DOE/RW-0215

Office of Civilian Radioactive Waste Management

Quality Assurance Program Description Document

U.S. Department of Energy
Office of Civilian Radioactive Waste Management
Washington, DC

U.S. DEPARTMENT OF ENERGY

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

QUALITY ASSURANCE PROGRAM DESCRIPTION

FOR THE

CIVILIAN RADIOACTIVE WASTE MANAGEMENT PROGRAM

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OCRWM Office of Quality Assurance

4/13/90
Date

Approved
John W. Bartlett, Director
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4/13/90
Date

POLICY

The U.S. Department of Energy is authorized by the Nuclear Waste Policy Act (NWPA), as amended in 1987, to site, obtain a license for, construct, and operate a geologic repository and a monitored retrievable storage facility, and to provide for the safe transportation of radioactive waste to those locations. It is the policy of the Office of Civilian Radioactive Waste Management (OCRWM) that these obligations will be met through the implementation of quality assurance controls that complement management actions to achieve the level of quality needed for the safe transportation, storage, and disposal of high-level radioactive waste.

This quality assurance program meets the requirements of Title 10 of the Code of Federal Regulations (CFR) Parts 50, 60, 71, and 72. The quality assurance controls necessary to achieve the high level of quality demanded by the transportation and storage of radioactive waste are mandatory, imposed on, and implemented by, each organization participating in the program through DOE/RW-0214, Quality Assurance Requirements Document for the Civilian Radioactive Waste Management Program (QARD). The QARD provides the requirements for development of a consistent framework for implementing quality assurance programs at every level within the Civilian Radioactive Waste Management Program.

John W. Bartlett, Director
Office of Civilian Radioactive
Waste Management

Date

INTRODUCTION

This document serves as the quality assurance program description document for Program activities performed by OCRWM. This document and DOE/RW-0214, Quality Assurance Requirements Document for the Civilian Radioactive Waste Management Program (QARD) reflect OCRWM policies and serve as the principal documents of the Program quality assurance program.

Sections 1 through 19 of this document, including the appendices, describe the provisions established by OCRWM to meet the requirements of the QARD. The appendices to this document describe amplifications to the quality assurance program requirements in Sections 1 through 19 which are specific to the geologic repository, monitored retrievable storage, and transportation activities.

This QAPD is developed under the assumption that OCRWM will establish three Project Offices, one each for the Mined Geologic Disposal System (MGDS), Transportation, and the Monitored Retrievable Storage (MRS). Concurrently, the Yucca Mountain Project (YMP) Office, is the only established Project Office.

The definitions given in ANSI/ASME NQA-1-1989, and supplemented by the definitions in the QARD are applicable to this document.

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SECTION 1

ORGANIZATION

1.0 GENERAL

This section describes organizational responsibilities for the Office of Civilian Radioactive Waste Management (OCRWM) and identifies organizational interfaces among Headquarters (HQ), HQ-managed program participants, Project Offices, and Project Office-managed program participants, and other affected organizations. The assignment of responsibilities reflects the philosophy that the line organization achieves quality and the quality organization overviews to verify the achievement of quality.

It is the responsibility of the Director, OCRWM, to ensure that appropriate quality assurance requirements and procedural controls are in place to provide confidence that structures, systems, and components will not cause undue risk to either the health or safety of the public or of the workers associated with high-level radioactive waste transportation and monitored retrievable storage or geologic repository facilities. Quality assurance controls for the Program are instituted in a flow-down management approach from the Director, OCRWM, through the Associate Directors; Director, Office of Quality Assurance (OQA); and the Operation Office and Project Office managers to each program participant and affected organizations.

1.1 OCRWM ORGANIZATION

OCRWM includes Headquarters (HQ) which is comprised of: the Office of the Director and the Offices of Quality Assurance (OQA), Program Administration and Resources Management (OPARM), Facilities Siting and Development (OFSD), Systems Integration and Regulations (OSIR), and External Relations and Policy (OERAP). OQA, OPARM, OFSD, OSIR, and OERAP report to the Director, OCRWM. OCRWM is also comprised of Project Offices. The organizational relationship of each office is illustrated in Figures 1-1A through 1-1F. The functional and quality assurance program responsibilities for positions within OCRWM are described in the following paragraphs.

1.1.1 OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT (OCRWM)

The Director, OCRWM is directly responsible to the Secretary of Energy and has overall responsibility for carrying out the functions of the Secretary under the Nuclear Waste Policy Act of 1982, as amended.

The quality assurance responsibilities of the Director, OCRWM, are to:

(a) Establish and execute a quality assurance program that ensures compliance with applicable regulatory requirements, satisfies the performance objectives of the Program, and meets licensing requirements.

(b) Establish quality assurance policy direction and controls that are commensurate with DOE management and quality assurance policies.

(c) Approve DOE/RW-0214, Quality Assurance Requirements Document for the Civilian Radioactive Waste Management Program (QARD).

(d) Approve DOE/RW-0215, Quality Assurance Program Description for the Civilian Radioactive Waste Management Program (QAPD).

(e) Provide for adequate funding and resources to effectively support the quality assurance objectives of the Program

(f) Provide for, or participate in, interactions with Federal regulatory agencies; the nuclear industry; and affected States, local governments, and Indian Tribes on quality assurance matters specifically related to their areas of interest.

(g) Maintain awareness of quality assurance issues and problems and effect resolution.

(h) Provide for the annual assessment of the scope of, status of, adequacy of, and compliance to the quality assurance program by OCRWM management, who are independent of the Office of Quality Assurance.

(i) Retain responsibility for the quality of work delegated to program participants, such as contractors, agents, and consultants.

(j) Establish and administer a system to prevent the continuance of work where public health and safety may be at risk.

1.1.2 OFFICE OF QUALITY ASSURANCE (OQA)

1.1.2.1 Director, Office of Quality Assurance

The Director, OQA, reports directly to the Director, OCRWM, and has been delegated the management responsibility and authority to direct and control quality assurance functions to ensure that Program quality assurance objectives are consistently met. The Director, OQA, has direct access to, and maintains liaison with, the Director, OCRWM; the Associate Directors and management of other affected organizations. This reporting relationship provides the organizational freedom and authority to identify quality problems; initiate, recommend, or provide solutions; and prevent or control further processing, delivery, or use of nonconforming items or activities, until disposition is obtained.

The Director, OQA, is responsible for coordination, integration, and overview of Program quality assurance activities and for ensuring that appropriate quality management, policy, training, and verification controls are in place. The Director, OQA, has appropriate management and quality assurance knowledge and experience and has no responsibilities that prevent his full attention to quality activities. This position is independent from cost and schedule when opposed to safety and waste isolation-related concerns.

The responsibilities of the Director, OQA, are to:

(a) Establish integrated Program quality assurance policies and requirements in baselined or other controlled documents.

(b) Coordinate development of the OCRWM quality assurance program documents including the QARD, the QAPD, and quality assurance procedures.

(c) Provide quality assurance guidance and direction to affected organizations.

(d) Serve as the focal point for OCRWM's quality assurance activities; provide coordination with other OCRWM offices and the Nuclear Regulatory Commission (NRC); and assure that Program activities affecting quality are conducted in accordance with OCRWM policies and objectives and in compliance with NRC regulations.

(e) Overview Program quality assurance activities by conducting internal and external verifications and selectively participating in Operation Office and Project Office verification activities, such as assessments, readiness reviews, or audits.

(f) Review the quality assurance program descriptions (including revisions to and interpretations thereof) of HQ-managed program participants and other affected organizations, for compliance with established Program quality assurance policies and requirements, develop recommendations relative to acceptance and submit recommendations to appropriate Associate Directors for action.

(g) Review HQ procurement documents for inclusion of quality assurance requirements.

(h) Assure development and implementation of a quality assurance indoctrination program for all Program personnel.

(i) Establish and maintain the indoctrination and training requirements for OQA personnel.

(j) Establish and maintain a Program quality assurance information system to facilitate effective communication of the status of the quality assurance program; status of resolution of issues, trends, and significant conditions adverse to quality; and a summary of management overview results.

(k) Manage the OQA staff and QA direct-support contractors.

(l) Ensure that OQA personnel who perform activities affecting quality are qualified by experience or education to perform assigned tasks.

(m) Establish and administer the resolution of allegations program.

1.1.2.2 Project Office Quality Assurance Division Directors

The QA Division Director(s) functionally report to the Director, OQA, and administratively to the Project Office manager. These positions are delegated the responsibility and authority to direct and control Project Office quality assurance functions.

In addition to having similar responsibility to that of the Director, OQA, as delineated in Section 1.1.2.1 (c), (e), (g), (h), (j), (k), and (l), the Project Office QA Division Directors are responsible for the review of quality assurance program descriptions (including revisions and interpretations thereof) of Project Office-managed participants, developing recommendations relative to acceptance and submitting the recommendations to the Project Manager for action.

1.1.3 OFFICE OF PROGRAM ADMINISTRATION AND RESOURCES MANAGEMENT (OPARM)

The Associate Director, Program Administration and Resources Management (ADPARM), reports directly to the Director, OCRWM, and has primary responsibility for the development, implementation, and maintenance of a Program Management System (PMS), a program management information system, project decision schedule, and program schedule. ADPARM is also responsible for management and administration of the Nuclear Waste Fund and the Interim Storage Fund, establishing OCRWM's annual procurement plan and coordinating the preparation, review, approval, and control of procurement documents, with the DOE's Procurement and Assistance Management Directorate.

The Associate Director, ADPARM, has the following quality assurance program responsibilities:

(a) Establishing or approving the scope of OPARM activities affecting quality commensurate with the QARD. This includes the assignment of appropriate controls to OPARM activities.

(b) Coordinating with other involved Associate Directors, the OCRWM verification of HQ-managed program participants' and other affected organizations' activities affecting quality for which OPARM has the lead responsibility and ensuring that applicable quality assurance program documents are accepted by OPARM prior to initiation of work activities.

(c) Ensuring that information and data systems meet the QA records requirements specified in the QARD.

(d) Reviewing and approving the indoctrination and training requirements for OPARM Division Directors and providing for the indoctrination and training of all OPARM personnel through the Training Officer.

(e) Ensuring that OPARM personnel, who perform activities affecting quality are qualified by experience or training to perform assigned tasks.

(f) Acting on the Director, OQA's, recommendations relative to acceptance of OPARM-managed program participants' and other affected organizations' quality assurance programs.

(g) Developing and maintaining those implementing line and quality assurance procedures and other quality assurance documents and records for which OPARM has lead responsibility.

(h) Ensuring that adequate funds and resources are provided for OPARM activities affecting quality.

(i) Identifying and reporting quality-related issues and problems to the Director, OCRWM, and the Director, OQA, and effect resolution for quality-related issues and problems in OPARM's area of responsibility.

1.1.4 OFFICE OF FACILITIES SITING AND DEVELOPMENT (OFSD)

The Associate Director, Facilities Siting & Development (ADFSD), reports directly to the Director, OCRWM, and has primary responsibility for characterization of the geologic repository site and screening for a monitored retrievable storage (MRS) site; repository facility development, design, and engineering; exploratory shaft design and engineering; MRS facility design and technology development; waste package design and engineering; providing management oversight of and technical direction to

Program geoscience activities; and socioeconomic and institutional planning.

The ADFSD has the following quality assurance program responsibilities:

(a) Establishing or approving the scope of OFSD activities affecting quality, commensurate with the QARD.

(b) Ensuring that OFSD personnel who perform activities affecting quality are qualified by experience or training to perform assigned tasks.

(c) Evaluating results of activities that verify quality achievement within the scope of work assigned to OFSD.

(d) Assigning responsibility for the quality of delegated work, prior to initiating the work activities.

(e) Ensuring the technical adequacy of items and activities including the technical adequacy of procurement documents, for which OFSD has lead responsibility, and the implementation of effective management controls.

(f) Acting on the Director, OQA's recommendations relative to acceptance of OFSD-managed program participants' and other affected organizations' quality assurance programs.

(g) Coordinating with other involved Associate Directors, the OCRWM verification of HQ-managed program participants' and other affected organizations' activities affecting quality, for which OFSD has lead responsibility, and ensuring that applicable quality assurance program documents are accepted by OCRWM prior to initiation of work activities.

(h) Ensuring that adequate funds and resources are provided for OFSD activities affecting quality.

(i) Identifying and reporting quality-related issues and problems to the Director, OCRWM, and the Director, OQA, and effect resolution for quality-related problems and issues in OFSD's area of responsibility.

(j) Developing and maintaining those implementing line and quality assurance procedures and other quality assurance documents and records for which the OFSD has lead responsibility.

(k) Reviewing and approving indoctrination and training requirements for OFSD Division Directors.

The responsibility for management of the Yucca Mountain Project Office rests with the ADFSD. The Manager, Yucca Mountain Project

Office, reporting to the ADFSD is delegated the responsibility for activities performed by the Project Office.

1.1.5 OFFICE OF SYSTEMS INTEGRATION AND REGULATIONS (OSIR)

The Associate Director, Systems Integration & Regulations (ADSIR), reports directly to the Director, OCRWM, and has primary responsibility for planning, managing, and overseeing integration of the Civilian Radioactive Waste Management system; managing programs for the development of technologies for use at the geologic repository or MRS (e.g. storage modules); developing a transportation system; preparation and coordination of Environmental Impact Statements; and serving as the official contact for the Program with the NRC and other regulatory agencies.

OSIR also develops licensing plans, license applications, and safety analysis reports for the geologic repository and MRS facility.

The ADSIR, has the following quality assurance program responsibilities:

(a) Establishing or approving the scope of OSIR activities affecting quality, commensurate with the QARD. This includes the assignment of controls to OSIR activities.

(b) Ensuring that OSIR personnel, who perform activities affecting quality, are qualified by education or experience to perform assigned tasks.

(c) Evaluating results of activities that verify quality achievement within the scope of work assigned to OSIR.

(d) Assigning responsibility for the quality of delegated work, prior to initiation of work activities.

(e) Ensuring the technical adequacy of items and activities including the technical adequacy of procurement documents, for which OSIR has lead responsibility and the implementation of effective management controls.

(f) Acting on the Director, OQA's, recommendations relative to acceptance of OSIR-managed, program participants' and other affected organizations' quality assurance programs.

(g) Coordinating with other involved Associate Directors, the OCRWM verification of HQ-managed, program participants' and other affected organizations' activities affecting quality, for which OSIR has the lead responsibility and ensuring that applicable quality assurance program documents are accepted by OCRWM prior to initiation of work activities.

(h) Ensuring that adequate funds and resources are provided for OSIR activities affecting quality.

(i) Identifying and reporting quality-related issues and problems to the Director, OCRWM, and the Director, OQA, and effect resolution for quality-related problems and issues in OSIR's area of responsibility.

(j) Developing and maintaining those implementing line and quality assurance procedures and other OCRWM quality assurance program documents and records for which the OSIR has lead responsibility.

(k) Reviewing and approving indoctrination and training requirements for OSIR Division Directors and providing for the indoctrination and training of Project personnel through the Training Office.

1.1.6 OFFICE OF EXTERNAL RELATIONS AND POLICY (OERAP)

The Associate Director, External Relations and Policy (ADERAP), reports directly to the Director, OCRWM, and has primary responsibility within OCRWM for developing overall program policy and strategy and is generally responsible for all external OCRWM interactions.

The ADERAP, is responsible for the following quality assurance program activities:

(a) Establishing or approving the scope of OERAP activities affecting quality commensurate with the QARD. This includes the assignment of controls to OERAP activities.

(b) Ensuring that OERAP personnel, who perform activities affecting quality are qualified by experience or training to perform assigned tasks.

(c) Assigning responsibility for the quality of delegated work, before the initiation of work activities.

(d) Acting on the Director, OQA's recommendations relative to acceptance of OERAP-managed, affected organizations' quality assurance programs.

(e) Ensuring that adequate funds and resources are provided for OERAP activities affecting quality.

(f) Reviewing and approving indoctrination and training requirements for OERAP Division Directors.

(g) Developing and maintaining those implementing line and quality assurance procedures and other OCRWM quality assurance program documents and records for which the OERAP has lead responsibility.

(h) Identifying and reporting quality-related issues and problems to the Director, OCRWM, and the Director, OQA, and effect resolution for quality related issues and problems in OERAP's area of responsibility.

(i) Coordinating with other involved Associate Directors, the OCRWM verification of HQ-managed program participants' and other affected organizations' activities affecting quality, for which OERAP has lead responsibility, and ensuring that applicable quality assurance program documents are accepted by OCRWM prior to initiation of work activities.

1.1.7 Project Office Managers

Project Office Managers are delegated the authority, responsibility, and accountability for Project Office cost, schedule, technical, and quality performance, for activities performed by the Project Office. The following responsibilities directly affecting the quality assurance program are specifically included:

(a) Approving plans as necessary to establish the basis for orderly achievement of technical and quality objectives.

(b) Ensuring adequate staffing and funding for essential technical and quality assurance activities.

(c) Ensuring effective implementation of the OCRWM quality assurance program by line management.

(d) Monitoring quality assurance program implementation on an ongoing basis and taking remedial action as necessary.

(e) Authorizing readiness reviews of Project Office-managed activities.

(f) Ensuring that Project Office personnel, who perform activities affecting quality, are qualified by education or experience to perform assigned tasks.

(g) Evaluating results of activities that verify quality achievement within the scope of work assigned to the Project Office.

(h) Assigning responsibility for the quality of delegated work, prior to initiation of work activities.

(i) Ensuring the technical adequacy of items and activities for which the Project Office has lead responsibility and the implementation of effective management controls.

(j) Concurring with the Project Office, QA organization's recommendations for the approval or disapproval of affected

organizations' quality assurance programs for which the Project Office has lead responsibility.

(k) Ensuring that applicable quality assurance program documents are approved, prior to initiation of work activities.

(l) Identifying and reporting quality-related issues and problems to responsible management and the QA organization, and effect resolution of quality related problems and issues in Project Office's area of responsibility.

(m) Developing and maintaining those line and administrative procedures and other OCRWM quality assurance program documents, and records for which the Project Office has lead responsibility.

(n) Reviewing and approving indoctrination and training requirements for his/her immediate subordinates and providing for the indoctrination and training of Project personnel through the Project training officer.

(o) Ensuring that activities are performed in an environmentally acceptable manner.

1.1.8 OCRWM DIVISION DIRECTORS

The OCRWM Division Directors report to the appropriate Associate Directors or the Project manager, as applicable, and have the following quality assurance program responsibilities.

(a) Establishing the scope of quality assurance activities and requirements for those activities under their purview, obtaining the approval of the Associate Director, or Project manager, as applicable.

(b) Ensuring that personnel who are under the direction of the Division Directors and perform activities affecting quality are qualified by experience or training to perform assigned tasks.

(c) Ensuring, by using methods that verify quality achievement, the technical adequacy of items and activities and the effectiveness of management controls.

(d) Coordinating with other involved OCRWM Divisions, the performance of quality verification activities.

(e) Ensuring adequate resources are available for quality achievement and verification activities.

(f) Identifying and reporting quality related issues and problems that affect, or potentially affect, the Division's activities, to the Associate Director or Project Manager, as appropriate, and obtaining resolution.

(g) Developing and maintaining those implementing line and quality assurance procedures and other quality assurance program documents and records for which the Division has lead responsibility.

(h) Reviewing and approving indoctrination and training requirements for Branch Chiefs and other personnel under their supervision.

1.1.9 BRANCH CHIEFS

The Branch Chiefs report to the Division Directors and have the following quality assurance program responsibilities.

(a) Ensuring that technical personnel under their direction and who perform activities affecting quality, are qualified by experience or training to perform assigned tasks.

(b) Identifying indoctrination and training requirements for Branch personnel.

(c) Ensuring the technical adequacy of items and activities within their area of responsibility.

(d) Coordinating the verification of quality achievement of technical activities of OCRWM and affected organizations that are within their area of responsibility.

(e) Reporting quality-related issues and problems that affect, or potentially affect, activities of the Branch to the Division Director and obtaining satisfactory resolution.

1.1.10 ORGANIZATIONAL INTERFACES

The organizational interfaces between OCRWM, and affected organizations are described in the appendices. Interfaces and the flow of Program direction and quality assurance overview direction from OCRWM to Project Offices and other affected organizations are illustrated in Figure 1-2.

1.1.10.1 OCRWM-managed Affected Organizations

Quality assurance requirements for each OCRWM-managed affected organization are identified in the appropriate procurement documents. OCRWM provides overview of each affected organization's quality assurance activities, by various verification methods, such as reviews, audits, and surveillances.

OCRWM direct-support contractors perform activities affecting quality under controls of the OCRWM quality assurance program. OCRWM direct-support-contractor activities include:

(a) program management, institutional, technical, scientific, and quality assurance support,

(b) records management services related to the licensing support system.

1.1.10.2 Operations Offices and DOE Offices

The Operations Offices and DOE Offices (e.g., Office of Environmental Restoration and Waste Management) Managers have overall line management responsibility and accountability for implementation of assigned tasks. Each Office Manager or Assistant Secretary or equivalent establishes a management organization, and delegates responsibility and authority for management and direction of Program tasks.

The Office Manager or Assistant Secretary or equivalent, has direct, primary responsibility and accountability for the execution and implementation of Program tasks in accordance with established management plans. In addition, the Office Manager is the point of contact for the flow of information to and from the Director, OCRWM, and other affected organizations and is responsible for implementing the quality assurance program.

Interfaces between Offices and affected organizations are addressed in quality assurance program descriptions and the implementing line and quality assurance procedures.

The Office Manager or Assistant Secretary or equivalent, identifies a position for directing and managing the respective quality assurance programs. These positions are occupied by individuals with appropriate management and quality assurance knowledge and experience and have:

(a) A responsibility and authority level equal to or higher than the highest-level, line manager responsible for performing activities affecting quality.

(b) Sufficient independence from cost and schedule.

(c) Responsibility for recommending approval of quality assurance program descriptions.

(d) No other duties or responsibilities unrelated to quality assurance that would prevent full attention to quality assurance matters.

(e) Authority to identify quality problems.

(f) Responsibility for initiating, recommending, or providing solutions to problems.

Areas of responsibility assigned to Offices are listed herein:

(a) Institutional planning, analysis, and management integration of the transportation systems; providing regulatory and administrative support, such as review of regulations on an as-needed basis; quality assurance support; and international program support.

(b) Preclosure performance assessments and waste package studies.

(c) Review of transportation-cask development, engineering development, and the waste form.

(d) Materials characterization.

(e) Technical support for waste isolation, characterization, and systems integration activities.

(f) Geosciences, shielding, systems integration, operations, and public-relations support.

(g) Technical support for postclosure performance assessment work.

(h) Geoscientific support and defense-waste studies.

1.1.11 Delegation of Work

Responsibility for the overall Program is retained by the Director, OCRWM. The tasks of establishing and implementing selected parts of the overall OCRWM quality assurance program for work associated with the Program have been delegated to Project Managers as indicated in Figure 1-3.

1.1.12 Resolution of Disputes

Differences of opinion involving quality assurance concerns at a given organizational level are brought to the attention of management at that level and, if not resolved, are elevated progressively to the Director, OQA, and, if necessary, to the Director, OCRWM.

1.1.13 Resolution of Allegations

A system is being established that provides individuals a means of registering an allegation of inadequate quality to OCRWM without fear of reprisal. Each allegation concerning inadequate quality will be investigated by personnel who are independent of the affected activity.

The investigation results are to be made available to the individual who registered the concern.

This system is available to employees of affected organizations and persons outside the Program. Employees of an affected organization are encouraged to use this system only when adequate resolution of a concern that involves potential inadequate quality cannot be obtained through normal reporting channels.

1.1.14 Stop-Work Authority

Stop-work authority at OCRWM is vested in line management whenever imminent danger to personnel is involved or continued work will produce results that are not in accordance with Program requirements or would be considered unacceptable. The stop-work process is delineated in approved procedures.

QAPD

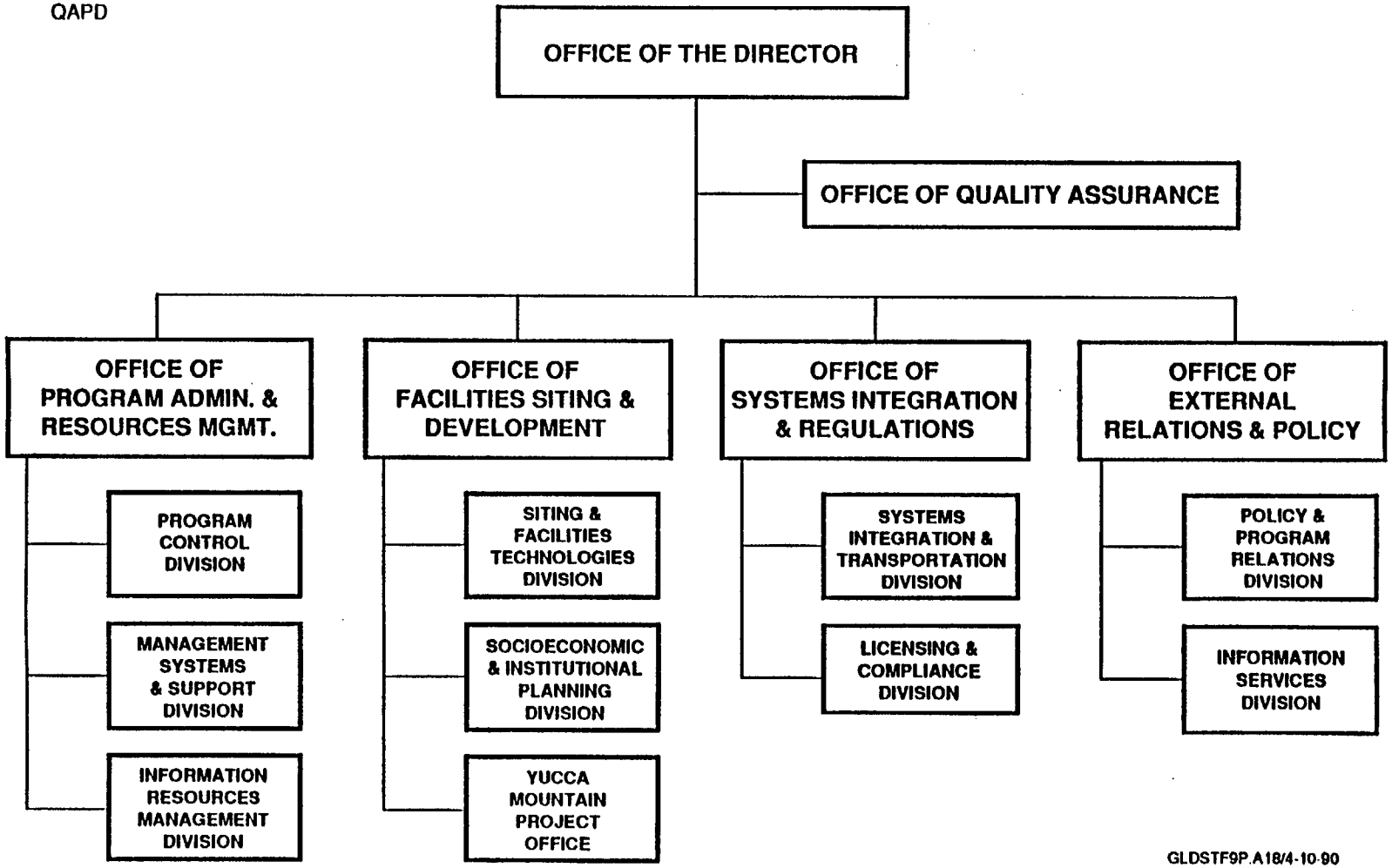

Figure 1-1A. Office Of Civilian Radioactive Waste Management Organization.

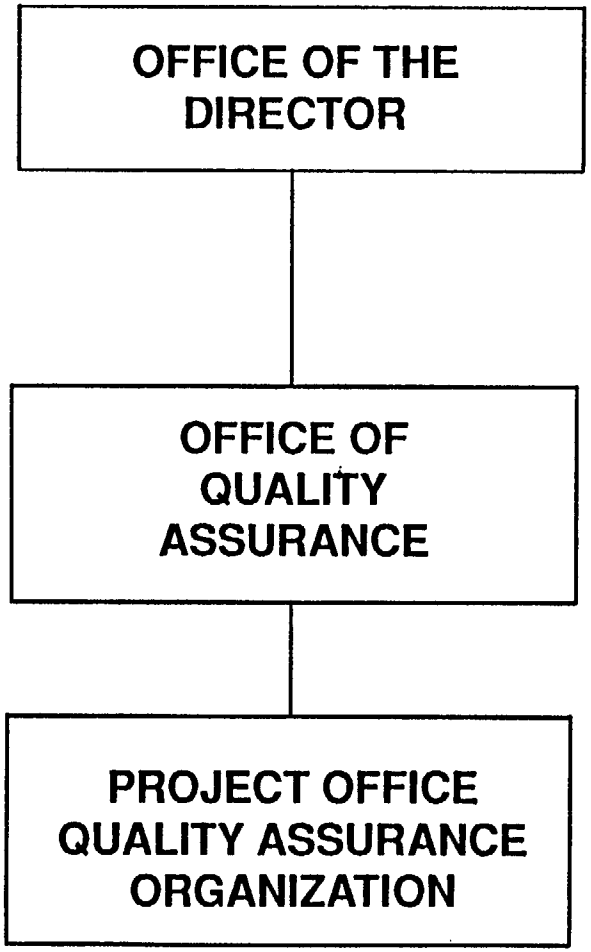

Figure 1-1B. Office of Quality Assurance Organization.

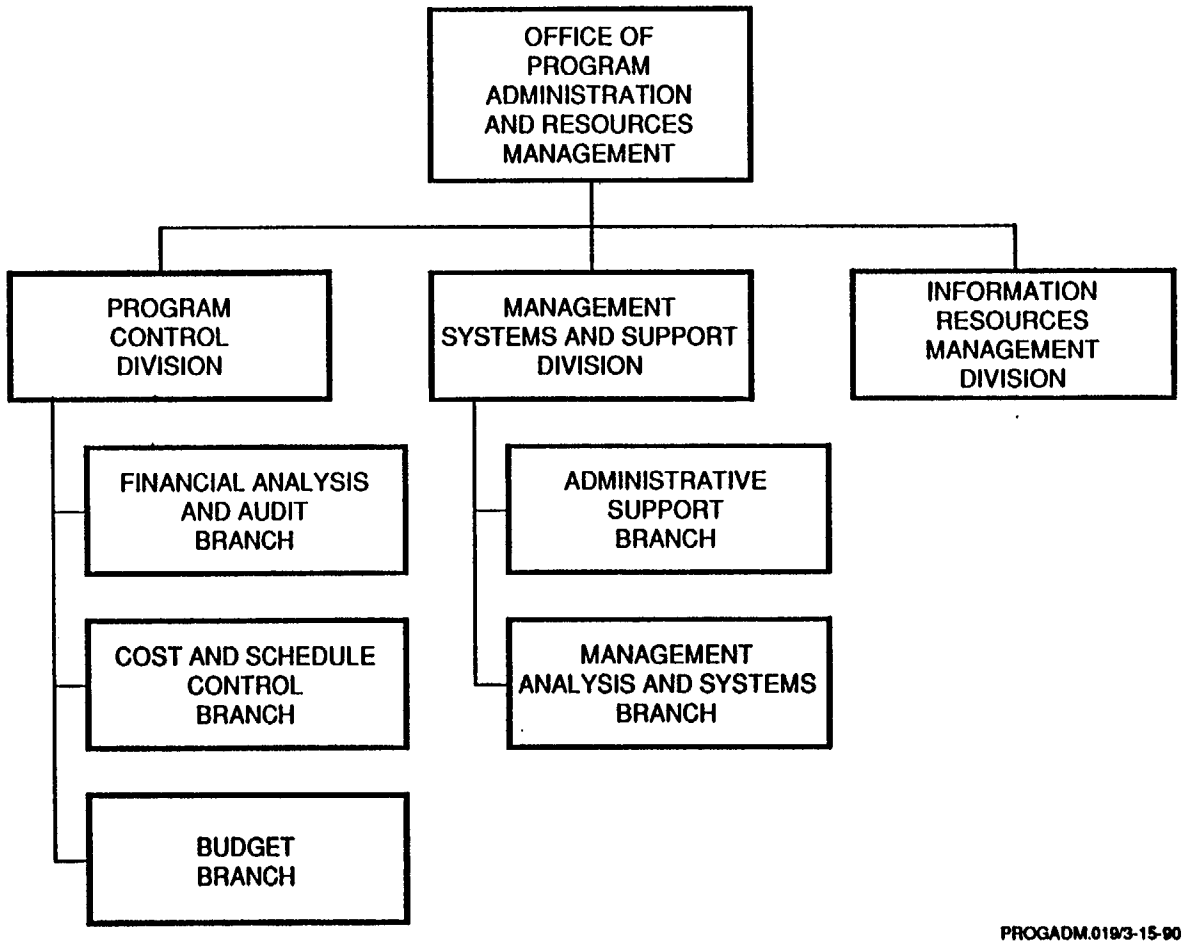

Figure 1-1C. Office of Program Administration and Resources Management Organization.

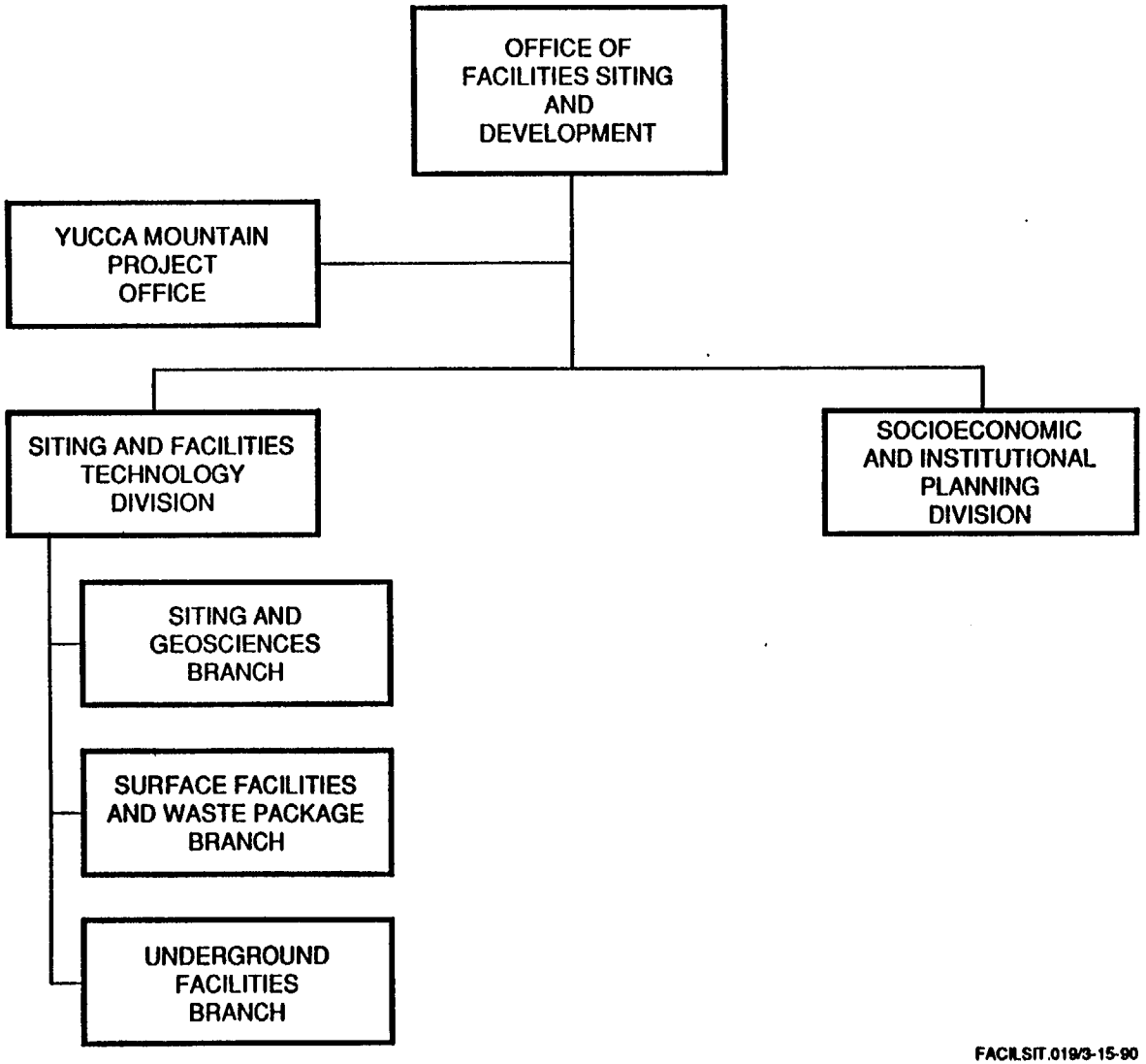

Figure 1-1D. Office of Facilities Siting and Development Organization.

QAPD

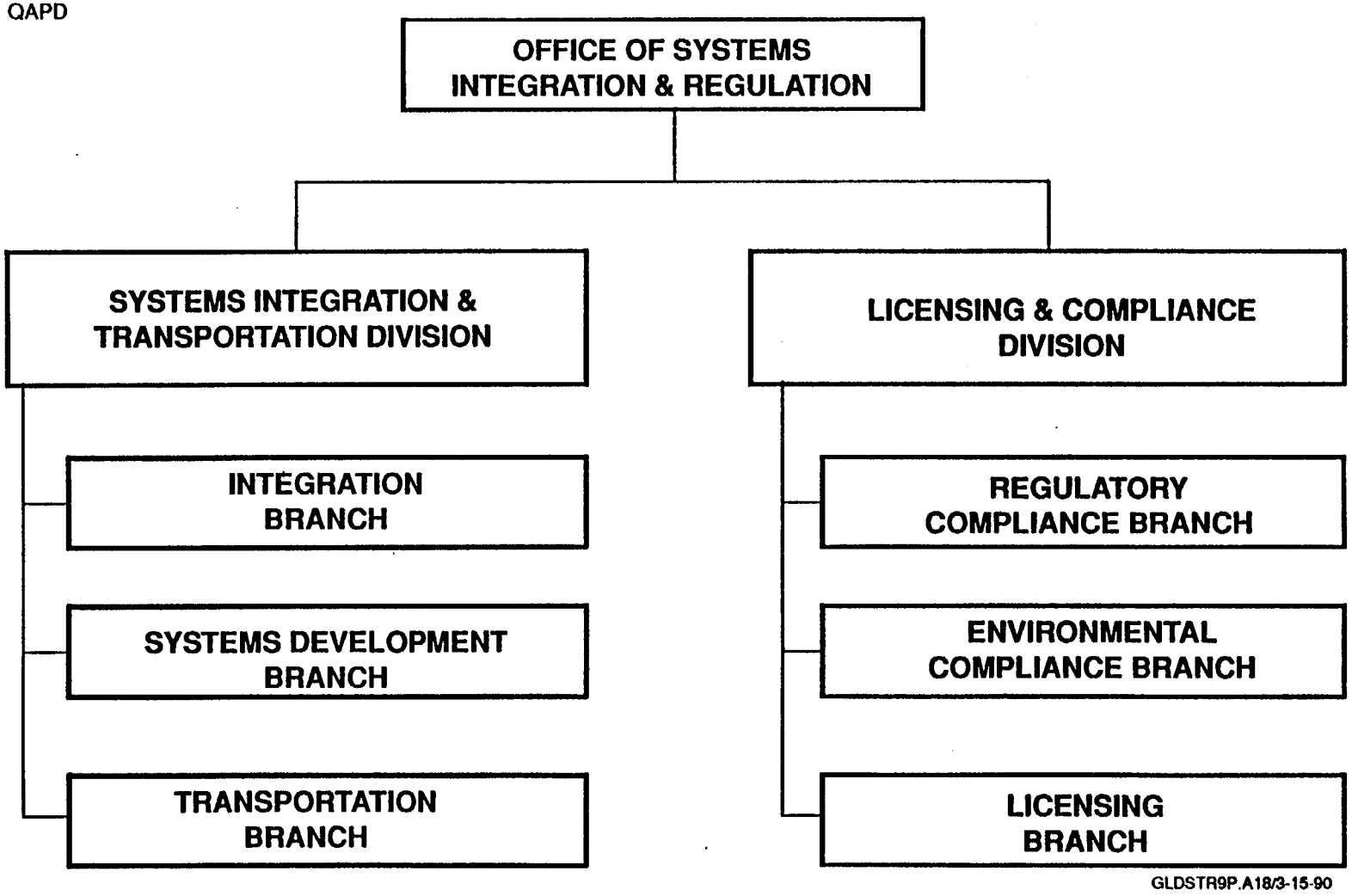

Figure 1-1E. Office of Systems Integration and Regulations Organization

QAPD

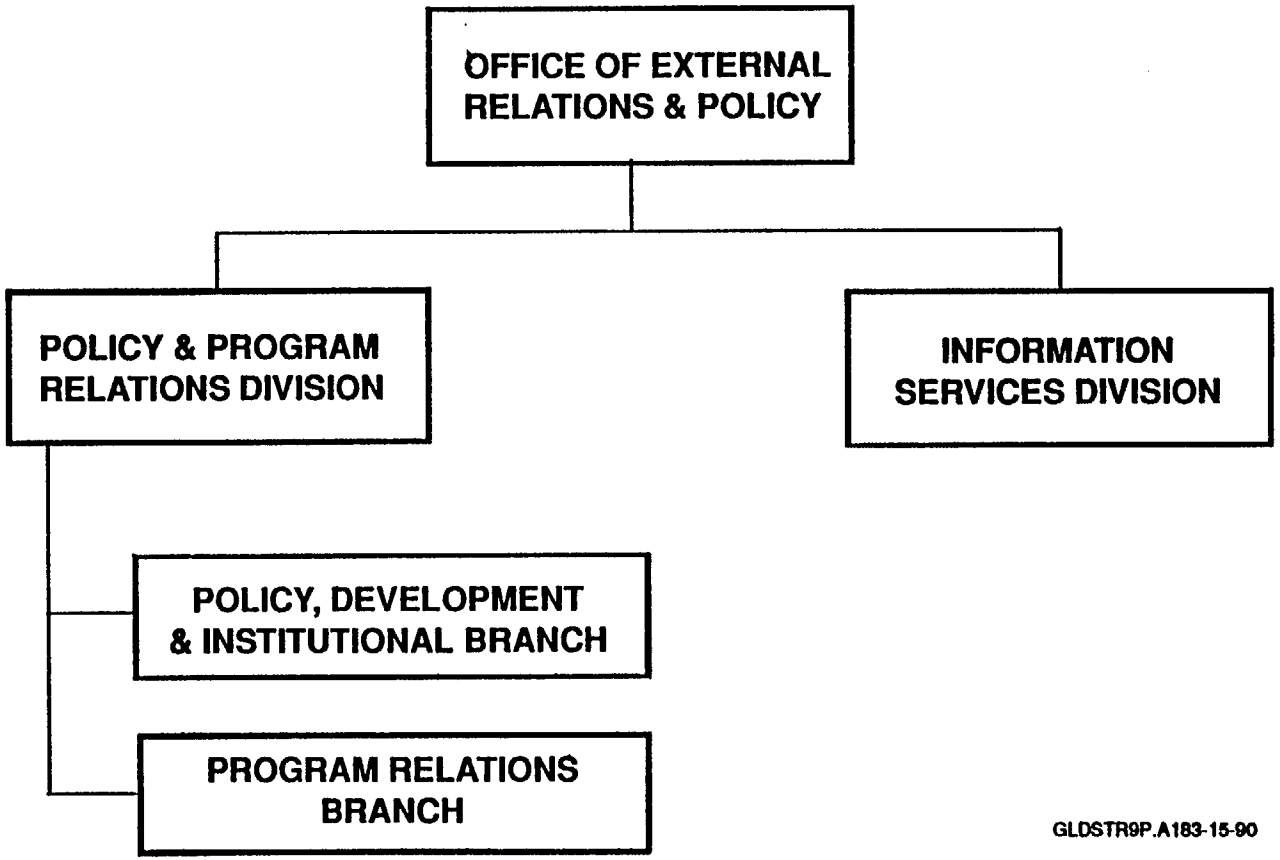

Figure 1-1F. Office of External Relations and Policy Organization

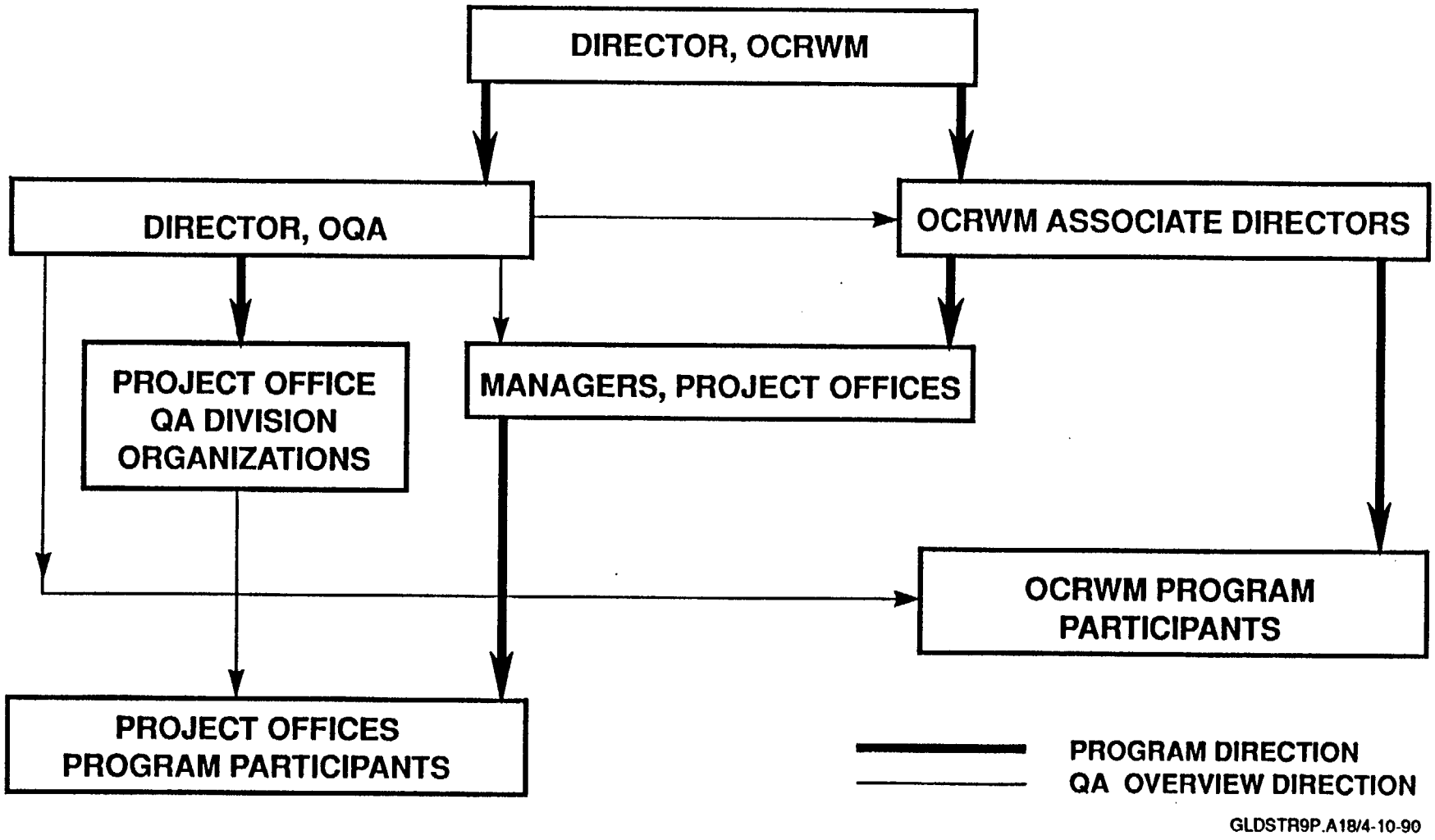

Figure 1-2. OCRWM Program Direction and Quality Verification.

DELEGATION OF QUALITY ASSURANCE WORK

Criteria No.	Topic	OCRWM	Project Offices/ Affected Organizations
1	Organization	X	X
2	Quality Assurance Program	X	X
3	Design Control (& Peer Review)	X	X
4	Procurement Document Control	X	X
5	Instructions, Procedures, and Drawings	X	X
6	Document Control	X	X
7	Control of Purchased Items & Services	X	X
8	Identification and Control of Materials, Parts, Components, and Samples	D	X
9	Control of Processes	D	X
10	Inspection	D	X
11	Test Control	D	X
12	Control of Measuring and Test Equipment	D	X
13	Handling, Storage, Transport, & Shipping	D	X
14	Inspection, Test, and Operating Status	D	X
15	Control of Nonconforming Items	D	X
16	Corrective Action	X	X
17	Quality Assurance Records	X	X
18	Audits	X	X
19	Computer Software	X	X

X - Means "Applicable commensurate with the Scope of Work"

D - Indicates that OCRWM delegates the work of establishing and implementing these criteria to Project Offices/Affected Organizations. However, OCRWM retains responsibility for ensuring that these activities are established and appropriately implemented, and carries out this responsibility through audits and surveillances of the activity.

Figure 1. Matrix describing the delegation of quality assurance work by criteria.

SECTION 2

QUALITY ASSURANCE PROGRAM

2.0 GENERAL

OCRWM, consists of Headquarters (HQ) and the Project Offices with responsibility for Monitored Geologic Disposal System (MGDS), Monitored Retrievable Storage (MRS), and Transportation, and has developed this Quality Assurance Program Description (QAPD) for its part of the Program. The OCRWM quality assurance program description complies with the requirements specified in the QARD that are applicable to OCRWM activities. A graded approach to the application of quality assurance requirements is used. Items and activities will be controlled to the extent required by the OCRWM quality assurance program. The OCRWM quality assurance program documents consist of this QAPD, the QARD, and OCRWM implementing line and quality assurance procedures.

This section describes provisions established by OCRWM to implement a quality assurance program to control items and activities affecting quality.

2.1 OCRWM QUALITY ASSURANCE PROGRAM

2.1.1 Quality Assurance Requirements

The quality assurance requirements for the Program are identified in DOE/RW-0214, Quality Assurance Requirements Document for the Civilian Radioactive Waste Management Program (QARD). The types of procedures described in the following sections are used at Headquarters and the Project Offices to ensure compliance and effective implementation of this QAPD and the QARD. A matrix, which cross-references OCRWM procedures and the QAPD to the QARD requirements, is established and maintained by the Office of Quality Assurance.

2.1.2 Quality Assurance Program Description

The QAPD describes provisions established by OCRWM to implement the applicable requirements of the QARD, the OCRWM organizational responsibilities for achieving and verifying quality, and the interfaces between OCRWM, and other affected organizations. Organizational charts are provided and the provisions that are implemented to meet each Section of the applicable requirements of the QARD are described. The QAPD is approved by the Director, OCRWM, and will be issued as a controlled document.

2.1.3 Quality Assurance Procedures

Quality assurance procedures are implemented for quality affecting activities that are performed by Headquarters and the Project Offices. Typically, Headquarters and the Project Offices work to the same procedures. However, where necessary, the Project Offices develop and implement quality assurance

procedures that are specific to their scope of work. These procedures are consistent with the QARD, and this QAPD, and delineate the specific administrative and quality assurance controls or the methods used to meet requirements established in upper-level program documents.

These procedures are contained in quality assurance procedure manuals and are issued and controlled by the Office of Quality Assurance or Project document control centers, as applicable. Provisions are established for the controlled distribution of individual procedures. Preparation is assigned to the discipline or group with lead responsibility for the activity or area. Each affected discipline or group reviews the procedures to ensure appropriate requirements and interfaces are defined. The procedures are approved by the Director, OQA, or the Project Office QA organization, as applicable, and the line organization.

2.1.4 Line Procedures

Line procedures provide instructions for Headquarters and Project Office personnel performing activities affecting quality. Line procedures include technical, management, and operating instructions necessary for performing work, including implementation of the QARD requirements. Typically, Headquarters and the Project Offices work to the same line procedures. However, where necessary, the Project Offices develop and implement line procedures that are necessary for their scope of work. Line procedures are prepared, reviewed, and approved by the highest line position responsible for performing the activities. The Office of Quality Assurance and Project Office QA organizations support and assist in the development of the line procedures. The respective quality assurance organizations also review and approve the line procedures, to ensure inclusion of quality assurance program requirements.

These procedures are contained in a line procedure manual and controlled and distributed by the Office of Quality Assurance or Project Document Control centers. Provisions are established to allow for controlled distribution of individual procedures.

2.1.5 Project Office Administrative Procedures

Administrative procedures are controlled procedures that assign responsibility and coordinate interfaces for the execution of activities of Project Offices involving significant responsibilities for more than one affected organization performing work under the direction of a Project Office.

2.1.6 Quality Assurance Program Controls

Quality assurance controls are applied to items and activities affecting quality.

The quality assurance program is implemented by management,

quality assurance staff, and line organization personnel at each organizational level.

The OCRWM staff evaluates the adequacy and effectiveness of programmatic systems and technical products through overview techniques such as audits, surveillances or reviews. The OCRWM staff may use the expertise of the QA organization, line organization and management personnel, other than those directly responsible for the work, in making these evaluations. The Director, OQA, in concert with the Quality Assurance Division Directors of Project Offices assist in developing and implementing the quality assurance program, provide overview to verify achievement of quality, and evaluate and report on quality assurance program compliance and implementation effectiveness.

Line organization personnel are responsible for achieving, as a minimum, the specified level of quality.

Management reviews quality assurance program status and line performance to determine acceptability of product quality, programmatic compliance, and implementation effectiveness, and to resolve quality problems.

Line managers supervising the work will ensure that specified quality is achieved by using appropriate means of management controls.

(a) Internal Controls

Quality assurance controls over items and activities affecting quality are executed by QA organizations and line organizations. The extent of these controls are established jointly by the line organization and the Quality Assurance organization and described in appropriate documents.

(b) Verification of the Achievement of Quality Activities

Verification of the achievement of quality is performed by personnel who are independent of the item or activity being verified.

Verification personnel have sufficient authority, access to work areas, and organizational freedom to (1) identify quality problems; (2) initiate, recommend, or provide solutions to quality problems through designated channels; (3) verify implementation of solutions; and (4) ensure that further processing, delivery, installation, or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred. When verification personnel are part of the line organization, the quality assurance organization overviews and monitors the verification activities by conducting independent QA audits, surveillances, or reviews.

(c) Direction, Overview, and Verification of Program Participants

Direction and overview of the quality assurance activities of other affected organizations is achieved by establishing Program quality assurance requirements; declaring these requirements through controlled documents, including procurement documents; and performing overview activities, such as reviews, audits, and surveillances.

2.1.7 Readiness Reviews

OCRWM performs selected readiness reviews and participates in selected readiness reviews performed by other affected organizations. Each Associate Director maintains a list of planned readiness reviews and submits revised lists to the Director, OCRWM, semiannually. Readiness reviews are conducted at critical phases of the Program to verify accomplishment of the following activities:

(a) Work activity prerequisites have been satisfied.

(b) Implementing line, quality assurance, and administrative procedures related to the next phase of work have been developed and reviewed for adequacy and appropriateness.

(c) Personnel have been suitably trained and qualified.

2.1.8 Graded Quality Assurance

OCRWM has adopted a quality assurance approach in which the extent of quality assurance and procedural controls are selectively applied to items and activities depending on the relative importance of the item or activity to safety, waste isolation, or Program objectives. The extent of quality assurance and procedural controls to be applied to items or activities will be based on fundamental considerations such as the consequence of failure of items, degree of importance of data, complexity of design and fabrication, degree to which functional control can be demonstrated by inspection or test, quality history and economic considerations. The OCRWM approach to grading is delineated in approved procedures. The approach to graded quality assurance specific to MGDS activities is delineated in Section 2 of Appendix A of this document.

2.1.9 Personnel Selection, Indoctrination, Training, and Qualification

Personnel assigned to perform activities that affect the quality of an item or activity will receive appropriate indoctrination and training prior to performing work. Procedures will address the performance of indoctrination, training, and qualification activities. Training Officers, who report to the Director, OQA, or responsible Project management, are delegated responsibility

and authority to implement the staff indoctrination and training program.

(a) Job Evaluation

"OCRWM management analyzes each job position to determine the quality-affecting task responsibilities of the position. Applicable personnel organizations establish and/or approve as applicable, position descriptions (in accordance with applicable laws and regulations) which set forth job duties that include the quality-affecting task responsibilities of the job. Minimum personnel qualification standards (including minimum education and experience requirements) for each position is established as a recognized standard for the position."

(b) Personnel Selection

Personnel assigned to perform activities affecting quality are required to have education, experience, and training commensurate with the functions associated with the work. A documented evaluation is made of the candidate's qualifications against the requirements. Minimum education and experience prerequisites are verified.

(c) Determination of Indoctrination and Training

A systematic approach to the determination of applicable indoctrination and training for personnel performing activities affecting quality is established. This includes training needs as identified by applicable Training Offices and the applicable manager or supervisor.

Personnel assigned responsibility for performing activities affecting quality are provided indoctrination and training as to the purpose, scope, and implementation of the QA Program, and as applicable, to the quality-affecting job function or task.

(d) Training and Qualification

Training is provided if needed, to adapt to changes in technology, methods, or job responsibilities.

Classroom training is performed in accordance with documented and approved lesson plans.

Records of training are maintained. As a minimum, documentation of training includes the training objective, course content, attendees, and date of attendance.

Persons verifying activities affecting quality, such as lead auditors, auditors, and peer reviewers, are qualified in the principles, techniques, and requirements of the activity

being performed. Specific qualification requirements are contained in procedures for those functions and qualification records are maintained.

(e) Proficiency Evaluation

Supervisors evaluate, at least annually, the proficiency of personnel in the performance of their assigned duties. These evaluations are documented and discussed with the person who was evaluated. Additional training is provided if it is necessary to improve or maintain proficiency.

2.1.10 Surveillance

In addition to audits described in Section 18 of this document, formal programmatic and technical surveillances are performed to provide timely, management information on Program activities affecting quality. Surveillances are performed by knowledgeable personnel on work they had no direct responsibility for performing. Surveillances are performed to written procedures, checklists, or plans and the results documented. Deficiencies identified are documented in accordance with the requirements in Sections 15 and 16, as appropriate. Deficiencies identified during the surveillance are reported to the organization responsible for the affected item or activity, for resolution. These deficiencies are tracked to verify corrective action implementation.

2.1.11 Management Assessments

An independent management assessment of the quality assurance program is conducted, at the direction of the Director, OCRWM, at least annually, by the Director, OCRWM or designees who are independent of the OCRWM QA organization.

The purpose of the independent management assessment is to evaluate the scope, status, adequacy, programmatic compliance, and implementation effectiveness of the quality assurance program. Results of the independent management assessment are documented. Deficiencies identified are documented in accordance with requirements in sections 15 and 16, as appropriate.

2.1.12 Management Information Reporting and Tracking

Communication and information systems are established to ensure timely reporting, dissemination, and tracking of quality assurance management information, such as the status of quality assurance programs, status of resolution of deficiencies and conditions adverse to quality, the status of quality assurance overview results, and the status of the quality concerns program.

SECTION 3

DESIGN CONTROL

3.0 GENERAL

Design activities are accomplished in accordance with written procedures. These procedures describe the systems engineering process by which design activities, from advanced conceptual design through final design, are planned, controlled, and implemented; and describe the control of design inputs, interfaces, outputs, reviews, changes, and deficiencies.

This section describes provisions established by OCRWM to implement design control activities.

3.1 OCRWM CONTROL OF DESIGN ACTIVITIES

3.1.1 Systems Engineering

OCRWM uses a systems engineering approach for control and management of Program design activities. Systems engineering is used as a disciplined means of transforming Program mission requirements into a description of system performance requirements and preferred configuration. It ensures that all elements of the system are properly integrated and that the system operates effectively and protects the health and safety of the public and the environment.

Systems engineering is a structured, formal method of managing the design process to aid in ensuring that cost, schedule, and technical performance objectives are met. It specifies:

(a) The engineering process that defines the technical baseline and development of the design to that baseline. The process is iterative, cycling between the definition of requirements (design, development, siting), evaluations against the requirements, and optimization, which leads to further definition and refinement.

(b) The process for integrating the disciplines involved in design development, interfacing between the various levels of the Program, controlling revisions to the technical baseline, and periodically reviewing the design development.

(c) The documentation required to establish the technical baseline and provide a traceable record of the design and siting process.

Systems engineering is implemented at the OCRWM Program level, and at the program-element level (MGDS, Transportation, and MRS). Activities associated with the elements of the system are assigned to other organizations (e.g., the Project Offices and Operations Offices) in appropriate governing documents (e.g.,

Office Charters, Memoranda of Understanding, Contract Scopes of Work).

The systems engineering approach addresses the control of design interfaces by defining who is responsible for each element of the design, describing the process for developing an integrated design, and establishing requirements for documenting, maintaining, and controlling a technical baseline to be used. Technical and quality assurance requirements address the control of design interfaces by defining work scopes and establishing requirements for information exchange between OCRWM and other affected organizations.

3.1.2 Processing of Data

Data collection, qualification, analysis, identification, and recording activities related to design of the individual repository program elements are discussed in Appendix A of this document.

3.1.3 Design Inputs

OCRWM Headquarters identifies regulatory requirements that affect design, such as 10 CFR 60, 10 CFR 70, 10 CFR 71, environmental regulations, applicable quality standards, etc. Project Offices and other affected organizations identify any additional state and local requirements. These requirements are baselined and maintained in system and subsystem design requirements documents, that require management, technical, and quality assurance review prior to approval at a level determined by the program level of the document.

Requirements documents are developed for the overall Program mission, each system element, and other organizations responsible for parts of the system, as identified in the next higher level design document. These controlled documents are reviewed and approved at the level for which they were written and also approved at the next higher level. Requirements for baselining and controlling these documents are discussed in Section 6.0 of this QAPD. The design input for these documents prepared by OCRWM includes processed data received from other affected organizations.

3.1.4 Design Process

Design activities are conducted primarily by program participants and other affected organizations. Computer programs used in design are developed and controlled in accordance with Section 19 of this document. Organizations responsible for design engineering within the Program are required (1) to prescribe their design processes at the level of detail necessary to permit the design to be carried out in a correct manner; and (2) to ensure that such activities are documented in a timely manner and in sufficient detail to support facility design, construction,

and operation; and (3) to permit verification that the design meets the established requirements.

Design processes are required to provide for planned, documented, controlled analyses, and to include the following features:

a. Legible analysis documents in a form suitable for reproduction, filing, and retrieval.

b. Sufficient detail as to purpose, method, assumptions, design input, references, and units to enable an individual technically qualified in the subject to review and understand the analysis and verify adequacy of the results without recourse to the originator.

c. Provisions for ensuring that calculations are identifiable for retrieval (e.g., by subject, originator, reviewer, and date; or by other uniquely identifying data).

3.1.5 Readiness Reviews for Design Activities

Readiness reviews are conducted at established hold points in the design. Readiness reviews are performed to confirm, as a minimum, the following elements:

(a) Required systems engineering approach to design development has been factored into design schedules and related planning documents.

(b) Applicable regulatory requirements, codes, standards, and controls have been identified. Implementing line procedures and procurement documents reflect these required design inputs.

(c) Design responsibilities and interface responsibilities are defined in procedures and procurement documents.

(d) Design schedules identify milestone design reviews.

(e) Procedures exist for baselining design documents and controlling subsequent changes.

3.1.6 Technical Reviews

The adequacy and correctness of OCRWM-generated technical documents are verified by technical review prior to approval and issuance. In this application, the review considerations include inputs and sources, assumptions, prescribed processes where applicable, and compatibility with established Program objectives and approaches. Technical reviews are performed by any competent individual(s) or group(s) other than those who prepared the technical document but who may be from the same organization.

Selected major designs are also subjected to OCRWM technical review. In this application, the reviews will evaluate compatibility of design and design approach with established Program design objectives and constraints and with the prescribed systems engineering requirements.

3.1.7 Design Verification

Design verification for Program-element designs is delegated to the responsible design organizations.

3.1.8 Design Change Control

Changes to OCRWM originated design-related documents, including design input documents, are justified and processed using the same methods applied to the preparation of the original document. Changes, with the exception of minor changes as described in Section 6.0, are reviewed and approved by the organizations that reviewed and approved the original design document except where an organization was originally responsible for approving the design document is no longer responsible. In these cases, OCRWM will designate a new responsible organization to review the document changes.

The impact of design changes on procedures and training are evaluated.

3.1.9 Design Deficiency Control

Deficiencies in approved design-related documents generated by OCRWM and in design information used by OCRWM are controlled and resolved in accordance with Section 16. The impact of such design document deficiencies on work previously performed using the affected document, is evaluated and corrective measures, if necessary, are applied.

SECTION 4

PROCUREMENT DOCUMENT CONTROL

4.0 GENERAL

This section describes provisions to implement procurement document control activities. Procurement by OCRWM is accomplished in accordance with written procedures. These procedures describe the process by which procurement planning is accomplished; the process by which procurement documents and revisions are prepared, reviewed, approved, and controlled; the contents of procurement packages; and the responsibilities for executing procurement document control activities. In addition, these procedures describe involvement of the quality assurance staff.

4.1 PROCUREMENT DOCUMENT PLANNING, PREPARATION, REVISION, REVIEW, AND APPROVAL

Procedures are established and implemented for the control of procurement documents. The procedures define the methods and responsibilities for procurement planning and for preparation, review, and approval of procurement documents and changes thereto. Procurement planning includes identifying the need for a specific service, determining the specific work to be accomplished, identifying appropriate technical and quality requirements, and identifying sources for the work.

4.2 PROCUREMENT DOCUMENT CONTENT

The OCRWM quality assurance program requires that organizations initiating a procurement include the following, as appropriate, in the procurement document "package":

4.2.1 A statement of the scope of work to be performed by the supplier.

4.2.2 Technical requirements:

(a) Reference to, and/or inclusion of, specific plans, drawings, specifications, codes, standards, regulations, procedures, or instructions that describe the services to be furnished.

(b) Identification of acceptance requirements for monitoring and evaluation of supplier performance.

(c) Technical acceptance/rejection criteria.

4.2.3 Quality assurance program requirements:

(a) Quality assurance requirements addressing applicable elements of the program, commensurate with the scope, complexity, and safety implications of the work, as determined by the procurement requestor.

(b) Permission for the supplier to work under the umbrella of the purchaser's quality assurance program, at purchaser option, when appropriate to the nature of the procurement, provided that the scope of the activity is adequately addressed therein. When these circumstances apply, the procurement documents will specify which parts of the purchaser's QA program are applicable to the supplier's work efforts.

(c) Requirement for the supplier to incorporate appropriate provisions of the quality assurance program in subtier procurement documents,

4.2.4 At each tier of procurement, the right of purchaser or designated or authorized parties, access to supplier facilities and records for verification, such as inspection and/or audit.

4.2.5 Documentation required of the supplier, including submittal of schedules, nature of documentation (i.e., information, review, or approval) and as appropriate, designation of retention times and disposition requirements for those records maintained by the supplier.

4.2.6 As applicable, the participant's requirements for reporting and review or approval of nonconformance dispositions.

4.3 PROCUREMENT DOCUMENT REVIEW

4.3.1 Organizations executing procurement document control activities, provide for documented technical and quality assurance review of procurement document packages to ensure that the documents include all necessary requirements and provisions. These reviews are performed by personnel who have access to pertinent information and who understand the requirements and intent of the procurement documents.

4.3.2 Procurement documents and changes are reviewed to verify that the procurement documents:

(a) Have been prepared in accordance with applicable procedural requirements.

(b) Reflect adequate and appropriate quality assurance requirements.

(c) Include applicable regulatory, design basis, and related technical information, and that these requirements are correctly stated.

4.3.3 Organizations are also required to include provisions in their applicable procedures for analysis of exceptions requested or specified by the supplier, in order to assess potential impact of such exceptions on intent of the procurement documents or on quality of the service.

4.4 PROCUREMENT DOCUMENT CHANGES

Changes to procurement documents, other than minor changes as described in Section 6, receive the same degree of control as utilized for the original documents. Changes are reviewed by quality assurance and technical personnel.

SECTION 5

PLANS, PROCEDURES, INSTRUCTIONS, AND DRAWINGS

5.0 GENERAL

OCRWM activities affecting quality are prescribed by, and controlled in accordance with, plans, procedures, and instructions. Plans, procedures, and instructions include or reference appropriate quantitative or qualitative acceptance criteria for determining that prescribed activities have been satisfactorily accomplished. Planning, preparation, and issuance of plans, procedures, and instructions is accomplished prior to the start of activities affecting quality.

This section describes provisions established by OCRWM to control the performance of activities affecting quality.

5.1 OCRWM PLANS, PROCEDURES, INSTRUCTIONS, AND DRAWINGS

Procedures are developed and implemented to ensure that methods to be used for performance of activities affecting quality are prescribed in documented plans, procedures, and instructions. Activities affecting quality are performed in accordance with these documents.

OCRWM delegates preparation and control of design drawings.

SECTION 6

DOCUMENT CONTROL

6.0 GENERAL

OCRWM develops and implements procedures that ensure that Program documents affecting quality are prepared, revised, reviewed, approved, and issued in a prescribed and controlled manner.

This section describes provisions established by OCRWM to control the preparation, revision, review, approval, and issuance of documents affecting quality.

6.1 OCRWM DOCUMENT CONTROL

6.1.1 Document Preparation, Revision, Review, and Approval

Documents that specify quality and technical requirements or prescribe activities affecting quality are prepared; revised; reviewed for adequacy, completeness, and correctness; approved; and released for issuance and distribution in accordance with written procedures. Procedures for preparation and revision of plans, manuals, procedures, instructions, and other documents address, as a minimum, the following requirements:

(a) Identification of the individuals or organizations responsible for the preparation, revision, review, approval, and release of the document.

(b) Review of documents affecting quality by individuals or organizational elements with responsibility for implementation.

(c) Review of documents affecting quality by individuals other than the preparer of the document.

(d) Access by reviewing organizations to pertinent background data or information to assure a complete review.

(e) Resolution of review comments for which resolutions are considered mandatory by the reviewing organization, prior to approval and issuance of the document. Review comments and resolutions are to be documented and maintained in accordance with approved procedures.

Changes to documents, other than those defined as minor changes, are considered major changes and shall be reviewed and approved by the same organizations that performed the original review and approval, unless other organizations are specifically designated by the organization responsible for the document.

Minor changes to documents, such as inconsequential editorial corrections or clarifications, are not subject to the same review and approval as the original documents. To avoid possible omission of a required review, the types of minor changes that are not subject to such review and approval, and the authority for such a decision, is clearly delineated in approved procedures.

6.1.2 Issuance and Distribution

Document issuance and distribution are controlled to ensure that correct, applicable, and current documents are available to the personnel performing prescribed activities, prior to commencing work and at the location where work is performed. Approved procedures delineate the responsibility and authority for such releases. Documents which require verification and are released prior to verification are identified as such and controlled and authorized for release by signature approval, with the described bases for release.

Document control procedures include the following provisions:

(1) Identification and marking of documents, including documents released prior to completion of the approval process.

(2) Use of receipt acknowledgment document transmittal forms.

(3) Maintenance of controlled document distribution lists.

(4) Marking, removal, or destruction of obsolete or superseded controlled documents.

(5) Maintenance of an index giving revision status for controlled documents (controlled document list).

Controlled document recipients are responsible for acknowledging document receipt; ensuring that the latest authorized documents are in use; and marking, destroying, or returning obsolete or superseded documents. Document recipients are responsible for ensuring that only the latest controlled documents are used and that obsolete or superseded documents are so identified, destroyed, or returned.

Program-level controlled documents (including technical baseline documents), other than the QARD and QAPD and associated procedures, that address OCRWM activities subject to quality assurance program requirements, are handled in accordance with the Program Change Control Procedure (DOE/RW-0223). These controlled documents are listed in a controlled documents register. The register is issued as changes or revisions occur to assist recipients in maintaining up-to-date files.

Requirements for program-element and project level, controlled documents, other than quality assurance program procedures, are

delineated in program-element and project level change control procedures.

Descriptions and responsibility assignments for development of program, program-element and project level controlled documents, including the technical baseline documents are described in DOE/RW-0043, OCRWM Program Management Systems Manual.

SECTION 7

CONTROL OF PURCHASED ITEMS, AND SERVICES

7.0 GENERAL

OCRWM develops and implements procedures that ensure that purchased services are controlled in accordance with specified requirements. The control of items is not performed by OCRWM, but delegated to other affected organizations.

7.1 OCRWM CONTROL OF PURCHASED SERVICES

Procedures are established to control purchased services. The system for control of purchased services includes:

(a) Procurement planning

Procurement planning is accomplished and documented as early as practicable to provide appropriate interface compatibility and to ensure a systematic approach to the procurement process. Planning is performed to determine what is to be accomplished; how is it to be accomplished; when is it to be accomplished; and who is to accomplish it. Requirements for supplier quality assurance programs are specified in the solicitation package.

(b) Supplier selection

Contracting Officers solicit bids and award contracts. Source selection officials are responsible for evaluating bid offers or proposals.

For procurements subject to the Federal Acquisition Regulations (FAR) and Department of Energy Acquisition Regulations (DEAR), the contract documents are prepared and contracts placed by the cognizant government procurement organization. Supplier's quality assurance programs are evaluated either before or after contract placement and any quality deficiencies are corrected prior to initiating quality-affecting work. Timing of the evaluation is in accordance with DOE procurement regulations and serves as an acceptable alternative to the QARD requirement that suppliers must be evaluated prior to contract award.

(c) Bid Evaluation

OCRWM's bid evaluation process determines the extent of the supplier's ability to meet the procurement document requirements. Based on the type of procurement, bid evaluations consider the following subjects:

- technical considerations.
- quality assurance requirements.
- personnel of potential supplier.
- past performance of potential supplier.

(d) Supplier performance evaluation

Methods and criteria for evaluating supplier performance for OCRWM procurement activities are delineated in approved procedures.

Interfaces with the supplier are established as necessary to ensure that the performance measurement methods are appropriate, adequate, and understood by each involved organization. The methods used include establishment and evaluation of performance objectives; review of supplier's records and nonconformance controls; and performance of reviews, audits, and surveillances. This documentation is evaluated to determine the supplier's quality assurance program effectiveness.

(e) Supplier generated document control

Supplier generated documents are submitted in accordance with the requirements delineated in the procurement documents. OCRWM receives, reviews, and evaluates these documents, as necessary, to ensure conformance to the procurement requirements. As a minimum, OCRWM ensures the supplier provides documentation that identifies the procurement requirements met, as well as documentation identifying procurement requirements that have not been met.

(f) Change control

Changes to procurement documents of purchased services are evaluated in the same manner and with the same criteria as the original procurement documents.

(g) Acceptance of services

When required by procurement documents, suppliers' QA Programs are reviewed and accepted prior to initiation of activities affected by the quality assurance program.

Services are accepted by one or more of the following methods:

(1) Results of audits or surveillances, as appropriate.

(2) Technical verification of data produced.

(3) Review of objective evidence for conformance to the procurement document requirements.

(4) Evaluation of suppliers certificates of conformance for services to ensure validity and documentation of results.

(h) Control of Nonconformances

OCRWM establishes and documents methods for disposition of services not meeting procurement document requirements, through approved procedures. These procedures include provisions for: evaluation of the nonconforming condition; submittal of the nonconformance

document to OCRWM by the supplier, as directed by OCRWM; OCRWM disposition of the supplier's recommendation of corrective action; verification of the implementation of the disposition; and maintenance of supplier submitted nonconformance documents.

SECTION 8

IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, COMPONENTS, AND SAMPLES

8.0 GENERAL

The identification and control of materials, parts, components, and samples is delineated in Appendix A.

SECTION 9

CONTROL OF PROCESSES

9.0 GENERAL

Process control is applicable to scientific investigations and engineered items. Control of special processes is applicable to engineered items. OCRWM does not perform engineered-item-related processes or special processes. The process control requirements delineated in the QARD applicable to OCRWM, are for scientific investigations and are included in Appendix A, Section 20 of this QAPD.

SECTION 10

INSPECTION

10.0 GENERAL

OCRWM performs no inspection activities. Therefore, the inspection requirements delineated in the QARD do not apply to this QAPD.

SECTION 11

TEST CONTROL

11.0 GENERAL

OCRWM performs no test control activities, other than the computer software test control requirements of Section 11 of the QARD. Application of these computer software requirements is addressed in Section 19 of this QAPD.

SECTION 12

CONTROL OF MEASURING AND TEST EQUIPMENT (M&TE)

12.0 GENERAL

M&TE activities performed by OCRWM apply to the MGDS. The application of requirements for M&TE activities is described in Section 12 of Appendix A of this QAPD.

SECTION 13

HANDLING, STORAGE, AND SHIPPING

13.0 GENERAL

OCRWM activities relative to handling, storage, and shipping activities apply to MGDS. The application for these activities is described in Section 13 of Appendix A of this QAPD.

SECTION 14

INSPECTION, TEST, AND OPERATING STATUS

14.0 GENERAL

OCRWM performs no inspection, test, and operating status activities. Therefore, the inspection, test, and operating status requirements of the QARD do not apply to this QAPD.

SECTION 15

CONTROL OF NONCONFORMING CONDITIONS

15.0 GENERAL

Identification and control of nonconforming conditions, which include both programmatic and hardware deficiencies, is in accordance with written procedures. These procedures describe the methods used to identify, document, track, segregate, review, disposition, and control nonconforming conditions.

Examples of programmatic deficiencies are those such as failures to comply with procedures, plans, regulations, and other established requirements. Examples of hardware deficiencies are those where items (i.e., materials, parts, or components) do not comply with established requirements, such as in drawings, specifications, and procurement documents.

Personnel assigned approval authority for nonconformance dispositions are identified and the quality assurance organization responsibilities are described in these procedures. The procedures associated with identification and control of nonconforming conditions are prepared and controlled by Project Offices or Headquarters.

Nonconforming conditions are evaluated to determine the degree of significance. If conditions are determined to be significant, by the criteria provided in Section 16, these conditions will be processed as significant conditions adverse to quality and documented in Corrective Action Reports in accordance with Section 16.

15.1 IDENTIFICATION OF NONCONFORMING ITEMS

Nonconforming items are identified by methods that do not adversely affect the end use of the item. Identification includes the nonconformance report number.

The authority for application and removal of the nonconformance status indicator is specified in approved procedures.

When identification of each nonconforming item is not practical, the receptacle or segregated storage area is identified.

Use or installation of nonconforming items may not proceed until the item is dispositioned and the specified actions are completed. If only a specific part of the item is in nonconformance, that specific part is identified and work may proceed on the remaining non-affected parts. In certain cases it is anticipated that use or installation of nonconforming items will need to continue prior to implementation of the disposition. In such cases, the approval and justification as delineated in approved procedures, is obtained.

15.2 SEGREGATION

Nonconforming items are segregated by placement in designated hold areas until dispositioned. When segregation is impractical, due to physical configuration, other precautions are employed to preclude inadvertent use.

15.3 DISPOSITION OF NONCONFORMING ITEMS

Nonconformance characteristics are reviewed and subsequent dispositions of nonconforming items are approved. The processing, delivery, installation, or use of nonconforming items are controlled, pending evaluation and approved disposition. Nonconformance documentation is distributed to affected organizations.

The organization responsible for dispositioning the nonconforming item ensures that the disposition identifies and documents the correction as repair, rework, use-as-is, or reject. In the case of use-as-is or repair dispositions, technical justification is required. Nonconformances affecting design requirements are subject to the same design controls as those applied to the original design. The design documentation (i.e., as-built records), if required, reflect the accepted deviation.

15.4 DISPOSITION OF ITEMS AND PROGRAMMATIC NONCONFORMANCES

Personnel performing evaluation to determine a disposition have competence in the specific area being evaluated; have adequate understanding of the requirements; and have access to pertinent background information.

The organization responsible for dispositioning the item or programmatic nonconformance ensures the following:

(a) The disposition references approved design documents, procedures, plans, work orders, etc., that are necessary for correction of the condition.

(b) The disposition complies with existing design documents, procedures, plans, etc.

(c) If the disposition affects design documents, procedures, plans, etc., revisions to those documents are noted in the disposition.

(d) The disposition identifies the organization responsible for implementation of the disposition.

15.5 IDENTIFICATION OF PROGRAMMATIC NONCONFORMANCES

Programmatic nonconformances are documented on nonconformance or deficiency reports and the reports receive unique nonconformance or deficiency report numbers.

15.6 CORRECTIVE ACTION

The action to correct the nonconforming condition is verified and documented in a timely manner. The QA organization concurs with the corrective action to ensure applicable QA requirements are satisfied. Repaired or reworked items are reexamined in accordance with original acceptance criteria, unless alternate acceptance criteria are specified in the disposition.

SECTION 16

CORRECTIVE ACTION

16.0 GENERAL

Significant Conditions Adverse to Quality (SCAQs) will be promptly identified and corrected in accordance with written procedures. These procedures which are reviewed and concurred by the QA organization, describe the process by which SCAQs are identified and evaluated to determine cause, generic implications to the Program, corrective action, and action to preclude recurrence. Provisions for reporting SCAQs to the cognizant Directorate or QA organization are also prescribed.

16.1 OCRWM CORRECTIVE ACTION

16.1.1 Significant Conditions Adverse to Quality (SCAQs)

SCAQs cited within OCRWM are reported to cognizant management and the appropriate OCRWM QA organization. A Corrective Action Report (CAR) is issued for repetitive conditions or any condition adverse to quality that, were it to remain uncorrected, could adversely affect safety or waste isolation. Cognizant managers are responsible for determining the cause of the condition, the generic implications to the Program, the corrective action, and the action to be taken to preclude repetition. The determinations made and corrective actions taken are documented and reported to the cognizant directorate or Project Office, and the applicable QA organization.

The OCRWM QA organizations are responsible for concurrence with the proposed corrective action, verification of the implementation, and completion of corrective action by signatory concurrence on the CAR.

Nonconformances, deficiencies, and conditions adverse to quality identified by OCRWM personnel at other affected organizations' facilities are documented in accordance with QA program requirements and brought to the attention of that organization's management or Project Office management.

16.1.2 Control

Methods and responsibilities for the analysis for trends; processing, control, and resolution of deficiencies; and handling of significant conditions adverse to quality are established.

Copies of Project Office deficiency reports and CARs are submitted to the Director, Office of Quality Assurance.

16.1.3 Trend Analysis

Information describing the degree of achievement of quality, such

as audit reports, surveillance reports, and deficiency and deviation reports identified within, or by, OCRWM are analyzed by OQA for Headquarters and by the Project Offices. Affected organizations and OCRWM analyses are reviewed by OQA to determine trends that are Program wide. Results of trend analysis are reported to upper management.

The trend analysis program is described in procedures and considers the following attributes, as a minimum:

(a) The quality indicators to be trended.

(b) The methods of data handling such as gathering, collecting, sorting, grouping, and coding.

(c) The statistical processes to be used such as type of charts, normalizing to remove bias, weighting, and control limits.

(d) The methods to be used in analyzing data and trend determination.

(e) The actions to be taken when an adverse trend is identified.

(f) The type, distribution and frequency of issue of trend results reporting.

SECTION 17

QUALITY ASSURANCE RECORDS

17.0 GENERAL

The quality assurance (QA) records program for the OCRWM is accomplished in accordance with written plans and procedures. These documents describe the integrated set of activities for creating, identifying, collecting, controlling, processing, organizing, distributing, storing, preserving, retrieving, and disposing of Program QA records. These documents identify responsibilities of the Quality Assurance organization and other organizations.

This section describes provisions established by OCRWM to implement QA records program activities.

17.1 OCRWM QA RECORDS SYSTEM

The OCRWM records management system is decentralized in that Central Records Facilities (CRFs) are established at Headquarters, the Project Offices, and the Operations Offices. OCRWM also establishes local records centers (LRCs) that serve as record collection centers. Typically, record-initiating organizations submit documents to the LRC for subsequent turnover to the CRF. The CRFs and LRCs are established in accordance with DOE/RW-0194, Records Management Policies and Requirements, (RMPR) and are described and operated in accordance with approved procedures.

The QA records system is a subset of the overall records management system. Headquarters prepares and issues the RMPR, and retains responsibility for the total QA records system, while delegating records management for work performed by Project Offices to the Project Offices. This delegation includes collection of records from affected organizations.

Control and maintenance of QA records are delegated to the records management contractor for those QA records generated or received by Headquarters. Control and maintenance of QA records generated or received by Project Offices are retained by the Project Offices. Project Office and Operations Office CRFs, as applicable, submit microfilm of completed records to the Headquarters records-management contractor.

Controlled documents and technical baseline documents, as appropriate, specify records to be generated, supplied, or maintained.

17.2 Record Definition

OCRWM quality assurance and implementing line procedures, and program plans, define minimum QA records generated as a result of implementation. In general, the following documents are considered QA records:

(a) Individual documents that have been executed, completed, and approved that furnish evidence of the quality and completeness of data (including raw data) and activities affecting quality.

(b) Documents prepared and maintained to demonstrate implementation of quality assurance programs.

(c) Procurement documents subject to quality assurance controls.

(d) Other documents, such as plans, drawings, correspondence, specifications, technical data, books, maps, papers, photographs, and data sheets subject to quality assurance controls.

(e) Other materials that provide data and document quality, regardless of physical form or characteristic including magnetic media.

A complete record is a document that will either receive no more entries or whose revision would normally consist of the reissue of the document; and when applicable is signed and dated by the originator and by personnel authorized to approve the document.

17.3 Record Generation

The applicable design specifications, procurement documents, and other documents specify the records to be generated, supplied, or maintained by OCRWM.

Documents designated to become records are to be legible, identifiable, accurate, complete, reproducible, microfilmable, and appropriate to the work accomplished.

Documents are considered valid records only if stamped, initialed, or signed and dated by authorized personnel, or otherwise authenticated in accordance with approved procedures. These records may be originals or reproduced copies. Authentication may take the form of a statement by the responsible individual or organization. Handwritten signatures are not required if the document is clearly identified as a statement by the reporting individual or organization.

OCRWM maintains lists that contain the signatures and initials of personnel authorized to authenticate records.

Complete records are suitably protected by the record initiator prior to turnover.

17.4 Receipt of Records

The receipt of records is applicable to LRCs and the CRFs.

A receipt-control system is established that is structured to permit a current and accurate assessment of the status of records.

The organization responsible for receiving the records provides for

protection from damage, deterioration, or loss, during the time that the records are in their possession.

17.5 Record Identification

Records or indexing systems provide sufficient information to permit identification between the record and its applicable items or activities.

The records are indexed and the indexing system or systems include the location of the record within the records system or systems.

17.6 Records Storage and Retrieval

Records are controlled from time of completion until the time of storage in a permanent storage facility. When necessary, records are controlled from when they are initiated to protect their integrity. Temporary storage, preservation, safekeeping, and retrievability of completed records is performed in accordance with requirements applicable to the storage of records delineated in the QARD.

17.7 Records Classification

All of OCRWM's quality assurance records are classified as permanent records.

17.8 Corrected Records

Records are corrected in accordance with approved procedures. These procedures provide for review or approval by the record-originating organization. Corrections to records include dates and identifications of the persons authorized to make such corrections.

SECTION 18

AUDITS

18.0 GENERAL

OCRWM has established requirements for a quality assurance audit program to provide independent verification of the status, adequacy, compliance, and implementation effectiveness of the quality assurance program and its elements.

This section describes provisions for implementing the quality assurance audit program.

18.1 AUDIT PROGRAM IMPLEMENTATION

Procedures describe the methods and responsibilities applicable to audit activities to determine compliance with requirements and to assess programmatic compliance and implementation effectiveness of OCRWM and other affected organizations' quality assurance programs. The audit program includes technical and programmatic verifications.

The Director, OQA, is responsible for the development, implementation, and maintenance of the OCRWM QA audit program. The OCRWM QA organization plans and conducts audits of the affected organization activities as well as activities performed by OCRWM staff.

18.1.1 Audit Process

Procedures for audit activities address accomplishment of the planning and scheduling of audit activities to ensure that Program-deliverable products and processes are evaluated commensurate with importance in achieving mission objectives and schedule completion dates assigned to the products or processes. Internal audits of implementation effectiveness of the quality assurance program are performed at least once each year.

18.2 AUDIT SCHEDULING

OCRWM develops, maintains, and implements an audit schedule for Headquarters and the Project Office that covers applicable quality assurance program elements.

After award of a contract by OCRWM, external audits are scheduled as appropriate.

Suppliers' quality assurance programs are evaluated for audit on at least an annual basis. Supplier audits are performed on a triennial basis, unless an annual evaluation indicates the need for an audit prior to the end of a triennial period. The need for audit of a supplier is also evaluated when major changes to contract scope or work methodology occurs. Preaward surveys may serve as the first audit, if the scope and conduct of the preaward survey addresses contract requirements.

OCRWM audits implementation of affected organizations' quality assurance programs on at least an annual basis. Audit schedules are adjusted in the event of significant changes in personnel, organization, or quality assurance program.

18.3 AUDIT TEAMS

Audit team leaders are required to be certified, lead auditors. Lead auditor qualifications comply with requirements of the QARD.

Members of the audit team are independent with respect to activities they will audit (i.e., no audit team member audits an activity for which he or she was directly responsible). Management personnel of audited activities are prohibited from participating in the selection of audit team members who will audit their activities.

Audit team members, collectively, have the necessary programmatic and technical expertise in the work being audited, by virtue of prior experience and/or specific, documented orientation or training.

Audit teams normally include members from appropriate technical disciplines, who will verify adequacy of technical processes employed to ensure the validity and correctness of technical work.

OCRWM auditor and lead auditor training and qualification programs are administered by the appropriate QA organization. Lead auditors are certified under the appropriate QA program.

18.4 AUDIT PREPARATION

As a minimum, preparation for individual audits includes: preparation of an audit plan and an audit checklist or procedure; study of auditee procedures applicable to the activities to be audited; evaluation of relevant surveillance results; results of previous audits of the same activities; relevant corrective action history; review of trend data; and review of the current status of the work.

The scope of each audit is based on an evaluation of the activities to be audited. The evaluation considers:

(a) Results of previous internal audits.

(b) Results of previous extrinsic audits.

(c) Impact of significant changes in personnel, organization, or quality assurance program.

The scope of an audit may include verification of product quality and technical adequacy of work being done, as well as programmatic compliance and implementation effectiveness. Personnel with appropriate technical knowledge are assigned as audit team members to evaluate technical aspects of processes and acceptability of the quality of products resulting from the processes. Technical requirements are

selected for audit verification from the governing technical requirements documents and are included in audit checklists.

18.5 AUDIT PERFORMANCE

Audit team members perform document reviews, interviews, and other activities described in the audit checklist or procedure under the direction of the audit team leader. Audit team members regularly communicate the status of assigned activities, as well as problems and potential problems to the audit team leader. The audit team leader ensures problems that require immediate attention are relayed to the audited organization's representatives in a timely manner. Regular discussions with the audited organization's representatives are held to provide the status of audit activities and promote effective communications between auditor and auditee. Audit performance includes documentation of the evidence examined and conditions observed, so that a sound basis exists for reported conclusions.

Results of the audit are presented to the audited organization's representatives by the audit team leader (and team members), in a post audit conference, to complete the audit conduct phase.

18.6 AUDIT REPORTING

The audit report includes the following information, as appropriate:

(a) A description of the audit scope.

(b) Identification of audit team members.

(c) Identification of personnel contacted during the audit.

(d) A summary of audit results, including a statement describing the effectiveness of the quality elements audited.

(e) A clear description of each audit finding that will allow the audited organization to understand the finding and take corrective action.

The audit report is signed by the audit team leader and approved by the Director, OQA, or Project Office QA organization, as appropriate, prior to transmittal and distribution. The audit report is issued to the audited organization for review, assessment, and appropriate action. Copies of the audit report are also distributed to other affected organizations as well as the management of the auditing organization.

Deficiencies require responses from the designated representative(s) of the affected organization, with specified action dates.

18.7 POST-REPORT ACTION

Management of the audited organization investigates audit findings, schedules corrective action, and notifies the auditing organization in writing of actions planned or taken.

Management of the cognizant organizational elements of the auditing organization, including QA and the audit team leader, review the audit response to determine:

(a) Adequacy of cause determinations.

(b) Acceptability of commitments for correcting the deficient (and similar) conditions (past and present).

(c) Acceptability of committed actions to preclude recurrence of the deficient conditions, and of the schedule for completing such actions.

(d) Adequacy of the evaluation of impact of the deficient work performed and the generic implications on the Program.

(e) Appropriateness of corrective action responsibility assignments.

Follow-up is performed by the auditing organization, to verify satisfactory implementation of corrective and preventive actions taken to resolve audit findings. Verification of corrective and preventive action implementation is documented to support close-out of findings.

SECTION 19

COMPUTER SOFTWARE

19.0 COMPUTER SOFTWARE DESIGN AND CONTROL

Requirements for design and control of computer software are delineated in Section 19 and Section 19 of Appendix A of the QARD. OCRWM describes application of those requirements in a Software Quality Assurance Plan or approved procedures.

APPENDIX A

AMPLIFICATIONS TO THE QUALITY ASSURANCE PROGRAM DESCRIPTION FOR MINED GEOLOGIC DISPOSAL SYSTEM ACTIVITIES

GENERAL

The purpose of this appendix is to amplify the Quality Assurance Program Description (QAPD) for Mined Geologic Disposal System (MGDS) activities. OCRWM performs activities related to the MGDS in accordance with Sections 1 through 19 of the QAPD. Specific amplifications to those requirements are provided below, as related to major, numbered QAPD sections except Section 20 of this Appendix, which is unique to scientific investigation. Where a QAPD section does not require amplification, the section reference is omitted from this appendix.

1.0 AMPLIFICATION OF QAPD SECTION 1 - ORGANIZATION

This section describes activities assigned to affected organizations performing work related to MGDS activities. Figure A1-1 depicts the MGDS organization.

Affected organizations are assigned the following work related to MGDS activities:

(a) Preclosure performance assessment and materials characterization.

(b) Waste-package scientific support and preclosure risk-assessment services.

(c) Geoscientific support.

(d) Transportation-operations planning, geosciences, shielding, and systems integration support and performs safeguards activities.

(e) Environmental, socioeconomic, and site characterization support.

(f) Defense waste studies.

(g) Postclosure performance assessments.

(h) Records management and related activities.

(i) Technical support services in planning and scoping an Environmental Impact Statement and implementation plan for the geologic repository.

(j) Operation of the Defense Waste Processing Facility (DWPF).

(k) Operation of the West Valley Demonstration Project (WVDP).

The Yucca Mountain Project Office (YMP) performs MGDS related activities under the direction of OFSD. The Yucca Mountain Project Office, headed by the Project Manager, is functionally organized as follows:

- o Engineering and Development Division
- o Regulatory and Site Evaluation Division
- o Project and Operations Control Division

Yucca Mountain Project Office

Each of the YMP managed program participants, is represented in its interchanges with the YMP Manager by a Technical Project Officer (TPO). For purposes of this Program, the TPO is the accountable officer of the organization being represented.

YMP direct support contractors perform activities affecting quality under controls of the OCRWM quality assurance program. YMP direct-support contractor activities include:

(a) Program management, integration, and quality assurance support.

(b) Technical and scientific support.

YMP-Affected Organizations

YMP-managed work is accomplished by scientific laboratories and engineering and construction contractors reporting to the YMP. These participants describe any major delegation of work involved in establishing and executing their quality assurance programs. Responsibilities assigned to these affected organizations are summarized in this section.

(a) Repository systems development.

(b) Repository conceptual design.

(c) Data management and analysis.

(d) Systems performance assessment of the repository.

(e) Determine of thermal properties of the host rock.

(f) Repository sealing performance requirements, materials evaluation, design, and testing.

(g) Definition of the waste package environment.

(h) Waste package material development and testing.

(i) Waste package design, performance analysis, and testing.

(j) Assistance to other YMP-affected organizations in areas of special expertise.

(k) Site characterization drilling activities.

(l) Characterization of site geology, hydrology, tectonism, volcanism, and seismicity.

(m) Coordination and scheduling of the exploratory shaft testing program.

(n) Nuclide migration studies.

(o) Geochemistry studies.

(p) Mineralogy and petrology studies.

(q) Design of the integrated data acquisition system for the exploratory shaft facility.

(r) Exploratory shaft subsurface design.

(s) Subsurface facilities construction and testing.

(t) Field surveillance and inspection of drilling and mining, and Title III inspection.

(u) Geotechnical services.

(v) Transportation, land access, and socioeconomic studies.

(w) Meteorological and radiological monitoring.

(x) ESF subsurface support systems design.

(y) ESF surface facilities.

(z) Field surveillance and inspection of construction activities, and Title III inspection.

(aa) Material test laboratory support.

(ab) Nondestructive examination services.

(ac) Field surveying.

(ad) Microfilming and archival storage of YMP records.

(ae) Engineering support for the site communications network.

(af) ESF surface and subsurface construction, drilling, and mining.

(ag) Drilling and trenching, as required for site characterization.

(ah) Operation and maintenance of site facilities.

(ai) Procurement and logistical services for the YMP, as requested.

2.0 AMPLIFICATION OF QAPD SECTION 2 - QUALITY ASSURANCE PROGRAM

The QARD requirements are implemented using a graded approach and are applied to items and activities important to safety and/or waste

isolation. Specifically, the quality assurance program applies to the following items and activities:

(a) Structures, systems, and components important to public radiological health and safety.

(b) Engineered items important to waste isolation.

(c) Activities that affect items important to safety or engineered items important to waste isolation.

(d) Activities that could affect natural barriers important to waste isolation or containment.

(e) Collection, reduction, and analysis of data in support of licensing.

(f) Other items or activities that are placed within the scope of the project quality assurance program by project management prerogative.

Additional guidance related to this subject as prescribed in NUREG-1318, "Technical Position on Items and Activities in the High-Level Waste Geologic Repository Program Subject to Quality Assurance Requirements" is delineated in Yucca Mountain Project Office Quality Assurance and Administrative Procedures.

3.0 AMPLIFICATIONS OF QAPD SECTION 3 - DESIGN CONTROL

In addition to the description in Section 3, the requirements in this appendix apply to design control

3.1 SCOPE OF PROJECT DESIGN CONTROL

Repository and exploratory shaft design are uniquely affected by considerations of the waste isolation characteristics of natural barriers and ultimately affects those barriers. Therefore, OCRWM has adopted design-related definitions specified by the Nuclear Regulatory Commission (NRC) in the NRC's Review Plan for High-Level Waste Repository Quality Assurance Program Descriptions. Consistent with definitions in the repository Glossary; design, design information, and design activities are used in this program description as follows:

3.1.1 Design

Specifications, drawings, design criteria, and component performance requirements for the natural and engineered components of the repository system, including design inputs and outputs at each stage of design development, from conceptual to final design.

3.1.2 Design Information and Design Activities

Data collection and analysis activities and computer codes used in supporting design development and verification, including:

(1) General plans and detailed procedures for data collection and analysis.

(2) Related information, such as test results and analyses.

3.1.3 Data Analysis

Data reduction, as well as broad level system analyses, such as performance assessments, which integrate analyses of individual parameters and other relevant data.

3.2 DESIGN INPUTS

Conventional design uses inputs such as applicable codes and standards, tables of material properties, etc. The Project Office requires responsible design organizations to implement procedures for selection and approval of, and changes to, inputs in that category.

3.2.1 Site Characteristics and Test Requirements Inputs

In addition to conventional design inputs, the design basis for site facilities (e.g., the Exploratory Shaft Facility) also includes site characteristics data, as well as requirements arising from site characterization testing and sampling needs. The responsible Project Office-managed scientific organizations have been charged with providing and controlling those categories of inputs.

These participants identify the best available data on relevant characteristics of the site and are required to accomplish the necessary technical and peer reviews to ensure that the data provided actually are the best available.

The responsible architect/engineering organization is then required to review such inputs and to return to the Project Office with any requests for modification.

Data collected and/or analyzed under controls not governed by provisions of this quality assurance program require qualification in accordance with OCRWM direction based on NUREG-1298, Generic Technical Position on Qualification of Existing Data for High-Level Nuclear Waste Repositories.

Methods for technical information flow to and from the Project technical data base and the Project Reference Information Base (RIB) are delineated in approved procedures.

3.2.2 Regulatory Requirements Inputs

The Yucca Mountain Project Office is responsible for identifying any unique State and local requirements that will affect design.

Those requirements, together with regulatory, consensus standard, DOE, and OCRWM requirements identified at Headquarters, are baselined and maintained in system and subsystem design requirements documents, that require management, technical, and quality assurance review prior to approval.

4.0 AMPLIFICATIONS OF QAPD SECTION 4 - PROCUREMENT DOCUMENT CONTROL

4.1 PROJECT OFFICE RESPONSIBILITIES

The Project Office procurement document package is sent to the respective contracts and procurement division for processing and award in accordance with applicable laws, regulations, and requirements. Subsequent controls for procurements are addressed in Section 7 of this document.

7.0 AMPLIFICATIONS OF QAPD SECTION 7 - CONTROL OF PURCHASED ITEMS, AND SERVICES

7.1 GENERAL

In addition to applying the requirements delineated in Section 7 of this QAPD, the following clarifications are provided for YMP.

7.2 SUPPLIER SELECTION AND EVALUATION

It is recognized that some of the research and analysis required for site characterization requires the services of specialists, or of institutions or agencies whose work does not ordinarily involve formal quality assurance activities. In these instances, selection is based on technical capability, and establishment of quality assurance measures appropriate to the services to be performed is required at the outset of their work.

7.3 BID EVALUATION

Participants using other participants to perform services or procure items do not evaluate other participants prior to award. A criteria letter is prepared and goes through the YMP to the supplier participant.

For DOE initiated procurements, the bid evaluation process is delegated to the DOE Nevada Operations Office.

7.4 ACCEPTANCE OF SERVICES

Methods for acceptance for DOE initiated procurements are established in the procurement document package.

8.0 AMPLIFICATIONS OF QAPD SECTION 8 - IDENTIFICATION AND CONTROL OF ITEMS, MATERIALS, AND SAMPLES

8.1 SAMPLES

The OCRWM site characterization program requires full sample traceability and accountability. The Sample Management Plan specifies sample-related interfaces among participants and defines the required sample accountability system. Requirements of the plan are implemented through internal procedures of those Project Office-managed participants who will have custody of samples at any point in the life of the sample. Those procedures are required to provide for the following:

(a) Custodial accountability, including auditable records of transfers of accountability between participants, or to or from external parties.

(b) Traceability of samples to applicable documentation, such as the scientific planning document, scientific notebook or technical procedures, drilling logs, photographs (where used), test records, inspection documents, and nonconformance reports, as applicable.

(c) Verification and documentation of correct sample identification prior to the release of samples for use or analysis.

(d) Use of separate, unique identifiers for multiple, discrete samples.

(e) Identification of the individual items or portions resulting from the subdivision that are readily traceable to the original sample in situations involving subdivisions of a sample.

Except when in use for data collection or analysis, or when consumed or destroyed by the analytical process, geotechnical samples are required to be stored in the Sample Management Facility, with archival controls and protection for the period during which additional examination or analysis by OCRWM may be needed. It is recognized that provisions available within existing technology cannot fully prevent natural time-dependent deterioration processes from affecting stored samples.

12.0 AMPLIFICATIONS OF QAPD SECTION 12 - CONTROL OF MEASURING AND TEST EQUIPMENT (M&TE)

12.1 GENERAL

This section applies the requirements necessary to ensure that tools, gages, instruments, and other measuring and test equipment (M&TE) used in Project Office activities that affect quality are properly controlled, adjusted, and calibrated at specified periods to maintain accuracy within necessary limits. The appropriate Project Office Division Directors(s) are responsible for the implementation of an effective calibration program in accordance with approved procedures.

12.2 APPLICABILITY AND SCOPE OF THE M&TE CONTROL PROGRAM

Controls noted in this section apply to tools, gages, instruments and other M&TE used primarily in the Sample Management Facility. However, controls of M&TE are also applied to activities used to calibrate,

measure, gage, test, or inspect for the purpose of either: (1) controlling or acquiring data to verify conformance to a specified requirement; or (2) establishing characteristics or values not previously known. The methodology for control of M&TE is described in approved procedures.

12.3 M&TE REQUIREMENTS

The application of generic requirements for control of M&TE are described herein.

12.3.1 Selection

Selection of M&TE is controlled to ensure that such equipment is of proper type, range, accuracy, and tolerance to accomplish the function of determining conformance to specified requirements. Each device has a unique identification number. The type, range, accuracy and tolerance of a measuring device is specified in approved procedures. This number is recorded on the data sheet, log, or equivalent, along with the measurement taken, to ensure traceability of the measurement to the device used to take the measurement.

12.3.2 Calibration

Measuring and test equipment is calibrated against certified equipment having known valid relationships to the National Institute of Standards and Technology or other nationally recognized standards and is calibrated, adjusted, and maintained at prescribed intervals. If no nationally recognized standards exist, the acceptability of the calibration standard used is justified. Calibrating standards have equal or greater accuracy than equipment being calibrated. Calibrating standards with the same accuracy may be used if it can be shown to be adequate for the requirements and the basis of acceptance is documented and authorized by the responsible Division Director.

12.3.3 Control

The method and interval of calibration for each M&TE item is defined, based on the type of equipment, stability characteristics, required accuracy, precision, intended use, degree of usage, and other conditions that affect measurement control. M&TE is labeled, tagged, or otherwise documented in a manner that indicates the due date of the next calibration and provide traceability to calibration data. If M&TE is found to be out of calibration, an evaluation is made and documented on the validity of previous results obtained, on acceptability of items previously inspected or tested or on data gathered since the last calibration. Out of calibration devices require the condition be documented in accordance with Section 15 of this QAPD, tagged or segregated, and not used until they have been dispositioned and corrective action has been satisfactorily verified. If any M&TE is found to be consistently out of calibration, it is repaired or

replaced. Calibration is performed when the accuracy of equipment is suspect.

12.3.4 Commercial Devices

Calibration and control measures are not required for rulers, tape measures, levels, and other such devices, if normal commercial equipment provides adequate accuracy.

12.3.5 Handling and Storage

M&TE is handled properly and stored to maintain accuracy in accordance with requirements specified by either the manufacturer or the respective Project Office Division Director.

12.3.6 Records

M&TE records are maintained and identify the calibration procedure (including revision) used to perform the calibration. These records are processed in accordance with Section 17 of the QAPD.

13.0 AMPLIFICATIONS OF QAPD SECTION 13 - HANDLING, SHIPPING, AND STORAGE

13.1 GENERAL

This section applies the requirements for controlling the packaging, handling, storage, shipping, cleaning, and preservation of material and equipment to prevent damage, loss, or deterioration. Handling, storage, and shipping of items (including packaging, cleaning and preservation), primarily applies to Sample Management Facility activities. However, these requirements also apply to any other quality affecting activities that fall within the scope of this criterion.

13.2 IMPLEMENTING DOCUMENTS

Handling, shipping, and storage activities are conducted in accordance with procedures, specifications, drawings, instructions, or other pertinent documents specified for use.

13.3 REQUIREMENTS

13.3.1 Special Equipment and Protective Environments

When required for particular items, technical documents specify controls for use of special equipment and special environments. These documents also require special equipment and environments to be provided and existence verified.

13.3.2 Specific Procedures

When required for critical, sensitive, perishable, or exceptionally expensive articles, specific procedures for handling, storage, packaging, shipping, and preservation are

used. Where appropriate, qualification of special lifting equipment, slings, and hoists is explicitly addressed.

13.3.3 Inspection and Testing of Special Tools and Equipment

When used, special handling tools and equipment are controlled as necessary to ensure safe and adequate handling. Special handling tools and equipment are inspected and tested in accordance with procedures at specified time intervals, to verify that the tools and equipment are adequately maintained.

13.3.4 Operators of Special Equipment

Operators of special handling and lifting equipment are experienced or trained to use the equipment; related training activities are conducted and documented in accordance with procedures.

13.3.5 Procedures

Procedures used for marking, labeling, packaging, shipping, handling, and storage of items include provisions addressing adequate identification, maintenance, and preservation of the items, including indication of the need for special environments or the need for special controls.

20.0 SCIENTIFIC INVESTIGATION CONTROL

20.1 GENERAL

Sufficient differences exist between the objectives, methodology and controls for design, and the studies and investigations for site characterization that this separate Section 20 has been developed to address scientific investigation separately from design.

20.2 SCIENTIFIC INVESTIGATION MANAGEMENT

The Regulatory and Site Evaluation Division Director has the YMP management responsibility for direction, guidance and review of scientific investigations in accordance with approved procedures. The responsibility for performing scientific investigations has been delegated to affected organizations.

20.3 SCIENTIFIC INVESTIGATION PLANNING CONTROL

YMP provides direction to affected organizations to develop a scientific investigation planning document prior to initiating the scientific investigation. Site characterization activities as defined in the Nuclear Waste Policy Act (as amended) utilize study plans as the scientific investigation planning document.

20.4 PLANNING DOCUMENT REVIEW AND APPROVAL PROCESS

The planning activity is designed to ensure compatibility of scientific investigation with conceptual or mathematical models used and the validity and representativeness of collected data. Where new or modified data collection or analysis methods are to be used in lieu of methods previously established and generally accepted within the scientific community, the modification or new methods will be subjected to technical and/or peer review by the YMP prior to being used in the scientific investigation.

The individual(s) assigned the responsibility for review of the planning document ensures the technical adequacy of the document by technical and/or peer review. The results of the technical and/or peer review and the resolutions of comments are to be retained as quality assurance records.

20.4.1 Technical Review

Technical reviews are performed when:

(a) The information or document under review is within the state-of-the-art and is based on accepted standards, criteria, principals and practices.

(b) Documents, activities, material, or data require technical verification or validation for applicability, correctness, adequacy, completeness and assurance that established requirements are satisfied.

The YMP requires that when technical reviews are required the initiator provide specific review criteria. The YMP also requires that technical reviews be performed by reviewers with sufficient technical knowledge of the subject matter to be able render an informed technical opinion and who did not direct or perform the work being reviewed.

20.4.2 Peer Review

Peer reviews are required when adequacy of the information (e.g., data, interpretations, test results, design assumptions, etc.) or suitability of essential procedures and methods cannot be confirmed by testing, alternate calculations, or reference to previously established standards and practices.

The YMP establishes and implements, when appropriate, procedures that comply with the peer review requirements specified in NUREG 1297, Peer Review for High-Level Nuclear Waste Repositories.

Documents generated during the peer review process are quality assurance records.

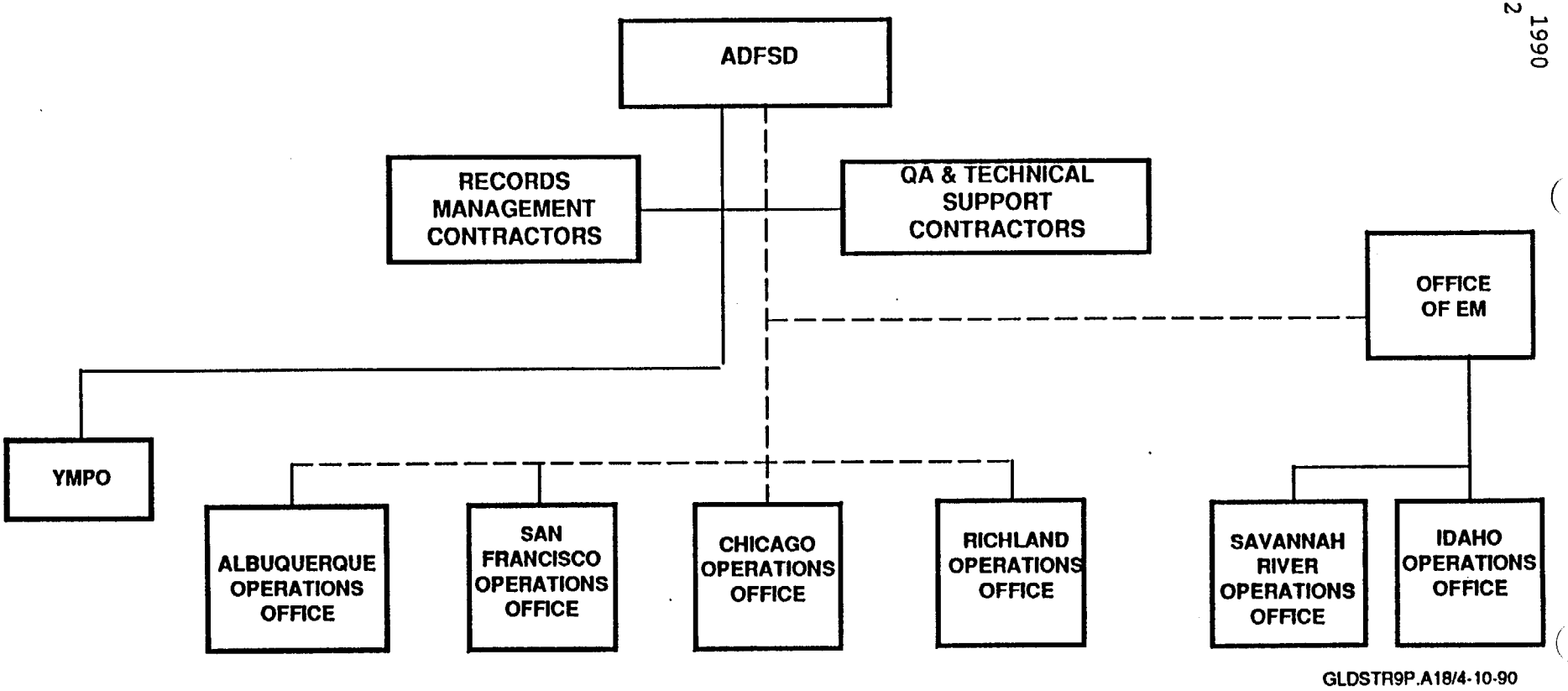

Figure A1-1 CRWM Geologic Repository Program Elements.

APPENDIX B

AMPLIFICATIONS TO THE QAPD FOR TRANSPORTATION

GENERAL

The purpose of this appendix is to amplify the QAPD for Transportation activities. OCRWM performs activities related to transportation in accordance with sections 1 through 19 of the QAPD. Specific amplifications to those requirements are provided below, as related to major numbered QAPD sections. Where a QAPD section requires no amplification, the section reference is omitted from this appendix.

1.0 AMPLIFICATION OF QAPD SECTION 1 - ORGANIZATION

This section describes the affected organization activities related to Transportation activities. Figure B1-1 depicts the transportation organizations.

Activities related to transportation which are performed by affected organizations include:

(a) Transportation-operations planning, geosciences, shielding, and systems integration support and performing safeguards activities.

(b) Institutional planning and analysis, and management integration.

(c) Cask development.

(d) Providing records management and related activities.

The Yucca Mountain Project Office performs Transportation related activities under the direction of OFSD, while interfacing with OSIR. For Transportation related activities; the YMP, reporting to the YMP manager, is functionally organized as follows:

- Engineering and Development Division
- Regulatory and Site Evaluation Division
- Project and Operations Control Division

Yucca Mountain Project (YMP) Office

Each YMP-managed affected organization, except YMP, is represented in its interchanges with the YMP Manager by a Technical Project Officer (TPO). For purposes of this Program, each TPO is the accountable officer of the organization being represented.

YMP direct support contractors perform activities affecting quality under controls of the OCRWM quality assurance program. YMP direct support contractor activities include, program management, technical, scientific, and quality assurance support.

YMP-Managed Participants

YMP-managed work is accomplished by scientific laboratories, engineering and construction laboratories, and engineering and construction contractors reporting to the YMP. These participants describe any major delegation of work involved in establishing and executing their quality assurance programs. Responsibilities assigned to participant organizations include:

(a) Transportation, land access, and socioeconomic studies.

(b) Microfilming and archival storage of YMP records.

(c) Procurement and logistical services.

YMP-Managed Participant Quality Assurance Responsibilities

Each YMP-managed participant implements the following quality assurance functions as delineated in the QARD:

(a) Establishing and implementing an effective internal quality assurance program.

(b) Approving the quality assurance programs of organizations performing Program-related activities under contract to the participant.

(c) Verifying effective implementation of the participant's internal quality assurance program and of the quality assurance programs of organizations or individuals doing Program-related work under contract to, or by agreement with, the participant.

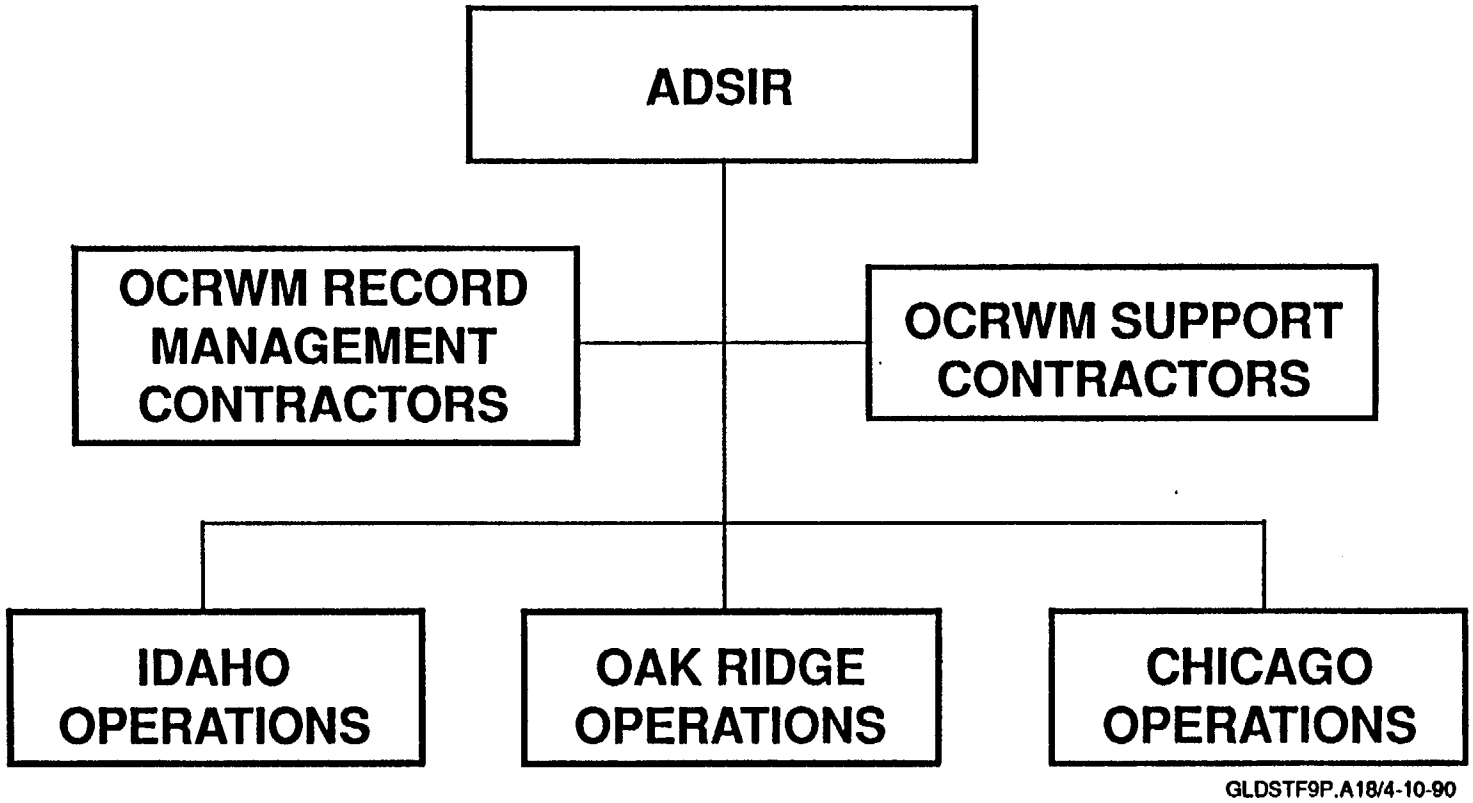

Figure B1-1. OCRWM Transportation Program Element.

APPENDIX C

AMPLIFICATIONS TO THE QAPD FOR THE MONITORED RETRIEVABLE STORAGE FACILITY

GENERAL

The purpose of this appendix will be to amplify the Quality Assurance Program Description for the Monitored Retrievable Storage (MRS) Facility activities. The planned MRS organization is depicted in Figure C1-1.

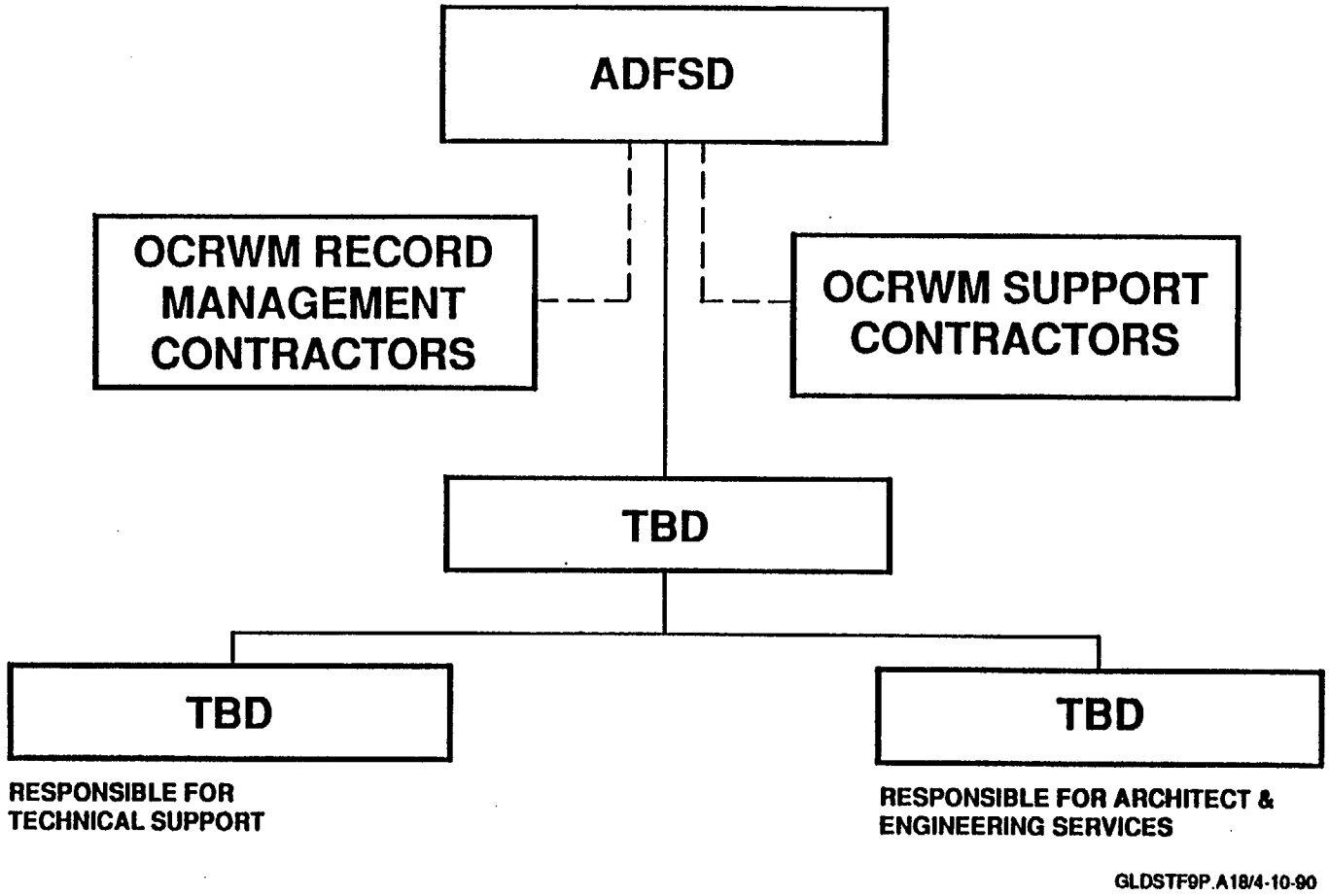

Figure C1-1. OCRWM MRS Program Participants.

NOTE: PLEASE LOG ALL [illegible]S SENT AND RECEIVED IN BOOK P[illegible]IDED.

TELECOMMUNICATION TRANSMITTAL

4-H-3

TO: MARK Delligatti, NRC

FROM: Bob CLARK, DOE

NUMBER OF PAGES: 26 (EXCLUDING THIS COVER SHEET)

U.S. DEPARTMENT OF ENERGY

OFFICE OF QUALITY ASSURANCE

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...view Plan	QARD	QAPD
...(overall responsibility by License Applicant)	Introduction	1.0, 1.1.1
1.2 (Authorities, duties); 1.6 (Respon for overall QA Pgm); 1.9 (Mgmt controls and communication lines)	1.1	1.1
1.3 (Pgm incl both line and QA functions)	1.0, 1.1, 2.0	1.0 Para. 2, 1.1, 2.1.6
1.4 (Def of QA functions); 1.14 Para. 1 a.b.c. (Suffic QA authority & freedom to ...)	1.1, 2.1, 2.2	1.1.1, 1.1.2
1.5 (Describe major delegations of QA Pgm work)	1.2	1.1.11
1.6 (With 1.2)		
1.7 (Eval of delegated work)	1.1, 2.9, 18.4	1.1.2.1, 1.1.2.2, 2.1.10, 18.1, 18.2
1.8 (Prestart identif of delegated respon.)	1.2	1.1, 2.1.7
1.9 (With 1.2)		
1.10 (Org charts, on-site & off-site org elements under QA Pgm)	1.1 (Does not specifically address "Charts")	Figures 1-1A, 1-1B, 1-1C, 1-1D, 1-1E, 1-1F, 1-2
1.11 (QA Organ. involved in HLWRP that affect safety & waste isolation)	Introduction	1.1.1
1.12 (Describe QA responsibilities of org elements on org charts)	1.0, 1.1 ("Charts" not explicitly addressed)	1.1
1.13 (QA mgmt position in each org; level = or > highest mgr directly respon for tech decis)	1.1 (Ult respons for overall QA Pgm)1.1.1, 1.1.2	1.1.1, 1.1.2
1.14a,b,c (With 1.4)		

NRC Review Plan	QARD	QAPD
1.14.d (Control of further processing); 1.14 Para. 2 (How and by whom control carried out)	2.2., 15.0	1.1.2.1, 15.1
1.15 (Resolution of quality disputes)	1.3	1.1.12
1.16 (Mandatory QA policy statement)	2.6	Policy Statement
1.17 (Quality concerns and allegations)	1.4	1.1.13

NRC Review Plan	QARD	QAPD
2.1 (Documented QA Pgm per 10CFR60 Part G, 10CFR50 App B, & Rvw Plan)	Intro Pur & Appl Para 5; 2.0; 2.1	2.0, 2.1.
2.2 (Commitment to NQA-1 Suppl 2S-1 & Append 2A-1); 2.14b (Verifiers qualified in activity being performed); 2.14e (Qualified personnel certif per appl codes & standards)	2.8.1, 2.8.2	2.1.9
2.3 (Written policies, proced, or instruc, and qualified individuals, prior to start of an activity)	2.1, 2.8.2	2.1.1 thru 2.1.5; 2.1.7
2.4 (Determ Q-list per NUREG-1318)	2.5.1	Appendix A Section 2.0
2.5 (Suitably controlled conditions); 2.6 (Taking account of special needs)	2.0	2.1.7
2.7 (Reqmts flowdown matrix)	2.7	2.1.1
2.8 (Policy stmt making implementation of QA program mandatory)	2.6	QAPD Policy Statement
2.9 (Commitment to comp software QA)	19.1	3.1.4; 19.0
2.10 (Consistency of QA and tech proceds to reg, licensing, and QA program rqmts)	2.1	2.1.3, 2.1.4, 2.1.5
2.11 (Review of, and documented concurrence with, procedures by QA or other desig orgs knowledgeable in QA controls)	5.1	1.1.2.1(g) (QA), 1.1.2.2 (QA), 6.1.1
2.12 (Mgmt assmt); 2.13 (Regular review of QA pgm status and adequacy)	2.0, 2.10	2.1.11

NRC Review Plan	OARD	OAPD
2.14, Sent. 1 (Indoc, trng, qualif pgms for suitable proficiency)	2.0, 2.8	2.1.9
2.14.a (Instruc as to purpose, scope, impl of quality-related docs); 2.14.c (Documentation for formal trng & qualif programs)	2.0, 2.8	2.1.9
2.15 (Readiness review for major milestones)	2.4	2.1.7, 3.1.5

NRC Review Plan	QARD	QAPD
3.2 (Correct transl of regulatory reqmts into design, procur, and proced docs); 3.3 (Transl of design bases, features devel in site charac into design)	3.0	3.1.3, 3.1.5, Appendix A Section 3.2.2
3.4 (Design control to apply to design of IITS & IITWI, site charac, & computer codes)	Appendix A Sections 2.1, 3.1	3.1.1, 19.0, Appendix A Section 3.1
3.5 (Design control for concep design that may become part of final design); 3.19 (Qualif of existing data); 3.20 (Design inputs timely and in sufficient detail)	3.0	3.1.4 and Appendix A Section 3.1.1
3.6 (Describe organiz respon for design doc prep, rvw, apprvl, verif, validation)	3.0, 3.3	3.1.1 Appendix A Section 3.2
3.7 (Action for design deficiencies)	3.2	3.1.9
3.8 (Design interfaces)	3.0	3.1.1
3.9 (Rvw by QA and/ or tech org for adherence to proceds and QA reqmts, and that approp quality stds are specified and included)	3.0, 5.1	3.1.3
3.10 (Methods of design verification)	3.0	3.1.6, 3.1.7
3.11 (Plan for data collection & analyzed prior to activity)	3.0	Appendix A, Section 3.1
3.12 (For design or tech reviews, identification of reviewers, area or features reviewed, methods of resolving comments); 3.13a (Establish criteria for determining method of verification)	3.3	3.1.1, 6.1.1
3.13b, 3.14 (Verifier qualification and independence)	3.0	3.1.6

NRC Review Plan	QARD	QAPD
3.13c (Verification timing)	3.0	3.1.6, 3.1.7
3.13d (Reqmt to define responsibilities of verifiers); 3.13e (Specification of areas and features to be verified); 3.13f (Reqmt to define extent of document'n)	3.3	3.1.7
3.15 (Host adverse design conditions)	3.0	3.1.7
3.16 (Peer Reviews)	Appendix A Section 3.2	Appendix A Section 20.4.2
3.17 (Design Change Control)	3.0, 3.2	3.1.8
3.18 (Certification of verified computer codes and specified of uses)	3.0, 19.7, 19.11	3.1.4

NRC Review Plan	QARD	QAPD
4.1 to semicolon (Tech rqmts in procurement documents)	4.0	4.2.1, 4.2.2
4.1 first to second semicolon (Adequate accept, reject criteria in procurem't documents)	4.0	4.2.2
4.1 after semicolon (Prep, rvw, appvl of procurem't documents)	4.0, 4.1	4.3.2
4.2 (Supplier QA program commens. with scope, complexity, safety)	4.2	4.2.3
4.2 (Subtier supplies QA reqmts)	4.0	4.2.3
4.3(1) (Organizational responsibilities described for procur. planning)	7.0	7.0, 7.1(a)
4.3(2) (Prep, rvw, appvl, control of procurement documents)	7.0	7.1
4.3(3) (Describe org. respon. for supplier selection)	7.0	7.1
4.3(4) (Describe org. respon. for bid evaluation)	7.0	7.1(c) (including discussion of alternative for procurements under DEARs and FARs)
4.3(5) (Describe org. respon. for supplier QA program rvw/concurrence before initiation of work; 7.3(a)(b) (Procedures provide for supplier evaluation/ selection & objective evidence of quality)	7.0, 7.1	7.1

NRC Review Plan	QARD	QAPD
5.1	5.0	5.0
5.2 (Organizational responsibilities for assuring 5.1 are described)	1.1, 5.1, 6.3	1.0, 5.1
5.3 (Acceptance criteria)	5.0	5.0
5.4 (Control of field/lab procedure changes for site charac. program)	Appendix A Section 20.2.1, 20.32	6.0

NRC Review Plan	QARD	QAPD
6.1 (Identify types of controlled documents - "such as" list)	6.0, 6.1	6.0
6.2, Sent. 1 (Reqmt for procedures for rvw, appvl, issuance, and revision of controlled documents)	6.0, 6.1	6.1
6.2, Sent 2 (Review by qualified, independent personnel	6.0, 5.1	6.1.1(c)
6.3 (Availability of documents at work location prior to start of affected work)	6.0	6.1.2
6.4 (Changes reviewerd by same org as original unless otherwise designated)	6.0	6.1.1
6.5 (Removal and replacement of obsolete or superseded docs)	6.1(e)	6.1.2, Para. 2, Item (4)
6.6 (Master rev status list or equivalent)	6.1(c)	6.1.2, Para. 2, Item (5)
6.7 (Controls on conditional issuance prior to completion of verification process)	6.2	6.1.2(1)

NRC Review Plan	QARD	QAPD
7.1 (Measures assure conformance to procurement document)	7.0	7.1(g) (Services only)
7.2 (Organiz. for control of purchased items services & software)	7.0	7.1(a)
7.3(c) (Procedures provide for inspections and audits of supplier activities, items, services, & software)	7.0	7.1(d)
7.3(d) (Receipt inspection)	7.2	Participant
7.4 (Supplier documentation)	7.0	7.1(e) (Services only)
7.5 (Records)	7.0, 17.0	17.0
		7.1(d)
7.6 (Assessments of supplier performance at intervals consistent with importance, complexity and quantity of product or services)	7.0	
7.7 (Periodic evaluation of Cert of Conformance system to assure validity and documentation of results)	7.0	7.1 (g.4)

NRC Review Plan	QARD	QAPD
8.1 (Estab and maintain ident items, samples, & software, traceable to tech & qual-related documents); 8.3 (Ident traceable to such documentation as dwgs, specs, purchase orders, tech repts, test records, drilling loc & logs, etc.)	8.0	Appendix A Section 8.1 for Samples
8.2 (Ident either on items, samples, and software, or on records, containers traceable thereto)	8.0	Participant
8.3 (Identification traceable to approp documentation such as dwgs, specs, purchase orders, tech repts, drilling locations & logs, test records, installation and use records, inspec documents, and NCRs)	8.0	Appendix A Section 8.1(b) for samples.
8.4 (Correct ident of samples verified and documented before release for use or analysis)	Appendix A, Section 8.3	Appendix A Section 8.1(c) for samples.
8.5 (Controls to preclude use of incorrect or defective items, samples, software)	Appendix A, Section 8.3	Participant

NRC Review Plan	QAPD	QAPD
9.1 (Determination and list of special processes)	9.1	9.0
9.2 (Requires org responsibilities, including those of QA, to be described for qualification of special processes, personnel, and equip)	9.2	Appendix A Section 20.0
9.3 Sent. 1 (Procedures, equip, and personnel assoc with special processes qualif & in conformance with appl codes and standards)	9.0, 2.0	2.9 (for personnel qual.)
9.3 Sent. 2 (Acceptable methods of qualifying special processes assoc with scientific invest: (1) Prototype test (2) Technical review (3) Peer review)	Exception per Appendix A Section 9.1	Appendix A Section 20.4
9.4 (Requires procedr for recording evidence of accep performance of special processes)	9.3	Appendix A Section 20.0
9.5 (Qualification records of personnel, procedures, equip assoc with special processes established and maintained)	9.0, 17.0	17.0

NRC Review Plan	QARD	QAPD
10.1 (Scope of inspection program described; procedures provide criteria for determining when insp of each work operation to be performed)	10.0	Participant
10.2 (Individuals performing inspec are qualified persons independent of org unit directly responsible for inspected work)	10.0	Participant
10.3 (Qualification pgm for inspectors estab, documented; qualifications & certs of inspection personnel are kept current)	10.0	Participant
10.4a (Inspec proceds, instruc, or checklists provide for identification of characteristics, activities); 10.4b (Description of method); 10.4d (...for acceptance criteria); 10.4f in part (... for recording results of inspec operation)	10.0	Participant
10.4c (Inspection procedures, instructions, or checklists provide for ident of individuals or groups responsible for performing inspec)	10.0	Participant
10.4e (Inspection proced, instruc, or checklists provide for identification of required proceds, dwgs, specs & revisions)	10.1	Participant
10.4f (Inspection proceds, instruc, or checklists provide for recording inspector or data recorder, results of inspection operation)	10.0	Participant
10.4g (Inspection procedures, instruc, or checklists provide for specifying necessary measuring and test equipment, including accuracy rqmts)	10.1	Participant

NRC Review Plan	QAIRD	QAPD
10.5 (Mandatory inspec hold points identified)	10.0	Appendix A Sections 20.3(i), 20.7.3(d) for scientific investig.
10.6 (Indirect controls by monitoring)	10.0	Participant
10.7 (Both inspec and process monitoring used when control inadequate without both)	10.0	Participant
10.8 (Inspec results documented, acceptability determined by responsible person)	10.0	Participant

NRC Review Plan	QARD	QAPD
11.1, 11.2 (Test program to include, as approp, proof tests prior to instln, preop tests, and operational tests during construction and operation)	11.0, Appendix A Section 11.1	Participant (software test control is addressed in Section 19.0)
11.2 (Procedural controls assure the test program includes as appropriate proof tests prior to instln, preop tests, and operational tests during site characterization)	11.0	Participant
11.3a (Pgm procedures for test control provide for determining when a test is required and how testing activities are performed)	11.0, 11.2	Participant
11.3b (Pgm proc for test control provide for assurance that the test program is conducted by trained and appropriately qualified personnel). 11.6g (Test procedures or instructions to include provisions for assuring test prerequisites have been met)	11.0	Participant
11.4 (Test plans and procedures to be reviewed per design verification reqmts)		Participant
11.5 (Potential sources of uncertainty in test plans, procedures, and parameters, that must be controlled and measured to assure that tests are well-controlled, are to be identified)	11.1	Participant

NRC Review Plan	QAID	QAPD
11. 6a,b,d,e,f (Test procedures or instructions provide for: a. Reqmts and accep-tance limits, including req'd levels of precision and accuracy, in appropriate documents b. Instructions for performing the test d. Mandatory inspection hold points (as required) e. Acceptance criteria, including required levels of precision and accuracy f. Methods of recording or documenting test data and results)	11.2, Appendix A Section 20.2.1Participant	
11.6c (Test procedures or instructions provide for test prerequisites such as: o Calibrated instrumentation o Adequate test equipment and instrumentation o Completeness of item to be tested o Suitable and controlled environmental conditions o Provisions for data collection and storage	11.0	Participant
11.7 (Test results documented, evaluated, acceptability determined by responsible person or group per reqmts for design verification by testing)	11.0	Participant
11.8 (Items tested are to be identified, controlled, dispositioned; samples to be archived, as required by procedures)	Appendix A Section 8.1	Participant

NRC Review Plan	QARD	QAPD
12.1 (Program required to control, calibrate, and adjust M&TE at specified periods to maintain accuracy within *necessary limits*);	12.0	Appendix A Section 12.1
12.2 (Describe responsibilities of QA and other orgs for establishing, implem, and assuring effectiveness of calibration program)	Participant	Participant
12.3 (Review & documented concurrence with calibration, maintenance and control functions required)	Participant	Participant
12.3, Sent. 1 (Procedures provide for calibration, maint, & control of M&TE); 12.5 (Calibration intervals based on required accuracy, precision, purpose, degree of use, stability, characteristics, and other conditions that could affect measurements)	12.0	Appendix A Section 12.2
12.4 (M&TE labeled, tagged, or otherwise documented to indicate due date of next calib and to provide traceability to calib test data)	12.0	Appendix A Section 12.3.3
12.6 (Calib standards traceable to nationally recognized standards, except where nationally recognized stds do not exist, document the acceptability of the calibration std used)	12.0	Appendix A Section 12.1
12.7, Sent. 1 (Validity and acceptability of affected results since last calib evaluated & documented when M&TE found to be out of calibration)	12.0	Appendix A Section 12.3.3
12.7, Sent. 2 (Inspec and tests to be repeated on suspect items)	12.0	Participant

NRC Review Plan	QARD	QAPD
12.8 (Calib stds to have greater accuracy than equip or stds being calibrated, ex-cept calib stds *with* same accuracy may be used if they can be shown to be adequate for the reqmts, and if the basis for accep-tance is documented and authorized by responsible management. The mgmt authorized to perform this approval is to be identified)	12.1	Appendix A Section 12.3.2

NRC Review Plan	OARD	DAPD
13.1 (Rqmts and procedures to prevent damage or deterioration of items and samples); use suitably trained people and predetermined work and inspection instructions)	13.0, Appendix A Section 13.1	Appendix A Section 13.2
13.1 (Handling, shipping, etc., to be performed by suitably trained people per predetermined work and inspection instructions)	13.0, 2.8.2(b)	2.1.9
13.2 (Control cleaning, handling, storage, packaging, shipping of items and samples per design & procurement requirements and mfr's recommendations to preclude damage, loss, or deterioration by environ conditions such as temperature or humidity)	13.0, Appendix A Section 13.1	Appendix A Section 13.2, 13.3
13.3 (As appropriate, methods to take into consideration controls for limited life and special cleanliness)	13.0, Appendix A Section 13.0	Appendix A Section 13.3.5

NRC Review Plan	QARD	QAPD
14.1 (Procedures for using markings to indicate the status of inspections & tests, and the operating status of individual items & software)	14.0	Participant
14.2 (Procedures for identification of items that have passed required inspections and tests, where necessary to preclude inadvertent bypassing of such inspections and tests)	14.0	Participant
14.3 (Measures, such as tagging, established to indicate the test or operating status of items)	14.0	Participant
14.4 (Procedures to control application and removal of inspec and welding stamps and of status indicators such as tags, markings, labels, stamps)	14.0	Participant
14.5, Sent. 1 (Procedures to control altering the sequence of required tests, inspections, other operations important to safety)	14.1	Participant
14.5, Sent. 2 (Alteration of sequence of required tests, inspec-tions & other operations important to safety subject to same controls as original procedure review and approval)	14.1	Participant
14.6 (Status of non-conforming, inoperative, or malfunctioning structures, systems, components documented and identified to prevent inadvertent use; organization responsible for this function identified)	Participant	Participant

NRC Review Plan	QARD	QAPD
15.1 (measures established to prevent inadverent use)	15.0	15.1
15.2, Sent. 1 (Procedures for control of nonconforming items, software, procedures, records, or activities provide for: o Identification o Documenting o Tracking o Segregating o Reviewing o Dispositioning o Notifying effected organizations	15.0	15.0
15.2, Sent. 2 (Procedures identify positions authorized to disposition and close out nonconformances)	15.0, 15.2	15.0, 15.4
15.3 (QA responsibilities related to nonconformance control are described)	2.2	15.0
15.4 (Rqmt for documentation identifying and describing nonconformances, dispositions and including authorized signature approval of the disposition)	15.2	15.0, 15.3, 15.6
15.5 (Rqmt for periodic QA analysis of nonconformance reports for quality trends - significant results reported to upper mgmt for review and assessment)	16.1	16.1.3

NRC Review Plan	QARD	QAPD
16.1, Sent. 1 (Procedures for corrective action pgm assure that conditions adverse to quality are promptly ident and corrected)	16.0	16.0
16.1, Sent. 2 (QA organization reviews and documents concurrence with corrective action procedures)	Appendix A Sec. 6.1	2.1.3
16.2 (Corrective action documented & initiated after nonconformance to preclude recurrence, with QA concurring that QA requirements are satisfied)	Exception to universal recurrence prevention	Exception to universal recurrence prevention
16.3 (QA follow-up to verify proper implementation of corr action and to close out in timely manner)	16.4	16.1.3
16.4, Sent. 1 (Determine cause of signifi-cent conditions adverse to quality and take action to prevent recurrence)	16.0	16.1.1
16.4, Sent. 2 (Document these actions; report them to immediate mgmt and upper levels of mgmt for review & assessment)	16.0	16.1.1

NRC Review Plan	QARD	QAPD
17.1, Sent. 1 (Records program to assure records affecting quality are identifiable, retreivable, and maintained)	17.0	17.3, 17.6
17.1, Sent. 2 (QA records include: o Scientific, engineering, and operational data & logs; o Geotechnical data; o Results of reviews, inspections, tests, audits, and material analyses; o Monitoring of work performance; o Qualification of personnel, procedures, and equipment; o Drawings; o Specifications; o Procurement documents; o Calibration procedures and reports; o Design review reports; o Peer review reports; o Nonconformance reports; o Corrective action reports)	2.3(f), 17.0, 17.1 Appendix A Section 20.7, 20.9	17.3
17.2 (Responsibilities of QA & other orgs described for defining, implementing record activities - particularly in retention, duration, and safe storage)	17.0	17.0

NRC Review Plan	QARD	QAPD
17.3 (Where applicable, inspec & test records contain: a. Ident of procedure &item inspec or tested; b. Description of type of observation; c. Date & results of inspection or test; d. Info related to conditions adverse to quality; e. Inspector or data recorder ident; f. Evidence as to acceptability of results, with signature & org; g. Action taken to resolve any discrepancies noted)	10.0, 10.2, 11.0 Appendix A Section 20.9, 20.10	Participant
17.4 (Criteria established & described in procedures, for determining when a document becomes a QA record)	17.0, 17.2	17.2
17.5 (Procedures for controlling, protection, maintenance of QA records prior to their being entered and stored in the quality record control storage area)	17.0, 17.2	17.6
17.6 (Procedures describing methods of documenting/ recording, reviewing, & confirming accuracy of records, which include lab and field notebooks and log books, data sheets, data reduction documents, and software)	17.0; Appendix A, Section 20.7	17.3
17.7 (Suitable facilities described & used to preclude deterioration, damage, loss, or misuse of records)	17.0	17.6

NRC Review Plan	QARD	QAPD
18.1, Sent. 1 (Internal and external audits carried out by DOE and its contractors to determine compliance and QA *program effectiveness*)	18.3, 18.4	18.0, 18.1
18.1, Sent. 2 (DOE & its contractors perform audits of prime contactors, subcontractors, consultants, vendors, and laboratories)	18.4	18.0
18.2, Sent. 1 (Audit program planned to identify: o Audits to be performed; o Audit frequencies & schedules, considering complexity, safety, importance, and degree of previous audits, inspections, and surveillances)	18.0, 18.3, 18.4	18.2
18.2, Sent. 2 (Audits regularly scheduled, based on status and safety importance of activities being performed, and initiated early enough to assure effective QA during: o Design; o Procurement; o Site characterization; o Manufacturing; o Construction; o Installation; o Inspection and testing)	18.0	18.2
18.3, Sent. 1 (Audits to include technical evaluations of applicable procedures, instructions, activities, and/or items)	18.1	18.1, 18.4
18.3, Sent. 2 (As applicable, audits should include review of documents & records including software and test data from samples, to ensure they are acceptable)	18.4	18.5

NRC Review Plan	QARD	QAPD
18.4 (Audit results to be documented and analyzed by the QA and technical staff org, and the results reported to responsible mgmt for review, assessment and appropriate action)	18.2, if "responsible management" includes tech staff of auditing organization	18.5, 18.6
18.5 (Audits to be performed to pre-established procedures or checklists and conducted by trained, qualified, competent QA and technical people whose expertise covers the area being audited, and having no direct responsibility in the areas being audited)	18.0, 18.1	18.3, 18.4
18.6 (Audit finding tracking system to help assure all findings approp addressed, prioritized, trended)	18.0	16.1.2, 16.1.3
18.7 (Audited org uses formal report to the auditing org or responsible mgmt to describe corrective action to be taken)	18.0	18.6
18.8 (Provisions to assure that causes of findings are identified, corrective action for the causes is described, and followup action is taken to assure proper closeout)	18.0	18.7