

*Office of Civilian Radioactive Waste Management*

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# *Quality Assurance Manual*

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*U.S. Department of Energy*  
*Office of Civilian Radioactive Waste Management*

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# QUALITY ASSURANCE MANUAL

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## OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

U.S. DEPARTMENT OF ENERGY  
WASHINGTON, D.C.

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**Office of Civilian Radioactive Waste Management**

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**Quality Assurance**  
**Requirements Document**

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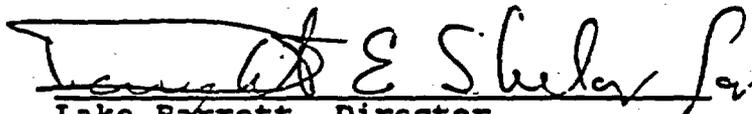
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**U.S. Department of Energy**  
**Office of Civilian Radioactive Waste Management**  
**Washington, DC**

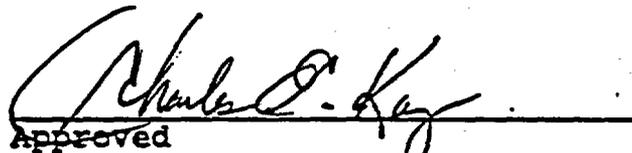
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U. S. DEPARTMENT OF ENERGY  
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

QUALITY ASSURANCE REQUIREMENTS  
for the  
CIVILIAN RADIOACTIVE WASTE MANAGEMENT PROGRAM

  
Lake Barrett, Director  
OCRWM Office of Quality Assurance

10/27/88  
Date

  
Approved  
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Office of Civilian Radioactive  
Waste Management

11/3/88  
Date

REVISION 1

QUALITY ASSURANCE REQUIREMENTS  
for the  
CIVILIAN RADIOACTIVE WASTE MANAGEMENT PROGRAM

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QAR  
October 24, 1988  
Revision 1

(v)

#### FOREWORD

OGR/B-3, Quality Assurance Plan for High Level Radioactive Waste Repositories August 1986; DOE/RW-0032, Quality Assurance Management Policies and Requirements October 1985; DOE/RW-0103, Quality Assurance Directive October 1986; and the "Director's Statements on Managing for Quality and Quality Assurance," July 14, 1987 were reevaluated in light of Congressional redirection of the Civilian Radioactive Waste Management Program in December 1987 and a major reorganization of the Office of Civilian Radioactive Waste Management in April 1988. As a result of the reevaluation, the four documents have been superseded and replaced by DOE/RW-0214, Quality Assurance Requirements for the Civilian Radioactive Waste Management Program (QAR) and DOE/RW-0215, Quality Assurance Program Description for the Civilian Radioactive Waste Management Program (QAPD).

LIST OF ACRONYMS AND ABBREVIATIONS

ANSI: American National Standards Institute  
ASME: American Society of Mechanical Engineers  
ASNT: American Society for Nondestructive Testing  
ASTM: American Society for Testing and Materials  
CAR: Corrective Action Report  
CRC: Chemical Rubber Company  
CFR: Code of Federal Regulations  
DOE: United States Department of Energy  
DWPF: Defense Waste Processing Facility  
ILP: Implementing Line Procedures  
ISFSI: Independent Spent Fuel Storage Installation  
MRS: Monitored Retrievable Storage  
NOA-1: ANSI/ASME Standard NOA-1-1986b  
NCR: Nonconformance Report  
NRC: United States Nuclear Regulatory Commission  
NWPA: Nuclear Waste Policy Act  
OCRWM: DOE, Office of Civilian Radioactive Waste Management  
OGR: Office of Geologic Repositories  
Q-List: Quality List  
QA: Quality Assurance  
QAAP: Quality Assurance Administrative Procedure  
QACG: Quality Assurance Coordinating Group  
QAL: Quality Activities List  
QAPD: DOE/RW-0215, Quality Assurance Program Description for the Civilian Radioactive Waste Management Program  
QAR: DOE/RW-0214, Quality Assurance Requirements for the Civilian Radioactive Waste Management Program  
SEMP: Systems Engineering Management Plan  
RD: Requirements Document  
SIP: Scientific Investigation Planning Document  
WBS: Work Breakdown Structure  
WVDP: West Valley Demonstration Project  
YMP: Yucca Mountain Project  
YMFO: Nevada Operations Office, Yucca Mountain Project Office.

## INTRODUCTION

### GENERAL

Quality achievement is a continuing responsibility of management at all levels in the U.S. Department of Energy's Civilian Radioactive Waste Management Program (PROGRAM). Well-defined quality assurance (QA) programs describing the set of management controls needed to achieve PROGRAM objectives are to be established and effectively implemented by all PROGRAM participants. These participants include the Office of Civilian Radioactive Waste Management (OCRWM), Operations Offices, Project Offices, contractors, subcontractors, national laboratories, and other government agencies performing activities affecting quality for the PROGRAM.

### PURPOSE AND APPLICABILITY

This document defines the quality assurance requirements governing activities affecting quality of all PROGRAM participants unless specifically stated otherwise herein. These requirements are applicable to the geologic repository, the monitored retrievable storage facility, transportation, and if required, the Federal interim storage facility. The amplifications specified in Sections 1 through 18 of this document are in addition to ANSI/ASME NQA-1-1986b (NQA-1) requirements and apply only to the geologic repository. Amplifications specific to the monitored retrievable storage facility, transportation, and if required, the Federal interim storage will be provided in subsequent versions of this document.

The quality assurance requirements specified in OGR/B-14, Specification of Quality Assurance Requirements for the High Level Waste Form Production are applicable to the PROGRAM's waste form producers. 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 the PROGRAM's radioactive material transportation cask systems. The quality assurance programmatic guidance of REGULATORY GUIDE 7.10 - Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material amplify the quality assurance program requirements for the packaging used in radioactive material transportation systems.

This document incorporates and supplements the applicable quality assurance program requirements from 10 CFR 60; 10 CFR 71; 10 CFR 72; 10 CFR 50, Appendix B; NQA-1; and DOE Orders. As such, only this document and the documents referenced specifically within the 18 sections of this document need be referenced for all OCRWM's quality assurance programmatic requirements. However, this document has not incorporated the technical implementation requirements and criteria of regulations, DOE Orders, and applicable NUREGs that are to be used when implementing the OCRWM quality assurance program.

NQA-1 has been chosen as the basic document for the OCRWM quality assurance program requirements because DOE ORDER 5700.6B, Quality Assurance has endorsed NQA-1 as the preferred standard for quality assurance requirements for the

nuclear area and the Nuclear Regulatory Commission (NRC) in Regulatory Guide 1.28 has found that the requirements of NQA-1 are acceptable for use in quality assurance programs for reactor design and construction. Many of the amplifications to the requirements set forth in the Basic Requirements and Supplements of NQA-1 came from the NRC review plan for high level nuclear waste repositories and from NUREGs that have been adopted as requirements documents by OCRWM for the geologic repository program. These NRC documents and other quality assurance program documents are listed in Appendix A.

Together, DOE/RW-0214, Quality Assurance Requirements for the Civilian Radioactive Waste Management Program (QAR) and DOE/RW-0215, Quality Assurance Program Description for the Civilian Radioactive Waste Management Program (QAPD) represent the "quality assurance plan" for OCRWM.

Deviations between requirements as stated in this document and any higher-tier requirements document accurately reflect approved exceptions to, or clarifications of, the higher tier requirements. In the event of differences between a requirement stated in this document and statements in any lower tier document, this document shall prevail unless the organization responsible for the lower tier document has obtained prior written OCRWM concurrence with the exception or clarification.

#### RESPONSIBILITY

The PROGRAM Director retains responsibility for the total quality assurance program; ensures its development, implementation, and verification; and retains ultimate review and approval authority on matters pertaining to the implementation of quality assurance program requirements.

#### QUALITY ASSURANCE PROGRAM BASIS

An important quality principle on which the quality assurance program has been based requires greater clarification. This principle is that each person in the PROGRAM is responsible for the achievement of quality in the work the person performs.

This quality assurance program provides for both the achievement of quality and the verification of that achievement. The line organization has total responsibility for the achievement of quality and the performance of quality control verifications, such as inspections and tests, to assure the achievement of quality. The quality assurance organization has the responsibility to provide assurance to senior line management of the line organization's achievement and verification of quality. This is accomplished through the conduct of overview activities such as audits, surveillances and assessments. This concept represents an approach that departs from the more traditional (classic) quality assurance found in most nuclear power plant quality assurance programs, in which the quality control verifications are performed by personnel who are part of the quality assurance organization.

The line organization ensures that people who perform quality reviews and quality control verifications meet the requirements of this document for reviewer independence from the work being performed.

The quality assurance organization maintains a strong overview presence in the quality assurance program. To implement a strong overview program the quality assurance organization performs sufficient and effective verifications (such as, audits, surveillances, and assessments) on activities affecting quality. Overview activities are scheduled to address the concerns of management and complement the actual performance of activities affecting quality. The scheduling process must be flexible to meet changes in work activities and newly identified concerns. While the quality assurance organization is required to perform an overview function for management, this overview role does not preclude the quality assurance organization from performing additional support functions that may be necessary to assure implementation of an effective quality assurance program.

## SECTION 1

### ORGANIZATION

#### 1.0 GENERAL

The provisions of NQA-1 Basic Requirement 1 and Supplement 1S-1 shall apply with the following amplifications.

#### 1.1 QUALITY ASSURANCE PROGRAM MANAGEMENT

The quality assurance organization is responsible to verify the proper performance of work through the implementation of appropriate quality assurance controls that include, as a minimum, audits and surveillances.

Each PROGRAM participant shall identify the quality assurance management position within their organization responsible for the establishment and implementation of their respective quality assurance programs. This quality assurance management position shall have the following characteristics:

- (a) An organizational position at the same or higher organizational level as the highest equivalent manager responsible for performing activities affecting quality
- (b) Knowledge and experience in the areas of quality assurance and management
- (c) The authority and responsibility to verify the adequacy and implementation effectiveness of the organizations and subtier organizations' quality assurance program
- (d) No other duties or responsibilities that are unrelated to quality assurance and that could prevent full attention to quality assurance matters
- (e) Sufficient freedom from cost and schedule considerations when opposed to quality considerations
- (f) Access to senior management and management at the next higher PROGRAM organizational level to identify, and obtain resolution to, unresolved quality concerns
- (g) Review and approval recommendation authority for quality assurance programs, revisions to, and interpretations thereof

#### 1.2 DELEGATION OF WORK

When OCFWM or a Project Office delegates work to other PROGRAM participants, a qualified individual or organization from within the

delegating office shall be designated as responsible for the quality of the delegated work. PROGRAM participants shall describe the major delegations of work involved in establishing the quality assurance program or any part thereof to any other organizations.

### 1.3 DISPUTE RESOLUTION

Provisions shall be made for the resolution of disputes involving quality arising from a difference of opinion at a given organizational level. These provisions shall include progressively elevating the dispute to the level of the PROGRAM Director if necessary.

### 1.4 ALLEGATION RESOLUTION

Provisions shall be established for individuals to express quality concerns directly to the PROGRAM Director without fear of reprisal. The provisions shall address allegations of inadequate quality from employees of PROGRAM participants and persons outside the PROGRAM. Allegations shall be investigated and resolved.

### 1.5 STOP WORK PROVISIONS

Provisions for issuing and lifting stop work orders shall be developed and implemented. The provisions shall include the following factors:

- (a) Criteria for stopping work and for lifting stop work orders
- (b) Authorities and responsibilities
- (c) Methodology for lifting stop work orders

## SECTION 2

### QUALITY ASSURANCE PROGRAM

#### 2.0 GENERAL

The provisions of NQA-1 Basic Requirement 2; Supplements 2S-1, 2S-2, 2S-3, and 2S-4; and Appendix 2A-1 shall apply with the following clarifications and amplifications.

#### 2.1 QUALITY ASSURANCE PROGRAM

PROGRAM participants shall develop quality assurance program documents that address quality assurance requirements applicable to their respective PROGRAM scope of work. Quality assurance program documents (hereafter referred to as the QA PROGRAM) consist of a quality assurance program description and detailed technical and quality assurance administrative procedures. The QA PROGRAM shall meet the requirements established by this document. The quality assurance program descriptions (or QA Plans) shall be reviewed and approved by line management of the next higher PROGRAM organizational level in a timely manner. PROGRAM-participant QA organizations shall review and make recommendations to line management concerning the approval of lower-tier quality assurance program descriptions (or QA Plans).

PROGRAM participants' quality assurance program documents shall include:

- (a) Descriptions of the management controls and lines of communication that exist with their contractors to assure direction of the quality assurance program
- (b) Descriptions of all onsite and offsite organizational elements that function under the cognizance of the quality assurance program and the lines of responsibility
- (c) Descriptions of the quality assurance responsibilities of each of the organizational elements noted on the organizational charts
- (d) Descriptions of persons and organizations that have authority to identify and resolve quality problems and of programs that will implement these actions
- (e) Identification of existing or proposed quality assurance administrative procedures
- (f) Description of the organizational responsibilities for reviewing, approving, verifying, and validating design criteria and design documents

- (g) Description of the inspection program including organizational responsibilities
- (h) Description of the test control program scope
- (i) Description of the scope and types of measuring and test equipment to be controlled by the quality assurance program
- (j) Description of the method of control of erroneous, rejected, superseded, or otherwise unsuitable data

## 2.2 REPORTING INDEPENDENCE OF PERSONNEL

If verification personnel are not part of the formal quality assurance organization, they 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 not part of the formal quality assurance organization (that is, part of the line organization), then the quality assurance organization shall overview the verification activities.

## 2.3 PLANNING

Participant's QA PROGRAMS shall include provisions for quality assurance program planning to be integrated and coordinated among participating organizations including the quality assurance organization to provide consistency and completeness and to avoid duplication of effort. Quality assurance program planning shall consider, as a minimum, the following elements:

- (a) Definition of activities
- (b) Assignment of quality levels to items and activities based on their importance to radiological safety, waste isolation, or other PROGRAM objectives
- (c) Selective application of appropriate quality assurance requirements and procedural controls within each quality level (that is, a graded approach) to items and activities
- (d) Assignment of responsibilities for quality assurance program control and verification activities

- (e) Identification of the specific scientific or technical information to be collected, analyzed, or used for design, performance assessment, or site characterization
- (f) Identification of applicable technical and quality assurance program management control and verification activities
- (g) Identification of field, laboratory, and engineering procedures for sampling, testing, and analysis activities
- (h) Provisions for the identification of required quality assurance records

#### 2.4 READINESS REVIEWS

Readiness reviews shall be planned, performed, and documented and shall apply to major scheduled or planned activities that affect or could affect quality. Readiness reviews shall provide visible evidence of the following characteristics:

- (a) Work activity prerequisites have been satisfied
- (b) Detailed technical and quality assurance administrative procedures have been reviewed for adequacy and appropriateness
- (c) Personnel have been suitably trained and qualified

#### 2.5 QUALITY LEVELS AND GRADED QUALITY ASSURANCE

The classification of quality levels shall be performed in accordance with the guidance provided in NUREG-1318, Technical Position on Items and Activities in the High-Level Waste Geologic Repository Program Subject to Quality Assurance Requirements, April 1988 and the following amplifications.

##### 2.5.1 Classification of Quality Levels

A three-tier quality classification system shall be used as an aid in the decision process for selecting and applying appropriate quality assurance requirements. Methodologies for the classification of items and activities into the three quality levels shall be developed. The rationale for the classification shall be documented. Wherever possible, the classification methodologies shall be technically based and shall include appropriate supporting failure analyses and risk assessments. Items and activities shall be identified and classified as one of the following quality level classifications:

- (a) **Quality Level 1 (QL1).** QL1 is the classification to be assigned to PROGRAM items and activities requiring application of the most stringent quality assurance requirements and procedural controls because of their importance to public radiological health and safety and waste isolation. The assignment of QL1 imposes the applicable quality assurance requirements of 10 CFR 60, Subpart G and ANSI/ASME NQA-1-1986b. OCRWM and each Project Office shall establish a Q-List and a Quality Activities List.
- (b) **Quality Level 2 (QL2).** QL2 is the classification to be assigned to PROGRAM items and activities requiring application of additional quality assurance requirements and procedural controls because of their importance to the success of the PROGRAM. The assignment of QL2 imposes the appropriate quality assurance requirements of ANSI/ASME NQA-1-1986b. QL2 will be assigned as a minimum of the following categories.
- (1) Items and activities designed to minimize nonradiological health and safety hazards to the public and PROGRAM workers
  - (2) Items and activities designed to protect workers from radiological hazards exceeding the limits of 10 CFR 20
  - (3) Items whose failure, omission, or degradation could affect the operational reliability, maintainability, and performance of engineered structures, systems, and components
  - (4) Items and activities of special programmatic importance designated as such by the appropriate director or program manager
- (c) **Quality Level 3 (QL3).** QL3 is the classification to be assigned to PROGRAM items and activities requiring routine quality assurance requirements and procedural controls to assure proper performance or service. The assignment of QL3 imposes the use of routine managerial, administrative, scientific, engineering, industry, and laboratory practices.

### 2.5.2 Graded Quality Assurance

Quality assurance requirements and procedural controls shall be selectively applied. The selective application and the degree of application of the quality assurance requirements assigned to each item and activity shall be commensurate with the following factors:

- (a) Consequence of failure
- (b) Importance of data
- (c) Complexity of function
- (d) Reliability of process
- (e) Reproducibility of results
- (f) Uniqueness of product
- (g) Degree of functional product demonstration
- (h) Degree of standardization
- (i) History of quality
- (j) Impact of schedule or cost or both
- (k) Necessity of special controls or processes
- (l) Significance to licensing process

## 2.6 PERSONNEL SELECTION, INDOCTRINATION, TRAINING, AND QUALIFICATION

2.6.1 Supplement 2S-1 and Appendix 2A-1 shall only apply to personnel who conduct inspections and testing activities to verify conformance of an item to specified requirements for the purpose of acceptance and to demonstrate that items will perform satisfactorily in service.

2.6.2 Supplement 2S-4 to NQA-1 shall apply except that Paragraph 2 is amplified with the following requirements:

- (a) Management of each PROGRAM-participant organization shall analyze each job position to determine the quality-affecting task responsibilities of the position. The results of each analysis shall be documented in position descriptions that includes the education and experience prerequisites for each position involved in the performance or verification of activities affecting quality.

- (b) Personnel selected to perform or verify activities affecting quality shall have education, experience, and training commensurate with the minimum requirements specified. Relevant education and experience shall be verified. The capabilities of an individual shall be based upon an evaluation of education and experience and compared to those qualification requirements established for the position. Management shall monitor the performance of personnel doing work affecting quality and, at least annually, determine the need for retraining or reassignment.

## 2.7 SURVEILLANCE

Surveillances shall be conducted to assess the quality of items or activities in process.

2.7.1 Surveillance of activities affecting quality shall be planned, performed, documented, and reported to appropriate management.

2.7.2 Surveillance shall be conducted to accomplish the following objectives:

- (a) Monitor work in progress
- (b) Document compliance or noncompliance with requirements and procedures
- (c) Identify actual and potential deficiencies and deviations promptly
- (d) Promote prompt corrective action by cognizant management responsible for performing the work
- (e) Provide management information on activities under surveillance
- (f) Verify timely implementation of corrective action

2.7.3 Surveillance shall be performed by personnel who are knowledgeable in, and not directly responsible for, the activities under surveillance.

2.7.4 Surveillance results shall be documented in a report that contains the following elements as a minimum:

- (a) Description of the activity or item under surveillance
- (b) Identification of the persons conducting the surveillance
- (c) Identification of the persons contacted during the surveillance
- (d) List of the requirements governing the activity or item
- (e) Summary of the surveillance results that identifies deficiencies, deviations, or exemplary practice noted during the surveillance
- (f) Summary of any immediate corrective actions taken

## 2.8 MANAGEMENT ASSESSMENT

Independent management assessments by persons above or outside the quality assurance organization shall be conducted at least annually by, or at the direction of, the highest management position identified in each PROGRAM-participant's organization. These management assessments shall evaluate as a minimum the following program aspects:

- (a) Effectiveness of the quality assurance program
- (b) Adequacy of planning and procedural controls
- (c) Effectiveness of the corrective action system
- (d) Adequacy of organizational structure and staffing to implement the quality assurance program
- (e) Adequacy of the indoctrination and training program
- (f) Adequacy of the quality assurance management information tracking, evaluation, and reporting system

## 2.9 QUALITY ASSURANCE MANAGEMENT-INFORMATION REPORTING AND TRACKING

2.9.1 PROGRAM participants shall report, disseminate, and track the following types of quality-related management information as a minimum:

- (a) Status of development and implementation of the quality assurance program

- (b) Status of resolution of significant conditions adverse to quality, issues, and trends
- (c) Summary of management overview results (Exemplary practices shall be reported but need not be tracked.)

2.9.2

Quality assurance management information shall be reported to the appropriate level of management and the next higher PROGRAM-participant organizational level at least quarterly.

### SECTION 3

#### DESIGN CONTROL

##### 3.0 GENERAL

The provisions of NQA-1 Basic Requirement 3 and Supplement 3S-1 shall apply to design from conceptual design through final design. The following amplifications apply to design and design activities.

##### 3.1 DESIGN ERROR AND DEFICIENCY CONTROL

Errors and deficiencies in approved design and design information documents shall be documented and corrective action shall be taken in accordance with Section 16 or Section 18 as appropriate.

##### 3.2 DESIGN CHANGES

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

##### 3.3 COMPUTER SOFTWARE CONTROL

Computer software used to calculate or develop data in support of a license application shall be verified, validated, and documented.

For the purpose of this document, computer software verification is defined as the process that demonstrates that the computer software correctly performs its stated capabilities and functions, whereas computer software validation is defined as the process that demonstrates that the mathematical model embodied in the computer software is a correct representation of the process or system for which it is intended.

3.3.1 Each PROGRAM participant shall control computer software development, testing, maintenance, and configuration management. The description shall include:

- (a) Criteria for application of the requirements of this document
- (b) Methods to be used to develop functional performance requirements, to translate those requirements into a detailed design, and to implement that design in computer software
- (c) Documentation to be prepared, reviewed, and maintained during computer software design, development, implementation, test, and use

- (d) Methodology for establishing computer software baselines and baseline changes and for tracking changes throughout the life of the computer software
- (e) Process to be used for verification and validation of computer software
- (f) Procedure for reporting and documenting computer software discrepancies, evaluating impacts of discrepancies on previous calculations, and determining appropriate corrective action

3.3.2 Computer software shall be placed under configuration control as each baseline element is approved. Baseline elements shall be uniquely identified to assure positive control of revisions and to provide traceability between the documentation and the computer software version.

3.3.3 Changes to computer software shall be systematically evaluated, coordinated, and approved to assure that the impact of a change is carefully assessed prior to updating the baseline. Information concerning approved changes shall be transmitted to all users or affected organizations. Changes to computer software shall be subjected to the same level of approval, verification, and validation as the original computer software.

3.3.4 As appropriate, computer software documentation shall meet the guidance in NUREG-0856, Final Technical Position on Documentation of Computer Codes for High-Level Waste Management, June 1983 and shall include the following elements:

- (a) A description of the computer software development history that identifies specific computer software versions and other basic information about the evolution of the computer software
- (b) An explanation of the mathematical model(s) and derivation of the numerical methods used in the computer software design. Physical and mathematical assumptions on which the computer software is based shall be listed along with an explanation of the capabilities and limitations inherent in the computer software.
- (c) Instructions enabling users to run the computer software and a description of anticipated errors with user responses
- (d) A description of formal reviews and of verification and validation testing

- 3.3.5 Computer software testing shall be performed for those inputs and conditions necessary to exercise the computer software to assure that unintended functions that would degrade the computer software will not be performed. The documentation shall include test boundary conditions and provide suitable benchmarks or sample problems.
- 3.3.6 If parameters that control experiments are not sufficiently defined to allow for validation, an independent assessment shall be performed to determine the degree of computer software validation achievable.
- 3.3.7 Computer software that was not developed under a documented quality assurance program meeting the requirements of Subsection 3.3.1 may be qualified for use provided that the computer software is verified and validated. A computer software baseline is to be established and controlled, and applicable documentation is to be prepared to support its use.

#### 3.4 TECHNICAL REVIEWS

- 3.4.1 A technical review shall be performed when the information or document under review is within the state of the art and is based on accepted standards, criteria, principles, and practices.
- 3.4.2 Technical reviews shall be used when documents, activities, material, or data require technical verification or validation for applicability, correctness, adequacy, completeness, and assurance that established requirements are satisfied.
- 3.4.3 Technical reviews shall be performed by individuals with sufficient technical knowledge of the area under review to be able to render an opinion. Individuals shall be independent of those who performed the work.
- 3.4.4 The results of technical reviews shall be documented.

#### 3.5 PEER REVIEWS

- 3.5.1 Peer reviews shall 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.

### 3.6 SCIENTIFIC INVESTIGATIONS

#### 3.6.1 Control of Scientific Investigations

Scientific investigations shall be defined, controlled, and verified. Process variables affecting scientific investigations shall be measured and controlled. Variables that affect interrelated scientific investigations shall be identified, documented, and controlled in each investigation.

The scientific notebook system and the technical procedures system are two approaches that may be used to control scientific investigations activities. The scientific notebook system may be used by qualified individuals who are required to use a high degree of professional judgment or trial and error methods or who are developing the methodology by which an activity will be accomplished. When the scientific notebook system is used, the scientific investigation planning document shall control the activities.

The technical procedures system shall be used by qualified personnel to perform repetitive work that does not include the use of a high degree of professional judgment nor trial and error methods. Technical procedures are required when it is not possible to deviate from a prescribed sequence of actions without endangering the validity of the results. Technical procedures shall be reviewed for technical adequacy and approved by qualified persons other than those who prepared the procedures. Changes to technical procedures for conducting scientific investigations shall be reviewed and approved by the same organizations that performed the original review and approval unless the PROGRAM participant designates another responsible organization. The technical aspects of procedures may be modified with the approval of an appropriately qualified reviewer if the change is within the scope of the scientific investigation planning document, the activity can be repeated, and the activity does not potentially impact the waste isolation capability of the site or interfere with other site characterization activities. Activities to develop new methods or procedures for conducting scientific investigations or critical processes shall be documented. Results shall be reviewed for adequacy and approved by qualified persons prior to use of the procedures to collect data.

### 3.6.2 Planning

Prior to the start of any scientific investigation, a scientific investigation planning document (for example, study plan) shall be developed. Planning documents shall contain:

- (a) Description of work to be performed
- (b) Rationale and justification for the information to be obtained
- (c) Proposed methodology
- (d) Rationale and justification for the proposed methodology
- (e) References to applicable documents
- (f) Identification, explanation, and justification for areas where scientific notebooks are to be used
- (g) Description of constraints
- (h) Description of the application of the results
- (i) Description of schedules and milestones

The intended use of data shall be documented as part of the planning for scientific investigations. Any alternate use of the data shall be evaluated for appropriateness and the justification documented. Planning shall assure the compatibility of scientific investigations with any conceptual or mathematical models used at each applicable stage. Planning shall establish provisions for the evaluation of data quality to assure that data generated is valid, comparable, complete, representative, precise, and accurate. Known sources of error and uncertainty and input data that is suspect or whose quality is beyond the control of the performing organizations shall be identified. These measures shall include or reference provisions for assuring that prerequisites for the given scientific investigation have been met, that adequate instrumentation is available and used, that necessary monitoring including witness or hold points is performed, and that suitable environmental conditions are maintained. The following prerequisites shall be considered: calibrated instrumentation; appropriate equipment; trained personnel; readiness of facilities, equipment, supplies, and items or samples; suitable environmental conditions; provision for acquisitions and recordings of data; and disposition of facilities after completion of scientific investigation activities.

The range, accuracy, and precision of equipment used for scientific investigations shall be specified in order to be commensurate with requirements. In developing quality assurance requirements for equipment, consideration shall be given to whether proper performance of a scientific investigation can be determined during or after the scientific investigation (that is, whether failure or malfunction of equipment can be detected). Where requirements are found to be necessary, special quality or performance verification requirements shall be established and described to govern the use of the equipment.

Scientific investigations shall be performed in accordance with nationally recognized standards (for example, ASTM) where available. Standards used without modification require documentation by reference only. If deviation from standards or establishment of specially prepared procedures is deemed appropriate, the modifications or new methods shall be documented in sufficient detail to be repeatable and shall be evaluated, justified, and approved.

### 3.6.3 Data Collection and Analysis

Equipments and methods used to obtain and analyze data shall be verified to assure technical adequacy and proper selection. Data collection and analysis shall be controlled by measures that provide sufficient detail to allow the processes to be repeated by an individual of comparable education or training to the person originally conducting the task. Where appropriate, verifications shall be performed using recognized methods.

Data transfer and reduction controls shall be established to assure data transfer is error free or within a prescribed permissible error rate, to assure that information is not lost in transfer and that the input is completely recoverable from the output. All processes that change either the form of expression or quantity of data, values, or number of data items (data reduction) shall be controlled by prescribed methods that allow verification of the conversion process.

### 3.6.4 Use of Data

Data collection and analysis shall be technically reviewed by qualified individuals other than those who performed the scientific investigation. Questions shall be resolved before the results are used as a baseline. Unreviewed data and data with unresolved questions shall be clearly identified when used or reported. Uncertainty limits shall be assigned to the data prior to use. Data collected should be reported so as to relate it to information needs and issue resolution.

### 3.6.5 Data Identification and Traceability

All data shall be recorded so as to be clearly identifiable and traceable to the source from which it was generated. Identification and traceability shall be maintained throughout the needed lifetime of the data.

Data found to be erroneous, rejected, superseded, or otherwise unsuitable for the intended use shall be controlled and dispositioned. Controls shall include the identification and segregation of unsuitable data to avoid inadvertent use. The disposition of unsuitable data shall be justified and documented.

### 3.6.6 Data Recording, Storage, and Retrievability

Original recorded data shall be considered a QA Record and shall be handled in accordance with Section 17.

Records shall, as appropriate, identify the following elements:

- (a) Scientific investigation requirements, plans, and procedures including applicable revisions
- (b) Item or sample investigated
- (c) Date of scientific investigation
- (d) Identification of the persons performing the scientific investigation and the performers' organizations
- (e) Results and acceptability for intended use
- (f) Action taken in connection with any deviations noted
- (g) Persons evaluating scientific investigation results and evaluators' organizations
- (h) Identification of equipment used

### 3.6.7 Qualification of Data of Indeterminate Quality

Data that was not collected under the control of a quality assurance program meeting the quality assurance requirements of 10 CFR 60 Subpart G or this document shall be qualified in accordance with NUREG-1298, Qualification of Existing Data for High-Level Nuclear Waste Repositories Generic Technical Position, February 27, 1988 prior to use. This may include data collected from such sources as professional journals, technical reports, and symposia proceedings but does not include design

## GLOSSARY

The terms and definitions of NQA-1 Supplement S-1 shall apply with the following additions. Where differences exist between this document and others, the definitions in this document shall take precedence.

**Activities Affecting Quality:** Deeds, actions, functions, processes, tasks, or work which influence the achievement or verification of CRWM program quality requirements or objectives. For the geologic repository this includes activities affecting the quality of all systems, structures, and components important to safety and the design and characterization of engineered or natural barriers important to waste isolation. Examples of such activities include site characterization, design, procurement, fabrication, construction, erection, installation, inspection, testing, auditing, surveillance, assessment, handling, packaging, transportation, storage, cleaning, operation, maintenance, repairing, modifying, performance confirmation, permanent closure, decontamination, and dismantling.

**Baseline:** (noun) A set of criteria or critical observations or data that are under change and distribution control and are used for comparison or as a control. (verb) The act of formally approving and accepting a set of criteria or critical observations or data for use as a comparison or as a control.

**Confirmatory Testing:** An evaluation conducted under a 10 CFR 60 Subpart G quality assurance program that investigates the properties of interest of an existing data base.

**Design:** The specifications, drawings, criteria, performance requirements, or similar documents that define the technical requirements and configuration of the natural and engineered structures, systems, components, and barriers of the geologic repository, MRS facility, transportation cask system, waste form, and Federal interim storage facility.

The act of defining the above technical requirements at each developmental stage of the final design (that is, from conceptual design through final design). Design control measures are exercised at each stage of the design.

Design information and design activities include the data collection and analysis activities that are used in supporting design development and verification. This includes general plans and detailed procedures for the data collection and analyses and related information such as tests results and analyses. Data analysis includes the initial step of data reduction as well as broad level system analysis, such as performance assessments, which integrate many other data and analysis of individual parameters.

**Design Activities:** Activities related to the design process including data collection and analyses activities that are used in supporting design development and verification.

**Design Review:** A formally documented evaluation conducted at various points during the design process that compares design documentation against applicable codes, standards, and other specifications to determine its adequacy and the extent to which the design conforms to stated requirements.

**Engineered Item:** Any structure, system, or component identified in design documents as being a functional part of the completed facility.

**Graded Quality Assurance:** A method used to identify QA program controls to be applied to items and activities consistent with their importance to safety, waste isolation, or achievement of quality objectives. The degree to which QA program controls are applied is commensurate with function, complexity, consequence of failure, reliability, replicability and economic considerations.

**Important to Safety:** Essential to or affecting the ability to prevent or mitigate an accident that could result in a radiation dose to the whole body, or any organ, of 0.5 rem or greater at or beyond the nearest boundary of the unrestricted area at any time until the completion of permanent closure.

**Important to Waste Isolation:** Essential to or affecting the ability to inhibit the transport of radioactive material so that amounts and concentrations of this material entering the accessible environment after permanent closure will be kept within limits prescribed by 10 CFR 60 and 40 CFR 191.

**Indoctrination:** Instruction or reading requirements to familiarize personnel in basic principles or elements or a fundamental skill.

**Item:** An all-inclusive term commonly used in place of any of the following: structure, system, component, material, and equipment.

**Items Important to Safety:** Those engineered systems, structures, and components essential to, or affecting, the ability to prevent or mitigate an accident that could result in a radiation dose to the whole body, or any organ, of 0.5 rem or greater at or beyond the nearest boundary of the unrestricted area at any time until the completion of permanent closure (10 CFR 60.2).

**Items Important to Waste Isolation:** Those natural and engineered barriers essential to, or affecting, the ability to prevent the release of radionuclides to the accessible environment and achieve the postclosure performance objectives prescribed in 10 CFR 60.

**Model:** A system of postulates, data, and inferences, presented as a mathematical description of an entity, state of affairs, process, or system.

**Procurement Document:** Purchase requisitions, purchase orders, drawings, contracts, specifications, or instructions used to define requirements for purchase and broadly interpreted by OCFWM to include work orders, work authorization letters, store orders, memoranda of understanding, field task proposals/agreements, and interagency agreements.

**O-List (Quality List):** A list of structures, systems, and components that have been determined to be important to safety and engineered barriers that have been determined to be important to waste isolation (Quality Level 1 item).

**Quality Achievement:** The act of attaining or exceeding a degree of excellence.

**Quality Activities List:** In the geologic repository program, a list of those major activities conducted during site characterization, construction, operation, or closure that relate to natural barriers that have been determined to be important to waste isolation. These activities are covered under a 10 CFR 60 Subpart G QA program and include data gathering, performance assessments, and those activities that could affect a natural barrier's ability to isolate waste.

**Quality Assurance Program:** A documented description of the controls used for achieving and verifying quality.

**Readiness Review:** An independent, systematic, documented review to determine, and inform management of, the readiness to advance from one phase, process, or activity into another. Readiness reviews are used to coordinate many elements, to provide attention to detail, and to assure that the project is ready to proceed to the comprehensive review of a total project or a particular segment of the project.

**Scientific Investigation:** Any research, experiment, test, study, or activity that is performed for the purpose of investigating the natural barriers or man-made aspects of the geologic repository including the overall design of the facilities and waste package. This includes the various studies of activities that are performed for, or in support of, the investigation, exploration, site characterization, design bases development, licensing, construction, operation, monitoring, performance evaluation, or closure of the geologic repository.

**Scientific Notebook:** A document which may be used to provide a written record of the results of scientific investigations and experiments when the work involves a high degree of professional judgment or trial and error methods or both. These notebooks may be used in lieu of technical procedures.

**Technical Review:** A documented, traceable, in-depth, critical review, analysis, or evaluation of documents, materials, or data that falls within the state of the art conducted to verify or validate or both its applicability, correctness, adequacy, and completeness. Technical reviews are performed by qualified personnel with technical expertise at least equivalent to those who conducted the original work, and who are independent of those who conducted the work being reviewed.

**Training:** In-depth instruction or practice or both to develop or maintain proficiency in a subject or activity.

**QUALITY ASSURANCE REQUIREMENTS DOCUMENT**

The following number is for OCRWM records management purposes only and should not be used when ordering this publication.

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reference codes and standards (for example, ASME Boiler and Pressure Vessel Code, ASTM standards, and CRC Handbooks). The organization using the data shall define the data-qualification process that describes how data will be assessed for quality characteristics, such as accuracy, precision, completeness, representativeness, and comparability. Acceptable qualification methods include any one or a combination of peer review, corroborating data, or confirmatory testing. Consideration shall be given to the following factors when available and measurable:

- (a) Qualifications of personnel or organizations generating the data
- (b) Technical adequacy of the equipment and procedures used in the scientific investigation
- (c) Environmental conditions
- (d) Confidence level associated with the corroborating data based upon the quality and reliability of the measurement control program under which the data was generated
- (e) Amount of corroborating data or confirmatory testing
- (f) Extent to which data demonstrates properties of interest (for example; physical, chemical, geologic, mechanical)
- (g) Extent to which conditions generating the data may partially meet requirements of this document
- (h) Prior uses of the data and associated verification process
- (i) Prior professional reviews of the data
- (j) Extent and reliability of the documentation associated with the data
- (k) Degree to which data-generating processes were independently audited
- (l) Importance of the data to show that performance objectives were met

The results of data qualification activities shall be documented. The information to be found in peer review reports is addressed in Section 3.5. Reports of data qualification by use of corroborating data shall include the following elements:

- (a) Identification of the corroborating data source
- (b) Tabulation of the corroborating data
- (c) Description of the corroborating data relationship to the data being qualified
- (d) Technical justification for use of the corroborating data
- (e) Identification of the corroborating data reviewers
- (e) Test results

## SECTION 4

### PROCUREMENT DOCUMENT CONTROL

#### 4.0 GENERAL

The provisions of NQA-1 Basic Requirement 4 and Supplement 4S-1 shall apply with the following amplifications.

#### 4.1 REVIEW

Procurement documents shall be reviewed by PROGRAM-participant QA representatives to assure that applicable quality assurance requirements are included.

#### 4.2 APPLICABILITY OF PURCHASER'S QA PROGRAM

When deemed appropriate, the purchaser may permit some or all supplier activities to be performed under the jurisdiction of the purchaser's quality assurance program provided that the scope of the activity is adequately addressed therein. This situation may exist when the scope of work or schedule requirements cannot justify the cost of development and maintenance of a quality assurance program at the supplier facility. When these circumstances apply, the procurement documents shall specify which portions of the purchaser's quality assurance manual and procedures are applicable to the supplier's work efforts.

## SECTION 5

### INSTRUCTIONS, PROCEDURES, AND DRAWINGS

#### 5.0 GENERAL

The provisions of NQA-1 Basic Requirement 5 shall apply with the following amplifications.

#### 5.1 REVIEWS

An independent review of instructions, procedures, and drawings shall be performed by the originating organization to assure technical adequacy including the correct translation of design requirements and inclusion of quality requirements. The review shall consider whether the activities have the potential to impact the waste isolation capability of the site or interfere with other site characterization tests.

#### 5.2 PROCEDURES LIST

PROGRAM participants shall maintain a list of detailed technical procedures that are applicable to the quality assurance program.

## SECTION 6

### DOCUMENT CONTROL

#### 6.0 GENERAL

The provisions of NQA-1 Basic Requirement 6 and Supplement 6S-1 shall apply with the following amplifications.

#### 6.1 CONTROL

Each PROGRAM participant shall assure that correct and applicable documents are available at the location where PROGRAM activities affecting quality will be performed prior to commencing the work.

#### 6.2 CONTROL SYSTEM

In addition to the elements identified in Supplement 6S-1 Section 2, the control system for document preparation, review, approval, and issuance shall include:

- (a) Access by reviewing organizations to pertinent background data or information to assure a complete review
- (b) Resolution of review comments for which the resolutions are considered mandatory by the reviewing organization prior to approval and issuance of the document
- (c) Documentation and maintenance of review comments and resolutions
- (d) Identification and control of documents released prior to completing the approval process
- (e) Evaluation of changes for the potential impact on the waste isolation capability of the site or interfere with other site characterization activities

#### 6.3 CONTROLLED DOCUMENTS

Certain documents within the quality assurance program shall be identified as controlled documents. Control measures shall be established for controlled documents that are in addition to the normal controls of Section 6. These additional control measures include the development of a controlled documents list, the establishment of a receipt acknowledgment system, and the development of an obsolete- or suspended-document control system.

**SECTION 7**

**CONTROL OF PURCHASED ITEMS AND SERVICES**

**7.0 GENERAL**

The provisions of NQA-1 Basic Requirement 7 and Supplement 7S-1 shall apply with the following amplification.

**7.1 SUPPLIERS' QUALITY ASSURANCE PROGRAMS**

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

## SECTION 8

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

#### 8.0 GENERAL

The provisions of NQA-1 Basic Requirement 8 and Supplement 8S-1 shall apply with the following amplifications.

#### 8.1 SAMPLES

Samples shall be identified and controlled in a manner consistent with the samples' intended uses. Such controls shall define the responsibilities including interfaces between technical specialties and organizations for collection, identification, and traceability of samples (including archival samples); for test allocation; for disposition of samples; and for generation of associated records.

##### 8.1.1 Sample Identification

Samples shall be identified by placing identification directly on the samples when possible, on the samples' containers, or on labels or tags attached to the samples or the samples' containers. Sample identification shall be verified and documented prior to release for testing or analysis.

##### 8.1.2 Sample Traceability

Identification systems shall assure traceability of samples to the appropriate source, requirement, or use document. Traceability of samples from initial acquisition through final disposition is required. Measures shall be taken to preclude the use of samples that cannot be identified.

##### 8.1.3 Archival Samples

Applicable technical specifications, procurement documents, test procedures, or other similar documents shall specify representative archival samples to be maintained as QA records from difficult-to-repeat, geologic, sample collection activities and from waste-form qualification activities.

**SECTION 9**  
**CONTROL OF PROCESSES**

**9.0 GENERAL**

The provisions of NQA-1 Basic Requirement 9 and Supplement 9S-1 shall apply with the following amplifications.

**9.1 APPLICABILITY**

The requirements of this Section apply to engineered items and do not apply to scientific investigation activities.

**9.2 LIST OF SPECIAL PROCESSES**

Each PROGRAM participant shall provide a list of special processes that they will perform or be responsible for.

**9.3 QA INVOLVEMENT IN QUALIFICATION ACTIVITIES**

The QA organization shall be involved in qualification activities to help assure satisfactory performance. As a minimum, the QA organization shall overview the development and implementation of special process qualification activities through the conduct of audits and surveillances.

**9.4 EVIDENCE OF ACCOMPLISHMENT**

Each PROGRAM participant shall establish provisions for recording evidence of acceptable accomplishment of special processes using qualified procedures, equipment, and personnel.

**SECTION 10**

**INSPECTION**

**10.0 GENERAL**

The provisions of NQA-1 Basic Requirement 10 and Supplement 10S-1 shall apply with the following amplifications.

**10.1 APPLICABILITY**

The requirements of this Section apply to engineered items and do not apply to scientific investigation activities.

**10.2 RECORDS**

In addition to the elements identified in Supplement 10S-1 Section 8, inspection records shall include:

- (a) Inspection procedure
- (b) Characteristics inspected
- (c) Inspection criteria or reference documents used to determine acceptance
- (d) Equipment used during the inspection
- (e) Special expertise used

## SECTION 11

### TEST CONTROL

#### 11.0 GENERAL

The provisions of NQA-1 Basic Requirement 11 and Supplement 11S-1 shall apply with the following amplifications.

#### 11.1 APPLICABILITY

The requirements of this Section apply to engineered items and do not apply to scientific investigation activities.

#### 11.2 UNCERTAINTY AND ERROR

Potential sources of uncertainty and error shall be identified in test plans and procedures. In addition, parameters that must be controlled and measured shall be identified.

#### 11.3 PRECISION AND ACCURACY

Precision and accuracy considerations shall be identified in test procedures.

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## SECTION 12

### CONTROL OF MEASURING AND TEST EQUIPMENT

#### 12.0 GENERAL

The provisions of NQA-1 Basic Requirement 12 and Supplement 12S-1 shall apply with the following amplification.

#### 12.1 ACCURACY OF CALIBRATION STANDARDS

Calibration standards shall have equal to or greater accuracy than the equipment being calibrated unless limited by the state of the art.

## SECTION 13

### HANDLING, STORAGE, AND SHIPPING

#### 13.0 GENERAL

The provisions of NQA-1 Basic Requirement 13 and Supplement 13S-1 shall apply with the following amplifications.

#### 13.1 SAMPLES

Handling, storage, and shipping requirements are also applicable to samples collected for site characterization.

##### 13.1.1 Sample Handling and Shipping

Samples shall be controlled during handling, storage, and shipment to preclude damage or loss and minimize deterioration. Controls shall be established for appropriate packaging, handling, and modes of transportation, with consideration being given to types of containers, time constraints on perishable materials (that is, shelf life), and any other environmental or safety considerations applicable to the samples. Measures shall be taken to avoid sample contamination during handling and shipment. Where multiple organizations are involved, appropriate procedures shall describe interface and custody responsibilities. Sample identification shall be verified and maintained when samples are handled, transported, or transferred from one organization's responsibility to another.

##### 13.1.2 Sample Storing

Provisions shall be made to maintain sample characteristics, integrity, and identification while in storage. These provisions shall be consistent with the planned duration and conditions of storage and shall describe actions to be taken where samples have a maximum life expectancy while in storage. Storage methodology shall be developed and implemented to assure that samples are maintained in predetermined environmental conditions commensurate with the samples' intended purposes. Samples shall be controlled to preclude mixing of like samples or contamination. Provisions shall be made for identification and storage of tested samples in areas physically separated from untested sample materials.

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## SECTION 14

### INSPECTION, TEST, AND OPERATING STATUS

#### 14.0 GENERAL

The provisions of NQA-1 Basic Requirement 14 shall apply with the following amplification.

#### 14.1 APPLICABILITY

The requirements of this Section apply to engineered items and do not apply to scientific investigation activities.

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## SECTION 15

### CONTROL OF NONCONFORMING ITEMS

#### 15.0 GENERAL

The provisions of QA-1 Basic Requirement 15 and Supplement 15S-1 shall apply.

## SECTION 16

### CORRECTIVE ACTION

#### 16.0 GENERAL

The provisions of NQA-1 Basic Requirement 16 shall apply with the following amplifications.

#### 16.1 TREND ANALYSIS

Quality information, such as audit reports, surveillance reports, nonconformance reports, corrective action reports, and related documents, shall be analyzed to identify both favorable and adverse quality trends. Trend analysis shall be performed in a manner and at a frequency that shall provide for prompt identification of adverse quality trends. Adverse quality trends shall be evaluated and reported to the organization responsible for corrective action.

#### 16.2 SIGNIFICANT CONDITIONS ADVERSE TO QUALITY

Criteria for determining the existence of significant conditions adverse to quality shall be developed at each PROGRAM-participant organizational level. Significant conditions adverse to quality shall be identified, documented, and corrected at each PROGRAM organizational level. Corrective action shall include root cause identification and resolution of the generic implications to the PROGRAM. Copies of corrective action documentation shall be provided to appropriate management of the next higher PROGRAM organizational level and the Director, OCRWM Office of Quality Assurance. QA organizational concurrence with proposed corrective action and QA verification of corrective action implementation are required.

**SECTION 17**

**QUALITY ASSURANCE RECORDS**

**17.0 GENERAL**

The provisions of NQA-1 Basic Requirement 17 and Supplement 17S-1 shall apply with the following amplification.

**17.1 COMPLIANCE WITH OCRWM RECORDS-MANAGEMENT PROGRAM**

Each PROGRAM participant shall develop quality assurance records programs or procedures appropriate for their scope of work that are consistent with, and meet the requirements in, DOE/RW-0194 Records Management Policies and Requirements.

## SECTION 18

### AUDITS

#### 18.0 GENERAL

The provisions of NQA-1 Basic Requirement 18 Supplement 18S-1 shall apply with the following amplifications.

#### 18.1 TECHNICAL CONSIDERATIONS

The audit program shall address the quality of products and technical work as well as programmatic compliance. Audit team members selected for technical consideration purposes to participate in audits shall have technical expertise or experience in the work being audited and shall be indoctrinated in audit techniques as a minimum. Management at all levels within each Program-participant organization shall be actively involved with the audit process.

#### 18.2 PROJECT OFFICE AUDITS

OCRWM shall audit the Project Offices' quality assurance programs annually to assess implementation effectiveness.

#### 18.3 ANALYSIS OF AUDIT DATA

Data from the performance of an audit shall be analyzed by the quality assurance organization and the results reported to responsible management for review, assessment, and appropriate action. A method for meeting this requirement is to include the data analysis results in the audit report.

#### 18.4 INTERNAL AUDIT SCHEDULING

- 18.4.1 Internal audits of the implementation effectiveness of the quality assurance program shall be performed at least once each year or at least once during the life of the activity affecting quality, whichever is shorter.
- 18.4.2 The scope of each audit shall be based on an evaluation of the activities to be audited. The evaluation shall consider:
  - (a) Results of previous internal audits
  - (b) Results of previous extrinsic audits
  - (c) Impact of significant changes in personnel, organization, or quality assurance program

## 18.5 EXTERNAL AUDIT SCHEDULING

- 18.5.1 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 shall 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 (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 shall be documented.
- 18.5.2 External audits of suppliers' quality assurance programs shall 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 frequent external audits of a supplier shall be evaluated when major changes to contract scope or work methodology occurs. Preaward surveys may serve as the first triennial audit if the scope of the preaward survey is similar to the scope of other triennial audits.
- 18.5.3 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.
- 18.5.4 Annual evaluations of suppliers shall be performed or arranged for. Evaluations shall be documented. These evaluations shall assess:
- (a) Supplier-furnished documents and records
  - (b) Previous verification results
  - (c) Supplier's experience with identical or similar products provided to others
  - (d) Extrinsic verification results

APPENDIX A

QUALITY ASSURANCE PROGRAM DOCUMENTS LISTING

1. DOE ORDER 5700.6B, Quality Assurance, September 23, 1986 - Provides policy, sets forth principles and designates responsibility for the implementation of DOE plans and actions to assure quality achievement and verification. DOE Order 5700.6 endorses NQA-1 as the preferred standard for DOE nuclear programs. The OCRWM quality assurance program is consistent with DOE Order 5700.6 with specific variances as defined in the QAR.
2. DOE ORDER 4700.1, Project Management System - Establishes the Department of Energy project management system and provides implementing instructions, formats, and procedures, and sets forth the principles and requirements which govern the development, approval, and execution of DOE's outlay program acquisitions.
3. ANSI/ASME NQA-1-1986b, Quality Assurance Program Requirements For Nuclear Facilities - Contains basic and supplementary requirements and non-mandatory guidance for establishing QA programs for nuclear facilities.
4. DOE/RW-0005, Mission Plan for the Office of Civilian Radioactive Waste Management Program, June 1985 - Responds to the requirements of the Nuclear Waste Policy Act of 1982 by providing an overview of and correct plans for the PROGRAM and presents the detailed information required by section 301 (a) of the Act. Quality assurance for the PROGRAM is covered in Part 1, Section 5.6 of the Mission Plan. In addition, the following amendments to the Mission Plan are applicable:
  - DOE/RW-0128, OCRWM Mission Plan Amendment, June 1987 - Amends the Mission Plan to apprise the Congress of significant recent achievements in the PROGRAM, the revised schedule for the first repository, the intent to postpone site-specific work for the second repository and plans for continuing the technology-development program for the second repository, and the proposal for the construction of a monitored retrievable storage (MRS) facility as an integral part of the waste-management system.
  - DOE/RW-0187, Draft 1988 Mission Plan Amendment, June 1988 - Amends the Mission Plan to inform the Congress of DOE's plans for implementing the new focus for the PROGRAM provided by the Nuclear Waste Policy Amendments Act of 1987.
5. DOE/RW-0043, Program Management System Manual (PMS), January 1986 - Provides the Director, OCRWM, and his staff with a set of policies and procedures that are used in managing for quality and in integrating the various PROGRAM elements and projects into cohesive and cost effective program. The management system that is described in the PMS Manual, along with specific implementing plans or procedures, define the elements of the OCRWM approach to managing for quality.

6. DOE/RW-0051, Systems Engineering Management Plan (SEMP), October 1985 - Prescribes the Systems Engineering Procedures to be implemented by the PROGRAM and the minimum requirements for Systems Engineering at the Program Element (Repository, Transportation, and Monitored Retrievable Storage) levels.
7. DOE/RW-0068, Program Baseline Procedures Notebook (OGR/B-1), February 1988 - Provides a description of the baseline management concept, establishes the Repository Program Baseline itself, and provides procedures to be followed for controlling changes to that baseline.
8. DOE/RW-0090, Generic Requirements (GR) for a Mined Geologic Disposal System (OGR/B-2), March 1987 - Establishes the technical baseline of generic repository requirements that are controlled by OCRWM using baseline procedures and is based on statutory, regulatory, and other requirements.
9. DOE/RW-0101, Issues Hierarchy for a Mined Geologic Disposal System (OGR/B10), August 1987 - Presents the issues DOE will use to guide development of site characterization plans and conduct site characterization activities.
10. DOE/RW-0125, Waste Acceptance Preliminary Specifications for the West Valley Demonstration Project High-Level Waste Form (OGR/B-8), December 1986 - Specifies the properties and requirements for high-level waste forms at West Valley, N.Y.
11. DOE/RW-0136, Waste Acceptance Preliminary Specifications for the Defense Waste Processing Facility High-Level Waste Form (OGR/B-9), March 1987 - Specifies the properties and requirements for high-level waste forms to be produced by the Defense Waste Processing Facility at the Savannah River Plant, South Carolina.
12. DOE/RW-0142, Annotated Outline for Site Characterization Plans (OGR/B-5), August 1987 - Provides a standard format and guidance for the preparation of Site Characterization Plans (SCP).
13. DOE/RW-0147, Annotated Outline for the SCP Conceptual Design Report (OGR/B6), June 1987 - Provides a standard format and guidance for the preparation of the SCP Conceptual Design Report.
14. DOE/RW-0194, Records Management Policies and Requirements, July 1988 - Establishes policies and requirements and assigns responsibility for the identification, collection, organization, processing, and storage of records of the civilian radioactive waste management program in order to document and facilitate the review of program activities.
15. DOE/RW-0214, Quality Assurance Requirements for the Civilian Radioactive Waste Management Program - Defines the quality assurance requirements for the PROGRAM and establishes a basis for development of consistent quality assurance programs by OCRWM, the Project Office(s), and all other PROGRAM participants.

16. DOE/RW-0215, Quality Assurance Program Description for the Civilian Radioactive Waste Management Program, - Defines responsibilities and describes means of implementation of the quality assurance requirements for the PROGRAM.
17. Office of Storage and Transportation Systems Quality Assurance Plan for the Transportation Casks Systems Development Program, Revision 0 - Implements DOE/RW-0032, Quality Assurance Management Policies and Requirements and DOE/RW-0103, Quality Assurance Directive, promulgated requirements for the casks systems development program element, and provides supplementary QA guidance to the DOE Idaho Operations Office.
18. OGR/B-7, Systems Engineering Management Plan for the Office of Geologic Repositories, April 1986 - The purpose of the Systems Engineering Management Plan is to prescribe how Repository Systems Engineering will be implemented at the OCRM level and sets forth the minimum requirements for Repository Systems Engineering at the Project Office level.
19. OGR/B-12, Project Charter for the Nevada Nuclear Waste Storage Investigation Project, June 1987 - Delineates management responsibility, authority, and accountability for the Nevada Nuclear Waste Storage Investigations Project. The project charter establishes the operational management relationships between Headquarters Office of Civilian Radioactive Waste Management and the Nevada Operations Office.
20. OGR/B-14, Specification of QA Requirements for High-Level Waste Form Production, February 1988 - Identifies the basic and supplementary requirements for quality assurance programs applied to the waste acceptance process activities of high-level waste form production.
21. Appendix B, 10 CFR 50, Quality Assurance Criteria for Nuclear Power Plants - Establishes general QA criteria for safety-related structures, systems, and components of nuclear power plants and fuel reprocessing plants.
22. 10 CFR 60, Disposal of High Level Radioactive Wastes in Geologic Repositories - Establishes requirements for siting, designing, licensing, constructing, operating and closing geologic repositories for high-level waste. Subpart G specifies the general QA criteria of Appendix B, 10 CFR 50.
23. 10 CFR 71, Packaging and Transportation of Radioactive Material - Subpart H establishes quality assurance requirements for packaging and transportation of radioactive materials which are similar to the general QA criteria of Appendix B, 10 CFR 50.
24. 10 CFR 72, Licensing Requirements for the Storage of Spent Fuel in an Independent Spent Fuel Storage Installation (ISFSI) - Subpart G establishes QA requirements for siting, designing, licensing, constructing, operating, and decommissioning a fuel-storage facility and specifies the general QA criteria of Appendix B, 10 CFR 50.

25. NRC REVIEW PLAN, Quality Assurance Programs for Site Characterization of High Level Nuclear Waste Repositories, June 1984 - Defines the criteria and methods by which the DOE Quality Assurance Program for Site Characterization activities will be reviewed by the NRC staff during the prelicensing phase.
26. NUREG-0856, Final Technical Position on Documentation of Computer Codes for High-Level Waste Management, June 1983 - Describes the guidelines (identified by OCRWM as requirements for the PROGRAM) for documentation of the codes used by the applicant in performing the analyses submitted in support of a license application under 10 CFR 60.
27. NUREG-1318, Technical Position on Items and Activities in the High-Level Waste Geologic Repository Program Subject to Quality Assurance Requirements, April 1988 - Provides guidance (identified by OCRWM as requirements for the PROGRAM) on how to identify items and activities subject to quality assurance in the High-Level Nuclear Waste Repository Program for pre-closure and post-closure phases of the repository.
28. NUREG-1297, Peer Review for High-Level Waste Repositories Generic Technical Position, February 29, 1988 - Provides guidance (identified by OCRWM as requirements for the PROGRAM) on the definition of peer reviews, the areas where peer reviews are appropriate, the acceptability of peers, and the conduct and documentation of a peer review.
29. NUREG-1298, Qualification of Existing Data for High-Level Nuclear Waste Repositories Generic Technical Position, February 27, 1988 - Provides guidance (identified by OCRWM as requirements for the PROGRAM) on the use and qualification of data that has not be initially collected under a 10 CFR 60, Subpart G, QA Program.
30. REGULATORY GUIDE 7.10, Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material, January 1983 - Provides NRC guidance (identified by OCRWM as requirements for the PROGRAM) on the development of quality assurance programs for the packaging used to transport radioactive material.

## APPENDIX B

### RATIONALE ON THE APPLICABILITY OF NRC REQUIREMENTS TO SCIENTIFIC INVESTIGATIONS

#### I. APPLICABILITY OF THE REQUIREMENTS OF NRC CRITERION IX, "SPECIAL PROCESSES" TO SCIENTIFIC INVESTIGATIONS

##### PURPOSE

The term "special" processes historically has been applied to processes used to produce items that are physical structures. The quality of the results of such processes (for example, welding) may be uncertain and highly dependent on the mechanical or interpretive skills of the individual performing the work. For these reasons, additional controls were placed on the conduct of such work (for example, the requirements for the procedure to be used being subjected to added tests and the individual being tested to provide additional confidence in the skills of the worker). The predictable results of such "special" process controls provides adequate confidence and reasonable assurance that the process, when applied, will provide an end product meeting the original design intent.

In contrast, processes used in scientific investigations focus on the controlled collection, preparation, and analysis of data; the results of which are intended to meet the licensing requirements for a geologic repository as specified in 10 CFR 60. This paper discusses the nature of processes in scientific investigations and the distinction between traditional special processes. The controls used to assure the quality of the data gathered through the use of such processes are also described.

##### DISCUSSION

Scientific investigations involve a large number of different processes, both laboratory and field, directed to the collection and analysis of data. For the geologic repository, this data is derived principally from the natural environment in and around Yucca Mountain. This includes studies of the waste package environment. There are at least four parts to any scientific investigation; the collection of data, the preparation of data, its analysis, and its interpretation. All of these activities are controlled processes which receive appropriate reviews and approvals as required by the quality program. We focus in this report on the first three activities since these are the ones most likely to be interpreted as involving special processes.

The scientific studies for the geologic repository include a wide range of activities some of which are:

1. Cutting and retrieving core specimens from boreholes
2. Waxing core specimens
3. Identifying the minerals in a sample of tuff through x-ray diffraction analysis of a powdered specimen

4. Identifying minerals in a sample of tuff using thin section analysis
5. Preparing and analyzing geophysical logs from a borehole
6. Determining ground water level through monitored boreholes
7. Determining the chemistry of pore waters extracted from a core
8. The shaping of a piece of core for resistivity or induced polarization measurements

This is a typical list and is not all inclusive, however, these scientific investigations use various analytical instruments which measure some parameters. The main variable is the material. It is the variability in some parameter or subset of parameters that is the object of the analysis. Note that in the case of the geologic repository since most of this material is natural, we do not know in advance the parameters and their variability. The instruments used in analyses provide information (output) due to a specific response between some input of energy and the material being examined. The output is the results of a set of physical and chemical laws that govern the interaction between the input energy (for example, x-ray beam of some intensity) and the material (for example, a mineral).

Theoretical and empirical evidence of the adequacy of these analytical instruments (with their associated procedures) to produce the desired results are established in a number of ways, principally through appropriate calibration of the instrument and through correlation with existing scientific literature. Given that the analysis is performed correctly, we are confident that the results reflect the parameter we want to measure because there is a large body of literature which supports our reading of the output. Further, this body of published support was obtained through controlled laboratory processes using calibrated equipment and has broad acceptance throughout the scientific community. Fundamentally, it is the mass of technical literature describing known responses of material to known physical and chemical laws that gives us confidence in our results.

The criteria in 10 CFR 50, Appendix B represents an adequate set of controls for the instrumental analysis used in scientific investigations without the need to categorize such processes as special. Sections of the DOE/RW-0214, Quality Assurance Requirements (QAR) which are applicable to the topic of this report are:

Section 2: QA Program - Personnel selected shall have education and experience commensurate with the minimum requirements specified in the position description.

Section 3: Scientific Investigations and Design Control - Criteria for the planning, review/approval, and performance of scientific investigations are prescribed. Scientific notebooks or technical implementing procedures can be used for describing how the work is to be done and for documenting the activity. Surveillances of scientific investigations are conducted to ensure that procedures are followed and documented.

Section 4: Procurement Document Control - Technical requirements for equipment and services used in data collection, preparation and analysis are adequately documented.

Section 5: Instructions, Procedure, Plans and Drawings - Activities affecting quality shall be prescribed and performed in accordance with documented instructions, procedures, plans or drawings. A technical review of the documents used to implement the activities is required.

Section 6: Document Control - applicable current documents are available at the location where they are to be used.

Section 7: Control of Purchased Items and Services - Measures are established to ensure that purchased material, equipment, and services conform to the procurement documents.

Section 8: Identification, Control of Items, Samples, and Documents - Procedures shall be developed and implemented to ensure that samples are identified and controlled in a manner consistent with their intended use.

Section 12: Control of Measuring and Test Equipment - Measures shall be established to ensure that tools, gages, instruments, and other measuring and test equipment used in activities that affect quality are properly controlled, calibrated, and adjusted at specific periods to maintain accuracy within necessary limits.

Section 13: Handling, Shipping and Storage - Measures shall be established to control packaging, handling, storage, shipping, cleaning, and preservation of material and equipment to prevent damage, loss, or deterioration.

Section 15: Control of Nonconforming Items - Measures shall be established to control items that do not conform to requirements to prevent their inadvertent installation or use.

Section 16: Corrective Action - A corrective action system is defined to ensure that significant conditions adverse or potentially adverse to quality are identified promptly and corrected as soon as possible.

Section 17: QA Records - Records that furnish documenting evidence of quality shall be specified, prepared, and maintained in accordance with Administrative Procedures.

Section 18: Audits - All activities affecting quality will be subject to planned and scheduled internal and external audits to assure that procedures and activities comply with the overall QA Program and to determine their effectiveness. The audit program will be supplemented by independent surveillance activities.

It is important to recognize then that there are controlled processes governing the collection, preparation, and analysis of data in scientific investigations. The interest is not in the sample per se, but in physical or chemical parameters obtained from the sample. Data is gathered from a sample the precise parameters of which are not known in advance. If the processes controlling the collection, preparation and analysis of the material are adequate and documented as having been followed during the activity by qualified scientists or technicians (Sections 2, 3, and 5), reasonable assurance that the data accurately represents the correct values is obtained. To further ensure the quality of the work, instruments used in the data collection and analysis processes are calibrated (Section 12).

While it is true that standards are included in the analysis of materials (for example, standard tables for the identification of minerals from x-ray diffraction data), there are not standards for the sample itself. That is to say there may or may not be clay in the sample and one or more clay mineral species may be present. Similarly a technician may use standard solutions (National Bureau of Standards (NBS) Standards) to calibrate the recording instrument prior to a chemical analysis. This calibration indicates that the instrument is reading values within an acceptable range and sensitivity.

The preparation of many samples must meet certain standards, but these can be evaluated with objective tests the results of which are not solely dependent on the certification or qualification of the operator and the procedures. For example: thin sections must be cut to a thickness of 30 microns (evaluated by recognizing the appropriate birefringence "color" of the contained minerals in polarized light); core specimens in resistivity and induced polarization measurements must be shaped on a saw (shape is measurable); and waxed core wrapped at the drill site to preserve the contained volume of fluids (preservation determined by weighing the sample at the drill site and weighing it at the laboratory) illustrate this. In all of these examples the uncertainty about the quality of the data (that is, does the sample measure up to standards) is very low.

Although there are some parallels between control of processes and special processes, there are significant differences.

1. The examples cited in 10 CFR 50, Appendix B, and in NQA-1 of the application of special processes are focused on items that are to be a permanent part of a facility rather than the collection of data. Special processes as defined in Basic Requirement #9 are as follows: "Special processes that control or verify quality, such as those used in welding, heat treating, and nondestructive examination, shall be performed by qualified personnel using qualified procedures in accordance with specified requirements.

2. The quality of the resulting items is solely a function of the processes having been performed and tested by qualified personnel using qualified procedures. Since one cannot directly test for the quality of the item (for example, an item undergoing welding), its quality can only be assumed predicated on the confidence that the material will, when subjected to the same process variables as those used during process qualification, yield the same material or chemical properties. It is necessary to establish the qualifications of the operator through some established requirements (for example, a written certification test or a performance test).

The scientists and technicians performing scientific investigation are qualified on the basis of their academic record or work experience or both (Section 2) prior to their appointment. Procedures in scientific investigations receive a technical review for adequacy and completeness (Sections 2, 3, and 5). Quality is further ensured through calibration of the instruments used in data collection, preparation, and analysis (Section 12). Audits and surveillances are conducted to be sure that procedures are being followed and the work properly documented (Section 18).

3. The item to be incorporated as a permanent part of a facility must meet certain pre-established criteria, codes, or standards. In special processes both the materials being used and the controlling variables on the process being applied to the materials are known quantities and are included in the industry-wide standards or codes required for such activities.

The parameters for materials being studied in scientific investigations are not known in advance. The purpose of the investigation is to determine the characteristics of the material. Except for situations where the size, amount or shape (for example, a 4-inch piece of whole core) of a sample is specified (and these are all measurable features) the sample itself cannot meet some predetermined acceptance criteria.

The evaluation of processes in scientific investigations involves several steps. Initially the purpose of the process (which may consist of one or more technical procedures) must be detailed in the scientific investigation planning document (SIPD) and the adequacy of the process determined through technical review. Individual technical procedures also receive a technical review. If a proposed process is beyond the state of the art, a peer review is used. These review processes are mechanisms for qualifying processes. A review of a process must determine whether the process is adequate for the purpose of the SIPD. Adequate as used in scientific investigations means that the process addresses the issues detailed in the SIPD and that there is sufficient confidence that the results generated by the process can be used in licensing. As part of the review process, the reviewers must determine if the controls specified in the 18 criteria of 10 CFR 50, Appendix B are adequately built into the technical procedures to produce quality results (that is, results in which there is a high degree of confidence that they are acceptable for use in licensing). Calibration of measuring equipment, confirmatory or corroborative measurements by independent processes, and use of the 18 criteria exclusive of special processes appear to be sufficient to ensure quality results in scientific investigations.

### SUMMARY

Processes in scientific investigations are oriented toward the collection and the analysis of data, not toward preparing an item for use as part of a permanent structure. Pre-established acceptance criteria for samples or for the results of data collection and analysis does not normally exist in scientific investigations. The main variable is the sample or material. It is the variability in some parameter or subset of parameters that is the object of an instrumental or chemical analysis or both.

Process controls which have traditionally been used where the product of an activity could be sensitive to the mechanical abilities of the worker (as in welding) or to the interpretative abilities (as in nondestructive examination) will not provide added assurance that the results of a scientific investigation will be substantially more accurate. There are many scientific processes used where the results do not depend on the ability or understanding of the process by the technician or scientist at all (for example, automated ultraviolet spectroscopy).

The results of all scientific investigation processes including those used in the High-Level Waste Repository program depend on the technical abilities of the scientists and technicians to apply the laws of physics, chemistry, engineering, and other sciences. This is supported by a very large volume of scientific data already in existence and accepted by the scientific community and regulatory bodies. The imposition of special process controls will not provide increased assurance that the results of a scientific investigation is more correct or accurate than the results obtained through the use of current controls.

## II. APPLICABILITY OF THE REQUIREMENTS OF NRC CRITERION X, "INSPECTION" TO SCIENTIFIC INVESTIGATIONS

Scientific investigations are conducted to discover and interpret the nature and extent of natural phenomena. It is important to emphasize the words "discover" and "interpret" when describing the goals of scientific investigations. Discovery is the process of acquiring knowledge that was previously unknown. Interpretation, of course, is the "...act of explaining the meaning of". Scientific investigations are unique in the sense that such activities do not have established acceptance criteria which may be used to verify conformance.

Predetermined acceptance criteria is an essential element in the conduct of inspections. Traditionally, inspections are performed to verify conformance of an engineered item to predetermined acceptance criteria. This same approach is inappropriate for verification of scientific investigations because such activities rely on discovery and the interpretation of those natural and physical laws of science that aid in the explanation of the phenomena. It follows that the requirements of Criterion 10, "Inspection" are not appropriate for use where scientific investigations must be controlled. However, controls are necessary.

The QAR describes a set of quality assurance requirements for scientific investigations that when properly implemented provide a high degree of confidence that the results of such activities are accurate and complete. The approach given by the QAR assures the following:

- A thorough plan of the investigation is prepared and approved.
- A technical review of the plan is completed by the participant.
- Activities are controlled by such measures as technical procedures or scientific notebooks.
- Computer programs are verified and validated.
- Interfaces, both internal and external to the investigations, are identified and controlled.
- Surveillances, which include technical team members, are performed to verify compliance.
- A close out verification is performed by the participant to assure adequacy and completeness.

From the description of the controls given by the QAR it is clear that scientific investigations are activities, not items. It is also clear that such controls are intended to capture the essence of an activity whose purpose is to discover and interpret.

### III. APPLICABILITY OF THE REQUIREMENTS OF NRC CRITERION XI, "TEST CONTROL," TO SCIENTIFIC INVESTIGATIONS

The QAR indicates that test control (Criterion XI) of 10 CFR 50, Appendix B, applies to engineered items but does not apply to scientific investigations. This paper is intended to document the rationale and approach to satisfy the intent of Criteria XI.

For engineered items, the requirements of 10 CFR 50, Appendix B, will be met by implementation of ANSI/ASME NQA-1-1986b. These requirements are supplemented in the QAR, Section 11, "Test Control," by the incorporation of guidance provided in the NRC Review Plan for QA Programs for Site Characterization of High Level Nuclear Waste Repositories.

The controls applied to scientific investigations are identified in Section 3 of the QAR. The following comparison with the NRC Review Plan, Chapter 11.0, depicts how the requirements for the controls that are applicable to scientific investigations have been incorporated. Where appropriate, the requirements of ANSI/ASME NQA-1-1986b for control of tests have also been incorporated.

It is important to note that the QAR allows at least two basic kinds of documentation which can be used for quality assurance, documentation, and control of scientific work. These are the scientific notebook system and the technical implementing procedure system. The scientific notebook system will generally be used by qualified individuals who are using a high degree of professional judgement or trial and error methods or who are developing the methodology by which an activity will be accomplished. The technical implementing procedure system will generally be used when qualified technicians are performing repetitive work which does not include the use of a high degree of professional judgement or trial and error methods in the performance of the work. Detailed technical implementing procedures are required when it is not possible to deviate from a prescribed sequence of actions, without endangering the validity of the results that will be obtained from the work. Logbooks or appropriate forms or both are used, particularly in repetitive work, to document the performance of the work according to the technical implementing procedure, and to maintain absolute control over all other aspects of the work. The following indicates where the NRC Review Plan requirements are implemented for procedures and scientific notebooks.

#### NRC Review Plan Requirement 11.1

The description of the scope of the test control program indicates an effective test program has been established. Program procedures provide criteria for (a) determining when a test is required or how and when testing activities are performed, and (b) the test program is conducted by trained or appropriately qualified personnel. The QA organization, as a minimum, audits these functions.

#### Response

The work is controlled in Section 3 of the QAR by requiring the preparation of scientific investigation planning documents for individual activities.

It is not appropriate in most cases for individual procedures to address when a test or testing activities are performed. Scientific investigation activities cannot necessarily be scheduled as construction activities (for example, take one set of concrete cylinders for every 50 C.Y. concrete poured). Procedures do, however, clearly define the sequence of steps to be performed for proper implementation.

Training requirements are covered in Section 2 of the QAR. For both scientific notebooks and technical implementing procedures it is required that any special training or qualification requirements be clearly defined.

The QAR requires QA organization overview of activities affecting quality.

#### NRC Review Plan Requirement 11.2

"Test plans and procedures are reviewed in accordance with the verification requirements in Section 3."

**Response**

This requirement is stated in Section 3.6.1 of the QAR.

**NRC Review Plan Requirement 11.3**

"the potential sources of uncertainty and error in test plans and procedures, and parameters which must be controlled and measured to assure that tests are well-controlled, are identified."

**Response**

This requirement is stated in Section 3.6.2 of the QAR.

**NRC Review Plan Requirement 11.4**

"Test procedures or instructions provide the following:

- a. The requirement and acceptance limits contained in applicable documents, including precision and accuracy."

**Response**

This requirement is stated in Section 3.6.2 of the QAR. These requirements are not applicable to scientific notebooks since the end product of research or experiment is data which is used to establish acceptance limits.

- b. "Instruction for performing the test."

**Response**

This requirement is stated in Sections 3.6.2 and 3.6.3 of the QAR. This requirement is not applicable to scientific notebooks since the purpose of experiment or research is to establish methodology.

- c. "Test prerequisites such as calibrated instrumentation, adequate test equipment and instrumentation, completeness of item to be tested, suitable and controlled environmental conditions, and provisions for data collection and storage."

**Response**

This requirement is stated in Sections 3.6.2 and 3.6.3 of the QAR. Inspections are not applicable to scientific investigation. This requirement is not applicable to scientific notebooks since at that phase of research, the methodology of process is not established.

- e. "Acceptance and rejection criteria, including required levels of precision and accuracy."

This requirement is stated in Section 3.6.4 of the QAR.

f. "Methods of data analysis."

**Response**

For technical implementing procedure this requirement is stated in Section 3.6.3 of the QAR. This requirement is not applicable to scientific notebooks as data is the end product.

g. "Methods of documenting or recording test data and results."

**Response**

This requirement is stated in Section 3.6.5 of the QAR. It is not applicable to scientific notebooks as the activity methodology has not been established at this point. Therefore, the data or its format cannot be readily determined.

h. "Provisions for assuring test prerequisites have been met."

**Response**

This requirement is stated in Section 3.6.2 of the QAR.

**NRC Review Plan Requirement 11.5**

"Test results are documented, evaluated, and their acceptability determined by a responsible individual or group as described in Section 3."

**Response**

This requirement is stated in Sections 3.6.1, 3.6.4, and 3.6.5 of the QAR.

**IV. APPLICABILITY OF NRC CRITERION XIV, "INSPECTION, TEST, AND OPERATING STATUS" TO SCIENTIFIC INVESTIGATIONS**

The QAR indicates that inspection, test, and operating status (Criterion XIV) of 10 CFR 50, Appendix B applies to engineered items and does not apply to scientific investigations. The rationale for this exception is provided as follows.

The rationale for the exceptions taken in the QAR for the inspection and test aspects of Criterion 14 (Criteria X and XI) are described in Sections II and III.

The operating status aspect of this criterion is not applicable to scientific investigations because the scientific investigations are not performed on operating equipment or systems that will affect their safe operation. This is the intent of Criterion XIV.

The controls placed on scientific investigations by Section 3.6 of the QAR require scientific investigations to be planned. The planning requirements of Section 2.3 of the QAR provide for sufficient controls to preclude inadvertent interruption of the investigations and to ensure operational compatibility with other site characterization activities.

In summary, since Criteria 14 focuses on the safe operation of equipment and systems (engineered items) being tested and inspected and scientific investigations are prior to repository construction and operation, an exception has been taken in the QAR such that Criterion 14 applies only to engineered items and not to scientific investigations. The controls established in the QAR for scientific investigations are sufficient to assure the proper conduct of scientific investigations and their impact on site characterization activities.

*Office of Civilian Radioactive Waste Management*

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***Quality Assurance Program***  
***Description Document***

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

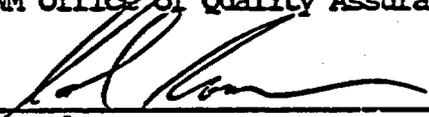
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U.S. DEPARTMENT OF ENERGY  
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

QUALITY ASSURANCE PROGRAM DESCRIPTION  
FOR THE  
CIVILIAN RADIOACTIVE WASTE MANAGEMENT PROGRAM

  
\_\_\_\_\_  
Lake Barrett, Director  
OCRWM Office of Quality Assurance

12/16/88  
Date

  
\_\_\_\_\_  
Approved  
Samuel Rouso, Acting Director  
Office of Civilian Radioactive  
Waste Management

12/20/88  
Date

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.

  
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Samuel Rousso, Acting Director  
Office of Civilian Radioactive  
Waste Management

12/20/88  
Date

## 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-0214, 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.

## 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 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-0214, Quality Assurance Requirements for the Civilian Radioactive Waste Management Program (QAR)
- (d) Approve DOE/RW-0215, 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 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, 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
- (c) Ensure that OFSD personnel who perform activities affecting quality are qualified by experience or training to perform assigned tasks
- (d) Evaluate results of activities that verify quality achievement within the scope of work assigned to OFSD

- (e) Assign responsibility for the quality of delegated work prior to initiating the work activities
- (f) Ensure the technical adequacy of items and activities for which OFSD has lead responsibility and the implementation of effective management controls
- (g) 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
- (h) 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
- (i) Ensure that adequate funds and resources are provided for OFSD 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 problems and issues in OFSD's area of responsibility
- (k) 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
- (l) 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.
- (c) Ensure that OSIR personnel who perform activities affecting quality are qualified by training or experience to perform assigned tasks
- (d) Evaluate results of activities that verify quality achievement within the scope of work assigned to OSIR
- (e) Assign responsibility for the quality of delegated work prior to initiation of work activities
- (f) Ensure the technical adequacy of items and activities for which OSIR has lead responsibility and the implementation of effective management controls
- (g) 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
- (h) 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
- (i) Ensure that adequate funds and resources are provided for OSIR 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 problems and issues in OSIR's area of responsibility

- (k) 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
- (l) 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

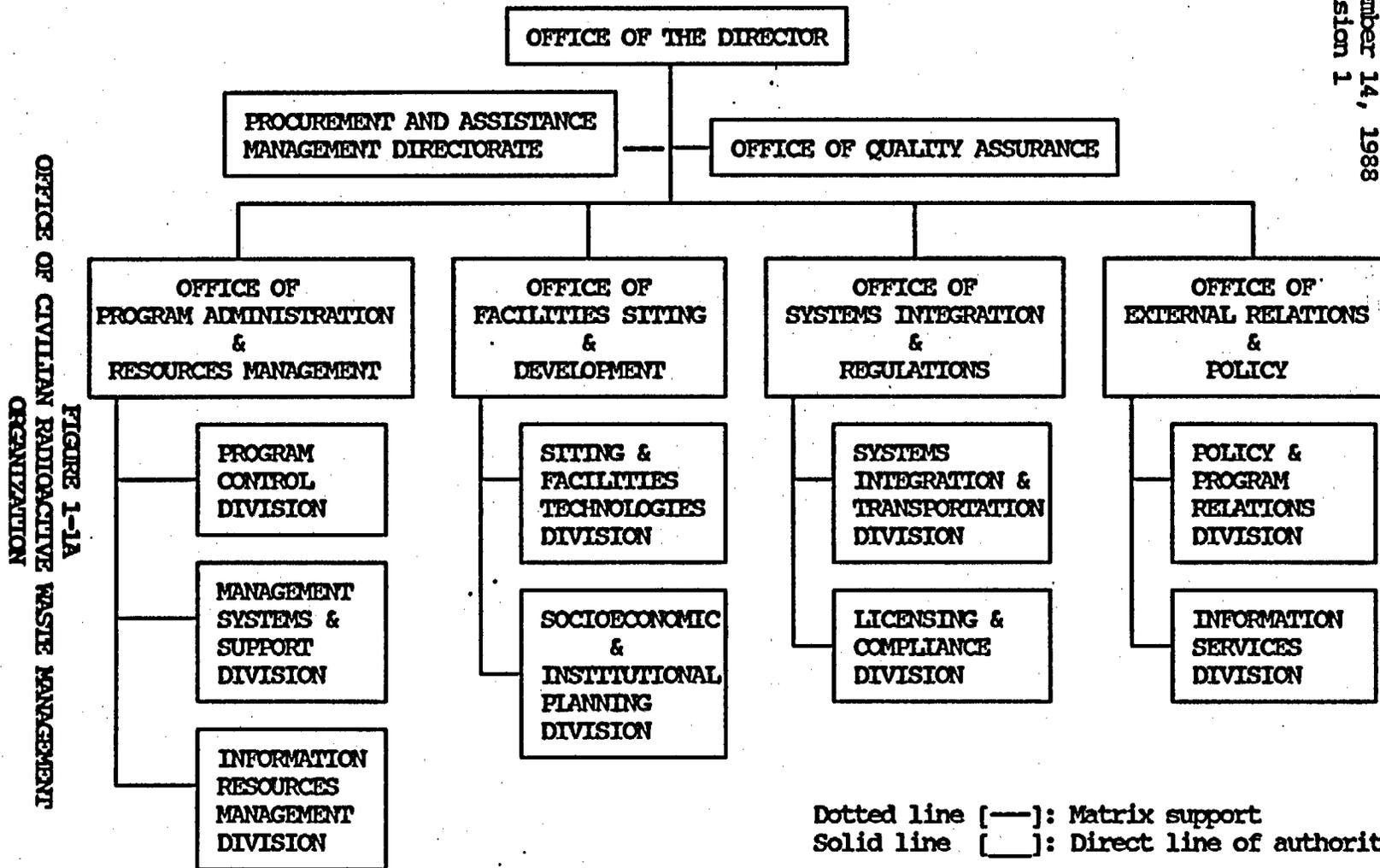
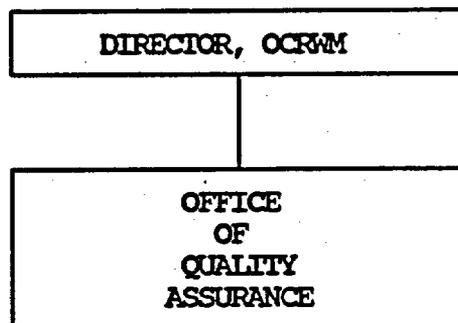
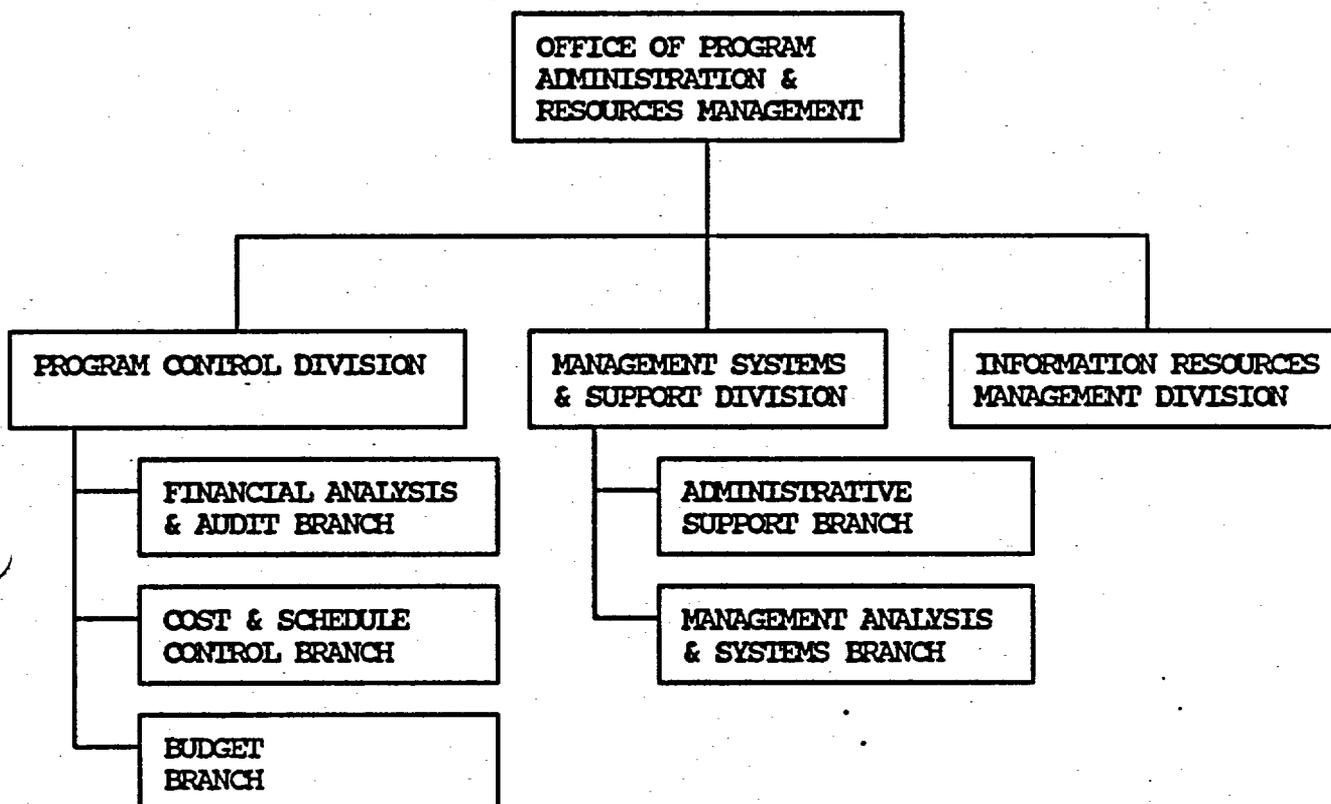


FIGURE 1-1A  
 OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT ORGANIZATION

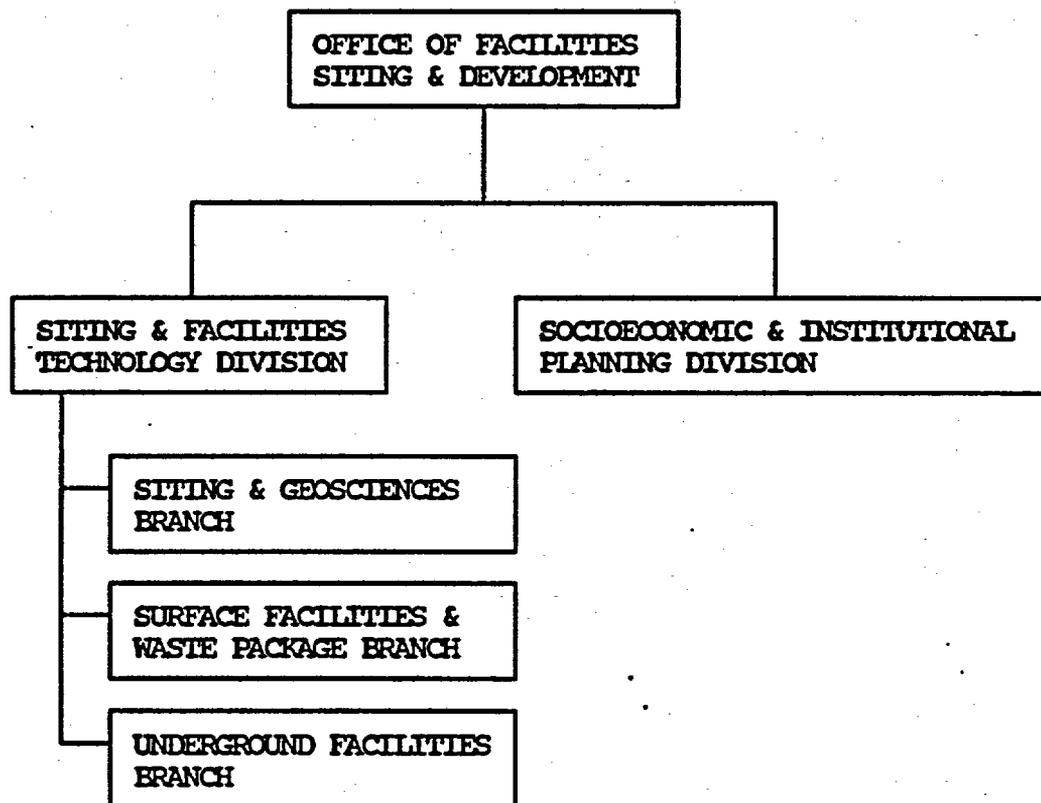
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Revision 1



**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**

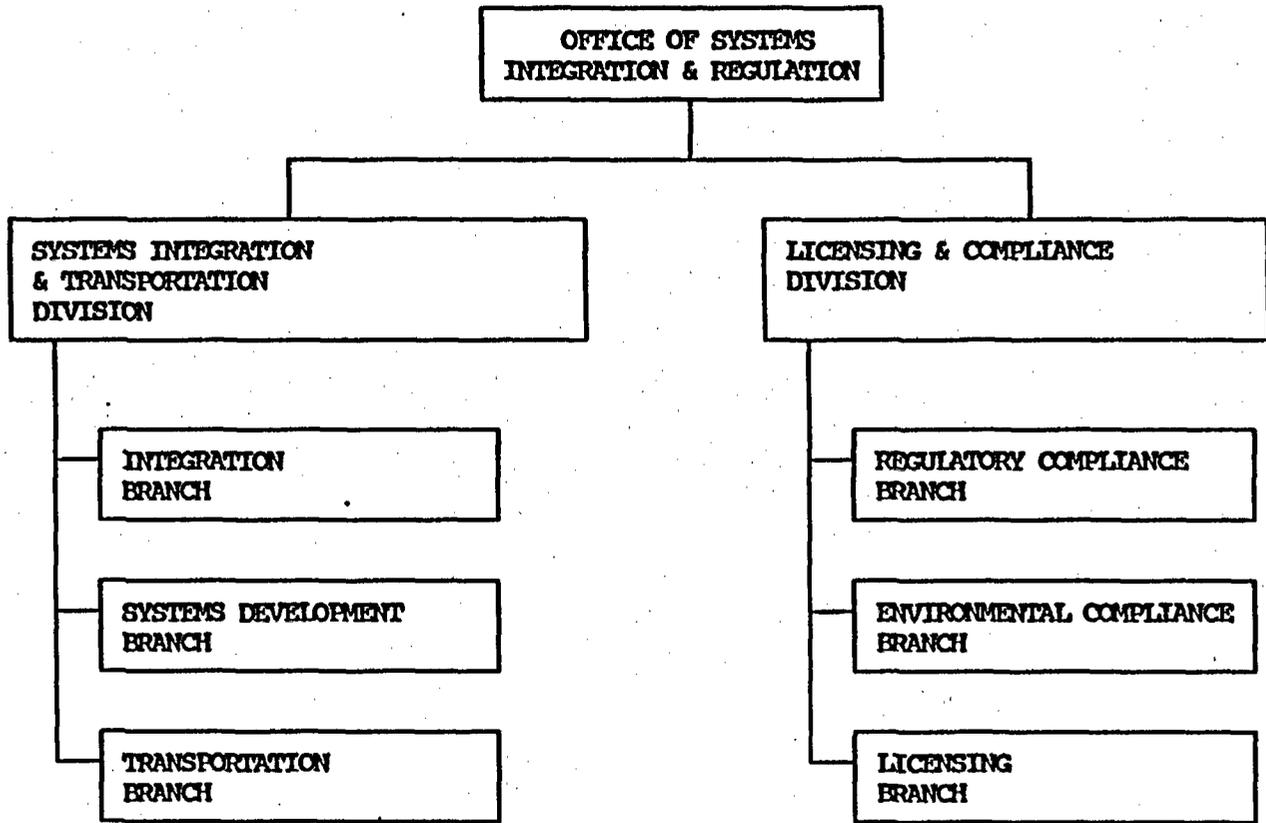
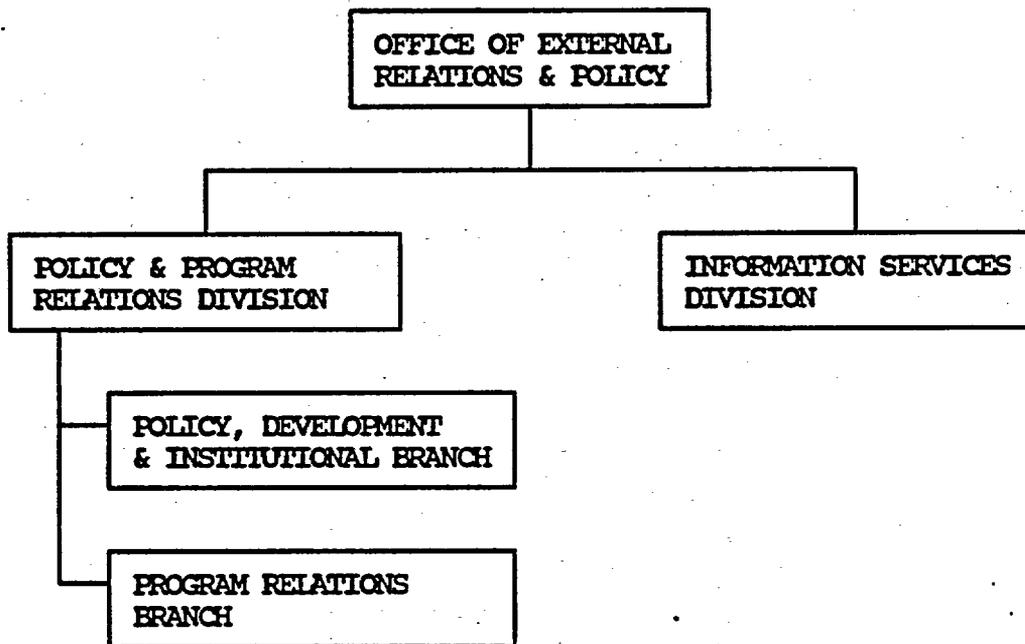


FIGURE 1-1E  
OFFICE OF SYSTEMS INTEGRATION AND REGULATIONS  
ORGANIZATION



**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 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. 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 (EMI)

EMI 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).

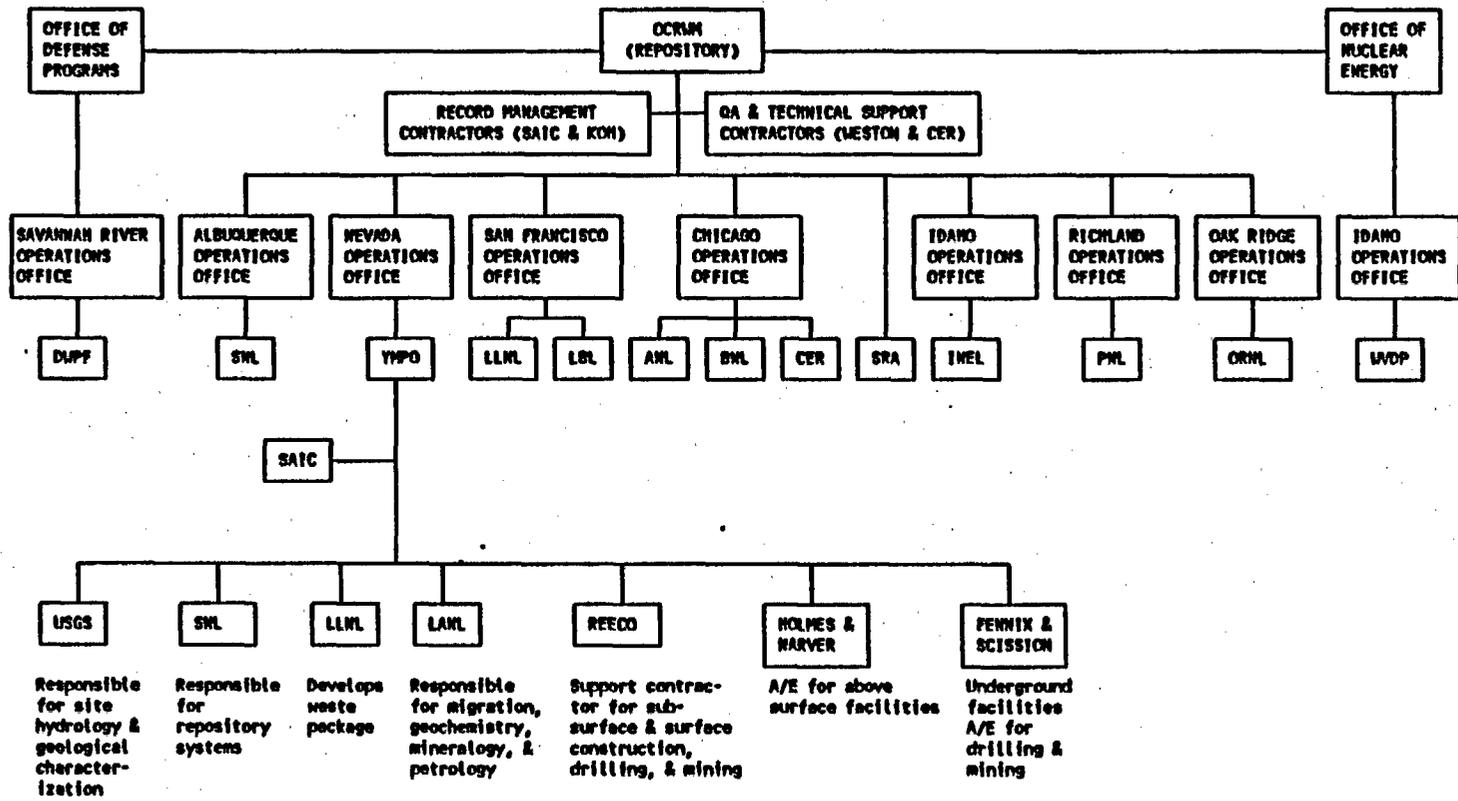
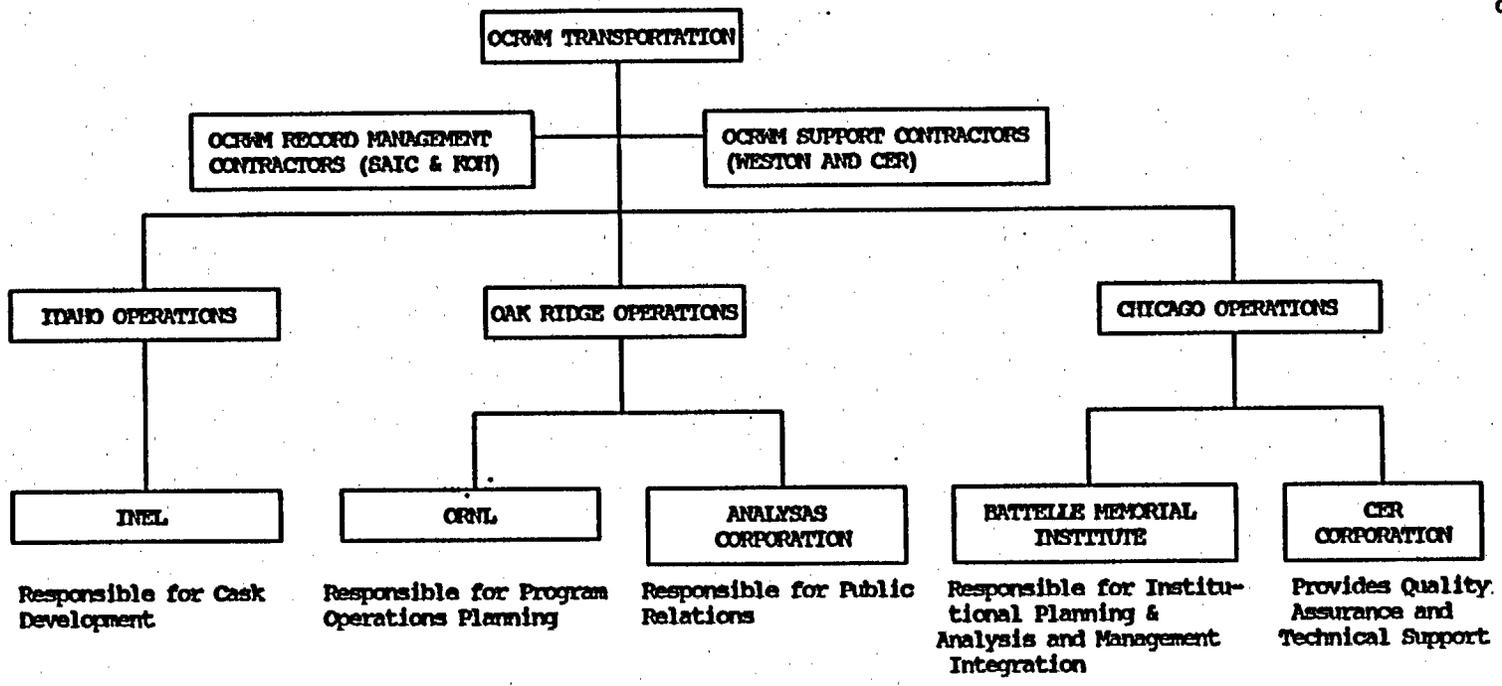


FIGURE 1-2A  
 ORNL GEOLOGIC REPOSITORY PROGRAM PARTICIPANTS



OCFWM TRANSPORTATION PROGRAM PARTICIPANTS  
FIGURE 1-2B

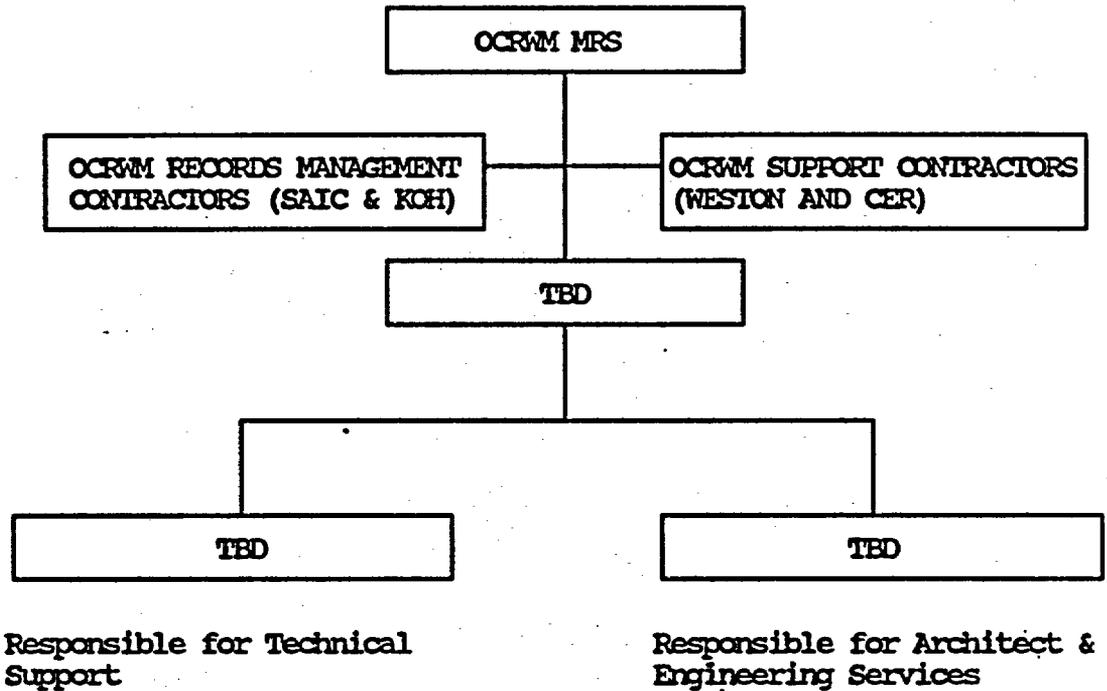


FIGURE 1-2C  
OCRWM MRS PROGRAM PARTICIPANTS

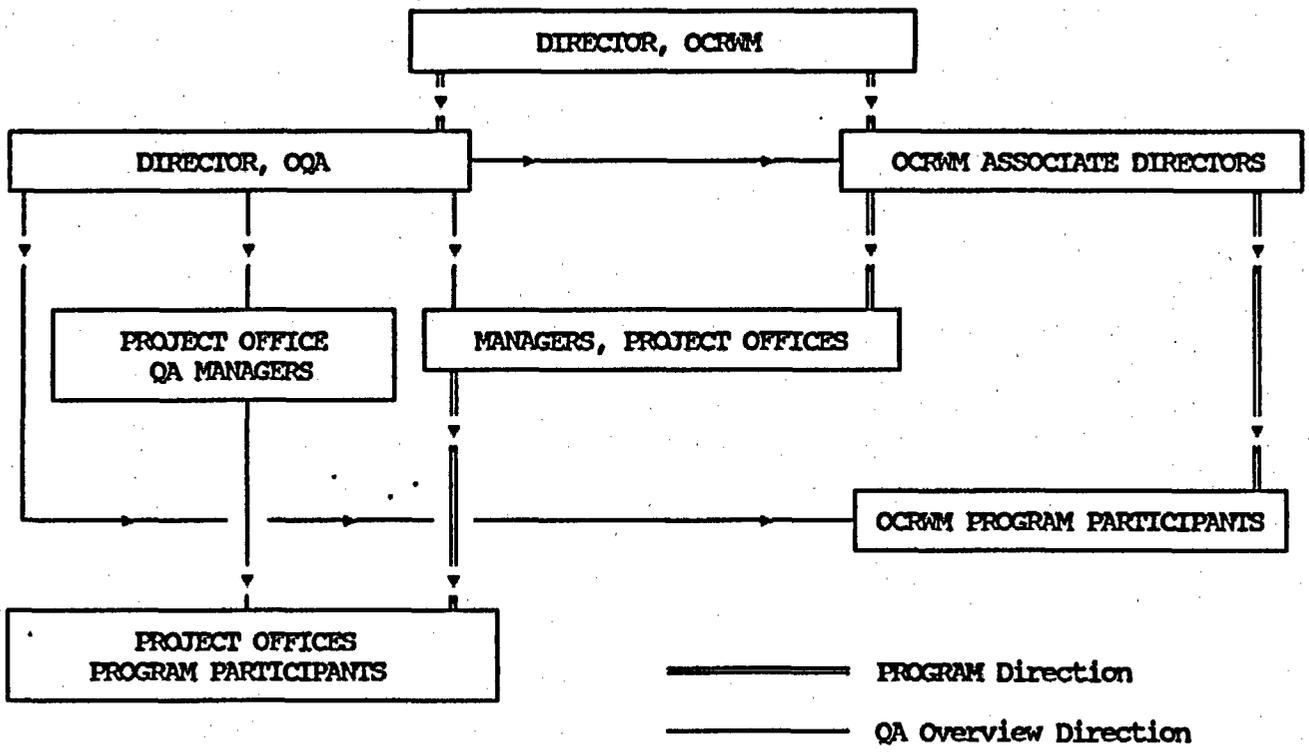


FIGURE 1-3  
CRM PROGRAM DIRECTION AND QUALITY VERIFICATION

#### 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.

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               |

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December 14, 1988  
Revision 1

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-0214, 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 Description

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.

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

OCFWM 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 Management Assessments

Associate Directors, Division Directors, and other line managers will periodically assess the effectiveness of those portions of the quality assurance program for which they are responsible. 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 OCRM'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

<u>QAAP No.</u>	<u>Title</u>
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.....	D	X
9	Control of Processes.....	D	X
10	Inspection.....	D	X
11	Test Control.....	D	X
12	Control of Measuring and Test Equipment	D	X
13	Handling, Storage, Transport, & Shipping	D	X
14	Inspection, Test, and Operating Status	D	X
15	Control of Nonconforming Items.....	D	X
16	Corrective Action.....	X	X
17	Quality Assurance Records.....	X	X
18	Audits.....	X	X

X - Means "Applicable commensurate with the Scope of Work"  
 D - Indicates that OCRWM delegates the work of establishing and implementing these criteria to Project Offices 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, controlling revisions to the technical baseline, and periodically reviewing the design development.

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

Systems engineering 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 SEMP 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 OCFWM- 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 OCFWM- 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

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 SEMP's. 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

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## 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. OCRM 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/FW-0068, Program Baseline Procedures Notebook (OGR/B-1) and DOE/FW-0083, Program Change Control Procedure. These controlled documents will be listed in the

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"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

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 OCFWM 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

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#### 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 :

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

#### 7.2 OTHER PROGRAM PARTICIPANES

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 OCRM IDENTIFICATION AND CONTROL

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

OCRM 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 OCRM 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. OCRM 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 OCFWM CONTROL OF MEASURING AND TEST EQUIPMENT

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

OCFWM 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 OCFWM 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. OCFWM 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 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

Conditions adverse to quality cited within OCRWM will be reported to the cognizant Associate Directors and the Director, OQA by using a 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 PARTICIPANES

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 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 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 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 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 (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 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

#### 18.1.4 Applicable Quality Assurance Administrative Procedures

The planned OCRM quality assurance administrative procedures applicable to OCRM'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. OCRM and the Project Offices will monitor audit control measures of the PROGRAM participants through the use of assessments, audits, and surveillances.

**QUALITY ASSURANCE PROGRAM DESCRIPTION DOCUMENT**

The following number is for OCRWM records management purposes only and should not be used when ordering this publication.

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