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TWRS CHARACTERIZATION PROJECT QUALITY POLICIES

COMPLETE

ENGINEERING CHANGE NOTICE

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Page 1 of 2

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9/26/95

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Cog. Engineer Signature & Date

Cog. Engineer Signature & Date

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L. F. Ermold	S7-84	1	R. S. Popielarczyk	R1-30	1
M. A. Payne	S7-84	1	T. J. Kelley	S7-21	1
J. G. Burton	S7-01	1	A. G. King	T6-03	1
B. H. Lueck	S7-81	1	J. S. Sparks	S7-07	5
J. M. Roberts	A4-79	1	T. C. Tribble	S7-07	1
R. E. Raymond	S7-12	1	<i>T. Demitruk</i>	<i>81-17</i>	<i>(2)</i>

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RELEASE AUTHORIZATION

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**This document was reviewed following the
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APPROVED FOR PUBLIC RELEASE

WHC Information Release Administration Specialist:


Kara Broz


10/2/95

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7. Abstract

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WHC-SD-WM-QAPP-025
Revision 1

**Tank Waste Remediation System
Characterization Project
Quality Policies**

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TANK WASTE REMEDIATION SYSTEM
CHARACTERIZATION PROJECT
QUALITY POLICIES

Westinghouse Hanford Company Approvals:

L.F. Ermold 9/26/95
Leonard F. Ermold Date
Director,
Characterization Project

Michael A. Payne 9/26/95
Michael A. Payne Date
Deputy Director,
Characterization Project

B.H. Lueck 9/25/95
Bernie H. Lueck Date
Acting Director, Emergency,
Safety and Quality,
Characterization Project

Joseph M. Roberts 9/27/95
Joseph M. Roberts Date
Director, Quality Assurance
Emergency, Safety and Quality

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EXECUTIVE SUMMARY

E1.0 INTRODUCTION

E1.1 PURPOSE AND SCOPE

These Quality Policies (QPs) describe the Quality Management System of the Tank Waste Characterization Project (hereafter referred to as the Characterization Project), Tank Waste Remediation System (TWRS), Westinghouse Hanford Company (WHC).

E1.2 POLICY

The Quality Policies and quality requirements described herein are binding on all Characterization Project organizations. To achieve quality, the Characterization Project management team shall implement this Characterization Project Quality Management System.

E1.3 CHARACTERIZATION PROJECT DESCRIPTION

Radioactive waste at the Hanford Site has been generated since 1944 as a by-product of U.S. national defense systems. Liquid radioactive and chemical waste from nuclear materials production was placed in underground, reinforced, steel-lined, single-shell tanks (SST), and later in double-shell tanks (DST), for storage.

149 SSTs and 28 DSTs, with capacities ranging from 208,000 to 3,800,000 L (55,000 to 1,000,000 gal) each, were constructed for high level radioactive waste storage on the Hanford Site. The SSTs contain approximately 137 million L (36.1 million gal) of waste, consisting of salt cake 88 million L (23.3 million gal), sludge 46 million L (12.1 million gal), and supernatant liquids 2.2 million L (0.6 million gal). The waste contains radionuclides and potentially hazardous nonradioactive substances.

After considering alternative approaches, the stakeholders agreed to retrieve and process wastes contained in the SSTs. This decision is reflected in the *Hanford Federal Facility Agreement and Consent Order* (also known as the Tri-Party Agreement) revised strategy (Ecology et al. 1994). Considering current technology, waste retrieval and treatment require that tank contents first be characterized.

*Ecology, EPA, and DOE, 1994, *Hanford Federal Facility Agreement and Consent Order*, as amended, Washington State Department of Ecology, U.S. Environmental Protection Agency, and U.S. Department of Energy, Olympia, Washington. This decision is subject to confirmation in the Tank Waste Remediation System, Environmental Impact Statement.

The mission of the Characterization Project is to provide information to our customers so they can (1) identify and resolve safety issues to ensure continued safe storage of tank wastes, (2) understand the properties of waste to develop pretreatment strategies, and (3) achieve the Hanford Site mission objective to dispose of waste stored in Hanford Site SSTs and DSTs.

E1.4 TANK WASTE CHARACTERIZATION PROCESS

The tank waste characterization process is depicted in Figure E-1.

The characterization process begins with the need to answer a question or solve a problem concerning the safe storage, pretreatment, or retrieval of tank waste. Those individuals or organizations requiring information, or having an interest in the resolution of an issue or problem, are customers of the tank waste characterization process.

Before requesting characterization data, customers deploy the data quality objective (DQO) process to determine the information (data) requirements that will solve their problem. DQOs generated by customers are the primary inputs to the characterization process. DQOs define the type, quantity, and quality of data that customers require. The Characterization Project facilitates the DQO process, and provides information about the types and quality of data that are available, or can be provided. The programs requesting data have final responsibility to define their respective data needs, and drive the development of the DQOs.

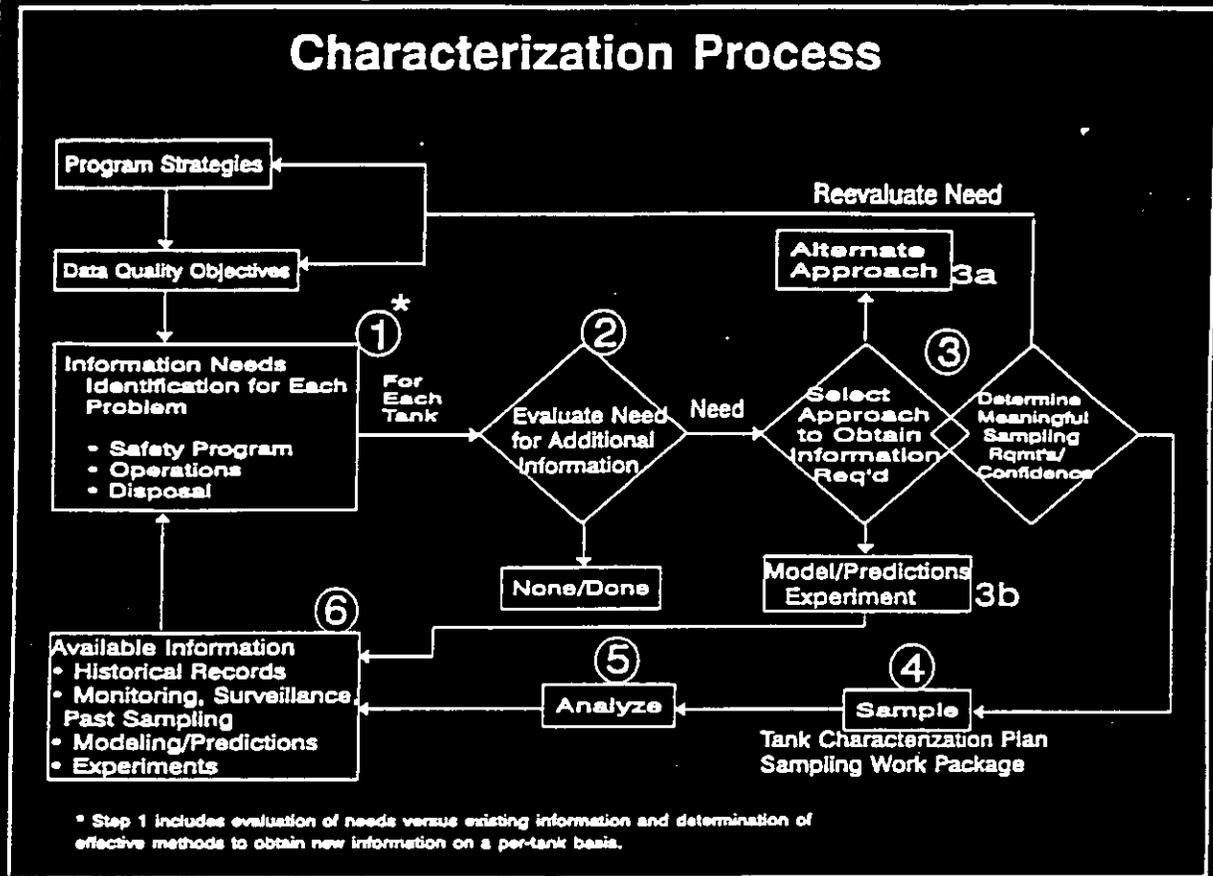
Using the outcome from the DQO process, the customers "enter" the characterization process with clearly defined information requirements. The characterization process determines what information is currently available and what must be obtained through additional effort.

If appropriate data are not available, collection and analysis of new samples are considered. The customer and Characterization Project personnel determine capabilities to collect and analyze new waste tank samples. Characterization Project personnel estimate the samples and analyses required to address the customer's problems, considering the data uncertainty that customers are willing to accept, as established by DQOs. Sampling and analyses requirements are provided to the customers to determine if an approach other than sampling is feasible.

Once the data, sampling and analysis requirements are determined, a "requirements matrix" is developed to determine which requirements apply to each of the waste tanks. This matrix specifies all the data that must be acquired from each tank, establishing priorities based on anticipated data needs. Alternative methods are determined to obtain the needed data. Optimization involves evaluating alternatives and determining the best approach for obtaining additional data.

Scheduling of tank sampling is coordinated to achieve priorities and to reduce the number of entries into the same tank. Optimization of tank sampling is determined and documented through tank characterization plans (TCP).

Figure E-1. Tank Waste Characterization Process.



The TCP integrates differing data needs required to satisfy customer DQO requirements. A sampling and analysis plan (SAP) integral to the TCP specifies the appropriate number of samples and measurement types required to resolve each customer's issue.

Collecting and analyzing tank waste samples is a complex and potentially hazardous operation. Consequently, considerable effort is expended in the design, construction, and testing of sampling equipment, apparatus and analytical procedures needed to safely obtain and analyze samples. The development of vapor sampling and rotary-mode core sampling equipment and associated analytical methods are examples of this effort.

Some Waste Tank Characterization data are collected in-situ while other problems require the collection and laboratory analysis of physical samples.

From the instructions provided by the TCP/SAP, tank samples are collected using documented methods and shipped to qualified, scheduled laboratories using appropriate chain-of-custody procedures. Samples are received and logged by sample custodians and distributed to trained and qualified analysts using documented analytical methods. Raw, analytical data are generated and verified by performing laboratories. Defensible data packages are assembled, independently validated, and transmitted to Characterization Project personnel. A tank characterization report (TCR) is written for the customer from the data package, and new data are entered into the TCD. Residual samples are archived for future use. The primary outputs of the tank characterization process are the TCR and TCD.

The customer receives the needed information, makes the necessary decision(s), and proceeds to address the waste tank issue or solve the problem. The characterization process is complete.

WHC-SD-WM-TA-163, *Tank Waste Characterization Process*, provides an extensive description of this process.

E1.5 CHARACTERIZATION PROCESS QUALITY ASSURANCE AND QUALITY CONTROLS: A GRADED QUALITY APPROACH

This Characterization Project Quality Management System focuses on the controls and systems necessary to ensure the output quality of the tank characterization process.

The quality controls and systems that Characterization Project management shall apply to processes, will depend upon the importance of those processes to the success of the Characterization Project - a graded approach to quality.

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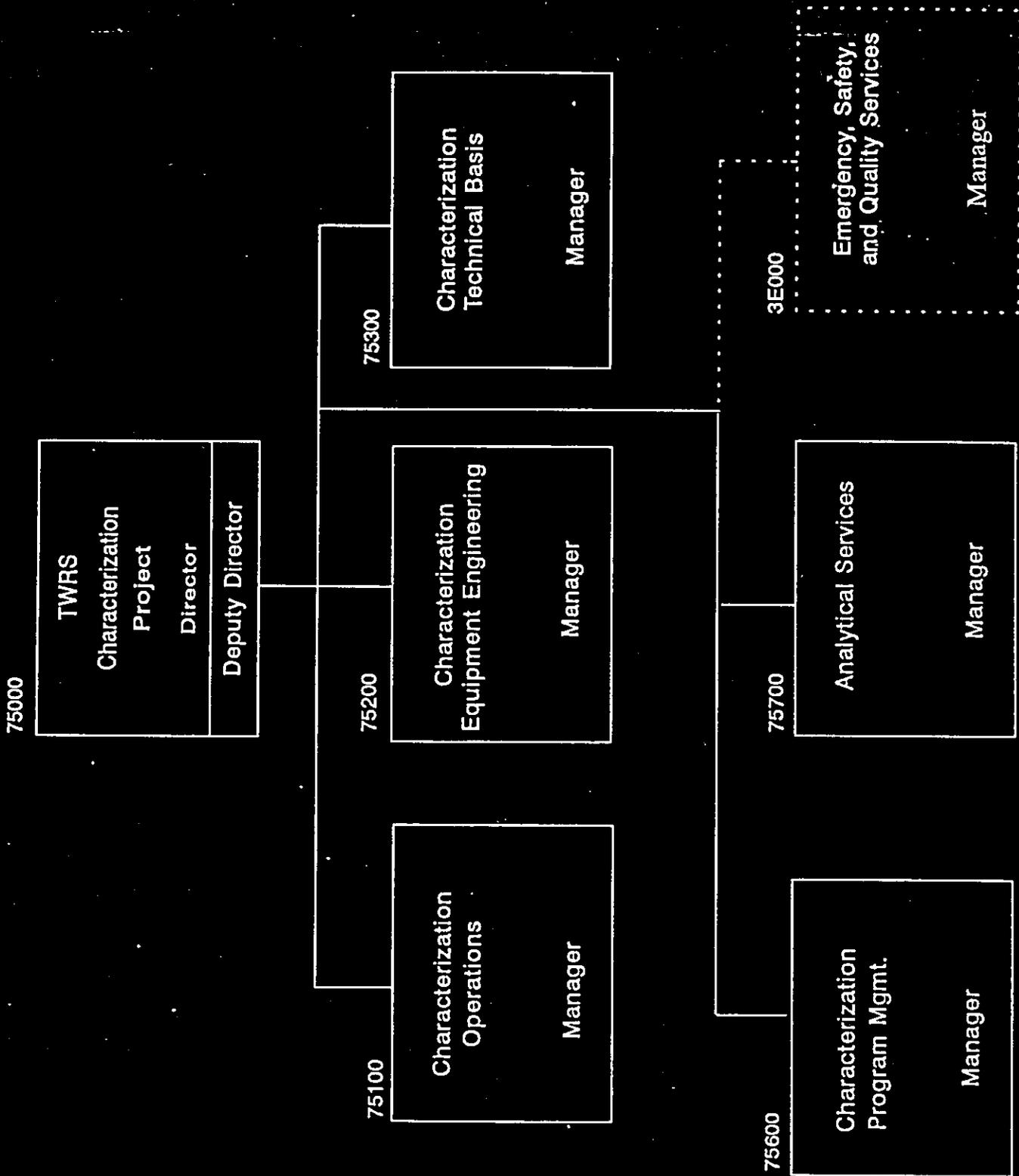
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QP 3.0	0	September 18, 1995
QP 4.0	0	September 18, 1995
QP 5.0	0	September 18, 1995
QP 6.0	0	September 18, 1995
QP 7.0	0	September 18, 1995
QP 8.0	0	September 18, 1995
QP 9.0	0	September 18, 1995
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CHARACTERIZATION PROJECT QUALITY POLICIES CHANGE CONTROL LOG

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Figure 1-1. Tank Waste Remediation System Characterization Project Organization and Management Team.

TWRS CHARACTERIZATION PROJECT



**TANK WASTE REMEDIATION SYSTEM CHARACTERIZATION
PROJECT QUALITY POLICIES**

QUALITY POLICY 1.0

CHARACTERIZATION PROJECT MANAGEMENT'S RESPONSIBILITIES AND QUALITY SYSTEM

1.1 PURPOSE AND SCOPE

Quality Policy 1.0 establishes the Tank Waste Characterization Project's (hereafter referred to as the Characterization Project) policy, requirements, responsibilities, and organization to achieve quality.

1.2 ORGANIZATION: CHARACTERIZATION PROJECT RESPONSIBILITY, AUTHORITIES, AND INTERFACES

Figure 1-1 depicts the Characterization Project organization and management team.

The following discussion summarizes the responsibilities of the Characterization Project management team.

1.2.1 Director, Characterization Project

The director leads the organization and coordinates the development and implementation of strategic plans. The director develops the Characterization Project Quality Policies and ensures that the Characterization Project is organized to achieve those policies. The director ensures that the Characterization Project achieves its policy of continuous process improvement and employee development. In cooperation with the senior management team, the director develops and implements Characterization Project management systems. In this capacity, the following positions report to the director:

- Deputy Director, Characterization Project
- Manager, Characterization Project, Emergency, Safety and Quality
- Manager, Operations
- Manager, Equipment Engineering
- Manager, Technical Basis
- Manager, Program Management
- Manager, Analytical Services

1.2.2 Deputy Director, Characterization Project

The deputy director acts on behalf of the director, as required.

1.2.3 Manager, ESQ, Characterization Project

As the quality representative, the ESQ manager represents the Characterization Project director in quality matters. The ESQ manager has direct access to the Characterization Project director and others at the management level where appropriate action can be effected. The ESQ manager has the organizational freedom, authority, and responsibility for ensuring that the requirements of the Characterization Project Quality Management System are defined, implemented and maintained.

The ESQ manager has sufficient authority, access to work areas, and organizational freedom to:

- Identify and recommend improvement to characterization processes
- Identify and resolve quality problems
- Initiate, recommend, or provide solutions to quality problems
- Verify implementation of corrective action measures and determine that solutions to quality problems are effective (empowered with stop work authority)
- Direct assessments, surveillances, inspections, reviews and audits
- Maintain the Characterization Project Quality Management System, and Quality Policies.

The Characterization Project ESQ manager may delegate authority to quality representatives throughout the Characterization Project Quality Assurance organization but shall retain overall responsibility. Quality representatives and alternate quality representatives may have other assigned duties within the organization but shall report directly to the Characterization Project ESQ manager for quality matters. However, those duties shall not include direct responsibilities for production, schedule, or cost.

1.2.4 Manager, Characterization Operations

The Operations manager manages tank waste characterization sampling including maintenance, production control, training for Characterization Operations personnel, and those personnel from supporting organizations matrixed to Characterization Operations. The operations manager conducts work in a manner that ensures compliance with applicable federal, state, and local environmental regulations.

1.2.5 Manager, Characterization Equipment Engineering

The Equipment Engineering manager provides equipment engineering development support for the Characterization Project. The manager incorporates safety, regulatory compliance, operability and maintainability into the development of Characterization Project equipment.

1.2.6 Manager, Characterization Technical Basis

The Technical Basis manager leads, controls and monitors the organization that provides the technical leadership and direction for the Characterization Project in support of TWRS tank waste data needs. The Technical Basis provides technical direction for collecting and analyzing samples. The manager guides and directs specialized management teams responsible for interfacing across multiple program boundaries.

1.2.7 Manager, Characterization Program Management

The Program manager integrates the efforts of the various Characterization Project organizations by: budgeting and tracking funds expenditures, scheduling activities of organizations, resolving issues between organizations and external activities that involve changes in contracts or relationships. The Program manager communicates with customers and stakeholders by providing commitment status and other periodic reports.

1.2.8 Manager, Analytical Services

The Analytical Services manager leads and directs WHC's Analytical and Chemical laboratories. The manager manages the resources needed to assure quality analytical results, timely completion of commitments, safe and effective facility operation and high customer satisfaction.

Within the Analytical Services group is the Office of Quality Assessment (OQA). OQA has primary responsibility for assessing the quality systems of each laboratory providing sample analysis services and measurement data to the Characterization Project. Assessments result in the "approval" or "non-approval" of supplier laboratories. Only approved laboratories are "qualified" to provide data to the Characterization Project.

1.3 ORGANIZATION: TANK WASTE REMEDIATION SYSTEM

Figure 1-2 depicts the Tank Waste Remediation System organization.

The TWRS Division is the parent organization for the Characterization Project. TWRS is responsible for the storage, treatment, and immobilization of Hanford Site tank waste in an environmentally sound, safe and cost-effective manner. This mission is accomplished jointly with the US Department of Energy (DOE), Richland Operations Office (RL), the Environmental Protection Agency (EPA), and the State of Washington.

1.4 ORGANIZATION: WHC EMERGENCY, SAFETY AND QUALITY SERVICES

Figure 1-3 depicts the WHC Emergency, Safety and Quality Services.

Within ESQ, the Quality Assurance Department is the interpretative authority concerning the customer's quality requirements, 10 CFR 830.120, for all WHC organizations. The ESQ Quality Assurance Department is depicted on Figure 1-4.

Within the Quality Assurance Department, Analytical & Environmental Quality Assurance conducts quality assessments of laboratories providing data to WHC. Assessments of laboratories supplying data to the Characterization Project are conducted jointly with the Office of Quality Assessment.

Within ESQ, but external to the Quality Assurance group, is Quality Compliance Assurance. Reporting to the director of ESQ, Compliance Assurance personnel conduct independent assessments of the Characterization Project to evaluate the achievement of the mission and goals of the organization.

1.5 ORGANIZATION: TWRS QUALITY ASSURANCE

Figure 1-5 depicts the TWRS Quality Assurance organization. TWRS Quality Control conducts assessments and inspections of Characterization Project sampling activities to determine conformance to WHC, TWRS and Characterization Project requirements.

Figure 1-2. Tank Waste Remediation System (TWRS) Organization.

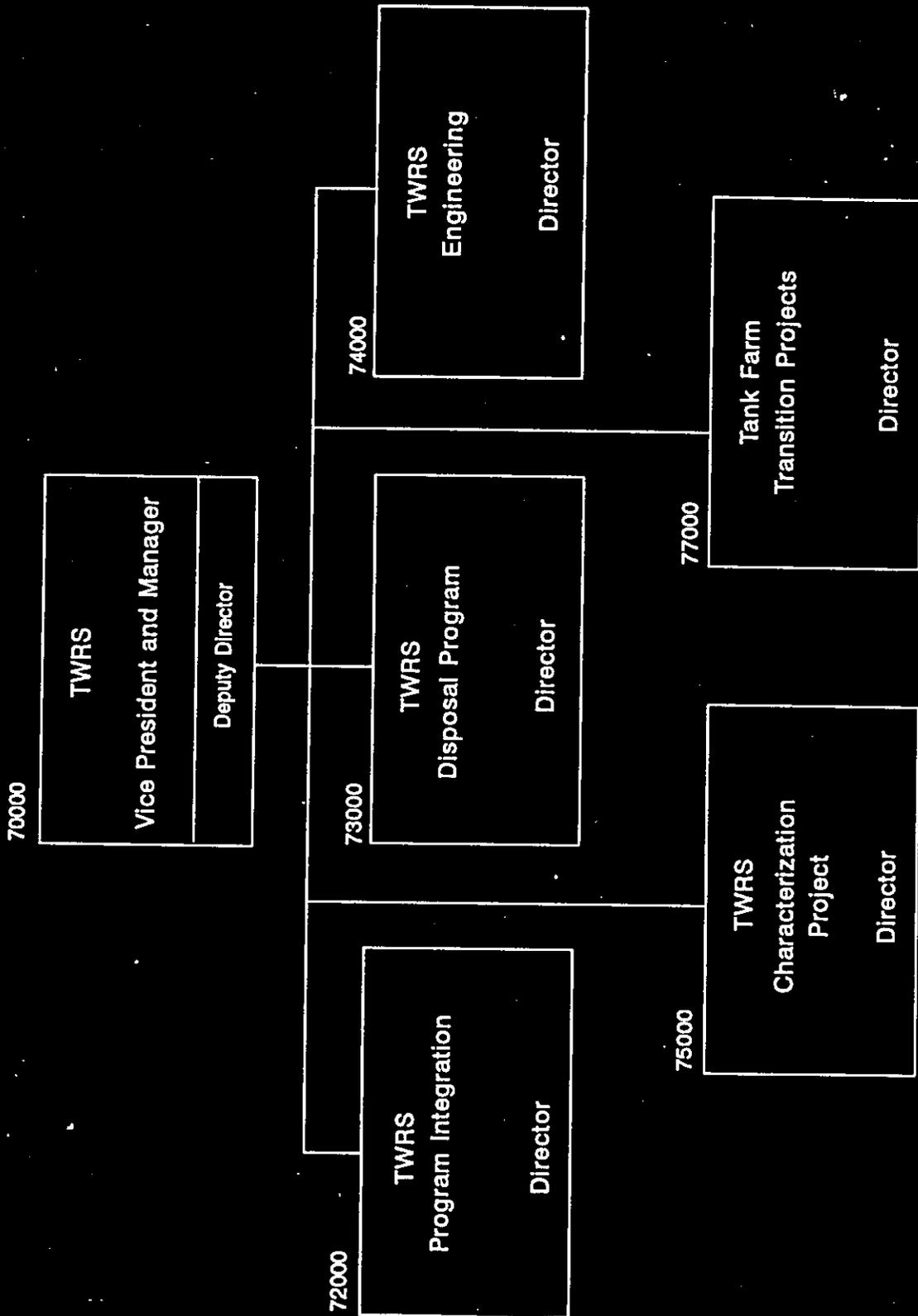


Figure 1-3. WHC Emergency, Safety and Quality Services

EMERGENCY, SAFETY, AND QUALITY SERVICES

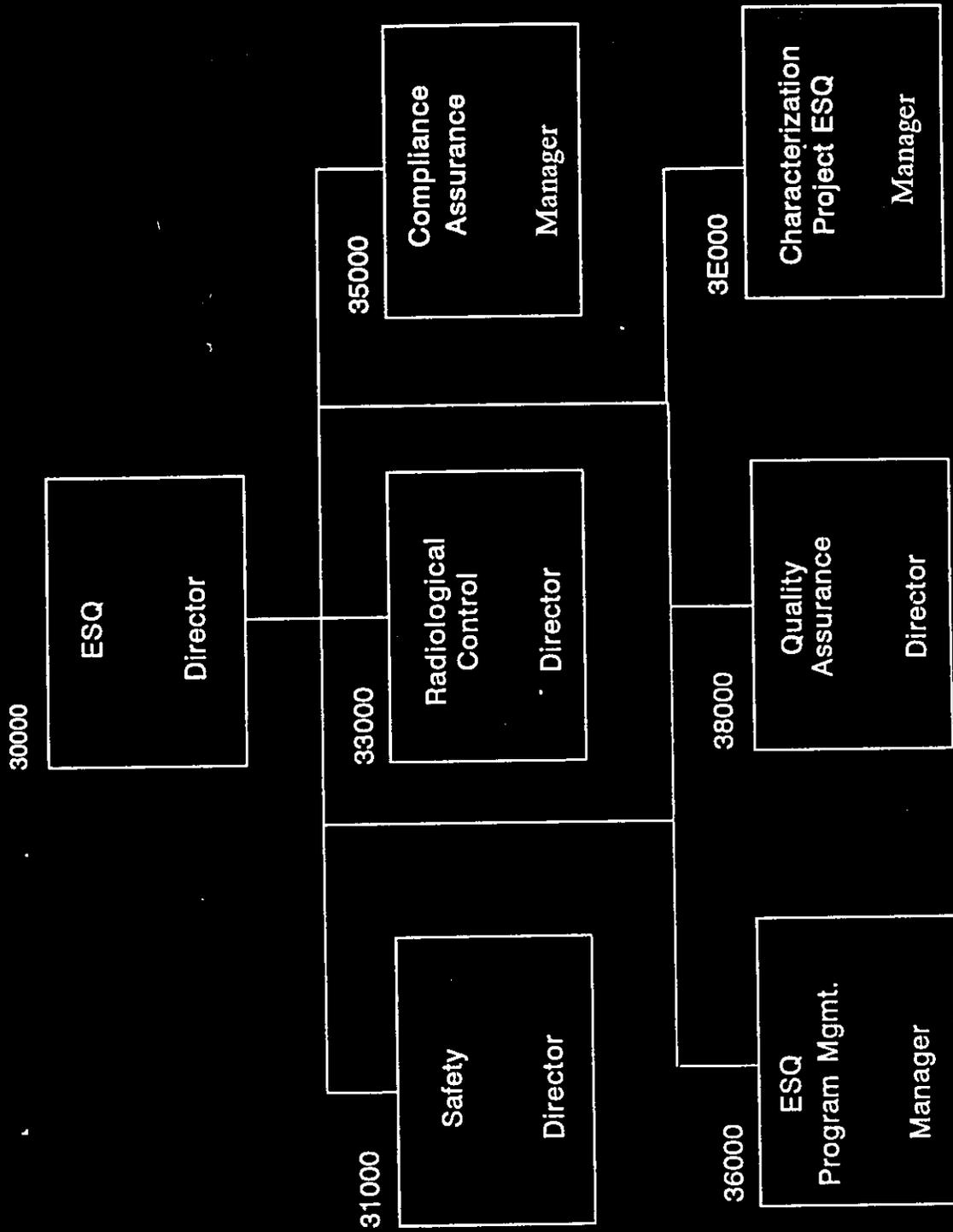


Figure 1-4. WHC ESQ Quality Assurance Organization.

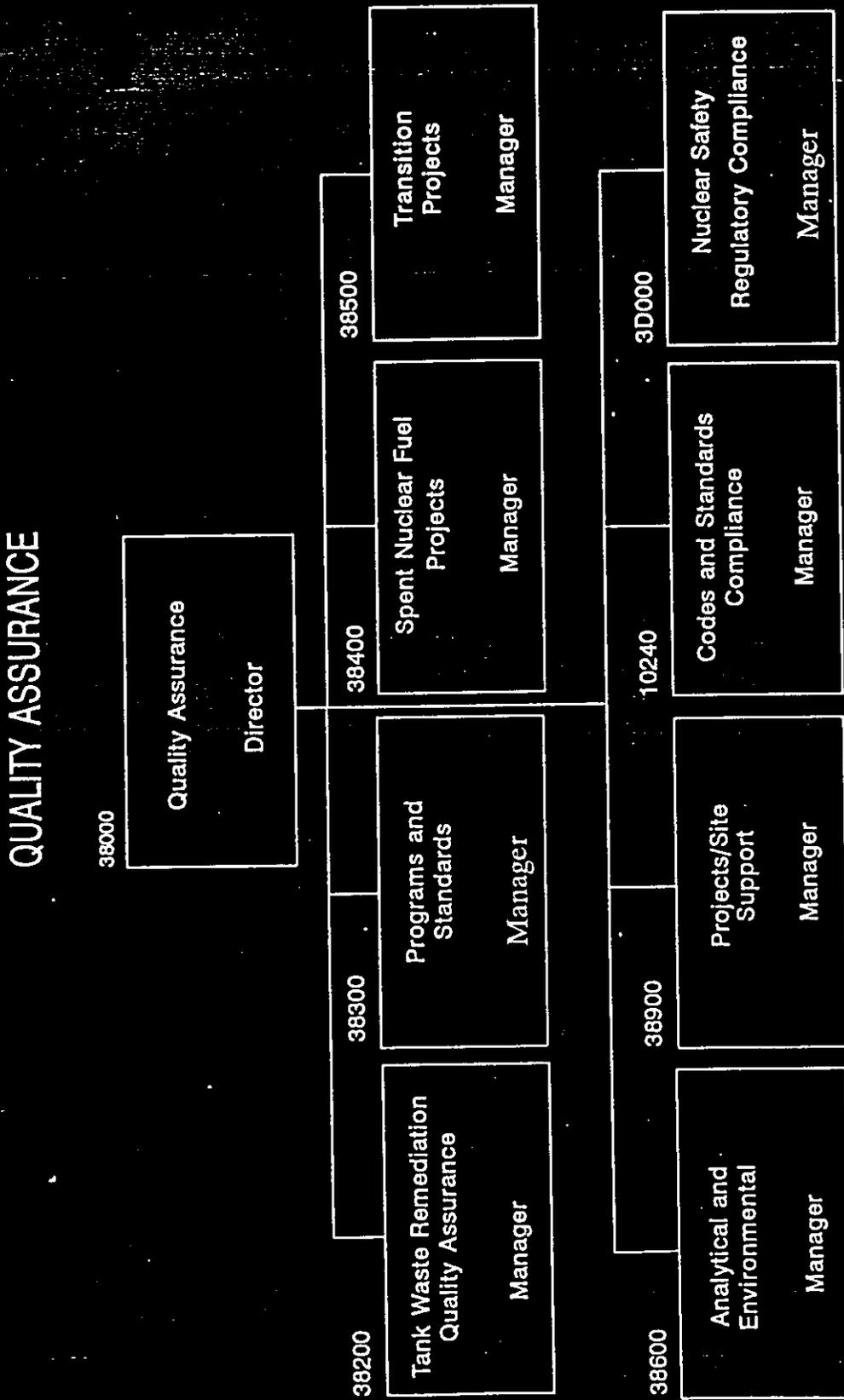
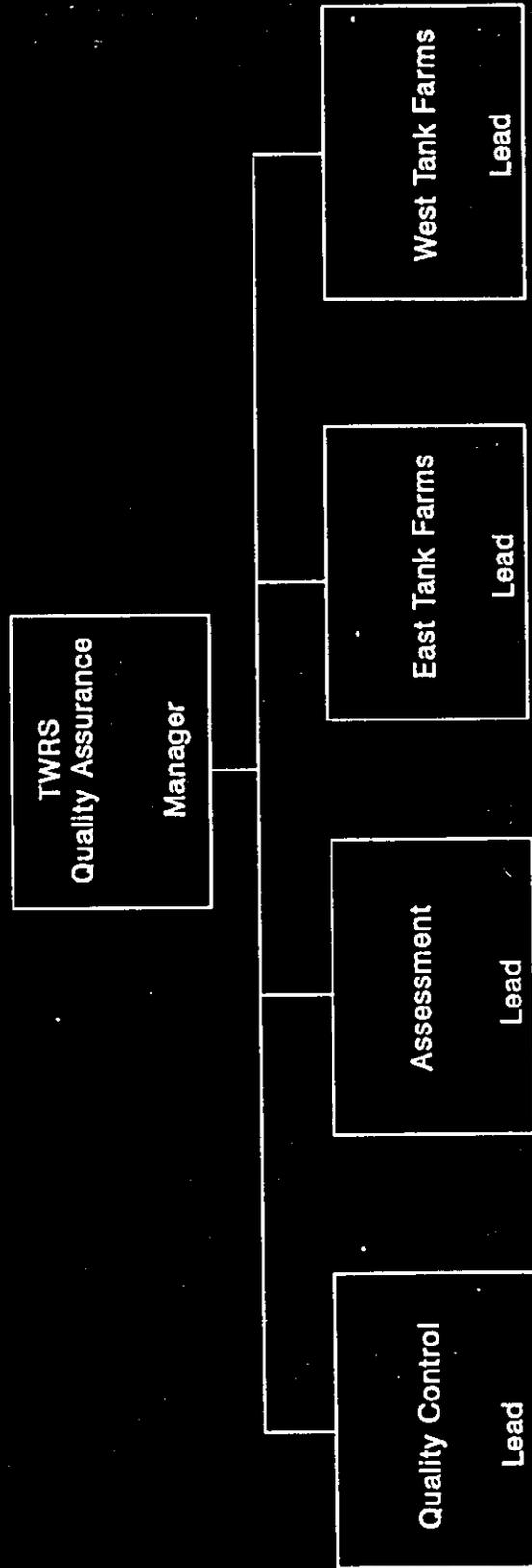


Figure 1-5. TWRS Quality Assurance Organization.

TANK WASTE REMEDIATION SYSTEM
QUALITY ASSURANCE



1.6 CHARACTERIZATION PROJECT QUALITY MANAGEMENT SYSTEM

The Characterization Project Quality Management System requirements apply to all Characterization Project organizations. The Characterization Project Quality Management System is planned and documented through these Quality Policies and supporting quality documents. The documented quality system will help us ensure that the Characterization Project product conforms to specified requirements.

Activities that affect quality shall be prescribed by these Quality Policies, through quality assurance program plans and quality assurance project plans, plant operating and standard operating procedures, tank characterization plans (TCPs), work packages, sampling and analysis plans (SAPs), and instructions or drawings appropriate for the work performed. The quality documents interlock with one another, providing users with an increasing level of detail appropriate for the systems being described.

Throughout these quality documents, we shall apply an appropriate level of control over quality affecting activities, commensurate with their importance--a graded approach to quality.

The QPs shall be understood, implemented, and maintained at all Characterization Project organizational levels. Characterization Project management, technical, administrative, and support personnel are responsible for implementing the Characterization Project Quality Management System described by these Policies.

Characterization Project employees shall not deviate from the requirements of the QPs, unless that deviation is justified. Deviations shall be approved by the Characterization Project ESQ manager or delegated Characterization Project quality assurance personnel.

1.7 CHARACTERIZATION PROJECT QUALITY MANAGEMENT SYSTEM DOCUMENTATION

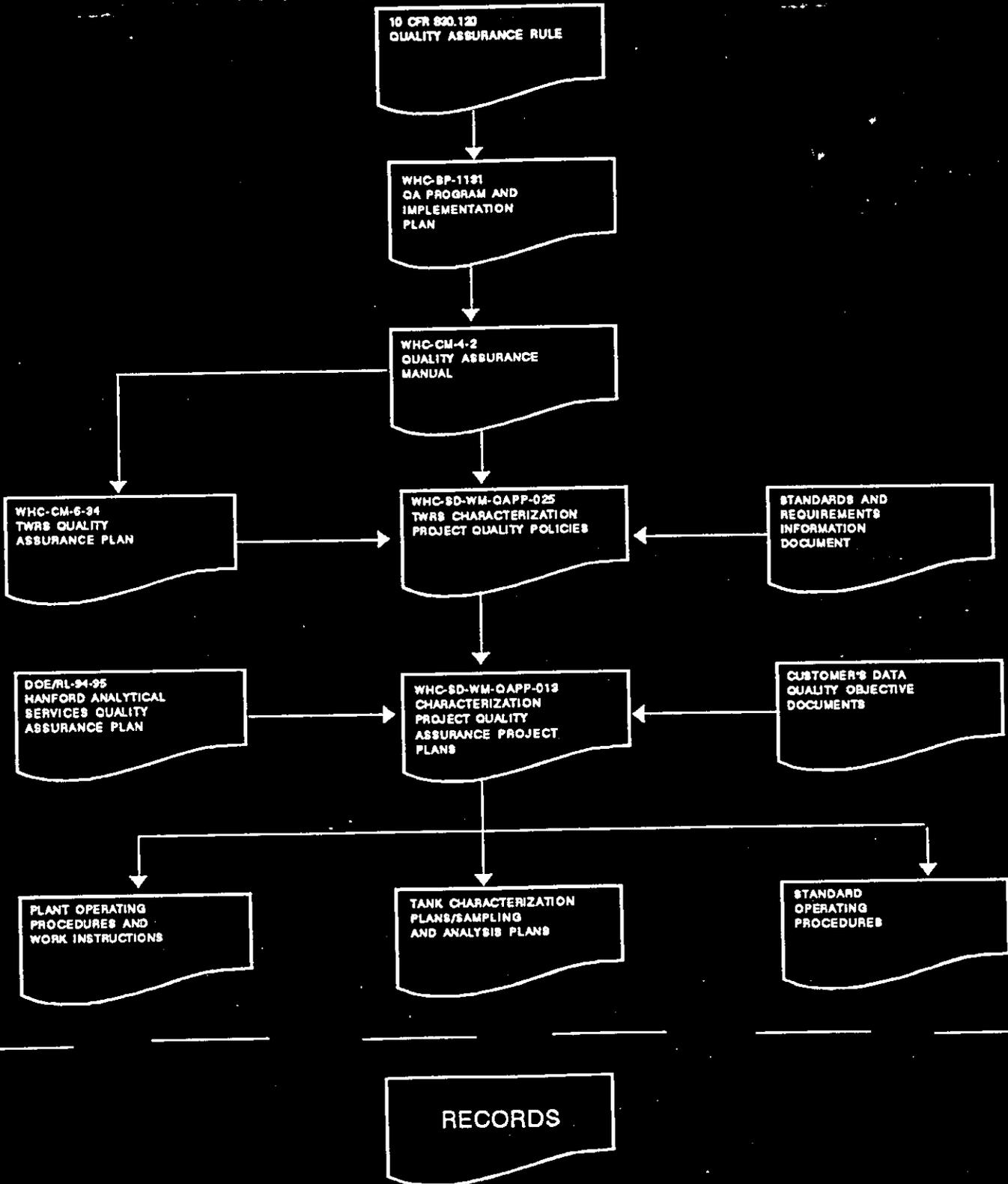
1.7.1 Quality System Documents

The Characterization Project quality system is described by several interrelated documents: the quality documents system. The quality documents system comprises four tiers in increasing level of detail: (1) The Characterization Project Quality Policies; (2) a number of quality assurance project plans or program plans; (3) various procedures, TCPs/SAPs, and work instructions; and (4) records. The hierarchy and relationship of these quality documents is shown in Figure 1-5.

1.7.2 Quality System Basis

This Characterization Project Quality Management System is designed to achieve our customer's quality requirements specified in 10 CFR 830.120, *Quality Assurance*. Additional customer quality requirements are derived from the *Hanford Federal Facility Agreement and Consent Order (Tri-Party Agreement)* (Ecology et al. 1994).

Figure 1-5. Tank Waste Remediation System Characterization Project Quality Documents System.



The interpretive authority for the customer's quality requirements is the Quality Assurance Department. The QA Department has described the plan to achieve the customer's quality requirements in WHC-SP-1131, *QA Program and Implementation Plan*. WHC-CM-4-2, the *Quality Assurance Manual*, is used at all company levels to implement WHC-SP-1131.

Consequently, this Characterization Project quality system is an adjunct to, and consistent with, the *Quality Assurance Manual*. Additional customer quality guidance originates from EPA QAMS-004/80, EPA QAMS-005/80, and EPA QA/G-4, including subsequent amendments or additions to those documents.

Within TWRS, quality is planned through WHC-CM-6-34, the *TWRS Quality Management Plan*. Among other TWRS topics, this document describes the functions, responsibilities, deliverables and interfaces for the Characterization Project.

The relationship of the customer's quality requirements to the Characterization QPs is shown in Table 1-1.

Table 1-1. Characterization Project Quality Policies Cross Reference Table.

Characterization Project Quality Policies	10 CFR 830.120 (c)
QP 0.1 Introduction	
QP 1.0 Management's Quality Policy, Responsibilities, and Quality System	(1)(i)
QP 2.0 Personnel Training and Qualification	(1)(ii)
QP 3.0 Quality Improvement Systems	(1)(iii)
QP 4.0 Document and Record Control	(1)(iv)
QP 5.0 Work Process, Item and Equipment Control	(2)(i)
QP 6.0 Design Process Control	(2)(ii)
QP 7.0 Procurement	(2)(iii)
QP 8.0 Inspection and Acceptance Testing	(2)(iv)
QP 9.0 Management Assessment	(3)(i)
QP 10.0 Independent Assessment	(3)(ii)

1.7.3 Characterization Project Quality Policies

Lead by the Project director, the Characterization Project senior management team establishes the Characterization Project quality goals and objectives through the Quality Policies. The QPs establish ten related quality policies - the Characterization Project quality management plan. Taken together, the QPs describe a Quality Management System, and what Characterization Project personnel must do to achieve quality.

1.7.4 Characterization Project Quality Policies Scope

The scope of the Characterization Project Quality Management System is limited to tank waste characterization work conducted by the organizations of the Characterization Project, and to our suppliers, as appropriate.

1.7.5 Characterization Project Quality Assurance Project Plans

Quality assurance project plans describe quality requirements for project tasks conducted by Characterization Project organizations or external suppliers (e.g., vapor sampling and analysis, core sampling, laboratory sample analysis, database management, sample archiving, etc.). Quality assurance project plans describe how the Quality Policies will be implemented, or deployed, for those specific project tasks. QA Project Plans can also specify both technical and quality requirements for conducting specific project activities, such as tank vapor sampling and analysis.

The Characterization Project maintains a number of quality assurance project plans in a combined document: WHC-SD-WM-QAPP-013, Characterization Quality Assurance Project Plan (to be completed). Other Characterization Project organizations (e.g. 222-S Laboratory) maintain separate quality assurance project plans. Additionally, requirements to achieve the Characterization Project quality objectives and incoming product quality are described in suppliers' quality assurance project plans, quality assurance program plans, and procurement documents. These must be consistent with Characterization Project management's quality goals and objectives.

Analytical laboratories performing work for the Characterization Project shall develop and implement quality assurance plans. These plans shall achieve the minimum quality requirements specified in DOE/RL-94-55, *Hanford Analytical Services Quality Assurance Plan* (HASQAP, RL 1994). If a conflict exists between the technical or quality requirements of the HASQAP and Characterization Project requirements, the Characterization Project requirements shall prevail.

1.7.6 Procedures, TCPs/SAPs and Work Instructions

Each organization within the Characterization Project, and external suppliers, shall develop and implement procedures and work instructions, as appropriate, for its work processes.

TCPs/SAPs are quality documents that provide instructions to field sampling teams and analytical laboratory personnel. TCPs/SAPs typically contain quality requirements for sample collection and laboratory methods.

1.7.7 Records

Records form the base of the quality documents system. Records provided documented evidence of achieved quality.

It shall be possible to determine Characterization Project data quality by evaluating appropriate Characterization Project records. We shall identify and maintain records that document conformance of characterization data to our requirements and to our customer's specifications.

1.7.8 Quality Assurance Program Index

A Quality Assurance Program Index (QAPI) identifies the implementing procedures required, in part, to achieve these Quality Policies. Implementing procedures are taken mainly from the *Quality Assurance Manual* and other WHC controlled manuals. The Characterization Project QAPI is shown in Appendix A.

1.8 CHARACTERIZATION PROJECT QUALITY MANAGEMENT SYSTEM REVIEWS

At least annually, the Characterization Project director and the director's management team shall review and document the overall effectiveness of its quality management system. System reviews are described in Quality Policy 9.0, MANAGEMENT ASSESSMENT.

In addition to assessments conducted by Characterization Project management, independent assessments of the Characterization Project will be conducted by an external organization, ESQ/Quality Compliance Assurance. These assessments are described in Quality Policy 10.0, INDEPENDENT ASSESSMENTS.

The Characterization Project director and management team shall annually review, revise as appropriate, and approve the Characterization Project Quality Policies. The QPs consists of ten policies and they may be revised by replacing individual policies, or by replacing the entire document.

Characterization Project managers shall review and approve quality assurance project plans and other quality documents for which they are responsible, as appropriate. Management approval of Characterization Project quality documents signifies a commitment by management to achieve specified quality requirements.

1.9 REQUIREMENTS AND RESPONSIBILITIES

1.9.1 Characterization Project Director

The Characterization Project director:

- Develops, authorizes and releases the Characterization Project Quality Policy statement. The director develops, approves and authorizes the Characterization Project Quality Management System and Quality Policies.
- Assesses and documents the effectiveness of the Characterization Project Quality Management System at least annually.

1.9.2 Characterization Project Managers

The Characterization Project managers:

- Approve the Quality Policies concurrent with the Characterization Project director.

- Implement the Characterization Project Quality Management System, Quality Policies, quality assurance project plans, and supporting quality documents.
- Ensure that the Quality Policies are understood by personnel within the managed organization.
- Develop and implement quality assurance project plans, as appropriate, for the organization managed. Quality assurance project plans shall implement the Quality Policies established by the Characterization Project director.
- Assess, at least annually, the effectiveness of the Characterization Project Quality Management System for the organization managed.

1.9.3 Characterization Project ESQ Manager

The Characterization Project ESQ manager:

- Maintains the Characterization Project Quality Management System as described by these Quality Policies.
- Develops, reviews and approves these Quality Policies prior to issuance and at least annually thereafter to incorporate changes and improvements.
- Reviews proposed changes to the Quality Policies.
- Resubmits the revised Quality Policies to the Characterization Project director for approval and authorization.

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QUALITY POLICY 2.0
PERSONNEL TRAINING AND QUALIFICATION

2.1 PURPOSE AND SCOPE

Quality Policy 2.0 establishes the Characterization Project's policy, requirements, and responsibilities for training and qualifying personnel.

2.2 POLICY

We shall train and qualify all personnel whose work processes affect product quality. Training and qualification shall ensure that personnel are capable of performing assigned work, before they attempt that work.

Training and qualification shall ensure that suitable proficiency is achieved initially and maintained thereafter. Training shall be provided to enable employees to adapt to changes in technology, methods, or job responsibilities.

Training and qualification shall be commensurate with the scope, complexity, and nature of the activities performed, and consistent with the education, experience, and proficiency of personnel.

2.3 REQUIREMENTS AND RESPONSIBILITIES

2.3.1 Characterization Project Managers

For the area managed, Characterization Project managers:

- Identify personnel to be trained and qualified.
- Identify specific job tasks that require qualification and commensurate training requirements to achieve qualification.
- Plan and provide personnel training as required.
- Qualify personnel on the basis of education, training, experience or other factors, and ensure that personnel have sufficient technical knowledge to perform assigned work.
- Maintain records of training and qualification.
- Periodically determine training effectiveness; modify training accordingly.
- Establish and maintain procedures, as required, to train and qualify assigned personnel, and to keep records of those processes.

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QUALITY POLICY 3.0
QUALITY IMPROVEMENT SYSTEMS

3.1 PURPOSE AND SCOPE

Quality Policy 3.0 establishes the Characterization Project's policy, requirements, and responsibilities to prevent conditions adverse to quality, to control nonconforming conditions, to take corrective action(s) when appropriate, and to continuously improve process and product quality.

3.2 POLICY

The Characterization Project is comprised of many work processes. To assure product quality, inputs to these processes shall meet our established requirements. When inputs do not meet requirements, nonconforming items or services shall be controlled to prevent their inadvertent use.

We shall establish quality controls for critical process characteristics, and those characteristics shall be monitored to ensure that processes meet our specifications. If problems occur, we shall take corrective action(s), as appropriate, to permanently remove those problems.

We shall monitor process outputs so that we can identify nonconforming products. Defect detection and correction are important, but not optimal methods to assure quality. We shall use various systems to measure the performance of our processes and we shall focus our efforts on process improvement to prevent quality failures.

3.2.1 Control of Nonconforming Items, Services, Processes, and Products

We shall specify appropriate quality requirements and control purchased items, services, and finished products that do not conform to those specified requirements. We shall prevent inadvertent use of nonconforming products in the characterization process, and the release of nonconforming data to the customer.

We shall identify, document, segregate when practical, report, evaluate, and disposition nonconforming items and products.

We shall continuously evaluate our work processes to ensure conformance with process specifications. Appropriate action shall be taken to prevent process failures. In the event that processes produce defective product, those work processes shall be stopped and appropriate action(s) taken to prevent recurrence.

We shall notify those organizations that are affected by nonconforming items, services and products. The Westinghouse Hanford Company (WHC) Nonconformance Report shall be used to record, report, and document nonconformances, and to disposition nonconformances and descriptions of rework or repair to items, services, and products that do not conform to specifications.

All Characterization Project and subcontractor personnel shall have sufficient freedom and authority to identify nonconforming items, services and products.

3.2.2 Corrective Action

The cause for recurring nonconformances, or nonconformances which have a significant negative impact on quality, shall be determined and permanently removed from processes through corrective action(s). We shall determine causes before preventive measures are planned and implemented.

We shall put in place controls to ensure that conditions adverse to quality are promptly identified and that effective corrective action(s) is taken.

The resources that we expend to permanently eliminate nonconformances, shall be commensurate with the significance of the problem.

All Characterization Project and subcontractor personnel shall have sufficient freedom and authority to identify nonconforming items and processes, identify and suggest improvements to work processes, and take corrective action(s), as appropriate.

3.2.3 Process Improvement and Problem Prevention

We shall collect and analyze data from nonconformance reports, corrective action(s), assessments and other process, item, and service quality measurements, as appropriate. Our objective is to quantify performance limitations and determine which processes need improvement.

As an aid to predicting and preventing quality problems before they occur, we shall conduct trend analysis.

Employees at all organizational levels shall participate in quality improvement, either individually or in teams, to improve process or product quality.

3.3 REQUIREMENTS AND RESPONSIBILITIES

3.3.1 Characterization Project Managers

For the area managed, Characterization Project managers:

- Establish a culture and work environment that encourage employees to improve processes and product quality. Provide the systems, framework, motivation, resources, and time for employees to improve process and product quality.
- Train assigned employees in the areas of identifying nonconforming items and services and completing corrective action(s).

- Detect and disposition nonconformances. Ensure that nonconformances which significantly impair quality or which recur are permanently corrected.
- Measure, gather, and analyze appropriate information and data to determine whether product and service quality is improving. Take action before quality problems occur.

3.3.2 Characterization Project Employees

All Characterization Project employees shall have the freedom, authority, and responsibility to identify, document, segregate when practical, report, evaluate, and disposition nonconforming items, products, and services.

All Characterization Project employees shall have the freedom, authority, and responsibility to improve work processes and to take corrective action(s) when required.

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QUALITY POLICY 4.0
DOCUMENT AND RECORD CONTROL

4.1 PURPOSE AND SCOPE

Quality Policy 4.0 establish the Characterization Project's policy, requirements, and responsibilities to control documents and records of quality affecting activities.

4.2 POLICY

We shall write down our quality policies, plans and requirements, and those procedures needed to implement those policies, plans and requirements. These documents form the written basis of our quality system. Our purpose is to communicate our quality objectives to everyone in the Characterization Project organization. We shall also provide our suppliers with documents specifying requirements for procured products and services, so they understand what quality we require from them.

Because it is not possible to determine data quality by just observing the finished product, we shall specify and control records that provide documented evidence of achieved quality required by our customer. We shall also require our suppliers to maintain and control specific records that document product quality.

4.2.1 Document Control

Documents are used to plan and control systems, projects and work. Documents are written at three levels of the Quality System: 1) Quality Policies; 2) Quality assurance program and project plans; and 3) Work instructions and procedures.

Records, which can be considered a fourth level of the quality documents system, are generated as an outcome of conducting work processes. Records are retained to provide proof of achieved quality.

Characterization Project divisions, departments, and projects shall ensure that our quality system documents (Quality Policies, quality assurance program plans, quality assurance project plans, SOPs, POPs, TCPs/SAPs, work instructions, design documents, procurement documents) are reviewed for adequacy, approved for release by authorized personnel, and distributed to and used at the location where the work is being performed.

Characterization Project document reviewers and approvers shall have access to pertinent background information on which to base their reviews.

Changes, other than minor changes, to Characterization Project Quality Management System documents shall be reviewed and approved by the same organization that performed the original review and approval, unless specifically designated otherwise.

4.2.2 Records and Documentation

We shall document and keep records of Characterization Project activities that affect quality. These records shall demonstrate to ourselves and to our customer that, for example, Characterization Project employees have received proper training, correct procedures are in place where work is being performed, sampling and analysis processes are in control, and purchased items and services meet specified requirements.

Because we use subcontractors to design and fabricate sampling equipment, conduct chemical analyses, write quality documents, and conduct other work needed to characterize tank waste, we shall maintain appropriate subcontractor documentation as part of the Characterization Project's records.

Records that we retain to document quality shall be legible, accurate, dated (including revision dates), clean, readily identifiable to the product or service involved, complete, and maintained in an orderly manner. Records and documentation may be stored via hard copy, or electronically or magnetically, but they must be readily retrievable.

We shall identify (list), specify, prepare, and maintain records that provide documentary evidence of achieved quality.

We shall protect those records against tampering, damage, deterioration, or loss.

When we develop or write design specifications, procurement documents, test procedures, and operational procedures, they shall specify the records to be generated, supplied, or maintained as a result of those activities.

4.3 REQUIREMENTS AND RESPONSIBILITIES

4.3.1 Characterization Project Director

The Characterization Project director is responsible for developing, authorizing and releasing the Characterization Project Quality Policy statement.

The Characterization Project director develops, approves and authorizes the Characterization Project Quality Management System as described by the Quality Policies.

4.3.2 Characterization Project Managers

Characterization Project managers:

- Develop and approve the Characterization Project Quality Policies.
- For the organization managed, develop, prepare, approve and authorize the release of quality assurance program plans, quality assurance project plans, laboratory quality assurance plans, standard operating procedures, plant operating procedures, and work instructions.

- For the organization managed, control Characterization Project Quality Management System documents according to approved document control procedures.
- For the organization managed, identify and authorize personnel who prepare, review, and issue original or changed documents and ensure that documents are reviewed for adequacy, completeness, and correctness prior to approval and issuance.
- Ensure that pertinent issues of appropriate documents are available at all locations where the prescribed work process is performed.
- Through appropriate quality assurance project plans, quality assurance program plans, or other documents, describe how quality documents and records will be identified, collected, indexed, filed, stored, maintained, and dispositioned.

4.3.3 Characterization Project ESQ Manager

The Characterization Project ESQ manager is responsible for developing, reviewing for adequacy, approving, maintaining, controlling and releasing the Quality Policies.

4.3.4 Authorized Copyholders of Quality Documents

All copyholders of quality documents are responsible for updating their assigned documents by removing obsolete material and inserting current material.

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QUALITY POLICY 5.0

WORK PROCESS, ITEM AND EQUIPMENT CONTROL

5.1 PURPOSE AND SCOPE

Quality Policy 5.0 establishes the Characterization Project's policy, requirements, and responsibilities to control work processes, equipment and critical process inputs that affect the quality of our services and products.

5.2 POLICY

All work is accomplished by a process. A process is a value-added transformation involving people and other resources. The outputs are the results of the process. Characterizing tank waste is a network of processes, the outcome of which is characterization data reported to customers and to the Tank Characterization Database.

In order to meet our customer's quality requirements for tank waste characterization data--that it is technically valid and defensible--critical inputs to characterization processes shall be specified and controlled. Inputs to the characterization process (see Figure E-1) are personnel (training and knowledge), equipment, procedures, work environment, supplies, samples, and performance specifications and technical requirements (e.g., DQOs).

We shall design, conduct, monitor and control work processes to produce outputs which conform to established specifications. Work processes shall be performed in a suitable work environment using suitable equipment.

5.2.1 Administrative Controls and Technical Standards

Work processes that we use to characterize waste shall be performed to established, and currently accepted, technical standards and to adequate administrative controls and documented procedures.

5.2.2 Use of Instructions and Procedures

We shall conduct processes which directly affect quality under controlled conditions using approved instructions, procedures, checklists, travelers, drawings, or other appropriate means.

So that they will be understood and used, we shall write procedures and instructions at a level and detail appropriate for the importance and complexity of the work process being performed.

Procedures and work instructions shall be readily available for use where the activity described by those instructions is performed.

5.2.3 Identification and Control of Items

Incoming products, materials, and items that are critical to the success of Characterization Project work processes shall conform to specified requirements.

When necessary, we shall identify the status of incoming critical process items to indicate that those items conform to established requirements. We shall maintain records which document that conformance.

We shall establish the identity of critical inputs to the tank waste characterization process so that we can trace those inputs back to their source, if necessary. Purchase documents for critical process items shall be retained in our project records.

When we collect tank characterization samples, we shall assign each sample a permanent number that is traceable throughout the handling, analysis, data reporting, data storage, and sample archiving processes. To ensure sample traceability and integrity, standardized Chain-of-Custody forms shall be completed by field personnel whenever samples are collected or transferred.

We, and our suppliers, shall keep records identifying critical process equipment used to collect samples, or to make measurements in the field, or to analyze samples of tank waste or vapors in the laboratory. If problems arise, we can determine which samples or data may be affected by equipment problems.

Because we must be certain that characterization processes are conducted by properly trained and qualified personnel, we shall record the names of personnel who perform or verify critical characterization process work.

In order to demonstrate that processes are in control during sampling and analysis, we shall record the results of quality control protocols used to verify sampling and test methods. This quality control data shall be traceable to specific tank samples and analysis reports. Our quality control and records systems shall enable us to trace tank sampling events and analytical reports to the people doing the work, the methods that were used to collect and analyze the samples, and to demonstrate that those processes were in control at the time of sample collection and analysis.

5.2.4 Maintenance and Preservation of Items

We shall implement controls to verify, store, and maintain tank characterization samples and other environmentally sensitive materials. These controls shall ensure that samples, or other items, and their associated documents and records, will be protected against deterioration, loss, damage, or other events that would render the materials unsuitable for use. We shall maintain this protection during the collection, storage, handling, preparation, analysis, and archiving of tank characterization samples.

To ensure the defensibility of characterization data, implement chain-of-custody procedures, and maintain the integrity of tank waste samples, performing laboratories shall be maintained as secured areas at all times. These laboratories will limit access to only authorized personnel and registered, accompanied visitors.

When an item or sample must be stored under specific environmental conditions (e.g., refrigerated), we shall maintain, monitor, and document those conditions. When a sample, test item, or associated document is to be held secure, storage and security arrangements shall be provided to protect the conditions and integrity of the secured items. Sampling media and tank waste samples and test items shall be maintained in a manner to minimize accidental or unintentional alteration.

When a tank waste sample, test item, or other material is lost, damaged, or otherwise becomes unsuitable for use, that event shall be reported to the appropriate Characterization Project customer and recorded using the appropriate records or forms. We shall develop controls to ensure that unsuitable damaged or deteriorated items are not used.

Laboratories that we use to conduct analyses of tank waste samples shall properly receive, document, and record the arrival of sampling media. Items and samples to be tested shall be uniquely identified upon receipt through documented log-in procedures. It is our policy that all performing laboratories shall accept custody of tank characterization samples, verify submitted information, and make the appropriate entries on standardized Chain-of-Custody forms and other records. If there are any abnormalities, departures, or nonconformances from standard conditions, the performing laboratories shall record that information upon receipt of samples and notify appropriate personnel.

Laboratories that we use to analyze Characterization Project samples are required to have, and use, documented procedures for receiving, retaining, and archiving Characterization Project samples.

5.2.5 Calibration and Maintenance of Equipment

Devices and equipment used during the collection, analysis, measurement, testing, and reporting of tank waste samples usually require periodic calibration and maintenance.

In order to assure the validity of Characterization Project samples and data, we shall control, uniquely identify, calibrate and maintain the equipment used in sampling and analysis processes. We shall use this equipment in a manner that ensures that measurement uncertainty is known and consistent with the required measurement capability. We shall select and use equipment that is of the correct type, and that has the proper range, accuracy, and tolerance for its intended purpose.

We shall specify the method and interval of calibration for each measuring and test equipment based on the type of equipment, stability characteristics, required accuracy, intended use, and other conditions affecting measurement control. We shall calibrate our measuring and test equipment prior to use or at prescribed intervals that conform to sampling, analytical, test method, or calibration procedures, and whenever the accuracy of measuring and test equipment is suspect.

The Characterization Project and subcontractor's calibration and verification systems shall be traceable to national standards of measurement, when available. When traceability to national standards does not exist, we shall document satisfactory evidence of correlation of results for calibration.

Except for measuring and test equipment that requires calibration or calibration verification prior to each use (e.g., emission spectrometers, mass spectrometers, etc.), we shall identify measuring and test equipment by use of a suitable indicator or approved identification record to show current calibration status. Whenever any equipment requiring calibration is determined to be out of calibration, previous results shall be evaluated to determine the validity of previously accepted tests or measurements.

Field, laboratory, and other equipment used in the characterization process shall be provided with periodic and routine preventive maintenance to prevent process and quality failures. Maintenance shall be conducted in accordance with manufactures', or other suitable recommendations. We shall maintain appropriate records of equipment maintenance to document acceptable operating conditions.

We shall tag or segregate defective or out-of-calibration equipment and devices, or equipment subjected to mishandling, and not use them until they have been recalibrated and verified as suitable. Equipment that is found to be consistently out-of-calibration shall be repaired or replaced.

5.3 REQUIREMENTS AND RESPONSIBILITIES

5.3.1 Characterization Project Managers

For the area managed, Characterization Project managers:

- Identify, develop, verify, assess, approve, maintain, and control appropriate quality documents in order to implement these Quality Policies and to control work processes.
- Ensure that personnel are provided with necessary training, suitable equipment, suitable working environment, and administrative controls to accomplish work processes.
- Monitor processes that affect quality to ensure that specified requirements are met and processes conform to documented procedures.
- Review and assess work and related information to ensure that the required quality is being achieved and to identify processes that require improvement.
- Establish and implement processes to identify, control, and maintain critical items, and to control supplies and items that have a limited shelf life. Identify items, samples, and materials that are held in storage in a manner that is consistent with the planned duration and conditions of storage.

- Provide the necessary equipment and administrative controls to collect, transport, receive, store, secure, analyze, and maintain tank characterization samples and materials according to Characterization Project requirements, customer requirements, and regulatory requirements.
- Ensure the identification and traceability of the following: tank characterization sampling media, samples and testing materials, critical process input materials, equipment calibration and calibration standards, personnel performing and verifying measurements, measuring equipment, quality control and verification data, test methods, analytical reports, and test results.
- Provide employees with the equipment required for the correct performance of test procedures and measurements. Ensure that measuring and test equipment is capable of the precision and bias (accuracy) for those measurements and tests.
- Develop, implement, and maintain a documented system for calibration and verification of measuring and test equipment used in the characterization process.
- Develop and maintain current lists or other records identifying each measuring and test device by name; type; serial or identification number; date and condition when received; manufacturer's instructions; service date; location, description, or method of calibration; acceptance criteria; action to be taken when results are not satisfactory; frequency of calibration required; and date of last calibration and date when next calibration is required.
- Ensure that measuring and test equipment is maintained according to documented procedures and that maintenance records are maintained, including records of any damage, malfunction, modification, or repair.
- Maintain calibration records of measuring and test equipment.
- Ensure that all procedures, instructions, manuals, and reference data are current and available to Characterization Project personnel at the site of sampling, test and measurement activities.

5.3.2 Characterization Project Employees

Characterization Project employees:

- Understand the requirements of the work performed and the capability of the equipment, systems, and processes used.
- Accept responsibility for achieving the requirements of work performed.
- Follow approved procedures and processes.

- Report to appropriate management those processes which do not conform with the Characterization Project's specifications or the customer's specifications, or which can be improved to reduce costs or improve quality.
- Maintain the care and custody of the customer's samples and materials during the collection, receipt, storage, analysis, disposal, or return of those samples and materials.
- Safeguard measuring and test equipment hardware and software from adjustments which would invalidate calibration settings.

QUALITY POLICY 6.0
DESIGN PROCESS CONTROL

6.1 PURPOSE AND SCOPE

Quality Policy 6.0 establishes the Characterization Project's policy, requirements, and responsibilities to control and verify tank characterization sampling designs and equipment engineering designs.

6.2 POLICY

Sampling systems, sampling plans, and sampling equipment must be designed in order to characterize tank wastes. To minimize rework, prevent failures and the collection of unneeded or unsuitable samples or data, and to ensure that specified requirements are met, we shall control the design of these systems, items and plans.

6.2.1 Design Standards and Design Inputs

When we design tank sampling or other equipment, or tank characterization sampling plans, we shall use correct standards and engineering/scientific principles. Applicable design bases and requirements shall be identified, documented, and incorporated into our designs.

To prevent the collection of unnecessary tank waste samples, customers must use the U.S. Environmental Protection Agency (EPA) Data Quality Objective process, or equivalent, to determine and specify tank characterization data requirements.

The EPA Data Quality Objective process, as applied to characterizing tank wastes, is described in WHC-EP-0732, *TWRS Data Quality Objective Strategy*. This document describes how to develop and transform a statement of stakeholder problems/issues into a design which specifies the type, quantity and quality of characterization data required. Additional tank characterization design inputs can be developed using WHC-SD-WM-TA-164, *Tank Waste Characterization Basis*.

The Characterization Project requires the completion of the DQO process by the customer to ensure that client requirements are adequately defined and documented. The DQO process provides the necessary interface between the Characterization Project and the customer to resolve differences between capabilities and data requirements. The DQO is the prerequisite to entry into the characterization process.

6.2.2 Organizational and Technical Interfaces

When we design equipment or sampling processes, the appropriate personnel shall participate in the design. We shall maintain effective communication and appropriate levels of involvement with affected personnel throughout the design process.

When we send information about designs to other people or organizations, we shall keep records of those transmittals. These transmittals shall identify what we are sending, its status, and what needs to be done with the transmitted information.

6.2.3 Design Process

When we develop a design, we shall identify those processes, components and structures which are critical to the quality, reliability or safety of the designed system. TCPs and sampling and analysis plans shall be based upon the customer's requirements for the type, quantity and quality of information required.

6.2.4 Design Output

When we complete the design of an item or system, or a plan to collect and analyze tank waste samples, we shall produce a suitable document to record that design. Design documents include drawings, specifications, Tank Characterization Plans, sampling and analysis plans and test/inspection plans.

6.2.5 Design Reviews and Verification

We shall verify our designs to ensure that they meet established requirements and the requirements of their intended customer. Designs shall be evaluated by analysis against customer requirements, comparisons with similar proven designs (if available), use of alternate calculations, performance of qualification tests, and other competitive or benchmark standards.

Characterization Project personnel who review and verify designs shall be qualified to do so; they shall be different from personnel who complete the original design.

Before tank characterization samples are collected, equipment fabricated, or designs implemented, we shall verify, validate and approve our designs.

6.2.6 Design Changes

When we propose a change to a final, approved design, we shall subject those proposed changes to commensurate controls that were applied to the original design. We shall assure the validity of the new design, considering how the proposed change will affect the original structure, system, or component.

6.2.7 Design Documentation and Records

We shall generate, collect, store and maintain design documentation and records, which provide evidence that the design and design verification processes were performed according to our and to our customer's requirements.

6.3 REQUIREMENTS AND RESPONSIBILITIES

6.3.1 Characterization Project Managers

Characterization Project managers:

- Ensure that Characterization Project engineering and sampling and analysis designs are defined, controlled, and verified.
- Ensure that applicable design inputs are appropriately specified in a timely manner and correctly translated into design documents.
- Identify and control design interfaces.
- Verify adequacy of design.
- Control design changes in a manner commensurate with the control of the original design.

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QUALITY POLICY 7.0
PROCUREMENT

7.1 PURPOSE AND SCOPE

Quality Policy 7.0 establishes the Characterization Project's policy, requirements, and responsibilities for ensuring that purchased items and services conform to established requirements and perform as specified.

7.2 POLICY

We shall control quality affecting inputs to the characterization process that are purchased from external suppliers. The control of inputs from internal suppliers is described in Quality Policy 5.0, "Work Process Control."

To assure process output quality, we shall control purchased process inputs. The extent of control that we apply shall depend on how important that product or service is to the success of the characterization process output. "Controlled" is defined as: (1) establish the proper requirements for the service or product that we need, (2) select vendors that can always meet our requirements, and (3) confirm that suppliers did, in fact, provide the quality that we specified, initially and thereafter.

7.2.1 Established Specifications

In order to obtain quality items and services, we shall first establish appropriate specifications for those items and services. We shall define quality as conformance to our established requirements. We shall establish and maintain specifications for critical services and materials that we purchase.

7.2.2 Supplier Qualifications

We shall select suppliers of critical items and services on the basis of their ability to meet our requirements, including quality characteristics for the items and services that we purchase. But we shall also evaluate suppliers on their ability to continuously meet our quality system requirements, because we must always purchase defect-free products.

We shall establish and maintain records or lists of suppliers that can meet and exceed our specifications and quality requirements. The extent of a supplier's quality system that we require, shall depend on the type and use of the item or service being purchased.

We shall qualify suppliers on the basis of one or more of the following criteria:

- Type of product supplied
- Onsite assessment
- Examination of product samples, or product test results
- Past performance for identical or similar items/services

- Demonstrated capability or documented experience of users
- Vendor-supplied product data
- Objective evidence of quality supplied by vendors.

7.2.3 Procurement Documents

When we purchase an item or service, we shall use standardized procurement documents. The documents shall clearly define the specified technical requirements to communicate the required quality of the purchased item, product, or service. Procurement documents shall contain data, as appropriate, describing the scope of work to be performed; the product ordered including where applicable; precise identification; applicable drawings, codes, standards, procedures, and inspection instructions; and other relevant technical data including the quality system standard to be applied to the product.

7.2.4 Supplier Performance Determined from Inspection and Acceptance Testing

Procurement documents shall identify any tests, inspection, or acceptance requirements for monitoring and evaluating the supplier's performance initially and thereafter. Quality Policy 8.0 describes our requirements for specifying and conducting inspection and testing of purchased items and services.

7.2.5 Supplier Performance Determined from Audits and Assessments

To ensure initial and continued performance of our suppliers, procurement documents shall provide for access to the suppliers' facilities and records for inspections or audits by Characterization Project personnel, or designated representatives, when we deem appropriate. Quality Policy 10.0 describes our requirements for conducting audits or assessments of vendors or suppliers.

7.3 REQUIREMENTS AND RESPONSIBILITIES

7.3.1 Characterization Project Managers

Characterization Project managers:

- For the area managed, as needed and appropriate, identify critical products and services that will be obtained through WHC procurement services. Provide that information to WHC procurement services.

7.3.2 Characterization Project ESQ Manager

Characterization Project ESQ manager:

- Assists in supplier reviews, audits, and assessments, as necessary.
- Maintains records of supplier reviews, audits, and assessments conducted by Characterization Project quality representatives.

QUALITY POLICY 8.0
INSPECTION AND ACCEPTANCE TESTING

8.1 PURPOSE AND SCOPE

Quality Policy 8.0 establishes the Characterization Project's policy, requirements, and responsibilities for inspection and testing of incoming, in-process, and finished items, services and processes and documenting the results of those verifications.

8.2 POLICY

8.2.1 Inspection and Acceptance Testing Planning

Through procurement documents and implementing procedures, we shall plan inspections or tests necessary to verify conformance of products, items, processes, and computer programs, or to demonstrate satisfactory performance of service received.

We shall specify or conduct inspections and acceptance tests only on those products, items, processes, and computer programs that are quality affecting or critical to the success of the process for which they will be used.

8.2.2 Measurement and Inspection of Quality Characteristics

When we write procurement documents and standard operating procedures, we shall specify the quality characteristics to be measured, inspected or verified, if any, and the methods that we shall use to conduct verification.

Characteristics selected shall be quality affecting. The type and extent of testing/inspection shall depend on the type of process, product or service, and, where appropriate, on the record of a supplier's previously demonstrated performance.

8.2.3 Documents and Records

We shall prepare and maintain records of our inspections and tests that document the conformance of items, processes, and products to specified requirements.

8.2.4 Receiving Inspection

Critical process items, products, and services that we receive shall be verified according to procurement documents and/or test inspection plans to ensure conformance to specified requirements. We shall not use or release critical incoming products or services until they have been verified as conforming with our requirements.

We shall segregate and hold critical incoming products that require inspection, laboratory or physical testing until those items meet acceptance requirements, or otherwise are dispositioned if found to be nonconforming. Materials pending inspection or acceptance testing shall be identified with WHC "HOLD" tags, or other equivalent means.

8.2.5 In-Process Measurement, Inspection and Verification

The TWRS Characterization Project plant operating or standard operating procedures or work instructions shall specify any quality characteristics to be measured, inspected or verified during the collection of tank waste samples, in-situ or laboratory measurements.

These procedures and instructions shall identify any mandatory hold points requiring verification of quality characteristics of an item or process.

Laboratories that characterize waste tank samples shall perform in-process verification of quality characteristics through self review, peer review, and supervisory review of measurement processes and completed data. The objective is to assure conformance with analytical process quality control and Data Quality Objective requirements. The review process shall be documented. Data shall not be released to Characterization Project personnel until verification of data is complete.

8.2.6 Training and Qualification Requirements

We shall use trained and qualified personnel to conduct verification, inspection and acceptance testing. These people shall have the freedom and responsibility to report nonconforming items, services, products and out-of-control processes.

8.2.7 Nonconforming Products and Services

We shall identify, as appropriate, rejected products and services with a WHC "REJECT" tag or other equivalent means. Disposition of nonconforming product and services is described in QP 3.0, Section 3.2.1, "Control of Nonconforming Items, Services, Processes and Products".

Before dispositioning incorrect or defective products and services, products and affected items shall be marked, or otherwise identified, or segregated if possible, to prevent their inadvertent use.

8.2.8 Final Inspection

We shall conduct final verifications and inspections of our completed products and services according to procedures to ensure conformance to specified requirements.

All Characterization Project employees are responsible for verifying that their final work process output conforms to specified requirements.

Those having final responsibility for a system, structure, or component shall verify that systems, structures, or components conform to specified requirements.

8.2.9 Inspection and Testing Equipment

We shall calibrate and maintain equipment that we use to conduct tests or inspections to determine acceptance of items, processes, or products.

Our quality requirements for measuring and test equipment used for inspection and acceptance testing are not different for similar equipment used for controlling work processes. These requirements are specified in QP 5.0, "Work Process Control," Section 5.2.5, "Calibration and Maintenance of Equipment."

8.3 REQUIREMENTS AND RESPONSIBILITIES

8.3.1 Characterization Project Managers

For the area managed, Characterization Project managers:

- Determine appropriate verification or inspection points; establish what will be inspected and commensurate acceptance criteria.
- Develop, prepare, implement, and maintain quality assurance project plans or procedures that describe in-process and final inspection, verification, and test procedures.
- Ensure that no data, information, or report is released until final inspection and verification demonstrate product conformance to specified requirements, and that all associated data and documents that confirm conformance to requirements are available and authorized.

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QUALITY POLICY 9.0
MANAGEMENT ASSESSMENTS

9.1 PURPOSE AND SCOPE

Quality Policy 9.0 establishes the Characterization Project's policy, requirements, and responsibilities to conduct management assessments.

9.2 POLICY

All levels of Characterization Project management shall periodically assess the organization for which they are responsible and determine the effectiveness of the Characterization Project Quality Management System. Our objective is to learn how well the quality system and other management systems are working and to take action to improve systems and quality.

The Characterization Project senior management team shall retain overall responsibility for management assessments. Managers at all levels shall participate in assessments. The responsibility to conduct assessments shall not be delegated, and the direct participation of each manager is required.

The outcome of assessments shall be documented, and management shall take prompt action to correct identified quality or management problems.

Management shall conduct follow-up evaluations of actions taken to determine the effectiveness of the respective action.

9.3 REQUIREMENTS AND RESPONSIBILITIES

9.3.1 Characterization Project Directors and Managers

Characterization Project directors and managers:

- Annually review and document the overall effectiveness of the Characterization Project Quality Management System and Quality Policies.
- Retain overall responsibility for management assessments.
- For the area managed, conduct management assessments. Identify and document performance problems and conditions adverse to quality. Identify opportunities for quality improvement.
- Take prompt action to resolve problems, deficiencies, and improve processes and quality. Follow up management actions to evaluate effectiveness.

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QUALITY POLICY 10.0
INDEPENDENT ASSESSMENT

10.1 PURPOSE AND SCOPE

Quality Policy 10.0 establishes the Characterization Project's policy, requirements, and responsibilities to conduct independent assessments.

10.2 POLICY

10.2.1 Independent Assessment

Independent assessments are a management tool to advise and inform management of the implementation and adequacy of quality systems. Assessments determine if planned quality systems are implemented and if those systems are producing processes, products, and services which meet and exceed the customer's requirements.

The intent is that management, once informed, will take prompt action to resolve conditions adverse to quality.

The Characterization Project ESQ group shall participate with, or plan and conduct assessments for, Characterization Project management to:

- Monitor work processes to determine if the customer's requirements are being achieved
- Evaluate products and services being produced to determine if they conform to specified requirements
- Identify abnormal performance and potential problems
- Identify opportunities, areas, and processes that can be improved.

ESQ/Quality Compliance Assurance shall conduct independent assessments of the Characterization Project, as determined by ESQ. These assessments shall determine the implementation of our planned quality arrangements, and the effectiveness of the Characterization Project Quality Management System.

10.2.2 Assessment Types

The Characterization Project shall participate in the following basic assessment types:

- Quality system audits and assessments
- Inspections
- Surveillances
- Laboratory performance evaluation audits.

10.2.3 Assessment Personnel

Personnel who conduct assessments shall not be directly responsible for the work processes and systems which they assess.

Personnel who conduct assessments shall be qualified and technically knowledgeable in the subject matter assessed.

Personnel who conduct assessments shall have sufficient authority and freedom from line organizations to carry out their responsibilities.

Personnel who conduct assessments shall focus on results and quality improvement.

10.2.4 Assessment Performance

We shall conduct assessments which are planned, scheduled, and documented according to established procedures or checklists.

We shall schedule assessments depending on how important the process is to the success of the Characterization Project. Also, those processes or areas that have been problematic shall receive increased assessments.

We shall conduct assessments to determine the effectiveness of the quality system and to verify conformance of activities with implementation plans, procedures, and quality specifications.

We shall evaluate elements of the quality system against specified requirements. We shall examine objective evidence to verify that quality requirements are being effectively implemented.

Laboratories that analyze tank waste samples for the Characterization Project shall participate in performance evaluation audits to assess the bias (accuracy) of total measurement systems or component parts thereof.

10.2.5 Assessment Results and Reports

We shall document the results of assessments and report to appropriate levels of management within the assessed organization. Adequate information shall be documented so meaningful action can be taken.

10.2.6 Management Responses and Actions

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

- Immediate action to correct (fix) a deficiency
- Root cause identification
- Actions taken to prevent recurrence
- Lessons learned shared with others in the organization.
- Actions taken to improve process or product quality.

10.3 REQUIREMENTS AND RESPONSIBILITIES

10.3.1 Characterization Project Managers

Characterization Project managers:

- Review assessment, surveillance, and audit reports. Investigate adverse findings and take timely, appropriate action.
- Ensure that assessment personnel have sufficient authority and organizational freedom to make the assessment process meaningful and effective.

10.3.2 Characterization Project ESQ Manager

Characterization Project ESQ manager:

- Assists in Characterization Project assessments, as necessary.
- Maintains records of assessments conducted by Characterization Project quality representatives.
- Schedule and perform assessments on the basis of the status of the activity and its importance to the success of the Characterization Project.
- Communicate the results of assessments to appropriate management using a written and signed report.
- Evaluate the adequacy of management responses to assessment deficiencies and conduct follow-up evaluations to verify that corrective action(s) has been accomplished, as scheduled.
- Maintain records of assessment plans, reports, written replies, and records of corrective action completion conducted by Characterization project quality representatives.

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- WHC-CM-2-1, *Procurement Manual and Procedures*, Westinghouse Hanford Company, Richland, Washington.
- WHC-CM-3-5, *Document Control and Record Management Manual*, Westinghouse Hanford Company, Richland, Washington.
- WHC-CM-4-2, *Quality Assurance Manual*, Westinghouse Hanford Company, Richland, Washington.
- WHC-CM-6-1, *Standard Engineering Practices*, Westinghouse Hanford Company, Richland, Washington.
- WHC-EP-0732, *TWRS Data Quality Objective Strategy*, Westinghouse Hanford Company, Richland, Washington.
- WHC-SD-WM-TA-163, *Tank Waste Characterization Process*, Westinghouse Hanford Company, Richland, Washington.

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WHC-SP-1131, *QA Program and Implementation Plan*, Westinghouse Hanford Company, Richland, Washington.

12.0 GLOSSARY

ABBREVIATIONS AND ACRONYMS

DQO	data quality objective
DST	double-shell tank
EPA	U.S. Environmental Protection Agency
ESQ	Emergency, Safety and Quality
POP	plant operating procedure
QA	quality assurance
QAP	quality assurance plan
SAP	sampling and analysis plan
SOP	standard operating procedure
SST	single-shell tank
TCDB	tank characterization database
TCP	tank characterization plan
TCR	tank characterization report
TWRS	Tank Waste Remediation System
WHC	Westinghouse Hanford Company

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APPENDIX A
QUALITY ASSURANCE PROGRAM INDEX

Table 1-2. Characterization Project Quality Assurance Program Index

QA Elements	10CFR 830.120	WHC-CM-4-2	WHC-SD-WM QAPP-25	Controlled Manuals
Quality Assurance Program	1 (i)	QR 1.0 QR 2.0	QP 1.0	CM-1-1, CM-1-2 CM-1-3 Cm-5-4 CM-6-1 CM-6-2
Personnel Training and Qualification	1 (ii)	QR 2.0 QR 9.0 QR 10.0	QP 2.0	CM-1-4 CM-4-39 CM-5-4 CM-7-5
Quality Improvement	1 (iii)	QR 15.0 QR 16.0	QP 3.0	CM-1-4 CM-5-4
Documents and Records	1 (iv)	QR 4.0 QR 6.0 QR 17.0	QP 4.0	CM-1-3 CM-3-5 CM-5-4 Cm-6-1
Work Processes	2 (i)	QR 5.0 QR 8.0 QR 9.0 QR 11.0 QR 12.0 QR 13.0 QR 14.0	QP 5.0	CM-1-3 CM-3-5 CM-5-3 CM-5-4 CM-6-1 CM-6-2
Design	2 (ii)	QR 3.0	QP 6.0	CM-1-3 CM-3-5 CM-6-1 CM-6-2 WHC-IP-1026
Procurement	2 (iii)	QR 4.0 QR 7.0	QP 7.0	CM-1-3 CM-2-1 CM-2-2 Cm-5-4 CM-6-1 CM-6-2
Inspection and Testing	2 (iv)	QR 1.0 QR 11.0 QR 14.0	QP 8.0	CM-1-3 CM-2-1 CM-5-4 CM-6-1 CM-6-2
Management Assessments	3 (i)	QAI 2.4 QR 16.0 QI 16.3 QI 16.4	QP 9.0	CM-4-2 CM-5-4
Independent Assessments	3 (ii)	QAI 10.4 QI 10.4	QP 10.0	CM-4-2 CM-5-4

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