Department of Energy
Washington, DC 20585

JAN 10 1989

John J. Linehan, Director
Repository Licensing and Quality
Assurance Directorate
Division of High Level Waste
Management
Office of Nuclear Material Safety
and Safeguards
U. S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Mr. Linehan:

On December 21, 1988, OCRWM transmitted a copy of the Quality Assurance Program Description (QAPD) document, Revision 1 to the NRC. In order to expedite NRC's review of this document, I have enclosed a marked up copy of the QAPD containing additions and deletions from Revision 0, submitted on September 16, 1988. If you have any questions, please call me on 586-1462 or Jay Jones on 586-1224.

Sincerely,

Gordon Appel, Chief
Licensing Branch
Licensing and Compliance
Division
Office of Civilian Radioactive
Waste Management

Enclosure

cc:
J. Kennedy, NRC

WM-1 NHC 4C

U.S. DEPARTMENT OF ENERGY

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

QUALITY ASSURANCE PROGRAM DESCRIPTION

FOR THE

CIVILIAN RADIOACTIVE WASTE MANAGEMENT PROGRAM

Lake Barrett, Director OCRWM Office of Quality Assurance	Date
Approved Samuel Rousso, Acting Director Office of Civilian Radioactive Waste Management	Date

REVISION 1

QAPD
December 14, 1988
Revision 1

QUALITY ASSURANCE PROGRAM DESCRIPTION FOR THE CIVILIAN RADIOACTIVE WASTE MANAGEMENT PROGRAM

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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; to provide Federal interim storage, if required; 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.

OCRWM will develop and implement a quality assurance program meeting 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 imposed on, and implemented by, each organization participating in the program through DOE/RW-YYYY, Quality Assurance Requirements for the Civilian Radioactive Waste Management Program (QAR). The QAR provides the requirements for the development of a consistent framework for implementing quality assurance programs at every level within the Civilian Radioactive Waste Management program. The OCRWM quality assurance program is applied to items and activities in a graded manner commensurate with importance to safety, waste isolation, and other OCRWM program objectives. OCRWM's quality assurance program is described in this document.

Samuel Rousso, Acting Director
Office of Civilian Radioactive
Waste Management

Date

QAPD
December 14, 1988
Revision 1

INTRODUCTION

The purpose of this document is to describe the quality assurance (QA) program of the U.S. Department of Energy (DOE), Office of Civilian Radioactive Waste Management (OCRWM), describe responsibilities for achieving and assuring quality at OCRWM, describe the interfaces between OCRWM and the Project Offices participating in the Civilian Radioactive Waste Management Program (PROGRAM) for achieving and assuring quality, reflect Congressional redirection of the PROGRAM, and serve as the quality assurance program description document for DOE. This document and DOE/RW-YYYY, Quality Assurance Requirements for the Civilian Radioactive Waste Management Program (QAR) reflect OCRWM policies and serve as the principal documents of the PROGRAM quality assurance program.

The PROGRAM quality assurance program covers activities affecting quality that are performed at each PROGRAM-participant organizational level. PROGRAM participants include OCRWM, OCRWM-managed contractors, Project Offices, Project Office-managed contractors, consultants, national laboratories, waste form producers, and other government agencies performing activities affecting quality for the PROGRAM. The OCRWM quality assurance program is applied to items and activities in a graded manner commensurate with importance to safety, waste isolation, or other PROGRAM objectives.

Each Section of this document describes the provisions established by OCRWM to meet the requirements of the QAR and addresses how other PROGRAM participants implement the requirements of the QAR.

The definitions given in ANSI/ASME NQA-1-1986b and supplemented by the definitions in the QAR are applicable to this document.

QAPD
December 14, 1988
Revision 1

SECTION 1

ORGANIZATION

1.0 GENERAL

This section describes the organizational responsibilities for OCRWM and identifies organizational interfaces with OCRWM-managed PROGRAM participants, Project Offices, and Project Office-managed PROGRAM participants. The assignment of responsibilities reflects the philosophy that the line organization achieves quality and the quality organization overviews to assess the achievement of quality.

The Nuclear Waste Policy Act (NWPA), as amended by the Nuclear Waste Policy Amendments Acts of 1987, authorizes the Department of Energy (DOE)/OCRWM to site, construct, and operate a geologic repository; to site, construct, and operate one monitored retrievable storage (MRS) facility; to provide for Federal interim storage; and to provide for the transportation of the waste in casks certified by the Nuclear Regulatory Commission (NRC). The NWPA as amended directs DOE/OCRWM to characterize only one site for the geologic repository.

It is the responsibility of 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, Federal interim storage, 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 Project Office managers to each PROGRAM participant.

1.1 OCRWM ORGANIZATION

OCRWM is the headquarters for the Civilian Radioactive Waste Management Program. OCRWM includes 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 ~~AND~~ OERAP report to the Director, OCRWM. The organizational relationship of each office is illustrated in Figures 1-1A through 1-1F. The functional and quality assurance program responsibilities for each OCRWM position are described in the following paragraphs.

1.1.1 Director, Office of Civilian Radioactive Waste Management (OCRWM)

The Director, OCRWM reports directly to the Office of the Secretary, U.S. Department of Energy and has overall responsibility for the PROGRAM.

The quality assurance responsibilities of the Director, OCRWM are:

(a) Establish and execute a quality assurance program which 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-YYYY, Quality Assurance Requirements for the Civilian Radioactive Waste Management Program (QAR)

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

(e) Approve PROGRAM plans essential to the OCRWM offices for achievement of technical and quality assurance program objectives

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

(g) 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

(h) Maintain cognizance of quality assurance issues and problems and effect resolution

(i) Provide for the annual ~~regular~~ assessment of the scope of, status of, adequacy of, and compliance to the quality assurance program by OCRWM management who are above or independent of the Office of Quality Assurance

(j) Retain responsibility for the quality of work delegated to other PROGRAM participants, such as contractors, agents, and consultants

1.1.2 Director, Office of Quality Assurance (OQA)

The Director, OQA reports directly to the Director, OCRWM and has been delegated the management responsibility and authority to direct and control the 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 of other OCRWM offices; and management of other PROGRAM participants. 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 the ~~execution~~, 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 and is independent from undue pressures due to cost and schedule considerations.

The responsibilities of the Director, OQA are:

(a) Establish integrated PROGRAM quality assurance policies and requirements in baseline or other controlled documents

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

(c) Provide quality assurance guidance and direction to PROGRAM participants

(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 Project Office verification activities, such as assessments, readiness reviews, and

audits

(f) Review the quality assurance program documents (including revisions to and interpretations thereof) of the Project Offices and OCRWM-managed PROGRAM participants for compliance with established PROGRAM quality assurance policies and requirements, develop a recommendation for approval or disapproval, obtain concurrence of the cognizant Associate Directors, and submit the recommendation to the Director, OCRWM for approval or disapproval action

(g) Direct the activities of the PROGRAM Quality Assurance Coordinating Group (QACG) and coordinate the activities of the QACG with participants from the NRC, States, Indian Tribes, local governments, and the nuclear industry

(h) Review OCRWM procurement documents for inclusion of quality assurance requirements

(i) Assure the development and implementation of a quality assurance indoctrination program for all PROGRAM personnel

(j) Review and approve the indoctrination and training requirements for OQA personnel

(k) Establish and maintain a PROGRAM quality assurance information system to facilitate effective communication of the status of development and implementation of the quality assurance program; status of resolution of issues, trends, and significant conditions adverse to quality; and a summary of management overview results including both adverse conditions and exemplary practices

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

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

1.1.3 Associate Director, Office of Program Administration and Resources Management (OPARM)

The Associate Director, OPARM reports directly to the Director, OCRWM and has primary responsibility for the development, implementation, and maintenance of a program management system,

program management information system, project decision schedule, and program schedule. OPARM 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, OPARM has the following quality assurance program responsibilities:

(a) Establish or approve the scope of OPARM activities affecting quality commensurate with the QAR. This includes the assignment of quality levels to OPARM activities.

(b) Ensure that technical and quality assurance requirements specified by other offices are incorporated into procurement documents

(c) Coordinate with other involved Associate Directors the OCRWM verification of OCRWM-managed PROGRAM-participants' activities affecting quality for which OPARM has the lead responsibility and ensure that applicable quality assurance program documents are approved by OCRWM prior to initiation of work activities

(d) Ensure that information and data systems meet the QA Records requirements specified in the QAR

(e) Review and approve the indoctrination and training requirements for OPARM Division Directors and provide for the indoctrination and training of all OCRWM personnel through the Training Officer

(f) Ensure that OPARM personnel who perform activities affecting quality are qualified by experience or training to perform assigned tasks

(g) Concur with the Director, OQA's recommendation for approval or disapproval of OPARM-managed PROGRAM-participants' quality assurance programs for which OPARM has lead responsibility

(h) Develop and maintain those implementing line and quality assurance administrative procedures and other quality assurance documents and records for which OPARM has lead responsibility

(i) Ensure that adequate funds and resources are provided for OPARM activities affecting quality

(j) Identify and report 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 Associate Director, Office of Facilities Siting and Development (OFSD)

The Associate Director, OFSD reports directly to the Director, OCRWM and has primary responsibility for screening and characterization of the geologic repository site and 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 and technical direction of the PROGRAM's geoscience activities; and socioeconomic and institutional planning.

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

(a) Establish or approve the scope of the OFSD activities affecting quality commensurate with the QAR. This includes the assignment of quality levels to OFSD activities.

(b) Develop the requirements documents for the PROGRAM

(bc) Ensure that OFSD personnel who perform activities affecting quality are qualified by experience or training to perform assigned tasks

(cd) Evaluate results of activities that verify quality achievement within the scope of work assigned to OFSD

(de) Assign responsibility for the quality of delegated work prior to initiating the work activities

(ef) Ensure the technical adequacy of items and activities for which OFSD has lead responsibility and the implementation of effective management controls

(fg) Concur with the Director, OQA's recommendation for approval or disapproval of OFSD-managed PROGRAM-

participants' quality assurance programs for which OFSD has lead responsibility

(gh) Coordinate with other involved Associate Directors the OCRWM verification of OCRWM-managed PROGRAM-participants' activities affecting quality for which OFSD has the lead responsibility and ensure that applicable quality assurance program documents are approved by OCRWM prior to initiation of work activities

(hi) Ensure that adequate funds and resources are provided for OFSD activities affecting quality

(ij) Identify and report 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

(jk) Develop and maintain those implementing line and quality assurance administrative procedures and other quality assurance documents and records for which the OFSD has lead responsibility

(kl) Review and approve indoctrination and training requirements for OFSD Division Directors

1.1.5 Associate Director, Office of Systems Integration and Regulations (OSIR)

The Associate Director, OSIR reports directly to the Director, OCRWM and has primary responsibility for planning, managing, and overseeing the integration of the Civilian Radioactive Waste Management system; managing programs for the development of technologies for use at the geologic repository or MRS (for example, 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 first geologic repository and MRS facility.

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

(a) Establish or approve the scope of OSIR activities affecting quality commensurate with the QAR. This

includes the assignment of quality levels to OSIR activities.

(b) Develop the Systems Engineering Management Plan for each system element of the PROGRAM.

(bc) Ensure that OSIR personnel who perform activities affecting quality are qualified by training or experience to perform assigned tasks

(cd) Evaluate results of activities that verify quality achievement within the scope of work assigned to OSIR

(de) Assign responsibility for the quality of delegated work prior to initiation of work activities

(ef) Ensure the technical adequacy of items and activities for which OSIR has lead responsibility and the implementation of effective management controls

(fg) Concur with the Director, OQA's recommendation for the approval or disapproval of OSIR-managed PROGRAM participants' quality assurance programs for which OSIR has lead responsibility

(gh) Coordinate with other involved Associate Directors the OCRWM verification of OCRWM-managed PROGRAM-participants' activities affecting quality for which OSIR has the lead responsibility and ensure that applicable quality assurance program documents are approved by OCRWM prior to initiation of work activities

(hi) Ensure that adequate funds and resources are provided for OSIR activities affecting quality

(ij) Identify and report 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

(jk) Develop and maintain those implementing line and quality assurance administrative procedures and other OCRWM quality assurance program documents and records for which the OSIR has lead responsibility

(kl) Review and approve indoctrination and training requirements for OSIR Division Directors

1.1.6 Associate Director, Office of External Relations and Policy (OERAP)

The Associate Director, OERAP 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 Associate Director, OERAP is responsible for the following quality assurance program activities:

(a) Establish or approve the scope of OERAP activities affecting quality commensurate with the QAR. This includes the assignment of quality levels to OERAP activities.

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

(c) Assign responsibility for the quality of delegated work before the initiation of work activities

(d) Concur with the Director, OQA's recommendation for approval or disapproval of OERAP-managed PROGRAM-participants' quality assurance programs for which OERAP has lead responsibility

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

(f) Review and approve indoctrination and training requirements for OERAP Division Directors

(g) Develop and maintain those implementing line and quality assurance administrative procedures and other quality assurance program documents and records for which the OERAP has lead responsibility

(h) Identify and report 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

1.1.7 Division Directors

The Division Directors report to the cognizant Associate Directors and have the following quality assurance program

responsibilities.

(a) Establish the scope of quality assurance activities and requirements for those activities under the cognizance of the Division Directors and obtain the approval of the Associate Director

(b) Ensure 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) Evaluate the quality of delegated work

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

(e) Coordinate with other involved OCRWM Divisions, the performance of quality verification activities

(f) Evaluate whether adequate resources are available for Division quality achievement and verification activities

(g) Identify and report quality-related issues and problems that affect, or potentially affect, the Division's activities to the Associate Director and obtain satisfactory resolution

(h) Develop and maintain those implementing line and quality assurance administrative procedures and other quality assurance program documents and records for which the Division has lead responsibility

(i) Review and approve indoctrination and training requirements for Branch Chiefs and other personnel under their supervision

1.1.8 Branch Chiefs

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

(a) Assure that technical personnel under the direction of the Branch Chiefs are qualified by experience or training to perform the assigned work and comply with the technical and quality assurance requirements applicable to the work being performed

(b) Identify indoctrination and training requirements for Branch personnel

(c) Ensure, by using methods that verify the achievement of quality, the technical adequacy of items and activities within their area of responsibility

(d) Coordinate the verification of quality achievement of technical activities at the OCRWM, OCRWM-managed PROGRAM participants, and the Project Offices that are within the Branch's responsibility

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

FIGURE 1-1A
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
ORGANIZATION

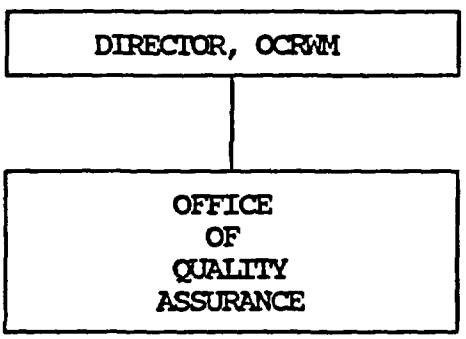

FIGURE 1-1B
OFFICE OF QUALITY ASSURANCE
ORGANIZATION

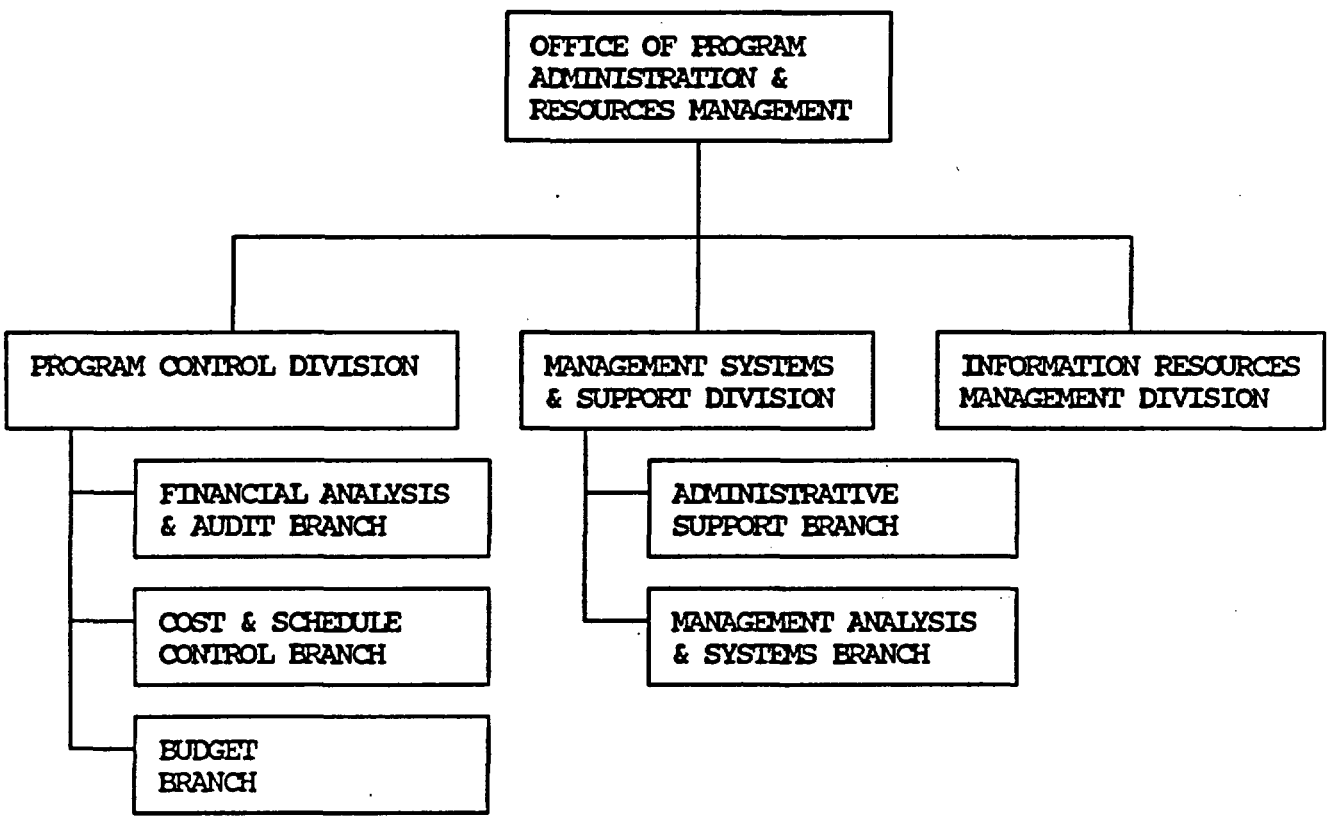

FIGURE 1-1C
OFFICE OF PROGRAM ADMINISTRATION AND RESOURCES MANAGEMENT ORGANIZATION

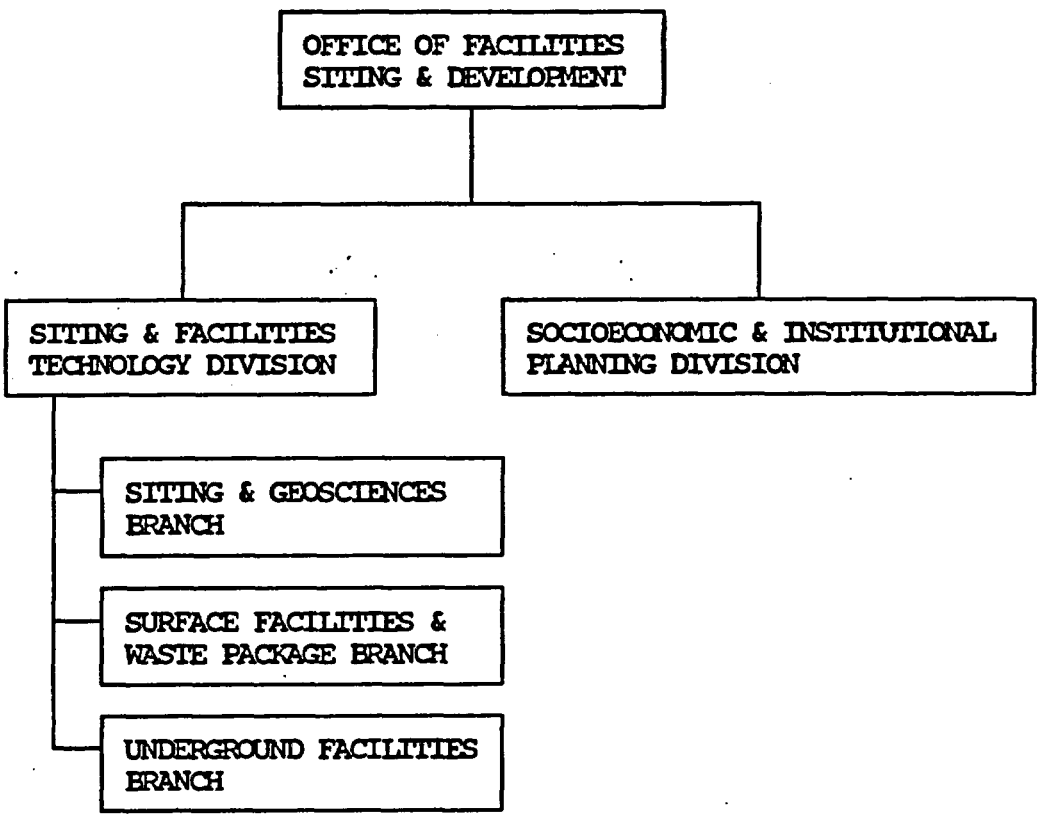

FIGURE 1-1D
OFFICE OF FACILITIES SITING AND DEVELOPMENT ORGANIZATION

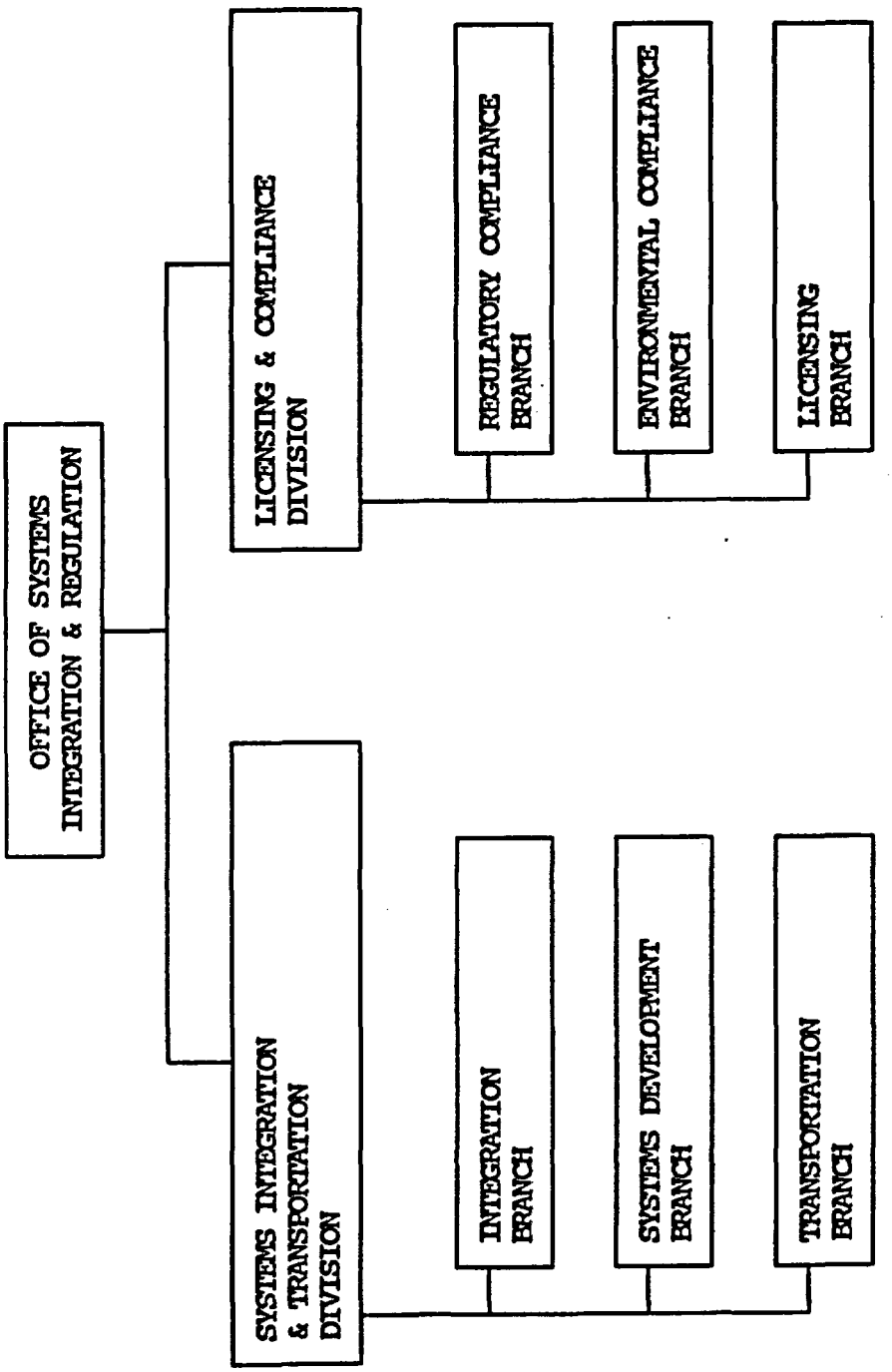

FIGURE 1-1E
OFFICE OF SYSTEMS INTEGRATION AND REGULATIONS
ORGANIZATION

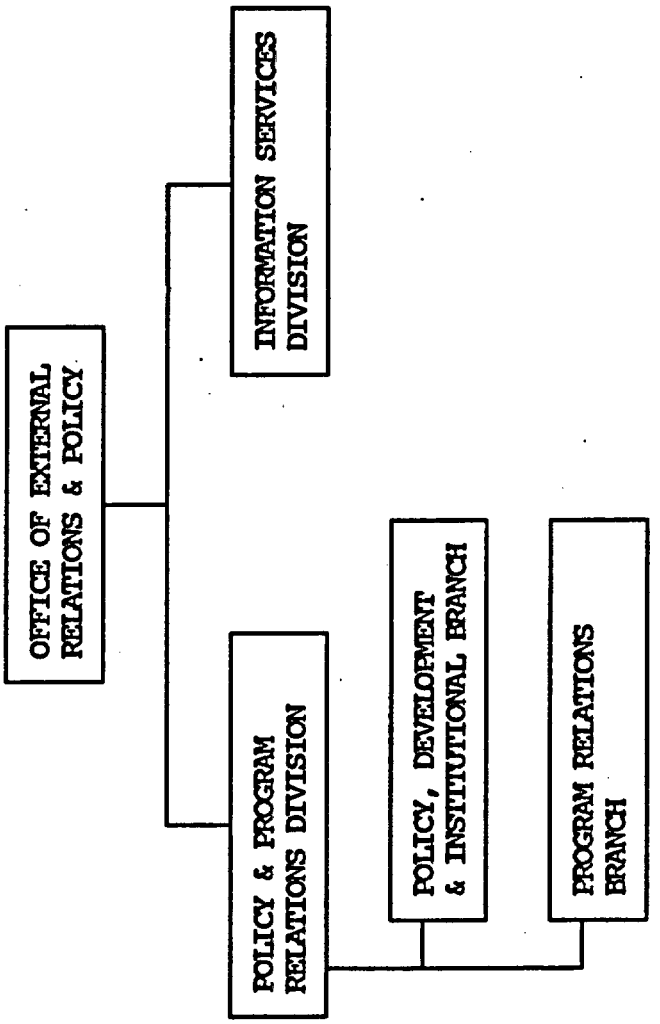

FIGURE 1-1F
OFFICE OF EXTERNAL RELATIONS AND POLICY
ORGANIZATION

1.1.9 Organizational Interfaces

The organizational interfaces between OCRWM, OCRWM-managed PROGRAM participants, Project Offices, and Project Office-managed PROGRAM participants are illustrated in Figures 1-2A through 1-2C. Interfaces and the flow of PROGRAM direction and quality assurance overview direction from OCRWM to the Project Offices and other PROGRAM participants are illustrated in Figure 1-3.

1.1.9.1 Operations and Project Offices

The Project Managers on behalf of the Operations Office Managers have overall line management responsibility and accountability for implementation of PROGRAM-assigned tasks. Each Project Manager and Operations Office Manager will establish a project management organization and delegated responsibility and authority for management and direction of PROGRAM tasks to the Project Manager.

The Project Manager has direct, primary responsibility and accountability for the execution and implementation of PROGRAM tasks in accordance with the Project Charter, Project Plan, and Project Management Plan. In addition, the Project Manager is the point of contact for the flow of information to and from the Director, OCRWM and the Project Office-managed PROGRAM participants and is responsible for implementing the Project quality assurance program.

The Project Manager and management at each Project Office-managed PROGRAM participant will identify 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 ~~Project Office's and Project Office-managed PROGRAM participants'~~ quality assurance program descriptions

(d) No other duties or responsibilities unrelated to

quality assurance which would prevent full attention to quality assurance matters

Interfaces between Project Offices and Project Office-managed PROGRAM participants will be addressed in quality assurance program descriptions and the implementing line and quality assurance administrative procedures.

Operations Offices and respective areas of responsibility are listed below:

(a) Nevada Operations Office, Yucca Mountain Project Office (YMPO). This Project Office is responsible for the characterization, design, and construction of the Yucca Mountain, Nevada site which is the candidate for the first geologic repository.

(b) Chicago Operations Office. This Operations Office is responsible for institutional planning, analysis, and management integration of the transportation systems and for providing regulatory and administrative support, such as review of regulations on an as-needed basis, quality assurance support, and international program support. This Operations Office performs preclosure performance assessments and waste package studies.

(c) Idaho Operations Office. This Operations Office is responsible for review of transportation cask development, engineering development, and the waste form from the West Valley Demonstration Project (WVDP).

(d) Richland Operations Office. This Operations Office is responsible for materials characterization and preclosure performance assessment. This Operations Office also provides technical support for waste isolation and characterization and for systems integration activities.

(e) Oak Ridge Operations Office. This Operations Office provides geosciences, shielding, systems integration, operations, and public relations support to the PROGRAM.

(f) Albuquerque Operations Office. This Operations Office provides technical support for postclosure

performance assessment work.

(g) San Francisco Operations Office. This Operations Office provides geoscientific support and performs defense waste studies.

1.1.9.2 PROGRAM Participants

Organizational interfaces between OCRWM and PROGRAM participants are illustrated in Figures 1-2A through 1-2C. The quality assurance requirements for each PROGRAM participant are identified in the appropriate procurement documents. Quality assurance program descriptions will be reviewed and approved. OCRWM provides overview of each PROGRAM-participant's quality assurance activities by various verification methods, such as reviews, assessments, audits, or surveillances.

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

(a) Roy F. Weston, Inc. (Weston) which provides program management, institutional, technical, scientific, and quality assurance support to OCRWM.

(b) CER Corporation which provides quality assurance support services to OCRWM and to the Chicago Operations Office through the Chicago Operations Office.

(c) Science Applications International, Corporation (SAIC) which provides records management services related to the licensing support system.

When appropriate, each PROGRAM participant, other than the direct-support contractors, will identify a position responsible for directing and managing the respective quality assurance programs. These positions will be occupied by individuals with appropriate management and quality assurance knowledge and experience ~~and will comply with the QAR~~. PROGRAM participants, other than OCRWM direct-support contractors, include:

(a) Battelle, Pacific Northwest Laboratories (PNL) PNL performs preclosure performance assessment and materials characterization.

(b) Brookhaven National Laboratory (BNL) operated by Associated Universities, Inc. (AUI)

BNL provides waste-package scientific support and preclosure risk assessment services.

(c) Lawrence Berkeley Laboratory (LBL) operated by the University of California

LBL provides geoscientific support.

(d) Oak Ridge National Laboratory (ORNL) operated by Martin Marietta Energy Systems, Inc. (Martin-Marietta).

ORNL provides transportation-operations planning, geosciences, shielding, and systems integration support and performs safeguards activities.

(e) Argonne National Laboratory (ANL) operated by the University of Chicago

ANL provides environmental, socioeconomic, and site characterization support.

(f) Battelle Memorial Institute (BMI)

BMI provides institutional planning and analysis and management integration.

(g) Lawrence Livermore National Laboratory (LLNL) operated by the University of California

LLNL performs defense waste studies.

(h) Sandia National Laboratory (SNL) operated by Western Electric Company, Inc.

SNL performs postclosure performance assessments.

(i) Idaho National Engineering Laboratory (INEL) operated by EG&G Idaho, Inc.

INEL is responsible for cask development.

(j) KOH Systems, Inc. (KOH)

KOH provides records management and related

activities support to OCRWM.

(k) SRA Technologies, Inc. (SRA)

SRA provides technical support services in planning and scoping an Environmental Impact Statement and implementation plan for the geologic repository.

(l) E. I. du Pont de Nemours & Co.

E. I. du Pont de Nemours & Co. operates the Defense Waste Processing Facility (DWPF).

(m) West Valley Nuclear Services

West Valley Nuclear Services operates the West Valley Demonstration Project (WVDP).

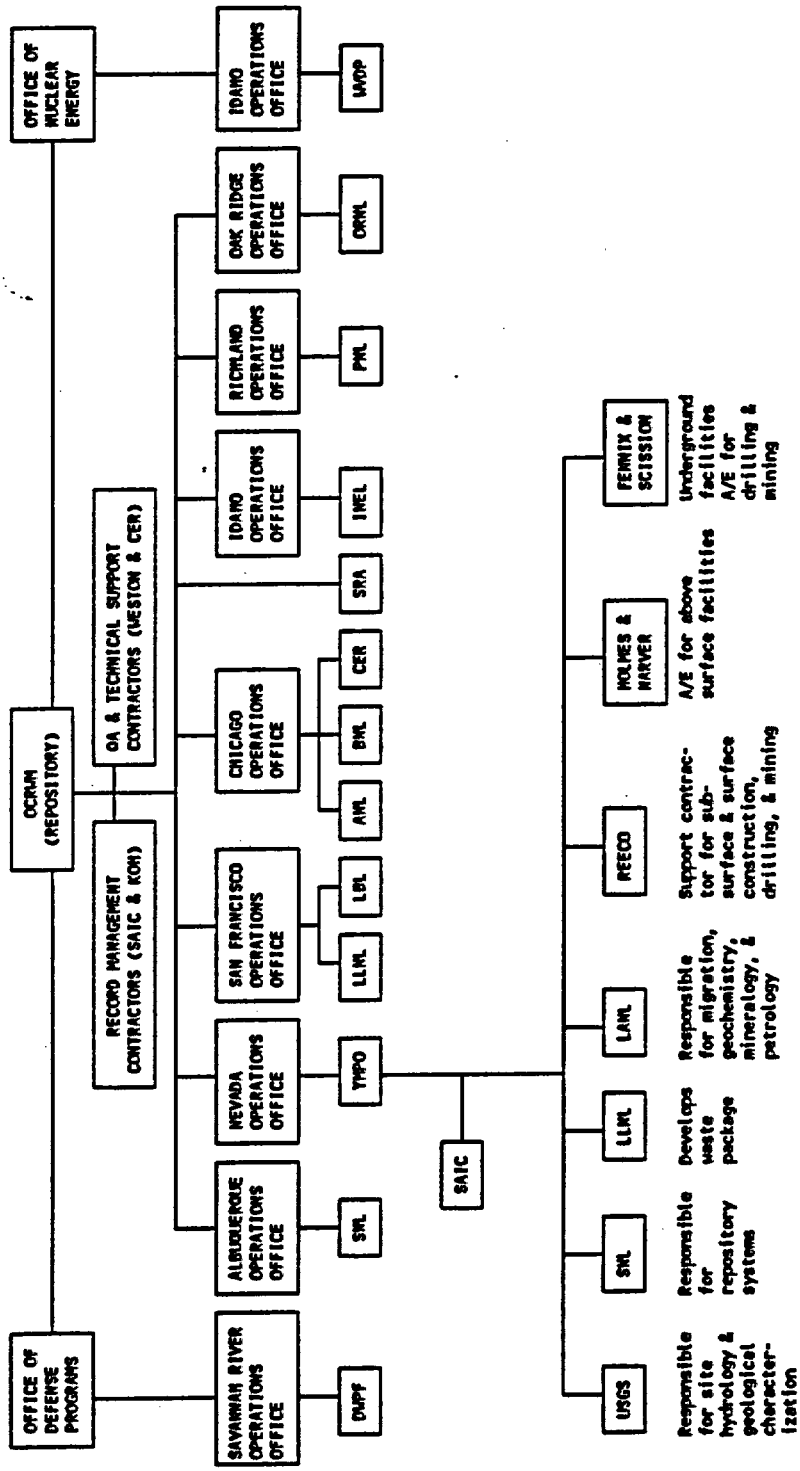

FIGURE 1-2A
CRWM GEOLOGIC REPOSITORY PROGRAM PARTICIPANTS

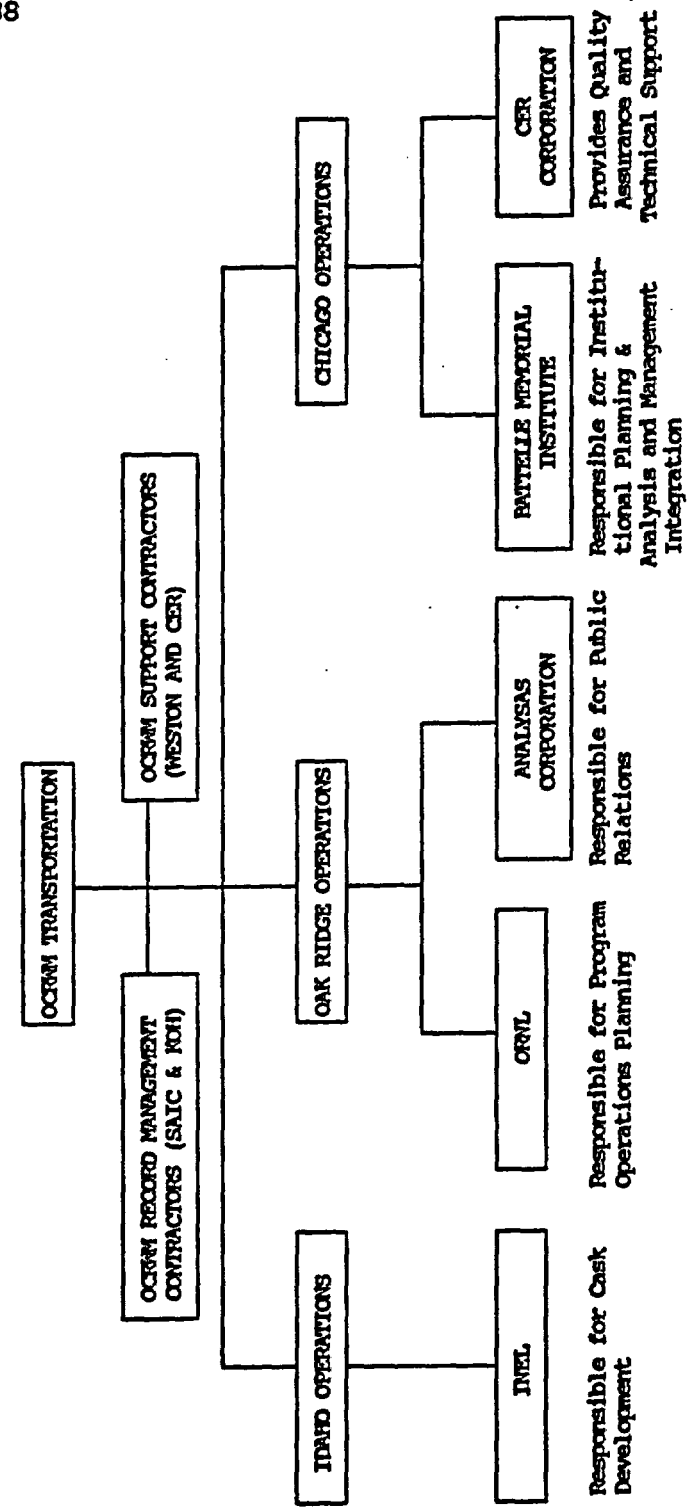

FIGURE 1-2B
CRWM TRANSPORTATION PROGRAM PARTICIPANTS

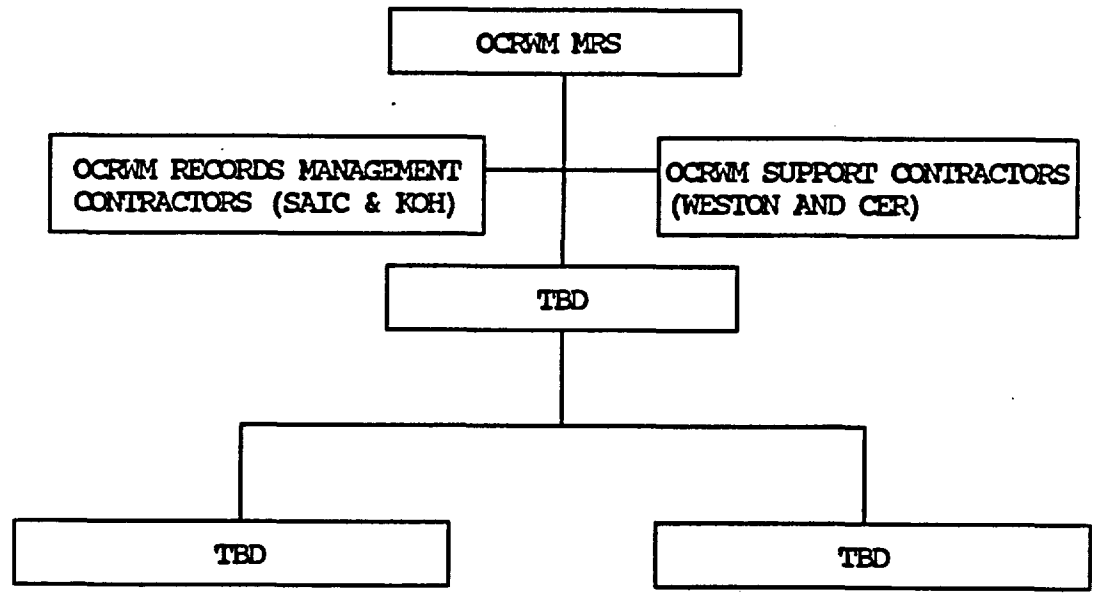

FIGURE 1-2C
CRWM MRS PROGRAM PARTICIPANTS

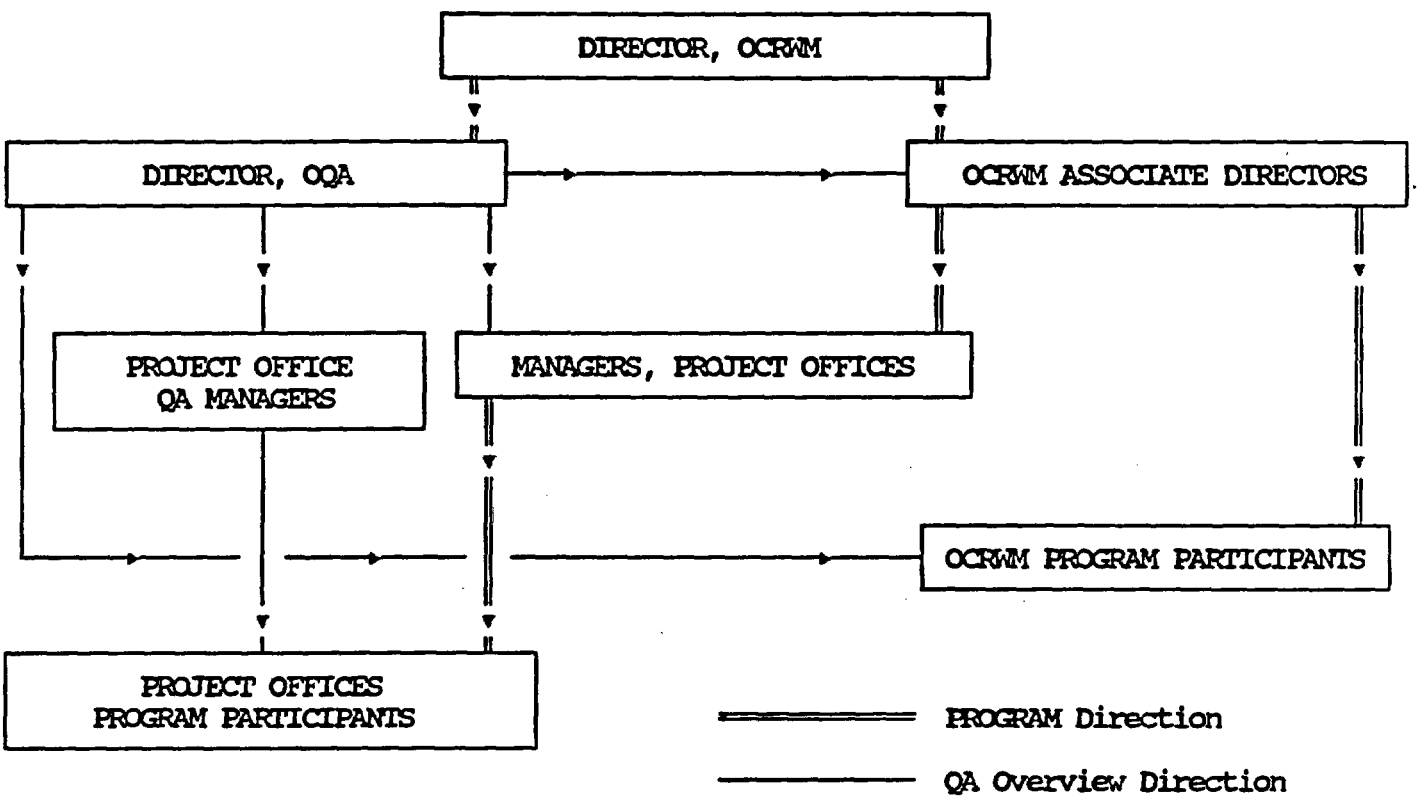

FIGURE 1-3
CRWM PROGRAM DIRECTION AND QUALITY VERIFICATION

1.1.10 Interactions

Interactions between OCRWM and other organizations are conducted as defined below. Interactions among organizations other than OCRWM will be described in PROGRAM-participant quality assurance program descriptions and the implementing line and quality assurance administrative procedures.

1.1.10.1 NRC and Other Regulatory Agencies

Project Offices advise the Director, OQA and the Director, OSIR on quality assurance matters in advance of intended meetings and other interactions with the NRC. Where interactions have PROGRAM significance, the interactions are arranged through the Director, OQA and the Director, OSIR. Interactions with other regulatory agencies on quality assurance matters are handled in a manner similar to NRC interactions.

1.1.10.2 States, Local Governments, and Indian Tribes

Project Offices advise the Associate Director, OERAP in advance of intended meetings and other interactions with the States, local governments, and Indian Tribes.

1.1.10.3 Other Organizations

OCRWM interactions with other organizations involving quality assurance activities are coordinated through the Director, OQA.

1.1.11 Delegation of Work

Responsibility for the overall PROGRAM is retained by OCRWM. The tasks of establishing and implementing selected portions of the overall OCRWM quality assurance program for work associated with the PROGRAM have been delegated to Project Offices and other PROGRAM participants as described in Section 2. The further delegation of work by the Project Offices and other PROGRAM participants is described in the respective quality assurance program documents.

1.1.12 Resolution of Disputes

Differences of opinion involving technical or quality assurance programmatic 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 directly to the Director, OCRWM without fear of reprisal. Each allegation concerning inadequate quality will be investigated by personnel who are independent of the affected activity. The individual who registered the concern is notified of the investigation results.

This system is available to employees of PROGRAM-participants and persons outside the PROGRAM. An employee of a PROGRAM-participant should 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, Project Offices, and the offices of other PROGRAM participants 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 contracting officer may, at any time, issue written stop work orders to the contractor.~~

In addition, the Director, OQA and quality assurance management at Project Offices and other PROGRAM-participants offices have authority to identify quality problems; initiate, recommend, or provide solutions to problems; and prevent or control further processing, delivery, or use of nonconforming or unsatisfactory work until proper disposition is obtained.

OCRWM personnel who identify quality problems while performing quality verification activities at the Project Offices inform the Project Office quality assurance management who initiates actions to prevent further work through the Project Manager.

1.1.15 Applicable Quality Assurance Administrative Procedures

The planned OCRWM quality assurance administrative procedures that are applicable to OCRWM's management control activities are:

QAAP-2.8	Handling of Allegations
QAAP-16.2	Stop Work

QAAP-16.3 Resolution of Differing Technical Opinions

QAAP-16.4 Resolution of Issues Involving Quality

1.2 OTHER PROGRAM PARTICIPANTS

The description of the organizational structure of the other PROGRAM participants and the control of disputes, allegations, stop work, and interfaces is contained in the respective quality assurance program descriptions and quality assurance administrative procedures.

SECTION 2

QUALITY ASSURANCE PROGRAM

2.0 GENERAL

OCRWM is developing a quality assurance program for its portion of the PROGRAM. The OCRWM quality assurance program will comply with the requirements specified in the QAR which are applicable to headquarter's activities. Quality Level 1, 2, and 3 items and activities will be controlled to the extent required by the OCRWM quality assurance program. The OCRWM quality assurance program consists of this QAPD, the QAR, and OCRWM implementing line and quality assurance administrative procedures. The PROGRAM-participants' quality assurance programs consist of the descriptions of the quality assurance programs and the implementing line and quality assurance administrative procedures (QA PROGRAMs).

Waste form producers [for example, West Valley Demonstration Project (WVDP) and Defense Waste Processing Facility (DWPF)] process waste for permanent disposal in the geologic repository. The processing and preparation of wastes for disposal are performed under the controls of quality assurance programs. Waste Form Producers' quality assurance program requirements are contained in OGR/B-14, QA Requirements for High-Level Waste Form Production. Quality assurance program descriptions will be reviewed and approved by OCRWM.

The quality assurance requirements specified in the Office of Storage and Transportation Systems Quality Assurance Plan for the Transportation Casks Systems Development Program are applicable to cask systems development.

This Section describes provisions established by OCRWM to implement a quality assurance program to control activities affecting quality. Quality assurance programs that will be implemented by other PROGRAM participants are also addressed.

2.1 OCRWM QUALITY ASSURANCE PROGRAM

2.1.1 Quality Assurance Requirements

The quality assurance requirements for the PROGRAM are identified in DOE/RW-YYYY, Quality Assurance Requirements for the Civilian Radioactive Waste Management Program (QAR). The QAR is approved by the Director, OCRWM on the recommendation of the Director, OQA and will be issued as a controlled document.

2.1.2 Quality Assurance Program Descriptions

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

2.1.3 Quality Assurance Administrative Procedures (QAAPs)

OCRWM QAAPs will be consistent with the QAR and QAPD and will delineate the specific administrative and quality assurance controls or methods used to meet the requirements established in the upper level quality assurance program documents. These procedures will be contained in a QAAP Manual and issued and controlled by OQA. Preparation of QAAPs has been assigned to the OCRWM discipline or group with lead responsibility for the activity or area. Each affected discipline or group reviews the QAAPs to assure appropriate requirements and interfaces are defined. QAAPs will be approved by the Director, OQA and implementing line management. A list of planned OCRWM QAAPs for the control of internal activities is presented in Figure 2-1.

2.1.4 Implementing Line Procedures

Implementing line procedures (ILPs) provide instructions for OCRWM personnel performing activities affecting quality. Implementing line procedures include technical, management, and operating procedures necessary for performing work at OCRWM which includes implementing the requirements of the QAR. Implementing line procedures will be prepared, reviewed, and approved by the OCRWM Branch performing the activities. The Office of Quality Assurance will support and assist in the development of implementing line procedures, as appropriate.

2.1.5 Delegated Work

Responsibility for the overall PROGRAM is retained by OCRWM. The tasks of establishing and implementing selected portions of the PROGRAM quality assurance program has been delegated to Project Offices and other PROGRAM participants as indicated in Figure 2-2. The Project Offices and other PROGRAM participants have further delegated work associated with the PROGRAM. This delegation is described in the PROGRAM-participant quality assurance program documents.

2.1.6 Quality Assurance Program Controls

Quality assurance controls are applied to items and activities affecting quality that are performed by OCRWM, OCRWM-managed PROGRAM participants, Project Offices, and Project Office-managed PROGRAM participants.

The PROGRAM quality assurance program will be implemented by management, quality assurance staff, and line organization personnel at each PROGRAM-participant organizational level.

The quality assurance staff will evaluate the adequacy of programmatic systems and technical products through verification techniques such as assessments, audits, and surveillances. The quality assurance staff will use the expertise of line organization and management personnel, other than those directly responsible for the work, in making these evaluations. The Director, OQA will 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. Performance objectives will be established to ensure that quality is achieved.

Intermediate- and upper-level managers will review 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 verification such as review, inspection, or observation.

(a) Internal Controls

Quality assurance controls over items and activities affecting quality will be executed by OQA and cognizant line organizations. The extent of these controls will be established jointly by the line organization and OQA and detailed in QAAPs.

(b) Verification of the Achievement of Quality for Internal Activities

Verification of the achievement of quality will normally be performed by line organization personnel who are independent of the item or activity being verified. ~~QA personnel will assure implementation of procedural controls by conducting independent QA assessments, audits, and surveillances.~~

Verification personnel shall 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) assure 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 shall overview and monitor the verification activities by conducting independent QA assessments, audits, and surveillances.

(c) Direction, Overview, and Verification of Project Offices and Other PROGRAM Participants

Direction and overview of the quality assurance activities of other PROGRAM participants will be achieved by establishing PROGRAM quality assurance requirements; promulgating these requirements through controlled documents and procurement documents; and performing quality verification through quality assurance reviews, assessments, audits, and surveillances.

2.1.7 Readiness Reviews

OCRWM will perform selected readiness reviews and participate in selected readiness reviews performed by other PROGRAM participants. Each Associate Director and Project Manager will maintain a list of planned readiness reviews and will submit revised lists to the Director, OCRWM semiannually. Readiness reviews will be conducted at critical phases of the PROGRAM to verify the accomplishment of the following activities:

(a) Work activity prerequisites have been satisfied

(b) Implementing line and quality assurance 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 Quality Levels and Graded Quality Assurance

OCRWM has adopted a quality assurance approach in which items and activities will be classified into one of three quality-level classifications. The extent of quality assurance requirements and procedural controls that are applied within the selected quality level will be graded depending on the item's or activity's relative importance to safety, waste isolation, or PROGRAM objectives. Grading will be accomplished by selective application of quality assurance requirements and procedural controls to the item or activity to be performed. The extent or level of quality assurance requirements 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. Each PROGRAM participant establishes procedures to describe the methodology for selecting the appropriate level or extent of quality assurance requirements and procedural controls to be applied to an item or activity within the scope of the PROGRAM.

OCRWM and each Project Office develops and maintains a list of Quality Level 1 and 2 items and activities. The list and any subsequent revisions thereto are based on risk assessments, failure analyses, and other technical considerations. The methodology used to establish a Quality List (Q-List) for items and a Quality Activities List (QAL) for activities for the geologic repository program will be consistent with the guidance of NUREG-1318, Technical Position on Items and Activities in the High-Level Waste Geologic Repository Program Subject to Quality Assurance Requirements, April 1988.

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. A Training Officer who reports to the Associate Director, OPARM has been designated with the responsibility and authority to implement the staff indoctrination, qualification, and training program that is subject to the approval of the Associate Director, OPARM.

(a) Job Evaluation

OCRWM management will analyze each job position to determine the quality-affecting task responsibilities of the position. The results will be documented in position descriptions that include education and experience prerequisites for each position involved in the performance or verification of activities affecting quality.

(b) Personnel Selection

Personnel assigned to perform activities affecting quality will be required to have education, experience, and training commensurate with the functions associated with the work. Initial qualification will be assured through DOE-mandated policies which provide for the inclusion of qualification requirements (selective placement and quality ranking requirements factors in vacancy announcements) in the position descriptions. A documented evaluation will be made of the candidate's qualifications against the requirements. Relevant education and experience will be verified.

(c) Determination of Indoctrination and Training

Associate Directors; the Director, OQA; Division Directors; and Branch Chiefs will review job functions or tasks involved in performing activities affecting quality for personnel under their supervision and determine, jointly with the Training Officer, any additional indoctrination and training required.

Personnel assigned responsibility for performing activities affecting quality will be provided indoctrination and training as to the purpose, scope, and implementation of the QA PROGRAM.

(d) Training and Qualification

Classroom training will be performed in accordance with documented and approved lesson plans. Records of training will be maintained. Persons verifying activities affecting quality such as lead auditors, auditors, and peer reviewers will be qualified in the principles, techniques, and requirements of the activity being performed. Specific qualification requirements will be contained in procedures for those functions and

qualification records will be maintained.

(e) Proficiency Evaluation

Supervisors will evaluate at least annually the proficiency of personnel in the performance of their assigned duties. These evaluations will be documented and discussed with the person who was evaluated. Additional training will be 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 will be performed to provide timely management information on PROGRAM activities affecting quality. Surveillance will be performed by knowledgeable personnel on work for which they had no direct responsibility for performing. Surveillance will be performed to written procedures or plans and the results documented. Deficiencies identified during the surveillance will be reported to the organization responsible for the affected item or activity for resolution. These deficiencies will be tracked to verify corrective action implementation.

2.1.11 ~~Independent~~ Management Assessments

Associate Directors, Division Directors, and other line managers will periodically ~~continually~~ assess the effectiveness of those portions of the quality assurance program for which they are responsible. ~~Independent~~ These management assessments will provide a basis for improving quality assurance controls and procedures, clarifying responsibilities and authorities, and indicating that adverse quality trends and significant conditions adverse to quality are prevented or have been corrected.

Independent management assessments of the quality assurance program will be conducted at least annually by the Associate Directors or their designees who are independent of OQA. The independent management assessment will be conducted by, or at the direction of, the Director, OCRWM.

The purpose of the independent management assessment is to evaluate the scope, status, adequacy, programmatic compliance, and implementation effectiveness of the quality assurance program. The results of the independent management assessment will be documented and corrective actions for those assessment results that indicate conditions adverse to quality will be

identified and tracked.

Independent management assessments will be conducted in accordance with written procedures.

2.1.12 Management Information Reporting and Tracking

Communication and information systems will be established to ensure timely reporting, dissemination, and tracking of quality assurance management information, such as the status of implementation of quality assurance programs, status of resolution of significant conditions adverse to quality, and the status of quality assurance overview results.

2.1.13 Applicable Quality Assurance Administrative Procedures

The planned quality assurance administrative procedures that are applicable to OCRWM's quality assurance program control activities are:

QAAP-2.1	Indoctrination and Training
QAAP-2.2	Personnel Qualification
QAAP-2.3	Quality Level Classification
QAAP-2.4	Quality Assurance Grading
QAAP-2.5	Quality Assurance Document Review
QAAP-2.6	Readiness Review
QAAP-2.7	Management Assessment
QAAP-18.1	Certification of Audit Personnel
QAAP-18.3	Surveillance Program

2.2 OTHER PROGRAM PARTICIPANTS

Other PROGRAM participants will develop a QA PROGRAM meeting the QAR covering the work delegated to them. The quality assurance program descriptions will be reviewed and approved by the next higher PROGRAM-participant organizational level. PROGRAM-participant QA organizations will review lower-tier quality assurance program descriptions and recommend approval or disapproval to line management.

FIGURE 2-1

LIST OF PLANNED
OCRWM QUALITY ASSURANCE ADMINISTRATIVE PROCEDURES

QAAP No.	Title
2.1	Indoctrination and Training
2.2	Personnel Qualification
2.3	Quality Level Classification
2.4	Quality Assurance Grading
2.5	Quality Assurance Document Review
2.6	Readiness Review
2.7	Management Assessment
2.8	Handling of Allegations
3.1	Technical Document Review
3.2	Design Review
3.3	Peer Review
3.4	Configuration Management
3.5	Preparation of Technical Documents
4.1	Procurement Document Review
5.1	Preparation of Quality Assurance Administrative Procedures
6.1	Controlled Documents
7.1	Control of Purchased Items and Services
16.1	Corrective Action
16.2	Stop Work
16.3	Resolution of Differing Technical Opinions
16.4	Resolution of Issues Involving Quality
16.5	Improvement of Quality
17.1	Records Management
17.2	Correspondence Control
18.1	Certification of Audit Personnel
18.2	Audit Program
18.3	Surveillance Program

FIGURE 2-2

MATRIX DESCRIBING THE
DELEGATION OF QUALITY ASSURANCE WORK
BY CRITERIA

DELEGATION OF QUALITY ASSURANCE WORK			
Criteria No.	Topic	OCRWM	Project Office & PROGRAM Participants
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.....	ND	X
9	Control of Processes.....	ND	X
10	Inspection.....	ND	X
11	Test Control.....	ND	X
12	Control of Measuring and Test Equipment	ND	X
13	Handling, Storage, Transport, & Shipping	ND	X
14	Inspection, Test, and Operating Status	ND	X
15	Control of Nonconforming Items.....	ND	X
16	Corrective Action.....	X	X
17	Quality Assurance Records.....	X	X
18	Audits.....	X	X

X - Means "Applicable commensurate with the Scope of Work"
ND - Indicates that OCRWM ~~will normally~~ delegates the work of establishing and implementing these criteria to Project Offices and other PROGRAM participants, however OCRWM retains responsibility for assuring that these activities are established and appropriately implemented, and carries out this responsibility through review and approval of Project Office and other PROGRAM participants procedures and through audits and surveillances of the activity.

SECTION 3

DESIGN CONTROL

3.0 GENERAL

The design activities at each PROGRAM-participant organizational level will be accomplished in accordance with written procedures. These procedures will describe the process by which design activities from conceptual design through final design are planned, controlled, and implemented; describe the control of design inputs, interfaces, outputs, reviews, changes, and deficiencies; and address the control of scientific investigation and data processing activities.

This Section describes provisions established by OCRWM to implement design control activities. Design control activities that are implemented by other PROGRAM participants are also addressed.

3.1 OCRWM CONTROL OF DESIGN ACTIVITIES

3.1.1 Systems Engineering

OCRWM will use a systems engineering approach to control and manage PROGRAM design activities. Systems engineering will be 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 will be properly integrated and that the system will operate effectively and protect the health and safety of the public and its 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 which defines the technical baseline and the 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 procedures for integrating the disciplines involved in design development, interfacing between the various levels of the PROGRAM, controling 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 will be implemented at the overall PROGRAM mission level, and the system element level such as geologic repository, transportation, or MRS. Responsibilities for elements of the system are assigned to other organizations (for example, Project offices and other Operations Offices) in various governing documents (for example, Office Charters, Memoranda of Understanding, Contract Scopes of Work). The Systems Engineering Management Plans (SEMPs) will be developed for the overall PROGRAM mission, each system element, and each Project Office in accordance with DOE/RW-0051, Systems Engineering Management Plan. In this tiered approach to controlling the design process, systems engineering documentation that is prepared at one level will be reviewed and approved at the next higher level as specified in the SEMP.

Compliance with the SEMPs and other PROGRAM requirements will be assured through surveillance and audits of the design process. The character of the audits and surveillances is dependent on the phase of design. As designs mature and grow in complexity, surveillances and audits will increase in scope, frequency, and duration.

3.1.2 Scientific Investigations

The adequacy of the geologic repository design is heavily dependent upon the results of the scientific investigations conducted for the characterization of the geologic repository site. Therefore, the performance of these scientific investigations will be controlled.

Scientific investigations will be conducted by OCRWM- or Project Office-managed PROGRAM participants. Provisions of the QAR for controlling scientific investigations will be imposed upon the PROGRAM participants.

3.1.3 Processing of Data

Data collection, qualification, analysis, identification, and recording activities related to the design of the geologic repository will be controlled. Data collection and processing will be conducted by OCRWM- or Project Office-managed PROGRAM participants. Provisions of the QAR for collecting and processing data and qualifying data of indeterminate quality will be imposed upon the PROGRAM participants.

3.1.4 Design Process

frequent external audits of a supplier will be evaluated when major changes to contract scope or work methodology occurs. Preaward surveys may serve as the first triennial audit if the scope and conduct of the preaward is similar to the scope and conduct of the other triennial audits.

(c) Audits conducted on a supplier by an external organization for the PROGRAM participant or for a group of purchasers that includes the PROGRAM participant are an acceptable alternative to a PROGRAM-participant conducted audit provided that the scope of the audit meets the needs of the PROGRAM and the audit report is provided to the PROGRAM participant. The PROGRAM participant remains responsible for the adequacy of these audits.

(d) Annual evaluations of suppliers will be performed or arranged for. Evaluations will be documented. These evaluations will assess:

(1) Supplier-furnished documents and records

(2) Previous verification results

(3) Supplier's operating experience with identical or similar products provided to others

(4) Extrinsic verification results such as audits by the customer, ASME, or NRC

18.1.34 Applicable Quality Assurance Administrative Procedures

The planned OCRWM quality assurance administrative procedures applicable to OCRWM's QA audit activities are:

QAAP-18.1 Certification of Audit Personnel
QAAP-18.2 Audit Program

18.2 OTHER PROGRAM PARTICIPANTS

Project Offices and other PROGRAM participants will implement audit activities as prescribed in their QA PROGRAMs. The provisions established will be in compliance with the QAR. OCRWM and the Project Offices will monitor audit control measures of the PROGRAM participants through the use of assessments, audits, and surveillances.

Design activities will be conducted primarily by OCRWM- or Project Office-managed PROGRAM participants. Provisions of the QAR for design will be imposed upon the PROGRAM participants. OCRWM is responsible for the preparation and control of requirements documents for the system elements.

Requirements documents will be developed for the overall PROGRAM mission, each system element, and other organizations responsible for portions of the system as identified in the next higher level SEMP. The requirements documents will be reviewed and approved at the level for which they were written and the next higher level. Requirements for baselining and controlling requirements documents are discussed in DOE/RW-0043, OCRWM Program Management System Manual.

Applicable design input, such as design bases, performance requirements, regulatory requirements, codes, and standards will be identified and controlled. The design input for the requirements documents prepared by OCRWM will include processed data received from other PROGRAM participants. OCRWM will not conduct further processing of data. Design interfaces will be controlled by managing design activities and interfaces in accordance with the SEMPs. OCRWM interfaces with other PROGRAM participants will be specified in PROGRAM-participants' procurement documents.

SEMPs will address 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 will address the control of design interfaces by defining PROGRAM-participant technical work scopes and establishing requirements for information exchange between OCRWM, the Project Offices, and other PROGRAM participants.

3.1.5 Computer Software

OCRWM is not directly involved in performing design activities that require the use of computer software. Design activities necessitating use of computer software will be conducted by OCRWM-managed and Project Office-managed PROGRAM participants. Provisions in the QAR for controlling computer software will be reflected in PROGRAM-participants' technical and quality assurance requirements.

3.1.6 Readiness Reviews for Design Activities

Readiness reviews will be conducted prior to the start of a critical design activity, such as collection of site characterization data, model development, or various design phases. 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 quality levels have been identified. Implementing line procedures and procurement documents reflect these required design inputs.

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

(d) Procedures discuss requirements for in-process and second level design reviews. Design schedules identify milestone design reviews.

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

3.1.7 Design Verification

The adequacy of technical documents will be verified prior to approval and issuance for use. Individuals assigned to review technical documents may supplement reviews with alternate calculations to verify the correctness of original calculations or qualification tests to demonstrate the adequacy of the design under the most adverse design conditions or both. Technical document reviews will be performed by one or more qualified individuals not involved in the performance of the original design. Reviews will be conducted in accordance with written procedures.

For the geologic repository, it may be necessary to conduct the design verification through the use of a peer review. Peer review will be used when the methods that were used were beyond the state of the art and the adequacy of information or the suitability of procedures and methods cannot be otherwise established through tests, alternate calculations, or reference to established standards. Peer reviews will be performed in accordance with the guidance provided in NUREG-1297, Peer Review

for the High-Level Waste Repositories Generic Technical Position, February 29, 1988 as provided in the applicable QAAP.

3.1.8 Second-Level Design Reviews

OCRWM will periodically verify design documents prepared by OCRWM- or Project Office-managed PROGRAM participants through the use of second-level design reviews. These second-level design reviews may be conducted as technical document reviews, as milestone reviews, or as peer reviews. Peer reviews will be performed in accordance with the guidance provided in NUREG-1297, Peer Review for the High-Level Waste Repositories Generic Technical Position, February 29, 1988 as provided in the applicable QAAP.

Technical management will periodically select key design documents for review to verify technical adequacy and gauge the effectiveness of PROGRAM-participant design control measures. Document reviews may be performed on PROGRAM-participant documents at any point in the design process.

Technical management will appoint a review team to verify the technical adequacy of the overall design at key milestones in the design process. Design schedules will indicate when milestone reviews are to be performed and will identify whether the review is to be performed by OCRWM or the cognizant Project Office. Reviews will be performed on a representative sample of completed documents not previously subjected to second-level review. The review will evaluate whether the overall design including interfaces is proceeding in accordance with governing SEMPs. Reports of milestone reviews will be sent to appropriate levels of management within OCRWM, the Project Offices, and other cognizant PROGRAM participants.

3.1.9 Design Change Control

Changes to OCRWM-originated design documents will be justified and processed using the same methods applied to the preparation of the original document. Changes will be reviewed and approved by the organizations who reviewed and approved the original design document.

The impact of design changes on procedures and training will be evaluated. The changes will be communicated to all affected groups or individuals.

3.1.10 Design Error and Design Deficiency Control

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

Design deficiencies identified during second-level reviews will be reported separately from editorial or administrative comments. Design deficiency reports will be sent to cognizant PROGRAM-participant management for information or action in accordance with the design deficiency system of the PROGRAM participants. Design deficiencies will be tracked by PROGRAM participants until disposition has been assigned, approved, and implemented. Deficiencies that represent significant conditions adverse to quality will be documented and controlled in accordance with Section 16.

3.1.11 Applicable Quality Assurance Administrative Procedures

The planned OCRWM quality assurance administrative procedures that will be applicable to OCRWM's design control activities are:

QAAP-3.1	Technical Document Review
QAAP-3.2	Design Review
QAAP-3.3	Peer Review
QAAP-3.4	Configuration Management
QAAP-3.5	Preparation of Technical Documents
QAAP-16.1	Corrective Action
QAAP-16.3	Resolution of Differing Technical Opinions

3.2 OTHER PROGRAM PARTICIPANTS

Project Offices and other PROGRAM participants will implement design control measures as prescribed in their QA PROGRAMs. The provisions established will be in compliance with the QAR. OCRWM and the Project Offices will monitor the design control measures of the PROGRAM participants through the use of assessments, audits, and surveillances.

SECTION 4

PROCUREMENT DOCUMENT CONTROL

4.0 GENERAL

The procurement of items and services at each PROGRAM-participant organizational level will be accomplished in accordance with written procedures. These procedures will describe the process by which procurement planning is accomplished as well as the process by which procurement documents and revisions are prepared, reviewed, approved, and controlled. The involvement of the quality assurance staff in the procurement document process will also be described.

This Section describes provisions established by OCRWM to implement procurement document control activities. Procurement document control activities that are implemented by other PROGRAM participants are also addressed.

4.1 OCRWM PROCUREMENT DOCUMENT CONTROL

4.1.1 Procurement Document Preparation, Revision, Review, and Approval

OCRWM will establish and implement procedures for the control of procurement documents. The procedures will 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 item or service, determining the specific work to be accomplished, identifying appropriate technical and quality requirements, and identifying sources for the work.

Procurement documents issued for items and services that affect quality will contain, as a minimum, the following provisions:

(a) Work Scope

(b) Technical requirements

(c) Supplier quality assurance program requirements

(d) Access rights

(e) Documentation requirements

(f) Nonconformance processing requirements

(g) Spare and replacement parts requirements

(h) Acceptance criteria

Procurement documents are prepared, issued, and controlled for OCRWM by the Procurement and Assistance Management Directorate. Procurement documents and changes will be reviewed by the Source Evaluation Board members representing the appropriate Associate Directors and the Office of Quality Assurance staff. Reviews will 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.

4.1.2 Applicable Quality Assurance Administrative Procedures

The planned OCRWM quality assurance administrative procedure applicable to OCRWM's procurement document control activities is:

QAAP-4.1 Procurement Document Review

4.2 OCRWM-MANAGED CONTRACTORS

Normally OCRWM-managed contractors will be required to develop and implement quality assurance programs that meet specified sections of the QAR. However, when the scope of work or schedule requirements do not justify the cost of development or maintenance of a quality assurance program by contractors, the contractors will work under OCRWM's quality assurance program. The technical and quality assurance requirements applied to contractors specify applicable OCRWM quality assurance administrative procedures that will be used by the contractors.

4.3 OTHER PROGRAM PARTICIPANTS

Project Offices and other PROGRAM participants will implement procurement document control activities as prescribed in their QA PROGRAMs. The provisions established will be in compliance with the QAR. OCRWM and the Project Offices will monitor the procurement document control measures of the PROGRAM participants through the use of assessments, audits, and surveillances.

SECTION 5

INSTRUCTIONS, PROCEDURES, AND DRAWINGS

5.0 GENERAL

PROGRAM activities affecting quality will be prescribed by, and controlled in accordance with, instructions, procedures, and drawings. Procedures, instructions, and drawings will include or reference appropriate quantitative or qualitative acceptance criteria for determining that prescribed activities have been satisfactorily accomplished. Planning, preparation, and issuance of instructions, procedures, and drawings will be accomplished prior to the start of activities affecting quality.

This Section describes the provisions established by OCRWM to control the performance of activities affecting quality. Instruction, procedure, and drawing activities that are implemented by other PROGRAM participants are also addressed.

5.1 OCRWM INSTRUCTIONS, PROCEDURES, AND DRAWINGS

5.1.1 Control

Associate Directors in conjunction with the Director, OQA will develop a list of instructions and procedures required to prescribe the methods to be used by OCRWM management and staff in performing activities affecting quality. Development of instructions and procedures will be accomplished prior to the start of activities affecting quality.

Procedures are being developed and implemented to ensure that the methods to be used for performance of activities affecting quality are also prescribed in documented instructions and procedures. Requirements are also being established to require that activities affecting quality are performed in accordance with these documents.

OCRWM does not prepare or control design drawings.

5.1.2 Applicable Quality Assurance Administrative Procedures

The planned OCRWM quality assurance administrative procedure applicable to OCRWM's instructions, procedures, and drawings control is:

QAAP-5.1	Preparation of Quality Assurance Administrative Procedures

5.2 OTHER PROGRAM PARTICIPANTS

Project Offices and other PROGRAM participants will implement instructions, procedures, and drawings as prescribed in their QA PROGRAMs. The provisions established will be in compliance with the QAR. OCRWM and the Project Offices will monitor the instructions, procedures, and drawings of the PROGRAM participants through the use of assessments, audits, and surveillances.

SECTION 6

DOCUMENT CONTROL

6.0 GENERAL

Each PROGRAM participant will develop and implement procedures that assure that PROGRAM documents affecting quality are prepared, revised, reviewed, approved, and issued in a prescribed and controlled manner.

This Section describes the provisions established by OCRWM to control the preparation, revision, review, approval, and issuance of documents affecting quality. Document control activities that are implemented by other PROGRAM participants are also addressed.

6.1 OCRWM DOCUMENT CONTROL

6.1.1 Document Preparation, Revision, Review, and Approval

Documents that specify quality requirements or prescribe activities affecting quality will be prepared; revised; reviewed for adequacy, completeness, and correctness; approved; and released for issuance and distribution in accordance with written procedures. Procedures for the preparation and revision of plans, manuals, procedures, instructions, reports, and other documents will 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

6.1.2 Issuance and Distribution

Document issuance and distribution will be controlled to assure 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. Document control procedures will include the following provisions:

(a) Identification and marking of documents including documents released prior to completion of the approval process

(b) Maintenance of document distribution lists

(c) Marking or removal of obsolete or superseded documents

(d) Maintenance of an index giving revision status for documents

6.1.3 Controlled Documents

(a) Provisions for controlled documents will include:

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

(2) Use of receipt acknowledgement 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)

(b) Controlled document recipients will be responsible for acknowledging document receipt, assuring that the latest authorized documents are in use, and marking, destroying, or returning obsolete or superseded documents.

(c) Controlled documents that are considered PROGRAM baseline documents will be handled in a manner consistent with the requirements in DOE/RW-0068, Program Baseline Procedures Notebook (OGR/B-1) and DOE/RW-0083, Program Change Control Procedure. These controlled documents will be listed in the "OGR Baseline Register." The "OGR Baseline Register" will be issued as changes or revisions occur to assist recipients in

maintaining up-to-date files. Document recipients will be responsible for assuring that only the latest baseline documents are used and that obsolete or superseded documents are so identified, destroyed, or returned.

6.1.4 Applicable Quality Assurance Administrative Procedures

The planned OCRWM quality assurance administrative procedure applicable to OCRWM's document control activities is:

QAAP-6.1 Controlled Documents

6.2 OTHER PROGRAM PARTICIPANTS

Project Offices and other PROGRAM participants will implement document control activities as prescribed in their QA PROGRAMs. The provisions established will be in compliance with the QAR. OCRWM and the Project Offices will monitor the document control measures of the PROGRAM participants through the use of assessments, audits, and surveillances.

SECTION 7

CONTROL OF PURCHASED ITEMS AND SERVICES

7.0 GENERAL

Each PROGRAM participant will develop and implement procedures that assure that purchased items and services are controlled to assure conformance with specified requirements.

This Section describes the provisions established by OCRWM to control purchased items and services. Purchased items and services control activities that are implemented by other PROGRAM participants are also addressed.

7.1 OCRWM CONTROL OF PURCHASED ITEMS AND SERVICES

7.1.1 Control

Activities to control purchased items and services will be established and will be implemented by procedures. These procedures will describe the methods used to evaluate Project Offices' and PROGRAM-participants' performances in meeting PROGRAM objectives.

OCRWM delegates procurement of items to Project Offices and other PROGRAM participants. The system for control of purchased items and services includes:

(a) Procurement planning

Procurement planning is accomplished and documented as early as practicable to provide appropriate interface compatibility and to assure a systematic approach to the procurement process.

(b) Supplier selection

~~Contracting Officers or~~ Source Selection Officials are responsible to solicit bid offers or proposals as well as to evaluate and select sources. The appropriate Associate Director and Director, OQA participate in the supplier selection process.

(c) Supplier performance evaluation

Methods and criteria for evaluating supplier performance are mutually established by the cognizant Associate Director and

the Director, OQA. 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 management assessments, audits, surveillances, and inspections.

(d) Supplier-generated document control

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

Requirements for submittal of documents generated by suppliers to OCRWM or other PROGRAM participants for use, review, approval or concurrence are specified in applicable technical and quality assurance requirements.

(e) Change control

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

(f) Acceptance of items and services

Acceptance of purchased items or services include one or more of the following techniques:

(1) Technical evaluation of the purchased item, data, or report produced

(2) Surveillance or audit of the supplier or both

(3) Review of objective evidence of conformance with procurement requirements

(4) Periodic evaluations of each supplier's certifications of conformance by audits, independent tests, peer review, or other appropriate verification methods to assure that the certifications are valid and that the proper results are documented

(5) Source or receiving inspections or both

(6) Post-installation testing

7.1.2 Applicable Quality Assurance Administrative Procedures

The planned OCRWM quality assurance administrative procedures applicable to OCRWM's purchased items and services control activities are ~~is~~:

QAAP-2.5	Quality Assurance Document Review
QAAP-7.1	Control of Purchased Items and Services

7.2 OTHER PROGRAM PARTICIPANTS

Project Offices and other PROGRAM participants will implement purchased items and services control activities as prescribed in their QA PROGRAMs. The provisions established will be in compliance with the QAR. OCRWM and the Project Offices will monitor the purchased items and services control measures of the PROGRAM participants through the use of assessments, audits, and surveillances.

SECTION 8

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

8.0 GENERAL

Identification and control of materials, parts, components, and samples at each PROGRAM-participant organizational level will be accomplished in accordance with written procedures. These procedures will describe the methods for assuring that only correct and accepted materials, parts, components, and samples are used. Identifications will be maintained on, or in documents traceable to, the materials, parts, components, and samples.

8.1 OCRWM IDENTIFICATION AND CONTROL

The work associated with identification and control of materials, parts, components, and samples will be delegated by OCRWM to Project Offices and other PROGRAM participants.

OCRWM will overview the work of the Project Offices and other PROGRAM participants to verify their implementation and effectiveness. this overview will include audits, surveillances and reviews by the OCRWM OQA.

8.2 OTHER PROGRAM PARTICIPANTS

Project Offices and other PROGRAM participants implement material, parts, components, and samples will control activities as prescribed in their QA PROGRAMs. The provisions established will be in compliance with the QAR. OCRWM and the Project Offices will monitor the materials, parts, components, and samples control measures of the PROGRAM participants through the use of assessments, audits, and surveillances.

SECTION 9

CONTROL OF PROCESSES

9.0 GENERAL

The control of processes at each PROGRAM-participant organizational level will be accomplished in accordance with written procedures. These procedures will describe the methods for assuring that processes and special processes are identified and controlled by qualified procedures and equipment in accordance with specified requirements.

9.1 OCRWM CONTROL OF PROCESSES

The work associated with control of processes will be delegated by OCRWM to Project Offices and other PROGRAM participants.

OCRWM will overview the work of the Project Offices and other PROGRAM participants to verify their implementation and effectiveness. this overview will include audits, surveillances and reviews by the OCRWM OQA.

9.2 OTHER PROGRAM PARTICIPANTS

Project Offices and other PROGRAM participants will implement process control activities as prescribed in their QA PROGRAMs. The provisions established will be in compliance with the QAR. OCRWM and the Project Offices will monitor process control measures of the PROGRAM participants through the use of assessments, audits, and surveillances.

SECTION 10

INSPECTION

10.0 GENERAL

Inspection activities at each PROGRAM-participant organizational level will be accomplished in accordance with written procedures. These procedures will describe the methods by which inspections that are required to verify conformance of items and activities to specified requirements are planned, executed, and documented.

10.1 OCRWM INSPECTION

The work associated with inspections will be delegated by OCRWM to Project Offices and other PROGRAM participants.

OCRWM will overview the work of the Project Offices and other PROGRAM participants to verify their implementation and effectiveness. this overview will include audits, surveillances and reviews by the OCRWM OQA.

10.2 OTHER PROGRAM PARTICIPANTS

Project Offices and other PROGRAM participants will implement inspection control activities as prescribed in their QA PROGRAMs. The provisions established will be in compliance with the QAR. OCRWM and the Project Offices will monitor inspection control measures of the PROGRAM participants through the use of assessments, audits, and surveillances.

SECTION 11

TEST CONTROL

11.0 GENERAL

Control of test activities at each PROGRAM-participant organizational level will be accomplished in accordance with written procedures. These procedures will describe the methods for assuring that tests that are required to verify conformance of an item to specified requirements, to demonstrate that items will perform satisfactorily in service, and to collect data, such as siting or design input, are properly planned, executed, documented, and evaluated.

11.1 OCRWM TEST CONTROL

The work associated with test control will be delegated by OCRWM to Project Offices and other PROGRAM participants.

OCRWM will overview the work of the Project Offices and other PROGRAM participants to verify their implementation and effectiveness. this overview will include audits, surveillances and reviews by the OCRWM OQA.

11.2 OTHER PROGRAM PARTICIPANTS

Project Offices and other PROGRAM participants will implement test control activities as prescribed in their QA PROGRAMs. The provisions established will be in compliance with the QAR. OCRWM and the Project Offices will monitor test control measures of the PROGRAM participants through the use of assessments, audits, and surveillances.

SECTION 12

CONTROL OF MEASURING AND TEST EQUIPMENT

12.0 GENERAL

Measuring and test equipment control activities at each PROGRAM-participant organizational level will be accomplished in accordance with written procedures. These procedures will describe the methods by which tools, gages, instruments, and other measuring and test equipment used for activities affecting quality are controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits.

12.1 OCRWM CONTROL OF MEASURING AND TEST EQUIPMENT

The work associated with control of measuring and test equipment will be delegated by OCRWM to Project Offices and other PROGRAM participants.

OCRWM will overview the work of the Project Offices and other PROGRAM participants to verify their implementation and effectiveness. this overview will include audits, surveillances and reviews by the OCRWM OQA.

12.2 OTHER PROGRAM PARTICIPANTS

Project Offices and other PROGRAM participants will implement measuring and test equipment control activities as prescribed in their QA PROGRAMs. The provisions established will be in compliance with the QAR. OCRWM and the Project Offices will monitor measuring and test equipment control measures of the PROGRAM participants through the use of assessments, audits, and surveillances.

SECTION 13

HANDLING, STORAGE, AND SHIPPING

13.0 GENERAL

The handling, storage, and shipping of items at each PROGRAM-participant organizational level will be accomplished in accordance with written procedures. These procedures will describe the methods for assuring control of activities associated with handling, storage, cleaning, packaging, shipping, and preservation of items to prevent damage or loss and to minimize deterioration.

13.1 OCRWM HANDLING, STORAGE, AND SHIPPING

The work associated with handling, storage, and shipping will be delegated by OCRWM to Project Offices and other PROGRAM participants.

OCRWM will overview the work of the Project Offices and other PROGRAM participants to verify their implementation and effectiveness. this overview will include audits, surveillances and reviews by the OCRWM OQA.

13.2 OTHER PROGRAM PARTICIPANTS

Project Offices and other PROGRAM participants will implement handling, storage, and shipping control activities as prescribed in their QA PROGRAMs. The provisions established will be in compliance with the QAR. OCRWM and the Project Offices will monitor handling, storage, and shipping control measures of the PROGRAM participants through the use of assessments, audits, and surveillances.

SECTION 14

INSPECTION, TEST, AND OPERATING STATUS

14.0 GENERAL

Inspection, test and operating status activities at each PROGRAM-participant organizational level will be accomplished in accordance with written procedures. These procedures will describe the methods used to identify the status of inspection and test activities to assure that required inspections and tests are performed and to assure that items that have not passed the required inspections and tests are not inadvertently installed, used, or operated.

14.1 OCRWM INSPECTION, TEST, AND OPERATING STATUS

The work associated with inspection, test, and operating status will be delegated by OCRWM to Project Offices and other PROGRAM participants.

OCRWM will overview the work of the Project Offices and other PROGRAM participants to verify their implementation and effectiveness. this overview will include audits, surveillances and reviews by the OCRWM OQA.

14.2 OTHER PROGRAM PARTICIPANTS

Project Offices and other PROGRAM participants will implement inspection, test, and operating status control activities as prescribed in their QA PROGRAMs. The provisions established will be in compliance with the QAR. OCRWM and the Project Offices will monitor inspection, test, and operating status control measures of the PROGRAM participants through the use of assessments, audits, and surveillances.

SECTION 15

CONTROL OF NONCONFORMING ITEMS

15.0 GENERAL

Identification and control of nonconforming items will be accomplished in accordance with written procedures at each PROGRAM-participant organizational level. These procedures will describe the methods used to identify and control nonconforming items to prevent inadvertent installation or use.

15.1 OCRWM CONTROL OF NONCONFORMING ITEMS

The work associated with identification and control of nonconforming items will be delegated by OCRWM to other PROGRAM participants because OCRWM neither directly produces nor directly procures hardware items.

OCRWM will overview the work of the Project Offices and other PROGRAM participants to verify their implementation and effectiveness. this overview will include audits, surveillances and reviews by the OCRWM OQA.

15.2 OTHER PROGRAM PARTICIPANTS

Project Offices and other PROGRAM participants will implement nonconformance control activities as prescribed in their QA PROGRAMs. The provisions established will be in compliance with the QAR. OCRWM and the Project Offices will monitor nonconformance control measures of the PROGRAM participants through the use of assessments, audits, and surveillances.

SECTION 16

CORRECTIVE ACTION

16.0 GENERAL

Conditions adverse to quality will be identified and promptly corrected at each ~~PROGRAM~~-participant organizational level in accordance with written procedures. These procedures will describe the process by which significant conditions adverse to quality are identified and evaluated to determine cause, generic implications to the PROGRAM, corrective action, and action to preclude recurrence. Provisions for reporting significant conditions adverse to quality to the cognizant Associate Director and the Director, OQA will also be prescribed in procedures.

This Section describes the provisions that will be established by OCRWM to implement corrective action. Corrective action measures that will be implemented by other ~~PROGRAM~~-participant offices are also addressed.

16.1 OCRWM CORRECTIVE ACTION

16.1.1 Control

Corrective action activities will be established and will be implemented by procedures. These procedures will define the methods and responsibilities for the analysis for ~~of~~-trends; the processing, control, and resolution of deficiencies; and the handling of significant conditions adverse to quality.

16.1.2 Trend Analysis

Information describing the degree of the achievement of quality, such as audit reports, surveillance reports, and other deficiency and deviation reports identified within, or by, OCRWM or OCRWM-managed PROGRAM participants will be analyzed by OQA to identify adverse trends in quality. OQA will perform trend analysis in accordance with written procedures. Adverse trends will be evaluated to determine PROGRAM impact and corrective action.

16.1.3 Significant Conditions Adverse to Quality ~~and Corrective Action~~

~~Significant c~~Conditions adverse to quality cited within OCRWM will be reported to the cognizant Associate Directors and the Director, OQA by using a ~~Corrective Action Report (CAR)~~ Deficiency Report (DR). The Director, OQA will evaluate deficiencies and will issue a Corrective Action Report (CAR) for any condition adverse to quality that, were it to remain

uncorrected, could adversely affect safety or waste isolation. Nonconformances, deficiencies, and conditions adverse to quality identified by OCRWM personnel at other participants' facilities will be brought to the attention of the participant and handled using the participant's nonconformance or corrective action system. Cognizant Division Directors, Branch Chiefs, and Project Office managers will be responsible for determining the root cause of the condition, the generic implications to the PROGRAM, the corrective action, and the action to be taken to preclude repetition. The determinations that are made and the corrective actions that are taken will be documented and reported to the cognizant Associate Directors and the Director, OQA for review and assessment. The Director, OQA will be responsible for verification of the implementation and completion of corrective action by signatory concurrence on the corrective action report.

16.1.4 Applicable Quality Assurance Administrative Procedures

The planned OCRWM quality assurance administrative procedures applicable to OCRWM's corrective action control activities are:

QAAP-16.1	Corrective Action
QAAP-16.3	Resolution of Differing Technical Opinions
QAAP-16.4	Resolution of Issues Involving Quality
QAAP-16.5	Improvement of Quality

16.2 OTHER PROGRAM PARTICIPANTS

Project Offices and other PROGRAM participants will implement corrective action control activities as prescribed in their QA PROGRAMs. The provisions established will be in compliance with the QAR. OCRWM and the Project Offices will monitor corrective action control measures of the PROGRAM participants through the use of assessments, audits, and surveillances.

SECTION 17

QUALITY ASSURANCE RECORDS

17.0 GENERAL

The quality assurance (QA) records program activities for the PROGRAM will be accomplished in accordance with written procedures. These procedures will describe the integrated set of activities for creating, identifying, collecting, controlling, processing, organizing, distributing, storing, preserving, retrieving, and disposing of PROGRAM QA Records.

Specific records management program requirements for all PROGRAM participants are delineated in DOE/RW-0194, Records Management Policies and Requirements.

This section describes the provisions that will be established by OCRWM to implement QA Records program activities. QA Records program activities that will be implemented by other PROGRAM participants are also addressed.

17.1 OCRWM QA RECORDS SYSTEM

17.1.1 QA Records

The PROGRAM QA Records system will be a subset of the overall PROGRAM records management system. OCRWM will retain responsibility for the total QA Records system while delegating work associated with certain functions to the Project Offices and other PROGRAM participants.

Requirements for the PROGRAM records management system are delineated in DOE/RW-0194, Records Management Policies and Requirements. These policies are developed by the Office of Program Administration and Resources Management (OPARM) and provide for the implementation and control of QA Records. The Information Resources Management Division within OPARM manages QA Records for the PROGRAM. Control and maintenance of QA Records is delegated to the records management contractor for those QA Records generated or received by OCRWM or OCRWM-managed PROGRAM participants.

QA Records will be generated and uniquely identified in accordance with written procedures. The unique identification for QA Records includes an accession number (a unique, sequential number), the designation "QA," a work breakdown structure (WBS) number, and a work package number when appropriate. The

quality-level designation is shown as part of the QA Record where practical or on accompanying documentation.

QA Records that are generated or received will be collected, identified, and transmitted to the OCRWM Central Records Facility. The OCRWM Central Records Facility will process each record into a central computerized database and prepare each record for storage in accordance with written procedures.

A central records facility will be established for QA Records in accordance with the "Records Management Policies and Requirements" document and will meet the fire and environmental conditions specified in the QAR.

17.1.2 Applicable Quality Assurance Administrative Procedures

The planned OCRWM quality assurance administrative procedures applicable to OCRWM's QA Records control activities are:

QAAP-17.1	Records Management
QAAP-17.2	Correspondence Control

17.2 OTHER PROGRAM PARTICIPANTS

Project Offices and other PROGRAM participants will implement QA Records control activities as prescribed in their QA PROGRAMs. The provisions established will be in compliance with the QAR. OCRWM and the Project Offices will monitor QA Records control measures of the PROGRAM participants through the use of assessments, audits, and surveillances.

PROGRAM participants will establish central and local records facilities as described in the OCRWM "Records Management Policies and Requirements" document.

QA Records generated or received by PROGRAM participants will be collected, identified, and, after processing at the local records facility, transmitted to a central records facility for processing into a computerized database and for storage in accordance with written procedures.

SECTION 18

AUDITS

18.0 GENERAL

OCRWM will establish and implement a quality assurance audit program to provide independent verification of the status, adequacy, and compliance and implementation effectiveness of the OCRWM quality assurance program and its elements. Internal and external audits will be conducted. Audits will be performed to determine the degree of conformance with quality assurance program requirements, compliance with procedural requirements, and the effectiveness in achieving quality assurance program objectives. Audit planning, scheduling, preparation, performance, reporting, follow-up, and close-out methods as well as methods for selection, training, and qualification of audit personnel will be addressed.

This Section describes the provisions to be established by OCRWM to implement the quality assurance audit program. Audit activities that are implemented by other PROGRAM participants are also addressed.

18.1 OCRWM AUDIT PROGRAM

18.1.1 Audit Program Implementation

Procedures will describe the methods and responsibilities applicable to audit activities to determine compliance with requirements and to assess the programmatic compliance and implementation effectiveness of OCRWM's and PROGRAM-participants' quality assurance programs. The audit program will include technical and programmatic verifications. Implementation of Project Offices' quality assurance programs will be audited on at least a triennial basis ~~annually~~ to assess compliance and implementation effectiveness.

The Director, OQA is responsible for the development, implementation, and maintenance of the OCRWM QA audit program.

18.1.2 Audit Process

Procedures for audit activities will address:

(a) Accomplishment of the planning and scheduling of audit activities to ensure PROGRAM-deliverable products and processes are evaluated commensurate with the importance in achieving mission objectives and scheduled completion dates assigned to the products or processes.

Internal audits of the implementation effectiveness of the quality assurance program will be performed at least once each year or at least once during the life of the activity affecting quality, whichever is shorter.

(b) Qualification and certification of audit team members and certification of lead auditors' qualifications. Audit team members collectively have the necessary programmatic and technical expertise in the work being audited. Audit team members may be from the same organization which was responsible for accomplishing the work being audited but they cannot be the individuals who actually performed or directly supervised the performance of the work being audited. Auditor and lead auditor training and qualification programs are administered by the Director, OQA. The Director, OQA also certifies lead auditors.

(c) Accomplishment of audit preparation activities under the direction of a designated audit team leader who is a certified lead auditor and independent of having direct responsibility for the work being audited. The audit team leader is selected by the Director, OQA. Preparation activities include the accumulation of reference materials; governing quality assurance program documents; and audit, management assessment, and surveillance records for the audit. These activities also include an evaluation of audit team member orientation needs and the development of orientation materials or presentations. Materials that are needed for conducting the audit are developed during the audit preparation phase and include an audit plan, an audit notification letter, and a written checklist or procedure.

(d) Conduct of audits in accordance with written procedures and checklists. Audit team members perform document reviews, interviews, and other activities described in the audit checklist 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 who ensures any 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 discuss the status of audit activities and to promote effective communications between auditor and auditee.

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

(1) Results of previous internal audits

(2) Results of previous extrinsic audits

(3) 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 the technical aspects of processes and the 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.

Potential audit deficiencies are discussed within the audit team and are formalized into findings and observations by the audit team leader. Results of the audit are presented to the audited organization's representatives by the audit team leader (and team members) in a postaudit conference to complete the audit conduct phase.

(e) Analysis by the OQA of data from the performance of the audit and documentation of the ~~Documentation of audit~~ results in a report containing an executive summary, findings, observations, audit activity summary, a participants list, and comments. Reports are transmitted to the audited organization for review, assessment, and appropriate action with copies ~~and~~ distributed to the audit team members; the Director, OCRWM; Director, OQA; Associate Directors; and cognizant (that is, responsible for audited areas) division, branch, Project Office, and contractor managers. In addition, copies will be provided to the NRC and the State of Nevada. Audit team leaders generate audit reports with data that is requested from audit team members. The Director, OQA approves audit reports prior to transmittal and distribution. Findings and observations require responses from audited organization-designated representatives with specified action dates.

(f) Review of audit responses by the cognizant Associate Directors, the Director, OQA, and the assigned audit team leader to determine:

(1) Adequacy of root cause determinations

(2) Acceptability of corrective action commitments for the deficient (and similar) conditions (past and present)

(3) Acceptability of committed actions to preclude recurrence of the deficient conditions

(4) Adequacy of the deficiency impact evaluation on the data or work performed and the generic implications on the PROGRAM

(5) Acceptability of an implementation and completion schedule for corrective and preventive action (to preclude recurrence)

(6) Appropriateness of corrective action responsibility assignments

(g) Conduct of follow-up actions by assigned OCRWM personnel who ~~that~~ are under the direction of the Director, OQA to verify satisfactory implementation of corrective and preventive actions that were taken to resolve audit findings and observations. Documented verification of corrective and preventive action implementation is documented to support close-out of each finding and observation.

18.1.3 External Audits

The following amplifies the program as applied to external audits:

(a) After award of the contract and based on the determination of the quality classification of each item or service to be procured, the need for external audits will be evaluated. A determination may be made that external audits are not necessary for procuring items that are (a) relatively simple and standard in design, manufacturing, and testing or and (b) adaptable to standard or automated inspections or tests of the end product to verify quality characteristics after delivery. The rationale for not performing an external audit will be documented.

(b) When external audits are determined to be necessary, audits of suppliers' quality assurance programs will be conducted on at least a triennial basis. External audits of the suppliers' quality assurance programs may be performed by a third party for PROGRAM participants. The triennial period begins when an audit is performed. The need for more