7.4.1** It is the supplier's responsibility to verify that the item or service meets procurement requirements prior to providing the item/service for acceptance and for providing documentary evidence when required by contract requirements.
- 7.4.2** Several methods for the acceptance of items and services are used, either singularly or in combination with each other:
- Certificates of conformance, when required, are identified in procurement documents and are verified during the item receipt or acceptance of service.
  - Source verification may be used to accept an item or service. Source verification may also be used to verify the validity of supplier-provided certificates.

- Receipt inspections or inspections at the supplier's facility are performed per approved inspection/test plans or procedures, including verification that specified documentation have been provided by the supplier.
- Post-installation testing requirements are typically called out in work documents that may include requirements or cite a test plan or procedure to be used. Test plans are developed by engineering with the assistance of QA and the requesting organization.

## **7.5 CONTRACTOR PERFORMANCE**

Contractor performance is monitored through inspection, surveillance, and assessment by FBP. On an ongoing basis, issues or trends associated with contractor or supplier/vendor performance are documented, communicated, and resolved.

## **7.6 CONTROL OF SUPPLIER NON-CONFORMANCES**

The process for control and disposition of supplier items and services which do not meet requirements are identified in procurement documents which provides for the identification, documentation, reporting, evaluation, and resolution of nonconforming conditions and prevents inadvertent use or installation of unacceptable or unqualified items. Identified potential nonconforming conditions are documented in accordance with the supplier quality program reviewed and approved by FBP.

## **7.7 COMMERCIAL GRADE ITEMS (CGI)**

FBP-NSE-PRO-00098, *Engineering Specifications for Procurement and Acceptance*, or an approved subcontractor CGI procedure, shall be used for the dedication, storage, and approval of CGIs and services. FBP-NSE-PRO-00098, *Engineering Specifications for Procurement and Acceptance*, will provide the guidance for evaluation of CGIs during procurement and subsequent use on the project.

# **8.0 INSPECTION AND ACCEPTANCE TESTING**

## **8.1 INSPECTION**

- 8.1.1** OSWDF inspections required to verify conformance of items, processes, and services to specified requirements, or the continued acceptability of items in service are planned, conducted, and documented using established performance and acceptance criteria.
- 8.1.2** Inspection personnel shall be qualified by discipline including, but not limited to, civil, electrical, mechanical, visual, and non-destructive testing. Inspections will be performed by individuals other than those who performed the work.
- 8.1.3** Inspection personnel shall be provided with appropriate training including on-the-job training under the supervision of a qualified person. Personnel performing inspections have the authority to access appropriate information and facilities to conduct inspection and have the freedom to report the results of inspections.
- 8.1.4** Mandatory inspection hold points required beyond which work cannot proceed without the specific consent of a designated discipline are indicated in work control documents including work documents, inspection plans, or procedures.

- 8.1.5** OSWDF work control documents are the primary documents used to identify mandatory hold points. Hold points identified as work control documents are developed based on input from various disciplines. In the sequence of steps, once a hold point is reached, it cannot be passed by until the conditions of the hold point have been satisfied. Continuation of work without obtaining hold point verification requires a revision to the work document and removal of the hold point from the work document instructions.
- 8.1.6** Completed items are inspected verifying the quality and conformance of the item for final acceptance to ensure that all requirements have been satisfied.
- 8.1.7** Final acceptance is approved only by authorized personnel. Accepted items are identified and controlled, and documented to ensure that periodic (e.g., in-service) inspections or tests are conducted to maintain continued adequate performance of their required function.
- 8.1.8** M&TE, when required, is selected based upon type, range, accuracy, and tolerance needed to achieve required precision and accuracy. See Subsection 5.4, *Control of Measurement & Testing Equipment*.

## **8.2 TEST CONTROL AND M&TE**

- 8.2.1** Test requirements and acceptance criteria are developed by OSWDF engineering, QA, and/or Subject Matter Experts (SMEs) and approved by designated organizations. Required tests including, as appropriate, vendor tests, receipt acceptance tests, construction acceptance tests, pre-operational tests, operational tests, and site acceptance tests are controlled.
- 8.2.2** Test requirements and acceptance criteria are based upon specified requirements contained in applicable design documents or other pertinent technical documents that provide approved requirements, including applicable codes, standards, and regulatory requirements.
- For additional testing requirements, **go to** Step 11.7.1.
- 8.2.3** Test plans, test procedures, or other work control documents include or reference the test configuration and test objectives. The testing may be for determination of hardware or software acceptance. They also include provisions for assuring that prerequisites and suitable environmental conditions are met, adequate instrumentation is available and used, appropriate M&TE are used, and necessary monitoring is performed.
- 8.2.4** As an alternative to this requirement, appropriate sections of related documents, such as ASTM International methods, supplier manuals, equipment maintenance instructions, approved drawings, or travelers with acceptance criteria can be used.
- 8.2.5** Item and process test requirements, including specified acceptance criteria, are provided or approved by the organization responsible for design. Engineering has the primary responsibility for establishing and approving test requirements and associated acceptance criteria. Designated operations personnel review the test packages for impact on and interface with operating systems and confirm that proposed testing will provide adequate validation that the equipment being tested will perform its design functions. Administrative controls and status indicators are used to preclude inadvertent bypass or non-completion of required tests or operation of untested items or processes.
- 8.2.6** Test controls requirements flow down to subcontractors in subcontract terms and conditions, as appropriate.

- 8.2.7 Test results are documented in test plans, test reports, or work documents as defined by implementing procedures for the specific testing application. Results are evaluated by a responsible authority as defined in implementing procedures or test plans to ensure that test requirements have been satisfied.
- 8.2.8 When items and processes do not meet documented test acceptance criteria, these deficiencies are documented on NCRs.
- 8.2.9 Equipment used for inspections and testing is controlled, calibrated, and maintained according to the program. Traceability and accountability of this equipment are also required. Refer to Subsection 5.4, *Control of Measuring and Test Equipment*, for additional M&TE requirements.
- 8.2.10 Test records are established and maintained to indicate the ability of the item or computer program to satisfactorily perform its intended function or to meet its documented requirements.

## 9.0 ASSESSMENTS

### 9.1 MANAGEMENT ASSESSMENT

- 9.1.1 The OSWDF management team is responsible for assessing their areas of responsibility on a scheduled frequency. Management assessments are planned and integrated into the site wide FBP assessment schedule through coordination and collaboration with the FBP Performance Assurance organization according to FBP-QP-PRO-00010, *Management Assessment*. OSWDF management assessments are planned prior to the beginning of each fiscal year.
- 9.1.2 The management assessments are performed by managers, or direct reports, to identify and correct problems that may hinder the organization from achieving its goals and objectives. Assessments measure the effectiveness of applicable policies, requirements, standards, processes, and procedures, and their implementation. Managers ensure results contribute to improved performance.
- 9.1.3 OSWDF management assessments can include evaluation of work being performed by subcontractors.
- 9.1.4 Assessors and Lead Assessors performing management assessments shall be trained and qualified per FBP-QP-PDD-00002, *Training and Qualification of Assessment Personnel*.

### 9.2 INDEPENDENT ASSESSMENT

- 9.2.1 The process for performing independent assessment are similar to management assessments, except those performing independent assessments have no direct responsibility for the work scope or organization being assessed.
- 9.2.2 Independent assessments are performed to measure the effectiveness of work control processes during the design, construction, and operations of the OSWDF according to FBP-QP-PRO-00011, *Independent Assessment*.
- 9.2.3 Assessors and Lead Assessors performing independent assessments shall be trained and qualified per FBP-QP-PDD-00002, *Training and Qualification of Assessment Personnel*.

- 9.2.4** The QA Assessor and Lead QA Assessor performing QA program assessments shall be qualified in accordance with procedure FBP-QA-PRO-00070, *Training, Qualification, and Certification of NQA-1 Auditors and Lead Auditors*.

### **9.3 SURVEILLANCE AND INSPECTION**

#### **9.3.1 SURVEILLANCE**

- A.** Surveillances augment the OSWDF assessment process and provide management with observation-based assessments of project or area conditions; quality of work being performed; adequacy of procedures; and compliance with requirements, material conditions, safety, and housekeeping practices. Surveillances are to be performed according to FBP-QP-PRO-00023, *Surveillances*.
- B.** Surveillances typically focus on a single operation, activity, or process. They frequently involve observation of real-time activities augmented by discussions and interviews with personnel, review of documentation to verify conformance with specified requirements, or detailed walk-downs of designated areas.
- C.** OSWDF QA will plan and schedule project surveillances during the design, construction, and operation of the OSWDF to verify effective implementation of project plans and procedures, to ensure work controls have been established, and to verify OSWDF is built in accordance with project design documents. The scope of surveillances will include subcontractor work activities and/or a review of subcontractor documentation.
- D.** Surveillances will be performed in accordance with, and by QA personnel qualified to FBP-QP-PRO-00023, *Surveillances*. Results will be documented and discussed with affected management and identified issues documented in accordance with FBP-QP-PRO-00020, *Problem Reporting and Issues Management*.

#### **9.3.2 INSPECTION**

- A.** Inspection may be performed by FBP or subcontract personnel. The qualification and training of inspection personnel shall be in accordance with Section 2.0, *Personnel Training and Qualification*, and applicable FBP and subcontract personnel training and qualification procedures.
- B.** The OSWDF will subcontract a CQC contractor to provide QC oversight during construction of the OSWDF and during placement of impacted materials in the cell during the operational phase of the OSWDF. See CQC key project responsibilities Step 1.2.8 of this PQAP.

### **9.4 REPORTING AND FOLLOW-UP**

Reporting and follow-up shall be performed in accordance with the applicable assessment procedure. Issues identified during assessments shall be documented in accordance with the FBP quality improvement program or for subcontracted work, in accordance with an FBP approved subcontractor QA Program.



## 10.0 SUSPECT/COUNTERFEIT ITEM (S/CI)

### 10.1 S/CI

- 10.1.1** The OSWDF project will implement the FBP S/CI program as defined in FBP-QA-PDD-00002, *Suspect/Counterfeit Item Oversight and Control Program Description*, and implemented by procedure FBP-QA-PRO-00014, *Suspect/Counterfeit Items*.
- 10.1.2** FBP implements the S/CI program using a graded approach. Through the procurement planning process, the QL is assigned based upon an analysis of the item's function relative to nuclear and radiological safety, mission critical, and consequence of failure. This ensures that those items with the greatest consequence upon failure (safety-class, safety system, mission critical, critical load path) will undergo inspection by QC inspectors trained in S/CI identification. For all other procurements and installed equipment, FBP will rely upon a workforce that has been trained and is aware of S/CI issues to be vigilant to the potential for suspect or counterfeit items and components. This training may take the form of group briefings or computer-based modules.
- 10.1.3** The principal objectives of the FBP S/CI controls program are to:
- Ensure that items intended for application in safety systems and mission critical facilities comply with design and procurement documents.
  - Maintain current, accurate information on S/CI and associated suppliers using all available sources within the government and industry and disseminate relevant information on S/CIs to field organizations and contractors.
  - Identify, control, and disposition S/CI that create potential hazards in safety systems and applications.
  - Report discoveries of and disseminate information about S/CI to field organizations, contractors, and government agencies.
  - Train and inform managers, supervisors, and workers of S/CI controls and indicators including prevention, detection, and disposition of S/CI.
- 10.1.4** All S/CIs, regardless of their application, quality level grading, or method of discovery are processed in accordance with FBP-QA-PRO-00014, *Suspect/Counterfeit Items*.
- 10.1.5** An occurrence report is required to be generated only on installed S/CI which is found to be part of a safety SSC or in any application which would present a safety hazard to the worker or public health. Determination of occurrence report ability is conducted according to the problem reporting system screening process. S/CI which requires an occurrence report is reported to the DOE Office of Inspector General (OIG).
- 10.1.6** After determination of any S/CI, whether installed or not installed, the OIG must be contacted before destroying or disposing of the S/CI and their corresponding documentation to determine whether to retain them for criminal investigation or litigation.

**10.1.7** FBP-QA-PRO-00014, *Suspect/Counterfeit Items*, includes the following commitments for:

- Preventing the introduction and use of S/CI through engineering involvement, design, procurement, receiving inspection, testing, field surveillance, maintenance, evaluation of reports, trend analysis, lessons learned, and work process controls.
- Ensuring that the procurement documents require the vendors or suppliers to certify that S/CIs are not contained in the items or materials they provide. A standard S/CI clause is contained in the procurement documents, regardless of the safety classification for material requisitions (as applicable).
- Training and informing appropriate managers, supervisors, and workers on S/CI processes and controls (including prevention, detection, and disposition of S/CI).
- Performing field surveillances to minimize the possibility of introduction and use of S/CI in equipment and facilities, and to identify S/CI that may have been inadvertently placed in service during previous work processing.
- Identifying, controlling, and dispositioning S/CI on-site.
- Restricting S/CI use to only those items that have been identified, documented, and found acceptable through engineering analysis and formal disposition process.
- Collecting, maintaining, disseminating, and using the most accurate, up-to-date information on S/CI and associated suppliers using all available sources. S/CI information sources include the following:
  - a) DOE S/CI Website
  - b) DOE Occurrence Reporting and Processing System
  - c) FBP Operating Experience/Lessons Learned Program
- Identifying the management Point-of-Contact (POC) responsible for these activities to ensure that the DOE Office of ES&H has a viable recipient for S/CI information notices. The FBP management point-of-contract for S/CI activities is the S/CI SME. It is the POC's responsibility to ensure the DOE Inspector General is notified and obtain concurrence prior to disposal or destroying of S/CI.

## **11.0 SOFTWARE QA (SQA)**

### **11.1 CONTROL OF COMPUTER SOFTWARE**

- 11.1.1** FBP has established a Software Management Program (SMP) compliant with DOE O 414.1D. The SMP was developed using ASME NQA-1 (2008/Addendum 2009), Part I and II. The SMP provides controls for the acquisition, development, maintenance, operation, and retirement of software.
- 11.1.2** Software is defined as computer programs and associated documentation and data pertaining to the operation of a computer system. Within the scope of the SMP, software includes spreadsheet or database calculations that are used to support decisions or as input to planning documents.

- 11.1.3** The details of the SMP are provided in FBP-SMPO-PDD-00005, *Software Management*, which establishes a common framework for controlling software for its entire lifecycle and applies to all FBP employees, affiliates, and subcontractors that develop, procure, modify, maintain, operate, use or retire software.
- 11.1.4** All software is evaluated, following a process defined in the SMP, to determine whether it is to be subjected to the requirements of the SMP.
- 11.1.5** The SMP does not apply to site licensed and metered software (e.g., Microsoft Outlook and Microsoft Word). However, it does apply to user-developed spreadsheets and database reporting applications based on software such as Microsoft Excel and Microsoft Access that are within the scope of the SMP.
- 11.1.6** Software determined to be within the scope of the SMP requirements is graded and categorized to identify the applicable Software Management Quality Assurance (SMQA) criteria for work activities.
- 11.1.7** The data processed by software applications are protected from unauthorized access due to the level of sensitivity (e.g., classified, unclassified sensitive). Access to FBP owned software is limited to authorized individuals either by password protection, physical location, network accessibility, or a combination of all three. Major applications have separated production and development environments to further protect data and performance. Subcontractors are responsible and accountable for ensuring that software data is controlled for subcontracted work. Subcontractor software management must be performed in accordance with the SMP.

## 11.2 ASSIGNING SOFTWARE LEVELS

### 11.2.1 SOFTWARE LEVELS

- A.** Software that is controlled by the SMP is characterized into two primary categories, Safety-Related (Nuclear) software, and other software.
- B.** Software grades determine applicability of Software Management Program Office (SMPO) program elements. Software grading designations are Software Levels (SL)-1, -2, -3, and -4.
- C.** Safety software refers to nuclear safety-related (nuclear) software and is designated as SL-1 or -2.
- D.** SL-1 is credited as Safety Class SSC Software. Software for a nuclear facility that performs a safety function as part of an SSC and is cited in either (a) a DOE-approved documented safety analysis; or (b) an approved hazard analysis per DOE Policy (P) 450.4A, *Integrated Safety Management Policy*, and 48 CFR 970.5223-1, *Integration of Environment, Safety, and Health into Work Planning and Execution*. SL-1 failure could likely compromise the safety function of a Safety Class SSC as cited in a DOE approved DSA.
- E.** SL-2 is Safety-Related (nuclear) Software that does not meet the definition for Level 1 software, but meets any of the following definitions:
  - **Safety System Software (SSS)** Software for a nuclear facility that performs a safety function as part of an SSC and is cited in either (a) a DOE-approved

documented safety analysis; or (b) an approved hazard analysis per DOE P 450.4A and 48 CFR 970.5223-1.

- **Safety and Hazard Analysis Software and Design Software (SHADS)**  
Software that is used to classify, design, or analyze nuclear facilities. This software is not part of an SSC but helps to ensure the proper accident or hazards analysis of nuclear facilities or an SSC that performs a safety function.
  - **Safety Management and Administrative Controls Software (SMACS)**  
Software that performs a hazard control function in support of nuclear facility or radiological safety management programs or technical safety requirements or other software that performs a control function necessary to provide adequate protection from nuclear facility or radiological hazards. This software supports eliminating, limiting, or mitigating nuclear hazards to workers, the public, or the environment as addressed in 10 CFR Parts 830 Subpart A and Part 835, *Occupational Radiation Protection*.
- F.** SL-3 is Non-Nuclear Safety Software that is important to the mission, safety, environment, or public; or warrants a higher SL of rigor.
- **Safety Affecting Software (SAS)** Software that contributes to the control of radiological, biological, chemical, and physical hazards defined by FBP's ISMS hazard analysis process. This includes software whose failure could have a high safety or health consequence.
  - **Critical Software (CS)** This is software that is relied upon to keep a facility or process operating as desired. This category involves software whose failure could pose a moderate to high consequence but not a direct health or safety consequence.
- G.** SL-4 is all other software that is not exempt from the FBP-SMPO-PDD-00005, *Software Management*, for which a minimum SL of rigor has been defined.
- Toolbox and Toolbox equivalent software applications acknowledged as part of DOE's Safety Software Central Registry such as ALOHA, CFAST, etc., should be acquired, maintained, and controlled per FBP-SMPO-PDD-00005, *Software Management*.
- H.** At FBP, all Safety-Related (nuclear) Software is designated SL-2 unless the software is part of a system or component determined to be SL-1. It is acceptable to upgrade the SL if the potential consequence of the software failure warrants the upgrade.

### 11.3 SOFTWARE TYPES

**11.3.1** In addition to the SLs, software is categorized as one of the following five types. The software type is used in conjunction with the SL in determining the SMQA work activities that apply to the software lifecycle.

- A.** Acquired
- B.** Configurable
- C.** Custom Developed

- D. Commercial Design and Analysis
- E. Utility Calculation

11.3.2 The software types and their applicability are described in the SMP.

#### 11.4 SOFTWARE MANAGEMENT QA (SMQA) WORK ACTIVITIES

11.4.1 The SMP describes applicable software implementation plan requirements.

11.4.2 There are ten work activities of SMQA that are to be incorporated into the software implementation plan using a graded approach, based on the SL and software type.

- A. Software Project Management and Quality Planning
- B. Software Risk Management
- C. Software Configuration Management (SCM)
- D. Software Procurement and Supplier Management
- E. Software Requirements Identification and Management
- F. Software Design and Implementation
- G. Software Safety
- H. Verification and Validation
- I. Problem Reporting and Corrective Actions
- J. Personnel Training

11.4.3 The SMQA element requirements for their application are described in the SMP.

11.4.4 Software owners are required to develop and maintain a Software Documentation Folder (SDF) that contains information documenting the application of the SMQA work activities.

#### 11.5 SOFTWARE LIFECYCLE

11.5.1 The SMP establishes requirements for the entire software lifecycle from initial planning through retirement. Lifecycle elements include:

- A. Planning and Requirements
- B. Design
- C. Implementation (Testing and Deployment)
- D. Operation ( Maintenance, Modification, and Configuration/Change Management)
- E. Retirement

11.5.2 Requirements associated with the phases of the software lifecycle are defined in the SMP.

#### 11.6 SOFTWARE INVENTORY LIST

11.6.1 A Software Inventory List (SIL) is maintained for all site identified software that falls under the purview of the SMP. Requirements for maintaining the SIL are defined in FBP-SMPO-PRO-00004, *Management of Software Inventory List*.

- 11.6.2** The SIL is required to include the following identifying information, as a minimum: software description, software name, version identifier, software classification, SL, facility application, platform, software owner, and safety software as defined in DOE O 414.1.D, Attachment 4.

## **11.7 SOFTWARE TESTING**

- 11.7.1** Requirements for testing of software are defined in the SMP and FBP-SMPO-PRO-00003, *Software Testing*.
- 11.7.2** FBP uses both commercial off-the-shelf and government off-the-shelf software that has been certified, validated by a third-party, or which is delivered with documentation that assures software functionality. The SMP requires that the software owners perform in-house testing to demonstrate that the software provides acceptable results on the platform on which the software is being used.
- 11.7.3** Nuclear Criticality Software (NCS) software, verification and validation are described in NCSR-12-001, *Nuclear Criticality Safety Report Configuration Control Plan for the Nuclear Criticality Safety Computer Workstations and Software*, and FBP-SMPO-PL-00001, *Software Configuration Management*. Verification and validation of NCS software is required when software is modified, a new version of software is installed, the area(s) of applicability of the software must be extended, or the Central Processing Unit (CPU), hard drive or operating system is replaced. An NCS Engineer is assigned to perform the verification and validation process which is documented and receives a peer review and approval. A pre-determined set of input files (verification input files) that is designed to test the applicable portions of the NCS software are run and compared to the results obtained from the configuration-controlled version. Validation of the NCS software includes developing or acquiring a set of input files to be executed by the computer code, ensure the input files selected represent the area(s) of applicability for which calculations will be performed, running the code, and evaluating the output to ensure adequate coverage throughout the area(s) of applicability. The results are documented and the NCS Manager reviews and approves the report.
- 11.7.4** Software test are maintained in accordance with the requirement of the SMP to document the software's ability to perform its intended function and meet defined specifications. The records will vary depending on the type, purpose, and application of the software.

## **11.8 SOFTWARE DOCUMENTATION FOLDER**

- 11.8.1** The SDF serves as the primary record for all aspects of the development and management of software controlled by the SMP.
- 11.8.2** Software documentation is to be maintained (i.e., digital format) in a repository within the SDF.
- 11.8.3** The SDF structure must be such that different applications or software programs are separated and identifiable, to allow ready retrieval of documents.
- 11.8.4** Requirements defining documentation that must be included in the SDF are provided in the SMP.

## 11.9 SOFTWARE ACQUISITION

### 11.9.1 Procured Software and Services

- A. All procured software must meet the requirements of the SMP.
- B. Procured software and software services shall be purchased in accordance with the requirements in FBP-BS-PRO-00039, *Request for Purchase*, FBP-NSE-PRO-00098, *Engineering Specifications for Procurement and Acceptance*, and FBP-QA-PRO-00016, *Procurement Quality*.

### 11.9.2 Commercial Dedication of Acquired Software

- A. Dedication of purchased CGIs and Services shall be applied to the acquisition of QL-1 and QL-2 Safety-Related Software that is procured from an unevaluated supplier.
- B. CGD shall be performed in accordance with FBP-NSE-PRO-00098, *Engineering Specification for Procurement and Acceptance*.
- C. CGD does not apply to non-nuclear safety related software (SL-3 and SL-4). However, SL-3 and SL-4 software is required to follow the requirements of the SMP.

## 11.10 ENVIRONMENTAL COMPUTER MODELING

FBP may utilize computer models in the course of completing the project scope. It is anticipated that FBP will use commercial off-the-shelf models or generate models from computer programs acquired from DOE Safety Software Central Registry. Controls for environmental Computer Models are described in the SMP.

## 11.11 SOFTWARE OWNERS

- A. Retain overall responsibility for assigned software and associated software documentation per FBP-SMPO-PDD-00005, *Software Management*, including Software Inventory List (SIL) data per FBP-SMPO-PRO-00004, *Management of Software Inventory List*.
- B. Ensure users of software under their purview are properly trained and qualified.
- C. Conduct annual self-assessments of their SDF and information for their software on the Software Inventory List. In addition, SMPO will be conducting independent assessments to ensure compliance with SMP Requirements.

## 11.12 SOFTWARE RECORDS

Software records are defined as Quality Records and must meet the requirements of this QAPD, the SMP, and FBP-BS-PRO-00062, *Records Management*.

## 12.0 DEFINITIONS/ACRONYMS

### 12.1 DEFINITIONS

- A. **Authentication** – The act of attesting that the information contained within a document is accurate, complete, and appropriate to the work accomplished. Authentication is accomplished by statements of authenticity, handwritten signatures, electronic signatures or other means which ensures traceability to a specific individual or group of authentication and associated date are acceptable methods of authentication. Electronic documents are required to have authentication information identified on the media or contained within or linked to the document itself.
- B. **Design Authority** - The organization having the responsibility and authority for approving the design bases, the configuration, and changes thereto.
- C. **Finding** – An individual item that does not meet requirements based on objective evidence.
- D. **Issue** – A problem that may require corrective measures to prevent reoccurrence which include deficiencies , non-conformances, non-compliances, findings, and observations that have a potential to cause adverse operational, conduct of operations, environmental, safety, health, or QA consequences.
- E. **Job Hazard Analysis** – A system that identifies hazards associated with each step of a job and develops solutions for each hazard that will either eliminate or control the hazard. This process is also known as activity hazard analysis, job task analysis, or other names.
- F. **Measuring and Test Equipment (M&TE)** – Devices or systems used to calibrate, measure, gage, test, or inspect in order to control or acquire data to verify conformance to specified requirements.
- G. **Observation** – A situation the assessor determines should be brought to management’s attention, but which in not an issue, noteworthy practice. An observation may be positive or negative and includes strengths, areas of improvement, and recommendations for process/program improvement or cost-saving ideas.
- H. **Operations** – The transfer and placement of impacted materials from the D&D facilities and soil excavation areas to the OSWDF and the operation of the Interim Leachate Treatment Facility/Modular Leachate Treatment System (ILTS/MLTS).
- I. **Quality Assurance (QA)** – All those planned and systematic actions necessary to provide adequate confidence that a SSC will perform satisfactorily in service.
- J. **Quality Control (QC)** – Part of quality management focused on verification of fulfilling requirements.
- K. **Quality Level (QL)** – The process for applying a graded approach using criteria to select an appropriate level of rigor for designing. Reviewing, planning, procuring, inspection, maintaining, and accepting activities performed for SSCs in the Documented Safety Analysis (DSA) or Basis for Interim Operations (BIO) or relative risk to employees, the environment, and the public.

### 12.2 ACRONYMS

- A. **A-E** – Architect-Engineer
- B. **ASME** – American Society of Mechanical Engineers



- C.** **ASNT** – American Society of Nondestructive Testing
- D.** **CFR** – Code of Federal Regulations
- E.** **CGD** – Commercial Grade Dedication
- F.** **CGI** – Commercial Grade Item
- G.** **CM** – Configuration Management
- H.** **CQA** – Construction Quality Assurance
- I.** **CQAPP** – Construction Quality Assurance Project Plan
- J.** **CQC** – Construction Quality Control
- K.** **CTR** – Contract Technical Representative
- L.** **D&D** – Decontamination and Decommissioning
- M.** **DOE** – U.S. Department of Energy
- N.** **DDF&O** – Director’s Final Findings and Orders
- O.** **EM** – Office of Environmental Management
- P.** **EPA** – U.S. Environmental Protection Agency
- Q.** **ES&H** – Environmental Safety and Health
- R.** **ESH&Q** – Environmental, Safety & Health, and Quality ESH&Q
- S.** **FBP** – Fluor-BWXT Portsmouth LLC
- T.** **ILTS/MLTS** – Interim Leachate Treatment System/Modular Leachate Treatment System
- U.** **ISMS** – Integrated Safety Management System
- V.** **ITS** – Integrated Tracking System
- W.** **NCR** – Nonconformance Report
- X.** **NCS** – Nuclear Criticality Software
- Y.** **NDE** - Non-Destructive Examination
- Z.** **NQA** – Nuclear Quality Assurance
- AA.** **O** – Order (when used with DOE)
- BB.** **OIG** – Office of Inspector General
- CC.** **OSWDF** – On-Site Waste Disposal Facility
- DD.** **P** – Policy (when used with DOE)
- EE.** **POC** – Point Of Contact
- FF.** **PQAP** – Project Quality Assurance Plan
- GG.** **QAP** – Quality Assurance Plan
- HH.** **QAPD** – Quality Assurance Program Description

- II.** QSL – Quality Suppliers List
- JJ.** R2A2 – Roles, Responsibilities, Authorities, and Accountabilities
- KK.** SA – Special Analysis
- LL.** SADQ – Sample Analysis Data Quality Assurance Project Plan
- MM.** S/CI – Suspect/Counterfeit Item
- NN.** SL – Software Levels
- OO.** SME – Subject Matter Expert
- PP.** SMP – Software Management Program
- QQ.** SMPO – Software Management Program Office
- RR.** SMQA – Software Management Quality Assurance
- SS.** SSC – Structure, System and Component
- TT.** UCAQE – Unreviewed Composite Analysis Question Evaluation
- UU.** UDQE – Unreviewed Disposal Question Evaluation UDQE
- VV.** U.S.C – United States Code

### 13.0 REFERENCES

- A.** 10 CFR Part 830 Subpart A, *Quality Assurance Requirements*
- B.** 10 CFR Part 835, *Occupational Radiation Protection*
- C.** 48 CFR 970.5223-1, *Integration of Environment, Safety, and Health into Work Planning and Execution*
- D.** 44 United States Code (U.S.C.) 3301, *Definition of Records*
- E.** ASME NQA-1, *Quality Assurance Requirements for Nuclear Facility Applications* (2008 with Addenda through 2009)
- F.** DOE EM-QA-001, *DOE Environmental Management Quality Assurance Program*
- G.** DOE O 413.3B, *Program and Project Management for Acquisition of Capital Assets*
- H.** DOE O 414.1D, *Quality Assurance*
- I.** DOE P 450.4A, *Integrated Safety Management Policy*
- J.** FBP-BS-PRO-00024, *Developing and Maintaining Performance Documents*
- K.** FBP-BS-PRO-00039, *Request for Purchase*
- L.** FBP-BS-PRO-00062, *Records Management Process*
- M.** FBP-BS-PRO-00077, *Procurement Pre-/Post-Award Process*
- N.** FBP-BS-PRO-00111, *Preparation for Request for Proposal*
- O.** FBP-BS-PRO-00113, *Control of Contractors*
- P.** FBP-BS-PRO-00135, *Immediate Procedure Change (IPC) Process*

- Q.** FBP-EP-PDD-00008, *Environmental Management System Description*
- R.** FBP-ER-PDD-00003, *Portsmouth Gaseous Diffusion Plant (PORTS) Construction, Demolition, Soil Excavation, Projects & On-Site Waste Disposal Facility (OSWDF) Operations Program*
- S.** FBP-ER-PRO-00299, *Unreviewed Disposal Question Evaluation (UDQE), Unreviewed Composite Analysis Question Evaluation (UCAQE), and Special Analysis (SA) Process*
- T.** FBP-ER-PRO-WD-PL-0006, *Sample Analysis Data Quality Assurance Project Plan (SADQ) at the Portsmouth Gaseous Diffusion Plant, Piketon, Ohio*
- U.** FBP-NSE-PDD-00002, *Configuration Management Program Description*
- V.** FBP-NSE-PRO-00050, *Design Verification and Technical Reviews*
- W.** FBP-NSE-PRO-00079, *Design Analysis and Calculations (DACs)*
- X.** FBP-NSE-PRO-00081, *Design Control*
- Y.** FBP-NSE-PRO-00083, *Engineering Software Control for Embedded Software and Programmable Logic Controls (PLCs)*
- Z.** FBP-NSE-PRO-00092, *Engineering Change Request (ECR)*
- AA.** FBP-NSE-PRO-00098, *Engineering Specifications for Procurement and Acceptance*
- BB.** FBP-OS-PRO-00028, *Work Stoppage Due to Environmental, Safety, Health and Quality Concerns*
- CC.** FBP-PM-PDD-00001, *Integrated Safety Management System*
- DD.** FBP-QA-PDD-00001, *Quality Assurance Program Description (QAPD)*
- EE.** FBP-QA-PDD-00002, *Suspect/Counterfeit Item Oversight and Control Program Description*
- FF.** FBP-QA-PRO-00006, *Inspection and Testing*
- GG.** FBP-QA-PRO-00008, *Graded Approach*
- HH.** FBP-QA-PRO-00014, *Suspect/Counterfeit Items*
- II.** FBP-QA-PRO-00016, *Procurement Quality*
- JJ.** FBP-QA-PRO-00034, *Certification of Discipline Inspection and Nondestructive Testing (NDT) Personnel*
- KK.** FBP-QA-PRO-00043, *Special Processes*
- LL.** FBP-QA-PRO-00070, *Training, Qualification, and Certification of Nuclear Quality Assurance (NQA)-1 Auditors and Lead Auditors*
- MM.** FBP-QA-PRO-00128, *Control of Nonconforming Items*
- NN.** FBP-QP-PDD-00002, *Training and Qualification of Assessment Personnel*
- OO.** FBP-QP-PRO-00010, *Management Assessments*
- PP.** FBP-QP-PRO-00011, *Independent Assessments*
- QQ.** FBP-QP-PRO-00020, *Problem Reporting and Issues Management*
- RR.** FBP-QP-PRO-00023, *Surveillances*

- SS.** FBP-SM-PRO-00842, *Measuring and Test Equipment Control & Calibration*
- TT.** FBP-SMPO-AG-002, *Software Procurement Administrative Guide*
- UU.** FBP-SMPO-PDD-00005, *Software Management*
- VV.** FBP-SMPO-PL-00001, *Software Configuration Management*
- WW.** FBP-SMPO-PL-00002, *Software Management Program Qualifications and Training*
- XX.** FBP-SMPO-PRO-00003, *Software Testing*
- YY.** FBP-SMPO-PRO-00004, *Management of Software Inventory List*
- ZZ.** FBP-TRN-PL-00001, *Training Program Plan*
- AAA.** FBP-TRN-PL-00002, *Training Implementation Matrix*
- BBB.** FBP-TRN-PRO-00005, *Qualification and Certification*
- CCC.** NCSR-12-001, *Nuclear Criticality Safety Report Configuration Control Plan for the Nuclear Criticality Safety Computer Workstations and Software*

**Appendix A**  
**REGULATORY REQUIREMENTS FLOW DOWN**

1. 10 CFR Part 830 Subpart A, *Quality Assurance Requirements*
2. 44 U.S.C. 3301, *Definition of Records*
3. ASME NQA-1, *Quality Assurance Requirements for Nuclear Facility Applications* (2008 with Addenda through 2009)
4. DOE EM-QA-001, *DOE Environmental Management Quality Assurance Program*
5. DOE O 414.1D, *Quality Assurance*
6. SNT-TC-1A, *Personnel Qualification and Certification in Nondestructive Testing*