PLAN APPROVALS:		
Jeff Shouse	Signature on File	
DIRECTOR OF QUALITY ASSURANCE	DIRECTOR OF QUALITY ASSURANCE (signature)	DATE
Rodney Baltzer	Signature on File	
PRESIDENT	PRESIDENT (signature)	DATE

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QUALITY ASSURANCE PROGRAM
POLICY STATEMENT

Waste Control Specialists LLC (WCS) has developed a comprehensive quality assurance program that establishes the quality assurance requirements and applicable management controls to control quality-affecting items and work activities for WCS waste facilities. The resulting WCS Quality Assurance (QA) Program applies as written to WCS quality affecting activities (i.e., deeds, actions, processes, tasks or work, which influence the achievement or verification of quality requirements and objectives for Quality Level 1 and 2 Structures, Systems, Components (SSC) and related work activities. This program consists of this policy statement, Quality Assurance Plan (QAP) and the WCS implementing procedures.

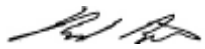
The WCS QA Plan and its implementing procedures defines the actions to be taken by WCS management and employees during the performance of quality affecting activities to ensure QA requirements are consistently met. This QA program is based on line and staff organizations being responsible and held accountable for the quality of their assigned work. The QA organization is charged with verifying the achievement of quality through audits, surveillances, assessments and reviews.

This program has my complete support and is to be followed at all times. Compliance with the requirements of the WCS QA program is mandatory.

The authority to administer the WCS QA Program described in the WCS QA Plan and implementing procedures is assigned to the WCS Quality Assurance Director.

All WCS Managers and employees are responsible for implementing the procedures required by this program. WCS personnel are given authority commensurate with their responsibility, including the authority to stop work that does not conform to established requirements. Stop-work authority, including investigation, resolution, completion of corrective actions and authorization for restarting work, is to be exercised in accordance with procedures.

All matters concerning quality that cannot be resolved at the normal organizational interfaces shall be referred to me for final resolution.



Rodney A. Baltzer
WCS President

INTRODUCTION

Waste Control Specialists LLC (WCS) maintains full responsibility for ensuring that WCS Waste Disposal Facilities are designed, constructed, operated (including the packaging and transportation of radioactive materials, 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.

The WCS QA Program described in this plan covers design, construction, and operations, of the WCS facilities. The design of the facility includes (1) characterization of the geologic setting, (2) predicting the long-term stability of the site, (3) predicting the environmental interactions, (4) planning and specifying processes for handling waste, (5) specifying the requirements for constructing and handling waste.

The WCS QA Plan is written to establish the quality assurance requirements and management controls applicable to quality affecting activities performed by WCS and WCS contractors. Selective application of these controls is managed utilizing a classification and grading process for each WCS business unit.

The following subsections provide the description of the applicable QA requirements and management controls for WCS quality affecting work activities.

SECTION 1
ORGANIZATION

WCS has full responsibility to ensure that the facility is designed, constructed, tested 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 continues 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 framework 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 individuals or organizations not directly responsible for performing the work.

The WCS Chief Executive Officer is the executive in charge of WCS. The Chief Executive Officer has assigned the WCS President as the executive in charge of managing all WCS functional areas. The WCS President establishes the basic policies of the WCS QA Program. The policies described in this QA Plan are transmitted to all levels of management and are implemented through approved procedures. The WCS QA organization has responsibility for development, management and verifying the proper implementation of the WCS QA Plan.

ORGANIZATIONAL RESPONSIBILITIES AND AUTHORITIES

The WCS President is the highest level of management responsible for WCS' QA policies, goals, and objectives. Reporting to the President are the; Executive Vice President, Licensing and Regulatory Affairs; Vice President, Operations; Vice President Community Relations, Director of Quality Assurance, Director of Information Technology; Senior Vice President/Chief Financial Officer/General Manager; and; Senior Vice President Planning and Business Development.. For the purposes of this document, only the positions that have QA responsibilities and authority will be described.

The WCS organization chart is included as Chart 1 and can be viewed at the end of this document.

EXECUTIVE VICE PRESIDENT, LICENSING AND REGULATORY AFFAIRS RESPONSIBILITIES AND AUTHORITIES

The Executive Vice President, Licensing and Regulatory Affairs is responsible for the development, submittal and compliance of the license application and permits.

SENIOR VICE PRESIDENT PLANNING AND BUSINESS DEVELOPMENT RESPONSIBILITIES AND AUTHORITIES

The Senior Vice President Planning and Business Development is responsible for the following function groups:

- Technical Services
- Intergration and Customer Services
- Business Development

SENIOR VICE PRESIDENT/CHIEF FINANCIAL OFFICER/GENERAL MANAGER AND AUTHORITIES

The Senior Vice President/Chief Financial Officer/General Manager directs the activities of the following facility functional groups:

- Environmental
- Health, Safety, Security and Training
- Radiation Safety Officer

- Contracts and Administrative Services
- Financial Services
- Human Resources

VICE PRESIDENT, OPERATIONS RESPONSIBILITIES AND AUTHORITIES

The Vice President, Operations is responsible for the overall operation and administration of the facility. The Vice President, Operations is responsible for ensuring that the facility complies with all applicable regulatory requirements.

- Operations
- Engineering
- Maintenance

QUALITY ASSURANCE RESPONSIBILITIES AND AUTHORITIES

WCS QA is responsible for establishing a documented Quality Assurance Program and verifying its effective implementation. QA personnel are organizationally independent from engineering, construction, operational, and decommissioning activities. QA personnel have the freedom and responsibility to identify quality problems; initiate, recommend or provide solutions, and to verify and report such solutions directly to management. QA 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.

The QA organization is responsible for the following activities.

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

During design, construction and operation, QA is an integrated part of the team and as such is included in day-to-day facility meetings and decisions with the facility staff. QA employees are able to make quality assurance decisions and have sufficient authority, access to work areas, and organizational freedom to:

- Identify quality problems,
- Initiate, 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,
- Have direct access to highest levels of management, and
- Be sufficiently independent from cost and schedule considerations and have stop-work authority.

DELEGATION OF WORK

The delegation of work between WCS and contractors is identified in procurement documents. In all cases of delegation, WCS retains the overall responsibility for all work performed under the direction of WCS. Responsible WCS managers have the authority to delegate tasks to another qualified individual within their organization provided the designated individual possesses the required qualifications. The responsible manager retains the ultimate responsibility and accountability for implementing the applicable requirements.

RESOLUTION OF DISPUTES

Disputes involving differences of opinion on quality matters or issues are brought to the attention of WCS line management, and if not resolved by the individual's manager, are elevated progressively to the QA Director. If satisfactory resolution cannot be obtained at that level, the matter is then elevated to the WCS President for final resolution.

STOP WORK AUTHORITY

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 any area 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.

SECTION 2
QUALITY ASSURANCE PROGRAM

QA PROGRAM BASIS

The WCS Quality Assurance Plan complies with regulatory requirements applicable to the specific WCS business unit and applies to all levels of the organization, including contractors, who perform quality-affecting work activities.

For purposes of understanding the applicability of the WCS QA Program, "Quality Affecting" is defined as "deeds, actions, processes, tasks or work which influence the achievement or verification of quality requirements and objectives for Quality Level 1and 2 structures, systems and components (SSCs) and their associated work activities."

ASME NQA-1-1994 *Quality Assurance Requirements for Nuclear Facility Applications* is used in conjunction with U.S. Nuclear Regulatory Commission, NUREG-1293, "Quality Assurance Guidance for Low-Level Radioactive Disposal Facility," and other applicable regulatory requirements and provides detailed guidance for the WCS QA Program. This QA Plan states WCS policies, assigns responsibilities and specifies requirements for managing the implementation of QA Program at WCS. The 18 criteria of ASME NQA-1 have been addressed to identify the total set of QA controls required for WCS work activities. This plan provides the guidance and direction for managing and controlling software used at WCS.

The QA Program requires that quality affecting work be planned and accomplished under suitably controlled conditions. Controlled conditions include the use of appropriate equipment, suitable environmental conditions for accomplishing the activity, and assurance that prerequisites for the given activity have been satisfied. The QA Program provides for any special controls, processes, test equipment, tools and skills to attain the required quality and verification of quality

WCS QUALITY LEVELS AND APPLICATION OF QA CONTROLS

Three QA Levels have been established and apply to WCS radioactive waste disposal facilities from design to construction, operation, and decommission. The three quality levels are defined as follows.

Quality Level	Description
1	Structures, Systems and Components (SSCs) and related quality affecting work activities relied on to satisfy facility performance objectives
2	SSCs and related work activities not relied on to satisfy facility performance requirements but whose performance may be important to ensuring operational or WCS mission-critical goals
3	SSCs that are not Quality Level 1, or Quality Level 2

The process of classification and grading for Quality Level SSCs and related work activities is prescribed in a WCS procedure.

The following criterion is applicable to the grading for SSCs and related work activities:

- Function and end use;
- Consequence of failure;
- Importance of the data being collected or analyzed;
- Complexity of the design or implementation of the activity;

- Reliability of the associated processes and components;
- Reproducibility of results;
- Uniqueness of the item or service quality;
- Necessity for special controls or processes;
- Degree which functional compliance can be demonstrated through inspection or test;
- Other relevant factor and risk as applicable.

QUALITY ASSURANCE INDOCTRINATION AND TRAINING

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 management. Detailed QA training is provided on the QA Program and job specific procedures prior to an employee beginning work. WCS managers are responsible for assuring that personnel performing work under their supervision are appropriately trained.

MANAGEMENT ASSESSMENT

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.

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.

QUALITY ASSURANCE PROGRAM STATUS REPORTING

WCS QA regularly advises WCS management regarding the status of the QA program. The status normally includes the results of reviews conducted on audit reports, internal surveillance reports, corrective action reports, management assessments, etc. Corrective action is initiated as necessary based on the review discussion.

SECTION 3
DESIGN CONTROL

WCS is responsible for the management and implementation the design control program. WCS managers are also responsible for ensuring that contractors performing design activities affecting quality implement an effective design control program. WCS QA is responsible for reviewing and approving the design contractor QA Plans.

The scope of the design program shall include, as needed to develop a compliant design, field design engineering, physics, seismic, stress, thermal, and geotechnical; associated computer programs; compatibility of materials; accessibility for in-service inspection, if needed, maintenance, and repair; quality standards.

DESIGN INPUT CONTROL

Applicable design inputs (such as design bases, conceptual design reports, performance requirements, regulatory requirements, codes and standards) shall be controlled to the following requirements:

- Design inputs shall be identified/documented and their selection reviewed/approved.
- Design inputs shall be specified and approved in a timely manner. Design inputs shall provide the necessary details to permit design to be carried out in a manner that provides a consistent basis for making design decisions, accomplishing design verification and evaluating design changes.
- Changes from approved design inputs and reasons for the changes shall be identified, approved, documented and controlled.
- Design inputs based on assumptions that require re-verification shall be identified and controlled by the appropriate procedures.

DESIGN PROCESS

The design process shall be controlled as follows:

- Design work shall be prescribed and documented on a timely basis and to the 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 and documented.
- Changes from specified standards, including the reasons for the change, shall be identified, approved, documented and controlled.
- Procedural controls shall be established for selecting and reviewing design methods, materials, parts, equipment and processes that are 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 without recourse to the originator of the design document.
- Design drawings, specifications or other design documents shall contain appropriate inspection, examination and testing acceptance criteria.

DESIGN ANALYSIS

Design analyses shall be planned, controlled and documented. Design analysis documents shall be legible, in a form suitable for reproduction, filing and retrieval. Design calculations shall be identifiable by subject, originator, reviewer and date or by other designators in order that approved calculations are traceable.

- Computer software used to calculate or develop data that is used as a design input shall be verified, validated and documented.
- Design analyses documentation shall include:
- Definition of the objective of the analyses,
- Definition of design inputs and their sources,
- Results of literature searches or other applicable background data,
- Identification of assumptions and designation of those that must be verified as the design proceeds,
- Identification of any computer calculation, including computer type, computer program, revision level, inputs, outputs and the bases (or reference thereto),
- Identification of analysis methods utilized,
- Identification of the design/analysis results and demonstration that applicable acceptance criteria is met,
- The conclusion of the design/analysis, and
- Design/analysis final review and approval.

DESIGN VERIFICATION

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

- Design verification is required for quality affecting design documents, 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. In some cases (such as when insufficient data exists) it may be necessary to release unverified designs to other engineering organizations or disciplines to support schedule requirements. Unverified portions of the design shall be clearly identified and procedurally controlled. In all cases, design verification shall be completed before relying on the item to perform its function. 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, re-verified.
- 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.

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.

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.

DESIGN CHANGE CONTROL

Design changes shall be 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.

- The design process and design verification methods and implementing documents 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.
- 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.

DESIGN INTERFACE CONTROL

Design interfaces shall be identified and controlled. Design efforts shall be coordinated among interfacing organizations including design contractors. Interface controls shall include the assignment of responsibility and the establishment of implementing documents 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.

SECTION 4
PROCUREMENT DOCUMENT CONTROL

WCS is responsible for developing and submitting procurement documents. At WCS, procurement documents include purchase requisitions, purchase orders, and contracts.WCS managers are responsible for ensuring that procurement documents are complete and in accordance with the QA program procedures.

WCS quality affecting procurements shall be issued to suppliers and contractors that have been evaluated and qualified by the QA Department 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 utilizing procurement documents approved by WCS. To the extent necessary, procurement documents require suppliers to have a quality assurance program consistent with the applicable WCS and regulatory requirements.

PROCUREMENT DOCUMENT CONTENT

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:
  - Design bases requirements, identified or referenced in the procurement documents.
  - 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 and regulatory 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 along with a document submittal schedule. Record retention times, disposition requirements and record maintenance responsibilities shall be identified for documentation that will become quality assurance records.
- 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 REVIEW AND APPROVAL

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 pertinent technical and quality assurance program requirements and contain appropriate provisions to ensure that material, equipment or services will meet the 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.

PROCUREMENT DOCUMENT CHANGE

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

SECTION 5
INSTRUCTIONS, PROCEDURES AND DRAWING

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

Instructions, procedures and drawings shall include appropriate quantitative and qualitative acceptance criteria for determining that prescribed activities have been satisfactorily accomplished.

WCS QA is responsible for the development of the QA Procedures related to QA responsibilities. WCS managers are responsible for developing quality affecting documents, Instructions or procedures that control the administrative and technical work processes.

WCS employees and contractors performing quality affecting work shall comply with instructions, procedures and drawings; however, when work cannot be accomplished as described in the procedure, instruction or 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 determined.

TYPES OF DOCUMENTS

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.

CONTENT OF DOCUMENTS

Documents shall include or reference the following information as appropriate to the work to be performed:

- Responsibilities of the organizations affected by the document,
- Quality, technical and regulatory requirements,
- A sequential description of the work to be performed including controls for altering the sequence of required inspections, tests and other operations, if applicable,
- Quantitative or qualitative acceptance criteria sufficient for determining that prescribed activities have been satisfactorily accomplished,
- Prerequisites, limits, precautions, process parameters and environmental conditions,
- In-process quality verification points and hold points,
- Methods for demonstrating that the work was performed as required,
- Identification of QA records generated by the document.

Scientific investigations will be performed utilizing WCS procedures, instructions 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.

SECTION 6
DOCUMENT CONTROL

WCS employees and contractors are responsible for developing, maintaining and using controlled documents. WCS Administrative Services is responsible for making controlled documents available for use by individuals needing controlled documents.

TYPES OF DOCUMENTS

Work Instructions, procedures, drawings and other documents specifying quality requirements or prescribing quality affecting activities shall be controlled in accordance with this section. WCS documents controlled under the WCS QA Program include: procedures, design requirements document, technical 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.

PREPARING AND REVIEWING DOCUMENTS

The document control process shall ensure that the identification of documents to be controlled and their specified distribution are proceduralized. The process 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.

CONTROLLING THE DISTRIBUTION AND USE OF DOCUMENTS

At WCS controlled documents are available on the WCS network and appropriate controls are to be implemented to ensure that the most current documents are posted for use.

If needed, hard copy documents needing to be placed under document control can be transmitted to Administrative Services with the distribution list of document holders. Administrative Services shall enter the document into the Administrative Services 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 the Document Control. The up-to-date master listing of controlled documents will be made available to document holders to verify that they have the current revisions.

The distribution and use of documents, including changes and editorial corrections to documents, shall be controlled.

CHANGES TO DOCUMENTS

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.

SECTION 7
CONTROL OF PURCHASED MATERIAL, EQUIPMENT AND SERVICES

WCS QA is responsible for ensuring and documenting that quality affecting purchased items conform to procurement document QA requirements. WCS is 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 and/or triennial evaluations, periodic audits and surveillances. Suppliers with an approved QA program are placed on the Qualified Suppliers List (QSL). Source audits and surveillances, as well as, evaluations of received items and services are performed, as needed, upon delivery or completion to ensure requirements specified in procurement documents are satisfied.

PROCUREMENT PLANNING

Procurements shall be planned and documented to ensure a systematic approach to the procurement process exists and supports the contract schedule. Procurement planning shall be utilized for significant procurements as follows:

- Identify procurement methods and organizational responsibilities, including what is to be accomplished, who is to accomplish it, how it is to be accomplished, and when it is to be accomplished.
- Be performed relative to the level of importance, complexity and quantity of the item or service being procured and the supplier's quality performance.
- Include the involvement of WCS QA.

SOURCE EVALUATION AND SELECTION

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 Qualified Suppliers List (QSL). 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.

SUPPLIER PERFORMANCE EVALUATION

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, and surveillances, 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.

CONTROL OF SUPPLIER GENERATED DOCUMENTS

Supplier generated documents shall be controlled, processed and accepted by WCS in accordance with the requirements established in the applicable procedures. 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.

ACCEPTANCE OF ITEMS OR SERVICES

Methods for accepting supplier furnished material, equipment or services shall include one or more of the following, as appropriate to the items or services being procured:

- Evaluating the supplier certificate of conformance
- Performing one or a combination of source verification, receiving inspection or post-installation test
- Technical verification of the product produced
- Surveillance or audit of the work
- Review of objective evidence for conformance to procurement requirements.

The supplier shall verify that furnished material, equipment or services comply with WCS procurement requirements before offering the items or services for acceptance and shall provide to WCS objective evidence that the items or services conform to procurement documents.

CERTIFICATE OF CONFORMANCE

When a certificate of conformance is used to accept material, equipment or services the following apply:

- The certificate shall identify the purchased items or service to the specific procurement document.
- The certificate shall identify the specific procurement requirements met by the purchased item or service. The procurement requirements identified shall include any approved changes, waivers or deviations applicable to the item or service.
- The certificate shall identify any procurement requirements that have not been met together with an explanation and the means for resolving nonconformances.
- The certificate shall be signed and dated or otherwise authenticated by an individual who is responsible for the supplier's quality assurance function.

SOURCE VERIFICATION

WCS may accept items or services by source verification. Source verification can include monitoring, witnessing or observing activities performed by the supplier. 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.

RECEIVING INSPECTION

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 established inspection instructions.
- 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.

NOTE: In most cases, receipt Inspections are performed by the organization that requisitioned the item.

POST-INSTALLATION TESTING

When post-installation testing is used as a method of acceptance, the WCS responsible manager and the supplier shall mutually establish test requirements and acceptance documentation.

CONTROL OF SUPPLIER NONCONFORMANCES

The responsible WCS manager and the supplier shall establish and document the process for disposition of items that do not meet procurement document requirements. The supplier shall evaluate nonconforming items according to the applicable requirements of Section 15 "Control of Nonconforming Items" and submit a report of nonconformance to the responsible WCS manager including supplier recommended disposition (for example, use-as-is or repair) and technical justification. Reports of nonconformances to procurement document requirements, or documents approved by WCS, shall be submitted to the responsible WCS manager for disposition whenever one of the following conditions exists:

- Technical or material requirements are violated.
- A requirement in supplier documents, which have been approved by WCS, is violated.
- The nonconformance cannot be corrected by continuation of the original manufacturing process or by re-work.
- 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.

QUALIFIED SUPPLIER LIST

WCS QA is responsible for the development and maintenance of the WCS Qualified Suppliers List (QSL). The QSL contains those suppliers with acceptable controls that have been evaluated and accepted by WCS. The WCS QA organization shall perform an evaluation of each supplier of Quality Level 1 items and service every 12 months. Satisfactory results will maintain the supplier on the QSL. Additionally, suppliers of Quality Level 2 items and services will be evaluated at least triennially. Suppliers that have unacceptable evaluations or that have not had a procurement placed with them in 3 years will be removed from the QSL.

SECTION 8
IDENTIFICATION AND CONTROL OF MATERIALS, PARTS AND COMPONENTS

The WCS managers are responsible for ensuring that material, parts, and components that are 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. These material, parts, and components also include such items 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 provided in technical specifications, drawings, and procurement documents.

IDENTIFICATION

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.

PHYSICAL MARKINGS

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 containers 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, and
- Not be obliterated or hidden by surface treatments or coatings, or after installation unless other means of identification are substituted.

TRACEABILITY

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.

OTHER REQUIREMENTS

The controls for items shall address the following requirements, as applicable:

- If codes, standards or specifications include specific identification or traceability requirements (i.e., identification or traceability of the item to applicable specification or grade of material; heat, batch, lot, part or serial number; or specified inspection, test or other records), then identification and traceability methods shall implement the requirements specified.
- If items have a limited operating or shelf life specified, then methods shall be established that preclude using the item beyond the shelf or operating life.

- If item storage is required, then methods shall be established for the control of item identification that are commensurate with the planned duration and conditions of storage. These methods shall provide for, as applicable:
  - Maintenance or replacement of markings and identification tags damaged during handling or aging,
  - Protection of identification markings subject to excessive deterioration resulting from environmental exposure, and/or
  - Updating related documentation.

SECTION 9
CONTROL OF SPECIAL PROCESSES

Processes are controlled to ensure quality is maintained by utilizing appropriately trained and qualified personnel. WCS employees and contractors are responsible for conducting quality affecting processes in accordance with documented procedures.

SPECIAL PROCESSES

Special processes that control or verify quality shall be controlled according to the requirements of this section whether or not they are covered by existing codes and standards, or whether or not the quality requirements specified for an item exceed those of existing codes or standards.

At WCS special processes includes, liner extrusion welding (seaming), structural welding, nondestructive testing and concrete production plants (batching).

PERSONNEL, PROCEDURES, AND EQUIPMENT QUALIFICATIONS

WCS instructions or procedures shall be used to ensure that process parameters are controlled and that the specified environmental conditions are maintained. Each special process shall be performed in accordance with an instruction or procedure that includes the following elements as applicable:

- The responsibility of the organization performing the special process to adhere to the approved procedures and processes,
- Qualification requirements for personnel, procedures and equipment,
- Conditions necessary for accomplishment of the special process shall include proper equipment, controlled parameters of the process and calibration requirements, and/or
- Requirements of applicable codes and standards, including acceptance criteria for the special process.

SECTION 10
INSPECTION

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 written instructions/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

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.

SELECTING INSPECTION PERSONNEL TO PERFORM INSPECTION

The individual who performs an inspection to verify conformance of an item to specified acceptance criteria shall be qualified to perform the assigned inspection tasks. Inspector qualifications are documented and maintained current. Inspections shall be performed by personnel other than those who performed or directly supervised the work being inspected.

INSPECTION HOLD POINTS

When mandatory hold points are used to control work that shall not proceed without the specific consent of the organization establishing the hold point, the specific hold points shall be identified in work control documents. Consent to waive specified hold points shall be documented and approved before continuing work beyond the designated hold point.

IN-PROCESS INSPECTIONS

Quality affecting items shall be inspected when necessary to verify quality. If inspection of processed items is impossible or disadvantageous, indirect control by monitoring of processing methods, equipment and personnel shall be provided. Inspection and process monitoring shall be conducted when control is inadequate with only one method. A combination of inspection and process monitoring methods, when used, shall be performed in a systematic manner to ensure that the specified requirements for control of the process and the quality of the item are met throughout the duration of the process. Controls shall be established and documented for the coordination and sequencing of inspections and monitoring at established inspection points during successive stages of the process or construction.

FINAL INSPECTION

Completed items shall be inspected for completeness, markings, calibration, adjustments, protection from damage or other characteristics as required in order to verify the quality and conformance of the item to specified requirements

INSPECTION DOCUMENTATION

Inspection records shall include:

- The item inspected, date of inspection, the name of the inspector;
- Results or acceptability;
- Measuring and test equipment if used; and
- Reference to information on actions taken in connection with nonconformances, as applicable.

SECTION 11
TEST CONTROL

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, shall be planned, executed, documented and evaluated.

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

TEST REQUIREMENTS

Test requirements and acceptance criteria shall be provided or approved by the organization responsible for the design of the item to be tested unless otherwise designated. Required tests, including, as appropriate, prototype qualification tests, production tests, proof tests prior to installation, construction tests, pre-operational tests, and operational tests are controlled. Test requirements and acceptance criteria are based upon specified requirements contained in applicable design or other pertinent technical documents.

TEST PROCEDURES

Test procedures shall include:

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

USE OF OTHER TESTING DOCUMENTS

Other testing documents (e.g., American Society for Testing and Materials (ASTM)) specifications, supplier manuals or other related documents containing acceptance criteria may be used instead of preparing special test procedures.

TEST RESULTS

Test results shall be documented and evaluated by a qualified individual to ensure that test requirements have been satisfied.

TEST RECORDS

Test records shall include:

- Item tested, date of test, names of tester and data recorders, type of observation and method of testing;
- Identification of test criteria or reference documents used to determine acceptance;
- Results and acceptability of the test;
- Actions taken in connection with any nonconformances or deviations noted;
- Name of the person evaluating the test results; and

- Identification of the measuring and test equipment (M&TE) used during the test.

SECTION 12
CONTROL OF MEASURING AND TEST EQUIPMENT

Tools, gauges, instruments, and other measuring and test equipment used for quality affecting activities shall be controlled and at specified periods calibrated and adjusted to maintain accuracy within necessary limits.

WCS managers are responsible for the implementation of the measuring and test equipment procedures and ensuring that calibrated items are used in quality affecting activities.

CALIBRATION

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. Calibration standards shall have a greater accuracy than the required accuracy of the M&TE being calibrated. If calibration standards with a greater accuracy than required of the M&TE being calibrated do not exist or are unavailable, calibration standards with accuracy equal to the required calibration accuracy may be used, provided they are shown to be adequate for the requirements. 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.

DOCUMENTING THE USE OF M&TE

The use of M&TE shall be documented. As appropriate to equipment use and its calibration schedule, the documentation shall identify the processes monitored, data collected or items inspected or tested since the last calibration.

OUT OF CALIBRATION M&TE

M&TE is 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 re-calibration.
- The device produces results known or suspected to be in error.

Out-of-Calibration M&TE is controlled. Out of calibration M&TE is 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 is evaluated to verify the acceptability of previously collected data, processes monitored, or items previously inspected or tested. If any M&TE is consistently found out-of-calibration during the re-calibration process, it is repaired or replaced.

HANDLING AND STORAGE

M&TE shall be properly handled and stored to maintain accuracy.

COMMERCIAL DEVICES

Calibration and control shall not be required for rulers, tape measures, levels and other normal commercial equipment that provides adequate accuracy

M&TE DOCUMENTATION

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 re-calibration due date;
- Results of the calibration and statement of acceptability;
- Reference to any actions taken in connection with out-of-calibration.

SECTION 13
HANDLING, STORAGE AND SHIPPING

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

WCS is responsible for handling, storage, and shipping controls as provided in technical specifications. WCS contractors are responsible for ensuring that handling, storage, and shipping activities are adequate and conform to WCS requirements.

In addition to the requirements found here, WCS and contractors are also responsible for complying with QAP-200, Quality Assurance Program for Packaging and Transportation of Radioactive Materials requirements when performing work with transportation casks.

CONTROLS

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

SPECIAL EQUIPMENT, TOOLS AND ENVIRONMENTS

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.

OPERATORS

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

MARKING AND LABELING

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 need for special controls if necessary.

SECTION 14
INSPECTION, TEST AND OPERATING STATUS

Status is indicated either on the items or in documents traceable to the items where it is necessary to assure that required inspections and tests are performed and to assure that items which have not passed the required inspections and tests are not inadvertently installed, used or operated. Status is maintained through indicators (i.e., physical location and tags, markings, shop travelers, stamps, inspection records or other suitable means). The authority for application and removal of tags, markings, labels and stamps are specified. Status indicators shall also provide for indicating the operating status of systems and components of the facility (i.e., tagging valves and switches) to prevent inadvertent operation.

WCS managers are responsible for identifying and implementing any inspection, test, and operating status procedures/instructions that may be necessary. Contractors, if applicable, are responsible for ensuring that inspection, test, and operating status activities are adequate and conform to direction provided by the WCS manager.

SECTION 15
CONTROL OF NONCONFORMING ITEMS

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.

DOCUMENTING AND EVALUATING NONCONFORMING ITEMS

Nonconformance reports shall clearly identify and describe the characteristics that do not conform to specified criteria. Nonconformance reports shall be reviewed by the responsible WCS organization and recommended dispositions of nonconforming items shall be developed. In addition, organizations affected by the nonconformance shall be notified. Recommended dispositions shall be evaluated and approved. The WCS QA organization is responsible for managing the nonconformance process. Further processing, delivery, installation or use of a nonconforming item shall be controlled pending the evaluation and approval of the disposition by the responsible WCS manager.

IDENTIFYING NONCONFORMING ITEMS

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 container, package or segregated storage area, as appropriate, shall be identified.

SEGREGATING NONCONFORMING ITEMS

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.

DISPOSITION OF NONCONFORMING ITEMS

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; and, 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.

TRENDING

Nonconformance documentation shall be periodically analyzed by the WCS QA to identify quality trends in accordance with Section 16 “Corrective Action.”

SECTION 16
CORRECTIVE ACTION

Conditions adverse to quality shall be identified promptly, reported to appropriate levels of management and corrected as soon as practical. Such conditions shall be tracked and evaluated so that adverse trends can be identified and appropriate corrective action can be taken.

QA procedures shall be established to provide requirements and processes for the following activities:

- Prompt identification, correction and trending of all conditions adverse to quality.
- Evaluating significant conditions adverse to quality and determining cause, including corrective actions to prevent recurrence.
- Stopping work, if applicable.
- Verifying implementation of corrective actions.

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.

FOLLOW-UP ACTION

The corrective action process shall include a requirement for WCS management to take follow-up action to verify implementation of corrective action taken to address significant conditions adverse to quality. The WCS QA organization shall be responsible for conducting periodic assessments of these follow-up actions.

TRENDING

Reports of conditions adverse to quality and significant conditions adverse to quality shall be evaluated to identify adverse quality trends and help identify causes. Trend evaluation shall be performed in a manner and at a frequency that provides for prompt identification of adverse quality trends. Identified adverse trends shall be reported to WCS management.

SECTION 17
QUALITY ASSURANCE RECORDS

Records that provide documentary evidence of quality shall be specified, prepared, and maintained. Records shall be legible, 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.

WCS staff and contractors are responsible for preparing, safeguarding, and submitting records to the WCS Administrative Services. WCS managers are responsible for ensuring that records are complete and submitted to Administrative Services electronic record management system (ERMS). Administrative Services is responsible for receiving, designating, validating, and filing quality records.

ELECTRONIC RECORD MANAGEMENT SYSTEM

The electronic record management system shall be described in procedures, instructions or other documentation such as an operating manual. Procedures describing the electronic record management system shall include methods for controlling records withdrawn from storage.

GENERATION OF QA RECORDS

WCS procedures shall specify the records to be generated and maintained. Documents that are 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.

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

- Those which would be of significant value in demonstrating capability for safe operation;
- Those which would be of significant value in maintaining, reworking, repairing, replacing or modifying an item;
- Those which would be of significant value in determining the cause of an accident or malfunction of an item; and/or
- Those, which provide required baseline data for in-service inspections.
- Other records as required to satisfy regulatory requirements and business purposes.

Lifetime records are required maintained for the life of the particular item while it is installed in the facility or stored for future use.

Nonpermanent records are those required to show evidence that an activity was performed in accordance with the applicable requirements but need not be retained for the life of the item because they do not meet the criteria for lifetime records. QA audits and surveillance reports are examples of nonpermanent records.

Individuals creating records shall ensure the records are legible, accurate and complete, and shall protect them from damage, deterioration or loss during the time the records are in their possession.

Documents shall be considered valid records only if authenticated (i.e., reviewed, initialed, signed and dated by responsible personnel).

RECEIVING QA RECORDS

Records shall be indexed to ensure retrievability. Records and/or indexing system(s) shall provide sufficient information to permit identification between the record and the item or activity to which it applies. The indexing system shall include:

- The location of the records within the records management system;

- Identification of the item or related activity to which the records pertain.

STORING AND PRESERVING QA RECORDS

Records shall be stored in facilities, containers, or a combination thereof, constructed and maintained in a manner which minimizes the risk of damage or destruction from the following:

- Natural disasters such as wind, floods or fires;
- Environmental conditions such as high and low temperature and humidity;
- Infestation of insects, mold and rodents;

The WCS records facility shall meet requirements specified in ASME NQA-1, 1994 Edition, Section 17 “QA Records”, supplement 17S-1 “Supplemental Requirements for QA Records”, Section 4.4 “Storage Facilities.”

Dual facilities, containers shall be provided for records storage if a single facility, container or combination thereof is not capable of providing adequate protection.

Records can be stored at the WCS departmental level provided the storage requirements described above can be satisfied. Records stored at the departmental level will be transition into the ERMS as schedule permits.

RETENTION OF QA RECORDS

Lifetime records shall be retained and preserved for the operating life of the item or facility. Nonpermanent records shall not be disposed of until the following conditions are met:

- Regulatory requirements are satisfied;
- Facility status allows document disposal; and
- WCS QA requirements are satisfied.

SECTION 18
AUDITS, SURVEILLANCE AND ASSESSMENT

WCS shall utilize 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. Assessments are conducted by the WCS line organizations for the purpose of self-identification of issues and performance improvement. The assessment process includes a review of the operational effectiveness of WCS departments performing quality affecting work activities.

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

The WCS QA audit process is responsible for ensuring that facility performances defined in 30 TAC 336.723 and the technical environmental analyses provided in 30 TAC 336.709 are accomplished. The audit process will validate if inspections or surveillance are used to verify results.

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 that have been 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.

AUDIT SCHEDULES

Internal or external audits shall be scheduled in a manner to provide coverage, consistency and coordination with ongoing work, and at a frequency commensurate with the status and importance of the work. An internal audit schedule shall be developed and revised as necessary to ensure that coverage is maintained. No schedule is required for external audits. External audits are conducted for evaluating potential WCS suppliers including contractors. Re-qualification of suppliers is managed under the requirements of Section 7.

AUDIT PLANS

An audit plan shall be developed for each internal audit. This plan shall identify the audit scope, requirements for performing the audit, type of audit personnel needed, work to be audited, and organizations to be notified, applicable documents, audit schedule, and implementing documents or checklists to be used.

AUDIT TEAMS

WCS QA shall assign auditors who are independent of any direct responsibility for performing the work being audited. The auditors shall have sufficient authority and organizational freedom to make the audit process meaningful and effective. The audit team should include one or more auditors comprised of representatives from the WCS QA organization and if applicable, technical organizations. A lead auditor shall be appointed to supervise the team, organize and direct the audit, prepare and coordinate issuance of the audit report and evaluate responses. Technical specialists may be used to assist in assessing the adequacy of technical processes. Before commencing the audit, the lead auditor shall ensure the personnel assigned to the audit team are prepared and collectively have experience and/or training commensurate with the scope, complexity or special nature of the work to be audited.

AUDIT PERFORMANCE

WCS QA shall provide notification of a planned audit to the affected organizations at a reasonable time before the audit is to be performed. The notification should include all relevant information pertaining to the

audit, such as schedule, scope and names of audit lead and team members, if known. In addition, the audit team leader shall ensure the following is performed.

- The audit team shall prepare before starting the audit.
- Audits shall be performed in accordance with procedures or checklists.
- QA program elements that have been selected for the audit shall be evaluated against specified requirements.
- Objective evidence shall be examined to the depth necessary to determine if the selected elements are being implemented effectively.
- Audit results shall be documented and reported to management.
- Identified audit findings shall be documented and the audited organization shall correct the findings according to the requirements of Section 16, “Corrective Action.”

REPORTING AUDIT RESULTS

The audit report shall be prepared and signed by the audit team leader and issued to the management of the audited organization in a timely manner after completion of the audit.

The audit report shall include the following information:

- A description of the audit scope.
- Identification of the auditors.
- Identification of persons contacted during the audit.
- A summary of audit results and the documents reviewed, persons interviewed and the specific results of the reviews and interviews.
- Statement as to the effectiveness of the implementation of the QA Program elements audited.
- A description of the adverse audit finding in sufficient detail to enable corrective action to be taken by the audited organization.
- A requested date for response by the audited organization.

RESPONDING TO AUDITS

Management of the audited organization or activity shall:

- Investigate adverse audit findings in a timely manner;
- Determine and schedule corrective action, including measures to prevent recurrence;
- Prior to or by the requested response date, notify the WCS QA of the actions taken or scheduled, according to the requirements of Section 16 “Corrective Action.”

EVALUATING AUDIT RESPONSES

The adequacy of corrective actions for adverse audit findings (conditions adverse to quality) shall be evaluated by WCS QA. When corrective actions are considered inadequate, notification of this determination shall be provided to the audited organization with a request for a revision to the corrective action plan.

CLOSING AN AUDIT

Follow-up action shall be taken by WCS QA to verify that corrective actions are accomplished as scheduled according to the requirements of Section 16 “Corrective Actions.” Notification of audit closure shall be provided upon verification that all corrective actions have been satisfactorily completed.

Audit records shall include audit plans, audit reports, written replies and the reference to completed corrective actions.

AUDIT PERSONNEL

Qualified personnel that do not have responsibility for the activity being audited are responsible for conducting audits. Audit personnel performing quality affecting activities shall be certified in accordance with WCS procedure requirements. ASME NQA-1- 1994 shall be used as guidance for documenting the qualification of lead auditors.

SECTION 19
SOFTWARE QUALITY ASSURANCE

WCS utilizes a graded approach to managing software used at WCS. WCS shall document in a Software QA Plan (SQAP) the process in which software is custom built, procured for use in WCS applications, installed and tested for use, and how issues related to the software are managed. ASME NQA-1, Part 2 Subpart 2.7 Quality Assurance Requirements for Computer Software for Nuclear Facility Applications should be used as a guide to establishing the requirements in this plan.

The SQAP shall provide the framework necessary to ensure a consistent approach to software quality assurance is utilized throughout the software life cycle.

Computer software used to calculate or develop data that is used as a design input shall be verified, validated and documented.

CHART1 WCS ORGANIZATIONAL CHART