

SECTION 9 QUALITY ASSURANCE AND QUALITY CONTROL

TABLE OF CONTENTS

Section Title	Page
9.0 QUALITY ASSURANCE AND QUALITY CONTROL.....	9-4
9.1 QA/QC Organization Authority and Responsibilities	9-5
9.1.1 Company Interrelation	9-5
9.1.2 Lines of Responsibility	9-8
9.1.3 QA/QC Authority.....	9-15
9.1.4 QA/QC Access to Management.....	9-16
9.1.5 Stop-Work Authority	9-16
9.1.6 QA/QC Program Delegation.....	9-16
9.2 QA/QC Implementation and Monitoring.....	9-17
9.2.1 QA/QC Program Personnel Qualification	9-17
9.2.2 QA/QC Program Efficiency.....	9-17
9.2.3 QA/QC Management Review	9-17
9.2.4 QA/QC Outside Review	9-18
9.3 Design Controls	9-18
9.3.1 QA/QC Pre-design Plan, Documentation, Implementation.....	9-18
9.3.2 Design Suitability Measures	9-19
9.3.3 Data Handling Measures.....	9-20
9.3.4 Design Interrelationship Measures	9-20
9.3.5 Design Change Measures.....	9-21
9.3.6 Error Documentation and Prevention	9-21
9.3.7 Effective Selection of Materials, Parts, and Equipment	9-21
9.4 Procurement of Materials, Equipment, and Services.....	9-22
9.4.1 Document Preparation, Review, and Approval Procedures.....	9-22
9.4.2 Conforming Materials, Equipment, and Services to Procurement Specifications.....	9-24
9.4.3 Material Damage, Loss, and Deterioration Prevention.....	9-26
9.4.4 Accurate Identification of Materials, Parts, and Components	9-26
9.4.5 Design Specification Compliance of Materials, Parts, and Components.....	9-27
9.4.6 Controlling Non-Conforming Materials, Parts, and Components	9-27
9.5 Processes, Procedures, and Instructions.....	9-28
9.5.1 Prescribing and Performing Activities that Affect Quality.....	9-28
9.5.2 Procedures Detailing Processes and Controls.....	9-29
9.6 Document Control.....	9-30
9.6.1 Document Review, Approval, Issuance, and Control.....	9-30
9.6.2 Maintenance of Records	9-31
9.7 Inspection and Testing	9-32
9.7.1 Verifying Conformance to Instructions, Procedures, and Drawings	9-32
9.7.2 Testing Program Requirements.....	9-33
9.7.3 Conduct for Testing Procedures.....	9-33
9.7.4 Sample Preservation.....	9-34
9.7.5 Measuring and Testing Device Maintenance and Control.....	9-35
9.8 Corrective Actions to Adverse Conditions	9-36

9.9	Audits, Surveillance and Managerial Control.....	9-37
9.9.1	QA/QC Program Audits.....	9-37
References	9-38

LIST OF FIGURES

Figure Title	Page
Figure 9.1.1-1. Interface Relationships.....	9-9
Figure 9.1.2-2. WCS Facility Organization.....	9-11
Figure 9.1.2-2. WCS Facility Organization.....	9-12
Figure 9.1.2-2. Operations Organization.....	9-13

LIST OF APPENDICES

Appendix Title

Appendix 9.0. Quality Assurance

9.0 QUALITY ASSURANCE AND QUALITY CONTROL

Provide a detailed description of the quality assurance program, tailored to disposal of low-level radioactive waste, developed and applied by the applicant for the determination of natural disposal site characteristics and for quality assurance during the design, construction, operation, and closure of the land disposal facility and during the receipt, handling, and emplacement of waste. [30 TAC §336.707(7)].

In developing the Quality Assurance (QA) and Quality Control (QC) section the applicant is referred to NUREG 1200, "Standard Review Plan for the Review of a License Application for Low-Level Radioactive Waste Disposal Facility," January 1991. The applicant shall provide descriptions and plans of the following:

Waste Management Specialists LLC (WCS) maintains full responsibility for ensuring that the Near-Surface Land Disposal Low Level Radioactive Waste Facility is designed, constructed, operated (including the receipt, handling, and emplacement of waste), and decommissioned in compliance with the applicable regulatory requirements, specified design requirements, and applicable industry standards in a manner to protect the health and safety of the employees and the public, and to protect the environment. Texas Administrative Code, Title 30, Chapter 336.707 requires that a description of the facility Quality Assurance (QA) program be included in the license application.

The WCS QA Program described herein covers design, construction, and operations of the LLRW facility. The design of the facility includes:

- Characterization of the geologic setting
- Prediction of the long-term stability of the site
- Prediction of the environmental interactions
- Planning and specifying processes for handling low-level radioactive waste (LLRW)
- Specifying the requirements for site construction and LLRW handling

The WCS QA Program addresses all requirements provided in Texas Commission on Environmental Quality (TCEQ) "Application for License to Authorize Near-Surface Land Disposal of Low-Level Radioactive Waste" and applicable regulatory guidance as follows:

- U.S. Nuclear Regulatory Commission. *Quality Assurance Guidance for a Low-Level Radioactive Disposal Facility*. NUREG-1293, Revision 1, April 1991.
- U.S. Nuclear Regulatory Commission. *Qualification of Existing Data for High-Level Nuclear Waste Repositories*. NUREG-1298, February 1988.

The WCS Quality Assurance Plan and the applicable draft QA implementing procedures are included as Appendix 9.0. The WCS program establishes the quality assurance requirements and management controls applicable to quality-affecting activities performed by WCS.

WCS will notify the TCEQ when changes are proposed in the TCEQ-accepted WCS QA plan provided in Appendix 9.0 that may reduce or degrade a quality requirement. WCS will not implement proposed changes until authorized by the TCEQ.

9.1 QA/QC Organization Authority and Responsibilities

Identify and describe the authority and responsibilities of organizations performing QA/QC activities.

9.1.1 *Company Interrelation*

Provide a single organization chart showing how major organizations or companies interrelate with one another throughout the site characterization, design, construction, operation, and closure of the facility.

Figure 9.1.1-1 outlines the interrelations between WCS and contractors supporting WCS during all phases of the facility, from site characterization to closure. The Sr. Vice President, Licensing and Regulatory Affairs, is responsible for managing the development of this license application and has continuing responsibilities for overseeing the design contractor. The work activities depicted on Figure 9.1.1-1 are quality affecting.

The following activities, structures, systems, and components are subject to the WCS Quality Assurance Program to satisfy regulatory requirements and provide for public and intruder protection, worker protection, and structural stability. A listing of the structures, system, components, work activities, and QA program applicability assignments that fall under the WCS QA program is described as follows:

9.1.1.1 Quality Assurance Activities

1. Quality assurance program implementation

WCS QA PROGRAM APPLICABILITY ASSIGNMENT																		
Organization	ASME NQA-1 Criterion																	
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
WCS Corporate	x	x	x	x	x	x	x								x	x	x	x
WCS Facility	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Site Characterization Contractor			x		x	x						x						x
Design Contractor	x	x	x		x	x									x	x	x	x
Construction Contractor	x	x		x	x	x	x	x	x	x		x	x	x	x	x	x	
Inspection Contractor	x									x		x			x	x	x	

WCS QA PROGRAM APPLICABILITY ASSIGNMENT	
	ASME NQA-1 Criterion
Criterion	Description
1	Organization
2	Quality Assurance Program
3	Design Control
4	Procurement Document Control
5	Instructions, Procedures and Drawings
6	Document Control
7	Control of Purchased Materials, Equipment & Services
8	Identification and Control of Material, Parts and Components
9	Control of Special Processes
10	Inspection
11	Test Control
12	Control of Measuring and Test Equipment
13	Handling Shipping and Storage
14	Inspection Test and Operating Status
15	Control of Nonconforming Items
16	Corrective Action
17	Quality Assurance Records
18	Audits

2. Quality assurance records maintenance
3. Audit and surveillance program
4. Control and resolution of nonconformances
5. Completion and control of special processes
6. Radiation safety program

9.1.1.2 Site Characterization and Monitoring

1. Site characterization activities directly related to analyses (see Note 1):
 - a. Geological interpretations and monitoring
 - b. Hydrological interpretations and monitoring
 - c. Environmental monitoring and data
 - d. Climatological data
 - e. Seismic network monitoring
 - f. Computer software use and development
 - g. Performance assessment

2. Further site investigation activities
 - a. Field research of monitoring system performance objectives
 - b. Trench slope investigation
 - c. Field research of trench engineered caps

Note 1: On-site instrumentation used to measure geotechnical, geochemical, or geohydrological parameters are subject to the Quality Assurance Program. Laboratory procedures related to radiological, geochemical, or geohydrological analyses are likewise subject to the Quality Assurance Program. Field data collection such as field interpretation recordation, chain-of-custody procedures, soil, water, and vegetation collection methods are subject to the Quality Assurance Program.

Note 2: Computer analysis is subject to the Quality Assurance Program. This includes software that is either federal or state agency confirmed software, standardized, off-the-shelf software or developed in-house software that has been validated and verified as required in the WCS QA Program. All software packages must be benchmarked and a copy of the proven code must be maintained in a secure file. A copy of the input must be identified or included in the file and a user's manual, if available, must be included.

Codes used for performance assessment include RESRAD, Version 6.22, developed and controlled by Argonne National Laboratory and HELP, Version 3.07, developed and controlled by the US Army Corp of Engineers.

9.1.1.3 Facility Design and Construction

1. Design of the overburden biobarrier and performance cover
2. Design and specification of the compacted clay liner and red bed clay geology
3. Design and construction of the canister disposal unit drainage system
4. Design and construction of the liners, leak detection, and leachate collection system in the mixed waste disposal units
5. Design and construction of the trench cover system
6. Design and construction of the surface water diversion berm
7. Canister construction and inspection

9.1.1.4 Facility Operation

1. Placement of modular concrete canisters, handling of waste shipment canisters, and waste matrix compaction and void elimination
2. Operation of the fire suppression system in quality-related buildings
3. Low-level radioactive waste disposal records

9.1.1.5 Closure

1. Design and construction of the final grade and trench cover

9.1.1.6 Post-Closure

1. Design and implementation of the post-closure monitoring system

The General Manager provides site characterization inputs based on site monitoring activities to the site characterization contractor and design inputs including operating experience to the design contractor. The General Manager oversees the construction contractor and manages the operations and closure of the facility.

9.1.2 *Lines of Responsibility*

Provide organizational charts and functional responsibility that denote lines of responsibility and areas of authority within each major organization in the project throughout the site characterization, design, construction, operation, and closure of the facility.

9.1.2.1 WCS Organizational Structure

WCS and contractors employed by WCS have full responsibility to ensure that the facility is designed, constructed, and operated in a manner to protect the health and safety of the public, the workers, and the environment. This responsibility begins with initial design and is maintained throughout the life of the facility. The WCS QA Program is designed to ensure that the necessary quality requirements for structures, systems, components, and work activities are achieved. This objective is attained by ensuring that the organizational structure and the responsibility assignments are such that quality is achieved and maintained by those who have been assigned responsibility for performing work and, quality achievement is verified by persons or organizations not directly responsible for performing the work.

The WCS President and Chief Financial Officer (President) establishes the basic policies of the WCS QA Program. The policies described in the WCS QA Program are transmitted to all levels of management and are implemented through procedures. The WCS QA Director has responsibility for facilitation of the development of procedures and verification of the proper implementation of the WCS QA Program requirements. Additionally, as part of this responsibility, the WCS QA Director imposes applicable QA/QC requirements on contractors and verifies contractor conformance.

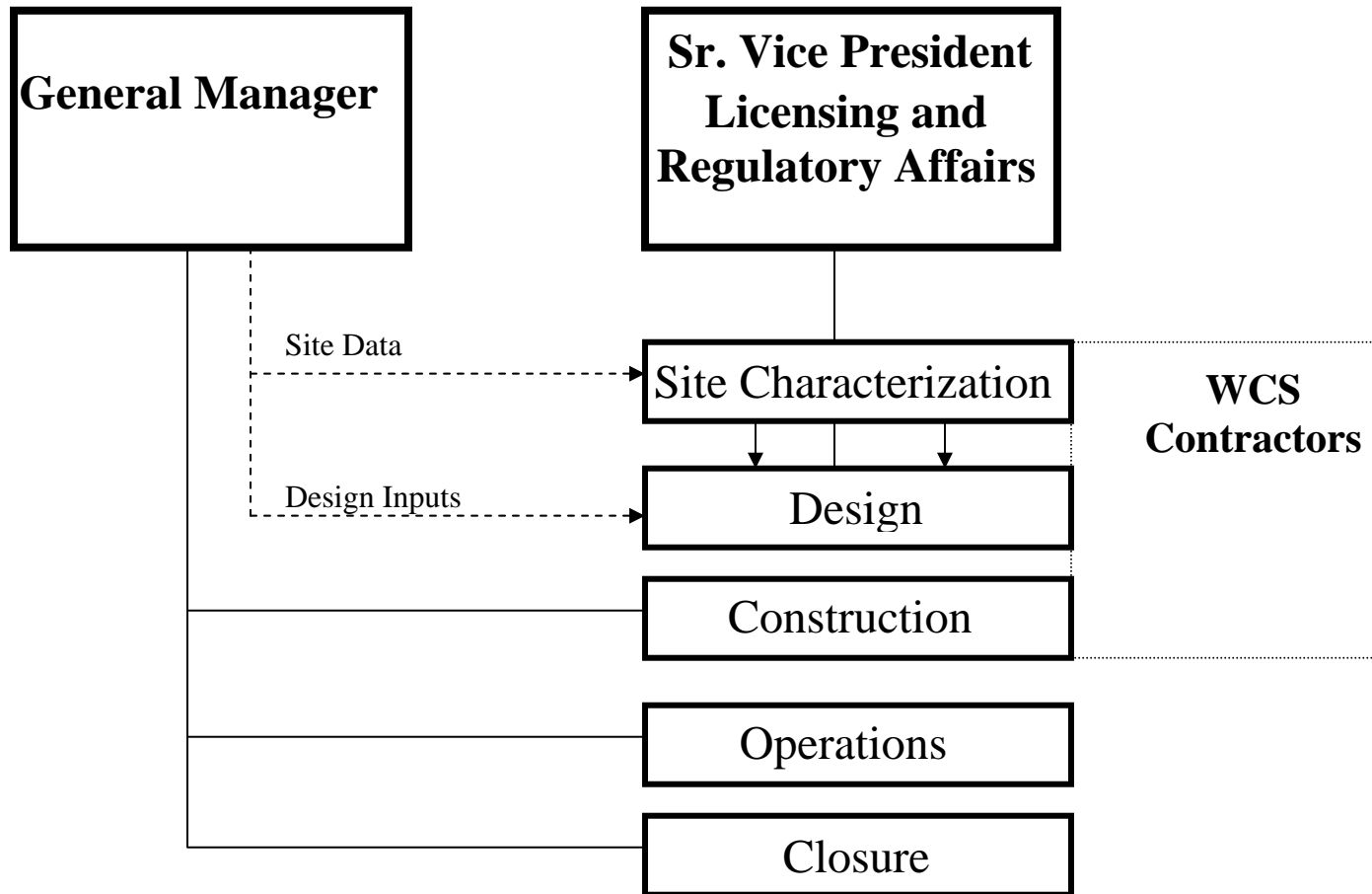


Figure 9.1.1-1. Interface Relationships.

9.1.2.2 Organizational Responsibilities and Authorities

WCS President and Chief Financial Officer (President)—The President is the executive responsible for quality assurance and is the highest level of management responsible for WCS' QA policies, goals, and objectives. Reporting to the President are the Director, Planning and Analysis; Senior Vice President, Licensing & Regulatory Affairs; Senior Vice President, Business Development; Director of Finance; Director, Quality Assurance, and the Vice President and General Manager.

Figure 9.1.2-1, WCS Corporate Organization, Figure 9.1.2-2, WCS Facility Organization, and Figure 9.1.2-3, Operations Organization, outline the reporting relationship and the lines of authority. For the purposes of this application section, the positions that have QA responsibilities and authority will be described.

Senior Vice President, Licensing and Regulatory Affairs – The Senior Vice President, Licensing and Regulatory Affairs, is responsible for the development and submittal of the “Application for License to Authorize Near-Surface Land Disposal of Low-Level Radioactive Waste.” Figure 9.1.1-1 outlines the interrelations between WCS and contractors supporting WCS during all phases of the facility, from site characterization to closure. Key contractors supporting the preparation of the application include URS Corporation and Cook-Joyce Inc. URS Corporation is responsible for developing the technical and design sections of the application. Cook-Joyce Inc is providing environmental engineering, geologic, and consulting services to WCS. The responsibility for managing the site characterization and design contractors continues to be a responsibility of this position during the construction period.

Interface meetings with key contractors are held on a regular schedule to ensure the proper integration of design information.

Vice President and General Manager (GM) – The GM is responsible for the construction, operation, closure, and administration of the facility. The GM is responsible for ensuring the facility complies with all applicable technical and quality requirements. In the discharge of these responsibilities, the GM takes direction from the President and directs the activities of the following functional groups:

- Operations
- Security
- ES&H
- Administrative Services
- Human Resources
- Radiation Safety Committee

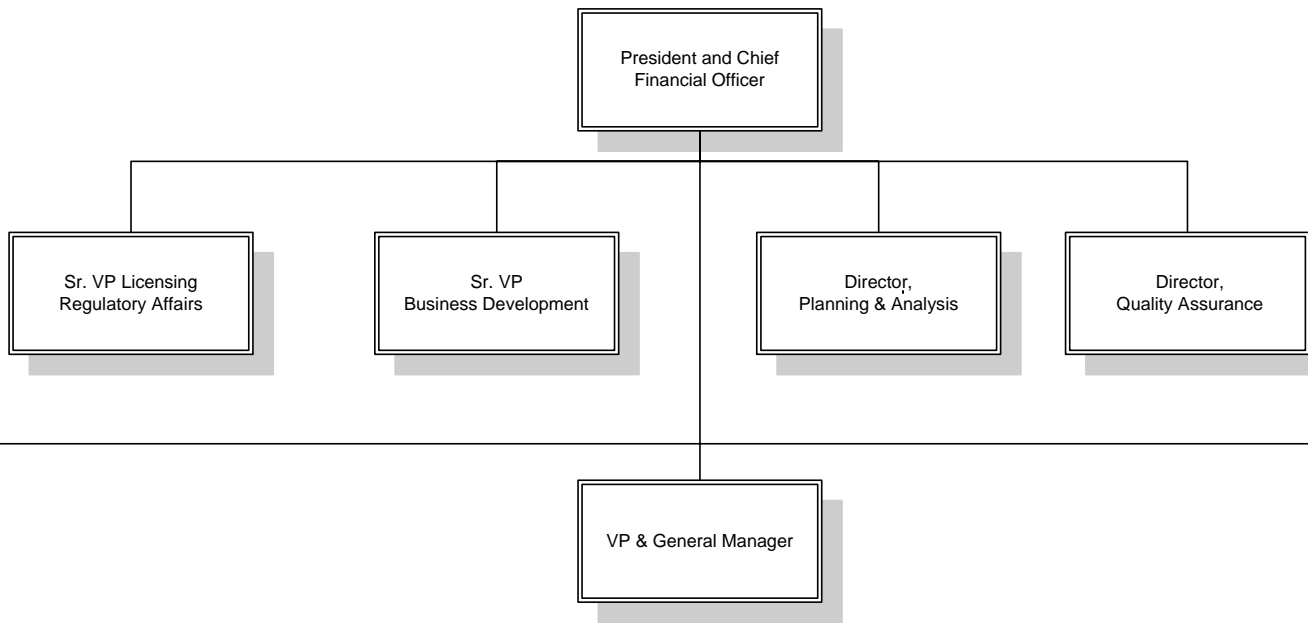


Figure 9.1.2-1. WCS Corporate Organization

**APPLICATION FOR LICENSE TO AUTHORIZE NEAR-SURFACE
LAND DISPOSAL OF LOW-LEVEL RADIOACTIVE WASTE
Section 9: Quality Assurance and Quality Control**

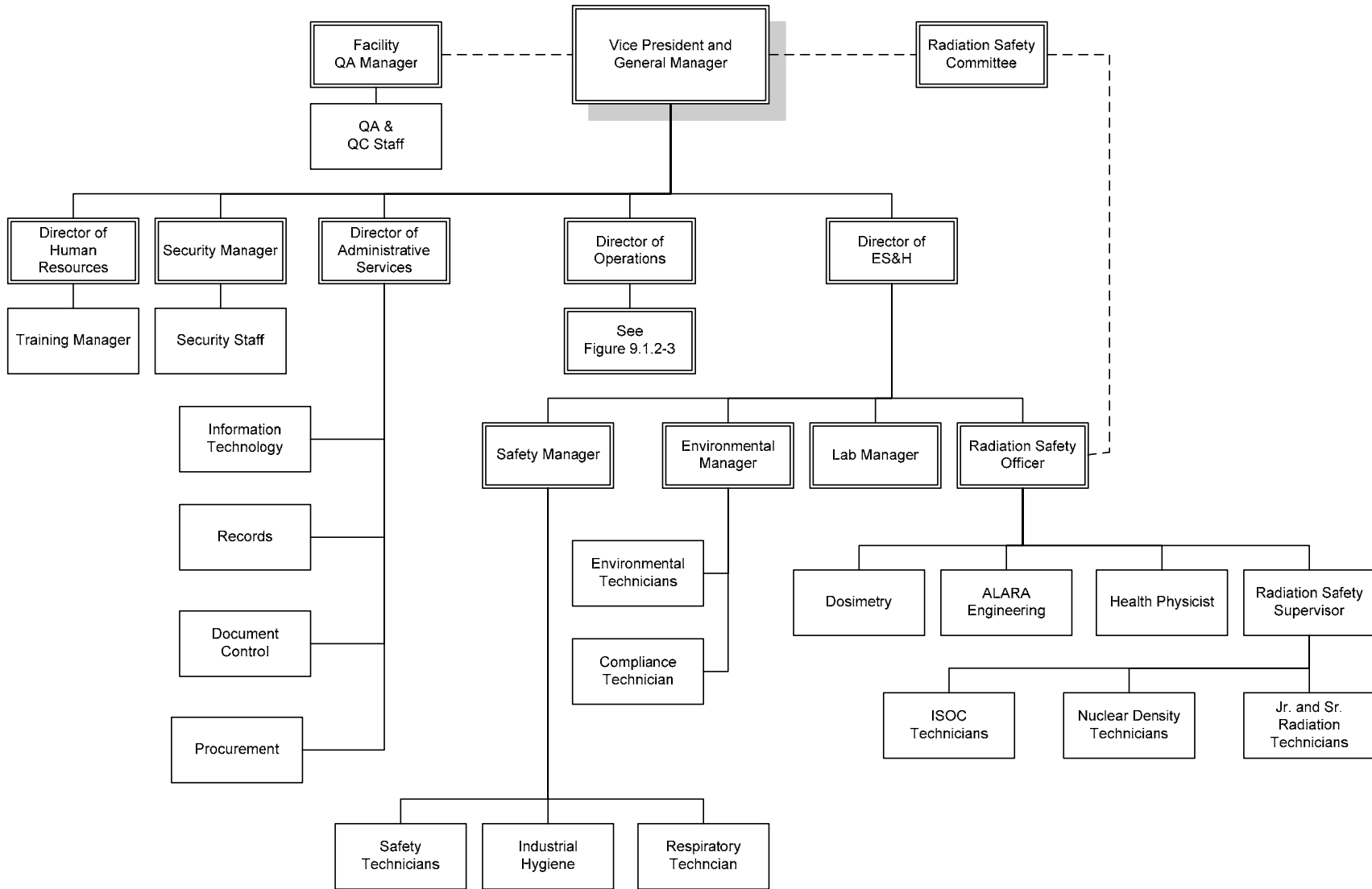


Figure 9.1.2-2. WCS Facility Organization

APPLICATION FOR LICENSE TO AUTHORIZE NEAR-SURFACE
LAND DISPOSAL OF LOW-LEVEL RADIOACTIVE WASTE
Section 9: Quality Assurance and Quality Control

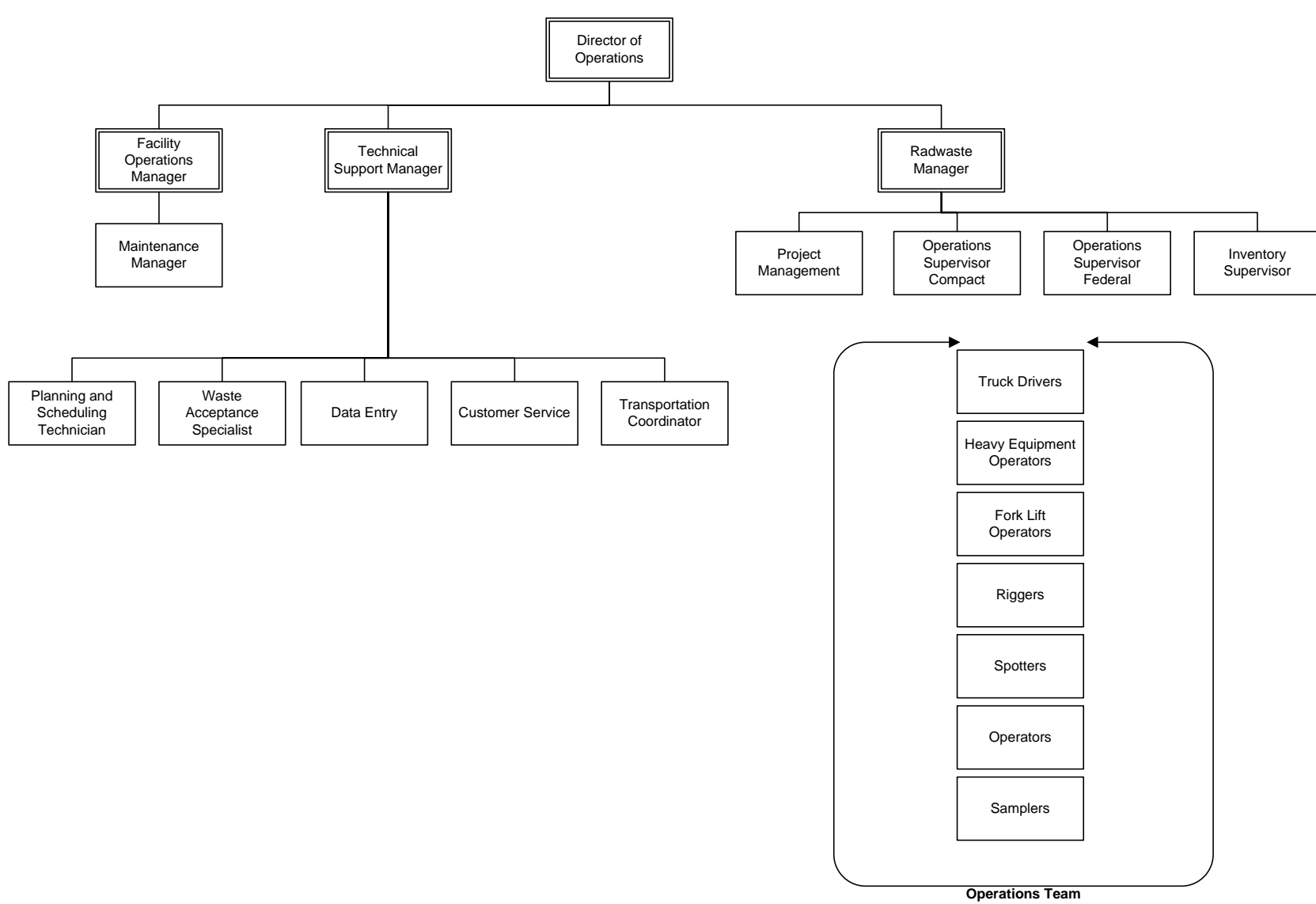


Figure 9.1.2-3. Operations Organization

Operations is responsible for the following functions:

- Radwaste Disposal
 - Federal Operations
 - Compact Operations
 - Inventory Management
 - Project Management
- Technical Support
 - Waste Acceptance
 - Planning and Scheduling
 - Customer Service and Requirements
 - Transportation Coordination
- Facility Operations
 - Maintenance

ES&H is responsible for the following functions:

- Safety and Health
 - Respiratory Protection
 - Industrial Hygiene
 - Industrial Safety
- Radiation Safety
 - Dosimetry
 - ALARA Engineering
 - Health Physics
- Laboratory Testing
- Environmental Management
 - Compliance

Administrative Services is responsible for the following functions:

- Procurement
- Records Management
- Document Control
- Information Technology

Human Resources is responsible for the following functions:

- Training and Qualification
- HR
- Staffing
- Local Outreach

Quality Assurance Management – WCS QA is responsible for establishing a documented Quality Assurance Program and verifying its effective implementation. The WCS QA Director has responsibility for facilitating the development of procedures and verifying the implementation of the WCS QA Program requirements. The QA organization is responsible for the following activities.

- Oversight of the quality of design, construction, testing and operations.
- Oversight of supplier QA programs, including development and approval of approved supplier's lists, conducting audits and surveillances of supplier QA programs, and the review, approval, and control of supplier and procurement QA records.
- Development, maintenance, approval, and issuance of the WCS QA procedures.
- Review and approve procedures for quality affecting work activities
- Management of the Audit and Surveillance Program.
- Specifying QA requirements for quality affecting procurements.
- Administering the non-conformance and corrective action processes including tracking and trending.
- Inspections as specified for quality affecting work activities.

9.1.3 QA/QC Authority

Describe measures that ensure that entities performing QA/QC activities have authority and freedom to: 1) identify problems, 2) initiate, recommend or provide solutions, and 3) verify implementation of a chosen solution.

QA/QC personnel are organizationally separate and independent from the organizations assigned to perform engineering, construction operations, and procurement activities.

As described in WCS QA procedures, QA/QC employees are able to make quality assurance decisions and have sufficient authority to:

- Identify quality problems
- Initiate and recommend solutions to quality problems through designated channels
- Verify implementation of solutions and ensure that further processing, delivery, installation, or use is controlled until proper disposition of nonconformances, deficiencies or unsatisfactory conditions has occurred

QA/QC personnel have the authority and responsibility to stop work in accordance with procedures when the continuance of the work could produce results adverse to quality.

9.1.4 QA/QC Access to Management

Describe how entities with primary responsibility for ensuring implementation of the QA/QC program have access to management, as necessary.

As described in the WCS QA policy statement and in QA procedures, QA/QC employees have direct access to the WCS GM and the President on matters pertaining to the quality of the work. The WCS QA Director reports to WCS President. The WCS QA Director provides QA Program periodic status of quality issues to the WCS management team.

During design, construction and operation, QA is considered part of the team and as such is included in day-to-day facility meetings and decisions with the facility management.

9.1.5 Stop-Work Authority

Identify positions that have written delegated responsibility and authority to stop work or control further processing, delivery, installation or use of non-conforming items.

Stop-work authority at WCS is vested in each WCS employee whenever the health and safety of workers or the public, or the protection of the environment is involved. Employees also have stop-work authority when continued work in their areas of responsibility will produce results adverse to quality. A WCS procedure addressing 'Stop-Work' defines the criteria, authorities and responsibilities for stopping work and the documentation and corrective actions required before resuming work. This process ensures that quality affecting work activities are controlled until the identified condition has been resolved.

9.1.6 QA/QC Program Delegation

Describe the extent to which the applicant will delegate to contractors or subcontractors the work of establishing and executing the QA/QC program including:

- (1) How requirements will be imposed on contractors and subcontractors to ensure that entities within their organization performing QA/QC functions have sufficient authority to implement the program; and**
- (2) How the applicant will maintain control over delegated portions of the QA/QC program.**

WCS contractors providing quality-affecting services will perform work either under the WCS Quality Assurance Program or under their own QA Program that has been qualified by WCS QA. Qualification of contractor QA programs and procedures reviews for adequacy followed by audits to verify implementation effectiveness.

Technical and quality requirements for quality affecting items and work activities shall be imposed on contractors using procurement documents.

WCS shall provide oversight of the contracted work using QA audit of surveillance to verify compliance with the contracted requirements.

9.2 QA/QC Implementation and Monitoring

Describe measures to implement and monitor the QA/QC program.

9.2.1 QA/QC Program Personnel Qualification

Describe qualification requirements for persons responsible for ensuring effective implementation of the QA/QC program.

The WCS QA Director reports to the President. This QA Director is responsible for managing the WCS QA Program. The QA Director shall be knowledgeable of regulatory requirements and experienced at managing QA activities such as audits and QA technical support.

The QA Director shall have, as a minimum, a bachelor's degree (or equivalent) and ten years of related experience.

For more information regarding the technical qualifications of key personnel see Section 10.2, "Technical Qualifications of Applicant and Staff," of this application.

WCS procedures require an annual assessment of the WCS QA Program. This assessment is conducted by an individual not assigned QA responsibility. The results are reported to the President for review and disposition.

9.2.2 QA/QC Program Efficiency

Describe indoctrination and training programs to ensure that suitable proficiency is achieved and maintained.

WCS employees who perform quality-affecting work activities will receive QA Indoctrination Training. This training includes general criteria, including introduction to applicable codes, standards, QA Procedures, QA Program elements, and job responsibilities and authorities. WCS personnel assigned to perform quality-affecting work activities are also required to complete training in the specific procedures needed to perform their job roles and responsibilities as assigned by their supervisor. Detailed QA training is provided on the QA Program and job-specific procedures prior to an employee beginning work. Supervision is responsible for assuring that personnel performing work under their supervision are appropriately trained.

For more information on WCS Training Plan, see Section 10.4 of this application.

9.2.3 QA/QC Management Review

Describe measures to ensure that there is regular management review within the QA/QC program to assess effectiveness of the program.

In accordance with the WCS QA procedures, the WCS QA Director regularly advises WCS management regarding the status of the QA program. The status normally includes: 1) results of reviews conducted on audit reports; 2) internal surveillance reports; 3) corrective action reports; and 4) management assessments, etc. Corrective action is initiated as necessary based on the review discussion.

9.2.4 QA/QC Outside Review

Describe provisions for review of the QA/QC program by personnel above or outside the QA/QC organization.

WCS conducts an annual management assessment to determine if the WCS QA Program is effectively implemented. Recommendations resulting from the assessment are provided to WCS management for action. The recommendations are managed and tracked until closure.

As part of the WCS verification process, line managers perform assessments of their respective work areas for the purpose of self-identification of conditions adverse to quality and performance improvement. The assessment results are reviewed by WCS management for the purpose of validating the adequacy of implementation of the QA Program and to direct any needed changes for program or process improvements.

9.3 Design Controls

This section addresses design related items including: specifications, plans, drawings, blueprints, theoretical analysis, exploration findings, experimentation results, the application of investigative findings and theories into practical applications, modeling, and testing results for devices, equipment, and materials

Measures are established in QA procedures to assure that applicable requirements are correctly translated into design documents. Design includes: 1) characterization of the geologic setting; 2) predicting the long-term stability of the site; 3) predicting environmental interactions between the site and its surroundings; 4) planning and specifying processes for handling waste; and 5) specifying requirements for site construction and handling waste. Controls are established for the selection and suitability of application of materials, parts, equipment, and processes essential to the functions of structures, systems, and components. Design interfaces to ensure completeness and efficiency of design are established. QA procedures detail the controls for design input, design process, design verification, design changes, and approval. The design process also includes use of computer codes used in modeling the characteristics of the geologic setting or in predicting environmental impacts. These procedures include appropriate quantitative and/or qualitative acceptance criteria for determining that activities have been satisfactorily accomplished. Design documents are prepared, reviewed, and approved by qualified individuals. Design is verified by utilizing design reviews. Design changes are governed by control measures commensurate with those applied to the original design.

Design work performed to support this application was prepared by a design contractor (URS Corporation) using the contractor's QA Program. WCS reviewed the URS QA Program and found it acceptable for preparing this license application.

9.3.1 QA/QC Pre-design Plan, Documentation, Implementation

Provide a description of how design control elements of the QA/QC plan are to be planned, documented, and implemented prior to the start of design work.

The design process is controlled as follows:

- Design work shall be prescribed and documented on a timely basis and a level of detail necessary to permit the design process to be carried out in a compliant and efficient manner.
- Design documents shall be adequate to support design, fabrication, construction, test, inspection, and operation.
- Appropriate standards shall be identified/documentated.
- Changes from specified standards shall be identified, approved, documented, and controlled.
- Procedural controls shall be established for selecting and reviewing design methods, materials, parts, equipment, and processes essential to the function of an item and suitability of application.
- Applicable information derived from experience reports, or other documentation, shall be made available as design input.
- Design documents shall be sufficiently detailed as to purpose, method, assumptions, design input, references, and units such that a person technically qualified in the subject discipline can understand the documents and verify their adequacy.
- Design drawings, specifications, or other design documents shall contain appropriate inspection, examination, and testing acceptance criteria.

9.3.2 *Design Suitability Measures*

Describe measures (including personnel and their responsibilities and procedures) to confirm that the design of the structures, systems, and components are suitable for the intended purpose (design verification) including:

- (1) Design review;**
- (2) Peer review; and**
- (3) Alternate calculation methods (if applicable)**

The following design control requirements are applied to verify the adequacy of design:

- Design verification is required for quality affecting designs and shall be performed using one or a combination of the design review, alternate calculations, and/or qualification testing methods.
- The particular design verification method used shall be documented.
- Results of design verification shall be documented.
- Competent individuals or groups, other than those who performed the original design (but may be from the same engineering organization), shall perform design verification. If necessary, this verification may be performed by the originator's supervisor provided that the engineering supervisor did not specify a singular design approach or rule out certain design considerations and did not establish the design

inputs used in the design; or the supervisor is the only individual in the engineering discipline competent to perform the verification.

Design verification shall be performed at appropriate times during the design process.

Verification shall be performed before release for procurement, manufacture, or construction, or release to another organization for use in other design work. Extent of design verification required shall be a function of the importance to safety, complexity of design, degree of standardization, state of the art, and similarity with previously proven designs.

Design reviews shall be controlled and performed to ensure:

- Design inputs were correctly selected and incorporated.
- Assumptions necessary to perform the design work were adequately described, reasonable and, where necessary, reverified.
- An appropriate design method was used.
- The design output is reasonable compared to the applicable design inputs.
- The necessary design input and verification requirements for interfacing organizations were specified in the design documents or in supporting implementing documents.

9.3.3 Data Handling Measures

Describe measures (including personnel and their responsibilities and procedures) to ensure that all data have been handled as intended (design checking) including:

- (1) Confirmation of computations; and**
- (2) Accuracy of data input into computer codes**

The appropriateness of assumptions, input data, and the computer program or other calculation methods used shall be evaluated and the results shall be checked through the use of alternate calculation methods to verify the correctness of the original calculations or analyses.

9.3.4 Design Interrelationship Measures

Describe measures for identifying and controlling design interrelationships and for providing coordination between participating design organizations.

Design interfaces shall be identified and controlled. Design efforts shall be coordinated among interfacing organizations. Interface controls include the assignment of responsibility among interfacing design organizations for the review, approval, release, distribution, and revision of documents involving design interfaces. Project design information transmitted across interfaces shall be documented and controlled. Transmittals of design information and/or documents shall reflect the status of the transmitted information and documents. Where necessary, incomplete designs that require further evaluation, review, or approval shall be identified as incomplete. When it is necessary to initially transmit the design information orally or by other informal means, design information shall be promptly confirmed by documenting the communication.

9.3.5 *Design Change Measures*

Describe how design changes will be subject to design control measures commensurate with those applied to the original design.

Design changes are controlled according to the following requirements:

- Changes to final designs and nonconforming items dispositioned as "use-as-is" or "repair," shall have documented justification for use and are subject to the same design control measures and reviews as those applied to the original design.
- Design control measures for changes shall include provisions to ensure that the design analyses for the item are still valid.
- Changes shall be approved by the same engineering disciplines/groups that reviewed and approved the original design documents, with the following clarifications:
 - If the engineering discipline/group that originally was responsible for approving a particular design document is no longer responsible, then a new organization shall be designated.
 - The designated engineering disciplines/groups 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 field change is approved other than revision to the affected design documents, field changes shall be incorporated into affected design documents when such incorporation is appropriate.

9.3.6 *Error Documentation and Prevention*

Describe how errors are documented, and how corrective action is to be taken to prevent recurrence of errors.

The design process and design verification methods and drawings, specifications, etc. shall be reviewed and modified, as necessary, when a significant design change is required because of an incorrect design. These design deficiencies shall be documented in accordance with the nonconformance and corrective action procedures.

9.3.7 *Effective Selection of Materials, Parts, and Equipment*

Describe measures for ensuring that the process of selecting materials, parts, and equipment is effective.

If design adequacy is to be verified by qualification testing, the tests shall be identified, controlled, and documented according to the following:

- The test configuration shall be defined and documented.
- Testing shall demonstrate the 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 design conditions.

- If the tests verify only specific design features, then the other features of the design shall be verified by other means.
- Test results shall be documented and evaluated to ensure that test requirements have been met.

If qualification testing indicates that a modification to an item is necessary to obtain acceptable performance, then the modification shall be documented and the item modified and re-tested or otherwise verified to ensure satisfactory performance.

9.4 Procurement of Materials, Equipment, and Services

9.4.1 *Document Preparation, Review, and Approval Procedures*

Describe procedures that clearly delineate the sequence of actions to be performed in the preparation, review and approval of procurement documents including, but not limited to:

- (1) Ensure qualified personnel will review and concur on the adequacy of quality requirements stated in procurement documents;**
- (2) Ensure that quality requirements and acceptance/rejection criteria are clearly stated;**
- (3) Ensure that quality requirements and acceptance/rejection criteria are inspectable and controllable;**
- (4) Ensure that documentation requirements are clearly stated; and**
- (5) Ensure procuring agency's right of access to the supplier's facility and records for source inspection and audit.**

WCS is responsible for preparing procurement documents. WCS managers are responsible for ensuring that procurement documents are complete and in accordance with the QA procedures. The WCS managers are responsible for notifying WCS QA when a item or service affecting quality is being purchased to ensuring that procurement documents include appropriate QA requirements.

WCS procurements shall be issued to suppliers that have been evaluated and qualified as acceptable for the specified scope of work, equipment, and services to be provided. The material, equipment and/or services shall be procured from approved suppliers. As applicable, procurement documents require suppliers to have a quality assurance program consistent with the applicable WCS and regulatory requirements.

WCS procurement documents issued for quality affecting items or services shall include the following items, as applicable to the procured material, equipment, or service:

- Statement of the scope of work to be performed by the supplier.
- Technical requirements including:
 - Specific documents (i.e., drawings, codes, standards, regulations, procedures or specification) describing the technical requirements of the material, equipment or services to be furnished shall be specified.

- Tests, inspections or acceptance criteria that WCS will use to monitor and evaluate the performance of the supplier shall be specified.
- Quality Assurance requirements including:
 - A requirement for the supplier to have a documented quality assurance program that implements applicable WCS quality requirements. The extent of the quality assurance program shall depend on the scope, nature or complexity of the material, equipment, or service to be procured. The supplier shall also incorporate the appropriate requirements into any sub-tier supplier issued procurement documents.
- Right of access to supplier, including sub-tier, facilities, and records for inspection or audit by WCS, or other designee authorized by WCS.
- Provisions for establishing witness/inspection hold points beyond which work cannot proceed by the supplier without WCS authorization.
- Documentation required to be submitted to WCS for information, review, or acceptance shall be identified.
- Requirements for the supplier to report to WCS in writing adverse quality conditions resulting in work stoppages and nonconformances. WCS approval of partial and full work releases and disposition of nonconformances is required.

Procurement document reviews shall be performed and documented before issuing the procurement documents to the supplier. A review of the procurement documents and any changes thereto shall be made to verify that documents include all applicable technical and quality assurance requirements and contain appropriate provisions to ensure that material, equipment or services will meet the governing requirements.

Personnel who have access to pertinent information and have an adequate understanding of the requirements and scope of the procurement shall perform reviews of the procurement documents. Reviewers shall include representatives from the technical and QA organizations. Review by the QA organization shall assure compliance to quality assurance requirements.

9.4.2 *Conforming Materials, Equipment, and Services to Procurement Specifications*

Describe measures to ensure that material, equipment, and services will conform to procurement document specifications including:

- (1) Evaluation and selection of sources of supply before contract is awarded;**
- (2) Surveillance at supplier's facility during design, manufacture, inspection and testing to verify compliance with quality requirements;**
- (3) Source and/or receipt inspection of procured items;**
- (4) Documentation from the supplier that procured items meet codes, standards, or specifications, or other quality requirements; and**
- (5) Periodic verification of the supplier's certificates of conformance.**

WCS QA is responsible for ensuring and documenting that quality-affecting purchased items conform to procurement document QA requirements. WCS inspectors are responsible for inspecting quality-affecting items when these items are received on site.

Procurement of quality-affecting items and services is controlled to assure conformance with specified technical and QA requirements. These controls include requirements for pre-award evaluations of suppliers' QA programs, annual evaluations, periodic audits/source inspections and surveillance. Suppliers with an approved QA program are placed on the Approved Suppliers List (ASL). Source inspections and surveillances, as well as evaluations of received items and services, are performed, as necessary, upon delivery or completion to ensure requirements specified in procurement documents are met. Supplier evaluations, annual evaluations, audits, surveillances, source inspections, and receipt inspections shall be documented.

Supplier selection shall be based on an evaluation, performed before the contract and/or purchase order is awarded, of the supplier's capability to provide items or services in accordance with procurement document (technical and quality) requirements. The WCS functional area needing the procurement shall request that WCS QA evaluate the potential supplier for placement on the WCS ASL. Measures for evaluating and selecting procurement sources are detailed in the applicable QA procedure and include one or more of the following methods for evaluating potential suppliers:

- Evaluation of the supplier's history for providing an identical or similar product that performs satisfactorily in actual use
- Evaluation of supplier's current quality assurance records supported by any documented qualitative and quantitative information
- Evaluation of the supplier's technical and quality capability based on an evaluation of supplier facilities, personnel, and quality assurance program implementation

The results of procurement source evaluation and selection shall be documented in accordance with the applicable QA procedure.

The responsible WCS manager shall establish measures to routinely interface with the supplier and to verify supplier performance. The measures shall include:

- Establishing an understanding between WCS and the supplier of the requirements and specifications identified in procurement documents
- Requiring the supplier to identify planning techniques and processes to be used in fulfilling procurement document requirements
- Reviewing supplier documents that are prepared or processed during work performed to fulfill procurement requirements
- Identifying and processing necessary change information
- Establishing the method to be used to document information exchanges between purchaser and supplier
- Establishing the extent of source surveillance and inspection

The extent of purchaser verifications shall be a function of the relative importance, complexity/quantity of items or services being procured, and the supplier's quality performance. WCS verifications shall be conducted as early as practical and shall not relieve the supplier of the responsibility for the verification of quality achievement. Verifications shall include supplier audits, surveillances or source inspections (or combinations) used as a method of evaluating the supplier's performance, and evaluation of purchaser's documentation to aid in the determination of the effectiveness of the supplier's quality assurance program.

WCS may accept items or services by monitoring, witnessing, or observing activities performed by the supplier. This method of acceptance is called source verification. Source verification shall be implemented consistent with the supplier's planned inspections, examinations, or tests at predetermined points and performed at intervals consistent with the importance and complexity of the item. Documented evidence of acceptance of source-verified items or services shall be furnished to the receiving destination of the item, to WCS, and to the supplier. Personnel qualified in accordance with the applicable requirements for the items or service being procured shall perform source verification.

When receiving inspection is used to accept an item:

- The inspection shall consider any source verifications/audits and the demonstrated quality performance of the supplier.
- The inspection shall be performed in accordance with inspection procedures.
- The inspection shall verify, as applicable, proper configuration; identification; dimensional, physical and other characteristics; freedom from shipping damage; and cleanliness.
- The inspection shall be planned and documented.
- Receiving inspection shall be coordinated with a review for adequacy and completeness of any required supplier documentation.

Supplier-generated documents shall be controlled, processed, and accepted by WCS in accordance with WCS requirements. Measures shall be implemented to ensure that the submittal of supplier-generated documents is accomplished in accordance with the procurement document

requirements. These measures shall also provide for the acquisition, processing, and recorded evaluation of technical, inspection, and test data compared against the acceptance criteria.

As applicable, WCS QA will verify the validity of supplier certificates and the effectiveness of the certification process (such as by audit of the supplier or by an independent inspection or test of the item). Verifications shall be conducted by WCS at intervals commensurate with the past quality performance of the supplier

9.4.3 *Material Damage, Loss, and Deterioration Prevention*

Describe procedures for cleaning, handling, packaging, preservation, storage, and shipping of materials, material samples, components and assemblies to prevent damage, loss, or deterioration by environmental conditions.

Handling, storage, cleaning, packaging, shipping, and preservation of items are controlled to prevent damage or loss and to minimize deterioration.

WCS is responsible for developing and implementing handling, storage, and shipping control procedures. WCS contractors are responsible for ensuring that handling, storage, and shipping activities are adequate and conform to WCS requirements.

Handling, storage, cleaning, packaging, shipping, and preservation of items are conducted in accordance with procedures, shipping instructions, or other specified documents. For critical, sensitive, and perishable items, specific instructions for handling, storage, cleaning, packaging, shipping, and preservation shall be prepared and used.

If special equipment and environments are used, provisions shall be made for their verification. Special handling tools and equipment shall be used and controlled as necessary to ensure safe and adequate handling. Special handling tools and equipment shall be inspected and tested at specified time intervals and in accordance with procedures to verify that the tools and equipment are adequately maintained. Operators of special handling and lifting equipment shall be experienced or trained in the use the equipment.

Measures shall be established for marking and labeling for the packaging, shipping, handling, and storage of items as necessary to adequately identify, maintain, and preserve the item. Markings and labels shall indicate the presence of special environments or the need for special controls if necessary.

9.4.4 *Accurate Identification of Materials, Parts, and Components*

Describe measures to ensure that materials, parts, and components can be identified accurately once obtained and located on site.

WCS managers are responsible for ensuring that applicable material, parts, and components that are identified as quality affecting are properly identified.

Contractors are responsible for establishing procedures to identify and control material, parts, and components which are used for quality-affecting work or activities. These material, parts, and components include such things as geologic cores, and field and laboratory samples.

The controls necessary to ensure that only correct and accepted items are used or installed will be required by the appropriate QA procedure. Identification requirements for materials, parts, and components are stated in design specifications, drawings, and procurement documents.

Identification on the items shall be established and maintained. Items shall be identified from the time of initial fabrication, or receipt, up to and including installation or end use. The identification shall relate the item to the pertinent specifying document.

Quality-affecting geologic and environmental data collected shall include the time and the location of origin. As applicable, identification shall be maintained from collection through shipment and subsequent analysis.

Item identification methods shall include use of physical markings. If physical markings are either impractical or insufficient, other appropriate means shall be employed (i.e., physical separation, labels or tags attached to canisters or procedural control).

Physical markings, when used, shall:

- Be applied using materials and methods that provide a clear and legible identification
- Not detrimentally affect the function or service life of the item
- Be transferred to each part of an identified item when the item is subdivided

Item identification methods shall ensure that traceability is established and maintained in a manner that allows an item to be traced to applicable design or other specifying documents. Item traceability documentation shall ensure that the item can be traced at all times from its source through installation or end use.

Item identification methods shall ensure that traceability is established and maintained in a manner that allows an item to be traced to applicable design or other specifying documents. Item traceability documentation shall ensure that the item can be traced at all times from its source through installation or end use.

9.4.5 *Design Specification Compliance of Materials, Parts, and Components*

Describe measures to ensure that materials, parts and components remain in compliance with design specifications in storage at the site.

Sections 9.4.3 and 9.4.4 provide the response to this section. In addition the QA audits and surveillances will monitor compliance with applicable storage requirements.

9.4.6 *Controlling Non-Conforming Materials, Parts, and Components*

Describe measures to control materials, parts, or components that do not conform to requirements in order to avoid their inadvertent use. Include measures for identification, segregation, disposition, repair or rework procedures, and documentation.

Items that do not conform to specified requirements shall be controlled to prevent inadvertent installation or use. Controls shall be provided for the identification, documentation, evaluation, segregation when practical, and disposition of nonconforming items.

WCS employees and contractors are responsible for identifying and reporting nonconforming items. WCS QA is responsible for managing the nonconformance process and concurring with the resolution provided by the WCS managers.

Nonconforming items shall be identified by marking, tagging, or other methods that do not adversely affect their end use. The identification shall be legible and easily recognizable. If the identification of a nonconforming item is not practical, the canister, 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 properly dispositioned. If segregation is impractical or impossible due to physical conditions, then other precautions shall be employed to preclude inadvertent use.

The disposition, such as “use-as-is”, “reject”, “repair”, or “rework” of nonconforming items shall be identified and documented. The technical justification for the acceptability of a nonconforming item that has been dispositioned “repair” or “use-as-is” shall be documented. Items that do not meet original design requirements that are dispositioned “use-as-is” or “repair” shall be subject to design control measures commensurate with those applied to the original design. If changes to the specifying document are required to reflect the as-built condition, the disposition shall require action to change the specifying document to reflect the accepted nonconformance. Any document or record change required by the disposition of the nonconformance shall be identified in the nonconformance documentation. When each document or record is changed, the justification for the change shall identify the nonconformance documentation. The disposition of an item to be reworked or repaired shall contain a requirement to reexamine (inspect, test, or nondestructive examination) the item to verify acceptability. Repaired or reworked items shall be reexamined in accordance with applicable procedures using the original process and acceptance criteria unless the nonconforming item disposition has established alternate acceptance criteria.

9.5 Processes, Procedures, and Instructions

9.5.1 Prescribing and Performing Activities that Affect Quality

Describe measures to be taken to ensure that activities affecting quality are prescribed and performed in accordance with documented instructions or procedures. Delineate the sequence of actions to be performed in the preparation, review, approval, and control of instructions and procedures.

Quality-affecting work activities will be conducted in accordance with approved procedures, instructions, and/or drawings as appropriate to the activity being performed.

Procedures, instructions, and drawings shall include appropriate quantitative and qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished.

WCS employees and contractors performing quality-affecting work shall comply with procedures, instructions, and drawings; however, when work cannot be accomplished as described in the procedure, instruction, drawing, or accomplishment of such work would result in an undesirable situation, a condition adverse to quality, or an unacceptable safety risk, the work shall be suspended until a solution can be provided.

The type of document to be used to perform work shall be appropriate to the nature and circumstances of the work being performed. Documents include procedures, instructions, drawings, and specifications. Work controlling procedures may also utilize approved checklists, travelers, or other means to assure process requirements are met including prerequisite requirements prior to starting work. Procedures provide a consistent method for process performance and documentation of completion as well as ensure specified safety and environmental conditions are maintained.

The procedure development process ensures that the responsibility for preparing, reviewing, approving, and issuing documents shall be assigned to the appropriate WCS manager. Procedures specifying quality requirements or prescribing quality-affecting activities shall be reviewed by impacted WCS managers for adequacy, correctness, and completeness and by the QA organization prior to approval and issuance.

9.5.2 Procedures Detailing Processes and Controls

Describe measures to ensure that processes and their controls are detailed in approved procedures. Measures to ensure training and qualification of personnel, formal instructions, drawings, checklists, and equipment specifications should be described.

WCS procedures include or reference the following information as appropriate to the work to be performed:

- Responsibilities of the organizations impacted
- Quality, technical, and regulatory requirements
- A sequential description of the work to be performed
- Quantitative or qualitative acceptance criteria
- Prerequisites, limits, precautions, process parameters, and environmental conditions
- Quality hold points
- Methods for demonstrating that the work was performed as required
- Identification of QA records

Scientific investigations will be performed using WCS procedures and/or nationally recognized standards. Standards used without modification require documentation by reference only. If a deviation from the standard or establishment of specifically prepared procedures is deemed appropriate, the modifications or new methods should be documented in sufficient detail to be repeatable and should be evaluated, justified, and approved.

9.6 Document Control

9.6.1 Document Review, Approval, Issuance, and Control

Describe measures to ensure the review, approval, and issuance, and control of documents related to design, construction, and operations, including:

- (1) Identification of entities responsible for reviewing, approving and issuing documents and revisions;**
- (2) Procedures to ensure that changes to documents are subject to the same level of review as initial version documents;**
- (3) Inclusion of approved changes in documents before change is implemented;**
- (4) Control of obsolete documents to eliminate inadvertent use; and**
- (5) Master list to establish the current revision number;**

WCS employees and contractors are responsible for developing, maintaining, and using controlled documents and ensuring that changes made to controlled documents are approved prior to use. WCS Document Control is responsible for distributing controlled documents as well as other technical documents as appropriate, and ensuring that these documents are available for use.

Procedures, instructions, drawings, and other documents specifying quality requirements or prescribing quality-affecting activities shall be controlled. WCS documents controlled under the WCS QA Program include procedures, design requirements documents, design basis documents, engineering specifications, instructions, drawings, calculations, procurement documents, computer codes, technical reports, and documents that need to be controlled due to being input to other WCS design documents or used for construction and operations affecting quality.

The document control system shall ensure that the identification of documents to be controlled and their specified distribution are controlled. The system shall further ensure that the responsibility for preparing, reviewing, approving, and issuing documents shall be assigned by procedure to the appropriate WCS manager. Documents specifying quality requirements or prescribing quality-affecting activities shall be reviewed in accordance with applicable procedures for adequacy, correctness, and completeness and by the QA organization as specified by procedure, prior to approval and issuance.

Documents needing to be placed under document control are transmitted to WCS Document Control with the distribution list for document holders. Document Control shall enter the document into the Document Control master list of controlled documents, assign document control numbers, complete transmittal forms, and distribute the documents and transmittal form to the document holders. Document holders shall acknowledge receipt on the transmittal and send the acknowledgement to Document Control. The up-to-date master listing of controlled documents will be made continuously available to document holders to verify that they have the current revisions. Controlled documents can also be made available on-line to WCS employees provided appropriate controls are implemented to control the documents.

The distribution and use of documents, including changes and editorial corrections to documents, shall be controlled as described below:

- Documents used to perform work shall be distributed to and used at the work location.
- Effective dates shall be established for approved documents. If an effective date is not documented on the coversheet then the document is assumed to be effective on the date approved.
- The disposition of obsolete or superseded documents shall be controlled. Controlling instructions are contained in the applicable procedures for document control and records management.
- The WCS document control master list shall be used to identify the current status of each document that is required to be controlled.

Changes to documents other than minor changes shall be reviewed for adequacy, correctness, and completeness prior to approval and issuance. Major changes shall be reviewed and approved by the same organization that performed the original review and approval unless other organizations are specifically designated.

9.6.2 *Maintenance of Records*

Describe measures that ensure that sufficient records are maintained to furnish evidence or activities affecting quality including, but not limited to:

- (1) Type of operation, inspector, equipment, data recorder;**
- (2) Test logs, operating logs, results of reviews, drawings, inspections, tests, audits, monitoring of work performance, materials analysis, personnel records, training records, equipment and procedure manuals; and**
- (3) Notation of any deficiencies and corrective action taken.**

Records that provide documentary evidence of quality shall be specified, prepared, and maintained. Applicable WCS design specifications, procurement documents, test procedures, operations procedures, and inspection procedures shall specify the records to be generated, supplied, or maintained.

Documents designated to become records shall be legible, accurate, and completed appropriate to the work accomplished. Records will be classified for retention purposes as lifetime or nonpermanent.

Records shall be identifiable and retrievable. Records shall be protected against damage, deterioration, or loss. Requirements and responsibilities for record transmittal, distribution, retention, maintenance, and disposition shall be established and documented.

Documentation of deficiencies and corrective actions taken to correct deficiencies are documented in the corrective action process. When appropriate, references are provided on the impacted records.

WCS staff and contractors are responsible for preparing, safeguarding, and submitting records to the WCS Records Center. WCS managers are responsible for ensuring that records are complete and submitted to the WCS Records Center. The WCS Records Center is responsible for receiving, designating, validating, and filing quality assurance records.

9.7 Inspection and Testing

9.7.1 *Verifying Conformance to Instructions, Procedures, and Drawings*

Describe measures that ensure that a program for inspection is established and implemented to verify conformance with the documented instructions, procedures, or drawings including:

- (1) Inspections to verify procedures, or to accept or reject completed work;
- (2) Inspection procedures and instructions with necessary drawings and specifications are available for use before the inspections are performed;
- (3) Replaced, reworked, modified, or repaired items are inspected in accordance with original inspection requirements;
- (4) Inspectors are appropriately qualified and independent of the group performing the activity being inspected;
- (5) Indirect control by monitoring is used if direct inspection is impossible or disadvantageous; and
- (6) Procedures to identify inspection status by use of markings.

WCS QA is responsible for coordinating development of inspection procedures. Quality Control is responsible for performing inspections of quality-affecting work activities as prescribed in procedures. When Quality Control activities are procured, the WCS QA organizations will provide oversight of the inspection work using QA audit or surveillance.

Inspections required to verify conformance of an item or activity to specified requirements are planned and executed. Characteristics to be inspected and inspection methods to be used are specified in procedures. Inspection results are documented. Persons other than those who performed or directly supervised the work being inspected shall perform inspection for acceptance.

Inspection planning shall be performed, documented, and include:

- Identification of work operation where inspection is necessary to ensure quality and implementing documents that shall be used to perform the inspections
- Identification of the characteristics to be inspected and the identification of when, during the work process, inspections are to be performed
- Identification of inspection or process monitoring methods to be employed
- The final inspection shall be planned to arrive at a conclusion regarding conformance of the item to specified requirements
- Identification of the qualification level of personnel performing inspections
- Identification of acceptance criteria
- Methods to record objective evidence of inspection results

9.7.2 Testing Program Requirements

Describe measures that establish a testing program that identifies all testing required to demonstrate:

- (1) The site's geologic, hydrologic, and geochemical characteristics are capable of providing long-term isolation; and**
- (2) Structures, systems, and components will perform satisfactorily in service.**

Managers and appropriate technical staff are responsible for coordinating the development of test procedures, as required and where appropriate. The WCS Managers are responsible for ensuring that contractors implement appropriate test procedures.

Quality Assurance is responsible for verifying the implementation and effectiveness of test procedures implemented by both the technical programs staff and contractors.

Tests required to verify conformance of an item or computer program to specified requirements and to demonstrate satisfactory performance for service are planned and executed.

Characteristics to be tested and test methods to be employed are specified. Test results are documented and their conformance with acceptance criteria is evaluated. Tests required to collect data, such as for site characterization or design input, or verification for long-term isolation shall be planned, executed, documented, and evaluated.

9.7.3 Conduct for Testing Procedures

Describe testing procedures to ensure that testing is conducted:

- (1) By trained and appropriately qualified personnel;**
- (2) According to written test procedures that incorporate requirements and acceptance limits;**
- (3) Using adequate test instrumentation and equipment;**
- (4) Under suitable environmental conditions; and**
- (5) Using adequate documentation to ensure that test requirements are satisfied.**

Managers and appropriate technical staff are responsible for coordinating the development of test procedures, as required and where appropriate. The WCS Managers are responsible for ensuring that contractors implement appropriate test procedures.

The testing procedures include the following controls:

- Test Objectives
- Test Requirements
- Qualifications of Test Personnel
- Selection and Identification of the Measuring and Test equipment
- Acceptance Criteria
- Test Documentation

9.7.4 Sample Preservation

Describe procedures to ensure that samples are preserved appropriately for future retrieval, and that documentation is provided to identify and control stored samples. These procedures shall include, but are not limited to:

- (1) Drill core samples**
- (2) Laboratory test samples**
- (3) Waste samples used for classification and material properties**

Samples shall be controlled and identified in a manner consistent with their intended use.

Procedures shall identify responsibilities including the interfaces between the organizations for documenting and tracking the sample possession from sample collection and identification through handling, preservation, shipment, transfer, analysis, storage, and final disposition.

Chain of custody shall be documented to provide a documentation trail including custodian and dates of sample receipt and transfer.

Each sample shall be uniquely identified from its initial collection through the final disposition. Sample identification shall be documented before each transfer or release for testing, analysis, or disposition.

Identification shall be maintained by placing the identification directly on the samples wherever possible or in a manner that ensures identification is maintained. If direct physical markings are either impractical or insufficient, other appropriate means shall be employed (e.g., physical separation, labels or tags attached to canisters, or procedural control). When used, physical markings shall:

- Be applied using materials and methods that provide clear and legible identification
- Not effect the sample content or form
- Be transferable to each identified sample part when the sample is subdivided
- Not be obliterated or hidden by surface treatments or sample preparation unless other means of identification are substituted

Handling, storing, packaging, shipping, and preserving samples shall be conducted in accordance with procedures. Controls shall provide for the maintenance of sample characteristics, sample integrity, and sample identification during storage. The controls shall be consistent with planned duration and storage conditions and shall describe actions to be taken where maximum sample life expectancy limits are identified.

9.7.5 *Measuring and Testing Device Maintenance and Control*

Describe measures taken to ensure that tools, gauges, instruments, and other measuring and testing devices are identified, controlled, adjusted, and calibrated at specified periods to maintain accuracy including:

(1) Adjustment and calibration is done using certified equipment or reference standards having known valid relationships to nationally recognized standards;

(2) If no national standard exists, the basis for calibration is documented;

(3) If equipment is found out of calibration, methods for evaluating previous test results and repeating testing if necessary; and

(4) Maintenance of documentation indicating calibration status of testing equipment.

WCS uses procedures to ensure adequate control of measuring and test equipment that relate to site characterization and the quality of design, construction, or operation. Measuring and test equipment (M&TE) is controlled and, at specified periods, calibrated and adjusted to maintain accuracy within necessary limits.

Measuring and test equipment (M&TE) shall be calibrated, adjusted, and maintained at prescribed intervals or, prior to use, against reference calibration standards having traceability to nationally recognized standards. If no nationally recognized standards or physical constants exist, the basis for calibration shall be documented. The basis for the calibration acceptance shall be documented. The method and interval of calibration for each device shall be defined, based on the type of equipment, stability characteristics, required accuracy, intended use, and other conditions affecting measurement control. Calibrated M&TE shall be labeled, tagged, or otherwise suitably marked or documented to indicate due date or interval of the next calibration and uniquely identified to provide traceability to its calibration data.

M&TE shall be considered to be out of calibration and not be used until calibrated if any of the following conditions exist:

- The calibration due date or interval has passed without recalibration.
- The device produces results known or suspected to be in error.

Out-of-Calibration M&TE shall be controlled. Out-of-calibration M&TE shall be tagged or segregated and not used until recalibration.

When M&TE is found out of calibration, the validity of results obtained using that equipment since its last valid calibration shall be evaluated to verify the acceptability of previously collected data, processes monitored, or items previously inspected or tested. This evaluation shall be documented. If any M&TE is consistently found out of calibration during the recalibration process, it shall be repaired or replaced.

M&TE calibration documentation shall include the following information:

- Identification of the measuring or test equipment calibrated
- Traceability to the calibration standard used for calibration

- Calibration data
- Identification of the individual or supplier performing the calibration
- Date of calibration and the recalibration due date
- Results of the calibration and statement of acceptability
- Reference to any actions taken in connection with out of calibration

9.8 Corrective Actions to Adverse Conditions

Describe measures to ensure that conditions adverse to quality such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformance items are identified and corrected. Describe how corrective action will be taken and documented to preclude repetition.

Conditions adverse to quality shall be identified promptly and corrected in a timely manner. Such conditions shall be tracked and evaluated so that adverse trends can be identified and appropriate corrective action can be taken.

WCS QA procedures provide requirements and processes for the following activities:

- Prompt identification, correction, and trending of all conditions adverse to quality
- Evaluating significant adverse conditions and stopping work, if applicable
- Determining root cause and preventive actions for significant conditions adverse to quality
- Verifying implementation of corrective actions

Items that do not conform to specified requirements shall be controlled to prevent inadvertent installation or use. Controls shall be provided for the identification, documentation, evaluation, segregation when practical, and disposition of nonconforming items.

WCS employees and contractors are responsible for identifying and reporting conditions adverse to quality. WCS QA is responsible for managing the corrective action process and concurring with the corrective action plans provided by the WCS managers.

9.9 Audits, Surveillance and Managerial Control

9.9.1 QA/QC Program Audits

Describe the program and that of the principal contractors for conducting comprehensive planned and periodic audits to verify compliance with all aspects of the QA/QC program to determine the effectiveness of the program including:

- (1) External audits to be performed on the respective suppliers;
- (2) Internal audits to be performed within the organization
- (3) Planning and scheduling of audits;
- (4) Conduct of audits in accordance with written procedures by appropriately trained personnel not having direct responsibility in the area being audited; and
- (5) Documentation of audit results with review by management personnel and (if needed) follow-up action, including re-audit.

WCS shall use QA audit, QA surveillance, and assessment to verify compliance with all aspects of the QA Program. QA audits represent the formal documented process of verification as described in this section. QA surveillance is less formal and does not require a schedule, plan, or checklist and can be conducted by a qualified QA employee. Surveillance results are documented. Additionally, quality and performance issues are identified during the performance of self-assessments by the line organizations. The assessment process includes an annual management review of the QA Program effectiveness. The results of the assessments are documented and conditions adverse to quality are documented in accordance with the corrective action procedure.

WCS procurement of quality-affecting items and services is controlled to assure conformance with specified technical and QA requirements. As appropriate to procurement scope of work and importance to safety, these controls include requirements for pre-award evaluations of suppliers' QA programs, annual evaluations, periodic audits/source inspections, and surveillance. Suppliers with an approved QA program are placed on the WCS Approved Suppliers List (ASL). Source inspections and surveillances, as well as evaluations of received items and services, are performed, as necessary, upon delivery or completion to ensure requirements specified are met. Supplier evaluations, annual evaluations, audits, surveillances, source inspections, and receipt inspections shall be documented.

WCS QA is responsible for establishing and implementing the audit and surveillance program. WCS QA is also responsible for planning and scheduling the audits. Lead auditors, auditors, and technical experts are responsible for conducting audits.

Audited organizations are responsible for reviewing audit and surveillance results and developing corrective actions as necessary. WCS QA shall verify compliance with elements of the WCS QA Program and determine QA Program effectiveness by ensuring that planned and scheduled audits are conducted. Elements selected for audit shall be evaluated against specified requirements. Objective evidence shall be examined to the depth necessary to determine if these elements are being implemented effectively. Qualified personnel that do not have responsibility for the activity being audited are responsible for conducting audits. Audit results are documented

and provided to the appropriate management for review and corrective action as applicable. Follow-up actions are taken where indicated.

REFERENCES

- American Society of Mechanical Engineers. *2001 Quality Assurance Requirements for Nuclear Facility Applications*. New York, NY, 2001.
- U.S. Nuclear Regulatory Commission. *Qualification of Existing Data for a High-Level Nuclear Waste Repositories*. NUREG-1298, February 1988.
- U.S. Nuclear Regulatory Commission. *Quality Assurance Guidance for Low-Level Radioactive Disposal Facility*. NUREG-1293, Revision 1, April 1991.