West Valley Demonstration Project

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CH2M HILL • B&W WEST VALLEY, LLC
QUALITY ASSURANCE PROGRAM

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West Valley Decommissioning Team

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STATEMENT OF POLICY AND AUTHORITY

The CH2M HILL B&W West Valley, LLC (CHBWV) contract with the U.S. Department of Energy (DOE), specifies that CHBWV will comply with applicable Federal and State Regulations and the listed DOE Orders (Contract DE-EM0001529, Section J, Attachments J.1 and J.2). For Quality Assurance (QA), this requires compliance with Title 10, Code of Federal Regulations, Part 830.122, *Quality Assurance Criteria*; Title 10 Code of Federal Regulations, Part 71, *Packaging and Transportation of Radioactive Materials*, Subpart H; DOE O 414.1D, *Contractor Requirements Document, Quality Assurance Requirements*; and DOE/RW-0333P, *Quality Assurance Requirements and Description; and State and Federal Environmental Regulations*.

The Quality Assurance Program (QAP) identifies our commitment to these contractual requirements. It establishes requirements, assigns responsibilities, and describes the management systems established to assure the quality of West Valley Demonstration Project (WVDP) activities and products. The QAP is a top-level document of CHBWV and compliance is mandatory. Implementation of the QAP is supported by procedures and instructions to ensure the quality of the CHBWV processes, activities and products.

The President of CHBWV has responsibility for the quality of CHBWV activities and products. The QA Manager has responsibility for developing and assuring the implementation of the QAP. CHBWV is accountable for managing its projects and performing CHBWV work in accordance with the quality requirements established by the QAP.

Every employee is responsible for performing work in accordance with the requirements set forth in this QAP. Those employees performing oversight and verification of QAP compliance are sufficiently independent of cost and schedule, and have the authority and responsibility to identify quality problems and to recommend solutions.

CHBWV is committed to performing work in accordance with the requirements of this QAP to ensure high quality products and services meeting DOE's needs and to fulfill the expectations of DOE to achieve adequate protection of workers, the public, and the environment, taking into account the work to be performed and the associated hazards. It is incumbent upon each employee to be open and candid in bringing to management's attention, without fear of recrimination, any instance of inferior work or any behavior that would compromise the attainment of quality.

Ryan A. Dodd ACTING
President and General Manager
CH2M HILL B&W West Valley, LLC

3-21-12
Date

CHBWV QUALTIY ASSURANCE PROGRAM

1.0 INTRODUCTION

CHBWV's objective is to safely deliver the WVDP Phase 1 Decommissioning and Facility Disposition Project, including: 1) Removal of High Level Waste (HLW) canisters from the HLW Interim Storage Facility and relocation to a new HLW Canister Interim Storage Facility; 2) Demolition and removal of the Main Plant Process Building (MPPB) and the Vitrification Facility; 3) Processing, shipping and disposal of all legacy waste off-site; 4) Demolition and removal of facilities defined in the contract as "Balance of Site Facilities"; and 5) Continued operation and maintenance of the Permeable Treatment Wall (PTW), Remote Handled Waste Facility (RHWF), Low Level Radiological Waste Treatment System, Waste Tank Farm (WTF), and NRC-Licensed Disposal Area (NDA). This QAP describes the quality requirements applicable to work performed by the CHBWV using a graded approach. The requirements in this QAP apply to CHBWV personnel and suppliers working under CHBWV's QAP. CHBWV retains the overall responsibility for its QAP. Activities within the scope of the following are included in program-specific quality plans, which supplement this QAP:

- Environmental Laboratory – WVDP-439, *ELAP Quality Manual*
- Analytical Laboratory – WVDP-123, *Laboratory Quality Assurance Manual*
- Environmental Monitoring – EM-109, *Environmental Monitoring Quality Assurance Plan*
- Environmental, RAD-NESHAPS – WVDP-504, *QAPP Environmental Measurements of Radionuclides for RAD-NESHAPS*
- Occupational Medicine – WVDP-202, *Occupational Medicine Quality Assurance Plan*
- Radiation Protection Laboratory – WVDP-317, *Radiation Protection Laboratory Quality Assurance Plan*
- Internal Dosimetry – WVDP-390, *Internal Dosimetry Quality Assurance Plan*
- External Dosimetry – WVDP-401, *External Dosimetry Quality Assurance Plan*
- High Level Waste Relocation and Storage – WVDP-074, *CH2M HILL ◦ B&W West Valley LLC Quality Assurance Program for High Level Waste Relocation and Storage*

2.0 REQUIREMENTS

This QAP incorporates both mandated requirements and best practices based on management experience, industry standards and guidance documents. Mandated requirements include DOE orders and federal and state regulations imposed through CHBWV's Prime Contract (DE-EM0001529); those directly relevant to QA are:

- Title 10, Code of Federal Regulations (CFR), Part 830.122, *Quality Assurance Criteria*
- 10 CFR 71, *Packaging and Transportation of Radioactive Material, Subparts H, Quality Assurance*
- DOE O 414.1D, *Quality Assurance*
- DOE O 226.1B, *Implementation of Department of Energy Oversight Policy*
- DOE O 460.1C, *Packaging and Transportation Safety*

The implementing standards for these contract requirements are specified in CHBWV's Prime Contract:

- ASME NQA-1-2008/2009a is the implementing standard for QA. This QAP is based upon Part I and Subparts 2.7 and 2.14 of ASME NQA-1-2008/2009a.
- DOE O 414.1D suggests the use of the International Organization for Standardization (ISO) ISO-9001, *Quality Assurance*, or equivalent, for non-nuclear activities. The requirements for non-

nuclear activities are instituted via a structure based on NQA-1-2008/2009a, using a graded approach consistent with 10 CFR 830.7.

- DOE/RW-0333P, Rev. 20, *Quality Assurance Requirements and Description*.

The U.S. Department of Energy's Office of Environmental Management (EM) issued the Quality Assurance Program (EM-QA-001), and tasked contractors to develop a Quality Assurance Implementation Plan (QIP) that describes implementation of this Program. For CHBWV, this QIP is comprised of this QAP document, which is based on NQA-1-2008/2009a and the implementing procedures listed in Appendix A of this document. The management expectations described in EM-QA-001 are implemented, using the graded approach, as described in the CHBWV QAP. All activities associated with financial performance, including assessment and oversight activities are performed in accordance with the CHBWV Earned Value Management System (EVMS) and are not specifically addressed in this QAP. Acquisition activities are conducted in accordance with applicable Department of Energy Acquisition Regulation (DEAR) clauses and include oversight to monitor cost and strive for best value. This QAP does not address this procurement process oversight function.

In order to develop and implement an effective management system consistent with the quality expectations of 10 CFR 830.122, and DOE O 414.1D, the guidance from the latest revision of the documents listed below is considered during the development and implementation of this QAP:

- DOE G 414.1-2B Admin Chg 1, *Quality Assurance Program Guide*
- DOE G 414.1-1B, *Management and Independent Assessments Guide for Use with 10 CFR Part 830, Subpart A*, and DOE O 414.1C, *Quality Assurance*; DOE M 450.4-1, *Integrated Safety Management System Manual; and DOE O 226.1B, Implementation of Department of Energy Oversight Policy*
- DOE G 414.1-4, *Safety Software Guide for Use with 10 CFR 830 Subpart A, Quality Assurance Requirements*, and DOE O 414.1C, *Quality Assurance*

3.0 QUALITY ASSURANCE PROGRAM STRUCTURE

Title 10 CFR 830, Subpart A, *Quality Assurance Requirements* (the QA Rule), and DOE O 414.1D (the QA Order) define 10 criteria as the elements of a QAP required to execute (1) DOE nuclear facility activities and (2) all DOE activities, respectively. The criteria for the QA Rule and DOE O 414.1D are equivalent.

The QAP is divided into 13 requirement sections (chapters), one for each of the 10 criteria as outlined within the DOE order and the CFRs. The additional 3 requirement sections address Suspect/Counterfeit Items, Software Quality Assurance, and Commercial Grade Items and Services. Appendix B contains the crosswalk between the 13 QAP sections, the 10 elements of DOE O 414.1D, the 10 elements of 10 CFR 830.122, the 18 requirements of 10 CFR 71, the 18 requirements of ASME NQA-1, and the 18 requirements of DOE/RW-0333P. A glossary of definitions is shown in Appendix C. This QAP is organized into three functional categories: Management, Performance, and Assessment as well as three supplemental areas: Suspect/Counterfeit Item Prevention, Software and Safety Software Quality Requirements, and Commercial Grade Items and Services Dedication. These categories capture the range of activities common to all work activities, from organizing and staffing to assessing results and providing feedback to improve the process. Within the three functional categories are the QA criteria that provide the basic requirements of a QAP. The application of these criteria extends from the planning and conducting of basic research and development, performing scientific investigation, and developing engineering design to the performance of operations, maintenance and repair activities, and finally to minimizing impact. As such, these QA criteria reflect a comprehensive way of doing business throughout the life cycle of WVDP programs and activities.

The three programmatic functional areas and their ten (10) respective supplements (criteria) are:

Part A – Management

- Criterion 1 - Program
- Criterion 2 - Personnel Training and Qualification
- Criterion 3 - Quality Improvement
- Criterion 4 - Documents and Records

Management provides the common elements needed in effective QAPs, regardless of the projects or programs to which they are applied. This QAP recognizes that it is management's responsibility to establish and cultivate principles that integrate quality requirements into the daily work routine. For this integration to be successful, the personnel performing the work must receive appropriate information, training, tools, empowerment, support, and encouragement. Management's role is to define requirements and expectations clearly; properly train, motivate and empower personnel; provide appropriate resources; and demonstrate integrity, commitment, and leadership through active involvement in the implementation of an effective and continuously improving QAP.

Part B – Performance

- Criterion 5 - Work Processes
- Criterion 6 - Design
- Criterion 7 - Procurement
- Criterion 8 - Inspection and Acceptance Testing

The above criterion contains the program elements that must be addressed for effective design, procurement, construction, installation, and operation of engineered items and systems and for decontamination and decommissioning. Line management is responsible for planning and achieving performance objectives; and for establishing and maintaining the technical requirements for project work. Performance objectives include the necessary implementation requirements for defining and performing work processes to assure that the right things are done right the first time, and to meet customer requirements.

Part C – Assessment

- Criterion 9 - Management Assessment
- Criterion 10 - Independent Assessment

This category provides for the periodic assessment of the QAP implementation to determine its effectiveness and to promote improvement, and describes the senior and line management assessment responsibilities. Management regularly assesses and documents the adequacy of the framework and infrastructure of the portions of the program for which they are responsible, to confirm the program's effective implementation. It also contains the independent assessment structure with the organizational freedom and authority for conducting inspections, surveillances, audits, and independent assessments. It provides for the auditing of operations, systematic handling of nonconforming conditions, issues resolution, and lessons learned through corrective actions, trending, and causal analyses.

Part D – Suspect/Counterfeit Item Prevention

Part E – Control of Software

Part F – Commercial Grade Item or Service Dedication

Each chapter addresses the elements using the following general structure:

- Section 1 Introduction - Purpose of the section
- Section 2 Requirements - Criteria of 10 CFR 830.122 and DOE O 414.1D that are implemented by the section along with any DOE guides or NQA-1 or DOE/RW-0333P requirements that were used in developing the requirements

- Section 3 Implementing Responsibilities – CHBWV organizational responsibilities associated with the management of the specific requirements
- Section 4 Implementation - Specific implementing requirements necessary for achieving compliance with the basic requirements

4.0 PROGRAM IMPLEMENTATION

This QAP requires approval by DOE prior to implementation. Implementing the Program requires the use of site procedures and departmental procedures which satisfy the provisions of this QAP. Separate supplemental QA plans/programs may be used for special programs and projects when additional controls or special emphasis is needed. Existing QA Plans that supplement this QAP are listed in Section 1.0, “INTRODUCTION,” of this document.

PART A: MANAGEMENT

Part A contains the program elements that define the framework for management processes supporting this QAP.

It provides the common elements needed to manage an effective QAP, regardless of the projects or programs to which they are applied. This portion of the QAP mandates that it is line management's responsibility to establish and cultivate principles that integrate quality requirements into the daily work routine.

For this integration to be successful, the people performing the work must receive appropriate information, tools, support, and encouragement. Line Management must define requirements and expectations clearly; appropriately train; motivate, and empower personnel; provide appropriate resources; and demonstrate integrity, commitment, and leadership through active involvement in the implementation of an effective QAP.

1.0 CRITERION 1 - PROGRAM

1.1 Introduction

This section describes CHBWV's QAP structure, as well as general responsibilities and interfaces related to implementation of the QAP. This section identifies the basic QA requirements imposed on CHBWV for items, activities, and products, including the associated implementing requirements for the quality management processes, and the responsibilities for process implementation.

It is the policy at CHBWV to establish and maintain a QAP to assure work is performed in compliance with applicable codes, standards and regulations, and contractual requirements. Individuals or organizations responsible for portions of the work and having delegated any and all of this work shall retain the responsibility for the work delegated. Individuals are responsible for achieving quality in the performance of their work activities. Quality achievement is verified by persons or organizations not directly responsible for performing the work.

The CHBWV scope to which this QAP is applied includes activities needed to perform the following:

- Resolve safety issues and provide an approved authorization basis for project activities;
- Operate, and maintain the facilities and supporting infrastructure;
- Waste Management, including storage, packaging and disposal; and
- Decontamination, Decommissioning and Demolition activities.

The CHBWV HLW Relocation and Storage work scope QAP is described in WVDP-074, *CH2M HILL ◦ B&W West Valley LLC Quality Assurance Program for High Level Waste Relocation and Storage*.

The CHBWV Radiological Laboratory activities QAP is described in: 1) WVDP-317, *Radiation Protection Laboratory Quality Assurance Plan*; 2) WVDP-390*, Internal Dosimetry Quality Assurance Plan*; and 3) WVDP-401, *External Dosimetry Quality Assurance Plan*.

The CHBWV Environmental Laboratory and Monitoring activities QAP is described in: 1) WVDP-439, *ELAP Quality Manual*; 2) WVDP-123, *Laboratory Quality Assurance Manual*; 3) EM-109, *Environmental Monitoring Quality Assurance Plan*; and 4) WVDP-504, *QAPP Environmental Measurements of Radionuclides for RAD-NESHAPS*.

The CHBWV Occupational Medicine QAP is described in WVDP-202, *Occupational Medicine Quality Assurance Plan*.

1.2 Requirements

The QAP shall be established and implemented by CHBWV to satisfy the requirements of 10 CFR 830.122 (a), "Criterion 1-Management/Program," and DOE O 414.1D Contractor Requirements Document (CRD), Attachment 2, " Criterion 1-Management/Program", which state:

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

The following were used in the development of the requirements for this section:

- ASME NQA-1-2008/2009a, Requirements 1 and 2
- DOE G 414.1-2B, Quality Assurance Program Guide

Record requirements are discussed in Part A, Section 4.0, "Documents and Records," of this document.

1.3 Implementing Responsibilities

1.3.1 Organization

A. Purpose and Applicability

This section defines the responsibilities for the establishment and implementation of the CHBWV's QAP. The organizational structure and the assignment of responsibility shall be such that quality is achieved and maintained by those who are assigned responsibility for performing the work, and the quality achievement is verified by persons not directly responsible for performing the work.

B. WVDP-524, *Project Management Plan* describes the CHBWV organizational structure and responsibilities for the implementation of the CHBWV mission.

C. CHBWV project and functional group personnel responsible for ensuring that the QAP has been properly implemented, and for verifying that activities affecting quality have been correctly performed, shall have direct access to management at a level where appropriate action can be effected. Such organizations and personnel shall report to a management level such that required authority and organizational freedom are provided, including sufficient independence from cost and schedule considerations.

D. The CHBWV QA Manager and staff have sufficient authority, access to work areas, and organizational freedom to:

- Identify quality problems;
- Initiate and recommend actions to resolve quality problems; and
- Verify implementation of actions and ensure that further processing, delivery, installation or use of defective materials, equipment, and services are controlled until proper disposition of the nonconformance, deficiency, or unsatisfactory condition has occurred.

1.3.2 Responsibilities

A. President and General Manager

The CHBWV President and General Manager (President) provides single-point accountability to the DOE for performance, compliance, and contractual matters regarding the CHBWV's scope of work. The President is responsible for the overall leadership, direction, and organization of the CHBWV. The President ensures that work for which CHBWV is responsible for is performed effectively and efficiently, ensuring quality while protecting the safety of workers, the public, and the environment. The President assigns responsibility and delegates authority to senior management for establishing expectations for effective implementation of the QAP and responsibilities for obtaining the desired end result.

The President is responsible for setting and implementing policies and priorities to ensure that the quality is achieved and maintained by those assigned responsibility for performing work, and quality achievement is verified by those

not directly responsible for performing the work. In addition, the President ensures that those responsible for verifying quality achievement have sufficient authority, direct access to management, the organizational freedom, and access to the work to perform their function. Supporting the President is an organization that is responsible for performing the work necessary to implement the contractually defined work scope, including providing related support.

B. Direct Report Senior Managers

Direct Report Senior Managers are responsible for the following:

- Implementation of the QAP that applies to their scope of responsibilities.
- Ensuring that assigned QA personnel who have the responsibility for verifying quality achievement have sufficient authority, direct access to management, the organizational freedom, and access to the work to perform their function.
- Incorporating the Integrated Safety Management Systems/Environmental Management Systems (ISMS/EMS) provisions into work processes.
- Performing evaluations and self-assessments on a planned and periodic basis to verify the QAP is being effectively implemented.
- Identifying causes of deficiencies found by self assessment, inspection, audit, or other means; determining appropriate disposition, corrective action, actions to prevent recurrence; and assigning responsibilities and schedules for such actions.
- Stopping or correcting work whenever there are changing conditions outside the scope of approved work requirements, the potential for violation of approved work requirements exists, possible equipment damage or the chance of personal injury may occur. Any employee may stop work when unsafe conditions are perceived to exist. Prime responsibility for this action rests with the responsible performing organization.
- Implementing Formal Stop Work action , if actions taken are ineffective in resolving the issue, or when violation of safety or quality requirements, approved work documents, product/equipment damage or personal injury are possible and the conditions are perceived as significant.
- Developing and maintaining a comprehensive set of management controls that align with the established company program, including regulatory and contractual compliance.
- Interfacing and communicating with other managers in accomplishing facility design, construction, modification, and operation.
- Ensuring there are adequate resources for their personnel to perform their work.
- Establishing and ensuring adequate training and indoctrination for all their personnel.
- Establishing management processes, including planning, scheduling, and providing resources for work.

C. Personnel

CHBWV employees are responsible for the following:

- Achieving the highest quality during the performance of work activities.
- Safely accomplishing work activities in accordance with instructions, procedures, and drawings.

- Stopping work activities and informing their supervisors when it appears that adherence to a procedure is not possible or may result in an unsafe condition.
- Promptly identifying and reporting safety and quality deficiencies to their supervisors.

D. Manager, Quality Assurance

The Manager of QA has the functional authority, independence, and responsibility to ensure the effective implementation of and compliance to the quality requirements. Consistent with this authority is the responsibility to document interpretations of those activities controlled by this program and the extent to which the requirements of this program apply.

The CHBWV QA Manager reports directly to the CHBWV Vice President, Environment, Safety, Health, and Quality (ESH&Q), and has direct access to the President and General Manager for quality-related matters. The QA Manager is responsible to ensure that an appropriate QAP, the scope of which includes all the systems and activities that affect safety and quality, is established and implemented in accordance with contractual requirements. This responsibility applies to QA Plans for specific work scopes or programs.

The Manager of QA reviews CHBWV activities with the goal of identifying areas where changes could lead to improvements in safety and/or quality. The Manager of QA has the authority to cross organizational lines to identify quality problems, recommend, or provide actions, and verify implementation.

The Manager of QA is responsible for the following major functions:

- Providing guidance and oversight for the CHBWV based on applicable requirements of 10 CFR 830, Subpart A; DOE O 414.1D CRD; and other contractual quality requirements.
- Defining the Quality Levels (grading process) to be used by CHBWV.
- Establishing the criteria and guidance for the application of QA measures to projects, programs, items, services, and activities, and documentation.
- Approving the QA related planning (including quality related manuals, procedures, and instructions) initiated by QA and other departments.
- Directing and overseeing the conduct of independent assessments and surveillances.
- Directing, overseeing, and maintaining the Issues Management process for corrective action and continuous improvement, including:
    - Establishing the processes to detect and prevent quality problems and recommend or assist in development of solutions with the affected organizations;
    - Assuring that quality problem correction includes identification of the causes of problems and actions to prevent recurrence; and
    - Assuring that any disagreements regarding quality problems or proposed solutions are promptly elevated to the necessary level of management for resolution.
- Providing guidance on quality to functional organizations and project teams, including reviewing and approving, in accordance with the graded approach (quality levels), other department's policies, procedures, management system requirements, (such as environmental, health, and safety) and supporting documents which control the quality of work.

- Monitoring the CHBWV QAP through overview activities that, as a minimum, include surveillances, audits, and management and independent assessments and/or reviews on a planned and periodic basis to verify the QAP is being effectively implemented.
- Providing for the review and acceptance of contractor and vendor QAPs, including monitoring work by CHBWV suppliers and subcontractors to assure that work is performed in accordance with approved requirements.
- Providing a working interface and line of communication with other company organizations and projects for QA matters.
- Assuring that adequate and effective provisions are established for individuals to express allegations and quality concerns.
- Interfacing with the DOE on quality matters on behalf of CHBWV.
- Establishing indoctrination and training programs for QA and Quality Control (QC) personnel.
- Providing input for QA indoctrination of personnel outside the QA organization.
- Verifying that necessary QA training and indoctrination are provided for qualified personnel whose work may have an effect upon quality, or who are responsible for verifying quality.
- Issuing periodic reports to appropriate management on the status of quality activities.
- Assuring that, where applicable, items, services, and processes which do not or may not conform to established CHBWV requirements, are identified, controlled to prevent inadvertent use until disposition is properly authorized, and that corrective actions are implemented and verified.
- Notifying appropriate management of any significant conditions adverse to quality.
- Implementing the Stop Work Order process whenever a violation of safety or quality requirements, approved work documents, product/equipment damage or personal injury are possible and are perceived as significant and unable to be resolved through other methods.

E. Interface Control

Where more than one organization is involved in the execution of activities, the responsibilities, interfaces, and authority of each organization shall be clearly defined and documented. The external interfaces between organizations and internal interfaces between organizational units shall be documented. These internal interfaces between project, facilities, functional groups and service providers are defined in procedures and other work agreement documents.

The CHBWV Team includes pre-selected subcontractors. The pre-selected subcontractors provide support to projects as needed based on their respective areas of expertise.

These pre-selected subcontractors are required by contract to comply with and implement the CHBWV QAP and associated implementing documents.

Interfaces with CHBWV subcontractors and suppliers are specified in governing subcontract/procurement documents.

Interface between CHBWV and the WVDP Environmental Characterization and Support Services contractor is documented.

1.4 Implementation

The CHBWV QAP applies, with appropriate grading of controls, to the scope of work defined in the CHBWV contract (Contract DE-EM0001529) with the DOE, and is implemented through a variety of procedures. The direct implementing documents are listed in Appendix A.

The following describes how the QAP requirements imposed by contract are flowed-down to lower tier procedures and effectiveness verified.

1.4.1 Structure of the CHBWV Quality Assurance Program

A. The CHBWV QAP is comprised of this QAP, company-wide implementing documents, work control procedures and other CHBWV documents. The CHBWV QA policy (located in the front of this QAP), signed by the CHBWV President and General Manager, establishes CHBWV's commitment to quality and to meeting customer requirements and expectations. (The policy is located in the front of this QAP.)

B. Processes that implement the QAP and are common to multiple CHBWV organizations are defined in company-wide procedures. Processes that implement the QAP and are not common to multiple CHBWV organizations are defined in functional area or project-specific procedures. CHBWV organizations shall implement applicable company-wide procedures, augmented on a limited basis, through functional area or project-specific procedures. The company-wide and functional area or project-specific procedures, and other policies, plans, and documents that are directly credited as being the implementing procedures for the QAP requirements are listed in Appendix A. The hierarchy of CHBWV QAP documents is shown in Figure 1 depicting typical flow down of requirements to work documents.

C. The QAP shall assure that the following functions are performed as appropriate:

- Determining the applicability of the customer QAP requirements. The QAP shall be established at the earliest time consistent with the schedule for accomplishing the activities.
- Establishing the requisite quality related control procedures.
- Identifying the responsibilities for the performance of activities affecting quality.
- Assigning quality levels (grading process) to the facilities, systems, components, and associated activities or services.
- Identifying the applicable codes and standards requirements.
- Establishing suitable requirements for control over, and interface with, the QAPs of key suppliers and contractors.
- Identifying, scheduling, and controlling plans, readiness reviews, procedures, and instructions that are specifically required for the project or program.
- Providing for independent verification of quality achievement by persons or organizations not directly responsible for performing the work.
- Providing for the identification, validation, collection, indexing, storage, disposition, and retrieval of required records.
- Reporting and tracking QAP information regarding program implementation, quality issues, quality trends, and the results from surveillances, assessments, and audits.

- Identifying any special controls, processes, test and measuring equipment, tools, and skills necessary to attain the required quality and to verify that quality is achieved and maintained.
- Establishing indoctrination and training, as necessary, for personnel performing activities affecting quality to assure that suitable proficiency is achieved and maintained.
- Establishing review criteria for applicability, acceptability, correctness, technical adequacy, completeness, accuracy, and compliance with established requirements for all quality affecting documents.
- Ensuring monitoring activities against acceptance criteria in a manner sufficient to provide assurance that the activities affecting quality are performed satisfactorily.

Quality assurance planning shall provide for traceability from the requirements contained in applicable standards to the documents that specify the performance of work. Such traceability may be provided through scope and applicability statements in procedures, through QAPs or indices, or through QAP descriptions appearing in such documents as Project Management Plans.

D. Because of unique requirements, the following activities require the development of QA Plans to address additional QA requirements that are not specifically addressed by this QAP:

- Environmental Laboratory – WVDP-439, *ELAP Quality Manual*
- Analytical Laboratory – WVDP-123, *Laboratory Quality Assurance Manual*
- Environmental Monitoring – EM-109*, Environmental Monitoring Quality Assurance Plan*
- Environmental, RAD-NESHAPS – WVDP-504, *QAPP Environmental Measurements of Radionuclides for RAD-NESHAPS*
- Occupational Medicine – WVDP-202, *Occupational Medicine Quality Assurance Plan*
- Radiation Protection Laboratory – WVDP-317, *Radiation Protection Laboratory Quality Assurance Plan*
- Internal Dosimetry – WVDP-390, *Internal Dosimetry Quality Assurance Plan*
- External Dosimetry – WVDP-401, *External Dosimetry Quality Assurance Plan*
- High Level Waste Relocation and Storage – WVDP-074*, CH2M HILL ◊*

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1.4.2 Graded Application of the Quality Assurance Program

10 CFR 830.7 requires contractors to use a graded approach, document the basis of the graded approach used, and submit that documentation to DOE. This document is CHBWV's submittal to satisfy this contractual requirement. 10 CFR 830.3 defines 'Graded Approach' as follows:

The process of ensuring that the level of analysis, documentation, and actions used to comply with a requirement in this part is commensurate with:

- The relative importance to safety, safeguards, and security;
- The magnitude of any hazard/risk involved;
- The life cycle stage of a facility;
- The programmatic mission of a facility;
- The particular characteristics of a facility;
- The relative importance of radiological and non-radiological hazards; and
- Any other relevant factor.

CHBWV considered the guidance of several DOE documents to develop a more detailed breakdown of factors to be considered during the grading process.

The graded application of QAP requirements is normally achieved through combinations of:

- The extent to which procedures, instructions, or specifications define the processes or work methods involved;
- The extent of assessment, verification, review, or oversight activities;
- The extent of documentation required; and
- The degree of control over activities.

The graded approach is most commonly applied:

- At the procedure or work document development level to provide the necessary detail to ensure the risk associated with the activity is adequately addressed or controlled;
- To develop procurement documents that define the level of controls and associated verification needed to ensure items and services perform as specified; and
- In the corrective action process to resolve the significance of issues of varying risk and organizational impact.

The graded approach process shall not be used to “grade to zero” (i.e., eliminate requirements). Even in the least stringent application of the graded approach process, compliance with the applicable requirements is mandatory.

A. Identification of Quality Levels

- A Quality Level (grading process) shall be assigned to each item and/or activity.

- The Quality Level shall be based on careful consideration of the function and importance of each item or activity. A quality level list(s) shall be prepared by Engineering. The appropriate Quality Level shall be assigned to, and included in design, procurement, equipment, material, and work documents by the engineering organizations. The assigned quality level list(s) shall be kept current throughout the life of the Project and shall be the basis for applying the appropriate controls over the item.

B. Application of Quality Level Classification

- During the design phase of the project, appropriate design control, environmental considerations, and document control measures shall be applied based on the item’s intended use.
- During the procurement, construction, operation, and D&D phases of the project, individual Quality Level classifications shall be assigned to the

specific items, activities, or services. Appropriate technical and quality requirements shall then be invoked on the supplier or subcontractor responsible for providing the item or service based on the assignment of Quality Level.

C. Quality Level Documentation

- The assigned Quality Level for structures, systems, and components (SSCs) shall be determined and documented in design documents and included in the CHBWV "Q List" (WVDP 204).
- The Quality Level documentation shall include the following as appropriate:
  - The Quality Level and other appropriate classification for the SSCs.
  - A description of the SSC.

D. Quality Level Determination

The Quality Level is a designation (grading process) determined by the probability and consequence of failure in a specified end use application that is assigned to systems, subsystems, structures, components, documents, or services based upon health and safety, environmental, operational, programmatic, and performance considerations. The current Quality Level classification system consists of three quality levels (B, C, and N). For SSCs and activities graded as Quality Level B or C, QA Department involvement is required.

- Quality Level B This grade requires that applicable portions of the CHBWV QAP be applied. An acceptable degree of independent verification can usually be obtained by normal CHBWV organizational participation.
- Quality Level C This grade requires verified application of the applicable portions of the CHBWV QAP. However, only those program elements determined essential by collaborative agreement between the cognizant, performing organization(s) and QA organization need be applied.
- Quality Level N This grade involves those items or activities where programmatic, environmental, or health and safety concerns are not an issue. The CHBWV QAP still applies. However, implementation of the applicable QAP controls is left to the judgment and responsibility of the involved performing organizations.

1.4.3 Work Planning

Planning to establish the necessary process steps to execute quality activities shall be accomplished, as appropriate, and consider the following:

- Planning activities must be performed and documented before start of work.
- Planning must ensure that work is accomplished under appropriate safety and quality controls, which includes the use of appropriate equipment, suitable environmental conditions for accomplishing the activity, and assurance that prerequisites for the given activity have been satisfied.
- Planning must provide for any special controls, processes, test equipment, tools, and skills needed to attain the required quality/verification of quality and safety, and the need for verification of quality by inspection and test.

1.4.4 Control of the Quality Assurance Program

The QAP must be initially submitted, modified as requested by DOE, and approved by the U.S. DOE, West Valley Office (DOE-WVDP). Subsequent revisions must be submitted to DOE at least annually in accordance with the requirements of Section 830.121(b)(3) of 10 CFR Part 830, Subpart A, and DOE O 414.1D CRD, Attachment 1, Paragraph 2 for review and approval. The submittal of a revision to the QAP shall include a justification for why the changes continue to satisfy the QA requirements. Changes made to correct spelling, punctuation, or other editorial items do not require explanation. The QA Manager as delegated by the CHBWV President shall maintain and approve all revisions to this plan.

1.4.5 Effective Date Implementation

Changes to implementing procedures resulting from changes to this QAP shall be incorporated within 90 days of the change approval date unless an interim action plan is defined and approved by the QA Manager.

1.4.6 Quality Assurance Program Review

The effectiveness of the QAP and its implementation is periodically assessed by management. The results of these assessments are documented in reports to senior management for evaluation and corrective action, as required. The effectiveness of the QAP is also evaluated and reported by the QA organization through the inspection, review, monitoring, surveillance, and assessment functions.

1.4.7 Resolution of Differences and Escalations

Differences of opinion involving QAP requirements shall, if possible, be resolved at the level at which they occur. If this is not possible, the differences shall be escalated through supervisory/management levels until resolution is achieved. A Differing Opinions process is addressed by the Employees Concerns program.

The QA Manager shall be the Technical Authority (TA) for the applicability and interpretation of the CHBWV QAP.

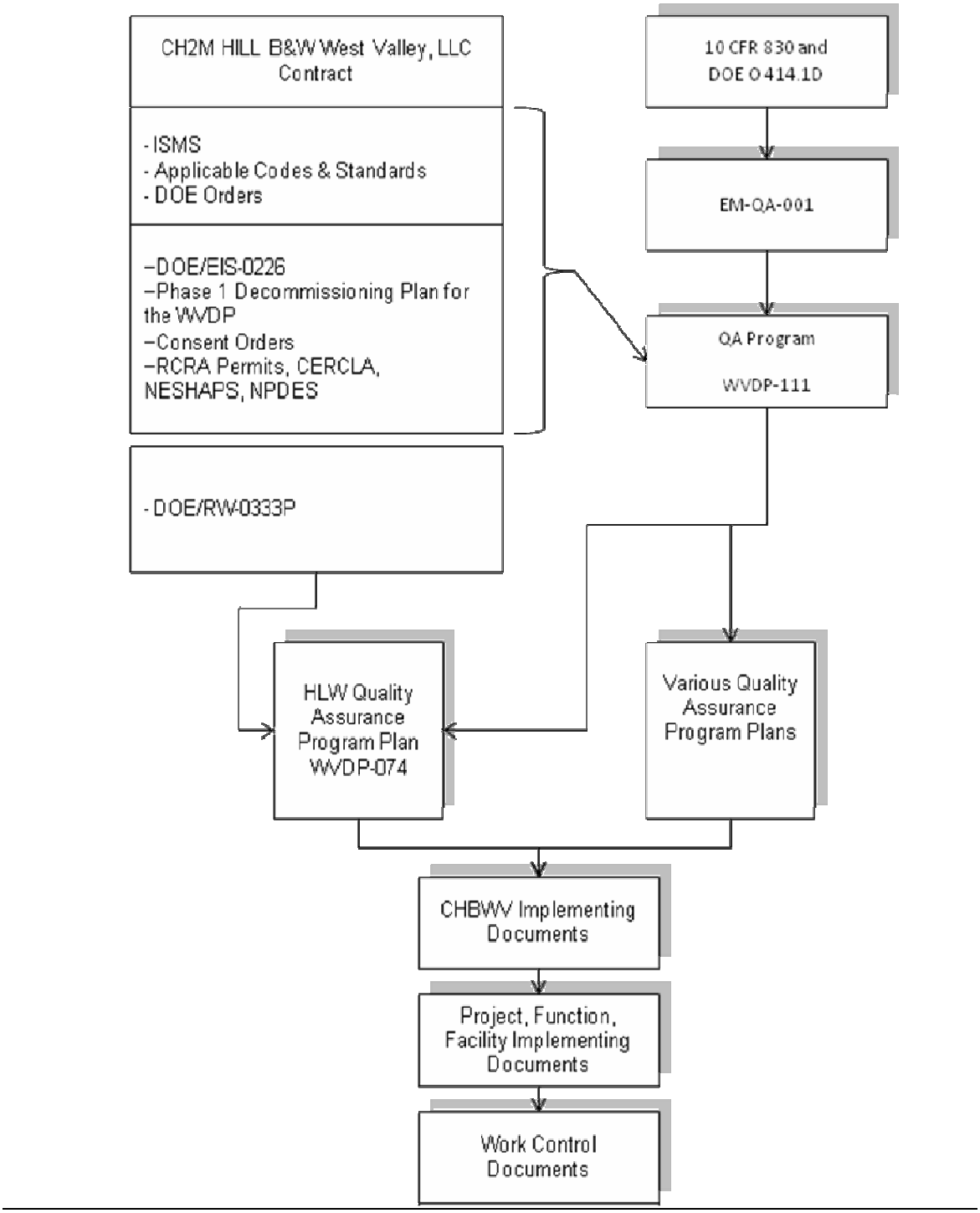
1.4.8 Integration with the Safety Management System

The QAP is integrated with the safety management system as part of a comprehensive management system that ensures work is performed safely and products and services meet quality requirements. The CHBWV safety management system is described in WVDP-310, *WVDP Safety Management System Description*. Effective implementation of the QA requirements will also provide processes and tools to support principles and functions of the Safety Management System. CHBWV management's fundamental QA expectation is that all work meets established requirements. In this regard, management ensures compliance with the approved procedures, so that the expectation for safe work within controls is met. This also ensures workers, the environment, and the public are reasonably protected from harm. The CHBWV's safety and quality requirements share a management systems approach to achieving their objectives. As such, compliance to established processes (e.g., procedures and instructions) satisfies safety and quality requirements.

1.4.9 Delegation of Work

Positions or organizations responsible for establishing and executing the QAP may delegate work to other CHBWV organizations, other WVDP contractors or subcontractors and suppliers. The positions or organizations making the delegations shall retain overall responsibility for the delegated work. These delegations shall be documented.

Figure 1 – CHBWV QA Program Document Hierarchy



2.0 CRITERION 2 - PERSONNEL TRAINING AND QUALIFICATION

2.1 Introduction

This section establishes the requirements and responsibilities for qualification and training to ensure that personnel achieve and maintain the required capabilities to perform their work. The training and qualification program shall provide for the development and maintenance of proficiency.

2.1.1 General

CHBWV policy requires that every employee be properly trained and qualified to perform his/her functions, and that each employee is evaluated for general and specific training needs for work performance and qualification.

CHBWV has established and implemented training programs and procedures to provide the adequacy of personnel proficiency for work to be performed. Appropriate training is performed and documented, and when job requirements change, the need for retraining is evaluated.

Management provides resources for required training and retraining so that personnel performing work are qualified and/or certified to perform assigned work, including and according to any project-specific requirements.

Management is encouraged to stimulate and focus professional development through membership in appropriate professional societies and the utilization of appropriate professional and management courses that have been developed and are available.

CHBWV uses educational programs to provide professional and management employees with the tools needed to perform their daily operations.

Management is encouraged to benchmark and maximize the use of training developed at other locations.

2.1.2 Inspection, Test, and Non-Destructive Examination (NDE)

It is the policy at CHBWV that personnel performing nondestructive examinations, inspections, and tests for the purpose of acceptability or to verify conformance to specified requirements, be qualified and certified to the applicable requirements. In addition, it is the policy to ensure that these personnel have experience or training commensurate with the scope, complexity, or special nature of the process qualified for, and that proficiency is achieved, maintained, and documented. The implementation of these requirements shall be through written procedures developed and approved by the affected organizations.

2.1.3 Audit Personnel and Lead Auditors

It is CHBWV policy to ensure that QAP audit personnel have experience or training commensurate with the scope, complexity, or special nature of the activities being audited. Other supporting personnel, such as management representatives and technical specialists, are required to have the appropriate background or shall be given training to permit them to adequately perform their audit function.

This policy applies to all CHBWV personnel performing audits. This policy provides the minimum requirements for establishing procedures to certify and document the qualifications of Auditor and Lead Auditor personnel performing audits for CHBWV.

2.2 Requirements

Training and qualification programs shall be established and implemented to satisfy the requirements of 10 CFR 830.122 (b), "Criterion 2-Management/Personnel Training and Qualifications," and DOE O 414.1D CRD, Attachment 2, "Criterion 2-Management/Personnel Training and Qualifications", which state:

- “Train and qualify personnel to be capable of performing assigned work.”
- “Provide continuing training to personnel to maintain job proficiency.”

ASME NQA-1-2008/2009a Requirement 2, DOE/RWP-0333P, QARD, Rev. 20, and the guidance presented in DOE G 414.1-2B were used in the development of the requirements for this section.

Record requirements are discussed in Part A, Section 4.0, “Documents and Records" of this document.

2.3 Implementing Responsibilities

Management is responsible for the training, qualification, certification and proficiency of personnel in their organizations. Project and functional organizations are responsible for developing training and qualification programs specific to their project/facility functions, obtaining the required training services, and working with the CHBWV Training Organization and QA to implement the requirements of this section.

2.3.1 Management

Management performing or managing activities affecting quality shall:

- Determine the need for a formal training program for personnel performing or managing activities affecting quality.
- Ensure that personnel required to receive indoctrination are identified and receive indoctrination on the following:
    - General criteria, including applicable codes, regulations, standards, policies, and programs;
    - Specific criteria, including applicable QAPs and implementing procedures; and
    - Job duties/responsibilities and authority.
- Ensure that individuals have the necessary experience, knowledge, skills, and abilities prior to performing work independently.
- Ensure that identified personnel are indoctrinated, and trained, and/or qualified commensurate with the following:
    - The scope, complexity, and special nature of the activity; and
    - The education, experience, and proficiency of the individual.
- Ensure that personnel receive indoctrination and training as needed, including on-the-job and hands-on training, and continuing training to achieve initial proficiency, maintain proficiency, and adapt to changes in technology, methods, job responsibilities, and QA implementing procedures, prior to or while performing any tasks subject to the QAP. For performing inspection, test, and NDE tasks, specific management responsibilities include:
    - Establishing training programs for inspectors and testers required for their organizations.
    - Documenting training and evaluation records. The qualification and certification of personnel will be documented.

  - Providing indoctrination and training of their inspection and test personnel of the technical objectives and requirements of the applicable codes and standards and the QA elements that are to be used.
  - Designating those activities that require qualified inspection and test personnel and specifying appropriate levels of qualification required, including requirements for personnel performing high-level waste acceptance inspections and testing.
  - Establishing written procedures for the selection, training and qualification of inspection and test personnel and assuring that only those personnel who meet the applicable requirements are permitted to perform inspection and test activities.
  - Assuring that inspection and test personnel are independent of the organization responsible for item being inspected or tested.
  - Evaluation and assessment of the need for additional indoctrination and training (as applicable), as assignments, requirements, positions, and procedures change.
- Evaluate and assess the need for additional indoctrination and training as assignments, positions, and policies and procedures change.
- Ensure that records of indoctrination and training are generated and maintained. Attendance sheets, personnel training and qualification records, required reading lists, and other forms that document a briefing or lesson learned are considered training records.
- Ensure, through the department self assessment program, that personnel are receiving the requisite indoctrination and training.

2.3.2 Business Management

The Human Resources organization within the Business Management Group is responsible for developing and/or maintaining position descriptions and associated individual experience and educational records and for verifying relevant education and experience.

2.3.3 Training

The Training organization, within the ESH&Q group, is responsible for the following:

- Establishing and supporting CHBWV training and qualification programs that comply with applicable requirements.
- Establishing CHBWV training standards and procedures, including needs analysis.
- Controlling and coordinating the indoctrination, and training, and qualification requirements for all those personnel where work activities may affect quality.
- Providing continuing training to personnel to maintain job proficiency.
- Evaluating technical and ESH training programs that support the conduct of operations, QA, and general employee training requirements.
- Support development and implementation of technical training, educational, and employee development programs. These programs are implemented under the performance-based training procedures.
- Evaluating the effectiveness of the training programs to determine the impact on improving the knowledge, skills, and abilities of CHBWV personnel. The evaluations are performed through the use of surveys, interviews, observations, audits, self-assessments, and appropriate policies and procedures.
- Providing job-specific and program based training such as Computer-Based Training (CBT), and ISM training.

- Providing general employee training (GET) for all CHBWV employees and subcontractors.
- Providing conduct of operations training for CHBWV organizations.
- Providing On-The-Job training (OJT) and workshops for instructors and classroom instructors.
- Interfacing with QA organization to ensure appropriate CHBWV QAP orientation and training are provided.

2.3.4 Quality Assurance

The QA organization is responsible for the following:

- Developing CHBWV QAP indoctrination materials for use by CHBWV QA and the Training organization.
- Developing and maintaining training and qualification programs for QC inspectors, assessors, lead assessors, QA auditors, and certified lead auditors.
- Preparing and issuing procedures for the qualification of QA personnel performing inspections and tests to verify compliance or acceptance of components, items, or services to specified requirements.
- Assigning certified lead auditors who are appropriately trained and qualified and are independent of any direct responsibility for performance of the activities being audited.
- Verifying that the necessary indoctrination, and training, and qualification is provided to personnel who perform activities affecting quality, including personnel performing inspection, tests, and NDE via the performance of audits, assessments, and surveillances.

2.4 Implementation

Methods shall be established to ensure that personnel receive indoctrination and training, including on-the-job and hands-on training, as specified to achieve initial proficiency; maintain proficiency; and adapt to changes in technology, methods, job responsibilities, and QA procedures, prior to or during the performance of a task or job duties. The extent of indoctrination and training shall be commensurate with the scope, complexity, importance of the activities, and education, experience, and proficiency of the individual.

2.4.1 Indoctrination and Training

A documented indoctrination program shall be established and provided to personnel performing or managing activities important to the WVDP to ensure understanding of their job responsibilities and authority that includes general criteria, technical objectives, requirements of applicable codes and standards, regulatory commitments; company procedures; and QAP requirements.

A training program shall be established and provided, based on project need, to personnel performing or managing activities affecting quality. Initial and continuing training shall be provided as determined necessary to ensure that these personnel can perform assigned tasks in a manner that minimizes risk to themselves, coworkers, and the public; minimizes negative impacts to the environment; and minimizes risk of damage to the facility and equipment. Continued training will be provided to maintain proficiency and adapt to changes in technology, methods, or job responsibilities.

2.4.2 Qualification and Certification

For positions that require qualification or certification, the initial capabilities of a candidate shall be determined by an evaluation of the candidate's education, experience, training, and either test results or capability demonstration. Job descriptions shall be developed,

based on the work to be performed, that describe minimum requirements for education and experience and, if required, physical condition and certification requirements. Management shall verify training, qualifications, and proficiency of personnel prior to assigning them to perform work. Qualification of personnel assigned to conduct inspection and/or activities for acceptance shall be documented.

A. Inspection, Test, and NDE Personnel

CHBWV (or subcontractor) inspection, test, and NDE personnel shall be qualified/certified and requalified/recertified in accordance with procedures based on ASME NQA-1, *American Society for Nondestructive Testing* SNT-TC-1A, or other standards applicable to the work performed. The specific standards used shall be identified in implementing procedures for qualification and certification. The job performance of inspection and test personnel shall be reevaluated at periodic intervals not to exceed 3 years. Reevaluation shall be by evidence of continued satisfactory performance or redetermination of capability. The qualification of personnel will be documented to include the information listed below, as applicable.

- Identification of person being certified.
- Activities certified to perform.
- Basis used for certification including such factors as:
  - Education, experience indoctrination, and training;
  - Test results where applicable;
  - Results of capability demonstration;
  - Results of periodic evaluations; and
  - Results of physical examinations when required.
- Date of certification and date of expiration.
- Identification of any special physical characteristics needed in the performance of each activity such as the need for initial and subsequent physical examination, etc.
- Signature of designated CHBWV representative who is responsible for documenting certification.

CHBWV may subcontract the performance of nondestructive examination methods such as radiographic, magnetic particle, ultrasonic, liquid penetrant, eddy current, or neutron radiographic nondestructive examination methods. If subcontracted, the contract documents shall specify requirements for qualification of subcontracted or supplier personnel performing nondestructive examination methods.

B. Lead Auditors

Qualification and certification of Lead Assessors and QA Lead Auditors requiring certification shall be documented in accordance with approved procedures. A lead assessor/auditor shall be capable of organizing and directing independent assessments, reporting assessment results, and evaluating planned and implemented corrective action. Lead Auditors shall be capable of communicating effectively, both in writing and orally. Lead Auditors shall be certified. Qualification requirements for assessment personnel are summarized as follows:

- Communication Skills - The prospective Lead Auditor shall have the capability to communicate effectively, both in writing and orally. These skills shall be attested to in writing by the CHBWV QA Manager.
- Training - Prospective Lead Auditors shall have training to the extent necessary to assure their competence in auditing skills. Training in the

following areas shall be given based on the CHBWV QA Manager's evaluation of the particular needs of each prospective Lead Auditor.

- Knowledge and understanding of codes, standards, regulations, and regulatory guides, as applicable.
- General structure of QAPs as a whole and applicable elements as defined in this QAP.
- Auditing techniques of examining, questioning, evaluating, and reporting; methods of identifying and following up on corrective action items; and closing out audit findings.
- Audit planning in the quality related functions and safety aspects of the activities and facilities being audited.
- On the job training to include applicable elements of the audit program.

- Audit Participation - The prospective Lead Auditor shall have participated in a minimum of five (5) QA audits within a period of time not to exceed three (3) years prior to the date of qualification, one (1) audit of which shall be a nuclear QA audit within the year prior to his/her certification. Participation in independent assessments including team assessment activities such as operations readiness reviews and regulatory inspections/surveys may be used to satisfy up to four of the five required QA audits, provided that the activities can demonstrate the following:
  - Independence from the functional areas being assessed;
  - Planning that establishes the scope of the activities and associated evaluation criteria;
  - Performance by technically qualified and experienced personnel;
  - Results that are documented and reported to management; and
  - Appropriate corrective action initiated and tracked to resolution.

  Such participation shall be subject to review and acceptance by the organization responsible for QA audits and/or the certifying authority prior to their use for qualification.
- Examination - The prospective Lead Auditor shall pass an examination which shall evaluate his/her comprehension of, and ability to apply the body of knowledge identified above. The test may be oral, written, practical, or any combination of the three types.

The processes for maintenance of proficiency, requalification, and administration of the Lead Auditor qualification shall be established and implemented per procedure to meet the applicable requirements.

Qualification examination activities may be delegated to an independent certifying agency, but CHBWV shall retain the responsibility for the examination administration and its conformance to established requirements.

Records shall be maintained to enable verification of personnel qualification and completion of required training. Processing, storing, and disposition of training and qualification records shall be in accordance with Part A, Section 4.0, "Documents and Records."

3.0 CRITERION 3 - QUALITY IMPROVEMENT

3.1 Introduction

This section describes the requirements, implementation, and responsibilities established to ensure that quality problems are prevented or minimized to ensure continuous quality improvement in activities and products and, when necessary, correct problems that occur.

It is CHBWV's policy to identify, control, and correct items and processes that do not meet established requirements. Correction includes identifying the causes of problems and preventing their recurrence. Item reliability and acceptability, process implementation, and other quality-related information are reviewed and the data analyzed to identify processes needing improvement.

The management approach integrates a continuous improvement focus into existing processes and implementing procedures to promote continued achievement and improvement of quality. Management develops annual project plans that include site goals, objectives and performance measures. The site goals and objectives are further supported by department goals, objectives, and performance measures, and further integrated on an individual basis.

CHBWV has established and implemented procedures and processes to promptly detect and prevent or correct quality problems as soon as practical. The implementing processes concentrate on problem prevention and work performance, based on the fundamental expectations described as follows:

- A condition adverse to quality shall be identified and documented when a failure, malfunction, deficiency, defective item, or nonconformance is identified.
- Conditions adverse to quality are classified and prioritized in regard to their significance, and corrective actions shall be taken accordingly.
- Categories of classification have been established to distinguish between: 1) Significant conditions adverse to quality, 2) Conditions adverse to quality, 3) Failure to meet CHBWV requirement that is not a regulatory compliance or DOE customer issue, and 4) Action tracking or trending only issue.
- Conditions adverse to quality and nonconformances for the existing canisters shall be evaluated for reportability in accordance with 10 CFR 21, *Reporting of Defects and Noncompliance*.
- Conditions adverse to quality and nonconformances (priorities 1-3) shall be evaluated for reportability in accordance with the Price-Anderson Amendments Act.
- Conditions adverse to quality and nonconformances are documented, tracked, and reported to the appropriate levels of management responsible for the conditions.
- Nonconformance documentation clearly identifies and describes the characteristics that do not conform to specified criteria.
- Responsible management shall complete remedial action as soon as practical.
- Criteria for determining a significant condition adverse to quality have been established and documented.
- Significant conditions adverse to quality shall be documented and reported to management responsible for the condition and their upper management in a prompt manner.
- Significant conditions adverse to quality shall be evaluated for a stop work condition by the QA organization to determine whether stopping work is warranted.
    - QA personnel shall issue stop work orders to responsible management after a stop work condition has been identified and approved in writing by the QA Manager.

    - QA management shall take appropriate action to lift and close (in part or total) the stop work issued by the QA organization based on the resolution of the related significant condition adverse to quality.
- Responsible management shall perform investigative action to determine the extent and impact of the condition, and document the results.
- Nonconforming characteristics are reviewed, and recommended dispositions of nonconforming items shall be proposed and approved.
- Responsible management shall determine, document, and complete remedial action.
- Recommended dispositions are evaluated and approved by individuals who are independent of the work that produced the disposition.
- Personnel performing evaluations to determine a disposition shall have demonstrated competence in the specific area being evaluated, have an adequate understanding of the requirements, and access to pertinent background information.
- Responsible management shall determine the root cause of the problem and take corrective action to prevent recurrence as soon as practical.
- Processes are established to verify the implementation of corrective actions associated with significant conditions adverse to quality.
- Further processing, delivery, installation, or use of a nonconforming item are controlled pending the evaluation and approval of the disposition.
- Reports of nonconformances and conditions adverse to quality shall be evaluated to identify adverse quality trends.
- Trend evaluation shall be performed in a manner and at a frequency that provides for prompt identification of adverse quality trends and assists in identifying root cause.
    - For HLW activities, trend evaluations shall be promptly distributed to HLW project management for review and appropriate corrective action.
- Criteria shall be established for determining adverse quality trends.

Management encourages new ideas, worker ownership of work process methods, and encourages identification and reporting of unsatisfactory conditions. Management encourages the voicing of differences of opinion, and the early identification and resolution of such differences. CHBWV has established and implemented an employee concerns program for reporting concerns such as potential environmental, safety, health, or quality problems. Management may periodically benchmark other outstanding quality initiatives and conduct periodic independent quality fitness reviews to verify that the quality process is producing continuous improvement in overall operations.

3.2 Requirements

Quality improvement processes shall be established and implemented to satisfy the requirements of this section in accordance with 10 CFR 830.122 (c), "Criterion 3-Management/Quality Improvement," and DOE O 414.1D CRD, Attachment 2, " Criterion 3-Management/Quality Improvement", which state:

- “Establish and implement processes to detect and prevent quality problems.”
- “Identify, control and correct items, services, and processes that do not meet established requirements.”
- “Identify the causes of problems, and include prevention of recurrence as a part of corrective action planning.”
- “Review item characteristics, process implementation, and other quality-related information to identify items, services, and processes needing improvement.”

The following were used in the development of the requirements for this section:

- ASME NQA-1-2008/2009a, Requirements 2, 15, and 16, DOE/RW-0333P, QARD, Rev. 20, and the guidance in DOE G 414.1-2B

Record requirements are discussed in Part A, Section 4.0, “Documents and Records" of this document.

3.3 Implementing Responsibilities

3.3.1 Senior management is responsible for establishing and leading the quality improvement process to oversee that proper focus is given and adequate resources are provided. Also they are responsible for establishing and implementing processes to promote and conduct continuous quality improvement in technical and management processes, including the identification of performance measures of success and standards of excellence.

3.3.2 Line Management is responsible for:

- Quality performance and encourages new ideas, worker ownership of work processes, and the identification of problems without fear of recrimination.
- Implementing corrective action for problems, for identifying root causes of problems, for recommending processes/procedures to prevent their recurrence, and for evaluating deficiency and corrective action data for systemic impact and application.
- Assuring that nonconforming items brought to their attention that affect quality are documented and reported to the QA Department.
- Assuring that the disposition of nonconforming items is technically sound and meets the requirements of this QAP.
- Providing the technical justification for the use of all nonconforming items dispositioned" use-as-is" or "repair" and performing the related Unreviewed Safety Question Determination process for such items.
- Coordinating the development of action plans for the resolution of nonconformances related to the HLW Canistered Waste Form.
- Conducting project/facility specific performance data analysis and taking actions to correct adverse trends, ensuring required corrective action effectiveness reviews are performed and documenting and submitting any organizational learning (Lessons Learned) to Issues Management.
- Identifying programmatic conditions adverse to quality within their organization.
- Acknowledging the existence of programmatic conditions adverse to quality identified by others.
- Ensuring that identified programmatic conditions adverse to quality are being appropriately documented and reported in accordance with the requirements of this QAP and CHBWV implementing procedures.
- Analyzing the condition to determine its significance.
- Establishing remedial actions.
- For significant conditions adverse to quality:
    - Determining the cause of the condition;
    - The extent of the condition (what other systems, items, or activities could be affected); and
    - Establishing corrective (preventive) actions to preclude recurrence.
- Obtaining QA department concurrence with the evaluation and reconciliation of programmatic condition adverse to quality.

3.3.3 Functional Organizations are responsible for:

- Evaluating performance analysis, taking actions to correct adverse trends, and performing required corrective action effectiveness reviews.

3.3.4 The QA Manager is responsible for:

- Establishing processes/procedures to prevent and detect quality problems and to identify, control, document, report, and resolve nonconforming conditions.
- Establishing the implementing procedures and coordinating the Issues Management process.
- Establishing the implementing procedures and coordinating the Performance Analysis process.
- Defining the necessary training for the systems.
- Periodically evaluating system data for trends and reporting results to management.
- Providing subject matter expertise as needed to support issue identification through resolution.
- Independently identifying conditions adverse to quality through such mechanisms as audits, assessments, surveillances, analysis of trends and/or trend reports, and inspections.
- Evaluating proposed remedial corrective actions to confirm that they are adequate and appropriate to the importance of the condition.
- Concurring with the causal determination and actions taken to prevent recurrence for significant conditions adverse to quality.
- Performing follow-up actions (audits, assessments, surveillances, etc.) to confirm that the corrective action commitments have been met.
- Confirming that, when completed, the records associated with the implementation of the corrective action(s) demonstrate the adequacy and completion of the committed actions.
- Receiving a DOE-WVDP generated "Corrective Action Request" (CAR) and, upon acceptance of same, immediately issuing, or causing to be issued, the appropriate CHBWV internal document.
- Verifying that nonconformances are properly documented, controlled, and dispositioned, and that the disposition has been implemented.
- Releasing properly dispositioned items for further processing.
- Evaluating nonconformances with respect to the need for further corrective/preventive action.
- Notifying DOE-WVDP of the existence of nonconformances related to HLW, as appropriate.
- Obtaining DOE-WVDP review and approval of action plans developed to resolve nonconformances against the canistered waste form.

3.3.5 All CHBWV personnel are responsible for identifying, controlling, and reporting items that do not meet established requirements (e.g., deficiencies, nonconformances). Each employee is empowered to identify improved methods of performing work.

3.4 Implementation

Quality improvement processes shall be established and implemented to detect, prevent, and correct quality problems. The quality improvement processes shall include, at a minimum, issue identification, evaluation, control, and tracking; issues management; and feedback and improvement. Management must set performance goals and standards, establish metrics and

monitor performance. Collectively, these systems provide for continuous evaluation and improvement of processes. They also ensure implementation of ISMS and EMS functions for feedback and improvement.

Personnel at all levels in the company are required to identify issues, potential deficiencies, and opportunities for improvement to their management or other responsible authorities. Items, services, and processes that do not meet established requirements shall be identified, controlled, and corrected.

3.4.1 Issues Management

It is the policy of CHBWV that conditions adverse to quality shall be identified promptly and corrected as soon as practical. In the case of a significant condition adverse to quality, the cause of the condition shall be determined and corrective (preventive) action taken to preclude recurrence. The identification, cause, extent, and corrective action for significant conditions adverse to quality shall be documented and reported to appropriate levels of management. Follow-up action shall be taken to verify implementation of corrective action. Conditions adverse to quality shall be trended, criteria for determining adverse quality trends established, and root causes identified when required.

A CHBWV issues management system has been developed for the timely identification and evaluation of adverse conditions. This process identifies appropriate corrective and preventive actions and track the issues to closure. The process also determines the extent of conditions on significant and adverse issues.

The system has been implemented using the graded approach such that the issue with the highest demonstrated risk receives the rigor, resources, management attention, and degree of verification commensurate with the risk. This graded approach is documented in the issues management procedures describing the prioritization process and associated criteria. Issues are assigned priority codes 1, 2, 3, or 4 as follows:

- Priority 1 - Includes items such as: contract deliverables, critical safety items, regulatory or environmental code compliance items, or any other item identified as a priority by CHBWV Senior Management.
- Priority 2 - Includes items such as: external commitments made to DOE or Regulators. This would include responses to DOE assessments and surveillances and request for DOE Directives information.
- Priority 3 - CHBWV requirement only (does not meet priority 1 or 2 above).
- Priority 4 - Tracking for non-regulatory type actions and “Tickle Reminders.”

The process requires issues that are simple to resolve and low risk to receive the least rigor and issues with significant demonstrated impact receiving the highest level of rigor and subsequent verification. A computerized tracking system is used to status actions from initial reporting to closure through verification of completion of actions and determination of the effectiveness of corrective actions for significant issues. Issue identification, response, and action effectiveness reviews are documented and tracked with results periodically reported to management.

A "Condition Adverse to Quality" is defined as a state of noncompliance with respect to specified requirements.

A "Significant Condition Adverse to Quality" is defined as a condition adverse to quality which, if uncorrected, could affect safety, operability, or acceptability of a waste form. Such conditions shall be evaluated for STOP-WORK/step back actions. The following are examples of such conditions:

- The issue or item deficiency could have an adverse effect on HLW acceptance; could result in on-site or off-site impacts to large numbers of persons; or have a serious effect on environmental, health, safety, quality, or operability.
- The issue or item deficiency is repetitive in nature and indicates that the current controlling measures are inadequate.
- The issue or item deficiency indicates a deliberate disregard for safety or quality assurance programmatic requirements.
- The issue or item deficiency, if uncorrected, could result in a deficiency in design, process, manufacturing, or testing, which would have a substantial impact on programs, environment, health or safety.
- The issue or item deficiency represents a willful noncompliance with customer or regulatory-specified requirements. This includes any hardware determined to be a suspect/counterfeit item (S/CI).
- The issue could result in a significant off-site release of radioactive or hazardous material, or off-site spread of radioactive contamination in excess of 100 times the surface radioactivity levels specified in the CHBWV Radiation Protection Program.
- The issue could result in the violation of approved Technical Safety Requirements.

3.4.2 Nonconformance Control

It is the policy of CHBWV that items which do not conform to specified requirements be controlled to prevent inadvertent installation or use. Controls provide for identification, documentation, evaluation, segregation when practical, disposition of nonconforming items, and for notification to affected organizations. The implementation of these requirements is through written procedures.

Nonconforming items are controlled to prevent their inadvertent installation or use in accordance with documented and approved procedures and affected organizations notified of the circumstances. Responsibility for preventing the use, delivery, installation, or operation of nonconforming items is designated in procedures. Nonconformance reports document the description, disposition, action, verification, and closure of nonconforming items.

Identification of nonconforming items shall be accomplished by legible marking, tagging, or other methods that do not adversely affect the end use of the item. If identification of each nonconforming item is not practical, the container, package, or segregated storage area, as appropriate, shall be identified.

Nonconforming items shall be segregated, when practical, by placing them in a clearly identified and designated hold area until proper disposition is implemented. When segregation is not possible or practical, other appropriate means shall be used to avoid or eliminate the risk of inadvertent installation or use until proper disposition is implemented. Further processing, delivery, installation, or use of nonconforming items shall be controlled pending evaluation and disposition.

Nonconforming characteristics are reviewed, and recommended dispositions are proposed and approved. The responsibility and authority for evaluation and disposition is defined. Items that deviate from design requirements whose disposition is "use-as-is" or "repair" are subject to design control measures commensurate with those applied to the original design. Such dispositions are documented, including justification. Required as-built documents shall reflect any deviations from design.

Disposition

- Nonconforming items (hardware) are dispositioned as one of the following:
  - SCRAP - The nonconforming material or item is to be rendered unusable for the intended function.
  - RETURN-TO-SUPPLIER - The nonconforming material or item is to be returned to the supplier.
  - REWORK - The nonconforming material or item is made to conform to the original specification requirements.
  - REPAIR - The nonconforming material or item is made usable, but does not completely conform to the original specification requirements.
  - USE-AS-IS - The nonconforming material or item is determined to be acceptable for the intended application without further modification and is no longer considered nonconforming.
- Technical justification for the acceptability of a nonconforming item, dispositioned as repair or use-as-is is documented. Nonconformances to design requirements dispositioned use-as-is or repair shall be subject to design control measures, commensurate with those applied to the original design. The technical justification shall include a determination by the cognizant, technical organization of the need to reflect the disposition in the design specifications and drawings and the design support documentation. The as-built records, if such records are required, shall reflect the accepted deviation.
- The disposition must be identified and documented, the action(s) taken to correct the nonconforming item shall be documented, the action(s) verified, and the verification documented. This disposition shall also include action(s) to preclude recurrence of the condition.

Repaired or reworked items are reexamined in accordance with applicable procedures and with the original acceptance criteria unless the nonconforming item disposition has established alternate acceptance criteria.

Replacement items shall be inspected and tested in accordance with the original inspection and test requirements or acceptable alternatives.

The status of nonconforming items shall be tracked to closure. Satisfactory completion of actions required by the nonconformance disposition shall be verified prior to closure.

3.4.3 Performance Analysis

Performance indicators shall be developed and analyzed to identify trends or potential opportunities for improvement relative to CHBWV performance. The results of data analysis shall be reported to appropriate levels of management. Appropriate actions shall be taken when adverse trends or improvement opportunities are identified. Similarly, evidence of sustained effective performance shall be recognized and reinforced.

3.4.4 Lessons Learned

A Lessons Learned process shall be developed and implemented. The Lessons Learned process shall incorporate relevant organizational learning and associated recommendations into processes to proactively prevent operational events. Any information deemed worthy of sharing should be submitted into the Issues Management process. Post job reviews are conducted to identify Lessons Learned and opportunities for improvement to be considered during future work planning activities.

4.0 CRITERION 4 - DOCUMENTS AND RECORDS

4.1 Introduction

This section establishes the requirements for the preparation, issue, and control of changes made to documents that specify quality requirements or prescribe activities affecting quality, specify quality requirements, or establish design. Records shall be identified, generated, authenticated, maintained, and their final disposition specified.

4.2 Requirements

Document and records control processes shall be established and implemented by CHBWV organizations to satisfy the requirements of this section in accordance with 10 CFR 830.122 (d), "Criterion 4-Management/Documents and Records," pursuant to DOE O 414.1D CRD, Attachment 2, "Criterion 4-Mangement/Documents and Records" which state:

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

The following were used in the development of the requirements in this section:

- ASME NQA-1-2008/2009a, Requirements 5, 6, and 17
- DOE/RWP-0333P, QARD, Rev. 20
- CRD O 243.1A, Records Management Program
- The guidance presented in DOE G 414.1-2B

4.3 Implementing Responsibilities

4.3.1 Management

Managers of CHBWV organizations are responsible for implementing the CHBWV processes for document and record control within their organizations to provide adequate and proper documentation and records of CHBWV work and to identify and control documents and records generated in the course of their activities. Responsibilities include the preparation, review and approval of quality-related documents and revisions; assuring the use of correct document revisions, and the identification, generation, preparation, validation, classification, preservation, and submittal of quality records.

4.3.2 Quality Assurance Organization

The QA organization is responsible for defining QAP requirements for CHBWV documents and records, reviewing and concurring with procedures affecting quality, and verifying the implementation of the document control and records management processes.

4.3.3 Records Organization

The Records organization is responsible for developing and maintaining the document control and records management processes. This includes performing as the technical authority, ensuring program compliance with applicable requirements, and the generation and control of the site file plan. CHBWV organizations that handle and maintain records are responsible for implementation of the requirements.

4.3.4 Personnel

CHBWV employees are responsible for performing his/her work to the requirements of the most current documents and for documenting the results of work activities as specified.

4.4 Implementation

CHBWV integrates the requirements of documents and records processes into implementing procedures for the timely preparation, issuance, control, and revision of documents that specify requirements of prescribed processes or quality-affecting activities. Management encourages the use of electronic data systems and requires that workers use the correct documents to perform their assigned duties.

CHBWV has established and maintains procedures to control documents. Such documents, including revisions, are reviewed for conformance with quality requirements and approved for release by authorized personnel. Procedures have also been developed to address the protection of information such as Confidential, Official Use Only, Export Controlled, and personal information.

Management oversees that documents are kept current, are available at the workplace as required, and are used by personnel performing work.

CHBWV has established procedures to require that sufficient records are specified, prepared, reviewed, authenticated, maintained, stored, and protected.

4.4.1 Document Control

A program is established and implemented to control the preparation, review, approval, issuance, use, and revision of documents that prescribe activities, specify requirements, or establish design. Examples of documents to be controlled include drawings, data files (including various media), calculations, specifications, computer codes, purchase orders and related documents, vendor-supplied documents, procedures, work instructions, and data sheets.

The need for, and level of detail in procedures and instructions shall be determined based on the complexity of the task, the significance of the item or activity, work environment, and worker proficiency and capability to assure consistent and acceptable results. The implementing documents shall include responsibilities and organizational interfaces affected by the document; quantitative and qualitative acceptance criteria sufficient for determining that activities were satisfactorily completed; and identification of lifetime or nonpermanent QA records generated by the implementing documents.

Major changes to documents shall be reviewed and approved by the same organizations that performed the original review and approval, unless other organizations are specifically designated. The reviewing organization shall have access to pertinent data or information upon which to base its approval. Specifically designating other organizations is permitted in cases where organizational responsibilities and authorities have changed, or review/approval requests are no longer valid.

Minor changes to documents, such as editorial corrections, do not require the extent of review and approval required for major changes. Minor changes shall be specified. Controlled instructions and procedures are made available for use prior to the start of work and are required to be adhered to by persons performing the activity.

The distribution of new and revised controlled documents is in accordance with established timeliness guidelines. At the time of distribution of new or revised controlled documents, it is required that the recipient (usually the person on controlled distribution) destroy, or identify superseded documents.

Electronic access is also available to view controlled documents.

4.4.2 Records

A program is established and implemented to require that records furnishing documentary evidence of the quality of items and processes (such as design, procurement, construction, data acquisition, inspection, testing, maintenance, modification, and decontamination and decommissioning) are specified, prepared, reviewed, approved, and maintained to reflect completed work. These records may take any form, such as optic, magnetic, electronic, handwritten, computer generated, or any others which are capable of being validated/authenticated. Records are to be legible, identifiable, and retrievable. Records shall be protected against damage, deterioration, and loss. The requirements and responsibilities for record generation, review, approval, transmittal, distribution, retention, maintenance, and disposition shall be established and documented. Records maintenance provisions include retention, protection, preservation, storage, traceability, accountability, and retrievability.

For records that require special processing and control, such as computer codes or information on computer disks, the hardware and software required to maintain and access the records are controlled to provide records that are useable.

Quality assurance records are classified in accordance with ASME NQA-1. Lifetime records shall be turned over to the DOE or its designee at the conclusion of the CHBWV contract or as otherwise specified.

There are two satisfactory methods of providing adequate permanent storage facilities, single or dual.

Single Storage Facility

Single Storage consists of a storage facility, vault, room, or container(s) with a minimum two-hour fire rating. Design and construction of a single record storage facility shall be reviewed for adequacy by a person competent in fire protection and fire extinguishing or contain a certification or rating from an accredited organization and meet the following criteria:

- Reinforced concrete, concrete block, masonry, or equal construction.
- Floor and roof with drainage control. If a floor drain is provided, a check valve (or equal) shall be included.
- Doors, structure and frames, and hardware shall be designed to comply with the requirements of a minimum 2 hour fire rating.
- Sealant applied over walls as a moisture or condensation barrier.
- Surface sealant on floor providing a hard wear surface to minimize concrete dusting.
- Foundation sealant and provisions for drainage.
- Forced air circulation with filter system.
- Fire protection system.
- Only penetrations used exclusively for fire protection, communication, lighting, or temperature/humidity control are allowed; all such penetrations shall be sealed or dampered to comply with the minimum 2 hour fire protection rating.

The construction details shall be reviewed for adequacy of protection of contents by a person who is competent in the technical field of fire protection and fire extinguishing. If the storage facility is located within a building or structure, the environment and construction of that building can provide a portion of all of these criteria.

Dual Storage Facilities

If dual storage facilities, containers, or a combination thereof for each record are provide d, the storage facilities shall be at locations sufficiently remote from each other to eliminate the chance of exposure to a simultaneous hazard. Each storage facility is not required to satisfy the full requirements of the single storage facility but shall be reviewed for adequacy by a person competent in fire protection and fire extinguishing or contain a certification or rating from an accredited organization.

PART B: PERFORMANCE

Part B contains the program elements essential for effective design, construction, and operation of engineered items and systems; for planning and achieving performance objectives; and for managing activities associated with establishing and maintaining the technical requirements for work. This section includes the necessary implementing processes for defining and achieving the performance objectives for work processes and operations, procurement of items and services, design, construction, and testing and operations of engineered items and systems. The responsibility for quality as work tasks are performed is assigned to the responsible line manager and ultimately to the worker who owns the task.

5.0 CRITERION 5 - WORK PROCESSES

5.1 Introduction

This section describes the requirements and responsibilities established to ensure work processes are defined and controlled to ensure the quality of CHBWV products.

It is CHBWV policy to perform work under suitable conditions using approved instructions, procedures, or other appropriate means. Items are identified and controlled to ensure their proper use, and are maintained to prevent their damage, loss, or deterioration. Defective items are identified and controlled to prevent inadvertent use.

5.2 Requirements

Work processes shall be described and implemented by CHBWV organizations to satisfy the requirements of this section in accordance with 10 CFR 830.122 (e), "Criterion 5-Performance/Work Processes," and DOE O 414.1D CRD, Attachment 2, "Criterion 5-Performance/Work Processes", which state:

- “Perform work consistent with technical standards, administrative controls, and other hazard controls adopted to meet regulatory or contractual requirements using approved instructions, procedures, or other appropriate means.”
- “Identify and control items to ensure proper use.”
- “Maintain items to prevent damage, loss, or deterioration.”
- “Calibrate and maintain equipment used for process monitoring or data collection.”

The following were used in the development of the requirements for this section:

- ASME NQA-1-2008/2009a Requirements 5, 8, 9, and 13
- DOE/RWP-0333P, QARD, Rev. 20
- The guidance in DOE G 414.1-2B

Software requirements as specified by NQA-1-2008/2009a, Subpart 2.7, are specified in Part E of this document. Control of measuring and test equipment is discussed in Section 8.0, “Inspection and Acceptance Testing.” Record requirements are discussed in Part A, Section 4.0, “Documents and Records” of this document.

5.3 Implementing Responsibilities

5.3.1 Management

CHBWV Managers are responsible for controlling their work processes by ensuring the following:

- Establishing policies and procedures for all aspects of work processes consistent with the processes' importance and programmatic impact, including defining criteria for acceptable work performance.
- Routine involvement in planning, designing, implementation, and continuous improvement of work processes in their area of responsibility.
- Placing qualified personnel in positions to accomplish work.
- Ensuring personnel are trained in the job requirements, including retraining when work is changed; and ensuring work is completed in accordance with applicable requirements.

5.3.2 Personnel

CHBWV employees are responsible for ensuring the quality of work by doing the following:

- Performing work to approved requirement documents (e.g., plans, procedures, drawings, specifications).
- Performing work with the proper tools and equipment.
- Striving to perform work correctly the first time.
- Contributing to continuous improvement of work processes.

CHBWV employees are also responsible for advising supervisors or managers when work cannot be performed safely and/or in accordance with the work control documents. Employees have the responsibility to notify management of conditions adverse to quality. Work stoppage for significant quality issues shall be accomplished through management processes.

5.3.3 Engineering Organization

The Engineering organization is responsible for the identification of special processes, the identification of applicable codes, standards, and specifications or high level waste activities which require specific identification or traceability requirements, and the specification of acceptance criteria.

5.3.4 Quality Assurance Organization

The CHBWV QA organization is responsible for providing assistance/input in the development and review of CHBWV procedures governing work processes, review and approval of procurement packages for quality-related purchases, and for conducting or coordinating verification activities or periodic oversight of work process performance and processes.

5.3.5 Records Organization

The Records organization is responsible for administration of the CHBWV procedures processes, which includes the document preparation, revision, and control processes.

5.3.6 Work Control

The CHBWV Operations organization is responsible for ensuring the development, the maintenance, and effective implementation and interpretation of the CHBWV Work Control Program and the Maintenance Program.

5.4 Implementation

CHBWV integrates work processes which are consistent with DOE Orders, such as DOE O 422.1, *Conduct of Operations*, and DOE P 450.4A, *Safety Management System Policy*. CHBWV fosters the attitude that personnel performing work are responsible for the quality of their work. Line management is directly involved in the achievement of quality, the assurance of quality, and the continuous improvement of work processes.

It is management policy that there is a proactive and continuing involvement by an independent QA organization, which supports and assists line management in their implementation of the QAP. This independent involvement in no way preempts or replaces the quality responsibilities of the performing personnel or the associated line managers. The extent and degree of the independent QA organizational involvement is established through graded application of the QAP.

CHBWV has established and implemented procedures to manage work activities by planning, performing, and assessing according to approved requirements documents (e.g., plans, procedures, drawings, specifications). Procedures, work instructions, or other documents shall be developed using the graded approach such that the scope and detail are commensurate with the relative safety and programmatic importance or intended use of the resulting item or activity. Procedures for special processes where conformance is difficult to measure, or where quality of the results cannot be readily determined by inspection or test of the product requires special attention for control of processes and/or worker skill shall be developed.

Project management shall conduct and document project planning. Work planning requires involvement of the line management before initiation of significant project activities to identify and determine the overall project scope of work and identify associated hazards and controls within which project activities are required to be performed.

5.4.1 Work Control

Activities that can affect the quality, safety, or the environment of CHBWV products and services shall be prescribed by and performed in accordance with documented, management-approved procedures, instructions, checklists, and design documents that comply with applicable regulatory, DOE orders, technical standards, and administrative control requirements. Instructions, procedures, and other forms of direction are developed, verified, validated, and approved by personnel knowledgeable, experienced, and authorized to provide direction in the area of work being addressed.

Line management confirms that personnel are provided with the necessary training and are given sufficient resources to accomplish assigned tasks. Line management also confirms that the appropriate administrative controls are in place to establish the criteria for acceptable work performance and quality achievement.

Line management reviews the quality of completed work and other quality related information to determine that the desired quality is being achieved and to identify work processes and process implementation areas potentially in need of improvement.

Work is planned, authorized, and accomplished under controlled conditions using approved instructions, procedures, or other appropriate means that are of a detail commensurate with the activity's complexity, risk, and importance. Those work processes that require the use of instructions, procedures, or other means are identified by line management.

5.4.2 Identification and Control of Items

A program is established and implemented to control samples and to identify, control, and maintain items (including consumable materials and items with limited shelf life) to prevent the use of incorrect or defective items. Engineering and procurement provides instructions for the identification and control of S/CI, and directions to preclude them from the project.

Identification of items shall be maintained so that the item can be traced to its documentation. When specified, items shall be identified from the initial receipt and fabrication of items up and including installation and use. When codes, standards, or specifications include specific identification or traceability requirements (such as identification or traceability of the item to applicable specification and grade of material; heat, batch, lot, part, or serial number; or specified inspection, test, or other records), implementing departmental procedures shall provide such identification and traceability control methods. This includes requirements for controlling quality related weld/braze filler metal and flux material. Items having limited calendar or operating life cycles shall be identified and controlled to preclude use of items whose shelf life or operating life has expired. Records that identify the calendar life, operating life and/or operating cycle

remaining shall be established. Traceability is maintained to the extent consistent with the item's importance.

Physical identification of items shall be used to the extent possible. Marking or labeling shall not be detrimental to the item. Where physical identification is either impractical or insufficient, physical separation, procedural control, or other means shall be employed (Such as physical separation, labels or tags attached to containers or procedural control)

Markings shall be applied using materials and methods that provide clear and legible identification and do not degrade the function or service life of the item. When specified, shall be transferred to each part of an identified item when subdivided and shall not be obliterated or hidden by surface treatment or coating unless other means of identification are substituted.

Provisions shall be included in departmental implementing procedures for the control of item identification consistent with the planned duration and conditions of storage, such as:

- Provisions for maintenance or replacement of markings and identification records due to damage during handling or aging;
- Protection of identifications on items subject to excessive deterioration due to environmental exposure;
- Provisions for updating existing plant records; and
- Provisions for precluding the introduction of suspect/counterfeit items at the WVDP.

5.4.3 Special Processes

Those processes that are highly dependent on process control, operator skill, and for which the quality of the product cannot be readily determined by inspection or test, shall be controlled as special processes and shall be performed by qualified personnel using approved procedures, drawings, checklists, travelers, or other appropriate means to specify requirements. Examples of special processes are welding, brazing, soldering, heat treatment, nondestructive assay (NDA), NDE, certain laboratory analysis, and others deemed necessary by the QA Manager.

The HLW production processes that have been established as HLW activities are specified in WVDP-200 and are categorized as Quality Level B in accordance with Part A, Section 1.0, “Program.” Therefore, these processes will require additional controls to ensure acceptance of the canistered waste form.

Process control procedures shall be in compliance with applicable specifications, codes, or standards. Control procedures shall specify the preparatory steps, processing details, test conditions, and the requirements for records. For special processes not covered by existing codes and standards, or where quality requirements specified exceed those of existing codes and standards, the necessary requirements for qualification of personnel, procedures, or equipment shall be specified or referenced in procedures or instructions.

Procedures specifying conditions necessary for the accomplishment of the process shall include proper equipment, controlled parameters of the process, environmental conditions, and calibration requirements where necessary.

NDE shall be performed in accordance with a written practice or procedure and operator qualification/certification to assure accurate, uniform, and reproducible results. Those NDE disciplines considered to be special processes are: radiography, magnetic particle, ultrasonic, liquid penetrant, eddy current, neutron radiography, acoustic emission, and leak testing. Results of NDE shall be recorded in accordance with applicable specifications, codes, standards, and procedures.

Production processes shall be performed by qualified personnel using approved procedures to control those activities that are:

- Critical to the acceptance of the canistered waste form such as those requirements identified in the Waste Acceptance Manual.
- Essential to maintaining process stability such that significant variances would or could have the potential to impact the acceptability of the canistered waste form.

Records shall provide objective evidence that special processes were performed in compliance with approved process control procedures by qualified personnel using qualified equipment.

5.4.4 Handling, Storage and Shipping

A program is established and implemented to control the handling, storage, shipping, cleaning, and preservation of items and consumables in accordance with design and procurement requirements, to prevent their damage, loss, or deterioration.

Handling, storage and shipping of items shall be conducted in accordance with approved work and inspection procedures, drawings, specifications, instructions, or other pertinent documents specified for use in conducting the activity.

Special protective measures (such as containers, shock absorbers, accelerometers, inert gas atmospheres, and specific temperature and moisture levels) are specified and provided when required to maintain acceptable quality.

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

Special handling tools and equipment shall be utilized and controlled as necessary to ensure safe and adequate handling. The tools and equipment shall be inspected and tested in accordance with procedures and at specified time intervals to verify that the tools and equipment are adequately maintained.

Items are marked and labeled during packaging, shipping, handling, and storage to identify, maintain, and preserve the items' integrity and indicate the need for special controls. Requirements for off-site transportation are established and implemented.

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

6.0 CRITERION 6 - DESIGN

6.1 Introduction

This section describes the requirements and responsibilities established to plan, control, and verify design activities, including design input, design output, configuration and design changes, documentation, and technical interfaces consistent with the graded approach.

It is CHBWV policy to design items and systems using sound engineering/scientific principles and appropriate standards. Design work, including changes, is incorporated with applicable requirements and design basis. Design interfaces are identified and controlled. The adequacy of design products is verified or validated by individuals or groups other than those who performed the work. Verification and validation work is completed before approval and implementation of the design.

CHBWV integrates a formal design control process which is consistent with the appropriate requirements of ASME NQA-1. Design controls are determined through a risk-based control process that considers ESH&Q impact, and programmatic risk. The extent of design verification and validation is based on complexity, risk, and uniqueness of the design.

CHBWV has established and implemented a formal design control program that requires engineered items and systems to be designed using sound engineering/scientific principles and appropriate standards. The formal design process defines the control of design inputs, processes, outputs, changes, lines of communication, interfaces, and records. This process provides for timely and correct translation of design inputs into design outputs, effective coordination and interfacing of organizations participating in the design process, and acceptable and verified design outputs. Designs shall provide for expected end use, including inspection, testing, acceptance criteria, hazard mitigation, and maintenance considerations.

CHBWV has a formal design verification process which confirms design adequacy by persons other than those who designed the system or item where appropriate. Verification is completed and documented before implementation of the design. Complex designs are verified at critical stages of development to enable timely correction of deficient conditions. Computer software used for design and associated design calculations is validated through testing or simulation prior to use.

Design documents specify the technical and quality acceptance criteria and the information required to verify acceptable construction and operation. Design changes, including field changes, are governed by control measures commensurate with those applied to the original design.

CHBWV policy establishes a grading process methodology (quality levels) which defines specific levels of QAP application. This policy takes into consideration the ESH&Q programmatic importance of the work, and intended use of items or systems.

All CHBWV engineering design activities shall be accomplished in accordance with documented and approved design control procedures which assure that the design is defined, controlled, and verified. Applicable design inputs shall be appropriately specified on a timely basis and correctly translated into design documents. Design interfaces shall be identified and controlled. Design adequacy shall be verified by persons other than those who designed the item. Design changes, including field changes, shall be governed by control measures commensurate with those applied to the original design.

6.2 Requirements

Design processes shall be established and implemented by CHBWV organizations to satisfy the requirements of this section in accordance with 10 CFR 830.122 (f), "Criterion 6-Performance/ Design," and DOE O 414.1D CRD, Attachment 2, "Criterion 6-Performance/Design", which state:

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

The following were used in the development of the requirements for this section:

- ASME NQA-1-2008/2009a, Requirement 3
- DOE/RW-0333P, QARD, Rev. 20
- The guidance in DOE G 414.1-2B

Software requirements as specified by NQA-1-2008/2009a, Subpart 2.7, are specified in Part E of this document. Record requirements are discussed in Part A, Section 4.0, "Documents and Records" of this document.

6.3 Implementing Responsibilities

The CHBWV Chief Engineer is responsible for implementing a formal design program for engineered items and systems that are designed using sound engineering/scientific principles and appropriate standards. He/she is also responsible to flow these requirements to other CHBWV engineers assigned to other departments or projects.

Engineers are responsible for planning, coordinating, and documenting design, construction, and operation of engineered items and systems used in protecting the environment, safety, and human health. Engineering activities shall be conducted such that the type and quality of inputs to design, construction, operation, and decontamination and decommissioning, are defined and documented to the extent necessary to confirm that participants in the engineering activities are informed of appropriate project requirements.

Engineers are responsible for the identification of the following elements as a minimum:

- Project/task scope and objectives, and a listing of primary activities involved.
- Associated hazards and their controls.
- Specific engineering systems components to be designed, fabricated, constructed, and operated.
- Technical, performance, quality standards, and design criteria or objectives.
- Correct translation of design inputs into design outputs.
- Coordination and interface organizations required to participate in the design process.
- Verifiable design outputs and acceptance criteria that are required.
- Special skills, equipment, and other resources that are required.
- Program technical reviews, peer reviews, surveillances, technical or QA audits, and other assessment processes.
- Provisions for precluding the introduction of suspect/counterfeit items.
- Project and QA records that are required.

QA organization is responsible for:

- Reviewing and approving procedures defining design controls to assure that they meet the established programmatic requirements.

- Periodically independently assessing compliance with the established design control processes and procedures.
- Reviewing and approving design basis documents, design documents, and changes thereto prior to their issue for Quality Level C and above.
- Participating, as a required reviewer, in Quality Level B or C design review activities.

6.4 Implementation

Designs shall be defined, controlled, and verified utilizing procedures that implement the requirements specified in this section.

6.4.1 Design Criteria

The design criteria shall be defined using the application of sound engineering, scientific principles, codes, and standards, and provide the appropriate level of definition of performance, environmental, safety, and operational requirements.

6.4.2 Design Input

Applicable design inputs shall be identified and documented, and their selection reviewed and approved by the responsible design organization. Design input shall be specified to a level of detail necessary to adequately support design decisions and design activity including design verification and evaluation of design changes. Changes from approved design inputs, including the reason for the changes, shall be identified, documented, approved by the responsible design organization, and controlled. Design inputs shall include the following as applicable:

- Design Bases;
- Functional Requirements;
- Operational Requirements;
- Performance Requirements;
- Regulatory Requirements;
- Codes and Standards;
- Environmental Conditions;
- Maintenance Requirements;
- Interfaces with new or existing Structures and Equipment;
- Quality Level Classification of Items and Services;
- Control of Experiments and Development Activities;
- Qualification of Existing Data;
- Waste minimization/pollution prevention requirements;
- Ergonomic conditions;
- Appropriate safety considerations; and
- Review and approval.

6.4.3 Design Process

The design shall be defined, controlled, and verified. Design documents shall support the facility design, construction, and operation. The design methods, parts, equipment, and processes that are essential to the function of the items shall be selected and reviewed for suitability of application. The design process shall translate design input into design output documents that are technically correct and meet the end user's requirements. Aspects of design that are important to safety, reliability, or environmental considerations shall be identified during the design process. The organization accomplishing the design

shall ensure design output documents meet design input requirements and are useable for their intended purpose. It shall verify any deviations from applicable standards or requirements have been approved and documented. Design output shall be approved and released in accordance with established procedures. The final design shall be relatable to the design input in sufficient detail to permit design verification without recourse to the originator. The final design shall specify acceptance and in-service inspections and test requirements and include or reference appropriate acceptance criteria. The final design shall identify assemblies and/or components that are part of the item being designed. When such an assembly or component part is a commercial grade item, the critical characteristics of the item to be verified for acceptance and the acceptance criteria for those characteristics shall meet the requirements of Part F of this QAP. Critical characteristics to be verified are those that provide reasonable assurance that the item will perform its intended safety function.

If a commercial grade item, prior to its installation, is modified or selected by special inspection and/or testing to requirements that are more restrictive than the Supplier's published product description, the component part shall be represented as different from the commercial grade item in a manner traceable to a documented definition of the difference.

Design documents, including changes, shall be based upon sound engineering/scientific principles and shall incorporate appropriate requirements, standards, and design bases. Design calculations shall be identifiable by subject (including SSCs to which the calculation applies), originator, reviewer, and date, or other data so the calculations are retrievable. Computer software used to originate or verify safety or other risk-significant design solutions during the design process shall be validated, and the status of validation shall be identified and documented prior to use.

Technical design interfaces shall be identified, documented, and controlled throughout the design process. Administrative interfaces, which include authorities, responsibilities, and lines of communication between project team members, shall be defined in sufficient detail to identify and establish relationships of such team members as end users, stakeholders, responsible design organizations, designers, purchasing agents, suppliers, and testers/inspectors. Transmittal of design information across organizational interfaces shall be documented and controlled.

6.4.4 Design Analysis

When design analysis is required, as defined by the Engineering Procedures, for items or activities affecting the quality of SSC, then the design analyses shall be performed in a planned, controlled, and documented manner. Design analysis documents shall be legible and in a form suitable for reproduction, filing, and retrieval. Documentation of design analyses shall include the following:

- The objective of the analyses;
- Design inputs and their sources;
- Results of literature searches or other applicable background data;
- Assumptions and indication of those assumptions that must be verified as the design proceeds;
- Identification of any computer calculation, including identification of the computer type, computer program name, and revision, inputs, outputs, evidence of or reference to computer program verification, and the bases (of reference thereto) supporting application of the computer program to the specific physical problem;
- Calculations shall be identifiable by subject (including SSC to which the calculation applies), originator, reviewer, and date, or by other designators such that the calculations are traceable and retrievable; and
- Review and approval.

When a computer program is used for design analysis, acceptability of the program shall be pre-verified or the results verified with the design analysis for each application. Pre-verified computer programs shall be controlled in accordance with the requirements described in Part E of this QAP.

- The computer program shall be verified to show that it produces correct solutions for the encoded mathematical model within defined limits for each parameter employed.
- The encoded mathematical model shall be shown to produce a valid solution to the physical problem associated with the particular application.

6.4.5 Design Verification

Design verification shall be performed in a planned and controlled manner and shall provide assurance that the final design is correct and satisfactory. Design verification methods may include, but are not limited to, one or more of the following:

- Technical reviews;
- Peer reviews;
- Alternate calculations; and
- Qualification testing.

The responsible design organization shall identify and document the particular design verification method(s) used.

Design verification shall be completed prior to releasing the design outputs and prior to relying on SSCs or computer programs to perform their function. However, if design outputs are used to support other work (e.g., procurement/acquisition, manufacture, construction, or experiment) before design verification is complete, then the unverified portion of the design outputs shall be identified and controlled. In those cases where design verification results in the need to revise the design output, the effect on previously performed work shall be determined, evaluated, and resolved prior to releasing the design output for use.

Design verification shall be performed by technically knowledgeable individuals or groups separate from those who performed the design. The results of design verification shall be documented and the identification of the verifier indicated.

If the design is modified to resolve verification findings, the modified design shall be verified prior to release or use.

A. Extent of Design Verification

The extent of design verification shall be commensurate with the design's complexity and importance to safety, the environment, the degree of standardization, state of the art, and similarity with previously approved designs. Known problems affecting the standard or previously proved designs and their effects on the other features shall be verified for each application. The original design and associated verification documentation shall be referenced in records of subsequent application of the design.

Where changes to previously verified designs have been made, design verification shall be required for the changes, including evaluation of the effects of those changes on the overall design and on any design analyses upon which the design is based that are affected by the change to previously verified design.

B. Methods

Acceptable verification methods include, but are not limited to, any one or a combination of design reviews, alternate calculations, and qualification testing.

1. Design Reviews: Design reviews are critical reviews to provide assurance that the final design is correct and satisfactory. The following shall be addressed, where applicable:

   a. Were the design inputs correctly selected?

   b. Are assumptions necessary to perform the design activity adequately described and reasonable?

   c. Was an appropriate design method used?

   d. Were the design inputs correctly incorporated into the design?

   e. Is the design output reasonable compared to design inputs?

   f. Are the necessary design input and verification requirements for interfacing organizations specified in the design documents or in supporting procedures or instructions?

   g. Have suitable materials, parts, processes, and inspection and testing criteria been specified?

2. Alternate Calculations: These are calculations or analyses that are made with alternate methods to verify correctness of the original calculations or analyses. The appropriateness of assumptions, input data used, and the computer program or other calculation method used shall also be reviewed.

3. Qualification Tests:

   a. Where design adequacy is to be verified by qualification tests, the tests shall be identified.

   b. The test configuration shall be clearly defined and documented.

   c. Testing shall demonstrate adequacy of performance under conditions that simulate the most adverse design conditions. Operating modes and environmental conditions in which the item must perform satisfactorily shall be considered in determining the most adverse conditions.

   d. Where the test is intended to verify only specific design features, the other features of the design shall be verified by other means.

   e. Test results shall be documented and evaluated by the responsible design organization to assure that test requirements have been met.

   f. If qualification testing indicates that modifications to the item are necessary to obtain acceptable performance, the modification shall be documented and the item modified and retested or otherwise verified to assure satisfactory performance.

   g. When tests are being performed on models or mockups, scaling laws shall be established and verified. The results of model test work shall be subject to error analysis, where applicable, prior to use in final design work.

6.4.6 Design Change Control

Design changes, including changes to design inputs, final design, field changes and temporary and permanent facility modifications, shall be justified and controlled by measures equal to those applied to the original design. Design change control measures shall include evaluation of effects of those changes on the overall design and on any analysis upon which the design is based. The evaluation shall include facility configurations that occur during operation, maintenance, test, surveillance, and inspection activities.

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

Changes shall be approved by the same affected groups or organizations that reviewed and approved the original design documents, except where an organization which originally was responsible is no longer available. In that case, the Chief Engineer, or his designee, shall designate a new responsible organization. The designated organization shall have demonstrated competence in the specific design area of interest and have an adequate understanding of the requirements and intent of the original design. When a design change is approved other than by revision to the affected design documents, measures shall be established to incorporate the change into these documents, where such incorporation is appropriate.

6.4.7 Configuration Management of Operating Facilities

Procedures implementing configuration management requirements shall be established and documented at the earliest practical time prior to facility operation. These procedures shall include the responsibilities and authority of the organizations whose functions affect the configuration of the facility including activities such as operations, design, maintenance, construction, licensing, and procurement.

Configuration management requirements shall include measures to ensure changes that may affect the approved configuration are recognized and processed.

The configuration shall be established and approved at the earliest practical time prior to initial operation of the facility, and maintained for the life of the facility.

The configuration shall include, as applicable, characteristics derived from regulatory requirements and commitments, calculations and analyses, design inputs, installation and test requirements, supplier manuals and instructions, operating and maintenance requirements, and other applicable sources.

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

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

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

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

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

6.4.8 Interface Control

Design interfaces shall be identified and controlled and the design efforts shall be coordinated among the participating organizations, and across technical disciplines. Interface controls shall include the assignment of responsibility and the establishment of procedures among participating design organizations and technical disciplines for the review, approval, release, distribution, and revision of documents involving design interfaces to ensure that SSC's are compatible geometrically, functionally, and with processes and environments.

Design information transmitted across interfaces shall be documented and controlled. Transmittals shall identify the status of the design information or documents provided and, where necessary, identify incomplete items which require further evaluation, review, or approval. Where it is necessary to initially transmit design information orally or by other informal means, the transmittal shall be confirmed promptly by a controlled document initiated in accordance with the initiating organization's approved implementing document.

6.4.9 Software Design Control

The requirements which apply to computer software design control shall be used instead of the sections shown above for Design Input; Design Process; Design Verification; and Change Control. Part II, Subpart 2.7, *Quality Assurance Requirements for Computer Software for Nuclear Facility Applications*, provides work practice requirements to implement the requirements of this paragraph. These requirements are presented in Part E of this QAP.

6.4.10 Design Documentation and Records

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

Design documentation and records, providing evidence the design and design verification processes were performed in accordance with the requirements of this section, shall be generated, collected, stored, and maintained in accordance with documented procedures that satisfy the requirements of Part A, Section 4.0, "Documents and Records."

7.0 CRITERION 7 - PROCUREMENT

7.1 Introduction

This section describes the requirements and responsibilities established to ensure items and services procured by CHBWV meet the appropriate technical and quality requirements.

It is CHBWV policy to require that procured items and services meet established requirements and perform as specified. Prospective suppliers are evaluated and selected on the basis of specified criteria. CHBWV requires that approved suppliers continue to provide acceptable items and services.

The CHBWV procurement process is consistent with the requirements of applicable DOE Orders, Federal Acquisition Regulations (FARs), and Department of Energy Acquisition Regulations (DEARS). The procurement program includes performance monitoring and continuous improvement concepts as appropriate to establish, maintain, and improve supplier performance. Procurement activities are established that require adequate quality requirements to be included or referenced in procurement documents for items and services. Controls include the sharing and improvement of supplier performance through internal and external communication, and the performance of supplier evaluation and monitoring.

CHBWV has established a program that requires the procurement process to be documented and controlled and that procured items and services conform to established specifications. Controls include procurement source evaluation and selection, evaluation of objective evidence of quality furnished by the supplier, source inspections, supplier audits, and examination of deliverables. Changes to procurement documents receive appropriate review and approval.

It is CHBWV policy that procurement documents and their changes contain technical, quality, and safety requirements relative to the scope, nature, importance, complexity and desired reliability of the procured items or services, and that those requirements are independently reviewed prior to issuing the documents.

The procurement process requires that procurement documents for items and services include requirement details commensurate with the established grading process (quality levels) and that suppliers have a QAP consistent with the specified requirements. End-user requirements shall be clearly communicated to the supplier. The QAP requirements apply to those suppliers of items or services for which there are established quality program requirements.

The procurement of "commercial-grade" items takes into consideration the design application to enable substantiation that these items fully meet the required design and acceptance criteria. Additional testing, inspection, or other actions taken to verify and validate acceptability is based on risk and service considerations as determined through existing QAP application.

The procurement program includes provisions for detection and identification of items or services of substandard quality. These provisions are consistent with the initiative for identification, control, and prohibiting delivery of suspect/counterfeit items in the DOE complex.

7.2 Requirements

Contractors conducting activities, including providing items and services that affect or may affect the safety of DOE nuclear facilities, must conduct work in accordance with QA criteria in 10 CFR 830.122 [10 CFR 830.121 (a)]. Procurement/acquisition processes shall be established and implemented by CHBWV organizations to satisfy the requirements of this section in accordance with 10 CFR 830.122 (g), "Criterion 7-Performance/Procurement," and DOE O 414.1D CRD, Attachment 2, "Criterion 7-Performance/Procurement", which state:

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

The following were utilized to develop the requirements in this section:

- ASME NQA-1-2008/2009a, Requirements 4 and 7
- The guidance in DOE G 414.1-2B.
- DOE-RW-0333P, OCRWM QARD, Rev. 20
- 10CFR71, Subpart H and Regulatory Guide 7.10

Commercial Grade Items and Services are addressed in Part F of this QAP. Record requirements are discussed in Part A, Section 4.0, "Documents and Records," of this document.

7.3 Implementing Responsibilities

7.3.1 Management

Management is responsible for establishing and implementing a management system to require the procurement process to be documented and controlled. This process shall provide for the following, as appropriate:

- Procurement source evaluation and selection;
- Evaluation of objective evidence of quality furnished by the supplier; and
- Source inspections, supplier audits, and examination of deliverables.

Management is responsible for:

- Defining the technical and QA requirements for CHBWV project/facility-related procurements/acquisitions and subcontracts.
- Using CHBWV procurement/acquisition process procedures for initiating procurement/acquisition activity managed by CHBWV unless certain levels of procurement/acquisition are delegated to a subcontractor by CHBWV.
- Conducting procurement/acquisition activities, including document review, in accordance with procedures that meet the requirements of this section.
- Assigning a technical representative for procurement/acquisition activities.

7.3.2 Contract/Procurement/Records

The Prime Contract/Procurement/Records organization, within the Business Management organization is responsible for:

- Awarding and administering applicable contracts between CHBWV and subcontractors. This includes ensuring the CHBWV QA requirements are included in contract documents for CHBWV services and products.
- Providing all phases of the acquisition process, contract interpretation, and serving as the procurement/acquisition focal point for projects and other CHBWV organizations.
- Serving as custodian of CHBWV procurement/acquisition policies and procedures.
- Coordinating CHBWV procurement/acquisition planning.
- Ensuring deficiencies in procured/acquired items or services that are reported to CHBWV by subcontractors, including potential noncompliances to 10 CFR 830.122, are reviewed by the appropriate technical and QA organizations.

- Controlling procurement/acquisition documents and maintaining procurement/acquisition records in accordance with this section and Part A, Section 4.0, "Documents and Records."

7.3.3 Quality Assurance

Quality Assurance is responsible for:

- Managing the CHBWV supplier evaluation program, including the CHBWV Acceptable Suppliers List.
- Performing source and receipt inspection.
- Verifying proper identification and traceability of received items and documentation.
- Verifying that suspect/counterfeit items are not accepted.
- Documenting/preparing inspection, test, and associated quality records.
- Performing supplier evaluations for Quality Level - B and Quality Level - C procurements and acquisitions, as applicable.

7.3.4 Contractors and Suppliers

Contractors and Suppliers are responsible for the quality of work performed or items and services provided by their subcontractors and suppliers.

7.3.5 Personnel

Personnel are responsible for identifying, controlling, and implementing procurement actions that will provide adequate quality and to verify as appropriate that procured items and services conform to established specifications.

7.4 Implementation

Development and application of procurement requirements are based on the use of the graded approach previously described in Section 1.4.2. In this case the graded approach is focused on managing the identified risks consistent with CHBWV's mission. The key considered factors for grading CHBWV procurement activities include:

- The relative importance to safety, safeguards, and security (predominantly environmental impact or risk);
- The magnitude of hazards involved (nuclear safety classification or hazard category, complexity of items, services, or processes involved); and
- The lifecycle stage and programmatic mission of a facility.

The quality determination utilizes a risk-based methodology predicated on the end use of the items or services to categorize the appropriate Quality Level. The Quality Level of an item or service establishes the range of suitable methods for acceptance of the delivered item or services. The basis of acceptance is a function of the Quality Level and the type and nature of the supplier for the items or service. A given item or service for a given end use can have only one Quality Level assigned; therefore, the more conservative determination of Quality Level is to be used. The current Quality Level classification system consists of three Quality Levels (B, C, and N). For SSCs and activities graded as Quality Level B or C, the QA Department involvement is required.

Quality Level B - This grade requires that applicable portions of the CHBWV QAP be applied. An acceptable degree of independent verification can usually be obtained by normal CHBWV organizational participation.

Quality Level C - This grade requires verified application of the applicable portions of the CHBWV QAP. However, only those program elements determined essential by collaborative agreement between the cognizant, performing organization(s) and the QA organization need be applied.

Quality Level N - This grade involves those items or activities where programmatic, environmental, or health and safety concerns are not an issue. The CHBWV QAP still applies. However, implementation of the applicable QAP controls is left to the judgment and responsibility of the involved performing organizations.

7.4.1 Content of Procurement/Acquisition Documents

Procurement documents for items or services shall contain the following information, as appropriate:

- The scope of the work to be performed by the supplier including the intended use of the item or service.
- Technical requirements are specified, as appropriate, by reference to specific drawings, specifications, codes, standards, regulations, procedures, or instructions, including revisions thereto that describe the items or services to be furnished.
- Test and inspection requirements including associated acceptance criteria are identified. Provisions for establishing hold points (if needed) beyond which work cannot proceed without purchaser authorization.
- QAP requirements specified with regard to the importance and/or complexity of the item or service being procured.
- Assignment of appropriate Quality Levels, B, C, or N.
- A requirement for the supplier to incorporate and flow down appropriate QAP requirements in sub-tier procurement documents.
- When deemed appropriate, the purchaser may permit some or all supplier work to be performed under the CHBWV QAP. In these cases, procurement documents shall specify that the CHBWV implementing documents are applicable to the supplier and that CHBWV shall provide these applicable documents to the supplier.
- Provisions for access to the supplier's and sub-tier supplier's facilities and records availability for the purpose of surveillance, inspection, or assessment activities by CHBWV or its designated representative.
- The documentation required to be submitted for information, review, or approval by CHBWV. (The documentation must be traceable to the specific purchase order/contract.)
- Delivery schedule, submittal schedule, and CHBWV review/approval requirements.
- Provisions for establishing hold points beyond which work cannot proceed without release from CHBWV.
- Provisions for prohibiting delivery of suspect/counterfeit items.
- Deficiency/nonconformance reporting, notification and disposition approval requirements.
- A requirement for the supplier to identify spare and replacement parts or assemblies and the related data required for ordering these parts or assemblies.
- Information security requirements, as necessary (e.g., classification level and associated methods of protection and marking).

When retention of records is imposed the retention times and disposition requirements shall be prescribed.

Procurement/acquisition documents shall be reviewed prior to award to ensure documents transmitted to supplier(s) meet the requirements of this section. Changes to procurement/acquisition documents shall be subject to the same controls and approvals as the original documents in accordance with Part A, Section 4.0, "Documents and Records."

7.4.2 Procurement Planning

Procedures shall be prepared that define a systematic, documented approach to the procurement process and shall reflect timeliness of procurement planning. Planning shall be performed as early as possible, and no later than at the start of the procurement activities which are required to be controlled, to ensure interface compatibility and a uniform approach to the procurement process. Planning shall include participation from the technical organizations and individuals that are trained and qualified in QA practices and concepts. These procedures shall consider the following:

- Procurement document preparation, review, and change control.
- Supplier selection and award based on bid evaluation and source evaluation.
- Supplier performance evaluation and control.
- Supplier surveillance, inspection, or audit requirements and notifications for Hold Point Release activities.
- Control of nonconformances and resulting corrective action activities.
- Final acceptance process of item or service.
- Obtaining/controlling CHBWV and Supplier generated QA records.

7.4.3 Supplier Evaluation and Selection

Before award of a contract, CHBWV shall evaluate the supplier's capability to provide items or services in accordance with the requirements of the procurement documents. Procurements designated as HLW, shall have a Supplier Survey and QAP evaluation performed prior to subcontract award. Supplier evaluation and selection and the results thereof shall be documented and shall include one or more of the following:

- Supplier's history of providing an identical or similar product that performs satisfactorily in actual use. The supplier's history shall reflect current capability.
- Supplier's current quality records supported by documented qualitative and quantitative information that can be objectively evaluated.
- Supplier's technical and quality capability as determined by an evaluation of the facilities, personnel, and the implementation of the supplier’s QAP.

The evaluation shall be performed by designated, technically-qualified individuals or organizations, including individuals that are trained and qualified in QA practices and concepts.

Supplier evaluations may be performed by outside organizations (third party) provided that evaluation results are reviewed by CHBWV and it can be established that the evaluation provides a CHBWV equivalent basis for approval.

7.4.4 Bid Evaluation

If bids are solicited, the bid evaluation shall include a determination of the supplier's capability to conform to the technical and QA requirements. Prior to the award of the contract, CHBWV shall resolve or obtain commitments to resolve unacceptable technical and QA conditions resulting from the bid evaluation.

Bid evaluation, when required by procurement planning, shall be accomplished considering the following:

- Supplier's response to technical and QA requirements.
- Supplier's personnel and production capability.
- Supplier's past performance relative to production of similar items or services.
- Alternatives and exceptions proposed by supplier.

7.4.5 Supplier Performance Evaluation

The requirements described in this section apply to Procurement activities related to Quality Levels B and C.

CHBWV Requisitioner, QA, and Procurement personnel shall develop an understanding between CHBWV and the supplier establishing measures for verification of supplier performance. These measures may include as appropriate:

- Requiring the supplier to define planning techniques and processes which will be utilized in fulfilling the contract.
- Reviewing supplier documents generated or processed.
- Identifying and processing necessary change information.
- Establishing documented information exchange between CHBWV and supplier.
- Establishing the extent of CHBWV inspection, surveillance, assessment, and audit activities, including, if applicable, "hold points" (i.e., pre-established inspection points in the manufacturing process that require inspection approval and release by the QA organization prior to further processing) and "witness points" during manufacturing and testing and before shipment.

The extent of verification activities required, including planning, is to be a function of relative importance, complexity, and quantity of items or services procured and the supplier's quality performance. CHBWV verification shall be accomplished by qualified personnel assigned to test, inspect, audit, assess or witness the activities of suppliers.

These verifications shall not relieve the supplier of responsibility for verification of quality achievement. The verification shall be accomplished as early as practicable.

Verifications shall include: 1) the use of audits or assessments to evaluate supplier performance and 2) evaluation of purchaser documentation to aid in the determination of the effectiveness of the supplier QAP. This documentation shall include evidence such as source surveillance and inspections, audits, receiving inspections, nonconformances, dispositions, waivers, and corrective actions.

For HLW activities, annual performance evaluations shall be performed on each supplier to determine the need to schedule additional audits or assessments. This evaluation shall be documented and based on:

- Review of supplier furnished documents and records (e.g., certificates of conformance, the American Society of Mechanical Engineers [ASME] Certificate of Authorization, ASME Quality System Certificate, supplier accreditations, supplier QA program reviews, test reports, nonconformance notices, and corrective actions).
- Results of previous source verifications, audits, assessments, management assessments, and receiving inspections, including results of audits from other sources (e.g., other customers, ASME and NRC).
- Operating experience of identical or similar products furnished by the same supplier.

7.4.6 Control of Supplier-Generated Documents

Controls shall be implemented to ensure that the submittal and evaluation of Supplier-generated documents and changes are accomplished in accordance with the procurement document requirements.

These controls shall provide for the acquisition, processing, and recorded evaluation of the QA, technical, inspection, and test documentation or data against acceptance criteria.

The proposal/bid evaluation process shall include a determination of the extent of conformance to procurement document requirements. This evaluation shall be performed by designated, technically-qualified individuals or organizations, including individuals that are trained and qualified in QA practices and concepts.

Prior to the award of contract, Procurement shall resolve or document rationale for not resolving conditions resulting from bid evaluation.

7.4.7 Acceptance of Items and Services

Prior to offering the item or service for acceptance, the supplier shall verify that the item or service being furnished complies with the procurement document requirements. The extent of the verification activities by the CHBWV shall be a function of the relative importance, complexity, and quantity of the item or services procured and the supplier's quality performance. Where required by code, regulation, or contract requirement, documentary evidence that items conform to procurement requirements shall be available at the nuclear facility site prior to installation or use.

A. Methods of Acceptance

Purchaser methods used to accept an item or service from a supplier may include one or more of the following: a supplier Certificate of Conformance, source verification, receiving inspection, or post installation test, or a combination of these methods.

1. Certificate of Conformance

When a Certificate of Conformance is used, the minimum requirements below shall be met.

- The certificate shall identify the purchased material or equipment by the purchase order number (for example).
- The certificate shall identify the specific procurement requirements met by the purchased material or equipment, such as codes, standards, and other specifications. This may be accomplished by including a list of the specific requirements or by providing, on-site, a copy of the purchase order and the procurement specifications or drawings, together with a suitable certificate. The procurement requirements identified shall include any approved changes, waivers, or deviations applicable to the subject material or equipment.
- The certificate shall identify any procurement requirements that have not been met, together with an explanation and the means for resolving the nonconformance.
- The certificate shall be signed or otherwise authenticated by a person who is responsible for this QA function and whose function and position are described in the supplier’s QAP or by CHBWV procedure.
- The certification system, including the procedures to be followed in filling out a certificate and the administrative procedures for review

and approval of the certificates, shall be described in the supplier's QAP or CHBWV procedure.

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

2. Source Verification

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

Source verification is planned and performed by individuals that are trained and qualified in QA practices and concepts in accordance with written procedures to ensure conformance to procurement requirements.

Procedures applicable to the method of procurement provide for:

- Specification of the characteristics or processes to be witnessed, inspected, or verified and the method of surveillance and the extent of documentation required.
- Audits, surveillance, or inspections to verify the effectiveness of the supplier QAP and quality control activities and to ensure that the supplier complies with QA and technical requirements.

3. Receiving Inspection

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

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

Receiving inspection shall be coordinated with review of supplier documentation when procurement documents require such documentation to be furnished before receiving inspection.

4. Post-installation Testing

When post-installation testing is used, post-installation test requirements and acceptance documentation shall be mutually established by CHBWV and the supplier.

5. Acceptance of Services Only

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

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

7.4.8 Control of Supplier Nonconformances

Methods for control and disposition of supplier nonconformance(s) for items and services that do not meet procurement document requirements shall include:

A. Evaluation of nonconforming items.

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

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

C. CHBWV disposition of supplier recommendation.

D. Verification of the implementation of the disposition.

E. Maintenance of records of supplier-submitted nonconformances.

7.4.9 Procurement/Acquisition Document Control, including Supplier-generated Documents

Procurement/acquisition documents, including supplier-generated documents, shall be issued, handled, revised, reviewed, approved, and controlled in accordance with documented procedures that meet the requirements of Part A, Section 4.0, "Documents and Records."

The purchaser shall require that supplier-submitted documentation, including nonconformance notification, be traceable to the originating procurement/acquisition document (e.g., Material Request, Contract Requisition, Work Package) number.

7.4.10 Suspect/Counterfeit Items

Methods shall be established to prevent procurement of S/CIs to the extent commensurate with the risk posed by failure of the item or service in accordance with the requirements of Part D of this QAP.

7.4.11 Subcontractor Oversight

When subcontractor oversight is used, purchased items and services are overviewed using plans developed and executed on activities to assure CHBWV subcontractors conform to specified contract requirements.

7.4.12 ASME Section III Code Items

For the procurement of items designed and fabricated in accordance with the American Society of Mechanical Engineers (ASME) Section III, *Rules for Construction of Nuclear Power Plant Components,* the Office of Civilian Radioactive Waste Management *Quality Assurance Requirements and Description* DOE/RW-0333P, section 7.2.13 shall be implemented in accordance with the CHBWV procedures. The following is summary of the requirements related to ASME Code III suppliers:

- For the purchase of ASME Section III Code items, ASME NQA-1 versions endorsed by the NRC may be used for the construction of ASME Section III Code items in conjunction with other QA, administrative, and reporting requirements contained in the Code.
- For supplier evaluations, credit may be taken for the fact that ASME has surveyed the ASME Code supplier and issued a Certificate of Authorization or Quality System Certification, without performing any additional evaluation of the supplier QAP.
- Audits of the ASME Code suppliers include confirmation of satisfactory implementation of ASME Code QAP, technical and QA requirements in purchase order, applicable QARD or CHBWV QAP description, and applicable regulatory requirements.

7.4.13 Commercial Grade Items and Services

When commercial grade items or services are specifically required by the CHBWV purchase documents/acquisition, the requirements of ASME NQA-1 Part II, Subpart 2.14, *Quality Assurance Requirements for Commercial Grade Items and Services*, shall apply and are an acceptable alternative to an approved supplier's NQA-1 QA Program, except that Supplier evaluation and selection, where determined necessary by the Purchaser, shall be in accordance with the applicable section of this Requirement.

Subpart 2.14 requirements are identified and described in Part F of this QAP.

7.4.14 Records

Records shall be established and maintained to indicate the performance of the following functions:

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

7.4.15 Records shall be issued, handled, revised, reviewed, approved, and controlled in accordance with documented procedures that meet the requirements of Part A, Section 4.0, "Documents and Records."

8.0 CRITERION 8 - INSPECTION AND ACCEPTANCE TESTING

8.1 Introduction

This section describes the requirements and responsibilities established to ensure SSCs or other items procured for use or operation under CHBWV work scope meet established design, performance, and quality requirements.

This section establishes requirements for developing an effective inspection program. Inspections required to verify conformance of items and activities to specified requirements shall be planned and executed.

It is CHBWV policy to perform inspection and acceptance testing of specified items and processes using established acceptance and performance criteria, and to require calibration and maintenance of equipment used for acceptance of inspections and tests.

CHBWV integrates the requirements for inspection and acceptance testing into existing NQA-1 based implementing procedures for engineered systems and components according to the intended use of the items as specified in approved design specifications or other planning documents. Required inspections and tests are established and conducted according to a grading process (quality levels). Acceptance parameters and other requirements are specified in design documentation. The organization with final responsibility for the system, structure, or component is responsible for verification and documentation of final acceptance. The technical organizations with the cognizant, engineering role have the primary responsibility for establishing the level, extent, and acceptability of inspection and testing, and for approval of test requirements and acceptance criteria. The degree of independence, including independent QA organizational oversight or verification, is determined and established through a grading process which incorporates environmental, safety, health, and quality programmatic considerations.

CHBWV has established and implemented procedures to perform inspections and acceptance testing of engineered systems, components, or parts according to the intended use of the items as specified in approved design specifications or other planning documents.

CHBWV has established and implemented procedures to demonstrate that items and processes will perform as intended. These procedures provide for an appropriate level of independence in the inspection or testing program, according to the design specifications and planning requirements. When acceptance criteria are not met, deficiencies are resolved and the resolution is approved by management, and retesting is performed as necessary.

It is the policy of CHBWV that the status of inspection and test activities shall be identified on the items or in documents traceable to the item to ensure that required inspections and tests have been performed, and to assure that items which have not passed the required inspections and tests are not inadvertently installed, used, or operated. The operating status indicator(s) of a system shall be provided.

CHBWV has established and implemented procedures to require that measuring and test equipment are of the proper type, range, and accuracy, and are properly calibrated, maintained, and used according to design specifications and other planning documents. Included are measuring and test equipment used for operational process monitoring and acceptance.

8.2 Requirements

Inspection and acceptance testing processes shall be established and implemented by CHBWV and its subcontractors to satisfy the requirements of this section in accordance with 10 CFR 830.122 (h), "Criterion 8-Performance/Inspection and Acceptance Testing," and DOE O 414.1D CRD, Attachment 2, "Criterion 8-Performance/Inspection and Acceptance Testing", which state:

- "Inspect and test specified items, services, and processes using established acceptance and performance criteria."

- "Calibrate and maintain equipment used for inspection and tests."

The following were used in the development of the requirements for this section:

- ASME NQA-1-2008/2009a Requirements 10, 11, 12 and 14
- DOE/RW-0333P, QARD, Rev. 20
- The guidance in DOE G 414.1-2B

Record requirements are discussed in Part A, Section 4.0, "Documents and Records," of this document.

The requirements for testing of computer software are described in Part E of this QAP.

8.3 Implementing Responsibilities

8.3.1 CHBWV Management

- Management is responsible for establishing and implementing procedures for inspections and acceptance testing of engineered systems, components, or parts according to the design specifications and planning requirements. These procedures will provide for an appropriate level of independence of inspection personnel.
- Management is responsible for establishing and implementing procedures requiring that measuring and test equipment is of the proper type, range, and accuracy, and is properly calibrated, maintained, and used according to design specifications. These controls are also applied to measuring and test equipment used for operational process monitoring and acceptance.

8.3.2 CHBWV Organizations

Organizations that perform inspection and acceptance test activities are responsible for implementing the requirements of this section.

- Implementing these requirements and ensuring that design and construction activities comply with the requirements of this section.
- Ensuring Design Authorities/Technical Authorities identify inspection and acceptance test requirements, including acceptance criteria, in design documents.
- Coordinating inspection and acceptance test activities to ensure design requirements are met.
- Monitoring subcontractors to ensure the subcontractors meet the specified QA requirements.

8.3.3 Quality Assurance Organization

The CHBWV QA organization is responsible for the following:

- Developing and maintaining the QA processes and procedures that meet the requirements of this section.
- Providing or acquiring inspection or acceptance test services for the project.
- Reviewing design, construction, and work planning documents that specify inspection and test requirements to ensure that inspection/test requirements and acceptance criteria are included and meet the requirements of applicable standards.
- Reviewing procurement documents for subcontractors providing inspection and test services to ensure the inclusion of applicable inspection and test requirements.

- Conducting project-level quality oversight of inspection and test functions.

8.4 Implementation

Inspections and tests are performed to verify that physical and functional aspects of SSCs meet requirements and are fit for use and acceptance, or continued acceptability of items in service. Procedures shall be prepared that govern inspection and acceptance testing associated with the application of the requirements of this section.

Test requirements and acceptance criteria shall be provided or approved by the organization responsible for the design of the item to be tested unless otherwise designated. Required tests, including, as appropriate, prototype qualification tests, production tests, proof tests prior to installation, construction tests, post installation tests, pre operational tests, and operational tests shall be controlled. Test requirements and acceptance criteria shall be based upon specified requirements contained in applicable design or other pertinent technical documents. If temporary changes to the approved configuration of a facility are required for testing purposes, approval by the design authority is required prior to performing the test.

8.4.1 Inspection and Acceptance Testing Planning

Test procedures shall include or reference the test configuration and test objectives. Test procedures shall include provisions for ensuring prerequisites and suitable environmental conditions are met, adequate instrumentation is available and used, appropriate tests and equipment are used, and necessary monitoring is performed. Prerequisites shall include the following, as applicable:

- Calibrated instrumentation;
- Appropriate equipment, including accuracy requirements;
- Trained personnel;
- Condition of test equipment and the completeness of the items to be tested;
- Suitable environmental conditions; and
- Provisions for data acquisition and storage.

As an alternative, appropriate sections of related documents, such as ASTM methods, Supplier manuals, equipment maintenance instructions, or approved drawings or travelers with acceptance criteria, may be used. Such documents shall include or be supplemented with appropriate criteria from this Section to assure adequate procedures for the test are used.

The inspection requirements and acceptance test criteria for items, services, and processes shall include specified requirements contained in the applicable design documents or other pertinent technical documents that provide approved requirements by the responsible design organization.

Inspection plans may be separate documents governed by procedural controls, or an integral part of approved implementing documents. Representatives of the interested technical organizations and individuals that are trained and qualified in QA practices and concepts shall participate in planning activities. Applicable codes, standards, specifications, and design documents shall be used to develop inspection plans. The elements of inspection plans identify:

- Characteristics to be inspected;
- Description of inspection or process monitoring that will be used;
- Identification of the organization responsible for performing the inspection;
- Identification of mandatory hold points, and/or witness points when required;
- Acceptance criteria;

- Measuring and test equipment to be used to perform the inspection to ensure the equipment is of the proper type, range, accuracy, and tolerance to accomplish the intended function;
- If applicable, identification of a sampling plan; and
- Methods to record inspection results.

Inspection points shall be identified in implementing procedures. Hold points are mandatory inspection points and work shall not proceed until the hold point requirement has been met. Consent to waive specified hold points shall be recorded prior to continuation of work beyond the designated hold point. (Hold points may only be waived in writing by the QA Manager or designee). Characteristics to be inspected, methods of inspections, and the acceptance criteria shall be specified at inspection planning phase. Final inspection shall be planned to arrive at a conclusion regarding conformance of the item to specified requirements.

Tests shall be controlled, planned, performed, and documented. This includes the following:

- Prototype qualification tests;
- Post installation tests;
- Operational tests;
- Post-maintenance tests;
- Functional tests;
- Proof tests; and
- Acceptance tests.

Acceptance parameters and other inspection or acceptance test requirements shall be specified as part of the design documentation and work planning process and included in work control procedures. When temporary changes to the approved configuration of a facility are necessary for testing purposes, approval by the Design Authority is required and shall be obtained prior to the performance of the test.

8.4.2 Selecting Inspection and Test Personnel

The individual who performs an inspection to verify conformance of an item to specified acceptance criteria shall be qualified to the requirements in this section.

Inspections for acceptance shall be performed by individuals other than those who performed or directly supervised the work being inspected, and those individuals shall not report directly to the supervisor immediately responsible for performance of the work, and who have the freedom of access and communication to conduct and report inspection and acceptance test results.

Personnel who perform testing shall be qualified according to the requirements as applicable based on the importance, complexity, and/or special nature of the test. Personnel qualification is required if the test is determined to be the final acceptance of the item, system, subsystem, or activity being tested.

Qualification of Inspection and Test personnel is in accordance with Part A, Section 2.0, “Personnel Training and Qualification”.

8.4.3 Inspection and Acceptance Testing Process

Inspections and acceptance tests shall be performed in accordance with approved procedures. Sampling procedures, where used, shall be based upon valid statistical methods.

Inspection shall confirm that the work conforms to the design requirements and that work and documentation are complete.

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

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

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

8.4.4 In-process Inspection

Inspection of items under construction or otherwise in process shall be performed as necessary to verify quality. If in-process inspection of items is impossible or disadvantageous, indirect control by monitoring of processing methods, equipment, and personnel shall be provided. Process monitoring shall be performed by qualified personnel or qualified automated means. Both inspection and process monitoring shall be provided when control is inadequate without both.

8.4.5 Final Inspection

Finished items shall be inspected for the following:

- Completeness;
- Markings;
- Calibration;
- Adjustments;
- Protection from damage; and
- Other characteristics as required for verification of the quality and conformance of the item to specified requirements.

Documentation not previously examined shall be examined for adequacy and completeness. Final inspection shall include a review of the results and resolution of previously identified nonconformances. Modifications, repairs, or replacements of items performed subsequent to final inspection shall require reinspection or retest, as appropriate to verify acceptability.

8.4.6 Inspection and Acceptance Testing Status

The status of inspection and acceptance test activities shall be identified on the items or in documents traceable to the items to ensure items that have not passed the required inspections and acceptance tests are controlled. The identification methods shall preclude the inadvertent installation, use, or operation of items that have not passed

required inspections and tests. The status of required inspection and tests of items shall be indicated when necessary to preclude inadvertent by-passing of such inspections and tests. The status of inspections and tests shall be identified either on the items or in documents traceable to the items. Status shall be maintained through the use of status indicators (such as tags, markings, labels, and stamps) or other means (such as travelers, inspection, or test records). The authority for applying and removing status indicators shall be specified. Status indicators shall be used to provide an indication of the test or operating status of items or facilities to prevent inadvertent changes in operating status.

8.4.7 Inspection and Acceptance Testing Results

Inspection and acceptance test results shall be documented and conformance with acceptance criteria evaluated to ensure requirements have been satisfied. The acceptance of the item shall be approved by authorized personnel.

8.4.8 In-Service Inspection

Periodic inspections (e.g., in-service inspections) or surveillances of SSCs shall be planned and executed to assure the continued performance of their required functions.

8.4.9 Inspection and Acceptance Testing Records

Appropriate records of Inspections shall be established, maintained, and, as a minimum, identify the following:

- Item inspected;
- Date of inspection;
- Inspector;
- Type of observation;
- The inspection criteria, sampling plan, or reference documents (including revision levels) used to determine acceptance;
- Results or acceptability;
- Measuring and test equipment used during the inspection, including the identification number and the most recent calibration date; and
- Reference to information on actions taken in connection with nonconformances, as applicable.

Test records shall be established and maintained to indicate the ability of the item to satisfactorily perform its intended function or to meet its documented requirements. Test records vary depending on the test type, purpose, and application. Test records shall, as a minimum, identify the following:

- The item or work product tested;
- The date of the test;
- The name of the tester or data recorder;
- The test procedure and the type of observation used to determine acceptance;
- The results and their acceptability;
- Actions taken in connection with any deviations noted;
- The name of the person evaluating the test results; and
- Identification of any M&TE used during testing, and the next calibration due date.

Inspection and Acceptance Testing records shall be maintained in accordance with Part A, Section 4.0, “Documents and Records.”

8.4.10 Calibration and Control of Measuring and Test Equipment

A program is established and implemented to control the calibration, maintenance, and use of equipment used for data collection and process monitoring of work including environmental data collection activities.

Process monitoring and data collection equipment is of the precision and type suitable for the intended use. The types of equipment used by the program are defined. Calibration certifications are traceable to nationally recognized performance standards, where possible. If no such nationally recognized standards exist, the basis for the calibration is documented and justified.

Measuring and Test Equipment (M&TE) used for verifying conformance to requirements, monitoring processes, or collecting data shall be controlled, calibrated at specified intervals, and maintained to required accuracy limits. M&TE shall be selected based on the following:

- Type;
- Range;
- Accuracy; and
- Tolerance needed to accomplish conformance to the specified requirements.

M&TE used at CHBWV for accepting material or equipment, controlling special processes, verifying correct facility operation, process monitoring or data collection, equipment used for inspection or test, or obtaining data used to verify conformance to specified requirements shall be calibrated at prescribed intervals or when the accuracy of the M&TE is suspect. The recognized standards shall meet the minimum accuracy for calibration of M&TE. Calibration shall be against certified equipment having known valid relationship to nationally recognized standards. If no recognized standard exists, the basis for calibration shall be documented.

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

Calibration procedures shall identify or reference required accuracy and shall define methods and frequency of checking accuracy.

The calibration method and interval of calibration shall be based on the type of equipment, stability characteristics, required accuracy, intended use, and other conditions affecting performance.

Measuring and test equipment shall be suitably marked, tagged, labeled, or otherwise identified to indicate calibration status and establish traceability to calibration records.

Measuring and test equipment shall be traceable to its application and use.

Control of M&TE shall be in accordance with established procedure(s) that specify methods and frequency of calibration and identification and control of M&TE found to be out-of-calibration or out-of-tolerance. If M&TE is found to be out-of-tolerance, an evaluation shall be conducted and documented commensurate with the significance of the condition, including the validity of previous inspection or test results and the acceptability of items previously inspected or tested. In the event M&TE is found to be out-of-calibration, it shall be removed from service and recalibrated prior to use.

Measuring and test equipment shall be used and calibrated in environments that are controlled to the extent necessary to ensure that the required accuracy and precision are maintained.

M&TE shall be marked or otherwise identified to indicate calibration status and shall be handled and stored in a manner to maintain the accuracy of the equipment.

Measuring and test equipment and reference standards submitted for calibration shall be checked (as-found) and the results recorded before any required adjustments or repairs are made. As-found and As-left data shall be included on calibration records.

These calibration and control methods are not required for commercial equipment such as rulers, tape measures, levels, if such equipment provides the required accuracy.

Records shall be established and maintained to indicate calibration status and the capability of measuring and test equipment to satisfactorily perform its intended function. Calibration reports and certificates reporting the results of calibrations shall include the information and data necessary for interpretation of the calibration results and verification of conformance to applicable requirements. M&TE records shall be maintained in accordance with Part A, Section 4.0, "Documents and Records."

PART C: ASSESSMENT

Part C provides for the periodic and regular assessment of the QAP and its implementation to determine its effectiveness and to promote improvement. It also describes the organizational and independent management system assessment requirements. Line management regularly assesses and documents the adequacy of the portions of the program for which they are responsible to verify the Program's effective implementation. This section also describes the independent assessment structure and establishes the organizational freedom and authority required for conducting surveillances, audits, and independent assessments. It provides for the auditing of operations, systematic handling of nonconforming conditions, and lessons learned through corrective actions, trending, and causal analyses. Organizational and independent assessments are planned, scheduled, and performed. Assessment results are documented and reported to and reviewed by line management. Conditions requiring corrective action are identified promptly and addressed as soon as practical. The cause of significant conditions adverse to quality are determined and appropriate response actions are taken by management to prevent their recurrence. Follow-up action(s) are taken to validate and verify implementation and effectiveness of the remedial action(s).

CHBWV has developed a site wide self-assessment program which evaluates project performance and compliance with applicable environmental, safety, health, QA, and administrative/support requirements and best management practices. Key elements of the program are oversight of line organization self assessments, conduct of independent internal assessments, interface during external assessments, and performance of analysis and trending to include: (1) root cause analysis, (2) performance trending, and (3) lessons learned dissemination.

9.0 CRITERION 9 - MANAGEMENT ASSESSMENT

9.1 Introduction

This section describes the requirements and responsibilities established to ensure that CHBWV managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives. It is CHBWV policy that management at all levels shall regularly assess their organization for the adequacy and effective implementation of the QAP for which they are responsible.

9.2 Requirements

Management assessment processes shall be established and implemented to satisfy the requirements of this section in accordance with 10 CFR 830.122 (i), "Criterion 9-Assessment/Management Assessment," and DOE O 414.1D CRD, Attachment 2, "Criterion 9-Assessment/Management Assessment", which state:

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

The following were used to develop the requirements for this section:

- ASME NQA-1-2008/2009a, Requirement 2
- DOE/RWP-0333P, QARD, Rev. 20
- The guidance in DOE G 414.1-1B and DOE G 414.1-2B
- Record requirements are discussed in Part A, Section 4.0, “Documents and Records,” of this document. Audits (NQA-1 Requirement 18) are discussed in Part C, Section 10.0, “Independent Assessment,” of this document.

9.3 Implementing Responsibilities

9.3.1 Management

Management is responsible for scheduling, planning, and conducting management assessments, and resolving identified issues in accordance with Section 3.0, “Quality Improvement.”

Senior management is responsible for taking prompt action and documenting resulting decisions in response to recommendations which result from the management assessment process.

9.3.2 Quality Assurance Organization

The CHBWV QA organization is responsible for coordinating the activities associated with developing and maintaining the QA processes and procedures that meet the requirements of this section and for coordinating external/customer assessments of the CHBWV QAP.

9.3.3 Performance Assurance Organization

Performance Assurance organization is responsible for administration of the Integrated Assessment Program which includes maintaining the project assessment procedures, performing periodic reviews of assessment activities, and maintaining the integrated assessment schedule.

9.4 Implementation

Management assessment is a periodic introspective self-analysis to determine whether the organization's activities are properly focused on achieving the desired results. This includes reviewing the processes, systems, and programs that are important to the organization's mission completion, objectives, and performance with regards to safety, quality, and performance. The purpose of this type of assessment is to identify management systems, processes, and programs that affect performance, to identify systemic and cultural management issues or problems, and to provide corrective actions with the objective of promoting continuous improvement. Written processes shall be established and implemented describing the management assessment process. This process shall include assessment planning, conduct, results reporting, and tracking of issues to closure.

Management assessment activities include the following:

- Self-Assessments (i.e., assessments performed by those within the group or organization having responsibility for the activities being assessed);
- Management Assessments conducted by or for CHBWV management, including reviews of program implementation, which may cross organizational boundaries;
- Management Workplace Visits, which promote the presence of management in the workplace, increase access to workers, provide opportunities for coaching and mentoring, and the identification of good practices and opportunities for improvement; and
- Readiness Reviews which ensure that new activities and activities starting can be safely performed.

9.4.1 Management Assessment Planning

Management assessments shall be planned in a systematic manner on an annual basis by Projects and Functional Group managers to address areas under their responsibility and to focus on those areas presenting the greatest risk for failure, potential for improvement, or recurring incidents. Performance data and results of independent assessments shall be periodically reviewed to identify areas for additional management assessment emphasis.

Management assessments evaluate all key QAP elements, including the following:

- The adequacy of resources and personnel provided to achieve and ensure quality;
- The scope, status, adequacy and effectiveness of the QAP (or portions thereof for which the manager is responsible);
- The adequacy of planning and procedural controls and effectiveness of implementation;
- The adequacy of the personnel qualification and training program;
- The effectiveness of the nonconformance and corrective action program;
- The adequacy of the management information tracking, evaluation, and reporting system as related to the particular area of responsibility.

For the HLW Project, management assessments shall be planned, documented and performed biennially. The programmatic compliance with the OCRWM QARD, Rev. 20 shall also be evaluated.

9.4.2 Management Assessment Performance and Reporting

Managers at every level shall be involved in the assessment of their management programs, systems, and processes important to achieving objectives. Implementation of the management assessment program may be delegated in part; however, Senior

Management retains overall responsibility for the program and actively and directly participates in the assessment activities. Specific support activities (i.e., data collection) may be delegated to staff.

Management assessments conducted by first line management shall focus on procedural adequacy, compliance, and effectiveness of the process being assessed. Management assessments conducted by facility/project/program managers shall focus on the effectiveness of their management systems. Personnel performing assessments shall be trained in the assessment process and shall be knowledgeable of the program, system, or process being assessed. Assessments shall be performed in accordance with documented instructions utilizing written checklists or procedures.

NOTE: First line management includes personnel assigned as Subject Matter Experts (SMEs) in support of either the facility/project or a functional organization. This includes Design Authorities, Shift Managers, Fire Projection Engineers, Nuclear Safety SMEs, Lock and Tag Administrators, Criticality Safety Representatives, Technical Authorities, persons designated as “Leads” and others.

Problems identified by management assessments that hinder the organization in achieving its objectives shall be resolved in accordance with the process described in Section 3.0, “Quality Improvement.”

Assessment results are documented. Management takes prompt action and documents the resulting decisions in response to the recommendations which arise from the assessment process. Follow-up includes an evaluation of the effectiveness of management's actions.

10.0 CRITERION 10 - INDEPENDENT ASSESSMENT

10.1 Introduction

This section describes the requirements and responsibilities established to ensure that senior management implements an independent assessment program to evaluate the performance of work processes with regard to requirements, expectations of customers, and efforts required to achieve the mission and goals of the organization. .

10.2 Requirements

Independent assessment processes shall be established and implemented to satisfy the requirements of this section in accordance with 10 CFR 830.122 (j), "Criterion 10-Assessment/Independent Assessment," and DOE O 414.1D CRD, Attachment 2, "Criterion 10-Assessment/Independent Assessment," which state:

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

The following were used to develop the requirements for this section:

- ASME NQA-1-2008/2009a, Requirements 1 and 18
- DOE/RWP-0333P, QARD, Rev. 20
- The guidance in DOE G 414.1-1B and DOE G 414.1-2B

ASME NQA-1-2008/2009a Requirements 2, 10, 11, 15, and 16 were not used in the development of this section. These requirements are discussed in Sections 1.0, 2.0, 3.0, and 8.0 of this document. Record requirements are discussed in Part A, Section 4.0, “Documents and Records,” of this document.

10.3 Implementing Responsibilities

10.3.1 Management

CHBWV Managers are responsible for cooperating with independent assessment personnel in conducting the following

- Planning, scheduling, and performing assessments;
- Evaluating assessment results to identify improvement actions and determining if similar problems exist elsewhere in the organization; and
- Promptly correcting deficiencies identified by independent assessments and ensuring corrective actions are effective in accordance with Section 3.0, “Quality Improvement” and associated procedures.

10.3.2 Quality Assurance Organization

The QA organization is responsible for establishing, performing and interpreting the requirements and processes for independent audit and surveillances.

10.3.3 Performance Assurance Organization

The Performance Assurance organization is responsible for administration of the Integrated Assessment Program which includes maintaining assessment procedures,

performing periodic reviews of assessment activities, and maintaining the integrated assessment schedule.

10.4 Implementation

A program of planned and periodic independent assessments is established and implemented. The independent assessment process uses both compliance-based and performance-based approaches directed toward satisfying customer expectations and achieving programmatic goals and objectives. Compliance-based assessments focus on verification of adherence to established requirements. Performance-based assessments are conducted on activities and processes that relate directly to performance expectations and emphasize safety and reliability.

Independent assessments shall evaluate program requirements, the quality of CHBWV items and services and promote improvement in CHBWV processes and activities. The effectiveness of management assessments and the effectiveness of corrective actions for previously identified issues shall be periodically evaluated as part of the independent assessment program. Independent assessments include reviews, surveillances, audits, and other evaluations and may be internal or external assessments.

10.4.1 Scheduling

Scheduling of assessments and allocation of resources is based on the status, complexity, risk, and importance of the activity and coordinated with ongoing activities. The schedule shall be developed and approved annually. The schedule shall be reviewed periodically and modified as new information about facilities or activities are obtained that changes the estimated risks or reflects changes in available resources. Scheduled assessments shall be supplemented by additional assessments of specific subjects when necessary to provide adequate coverage or as a result of performance data reviews.

10.4.2 Frequency

Quality Assurance audits or assessments of the adequacy and effectiveness of CHBWV QAP shall be performed triennially or at least once during the life of major projects, whichever is shorter, by evaluating each of the applicable criteria as defined in this document. However, external audits of suppliers, including HLW suppliers, may not be required where procured items are relatively simple and/or standard in design, manufacturing, and testing or the items are adaptable to standard or automated inspections or tests of the end product verifying quality characteristics after delivery. The rationale for not performing audits of suppliers for HLW items shall be documented. This includes third party independent assessments of CHBWV compliance to imposed requirements (e.g. annual Independent Assessment of the Radioactive Waste Certification Program in accordance with Nevada Test Site Waste Acceptance Criteria). Pre-award surveys, if applicable, may serve as the first triennial audit.

Periodic performance evaluations of suppliers listed on the Acceptable Suppliers List (ASL) shall be performed to determine the need to schedule additional audits or assessments. The need to schedule additional external audits or assessments should be evaluated when a major change in the contract scope, supplier QAP, or work methodology occurs.

10.4.3 Preparation

Plans shall be developed to identify the assessment scope, requirements, team members; activities included in the assessment, organizations to be notified, applicable documents, assessment schedule, and shall be performed in accordance with CHBWV procedures and checklists.

Independent assessments shall be planned to measure the adequacy of work performed in complying with applicable requirements and determine the effectiveness of QAP implementation. Independent assessments shall evaluate program requirements, the quality of CHBWV items and services and promote improvement in CHBWV processes and activities. The effectiveness of management assessments and the effectiveness of corrective actions for previously identified issues shall be periodically evaluated as part of the independent assessment program

10.4.4 Performance

The organization or staff performing independent assessments shall have sufficient authority and freedom from the line organization to carry out its responsibilities. Personnel performing independent assessments shall be identified prior to performance of the assessment. Assessment teams shall consist of one or more members and shall not have direct responsibility for work in the areas they are assessing. An individual shall be designated to organize and direct the assessment activities. Assessment team members shall be technically qualified and knowledgeable in the areas they assess. Lead auditors shall be capable of communicating effectively, both in writing and orally. Lead auditors shall be certified. Qualification of assessment team members shall be in accordance with established procedures relevant to the assessment type (e.g., assessments, audits, and surveillances).

Assessment elements shall be evaluated against specified requirements. Evaluation shall include examination of objective evidence to the depth necessary to determine if the elements are being implemented effectively. Conditions requiring prompt corrective action shall be immediately reported to responsible management.

10.4.5 Reporting and Tracking of Independent Assessment Results

Assessment results are documented and reviewed by assessor's management and by line management having responsibility in the area being assessed. Conditions requiring corrective action are identified promptly and addressed as soon as practical. The report shall include, as a minimum, the scope of the assessment, identification of the assessment team members, summary of results, and adverse conditions identified during the assessment. Follow-up actions shall be taken where indicated. Adverse conditions shall be tracked and corrected in accordance with Section 3.0, *Quality Improvement*.

Management of the assessed organization or activities shall investigate adverse conditions and identify and schedule corrective actions, including measures to prevent recurrence. Follow-up action is taken to validate and verify the implementation and effectiveness of the response action.

Assessment records shall include the assessment plans, audit reports, supplier assessment reports, written replies, and the corrective actions.

PART D: SUSPECT/COUNTERFEIT ITEM PREVENTION PROCESS

1.0 Introduction

This section provides the requirements to assist CHBWV in the mitigation of the introduction of S/CIs into projects and facilities. CHBWV identifies processes for preventing the requisition/procurement and installation or use of S/CIs. Processes also address the identification, documentation, disposition, reporting, and control of S/CIs.

2.0 Requirements

Methods shall be established to prevent procurement of suspect counterfeit items to the extent commensurate with risk posed by the facility. The CHBWV S/CI control process implements the applicable requirements of DOE O 414.1D CRD, Attachment 3. CHBWV shall establish provisions to control S/CIs. The provisions shall accomplish the following:

- "Ensure items and services meet specified requirements."
- "Prevent entry of S/CIs into the DOE supply chain."
- "Ensure detection, control, reporting, and disposition of S/CIs."

The guidance in DOE G 414.1-2B was used in the development of the requirements for this section.

Record requirements are discussed in Part A, Section 4.0, "Documents and Records," of this document.

3.0 Implementing Responsibilities

3.1 Engineering is responsible for the following:

- Developing Engineering procedures and processes that implement the CHBWV S/CI requirements.
- Identification of technical and QA requirements in procurement specifications.
- Involvement during inspection and testing processes.
- Involvement when maintaining, replacing or modifying equipment.

3.2 Quality Assurance Organization

- Perform receipt inspection, verify proper identification and traceability of received items and documentation, verify that suspect/counterfeit items are not accepted, and document/prepare inspection, test, and associated quality records.
- Performing S/CI self-assessment activities.
- Developing procedures and processes that implement the CHBWV S/CI requirements.
- Conducting trend analysis and issue lessons learned reports, as necessary for use in improving the S/CI prevention.

3.3 Warehouse personnel and/or requisitioner examine items not receipt inspected by QA to ensure they are not suspect/counterfeit.

4.0 Implementation

Discovery of any actual or potential S/CI shall be documented, reported, and disposition implemented in accordance with CHBWV procedures. CHBWV activities to prevent the introduction and use of S/CIs on site include the following:

- Identification of a management point of contact for S/CI activities.
- Training and informing managers, supervisors, and workers on S/CI processes and controls including prevention, detection, and disposition of S/CIs.

- Processes for inspection, identification, evaluation, and disposition of S/CIs on site are defined and implemented. The evaluations must consider potential risks to the public and worker and cost-benefit impact, and include a schedule for replacement (if required).
- Engineering shall be involved in the development of procurement specifications, during inspection and testing, when replacing, and maintaining, or modifying equipment. Engineering controls shall be established to minimize the potential for installation and use of S/CI.
- Restrict S/CI use to only those items that have been found acceptable through engineering analysis and formal disposition process.
- Inspecting inventory and storage areas to identify control and disposition for S/CIs.
- Collecting, maintaining, disseminating, and using the most, accurate, up-to-date information on S/CIs and associated suppliers using all available sources. S/CI information sources include the following:
    - DOE S/CI Web Site www.hss.energy.gov/csa/csp/sci/
    - Government-Industry Data Exchange Program www.gidep.org
    - Institute of Nuclear Power Operations www.hss.energy.gov/CSA/CSP/inpo/
    - DOE Occurrence Reporting and Processing System www.hss.energy.gov/csa/

S/CIs discovered shall be evaluated for reportability per the Occurrence Reporting and Processing System in accordance with DOE O 232.2, *Occurrence Reporting and Processing of Operations Information* and WVDP-242, *Event Investigation and Reporting Manual*, when found during any of the following:

- Receipt;
- Maintenance;
- Testing;
- Inspection;
- Use; and
- When there is a reason to believe that a fraudulent act occurred during the manufacture, shipping, testing, or certification of an item.

PART E: SAFETY SOFTWARE QUALITY REQUIREMENTS

1.0 Introduction

This section provides requirements for the acquisition, development, operation, modification, maintenance, and retirement of software.

It is CHBWV policy to ensure that safety software in nuclear and industrial facilities performs it's intended specific functions in relation to structures, systems, or components; that the classification, design, and analysis associated with facilities operation are correct.

Software Control is a key element to ensure that essential and critical methods of process control, analysis, evaluation, and assessment are performed in a manner to provide consistent and accurate results.

This Part is organized to describe the requirements that govern software, the associated CHBWV responsibilities for implementing the requirements, and the implementation process requirements. The basic requirements for implementation are organized and described from NQA-1-2008/2009a. Implementing process requirements and description which are specific to the HLW program as defined in DOE/RW-0333P, Rev. 20 are presented in Section 5.0 of this Part.

2.0 Requirements

A software quality assurance (SQA) program shall be established and implemented by CHBWV to satisfy the requirements of DOE O 414.1D CRD, Attachment 4, which states:

- "Safety software must be acquired, developed and implemented using ASME NQA-1-2008 with the NQA-1a-2009 addenda (or a later edition), *Quality Assurance Requirements for Nuclear Facility Applications*, Part I and Subpart 2.7, or other national or international consensus standards that provide an equivalent level of QA requirements as NQA-1-2008."

Management of safety software must include the following elements.

- Involve the facility design authority, as applicable, in: the identification of; requirements specification; acquisition; design; development; verification and validation (including inspection and testing); configuration management; maintenance; and, retirement.
- Identify, document, control and maintain safety software inventory. The inventory entries must include at a minimum the following: software description; software name; version identifier; safety software designation (e.g., safety system software, safety and hazard analysis software and design software, safety management and administrative controls software); grade level designation; specific nuclear facility application used; and, the responsible individual.
- Establish and document grading levels for safety software using the graded approach. Grading levels must be submitted to and approved by the responsible DOE approval authority.
- Using the consensus standard selected and the grading levels established and approved above, select and implement applicable SQA work activities from the list below.
    - Software project management and quality planning;
    - Software risk management;
    - Software configuration management;
    - Procurement and supplier management;
    - Software requirements identification and management;
    - Software design and implementation;
    - Software safety analysis and safety design methods;
    - Software verification and validation;
    - Problem reporting and corrective action; and
    - Training of personnel in the design, development, use, and evaluation of safety software

The following were used in the development of the requirements for this section:

- ASME NQA-1-2008, Part 1 Requirement 3, paragraph 800
- ASME NQA-1-2008, Part 1 Requirement 11, paragraph 400
- ASME NQA-1-2008, Part II, Subpart 2.7
- DOE G 414.1-2B and DOE G 414.1-4
- DOE/RW-0333P, Rev. 20

3.0 Implementing Responsibilities

3.1 CHBWV Management is responsible for:

- Acquiring software, acquiring software services, new software being developed, existing software being modified, or a change in software use/requirements.
- Ensuring the software or software services are evaluated for the applicable grading level to determine the appropriate level of rigor of work activities.
- Selecting the Code Custodian and ensuring the application of software controls are in accordance with the requirements of this QAP and implementing procedures.

3.2 CHBWV Organizations

- CHBWV organizations that own and manage software are responsible for implementation of the applicable requirements.

3.3 Code Custodian

- Responsible for all technical functions related to software maintenance, evaluation of software problems, implementing corrections to errors and defects, and consultation with the users.

3.4 Information Technology Organization

- Develops and interprets SQA processes for the acquisition, development, operation, maintenance, and retirement of software, and overseeing compliance with these requirements.
- Develops computer programs, associated tests, and evaluations and establishing basic design and coding standards and conventions.

3.5 Quality Assurance

- Responsible for coordinating QA requirements associated with software control and ensuring that, (through assessment, surveillance, or audit activities), software control activities are in accordance with approved procedures.

3.6 Records Management

- Responsible for the receipt and issuance of supplied software documentation and control and issuance of developed documentation.
- Responsible for establishing and maintaining software configuration control and status accounting.

4.0 Implementation – CHBWV Nuclear Facilities

The processes for acquisition, installation, development, operations, control, maintenance, retirement and use of computer software as applicable to design, construction, operations, modification, repair, and maintenance of nuclear facilities, including safety basis, shall be developed, established, and

documented based on ASME NQA-1, Subpart 2.7, *Quality Assurance Requirements for Computer Software for Nuclear Facility Application*, 2008 Edition and 414.1D CRD, *Quality Assurance*.

Computer software used in applications important to safety, health, environmental, and quality aspects of CHBWV activities, including design calculations and laboratory analysis, shall be subject to appropriate controls, including configuration management, throughout the software life cycle. Engineering methods shall ensure that software life cycle activities are planned, performed, documented and traceable to the software utilized. Method(s) for documenting, evaluating, correcting and reporting of software problems shall be established and approved.

Software shall be placed into the following categories:

- Category 1 - Software developed or modified by CHBWV or by contracted services.
- Category 2 - Acquired Software not developed or modified in accordance with CHBWV software processes.
- Category 3 - Acquired Software developed or modified in accordance with CHBWV software processes.

The CHBWV software quality assurance process is implemented by procedures in accordance with the following requirements and principles.

4.1 Exclusions

The following types of software are excluded from the requirements specified by this chapter.

- Support software, system software (Microsoft Windows), or other software that does not generate data or perform process control functions that could affect the design, analysis and operation of a structure, system or component.
- Systems that have embedded software (i.e., firmware) that is not altered by the user and where functionality of the system is demonstrated through Acceptance or Operational Tests.
- Licensed software that is purchased with and integral to, the operation of measuring and test equipment that is not altered by the user organization, and where the functionality of the system is demonstrated through calibration over the operational range.
- “Flat-file” spreadsheets that are wholly incorporated into technical reports, calc-notes or other documentation where the calculations, mathematical formulas, and input data can be exactly verified during the technical review of the report.
- Legacy Software that has been placed into the “standby” status.

4.2 Graded Approach to Software QA

The graded approach for software is used to determine, for the applicable software category, the level of control, the required life-cycle phase documentation and verification activities. The rationale for the grading criteria is to provide for differing levels of review, testing activities and documentation based on the safety significance of the software, regulatory requirements, quality function and the risk of software failure. This includes software applications important to safety that may be included or associated with SSCs for less than hazard category 3 facilities. Safety software includes safety system software, safety and hazard analysis software and design software, and safety management and administrative control software. Safety software classification/grading criteria are defined (from DOE G 414.1-4) as follows:

- Safety system software – Software for a nuclear facility that performs a safety function as part of an SSC and is cited in either a DOE approved documented safety analysis or an approved hazard analysis per DOE P 450.4A, *Integrated Safety Management Policy*.
- Safety and hazard analysis software and design software – Software that is used to classify, design, or analyze nuclear facilities. This software is not part of 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 – 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. (Examples could include the radiological access control entry software and chemical inventory tracking software, as applicable)
- Level A – Safety Software applications that meet one or more of the following criteria:
    - Software failure that could compromise a limiting condition for operation.
    - Software failure that could cause a reduction in the safety margin for safety SSC that is cited in DOE approved documented safety analysis.
    - Software failure that could cause a reduction in the safety margin for other systems such as toxic or chemical protection systems that are cited in either (A) a DOE approved documented safety analysis or (b) an approved hazard analysis per DOE G 450.4-1C, *Integrated Safety Management System Guide.*
    - Software failure that could result in non-conservative safety analysis, design, or misclassification of facilities or SSCs.
- Level B –Safety software applications that do not meet Level A criteria but meet one or more of the following criteria:
    - Safety management databases used to aid in decision making whose failure could impact safety SSC operation.
    - Software failure that could result in incorrect analysis, design, monitoring, alarming, or recording of hazardous exposures to workers or public.
    - Software failure that could compromise the defense-in-depth capability for a nuclear facility.
- Level C – Software applications that do not meet Level B criteria but meet one or more of the following criteria:
    - Software failure that could cause a potential violation of regulatory permitting requirements.
    - Software failure that could affect ES&H monitoring or alarming systems.
    - Software failure that could affect the safe operation of an SSC.
- Level D – Software used to support quality affecting, general service applications, or business practice where software failure or application error could result in the potential for high business risk.
- Level E – Software used in applications where software failure or application error could result in the potential for moderate project risk.

4.3 Computer Software Controls

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

- The following two reviews are required and can be combined with or be part of the design verification process:
    - One review shall consider the requirements related to the activities of preparing the computer program for acceptance testing. This review can be combined with or be part of the software design verification.
    - The second review shall provide assurance of satisfactory completion of the software development cycle including acceptance testing. This review can be

combined with or be part of software design verification. Individual(s) familiar with the design detail and the intended use of the computer program shall be included in the review.

- When review alone is not adequate to determine requirements are met, alternate calculations shall be used or tests shall be developed and integrated into the activities of the software development cycle.
- Reviews shall identify the participants and their specific review responsibilities. Documentation of review comments and their disposition shall be retained until they are incorporated into the updated software. Comments not incorporated and their disposition shall be retained until the software is approved for use.
- Tests performed in support of a review can be used to complement acceptance testing. The tests and test results shall be included in the acceptance testing documentation. Such tests shall be subjected to the same criteria as the acceptance tests. These tests do not substitute for performing the comprehensive, end of development, acceptance test.
- Engineering methods shall ensure that software life cycle activities are planned, performed, documented and traceable to the software utilized. Method(s) for documenting, evaluating, correcting and reporting of software problems shall be established and approved.

4.4 Software Engineering and Design

- Software engineering method(s) shall be documented. The selected software engineering method shall ensure that software life-cycle activities are planned and performed in a traceable and orderly manner.
- Software design requirements shall address technical and SQA requirements. Software design requirements shall be traceable throughout the software life cycle. An integral part of software design is the design of a computer program that is part of an overall system. Thus, the software design shall consider the computer program's operating environment. Measures to mitigate the consequences of problems shall be an integral part of the design. These potential problems include external and internal abnormal conditions and events that can affect the computer program.
- Software design verification shall evaluate the technical adequacy of the design approach and ensure internal completeness, consistency, clarity, and correctness of the software design and shall verify that software design is traceable to the software design requirements. Software design verification shall include review of test results. The software design verification shall be completed prior to approval of the computer program for use. The requirements for the software design verification activity shall be documented in the software engineering method.
- Computer software used to originate or verify safety or other risk-significant design solutions during the design process shall be validated, and the status of validation shall be identified and documented prior to software use.

4.5 Software Acquisition

- Software acquisition includes software or software services procured, or otherwise acquired. The purchaser shall be responsible for the appropriate requirements of this section upon acceptance of the software or related item (e.g., programmable device). Procurement documents shall identify requirements for supplier's reporting of software errors to the purchaser and, as appropriate, the purchaser's reporting of software errors to the supplier.
- For procured software services, the organization providing the services shall have plan(s) for software QA that meets the requirements of this section. The purchaser organization shall determine the adequacy of this plan.

4.6 Otherwise Acquired Software

- Software that has not been previously approved under a program consistent with this program for use in its intended application (e.g., freeware, shareware, procured commercial off-the-shelf, or otherwise acquired software, including legacy software not previously approved), shall be evaluated using a graded approach in accordance with the requirements of this section. The software shall be identified and controlled prior to evaluation. The evaluation, specified by this section, shall be performed and documented to determine adequacy to support operation and maintenance and identify the activities to be performed and the documentation that is needed.
- This determination shall be documented and shall identify as a minimum:
    - Capabilities and limitations for intended use.
    - Test plans and test cases required to demonstrate the capabilities within the limitations.
    - Instructions for use within the limits of the capabilities.
- Exceptions from the documentation requirements of this section and the justification for acceptance shall be documented.
- The results of the above evaluation and the performance of the actions necessary to accept the software shall be reviewed and approved. The resulting documentation and associated computer program(s) shall establish the current baseline.
- Revisions to previously baseline software received from organizations not required to follow DOE O 414.1D shall be evaluated in accordance with this section.

4.7 Computer Program Testing

- Verification tests, hardware integration tests, and in-use tests shall be conducted and appropriate controls applied. Acceptance testing shall be performed prior to approval of the computer program for use. Software verification and validation processes shall:
    - Ensure the software adequately and correctly performs the intended functions.
    - Ensure the software does not function in a manner in which the system can be degraded.
    - Be planned and performed for system configuration that may impact the software.
    - Be documented.
- Computer program test procedures shall provide for demonstrating the adherence of the computer program to the documented requirements.
    - Computer programs used for design activities, the computer program test procedures shall provide for ensuring the computer program produces correct results.
    - Computer programs used for operational controls, the computer program test procedures shall provide for demonstrating performance over the range of the operation of the controlled function or process.
    - In-use test procedures shall be developed and documented to permit confirmation of acceptable performance of the computer program in the operating system.
- The acceptance testing activity shall demonstrate that the computer program adequately and correctly performs all intended functions (i.e., specified software design requirements). Acceptance testing shall demonstrate, as appropriate, that the computer program properly handles abnormal conditions and events as well as credible failures, does not perform adverse unintended functions, and does not degrade the system either by itself, or in combination with other functions or configuration items.
- Acceptance testing shall be performed prior to approval of the computer program for use. Configuration items shall be under configuration change control prior to starting

acceptance testing. Acceptance testing shall be planned and performed for all software design requirements. Acceptance testing ranges from a single test of all software design requirements to a series of tests performed during computer program development. Performance of a series of tests provides assurance of correct translation between activities and proper function of individual modules. Testing shall include a comprehensive acceptance test performed in the operating environment prior to use.

- The test plans, test cases, and test results shall be documented, reviewed, and approved prior to use of the computer program in accordance with Part B, Section 8.0, "Inspection and Acceptance Testing." Observations of unexpected or unintended results shall be documented and disposition implemented prior to test result approval. The acceptance testing of changes to the computer program shall be subjected to selective retesting to detect unintended adverse effects introduced during the change. Such testing shall provide assurance that the changes have not caused unintended adverse effects in the computer program, and to verify that a modified system(s) or system component(s) still meets specified software design requirements.

4.8 Software Configuration Management

- Software configuration management activities shall include documentation (e.g., software design requirements, instructions for computer program use, test plans, and result[s]); computer program(s) (e.g., source, object, backup files), and support software.
- The software configuration change control process shall include initiation, evaluation, and disposition of change requests, control and approval of changes prior to implementation, and requirements for retesting and acceptance of the test results.

4.9 Problem Reporting and Corrective Action

- Method(s) for documenting, evaluating, and correcting software problems shall:
  - Describe the evaluation process for determining whether a reported problem is an error or other type of problem (e.g., user mistake); and
  - Define the responsibilities for disposition of the problem reports, including notification to the originator of the results of the evaluation.
- When the problem is determined to be an error, the method shall provide, as appropriate, for:
  - How the error relates to appropriate software engineering elements;
  - How the error impacts past and present use of the computer program;
  - How the corrective action impacts previous development activities; and
  - How the users are notified of the identified error, its impact, and how to avoid the error, pending implementation of corrective actions.

4.10 Operation

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

- Application documentation (e.g., application log);
- Access control specifications;
- Problem reporting and corrective action;
- In-use tests; and
- Configuration change control process.

4.11 Maintenance

The appropriate SQA procedures and documents shall identify how changes to the software are controlled. Typically, changes are in response to:

- Enhancement requests from the user community;
- Revisions to software based on software design requirements;
- Changes to the operating environment; or
- Reported software problems that must be corrected.

4.12 Retirement

During retirement, support for the software product is terminated, and the routine use of the software shall be prevented.

4.13 Support Software

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

4.14 Software Tools

- Software tools shall be evaluated, reviewed, tested, and accepted for use, and placed under configuration control as part of the software development cycle of a new or revised software product. Software tools that do not affect the performance of the software need not be placed under configuration control.
- In cases involving modifications of software products using the software tools, the configuration of the support software associated with that modification shall be managed. Changes to the software tool shall be evaluated for impact on the software product to determine the level of reviews and retesting that will be required.

4.15 System Software

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

4.16 Records

- The SQA processes shall define the baseline documents that are to be maintained as records. Although multiple documentation requirements are specified within this section, they can be provided as separate or as combined documents.

5.0 Implementation – CHBWV-HLW

The software quality assurance process organization and requirements address the same fundamental expectations for control of software as described above, but is organized to focus on planning and life-cycle process description. This section represents those HLW-specific expectations.

For HLW activities, requirements of this section shall be implemented through policies, procedures, plans, specifications, work practices, etc, that provide the framework for software engineering activities. Software engineering elements must define the baseline documents that are to be maintained as records.

5.1 Software Engineering

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

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

5.2 Software Verification

Software verification shall be performed at the end of the requirements, design, implementation, and testing life cycle phases to ensure that the products of a given life cycle phase are traceable and fulfill the requirements of the previous phase and/or previous phases.

5.3 Software Planning

A plan addressing software QA shall be in existence for each new software project at the start of the software life cycle. The plan for software QA shall identify:

- A description of the overall nature and purpose of the software.
- The software products to which it applies.
- The organizations responsible for performing the work and achieving software quality and their tasks and responsibilities.
- Required documentation.
- Standards, conventions, techniques, or methodologies that shall guide the software activity.
- Required software reviews.
- Methods for error reporting and corrective action.

5.4 Software Life-Cycle

5.4.1 Requirement Phase

- Software requirements that address functionality, performance, design constraints, attributes, and external interfaces shall be specified, documented, and reviewed.
    - Functionality–The functions the software is to perform.
    - Performance–The time-related issues of software operation such as speed, recovery time, and response time.
    - Design constraints imposed on implementation phase activities–Elements that will restrict design options.
    - Attributes–Non-time-related issues of software operation such as portability, acceptance criteria, access control, and maintainability.
    - External interfaces–Interactions with people, hardware, and other software.
- A software requirement shall only be specified if its achievement can and will be verified and validated.

- Software requirements shall be traceable throughout the remaining stages of the software life cycle (i.e., design, installation, and validation test cases, and user manual). Traceability shall be documented.
- Software requirements shall provide enough detail to either design the software or make an acquisition decision.

5.4.2. Design Phase

- The software design shall be developed, documented, and reviewed based on the requirements depicted in the requirements document.
- The software design shall consider the computer software operating environment.
- Measures to mitigate the consequences of potential problems shall be an integral part of the design. These potential problems include external and internal abnormal conditions and events that can affect the computer program.
- The software design documentation shall specify:
    - A description of the major components of the software design as they relate to the software requirements.
    - A technical description of the software with respect to the theoretical basis, mathematical model, control flow, data flow, control logic, and data structure.
    - A description of the allowable or defined ranges for inputs and outputs.
    - The design, described in a manner that can be translated into code.
    - The generation of design-based test cases.
    - The generation of test plans/cases, based on the requirements and design, shall provide for acceptance criteria and verification of results.
    - For those computer programs used in design activities, the test plans shall provide for ensuring that the software produces correct results.
- For those computer programs used for operational control, computer test plans shall provide for demonstrating required performance over the range of operation of the controlled function or process.

5.4.3 Implementation Phase

- The design shall be translated into source code and resulting executables necessary to perform the functions required.
- The source code and resulting executables shall adhere to specified coding standards, conventions, and design specifications.
- User information shall be developed, documented, and reviewed in accordance with the design to delineate how to use the software, including the following, as applicable:
    - Instructions that contain an introduction (e.g., purpose, and scope), description of the user's interaction with the software, and a description of required training necessary to use the software.
    - Input and output specifications.
    - Data files, input and output data, defaults, and file formats.
    - A description of the allowable and tolerable ranges for inputs and outputs.
    - Anticipated errors and how the user can respond.
    - The hardware and software environments.
    - Available sample problems.
    - Installation procedures.

5.4.4 Testing Phase

- Configuration items shall be under configuration change control prior to acceptance testing.
- Software validation activities shall be planned, performed, documented, and verified at the end of the implementation phase to ensure that the software installs properly and satisfies the requirements for its intended use.
- Testing to an approved plan or process and on a different computer with the same operating environment in which the software will be used shall be the primary method of software validation to ensure adherence to the requirements and to ensure the software produces correct results for the test cases.
- Testing shall demonstrate, as appropriate, that the computer program:
    - Properly handles abnormal conditions and events as well as failures.
    - Does not perform adverse unintended functions. Observations of unexpected or unintended results shall be documented and dispositioned prior to test result approval.
    - Does not unexpectedly degrade the system either by itself or in combination with other functions or configuration items.
- To evaluate technical adequacy, the software test case results may be compared to results from alternative methods, such as:
    - Analysis without computer assistance (hand calculations).
    - Other validated computer programs.
    - Experiments and tests.
    - Standard problems with known solutions.
    - Comparisons to confirmed published data correlations.
- Software validation documentation shall describe the task and criteria for accomplishing the validation of the software at the end of the development cycle. The documentation shall:
    - Specify the hardware and software configurations.
    - Be organized in a manner that allows traceability to both software requirements and design.
    - Contain the results of the execution of the validation activity.
    - Include the results of reviews and tests along with a summary of the status of the software (i.e., indication of incomplete design performance and application requirements).
- Failure to successfully execute the test cases shall be documented and reviewed to determine if modifications to the requirements, design, implementation, or test plans and cases are required.
- Software validation of modifications to released software shall be subjected to selective testing (i.e., regression) to detect unintended adverse effects introduced during the modification of the software, to verify that the modifications have not caused unintended adverse affects, and to verify that a modified software still meets specified requirements.

5.4.5 Installation and Checkout Phase

- Software installation and checkout activities shall be performed and documented when the software is installed on a computer or when there are changes in the operating system to ensure that the software installs properly and satisfies the requirements for its intended use.
- The software validation activities for the installation and checkout shall consist of:
    - The execution of tests for installation.

- The documentation that the software was successfully installed and ready for operational use.

5.4.6 Operations and Maintenance Phase

- Upon acceptable validation of the software performed in accordance with the Testing Phase, the software shall be baselined and placed under Configuration Management controls.
- After the software is approved for use and installed in the operating environment, the use of the software shall be controlled, within the approved procedures and instructions.
- Continuing software maintenance activities consist of:
  - Removal of latent errors (corrective maintenance).
  - Responding to new or revised requirements (perfective maintenance).
  - Adapting the software to changes in the operating environment (adaptive maintenance).
- Software modifications shall be approved, documented, verified and validated, and controlled.
- In-use tests shall be developed, performed, documented, and verified to provide confirmation of acceptable performance of software that is performing continuous data acquisition or process control functions. Periodic manual or automatic self-check in-use tests shall be defined and performed for that software where computer program errors, data errors, computer hardware failures, or instrument drift can affect the required performance.

5.4.7 Retirement Phase

During the retirement phase, the support for a software product is terminated and continued routine use of the software shall be prevented.

5.4.8 Control of the Use of Software

- User organizations control and document the use of issued software items such that comparable results can be obtained, with differences explained, through independent replication of the process.
- Use of software shall be independently reviewed and approved to ensure that the software selected is suitable to the problem being solved
- If the intended use of the software item will require the use of inputs outside the ranges verified during validation testing, the appropriate baseline elements shall be re-verified and revalidated for the expected range of inputs prior to continuing use.
- Documentation for the receipt of software obtained shall be provided and maintained for software in operation or use.
- Controls shall be established to permit authorized access and prevent unauthorized access to operating environment.

PART F: COMMERCIAL GRADE ITEMS AND SERVICES

1.0 Introduction

This section describes the requirements and responsibilities established to demonstrate that a commercial grade item or service is suitable to satisfactorily perform its safety function. As described, this section applies to Safety Class and Safety Significant items and services (CHBWV Quality Level B).

2.0 Requirements

Procurement processes shall be established and implemented by the CHBVW organizations to satisfy the requirements of this section in accordance with 10 CFR 830, Subpart A, and DOE O 414.1D CRD, Attachment 2, which state:

- "Procure Items and services that meet established requirements and perform as specified."

ASME NQA-1-2008/2009a, Requirements 3, 4, 7, Subpart 2.14, and the guidance presented in DOE G 414.1-2B were utilized to develop the requirements in this section.

3.0 Implementation

The CHBVW project does not plan to utilize commercial grade items or services for mission activities. If the need arises, a commercial grade items and services dedication process will be implemented in accordance with the applicable requirements, as described below.

3.1 Commercial Grade Items and Services

When procuring commercial grade items, source evaluation and selection, where determined necessary by requisitioner, Buyer, and QA, based on complexity and importance to safety, shall be in accordance with Part B, Section 7.4.3 of this QAP.

When commercial grade items or services are utilized for Quality Level B, the requirements of NQA-1 Part II Subpart 2.14, Quality Assurance Requirements for Commercial Grade Items and Services shall be implemented and are an acceptable alternative to Part B, Sections 7.4.2-7.4.12 of this QAP.

Commercial Grade Item Definition Applications - A facility utilizing commercial grade items or services shall utilize the appropriate commercial grade item definitions to determine if the item or service can be procured commercial grade. An item or service performing a safety function that does not meet the commercial grade definition is subject to the requirements in Part B, Sections 7.4.2-7.4.12 of this QAP.

3.2 Utilization

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

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

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

Items or services that successfully complete the dedication process are subsequently subject to the controls of Part B, Section 7 of this QAP.

3.3 Technical Evaluation

A. General

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

- Determine the safety function(s) of the item or service
- Identify performance requirements, the component/part functional classification, and applicable service conditions
- Confirm that the item or service meets the commercial grade definition criteria
- Identify the critical characteristics, including acceptance criteria
- Identify the dedication method(s) for verification of the acceptance criteria
- Determine if a replacement item is a like-for-like or equivalent item.

The requirements of this section are only applicable to commercial grade items or services that perform a safety function. Design output documents, supplier technical information, and other relevant industry technical and operating experience information, as appropriate, shall be utilized to prepare the technical evaluation.

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

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

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

If the design criteria or safety function of the original item have changed, the replacement item must meet the new design criteria and safety function. Like-for-like and equivalent items are not a design change subject to Part B, Section 6, of this QAP.

B. Like-for-like Items

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

- The item is provided from the original equipment manufacturer (successor companies that maintain equivalent quality controls are acceptable), and has not been subject to design, materials, manufacturing, or nomenclature changes.
- The item was purchased at the same time and from the same supplier, as determined by the purchase date, shipping date, date code, or batch/lot identification.

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

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

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

C. Equivalent Items

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

The equivalency evaluation shall be documented and include the following:

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

If the change(s) adversely affects or is not bounded by the current approved design bases, the replacement item is not equivalent and must be rejected or processed as a design change in accordance with Part B, Section 6, of this QAP.

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

3.4 Critical Characteristics

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

The manufacturer's published product description or additional technical information typically identifies technical criteria or performance characteristics inherent in the design and manufacturing of the item. The manufacturer can employ standard tests or inspections as part of

the manufacturing process and utilize a quality program to assure that appropriate controls are applied. This type of information is an example to be considered in the selection of critical characteristics and the related acceptance criteria.

In cases where the critical characteristics and acceptance criteria cannot be determined from the manufacturer's documentation or other documentation, the dedicating entity may perform an engineering evaluation, examination, or test (or any combination thereof) of the original item to develop the critical characteristics and acceptance criteria.

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

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

3.5 Methods Of Accepting Commercial Grade Items And Services

A. Dedication

1. For CHBWV, the "dedicating entity" includes the "customer/system owner" (such as Nuclear Storage and Operation) and is supported by CHBWV Engineering, the HLW Project, and CHBWV QA in the dedication activity.

2. To provide reasonable assurance that a commercial grade item or service will perform its intended safety function, the dedicating entity shall verify that the commercial grade item or service meets the acceptance criteria for the identified critical characteristics by one or more of the following dedication methods:

   - Method 1: inspections, tests, or analyses performed after delivery
   - Method 2: commercial grade survey of the supplier
   - Method 3: source verification of the item or service
   - Method 4: acceptable supplier/item performance record

3. Prior to classifying the item or service as acceptable to perform its safety function, the dedicating entity shall determine that the following have been successfully performed, as applicable:

   - Damage was not sustained during shipment.
   - The item or service has satisfied the specified acceptance criteria for the identified critical characteristics.
   - Specified documentation was received and is acceptable.

4. The dedication method(s) described in paragraphs. 3.5.B - 3.5.E below shall provide a means to assure that the commercial grade item or service meets the acceptance criteria for the selected critical characteristics. The selection of acceptance method(s) shall be planned and based on the type of critical characteristics to be verified, available supplier information, quality history, and degree of standardization. If a critical characteristic cannot be verified by the selected dedication method, the dedicating entity may select another or combination of dedication methods to verify the critical characteristic.

5. The organization that performs or directs the dedication activity and determines the item or service has satisfactorily met the acceptance criteria for the selected critical characteristics is the dedicating entity. The dedicating entity can be the

manufacturer, a third-party organization, the purchaser, or the nuclear facility organization.

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

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

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

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

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

When critical characteristics acceptance criteria is based on certified material test reports or certificates of conformance, the criteria of Part B, Section 7.4.7.A.1 of this QAP shall be met.

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

C. Method 2: Commercial Grade Survey of the Supplier

1. A commercial grade survey is a method to verify critical characteristics by evaluating the adequacy and effectiveness of the supplier's commercial quality controls. A commercial grade survey is performed in accordance with a checklist or plan at the supplier's facility and includes or addresses the following:

    - Identification of the item(s), or product line, or service included within the scope of the survey.
    - Identification of the critical characteristics to be controlled by the supplier.
    - Verification that the supplier's processes and quality program controls are effectively implemented for control of the critical characteristics.
    - Identification of the survey methods or verification activities performed with results obtained.
    - Documentation of the adequacy of the supplier's processes and controls.

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

3. When critical characteristics acceptance criteria is based on certified material test reports or certificates of conformance, the criteria of Part B, Section 7.4.7.A.1 of this QAP shall be met.

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

    - The distributor acts only as a broker and does not warehouse or repackage the items.
    - In cases where traceability can be established by other means such as verification of the manufacturer's markings or shipping records.

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

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

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

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

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

D. Method 3: Source Verification

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

applicable to the identified critical characteristics. Organizations performing source verification shall develop criteria for the personnel qualifications and processes used to perform source verification. Source verification documentation shall provide objective evidence that the supplier's activities for the identified characteristics were observed and evaluated for acceptance.

Source verification is only applicable to the actual item(s) or service(s) that are verified at the supplier's facility or other applicable location. Source verification shall be performed in accordance with a checklist or plan with the documented evidence of the source verification furnished to the dedicating entity and shall include or address the following:

- Identification of the item(s) or service(s) included within the scope of the source verification.
- Identification of the critical characteristics, including acceptance criteria, being controlled by the supplier.
- Verification that the supplier's processes and controls are effectively implemented for the identified critical characteristics.
- Identification of the activities witnessed during the source verification and the results obtained.
- Identification of mandatory hold points to verify critical characteristics during manufacture and/or testing for those characteristics that cannot be verified by evaluation of the completed item.
- Documentation of the adequacy of the supplier's processes and controls associated with the critical characteristics and acceptance criteria.

E. Method 4: Acceptable Supplier Item or Service Performance Record

A documented supplier item or service performance record is a method of acceptance to verify conformance with the identified critical characteristics and acceptance criteria of a commercial grade item or service against the supplier's performance record for identical or similar services. This allows the dedicating entity to have reasonable assurance of the item's or service's performance based upon historical performance gained from the successful utilization of other acceptance methods, and/or pertinent industry-wide performance data.

Acceptable data for historical performance may be compiled utilizing monitored performance of the item, industry product tests, certification to national codes and standards (non-nuclear specific), and other industry records or databases. The supplier item or service performance record or data shall be from the condition of service, environmental condition, failure mode, maintenance program, testing, or other conditions equivalent to the intended application of the commercial grade item or service.

1. An acceptable supplier item or service performance record shall include the following:

    - Identification of the supplier item or service being evaluated.
    - Identification of previously established critical characteristics specific to the supplier item or service.
    - Identification of data examined to evaluate the supplier, item or service.
    - Identification of basis for determining that performance data substantiates acceptability of the supplier, item or service.
    - Documentation of the adequacy and acceptance of the supplier/item/service performance record.

2. An acceptable item or service performance record shall not be employed alone as a method of acceptance unless:

- The established historical record is based on industry-wide performance data that is directly applicable to the critical characteristics and the intended facility application, i.e., single sources of information are not adequate to demonstrate satisfactory performance.
- The manufacturer's/supplier's measures for the control of applicable design, process, and material change have been accepted by the dedicating entity, as verified by survey.

Continued application of an acceptable supplier/item/ service performance record as a method of acceptance shall include a documented periodic update and review to assure the supplier/item/service maintains an acceptable performance record.

F. Supplier Deficiency Correction

Deficiencies with the supplier's processes and controls identified by the acceptance method(s) shall be corrected by the supplier if it affects the acceptance criteria for critical characteristic(s) utilized for commercial grade dedication. Corrective actions shall be evaluated for acceptability by the dedicating entity. Uncorrected deficiencies in processes or controls may result in the selection of another dedication method for determining acceptance.

3.6 Commercial Grade Services

Some examples of services that may be provided as commercial grade include training, calibration, testing, engineering, computer software support, and other technical support activities. Services on equipment or items, including installation, repair, cleaning, or maintenance, that do not physically alter an item's critical characteristics are additional examples. Personnel qualification, activity controls, independent certifications, and documents are typical examples of critical characteristic for dedication of services.

Part B, Section 7.4.7.A.5, Acceptance of Services Only (in this QAP), shall be reviewed to determine if this requirement is applicable before considering the dedication of a service. As an alternative to commercial grade dedication, services may be performed under the dedicating entity's or other organization's quality program and procedures that meet the requirements of this Standard. Physical, mechanical, or other service activities that alter or create new critical characteristics of an item that can be used to determine the acceptability of the service that produced the critical characteristic shall not be considered a commercial grade service. For example, if a plate is rolled to a defined radius, the new critical characteristic produced is the radius of the rolled plate and not the rolling process or service that produced the curvature. Original critical characteristics of the plate material and the plate thickness can remain unchanged or be specified by the design organization for the rolled plate. Another example of a commercial grade service is the repair or calibration of an installed instrument by the manufacturer's service representative. The instrument could have been previously dedicated, but now requires service using special tools from the manufacturer that does not have a quality assurance program that meets the requirements of this Standard. The successful results of the calibration service to return the item to the original performance characteristics can be verified by the dedicating entity for acceptance of the commercial grade service.

3.7 Documentation

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

- Dedication plans or procedures including the essential elements of the dedication process;
- Commercial grade item or service procurement documents;
- Technical evaluations;

- Critical characteristic identification and acceptance criteria;
- Test reports or results, inspection reports, analysis reports;
- Commercial grade survey reports;
- Source verification reports;
- Historical performance information; and
- Dedication report containing sufficient data to accept the item or service.

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APPENDIX A: KEY QUALITY ASSURANCE IMPLEMENTING DOCUMENTS

CHBWV ensures environment, safety, health and quality requirements are integrated into work activities through the QAP documents. The following table and appendices present a listing of the key documents implementing QA requirements.

This table below demonstrates the relationship between the QAP and the CHBWV implementing documents, as required by Title 10, *Code of Federal Regulations,* Part 830, *Nuclear Safety Management,* Section 122 (10 CFR 830.122) and DOE O 414.1D, *Quality Assurance*.

Criterion Number	10 CFR 830.122 Program Element	CHBWV Document Number and Title
1	Program	QM 2-1 – To be captured in WVDP-126, *Performance-Based Training Program Manual* WV-100, *Integrated Safety Management and Control of Documents* WV-101, *External and Internal Open Items* WV-108, *Preventive & Predictive Maintenance and Recurring Task System* WV-109, *Instrument Data and Recall Tracking System* WV-120, *Quality Assurance* WV-121, *Integrated Assessment Program* WV-538, *Employee Indoctrination and Training* WV-552, *Required Reading/Briefing for CHBWV Personnel* WV-620, *Purchase Requisitions and Supplements* WVDP-106, *WVDP Conduct of Operations Applicability Matrix* WVDP-127, *CHBWV Procurement System*
2	Personnel Training and Qualification	QM 2-1and QM 2-3 – To be captured in WVDP-126, *Performance-Based Training Program Manual* QM 2-2 – To be captured in WVDP-126, *Performance-Based Training Program Manual* and WVDP-109, *Written Practice For Training, Qualification And Certification Of Nondestructive Examination (NDE) Personnel* WV-121, *Integrated Assessment Program* WV-538, *Employee Indoctrination and Training* WV-552, *Required Reading/Briefing for CHBWV Personnel* WVDP-106, *WVDP Conduct of Operations Applicability Matrix*
3	Quality Improvement	QM 3-2 and QM 3-3 – To be captured in quality procedures WV-100, *Integrated Safety Management and Control of Documents* WV-120, *Quality Assurance*

Criterion Number	10 CFR 830.122 Program Element	CHBWV Document Number and Title
		WV-121, *Integrated Assessment Program* WV-990*, Employee Concerns Program* WVDP-357, *WVDP Issues Reporting Program Manual*
4	Documents and Records	QM 17 – To be captured in WVDP-262, *WVDP Records Management Plan and* WVDP-529, *WVDP Records Disposition Plan* WV-100, *Integrated Safety Management and Control of Documents* WV-108, *Preventive & Predictive Maintenance and Recurring Task System* WV-109, *Instrument Data and Recall Tracking System* WV-730, *Records Management Program Policy* WVDP-106, *WVDP Conduct of Operations Applicability Matrix* WVDP-257, *WVDP Manual for the Preparation, Review, Approval, Distribution, and Revision of Controlled Documents*. WVDP-262, *WVDP Records Management Plan* WVDP-402, *Information Protection* WVDP-529, *WVDP Records Disposition Plan*
5	Work Processes	WV-100, *Integrated Safety Management and Control of Documents* WV-108, *Preventive & Predictive Maintenance and Recurring Task System* WV-109, *Instrument Data and Recall Tracking System* WVDP-106, *WVDP Conduct of Operations Applicability Matrix* WVDP-485, *Work Control*
6	Design	WVDP-201, *Software Management Plan*
7	Procurement	QM 4 – To be captured in quality procedures WV-361, *Control of Technical Information to Subcontractors* WV-620, *Purchase Requisitions and Supplements* WV-695, *Procurement Card Purchases* WVDP-127, *CHBWV Procurement System*
8	Inspection and Acceptance Testing	QM 2-2 – To be captured in WVDP-126, *Performance-Based Training Program Manual* and WVDP-109, *Written Practice For Training, Qualification And Certification Of Nondestructive Examination (NDE) Personnel* QM 11-1 – To be captured in WVDP-099 *Environmental Compliance*

Criterion Number	10 CFR 830.122 Program Element	CHBWV Document Number and Title
		Manual QM 12 – To be captured in WV-129, *Control of Calibrated Instrumentation and Measuring & Test Equipment* WV-100, *Integrated Safety Management and Control of Documents* WV-129, *Control of Calibrated Instrumentation and Measuring & Test Equipment*
9	Management Assessment	QM 2-4 – To be captured in Integrated Assessment Program implementing procedure WV-121, *Integrated Assessment Program* WV-368, *Operational Readiness Determination for Startup and Restart of WVDP Facilities*
10	Independent Assessment	QM 2-3 – To be captured in WVDP-126, *Performance-Based Training Program Manual* WV-121, *Integrated Assessment Program*
N/A	Suspect Counterfeit Item Program	WV-121, *Integrated Assessment Program* WVDP-242, *Event Investigation and Reporting Manual* WVDP-357, *WVDP Issues Reporting Program Manual*
N/A	Software Quality Assurance	QM 3-1 - To be captured in software quality implementation procedure WVDP-201, *Software Management Plan*
N/A	Commercial Grade Items and services	CHBWV will only be procuring quality level B items and services from suppliers on Acceptable Suppliers List. CHBWV will develop a commercial grade items and services procedure to be available if needed.

APPENDIX B: CROSSWALK TO REQUIREMENTS DOCUMENTS

A crosswalk between the 13 QAP sections (green), the 10 elements of DOE O 414.1D (peach), the 10 elements of 10 CFR 830.122 (peach), the 18 requirements of 10 CFR 71 (pink), and the 18 requirements of ASME NQA-1 (blue).

			10 CFR 71 Sub-part H	Quality Assurance Organization		Quality Assurance Program		Package Design Control		Procurement Document Control		Instructions, Procedures & Drawings		Document Control		Control of Purchased Material, Equipment & Services	
WVDP-111	830.122	414.1 D	NQA-1-2008/ 2009a	Organization		Quality Assurance Program		Design Control		Procurement Document Control		Instructions, Procedures, and Drawings		Document Control		Control of Purchased Items and Services	
Program	X	X		X	X	X	X										
Personnel Training & Qualification	X	X				X	X										
Quality Improvement	X	X				X							X				X
Documents & Records	X	X								X	X	X		X	X		
Work Processes	X	X										X	X				
Design	X	X						X	X								
Procurement	X	X								X	X					X	X
Inspection & Acceptance Testing	X	X															X
Management Assessments	X	X			X	X											
Independent Assessments	X	X		X		X											
Suspect Counterfeit Items		X															
Software Quality Assurance		X						X									
Commercial Grade Items and Services		X						X		X						X	

APPENDIX B: CROSSWALK TO REQUIREMENTS DOCUMENTS (CONT'D)

			10 CFR 71 Sub-part H	Identification & Control of Materials, Parts & Components		Control of Special Processes		Internal Inspection		Test Control		Control of Measuring & Test Equipment		Handling, Storage & Shipping Control		Inspection, Test & Operating Status	
WVDP-111	830.122	414.1D	NQA-1-2008/ 2009a	Identification and Control of Items		Control of Special Processes		Inspection		Test Control		Control of Measuring and Test Equipment		Handling, Storage, and Shipping		Inspection, Test, and Operating Status	
Program	X	X															
Personnel Training & Qualification	X	X					X		X								
Quality Improvement	X	X															
Documents & Records	X	X															
Work Processes	X	X		X	X	X	X				X	X	X	X	X	X	X
Design	X	X															
Procurement	X	X			X		X										
Inspection & Acceptance Testing	X	X		X	X			X	X	X		X	X		X	X	X
Management Assessments	X	X															
Independent Assessments	X	X															
Suspect Counterfeit Items		X															
Software Quality Assurance		X								X							
Commercial Grade Items and Services		X															

APPENDIX B: CROSSWALK TO REQUIREMENTS DOCUMENTS (CONT'D)

			10 CFR 71 Sub-part H	Non-conforming Materials, Parts, or Components		Corrective Action		Quality Assurance Records		Audits			
WVDP-111	830.122	414.1D	NQA-1-2008/ 2009a; DOE/RW-0333P	Control of Non-conforming Items		Corrective Action		Quality Assurance Records		Audits		Sub-part 2.7 Soft-ware	Subpart 2.14 Commercial Grade Dedication
Program	X	X											
Personnel Training & Qualification	X	X							X	X	X		
Quality Improvement	X	X		X	X	X	X						
Documents & Records	X	X						X	X				
Work Processes	X	X							X				
Design	X	X											
Procurement	X	X											
Inspection & Acceptance Testing	X	X			X								
Management Assessments	X	X											
Independent Assessments	X	X								X	X		
Suspect Counterfeit Items		X											
Software Quality Assurance		X										X	
Commercial Grade Items and Services		X											X

APPENDIX C: DEFINITIONS

Activities Affecting Quality - Activities which influence or affect the achievement or verification of quality objectives or requirements.

Assessment - An all-inclusive term used to denote any of the following: audit, performance evaluation, management systems review, peer review, inspection, or surveillance.

Audit - A planned and documented investigative evaluation of an item or process to determine the adequacy of and compliance with established procedures, instruction, drawings, QAPs, and other applicable documents.

CHBWV - CH2M HILL • B&W West Valley, LLC - When used herein it also includes CHBWV subcontractors and suppliers that perform activities for the WVDP.

Commercial Grade Item - An item satisfying a), b), and c) below:

a) not subject to design or specification requirements that are unique to nuclear facilities;

b) used in applications other than nuclear facilities;

c) is to be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacture's published product description (for example, catalog).

Data Quality - The totality of features and characteristics of data that bears on its ability to satisfy a given purpose. The characteristics of major importance are accuracy, precision, completeness, representativeness, and comparability.

Data Validation - A systematic effort to review data to identify any outliers or errors and thereby cause deletion or flagging of suspect values to ensure the validity of the data to the user. This "screening" process may be done by manual and/or computer methods, and it may utilize any consistent techniques such as sample limits to screen out impossible values or complicated acceptable relationships of the data with other data.

Design - The act of conceiving and planning the structure and parameter values of a system, device or process, including the act of conceiving and developing design documentation and system analysis.

Design Activities - The use and integration of design information for the purpose of design development and verification. Design activities are documented as design inputs and results of verification and may include data analysis, computer models or systems analysis such as performance assessments.

Design Review - A formally documented review of design documentation conducted at various points during the design process by individuals independent of those performing the design work, but who may be members of the organization within which the work was done. The design review compares design documentation against applicable codes, standards and other specifications to determine its adequacy and the extent to which the design conforms to stated requirements. Individuals performing a design review are completely knowledgeable in the codes, standards and other requirements forming the basis for the design.

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

Environmentally-Related Engineering and Process Evaluation Measurements - A term used to describe essentially all: field and laboratory investigations that generate data involving the measurement of chemical, physical, or biological parameters in the environment and determining the presence or absence of priority pollutants in waste streams; health and ecological effect studies; clinical and epidemiological investigations; engineering and process evaluations; studies involving laboratory simulation of environmental events; and studies or measurements on pollutant transport, including diffusion models.

Graded Approach (Grading Process) - The process by which the level of analysis, documentation, and actions necessary to comply with a requirement are commensurate with: (1) the relative importance to safety,

safeguards, and security; (2) the magnitude of any hazard involved; (3) the life cycle stage of a facility; (4) the programmatic mission of a facility; (5) the particular characteristics of a facility; and, (6) any other relative factor. Graded Approach is the "Grading Process" at CHBWV.

Independent Assessment - An assessment performed by a qualified individual, group, or organization that is not a part of the organization directly performing the work being assessed.

Inspection - An examination or measurement to verify whether an item or process meets specified requirements.

Item - An all-inclusive term used in place of the following: appurtenance, facility, samples, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, unit, documented concepts, or data.

Line-Organization Self-Assessment - A formal, documented internal self-evaluation performed or directed by line management to evaluate the way the organizations do business as it relates to compliance with applicable laws, regulations, and best management practices. Identifies problems and trends within specified areas of inquiry, assesses causes, develops corrective action plans and schedules, and identifies lessons learned.

Self-assessments are conducted by line-organizations in accordance with this policy, the self-assessment program, and the individual department self-assessment schedules which implement this policy.

Management - (including staff and line) Those individuals directly responsible and accountable to provide technical (overall) guidance and direction for the performance of work. Management refers to those personnel who are responsible and accountable for mission accomplishment, QAP implementation, and development of plans, procedures and self assessments to maintain compliance and achieve excellence. Management is responsible for the planning, scheduling and executing of programs. Managers are accountable for operating functions, items and services, in support of line operations.

Measuring and Test Equipment (M&TE) - As used at CHBWV, includes calibrated equipment for accepting material or equipment, controlling processes, verifying correct facility operation, or obtaining data used to verify conformance to specified requirements.

Objective Evidence - Any substantiated statement of fact, other information, or record, either quantitative or qualitative, pertaining to the quality of an item or activity, based on observations, measurements, or tests which can be verified.

Out of Calibration - A condition which exists when an item included in the Measuring and Test Equipment program (i.e.: calibrated equipment) has exceeded its due date for re-calibration.

Out of Tolerance - A condition which exists when an item included in the CHBWV Measuring and Test Equipment program is found to be outside of its established accuracy parameters. This is usually discovered during the calibration process.

Peer Review - A documented assessment of an item, activity, or work performed that is conducted by one or more individuals independent of the originator who are regarded as technically expert in the subject area being assessed. Peer reviews provide an independent evaluation of a subject where quantitative methods of analysis or measures of success are unavailable or undefined, such as in research and development.

Planned and Systematic Activities - is an all encompassing phrase which includes the activities of all persons involved in a work process to produce a product or provide a service. Essentially this means that "the assurance of quality is the responsibility of all persons involved in the work process to produce a product or provide a service."

Procedure - A documented set of steps or actions that systematically specify or describe how an activity is to be performed.

Process - A system of actions that achieves an end result.

Quality - A term that characterizes the degree or grade of excellence of a product, service, or process. A product, service, or process that meets its prescribed "quality requirements" is described as a quality product, quality service, or quality process. The key words are "quality requirements." Communications between the "performer" and "client" must be constant to provide that quality requirements are understood and addressed in a timely manner. It is through effective communications that the performer and client agree upon the quality requirements in order that the right job is done right the first time.

Quality Assurance (QA) - All those planned and systematic activities necessary to provide adequate confidence that a product or service meets established (agreed-upon) requirements.

Quality Assurance Program (QAP)- A structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for requiring quality in its work processes, products (items), and services. The QAP provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out required QA and quality control activities.

Quality Improvement - A management program for improving the quality of operations. Such management programs generally entail a formal mechanism for encouraging worker recommendations with timely management evaluation and feedback or implementation.

Quality Requirements - Those qualitative and quantitative measures that determine whether a product, service, or process is satisfactory to performer and client. As an example, data quality objectives as defined by the EPA provide quantitative requirements for the accuracy, precision, and completeness of data measurements. It is somewhat easier to define the quality requirements for a product such as a component, a report, or even raw data than it is to define requirements for a service. For that reason it is paramount to the successful completion of the service that client and performer communicate on the subject to the point that either can articulate the quality requirements and the other will agree.

Repair - The process of restoring a nonconforming characteristic to a condition such that the capability of an item to function reliably and safely is unimpaired, even though that item still does not conform to the original requirement.

Rework - The process by which an item is made to conform to original requirements by completion or correction.

Service - The category of economic activity that does not produce manufactured items. In environmental data operations or engineering projects, such activities include design, fabrication, inspection, laboratory analysis, repair, or installation.

Senior Management - The manager or managers responsible for mission accomplishment and overall operations. For CHBWV, the Project Manager and his senior managers are responsible for mission accomplishment and overall performance.

Subcontractor/Supplier - This is an all-inclusive term used in place of any of the following: vendor, seller, contractor, fabricator, or consultant. Those personnel/organization/companies performing work or otherwise supplying services/items in accordance with contractual requirements or financial assistance agreements issued by CHBWV. The requirements of WVDP-111, as appropriate to the items/work/services are imposed by technical specification and /or purchase order requirements, in accordance with the CHBWV grading process.

Surveillance - The act of monitoring or observing a process or activity to verify conformance to specified requirements.

Testing - The determination of the capability of an item or process to meet specified requirements by subjecting it to a set of physical, chemical, environmental, or operating conditions.

Use-as-is - A disposition permitted for a nonconforming item when it can be established that the item is satisfactory for its intended use.

Validation - An activity that demonstrates that an item or process will perform under conditions of actual use and satisfy prescribed requirements of the end user.

Verification - The act of reviewing, inspecting, testing, checking, conducting surveillances, auditing, or otherwise determining and documenting whether items, processes, services, or documents meet specified requirements.

Work - Process of performing a defined task or activity; for example, research and development, operations, administration, inspection, data collection, and analysis.

WVDP RECORD OF REVISION

Rev. No.	Description of Changes	Revision On Page(s)	Dated
0	Original Issue to meet the requirements of DOE Order 5700.6C	All	03/13/92
1	General Administrative changes to incorporate DOE-HQ comments	All	07/20/92
2	General Administrative changes to incorporate additional "guidance" from DOE Order 5700.6C resulting from GOCO Appraisal Team Comments	All	05/27/93
3	Reviewed to reflect the reorganization putting the Quality Assurance Manager under the Vice President of Environmental, Safety, Health, and Quality	All	10/29/93
4	Revised to meet the requirements of10 CFR 830.120 QA Rule. APPENDIX B, Site Implementing Procedures, has been deleted from this document and included in the implementation plan for the QA Rule.	All	10/14/94
5	Integrated the Implementation Plan into this document, added description of ISMS and S/CI, included current management and corporate structure, added appropriate detail from Implementation Guide (G414.1-2) to the implementation matrix (appendix C), Changed environmental requirements from ANSI/ASQC-E4 and WVDP-099 references to the DOE O 414.1A, NQA-1, and ISMS requirements for Environmental, Safety, Health, (ESH) and Quality. Made editorial and grammatical changes.	All	10/28/99
6	Section 4, 2nd para., 2nd sentence, removed "to", Section 7.1 last para., replaced semicolon with Comma, section 1.4.3, 2nd and 3rd sentences, Reworded for clarity, section 7.3.6, 2nd sentence, added comma, page 58, title changed WVDP-022 to WVDP-002. Revision 6 incorporates OH/WVDP Comments. (Ref; DW:2000:0303)	3,6,15,42 58	05/19/00
7	Changed title page names/titles, changed WVNS to WVNSCO, changed 10 CFR 830.120 to 10 CFR 830.122, revised WV-914 USQP statement, added electronic viewing of controlled documents, updated the matrix to current implementing documents, and numerous minor editorial corrections. No departments are affected by this change.	All	02/22/02
8	This revision updates the President's name and updates the implementation matrix to the, current implementing documents. Also updated per DCIP-100 and repaginated to allow for change. No departments are affected by this change.	Cover Sheet, 3, 6, 55, 73 75, 76, 78 81, 82	10/27/03

WVDP RECORD OF REVISION CONTINUATION FORM

Rev. No.	Description of Changes	Page(s)	Revision On Dated
9	Last paragraph of section 1.0 revised to meet the program statement associated with the Technical Safety Requirement Administrative Controls program of WVDP-146. (ref.IC:2004:0007) No departments are affected by this change.	5	03/11/04
10	Added to 3.0 and decommissioning 2.4.1 was reworded 6.4.1 reworded 6.3.10 words decommissioning added 7.3.8 knowingly supplied items and services changed to read knowingly supplied suspect/counterfeit items and/or services 8.3.1 e.g., source, in-process, final receipt-coma added after final Appendix C, WV-532 changed to WV-552 Appendix C, Deleted WV-911 Appendix C, [and decommissioning] added Appendix C, WV-129 added	6 17 31 34 61 64 67	04/27/06
11	Cover: Change R. A. Mellor to A. H. Konetzni Change R. A. Mellor to A. H. Konetzni the DOE Ohio Field Office Manager changed to read DOE EM HQ (EM-3) the DOE OH/WVDP changed to read DOE EM HQ (EM-3) ESHQ and QA Departments impacted by this change	 3 6 6	09/21/06
12	Section 4.0 Corrected typo to read “periodically evaluated by WVDP-DOE” No departments are impacted by this change	6	10/25/06
13	Changes reflect 414.1A being replaced by 414.1C Staff Manager replaced by senior manager. Staff Management replaced by senior management WVNSCO, WVNS replaced by WVES Added to Implementation Matrix QM-10, QM 3-1, WVDP-201 Added DOE G 414.1-3 Suspect Counterfeit Items Guide for use with 10 CFR 830, Subpart A, and DOE O 414.1B Quality Assurance DOE G 414.1-4 Safety Software Guide for use with 10 CFR 830, Subpart A, and DOE O 414.1C Quality Assurance Added last two rows to Appendix C, 10 CFR 830.122 Implementation Matrix ESHQ and QA Departments impacted by this change	All 65 72 71	09/07/07
14	General Revision Updated Signatures on Cover page and Policy page. Add 10CFR 851, Worker Safety and Health Program. Delete DOE O 440.1 “Worker Safety” Add approved by the Project Manager of WVES Update DOE-WVDP reference. Delete WVNS, replace with WVES	 1,3 5 5 6 6 9	10/28/09

WVDP RECORD OF REVISION CONTINUATION FORM

Rev. No.	Description of Changes	Page(s)	Revision On Dated
14 (Cont)	Deleted sentence with “Conduct of Maintenance and Operations Manuals”	24	
	Update reference DOE G 414.1-2 to DOE G 414.1-2A	57-60	
	Delete sentence regarding enforceablity.	57	
	Update Appendix C Matrix with DOE G 414.1-2A changes.	61-73	
	Deleted Not Enforceable from Appendix C Matrix Header, deleted WV-110 from Matrix, replaced with WVDP-106.	61-73	
	Add DOE G 414.1-2A to Appendix D – References	74	
15	General revision to incorporate new requirements/changes in NQA-1-2008/2009a and DOE/RWP-0333P, QARD, Rev. 20. Also incorporated information from WVDP-002, Quality Management Manual, which is being deleted. Updated company name and logo, department name and titles. DOE approval received via DW:2012:0209 and DW:2012:0210. Departments who implement elements of the QA program are affected by these changes.	All	03/21/12