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OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

QUALITY ASSURANCE REQUIREMENTS DOCUMENT

FOR THE

CIVILIAN RADIOACTIVE WASTE MANAGEMENT PROGRAM

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Date

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FOREWORD

In February of 1990 the Office of Civilian Radioactive Waste Management (OCRWM) consolidated the Quality Assurance Programs of OCRWM and the Yucca Mountain Project Office. The primary purpose in doing so is to provide an effective QA program with requirements for all program participants and provide amplified program-element requirements. The results are included in this revision of the OCRWM QA program. As a result of this consolidation effort, the Yucca Mountain Project Quality Assurance Plan (88-9, Rev. 4) has been superseded.

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 minimum management controls needed to achieve PROGRAM objectives are to be established and effectively implemented by all affected organizations . These organizations include the Office of Civilian Radioactive Waste Management (OCRWM), The Office of Environmental Restoration and Waste Management (EM), Operations Offices, Project Offices, contractors, subcontractors, national laboratories, and other government agencies or PROGRAM participants performing activities affecting quality for the PROGRAM.

PURPOSE AND APPLICABILITY

This document defines the quality assurance requirements governing activities affecting quality of all affected organizations unless specifically stated otherwise herein. These quality assurance requirements are applicable to the Mined Geologic Disposal System (MGDS), Waste Acceptance Process Activities of High-Level Waste Form Production, Transport of Spent Fuel and High-Level Nuclear Waste, and Monitored Retrievable Storage.

The amplifications identified in Sections 1 through 19 of this document are in addition to ANSI/ASME NQA-1-1989 (NQA-1) requirements and apply to all PROGRAM elements. The previously committed to 1986 revision to ANSI/ASME NQA-1 was reviewed against the 1989 revision and it was found there was no relaxation of requirements.

Specific amplifications of OCRWM's quality assurance program applicable to the following programs, Mined Geologic Disposal System, Waste Acceptance Process Activities of High-Level Waste Form Production, Transport of Spent Fuel and High-Level Waste, and Monitored Retrievable Storage are identified in the appendices to this document.

Affected organizations develop quality assurance program descriptions and lower-tier documents to implement the requirements of the QARD.

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 identified herein need be referenced for OCRWM's quality assurance program requirements. However, this document has not incorporated the detailed 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.

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. 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 reviews. 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 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.

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LIST OF ABBREVIATIONS AND ACRONYMS

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
CFR:	Code of Federal Regulations
DOE:	United States Department of Energy
DWPF:	Defense Waste Processing Facility
HLWF:	High-Level Waste Forms
MGDS:	Mined Geologic Disposal System
MRS:	Monitored Retrievable Storage
NQA-1:	ANSI/ASME Standard NQA-1-1989 - Quality Assurance Program Requirements for Nuclear Facilities
NCR:	Nonconformance Report
NRC:	United States Nuclear Regulatory Commission
NUREG:	Nuclear Regulation
NWPA:	Nuclear Waste Policy Act
OCRWM:	DOE, Office of Civilian Radioactive Waste Management
Q-List:	Quality List
QA:	Quality Assurance
QAL:	Quality Activities List
QAPD:	DOE/RW-0215, Quality Assurance Program Description
QARD:	DOE/RW-0214, Quality Assurance Requirements Document
SEMP:	Systems Engineering Management Plan
SIPD:	Scientific Investigation Planning Document
WAC:	Waste Acceptance Committee
WAS:	Waste Acceptance Specification
WBS:	Work Breakdown Structure
WCP:	Waste-Form Compliance Plan
WQR:	Waste-Form Qualification Report
YMP:	Yucca Mountain Project

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 extent of QA controls applied to items and activities is determined by the line organization staff in combination with the QA organization staff. The quality assurance organization is responsible for the following:

- Describing, integrating, and monitoring agreed-upon quality assurance activities within the scope of the quality assurance program.
- Ensuring the quality assurance program is described in a quality assurance program description document.
- Ensuring the correct application of appropriate quality assurance requirements by line management through review and concurrence of the quality assurance program detailed technical and quality assurance administrative procedures.
- Monitoring the quality assurance program through overview activities that, as a minimum, include surveillances, audits, and reviews.

Each affected organization shall identify the quality assurance management position within its 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 line 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 organizations' and subtier organizations' quality assurance programs.

d. No other duties or responsibilities unrelated to quality assurance that could prevent full attention to quality assurance program 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 OCRWM or another program participant delegates work to other program participants, a qualified individual or organization from within the delegating office shall be designated as accountable 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 any given organizational level. These provisions shall include progressively elevating the dispute to the appropriate level of management, and the Program Director, if necessary.

1.4 RESOLUTION OF ALLEGATIONS

OCRWM will develop a system under which affected organizations, including OCRWM, may report allegations of inadequate quality.

1.5 STOP WORK PROVISIONS

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

a. Criteria and methodology for stopping work and for lifting stop work orders/requests.

b. Exact definition of work being stopped.

c. Authorities and responsibilities.

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; Appendices 2A-1 and 2A-3 shall apply with the following clarifications and amplifications.

2.1 QUALITY ASSURANCE PROGRAM

Affected organizations shall develop quality assurance program documents that address quality assurance program requirements applicable to their respective program scope of work. Quality assurance program documents shall consist of a Quality Assurance Program Description and detailed technical and quality assurance administrative procedures. The quality assurance program shall meet the requirements established by this document. The quality assurance program descriptions shall be reviewed and accepted in a timely manner by the Line Organization management of the next higher organizational level. Affected organizations quality assurance organizations shall review and make recommendations to line management concerning the acceptance of lower-tier quality assurance program descriptions.

Each participant has the responsibility to define the specific applicability of these quality assurance program requirements to their subtier program participants.

2.2 REPORTING INDEPENDENCE OF PERSONNEL

Verification personnel including those who are not part of the formal quality assurance organization, 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 has occurred to resolve a nonconformance, deficiency, or unsatisfactory condition. 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 by surveillance, audit, and review.

2.3 PLANNING

Affected organizations' participants' 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. Selective application of appropriate quality assurance program requirements and procedural controls (that is, a graded approach) to items and activities.

c. Assignment of responsibilities for quality assurance program control and verification activities.

d. Identification of the specific scientific or technical information to be collected, analyzed, or used.

e. Identification of applicable technical and quality assurance program management control and verification activities.

f. 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 quality affecting activities that are critical or complex in nature. Readiness reviews shall provide visible evidence of the following characteristics:

a. Work activity prerequisites have been satisfied.

b. Detailed technical and quality assurance program administrative procedures have been reviewed for adequacy and appropriateness.

c. Personnel have been suitably trained and qualified.

2.5 GRADED QUALITY ASSURANCE PROGRAM

2.5.1 Method

A methodology shall be developed to identify those items and activities to which the quality assurance program applies.

2.5.2 Application of Requirements and Controls

Quality assurance program requirements and procedural controls shall be selectively applied. The selective application and the degree of application of the quality assurance program 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 on schedule or cost to replace in the event of failure.

k. Necessity of special controls or processes.

l. Significance to licensing process.

2.6 POLICY STATEMENT

A policy statement signed by senior management official shall render the implementation of the QA program mandatory.

2.7 QA REQUIREMENTS MATRIX

Provisions shall be established that demonstrate through a matrix system that each of the applicable requirements of this document is properly documented and covered by the QAPD, implementing procedures and instructions.

2.8 PERSONNEL SELECTION, INDOCTRINATION, TRAINING, AND QUALIFICATION

A systematic approach to the determination of applicable indoctrination and training for personnel performing activities affecting quality shall be established.

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

Management of each affected organization shall evaluate each job position to determine the quality-affecting task responsibilities of the position. Organizations shall establish position descriptions (in accordance with applicable laws and regulations) which set forth job duties that include the quality-affecting responsibilities of the job. Minimum education and experience requirements for each position shall be established as a recognized standard for the position.

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. Documentation for affected organization training and qualification programs shall include the objective, content of the program, attendees, and date of attendance.

The suitable proficiency of personnel performing activities that affect quality is maintained through indoctrination and training. Indoctrination and training is verified through the audit, surveillance and trend program.

Supervisors shall evaluate and assess the need for additional indoctrination and training, as applicable; as assignments, positions, and procedures change.

2.9 SURVEILLANCE

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

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

b. Surveillance shall be conducted to accomplish the following objectives:

   1. Verify quality of work in progress.

   2. Identify and document actual and potential deficiencies and deviations and promote prompt corrective action by cognizant management responsible for performing the work.

3. Verify timely implementation of corrective action.

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

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

1. Date of surveillance.

2. Description of the activity or item under surveillance.

3. Persons conducting the surveillance.

4. Persons contacted during the surveillance.

5. The requirements governing the activity or item.

6. Deficiencies identified during the surveillance.

7. Measuring and test equipment used during the surveillance.

8. Summary of any immediate corrective actions taken.

2.10 MANAGEMENT ASSESSMENT

Independent management assessments by persons above or outside the quality assurance organization shall be planned, conducted and documented at least annually by, or at the direction of, the highest line management position identified in each affected organization. These management assessments shall evaluate, as a minimum, the following program aspects:

a. Adequacy of organizational structure and staffing to implement the quality assurance program.

b. Effectiveness of quality assurance program implementation.

c. Adequacy of the indoctrination and training program.

d. Adequacy of planning and procedural controls.

e. Effectiveness of the nonconformance and corrective action system.

f. Adequacy of the quality assurance management information tracking, evaluation, and reporting system.

2.11 QUALITY ASSURANCE PROGRAM MANAGEMENT-INFORMATION REPORTING AND TRACKING

a. Affected organizations shall report, disseminate, and track the following types of quality-related management information as a minimum:

1. Status of development of the quality assurance program.

2. Status of resolution of significant conditions adverse to quality, QA issues, and trends.

3. Summary of required management and QA overview results.

b. Quality assurance program management information shall be reported at least quarterly to the appropriate level of management and the next higher affected organizational level.

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 clarifications and amplifications shall apply to design and design activities.

3.1 DESIGN DEFICIENCY CONTROL

Deficiencies in approved design and design information documents shall be documented, and corrective action shall be taken in accordance with Section 16.

3.2 DESIGN CHANGES

The impact of design changes on procedures and training shall be evaluated.

3.3 DESIGN VERIFICATION

Procedures for design verification shall require the identification of the reviewers, the area or features reviewed, and the resolution methods for resolving comments.

Design verification procedures assure the following:

a. Criteria for determining the method of verification are established.

b. Responsibilities of the persons performing the verification or validation are defined.

c. Areas or features to be verified are specified.

d. Extent of documentation is defined.

3.4 TECHNICAL REVIEWS

a. Technical reviews 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.

b. Technical reviews shall be used when documents, activities, material, or data require technical evaluation for applicability, correctness, adequacy, completeness, and assurance that established requirements are satisfied.

c. Technical reviews shall be performed by individuals with sufficient technical knowledge of the area under review.

d. Results shall be documented.

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 affected organization's technical and quality assurance organization representatives to assure that applicable technical and quality assurance program requirements are included.

4.2 APPLICABILITY OF PURCHASER'S QUALITY ASSURANCE 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 developing and maintaining a quality assurance program at the supplier's 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, PLANS, 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, plans, 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.

5.2 QUALITY ASSURANCE RECORDS

Controlled documents shall delineate those documents generated as a result of implementation which are to be designated as quality assurance records.

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 SYSTEM

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

a. Resolution of review comments for which the resolutions are considered mandatory by the reviewing organization prior to approval and issuance of the document

b. Documentation and maintenance of review comments and resolutions.

c. Development of a controlled documents list.

d. The establishment of a receipt acknowledgment system.

e. The development of an obsolete or superseded document control system.

6.2 CONTROLLED DOCUMENTS

When controlled documents which require verification or approval are released prior to verification, or approval, they shall be so identified, controlled, and authorized for release through signature approval, with the bases for release described and the unverified portions identified.

6.3 QUALITY ASSURANCE ORGANIZATION REVIEW

The quality assurance organization shall review, and where applicable concur with controlled documents that contain or implement quality assurance requirements.

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 amplifications. In addition, for receiving inspection (7S-1 Section 8.2.3), NQA-1 Supplement 10S-1 Sections 4, 6.1 through 6.4, and 8 shall apply with the provision that the term final inspection shall be interpreted to be receipt inspection.

7.1 SUPPLIER QUALITY ASSURANCE PROGRAMS

Supplier Quality Assurance programs shall be reviewed and accepted prior to initiation of activities affecting quality. For procurements subject to the Federal Acquisition Regulations (FAR) and Department of Energy Acquisition Regulations (DEAR), the contract documents are prepared and contracts placed by the cognizant government procurement organization. Supplier's quality assurance programs are evaluated either before or after contract placement and any quality deficiencies are corrected prior to initiating quality-affecting work. Timing of the evaluation is in accordance with DOE procurement regulations and since it is required that supplier QA programs be reviewed and accepted prior to initiating activities, this serves as an acceptable alternative to the NQA-1 requirement that suppliers must be evaluated prior to contract award.

7.2 RECEIPT INSPECTION PLANNING

Receipt inspection activities to verify that items conform to specified requirements shall be planned, executed, and documented via inspection procedures, instructions, or checklists.

7.3 RECEIPT INSPECTION RECORDS

As a minimum, receipt inspection records shall identify the following:

- Characteristics receipt inspected and the objective evidence of the results of the receipt inspection operation.
- Receipt inspection criteria including identification of applicable drawings, specifications, procedures, etc. (and applicable revision).
- Identification of material and test equipment used during the receipt.

SECTION 8

IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS

8.0 GENERAL

The provisions of NQA-1 Basic Requirement 8 and Supplement 8S-1 shall apply.

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 LIST OF SPECIAL PROCESSES

Affected organizations' QA program documents shall provide a list of special processes that the program participant will perform or be responsible for. Criteria shall be established and documented for determining which processes are to be controlled as special processes.

9.2 QUALITY ASSURANCE ORGANIZATION INVOLVEMENT IN QUALIFICATION ACTIVITIES FOR SPECIAL PROCESSES

As a minimum, the quality assurance organization shall monitor the development and implementation of special process qualification activities through the conduct of audits and surveillances.

9.3 EVIDENCE OF ACCOMPLISHMENT OF SPECIAL PROCESSES

Provisions for recording evidence of acceptable accomplishment of special processes shall be established.

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 INSPECTION PLANNING

Inspection planning shall provide:

a. Criteria for determining when inspections of each work operation are to be conducted.

b. Identification of required procedures, drawings, and specifications including revisions.

c. Specification of necessary measuring and test equipment, including accuracy requirements.

10.2 RECORDS

Inspection records shall include:

a. Characteristics inspected and objective evidence of the results.

b. Identification of the inspection criteria or reference documents used to determine acceptance.

c. Identification of the measuring and test equipment used during the inspection.

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 UNCERTAINTY AND ERROR

Potential sources of uncertainty and error shall be identified in test plans and procedures. In addition, parameters affected by potential sources of uncertainty and error shall be identified and controlled.

11.2 TEST PLANNING

Test planning shall provide instructions for the following:

- When a test is to be performed.
- Mandatory hold points as required.
- Delineate precision and accuracy considerations for measuring and test equipment.

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 amplifications.

12.1 CALIBRATION STANDARDS

Calibration standards should have greater accuracy than equipment or standards being calibrated. Calibration standards with the same accuracy may be used if they can be shown to be adequate for the requirements and the basis for acceptance is documented and authorized by responsible management. The management authorized to perform this function shall be identified.

SECTION 13

HANDLING, STORAGE, AND SHIPPING

13.0 GENERAL

The provisions of NQA-1 Basic Requirement 13 and Supplement 13S-1 shall apply.

SECTION 14

INSPECTION, TEST, AND OPERATING STATUS

14.0 GENERAL

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

14.1 SEQUENCE OF OPERATIONS

Procedures are established and described to control altering the sequence of required tests, inspections, and other operations important to safety. Such actions shall be subject to the same controls as the original review and approval.

SECTION 15

CONTROL OF NONCONFORMING ITEMS

15.0 GENERAL

The provisions of NQA-1 Basic Requirement 15 and Supplement 15S-1 shall apply with the following amplification.

15.1 CLOSURE

The action taken to correct the nonconforming item shall be verified and the verification documented.

15.2 NONCONFORMANCE DISPOSITION

The person or organization assigned the responsibility of dispositioning the nonconformance shall ensure the following:

- Nonconformance documentation adequately identifies and describes the nonconformance.
- If a change to reflect the as-built condition is appropriate, then the disposition addresses action to change the existing design documents, test plans or procedures, reports, etc. Any document change shall reference the NCR and also be cross-referenced on the nonconformance report.
- The signature of personnel or organizations authorized to approve the disposition is documented.

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 other deficiency documents, shall be analyzed to identify adverse quality trends and help identify root causes. Trend analysis shall be performed in a manner and at a frequency that shall provide for prompt identification of adverse quality trends. Quality trends shall be evaluated and the significant results reported to the organization responsible for corrective action and upper-management for review and assessment. Trend analysis shall be performed by the quality assurance organization.

16.2 CORRECTIVE ACTION FOR SIGNIFICANT CONDITIONS ADVERSE TO QUALITY

Criteria for determining the existence of significant conditions adverse to quality shall be developed. Quality assurance organizational concurrence with proposed corrective action and quality assurance organizational verification of corrective action implementation within prescribed time limits are required.

16.3 DEFICIENCIES

A tracking system for all deficiencies shall be established to assure that they are appropriately addressed, prioritized, and trended.

16.4 REMEDIAL ACTION

Remedial action shall be documented and initiated after a deficiency has been identified. The QA organization shall concur with the remedial action to assure that QA requirements are satisfied. Follow-up action shall be taken by the QA organization to verify proper implementation of remedial action and to close out the remedial action in a timely manner.

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 amplifications.

17.1 QA RECORDS

Documents that are to become QA Records are considered QA Records upon completion and authentication by all required signatures. A complete QA record is a document that will receive no more entries and whose revision would be subject to a change control process. Prior to this final authentication, interim protection shall be afforded.

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 audits shall include technical evaluations of the applicable procedures, instructions, techniques and items as well as programmatic compliance. The audit team shall consist of qualified QA organization and where applicable, technical organization personnel. 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 affected organization's organization shall be actively involved with the audit process.

18.2 ANALYSIS OF AUDITS

Data obtained from audit results shall be analyzed by the audit team to determine quality assurance program adequacy and effectiveness and the results reported to responsible management for review, assessment, and appropriate action.

18.3 INTERNAL AUDITS

Internal audits of the adequacy and 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. An audit schedule shall be developed annually and updated as changes occur.

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

a. Results of previous surveillances and audits.

b. Impact of significant changes in personnel, organization, or quality assurance program.

18.4 EXTERNAL AUDITS

a. OCRWM shall annually audit implementation of quality assurance programs of the next lower-tier affected organizations for which they are responsible. An audit schedule shall be developed annually and updated as changes occur.

b. Supplier's quality assurance programs will be evaluated for audit on at least an annual basis. This evaluation shall be documented. Supplier audits shall be performed on a triennial basis when supplemented by annual evaluations. If those annual evaluations indicate the need for an audit, one shall be performed prior to the triennial period. The need for audits of a supplier will also be evaluated when major changes to contract scope or work methodology occurs. Preaward surveys may serve as the first audit if the scope and conduct of the survey is similar to the scope of other supplier audits where the scope of work is comparable.

When audits are performed triennially each affected organization shall perform or arrange for annual evaluations of suppliers. This evaluation shall be documented and shall take into account, where applicable, the following:

- Review of supplier-furnished documents and records such as certificates of conformance, nonconformance notices, and corrective actions.
- Results of previous source verifications, surveillances, audits, management assessments, and receiving inspections.
- Operating experience of identical or similar products furnished by the same supplier.
- Results of audits from other sources.

c. After award of the contract and based on the determination of the quality assurance program applicability 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:

1. Relatively simple and standard in design, manufacture, and test;

or

2. 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 and maintained as part of the QA records.

d. Audits conducted on a supplier by an external organization for the affected organization, or for a group of purchasers that includes the affected organization, are an acceptable alternative to an affected organization conducted audit. However, the scope of the audit must meet the needs of the program, and the audit report must be provided to the affected organization. The affected organization remains responsible for the adequacy of these audits.

SECTION 19

COMPUTER SOFTWARE

19.0 APPLICATION OF REQUIREMENTS

a. A computer software development and control program shall be developed to meet the minimum requirements of this subsection and shall be consistent with the documentation guidance specified in NUREG-0856, Final Technical Position on Documentation of Computer Codes for High-Level Waste Management, June 1983. Computer programs developed and/or modified shall be documented in accordance with the applicable elements of NUREG-0856.

b. Affected organizations implementing computer software development activities shall adhere to a computer software life cycle model. The relative emphasis placed on each phase of the computer software life cycle will depend on the nature, complexity, and importance of the computer software being developed.

c. The documentation for each phase of the computer software life cycle shall be reviewed and approved as specified in each affected organization's computer software QA Plan.

d. An example of one computer software life cycle model is described below:

   1. Requirements.

   2. Design.

   3. Implementation.

   4. Test.

   5. Installation and checkout.

   6. Operation and maintenance.

19.1 COMPUTER SOFTWARE QUALITY ASSURANCE PLAN (SQAP)

The application of the computer software life cycle to computer software development and use shall be as described in a computer SQAP.

Each affected organization shall prepare a description of their computer software development, test and configuration management system in their SQAP and/or procedures (Software Quality Assurance Program), and submit it to the next higher

program organizational level for review and approval (e.g., DOE Project Office approves the SQAP's for those affected organizations who directly perform work for the Project Office). The description shall:

- Provide criteria for application of the requirements of this Section based on the nature, complexity, and importance of the software used to perform analysis.
- Indicate the methods to be used to develop computer program requirements, to translate those requirements into a detailed design, and to implement that design in executable code.
- Identify the types of documentation to be prepared, reviewed, and maintained during computer software design, code implementation, test, and use.
- Describe the methods for managing interfaces involving computer software documentation.
- Identify the methodology for establishing computer software baselines and baseline updates (changes) and for tracking changes throughout the life of the computer software.
- Specify the process to be used for verification of the computer software and validation of models developed or applied to analyses.
- Identify the procedure for reporting and documenting computer software discrepancies, including sources, evaluating impacts of discrepancies on previous calculations, and determining appropriate corrective action.

19.1.1 A computer SQAP shall be prepared for each computer software development or application effort at the start of the computer software life cycle. The plan may be prepared individually for each piece of computer software or may exist as a generic document to be applied to all computer software prepared within an organization. The computer SQAP shall identify:

1. Computer software products to which it applies.
2. Organizations responsible for computer software quality and their tasks and responsibilities.
3. Required documentation.
4. Required computer software reviews.

If the SQAP references any standards, conventions, techniques, or methodologies used during computer software development, the SQAP shall: identify those portions of the references to be followed: and describe methods to assure compliance to these documents.

19.1.2 Within the computer SQAP, computer software life-cycle management shall be described. Each affected organization shall present the specific computer software life-cycle controls for their organization in their computer SQAP. The following life-cycle elements shall apply, as appropriate, for the specific life-cycle model defined, interpreted, and described in each affected organization's computer SQAP.

a. Requirements Phase

Requirements that pertain to functionality, performance, design constraints, attributes, and external interfaces of the completed computer software shall be specified, documented, and reviewed.

These requirements shall have the following characteristics:

1. Format and language understandable by the programming organization and the user.

2. Sufficient detail to allow for objective verification.

3. Adequate definition to provide for the response of the computer software to the identified input data.

4. Information necessary to design the computer software without prescribing the computer software design.

b. Design Phase

A computer software design based on the requirements shall be specified, documented, and systematically reviewed. The design shall specify the overall structure (control and data flow) and the reduction of the overall structure into physical solutions (algorithms, equations, control logic, and data structures). The design may necessitate the modification of the requirements documentation.

Design-phase verification activities shall consist of:

1. Generation of design-based test cases.

2. Review and analysis of the computer software design.

3. Verification of the computer software design.

c. Implementation Phase

The design shall be translated into code using a programming language. Only minor, if any, design issues shall be resolved at this phase.

Implementation-phase verification activities shall consist of:

1. Possible modification of test cases necessary due to design changes made during coding.

2. Examination of source code listings to assure adherence to coding standards and conventions, if any.

3. Developer test and inspection of the implemented computer software to remove errors in the coding i.e., debugging.

d. Testing Phase

The design as implemented in code shall be exercised by executing the test cases. Failure to successfully execute the test cases may require the modification of the requirements, the design, the implementation, or the test plans and test cases.

Testing-phase verification activities shall consist of:

1. Evaluation of the completed computer software to assure adherence to the requirements.

2. Preparation of a report on the results of computer software verification.

Testing of computer software, including new or modified computer software, shall be performed for those inputs and conditions necessary to exercise the software, identify boundary conditions and to provide a suitable benchmark or sample problem for installation.

e. Installation and Checkout Phase

Computer software becomes part of a system incorporating other computer software components, the hardware, and production data. The process of integrating the computer software with other components may consist of installing hardware, installing the program, reformatting or creating databases, and verifying that all components have been included.

Testing activities during the installation and checkout phase shall consist of executing test cases for installation and integration. Test cases from earlier phases shall be enhanced and used for installation testing.

f. Operation and Maintenance Phase

The computer software shall be approved for operational use. Further activity shall consist of computer software maintenance to remove latent errors (corrective maintenance), to respond to new or revised requirements (preventative maintenance), or to adapt the computer software to changes in the computer software environment (adaptive maintenance). Computer software modifications shall be approved, documented, tested (including regression testing, as appropriate), and controlled in accordance with Subsection 19.2.

19.2 COMPUTER SOFTWARE VERIFICATION AND VALIDATION

a. Verification of computer software and model validation shall be performed prior to the use of such computer software to perform technical calculations. In those cases where this requirement cannot be met, the portion or portions of computer software which have not been verified and those models which have not been validated shall be identified and controlled and written justification of the reason shall be generated. A schedule indicating the date that such computer software will be verified and models validated, to the extent that the computer software will be used, shall be generated and maintained. This schedule shall be either included as part of the NUREG-0856 section III, D, Code Assessment and Support document or as a separate document. In all cases, the verification shall be completed prior to submittal of the license application to the extent that the software has been used to support the license application. Model validation shall be performed and documented to such a degree that the results obtained are justified for the specific process or system that the model is intended to represent.

b. The responsible affected organization shall develop verification and validation plans that shall employ methods such as inspection, analysis, demonstration, and test to assure that the computer software adequately and correctly performs all intended functions and that the computer software does not perform any function that, either by itself or in combination with other functions, can degrade the entire system.

c. Verification and validation activities shall be planned and performed relative to specific hardware configurations. The degree of verification and validation activity shall be determined by the type and complexity of the computer software. Prior to use for a licensing activity, verification and validation of the final version of the software product, with respect to it's intended application, shall be accomplished by an independent individual or organization, one who did not work on the original software development. The results of verification and validation activities shall be documented.

Note: Verification of computer software and/or validation of the model, performed by the developer, should involve activities (that is, iterations of tests and runs) to arrive at a final product. It is not required to document all of the activities performed to satisfy the computer software developer.

19.3 VERIFICATION

Verification activities shall be integrated into applicable phases of the computer software life cycle and shall be performed to an extent commensurate with the critical importance of the computer software. Computer software verification shall be performed to assure that the computer software requirements are implemented in the computer software design and that the computer software design is correctly implemented in code.

19.4 VALIDATION

a. Model validation activities of computer software shall be documented. Validation activities are performed to demonstrate that the model as embodied in the computer software is a correct representation of the process or system for which it is intended. This is accomplished by comparing computer software results against verified and traceable data obtained from laboratory experiments, field experiments, or observations or in situ testing. Where such comparison for model validation has been performed, specific sets of data used in the validation process shall be identified, and their use shall be justified.

b. When data are not available from the sources mentioned above, alternative approaches shall be documented and used to validate models. Alternative approaches may include peer review and comparisons with the results of similar analyses performed with verified computer software.

19.5 COMPUTER SOFTWARE CONFIGURATION MANAGEMENT

A computer software configuration management system shall be established to assure positive identification of computer software and control of computer software baselines and changes.

a. Configuration Identification

Computer software shall be placed under configuration management control as each baseline element is approved. A configuration baseline shall be identified at the completion of each major phase of the computer software life cycle. Approved changes to a baseline shall be added periodically to the baseline as updates. A baseline plus updates shall specify the most recent computer software configuration. Updates shall be incorporated into subsequent baselines. Both baselines and updates shall be defined by their composition of computer software configuration items.

A labeling system for configuration items shall be implemented that:

1. Uniquely identifies each configuration item or version, including identification of software version in the output, when feasible.

2. Identifies changes to configuration items by revision.

3. Places the configuration item in a relationship with other configuration items.

4. Directly relates each code version with its associated documentation.

b. Configuration Change Control

Changes to baselined computer software configuration items shall be formally documented. This documentation shall contain a description of the change(s), the identification of the originating organization, the rationale for the change(s), and the identification of affected baselines and computer software configuration items. The change should be formally evaluated by a qualified individual or organization with the ability to approve or disapprove proposed changes. Assurance shall be provided that only authorized changes are made to computer software baselines and computer software configuration items.

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, required action is documented, and the information concerning approved changes is transmitted to all affected organizations. Changes to computer software shall be subject to the same level of approval, verification, and validation as the original computer software.

c. Configuration Status Accounting

The information that is needed to manage computer software configuration items shall be recorded and reported. This information shall include:

- A listing of the approved configuration identification.

- The status of proposed changes to the configuration.
- The implementation status of approved changes.
- A brief chronology of the computer software versions, including descriptions of the changes made between versions.
- Information to support the functions of configuration identification and configuration control.

19.6 QUALIFICATION OF EXISTING SOFTWARE

Existing computer software shall be qualified for use. This qualification shall be based on the ability of the computer software to provide acceptable results for specific applications and compliance with the requirements of this Section. Computer software that has not been developed in accordance with this Section may be qualified for use provided the computer software is verified and validated, a computer software baseline established, and applicable documentation prepared to support the software in accordance with the provisions of this Section.

Where commercial auxiliary computer software is used, all available documentation from the supplier shall be obtained. It is recognized that source code is generally not available and controls are limited to unique version identification and user-related manuals. (Commercial auxiliary computer software is also considered to be a subset of acquired computer software.)

19.7 DOCUMENTATION

Minimum acceptable life-cycle documentation of computer software that has been developed or modified shall be specified in each affected organization's computer SQAP. The documentation provided shall meet the requirements of Subsections 19.7.a through 19.7.e, as applicable.

Lifecycle documentation for scientific and engineering computer software shall include the following, as a minimum, as described in following text:

- Computer software requirements specification.
- Computer software design and change documentation.
- Computer software verification and model validation documentation.
- User documentation.

and the following, as a minimum, as described in NUREG-0856:

- Description of mathematical models and numerical methods.
- Code assessment and support.
- Continuing documentation and code listings.
- Software summary.

Additional documentation may also be identified in the computer SQAP for each affected organization's computer software project.

a. Computer Software Requirements Specification

Computer software requirements documentation shall outline the requirements that the proposed computer software must fulfill. The requirements shall address the following:

1. Functionality - functions the computer software are to perform.
2. Performance - time-related issues of computer software operation such as speed, recovery time, response time, etc.
3. Design constraints imposed on implementation - any elements that will restrict design options.
4. Attributes - non-time-related issues of computer software operations such as portability, correctness, security, maintainability, etc.
5. External Interfaces - interactions with other participants, hardware, and other computer software.

b. Computer Software Design Documentation

Computer software design documents or series of documents shall contain:

1. A description of the major components of the computer software design as they relate to the requirements in the computer software r equirements specification.
2. A technical description of the computer software with respect to control flow, data flow, control logic, and data structure.
3. A description of the allowable and tolerable ranges for inputs and outputs.

4. The design described in a manner that is easily traceable to the computer software requirements.

5. Code assessment and support documentation and descriptions of mathematical models and numerical methods as required by NUREG-0856 shall be initiated.

c. Computer Software Implementation Documentation

Design changes made to the requirements and design phase documents shall be assessed as to the impact on the design. The revised requirements and design phase documents shall be reviewed to the same level of review as the original documents. The results shall be the basis for the computer software verification and validation plans, at least in part.

d. Computer Software Verification and Model Validation Documentation (TEST)

Computer software verification and model validation documentation shall include a plan that describes tasks and criteria for accomplishing the verification of the computer software in each phase and any plans for model validation. The documentation shall also specify the hardware and system computer software configuration pertinent to the computer software.

The documentation shall be organized in a manner that allows traceability to both the computer software requirements and the computer software design. This documentation shall also include a report on the results of the execution of the verification and validation activities. This report shall include the results of reviews, audits, tests, and a summary of the status of the computer software.

e. User Documentation

User documentation shall be prepared in accordance with NUREG-0856 and shall include a description of:

1. Program considerations, options, and initialization procedures.

2. Anticipated error situations and how the user can correct them.

3. Internal and external data files, their input sequence, structures, units, and ranges.

4. Input and output options, defaults, and formats.

5. System interface features and limitations.

6. Information for obtaining user and maintenance support.

7. Sample problems.

19.8 REVIEWS

Reviews of computer software development activity shall be performed as each life cycle phase is completed to assure the completeness and integrity of each development phase. The procedures used for reviews shall identify the participants and their specific responsibilities during the reviews and in the preparation and distribution of the review reports.

The documentation for reviews shall contain a record of review comments, a plan, timetable for resolution of the review comments, and the persons responsible for this resolution.

After review comments are resolved, the approved documents shall be updated and placed under configuration management.

a. Computer Software Requirements Review

The review of computer software requirements shall be performed at the completion of the computer software requirements documentation. This review shall assure that the requirements are complete, verifiable, and consistent. The review shall also assure that there is sufficient detail available to complete the computer software design.

b. Computer Software Design Review

The computer software design review shall be held at the completion of the computer software design documentation. This review shall evaluate the technical adequacy of the design approach and assure that the design complies with the criteria in the computer software requirements specification. The complexity of the computer software design may require the performance of two design reviews, one at the completion of the overall computer software architecture and the second at the completion of the total design.

c. Computer Software Implementation Review

The computer software implementation review is an evaluation of the completed requirements, design, and implementation process prior to independent verification and validation.

d. Computer Software Verification and Model Validation Review

The computer software verification and validation review is an evaluation of the adequacy of verification and validation plans or procedures and completed verification and validation activities. The review results in an approval of verification and validation documentation.

19.9 DISCREPANCY REPORTING AND CORRECTIVE ACTION

A formal computer software discrepancy reporting and corrective action system shall be established. This discrepancy reporting system shall be integrated with the configuration management system to assure formal processing of discrepancy resolutions. Computer software discrepancy reporting and corrective action systems shall assure that, as a minimum:

1. Defects are documented and corrected.

2. Defects are assessed for criticality and impact on previous applications.

3. Corrections are reviewed and approved before changes to the computer software configuration are made.

4. Preventive and corrective actions provide for appropriate notification of affected organizations.

If a deficiency is identified in use of the software that impacts previous work, such that analyses must be rerun to assure accurate and correct results, the deficiency shall be documented and controlled in accordance with the requirements of Section 16 for Corrective Action.

19.10 MEDIA CONTROL AND PHYSICAL SECURITY

Physical media containing the images of computer software shall be physically protected to prevent their inadvertent damage or degradation.

19.11 ACQUIRED COMPUTER SOFTWARE

a. Procedures shall be established for controlling the transfer of computer software from an outside source to a user organization and from a user organization to an outside requesting organization. Computer software transfer requests of the organization (or purchases) from an outside source shall include appropriate criteria to enable the computer software received to comply, as much as possible, with the requirements of this Section and the needs of the affected organization's computer system. Those requirements not met by the computer software received shall be completed by the organization in the relative phase of the computer

software life cycle that is incomplete or, if that is not possible, the reason shall be documented and maintained with the computer software and distributed to the users.

b. Configuration management change controls shall be established for documenting the conversion of computer software to be used on a computer system, or peripheral hardware, other than that for which it was designed. Conversion includes all modifications and tests made to the input, output, source code, or additional computer software written to run the original computer software on the new system.

c. Computer software conversion shall be documented and maintained for the specific version of the computer software and the computer system on which it is installed. Computer software conversion changes shall be evaluated and activities performed in accordance with the appropriate configuration management system elements.

19.12 COMPUTER SOFTWARE APPLICATION

a. Technical calculations using computer software shall be performed with computer codes and with computer software operating procedures defined sufficiently to allow independent repetition of the entire computation. If any technical calculations fall outside the range of tests performed to validate the model, model validation shall be performed for these specific technical calculations. If model validation has not been performed previously, the model shall be validated and documented to the degree discussed in 19.2.

b. Affected organizations shall establish procedures for controlling the application of verified computer software and/or validated models to technical calculations generating primary data.

c. Affected organizations shall establish procedures for documenting and reviewing computer software application and analyses and for assuring that results are accurate and reproducible. Requirements shall be established for identifying or otherwise marking record copies of analyses and supporting documentation. Supporting documentation includes computer output (results), code input data including databases and original sources or references of and assumptions used to obtain such data, code design, user's or operation manuals, verification or validation test results, and hand calculations.

d. Controls shall be established for generating and documenting computer software used to perform technical calculations. Auxiliary computer software used shall be included in documentation of technical calculations performed and shall be included in independent review as part of the calculations. Auxiliary computer software used to support primary analysis computer software shall be controlled at a level commensurate with the complexity of that computer software.

e. Applications of computer software shall be independently reviewed and approved to assure that the computer software selected is applicable to the problem being solved and that input and assumptions are valid and traceable.

19.13 EXCEPTIONS TO ASME NQA-1, 1989 EDITION

Supplement 11S-2, Section 2.2, In-Use Tests; Section 3, Test Procedures, item (e); Section 5, Test Records, Part A, items (3), (4), (5), and (6) and Part B in its entirety.

APPENDIX A

AMPLIFICATIONS OF QUALITY ASSURANCE PROGRAM REQUIREMENTS FOR THE MINED GEOLOGIC DISPOSAL SYSTEM (MGDS)

1.0 GENERAL

The purpose of this appendix is to amplify the basic OCRWM quality assurance program requirements by specifying requirements unique to the MGDS. Program participants who perform activities related to the MGDS shall comply with the quality assurance program requirements contained in QARD Sections 1 through 19. Section 20 has been added to this Appendix as it applies only to MGDS. Specific amplifications of the requirements are given below as they relate to a major, numbered QARD section (criteria). Where a major QARD section requires no amplification or clarification, the section reference is omitted from this Appendix.

2.0 AMPLIFICATION OF QARD SECTION 2 - QUALITY ASSURANCE PROGRAM

2.1 QUALITY ASSURANCE PROGRAM

A methodology shall be developed to identify those items and activities to which the quality assurance program applies. This methodology shall be consistent 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.

3.0 AMPLIFICATION OF QARD SECTION 3 - DESIGN CONTROL

3.1 PEER REVIEWS

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 1988.

5.0 AMPLIFICATION OF QARD SECTION 5 - INSTRUCTIONS, PLANS, PROCEDURES, AND DRAWINGS

5.1 SCIENTIFIC NOTEBOOKS

When Scientific Notebooks are used to document scientific investigations the requirements of Section 20 of this Appendix shall prevail over the requirements of this section.

6.0 AMPLIFICATION OF QARD SECTION 6 - DOCUMENT CONTROL

6.1 DOCUMENT PREPARATION

The document control system for document preparation, review, approval, issuance and changes thereto shall include the evaluation of changes for potential impact on the waste isolation capability of the site or interference with other site characterization activities.

8.0 AMPLIFICATION OF QARD SECTION 8 - IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, COMPONENTS, AND SAMPLES

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:

a. Collection, identification, and traceability of samples including archival samples).

b. Test or experiment allocation.

c. Disposition of samples.

d. Generation of associated records.

8.2 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.

8.3 SAMPLE TRACEABILITY

Identification systems shall assure traceability of samples to the appropriate documentation such as drawings, specifications, purchase orders, technical reports, drilling locations and logs, (including well bore and depth), test records, installation and use records, inspection documents, and nonconformance reports. Controls are established to preclude the inadvertent use of incorrect or defective samples. 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.

8.4 ARCHIVAL SAMPLES

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

9.0 AMPLIFICATION OF QARD SECTION 9 - CONTROL OF PROCESSES

9.1 APPLICABILITY

The requirements for control of processes apply to both engineered items and scientific investigations. The requirements for special processes apply to engineered items and do not apply to scientific investigation activities.

10.0 AMPLIFICATION OF QARD SECTION 10 - INSPECTION

10.1 APPLICABILITY

The requirements of this section apply to engineered items only and not to scientific investigation activities.

11.0 AMPLIFICATION OF QARD SECTION 11 - TEST CONTROL

11.1 APPLICABILITY

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

13.0 AMPLIFICATION OF QARD SECTION 13 - HANDLING, STORAGE, AND SHIPPING

13.1 GEOTECHNICAL SAMPLES

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

13.2 GEOTECHNICAL 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 type 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.

13.3 GEOTECHNICAL SAMPLE STORAGE

a. 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.

b. Samples shall be controlled to preclude unintentional mixing of like samples or contamination. Provisions shall be made for identification and storage of tested samples in area physically separated from untested sample materials.

14.0 AMPLIFICATION OF QARD SECTION 14 - INSPECTION, TEST, AND OPERATING STATUS

14.1 APPLICABILITY

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

19.0 AMPLIFICATION OF QARD SECTION 19 - COMPUTER SOFTWARE

19.1 APPLICABILITY

The purpose of this section is to establish requirements for the development, management control, and documentation of software used to support the MGDS. The attainment of software quality is dependent upon the control of the entire software development process, and is not assured solely by inspection and test of the end product. The detailed requirements set forth in this section apply to computer software used to produce or manipulate data which is used directly in site characterization, and the design, analysis, performance assessment, and operation of repository structures, systems and components. The extent to which these requirements apply is related to the nature, complexity, and importance of the software and its use.

20.0 SCIENTIFIC INVESTIGATIONS

20.1 PLANNING

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

1. Description of work to be performed.
2. Rationale and justification for the information to be obtained.
3. Proposed methodology.
4. Rationale and justification for the proposed methodology.
5. References to applicable documents.
6. Identification, explanation, and justification for areas where scientific notebooks are to be used.
7. Description of constraints.
8. Description of the application of the scientific investigation's results.
9. Description of schedules and milestones.

b. These planning measures shall include or reference provisions for assuring that:

1. Prerequisites for the given scientific investigation have been met.
2. Adequate instrumentation is available and used.
3. Necessary monitoring including witness or hold points have been performed.
4. Suitable laboratory conditions are maintained.
5. Scientific investigations at each step are compatible with applicable conceptual or mathematical models used at each applicable stage.
6. The evaluation of data quality to assure that generated data is valid, comparable, complete representative, precise, and accurate.

7. Sources of error and uncertainty and input data that is suspect or whose quality is beyond the control of the performing organizations is identified.

c. Prerequisites

The following prerequisites shall be considered:

1. Calibrated instrumentation.

2. Appropriate equipment.

3. Trained personnel.

4. Readiness of facilities, equipment, supplies, and items or samples.

5. Suitable environmental conditions.

6. Provision for acquisition and recording of data.

7. Disposition of facilities after completion of scientific investigation activities.

8. Environmental compliance and land access approval.

The responsible Project affected organization shall conduct a technical review or peer review of the scientific investigation planning document prior to data collection or analysis activities. Technical Reviews shall be performed in accordance with Section 3.4 in the main body of this document. In exceptional cases, the originator's immediate supervisor can perform the review if the supervisor is the only technically qualified individual, and if the need is individually documented and approved in advance with the concurrence of the QA manager of the originating organization. The results of this technical or peer review, and the resolution of any comments by the reviewer or reviewers, shall be documented, and shall become a part of the QA records.

All changes in scientific investigation planning documents shall go through the same review and approval process as the original planning documents.

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.

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 program 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 special quality assurance program requirements are found to be necessary, specific performance verification requirements shall be established and described to govern the use of the equipment.

20.2 CONTROL OF SCIENTIFIC INVESTIGATIONS

a. 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.

b. Either the scientific notebook system or the technical procedures system are the two approaches that will be used to control scientific investigation activities.

c. 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.

d. Activities used to develop new methods or procedures for conducting scientific investigations or critical processes shall be documented. Results of scientific investigations or critical processes shall be reviewed and documented for adequacy and approved by qualified persons prior to use.

20.2.1 Technical Procedures

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 affected organization designates the responsibility in writing to another organization.

The technical aspects of procedures may be modified by the individual utilizing the procedure. The approval of an appropriately qualified reviewer is required if the change is not within the scope of the scientific investigation planning document, the activity can not be repeated, or the change could potentially impact the waste isolation capability of the site or interfere with other site characterization activities. Such changes shall be communicated to all affected groups.

Technical procedures utilized for scientific investigations shall provide for the following as appropriate:

- Requirements, objectives, methods, and characteristics to be tested or observed.

- Acceptance limits, if applicable, contained in applicable documents, including precision and accuracy.

- Prerequisites such as calibrated instrumentation; adequate and appropriate equipment and instrumentation; readiness of facilities, equipment, supplies, items, and samples; suitable and controlled environmental conditions; provisions for data collection and storage; and disposition of facilities at completion of the scientific investigations. For activities of long duration, specific provisions shall be established and documented for instrumentation whose calibration interval is shorter than the expected duration of the activity. Such provisions are to be designed to ensure validity of data throughout the scientific investigation.

- Mandatory verification points, as applicable.

- Acceptance criteria, including required levels of precision and accuracy (NOTE: "Accept criteria: means those features or characteristics of a procedure that make it possible to determine whether the work has been, or is being, performed in such a way that it produces the intended results. A data acquisition task produces output that, in itself, cannot be characterized as acceptable or unacceptable. However, the task of acquiring the data is acceptable if all specified prerequisites were met and the work was accomplished in the specified manner. In that instance, the "accept criteria" are simply the conditions and methods stated in the procedure.)

- Methods of documenting or recording data and results, including precision and accuracy.

- Methods of data reduction or reference to procedures containing this information.

- Provision for ensuring that prerequisites have been met.

- Special training or qualification requirements for personnel performing the scientific investigation.

- Personnel responsibilities.

Procedures shall be complete to the extent that another qualified individual may, at a later date, repeat the scientific investigation. The potential sources of uncertainly and error in technical implementation procedures which must be

controlled and measured to assure that scientific investigations are well controlled as well as input data that is suspect or whose quality is beyond the control of the performing organization shall be identified. Parameters that need to be measured and/or controlled to minimize uncertainties or error, and to ensure adequate control, shall be addressed explicitly in procedures.

20.2.2 SCIENTIFIC NOTEBOOKS

The scientific notebook system will be used by qualified individuals who are using a high degree of professional judgment, trial and error methods, or developing the methodology by which an activity will be accomplished. When the scientific notebook system is used, the study plan or scientific investigation planning document shall be the controlling document used to perform the activity. The contents of the notebook shall be sufficient such that another qualified scientist can use the notebook to retrace the investigation and confirm the results if feasible, or repeat the investigation and achieve the same results without recourse to the PI. Documentation of scientific investigation work (i.e., experiments and research) shall be performed using logbooks or notebooks to provide written record of the experiment or research.

Prior to initiation of the experiment or research, the following entries, as a minimum, shall be made in the scientific notebook:

- Title of the experiment or research.
- Name of the qualified individual or individuals performing the experiment or research.
- Description of the experiment's objective or objectives and the proposed approach or procedure for achieving these objectives. (This may be accomplished by reference to the appropriate study plan or other scientific investigation planning document that controls the work.)
- Equipment and materials to be employed during the experiment or research, including any necessary fabrication of experimental equipment and any needed characterization of starting material.
- Calibration requirements.
- Special training or qualification requirements.
- Documentation of suitable and controlled environmental conditions, if applicable.
- Required levels of precision and accuracy.

- Input data that is suspect or whose quality is beyond the control of the performing organization.

- Dated signature of the individual or individuals making the initial entries.

The initial entries described above are considered to be "general" procedure and shall be entered into the scientific notebook prior to beginning an investigation. Modifications may be made to the initial entries by the individual performing the investigation. If the change or modification is not within the scope of the study plan or scientific investigation plan, and the investigation is not repeatable, or the change could potentially impact the waste isolation capability of the site, or interfere with other site characterization activities, approval shall be obtained from an appropriately qualified reviewer.

Subsequent entries made in a scientific notebook during the experiment or research shall be sufficiently detailed so that another competent experimenter/researcher could repeat the experiment or research, and shall include:

- Date and name of individual making the entry.

- Provisions for assuring prerequisites have been met.

- Description of the experiment or research attempted, including detailed step-by-step process followed; either by reference to implementing procedure or by actual entry into the notebook.

- Description of any conditions which may adversely affect the results of the experiment or research.

- Identification of samples used and any additional equipment and materials not included as part of the initial entries previously prescribed.

- Data taken or reference to its identification and location (e.g., magnetic media) and a brief description of the results, to include notation of any unaccepted results.

- Any deviations from the planned experiment or research.

- Any interim conclusions reached, as appropriate.

- Final disposition of facilities.

The final entries in the record shall have, as a minimum, the signature of the experimenter and the signature of a competent technical reviewer.

20.3 STANDARDS

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.

20.4 DATA COLLECTION AND ANALYSIS

a. Equipment to be used to obtain and analyze data shall be evaluated to assure 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 with qualifications comparable to the person originally conducting the task. Where appropriate, verifications shall be performed using recognized methods.

   Documentation of interpretation/analysis shall include the following:

   - Definition of the objective of the interpretation/analysis.
   - Definition of input and their sources.
   - A listing of applicable references.
   - Results of literature searches or other background data.
   - Identification of assumptions.
   - Identification of any computer calculations, including computer type, program name, revision, input, output, evidence of program verification, and the bases of application to the specific problem.
   - Signatures and dates of review and approval by appropriate personnel.

b. 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.

20.5 DATA COLLECTION AND ANALYSIS REVIEW

Methods used to obtain data shall be reviewed for technical adequacy. Data analysis shall be technically reviewed. These reviews shall be performed by qualified individuals other than those who performed the scientific investigation. Questions shall be resolved before the results are entered into the Reference Information Base (RIB). 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. Collected data shall be reported so as to relate it to information needs and issue resolution.

20.6 DATA IDENTIFICATION AND TRACEABILITY

a. 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.

b. Data found to be erroneous or superseded 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.

20.7 SCIENTIFIC INVESTIGATION RESULTS

Final results and a summary of the outcome of the experiment or research shall be documented (e.g., in a technical report). This shall include a discussion of whether the experiment's objectives as outlined in the initial entries were achieved. This documentation shall become part of the QA records of the activity.

The affected organization shall have implementing procedures for the technical and/or peer review and approval of the results of scientific investigations. 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 shall be reported so as to relate it to information needs and issue resolution.

20.8 INTERFACE CONTROL

Ongoing field or laboratory scientific investigations shall be identified to preclude inadvertent interruption and to ensure operational compatibility. Such identification shall be clearly evident at the location at which the scientific investigation is being performed. Field investigations shall identify the location of the investigation to the extent necessary to preclude interference.

20.9 DATA RECORDING, STORAGE, AND RETRIEVABILITY

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

Records shall, as appropriate, identify the following elements:

a. Scientific investigation requirements, plans, procedures (including applicable revisions), scientific notebooks, logs, and logbooks.

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' organization.

h. Identification of equipment used.

20.10 QUALIFICATION OF DATA OF INDETERMINATE QUALITY

Data that will be needed to be qualified to support a license application and that were not collected under the control of a quality assurance program meeting the quality assurance program 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 in support of license application activities.

a. Data may include information collected from such sources as professional journals, technical reports, and symposia proceedings; such data does not include design reference codes and standards, for example, ASME Boiler and Pressure Vessel Code, ASTM standards, and CRC Handbooks.

b. 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.

c. Acceptable qualification methods include any one, or a combination of, peer review, corroborating data, or confirmatory testing.

d. Consideration shall be given to the following factors when available and measurable:

1. Qualifications of personnel or organizations generating the data.

2. Technical adequacy of the equipment and procedures used in the scientific investigation.

3. Laboratory conditions.

4. Confidence level associated with the corroborating data based upon the quality and reliability of the measurement control program under which the data was generated.

5. Amount of corroborating data or confirmatory testing.

6. Extent to which data demonstrates properties of interest (for example; physical, chemical, geologic, mechanical.

7. Extent to which conditions generating the data may partially meet requirements of this document.

8. Prior uses of the data and associated verification process.

9. Prior professional reviews of the data.

10. Extent and reliability of the documentation associated with the data.

11. Degree to which data-generating processes were independently audited.

12. Importance of the data to show that performance objectives were met.

e. The results of data qualification activities shall be documented. The information to be found in peer review reports is addressed in paragraph 3.1 of this Appendix.

20.10.1 Qualification of Data by Use of Corroborating Data

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.

f. Test results.

APPENDIX B

AMPLIFICATIONS OF QUALITY ASSURANCE PROGRAM REQUIREMENTS FOR WASTE ACCEPTANCE PROCESS ACTIVITIES OF HIGH-LEVEL WASTE FORM PRODUCTION

1.0 GENERAL

The purpose of this appendix is to amplify the basic OCRWM quality assurance program requirements by specifying those requirements that are unique to the Waste Acceptance Process Activities of High-Level Waste Form Production. Program participants who perform Waste Acceptance Process Activities of High-Level Waste Form Production shall comply with the quality assurance program requirements specified in QARD Sections 1 through 19. Specific amplifications of the requirements are given below as they relate to a major, numbered QARD section (criteria). Where a major QARD section requires no amplification or clarification, the section reference is omitted from this Appendix.

2.0 AMPLIFICATION OF QARD SECTION 2 - QUALITY ASSURANCE PROGRAM DESCRIPTION FOR THE WASTE ACCEPTANCE PROCESS

2.1 METHOD DESCRIPTION

The Waste Form Producers shall identify in their Quality Assurance Program Descriptions those items and activities which are included in the Waste Acceptance Process.

2.2 READINESS REVIEWS

Readiness Reviews shall be planned, scheduled, and conducted at significant transitional events in Waste Acceptance Process Activities leading up to and during high-level waste form production to assure that necessary activities and actions have been satisfactorily completed before subsequent activity initiation is authorized.

2.3 GRADED QUALITY ASSURANCE PROGRAM

The methodology developed to identify those items and activities to which the quality assurance program applies and to selectively apply the quality assurance program requirements and controls shall be described in the Waste Form Compliance Plan. This methodology shall be consistent 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.

2.4 PERSONNEL SELECTION, INDOCTRINATION, TRAINING, AND QUALIFICATION

Inspection and test personnel shall meet the qualification requirements of QARD Section 2.8. All other persons requiring qualification shall meet ANSI/ASME NQA-1 Supplement 2S-1, excluding paragraphs 2.7 and 2.8

2.5 MANAGEMENT ASSESSMENTS

In addition to the requirements QARD Section 2.8, management assessments shall evaluate conformance to the Waste Acceptance Specifications.

3.0 AMPLIFICATION OF QARD SECTION 3 - DESIGN CONTROL

3.1 PEER REVIEW

Peer Reviews shall be performed in accordance with the guidance provided in NUREG-1297. Peer Review for High-Level Waste Repositories Generic Technical Position, February 1989.

3.2 CONTROL OF EXPERIMENTS AND DEVELOPMENTAL ACTIVITIES

3.2.1 Experiment and Developmental Activities

Experiments and developmental activities to support Waste Acceptance Process Activities of high-level waste form production shall be controlled and documented in a manner which ensures that:

a. Data is suitable for its intended use.

b. Independent reconstruction and evaluation of the activities can be performed.

3.2.2 Minimum Controls for Experiments and Developmental Activities

Controls for experiments and developmental activities shall address the following:

a. Responsibility for initiating experiments and developmental activity.

b. Selection and qualification of personnel.

c. Review and approval of procedures.

d. Surveillance and auditing of experiments and developmental activities.

e. Review and evaluation of the results of experiments and developmental activities.

f. Documentation of experiments and developmental activities and results.

g. Responsibility for preparation and retention of documentation.

3.2.3 Documentation

While in progress, experiments and developmental activities shall be documented on a day-to-day basis and the documents shall be maintained in a retrievable form.

3.2.4 Experimental and Developmental Records Control

a. Experimental and developmental records shall be sufficiently detailed so that the following can be clearly identified, either directly or by reference:

1. Purpose of the experiment or developmental activity.

2. Persons initiating the experiment or developmental activity.

3. Persons performing the experiment or developmental activity.

b. Experimental or developmental records shall also identify equipment, materials, and procedures actually used in sufficient detail to allow an individual skilled in the technology to reproduce the results.

c. Experimental or developmental records shall also include original records of data or facsimiles of the original records.

d. Experimental or developmental records shall be signed by the persons performing the experiment or developmental activities.

e. Summaries, reports, or evaluations of the experiments, developmental activities, or their results that are used for Waste Acceptance Process Activities shall clearly reference the experimental records.

f. Experimental or developmental records of Waste Acceptance Process Activities are to be collected and maintained as QA records.

3.2.5 Qualification of Data

Data or data interpretations in support of Waste Acceptance Process Activities of high-level waste form production shall be acquired or produced under a quality assurance program that meets the requirements of the QARD and this

Appendix. Data or data interpretations that were generated outside of a quality assurance program, as defined herein, may be accepted based upon the results of a peer review or may be qualified through corroborating data, confirmatory testing, or by having been acquired or produced under an equivalent quality assurance program. Such data or data interpretations shall be qualified in accordance with NUREG-1298, Qualification of Existing Data for High-Level Waste Repositories, February 27, 1988.

3.2.6 Modification Control

a. Controls shall be established and implemented by Program participants to assure that only approved modifications are made in Waste Acceptance Process Activities of high-level waste form production. These controls shall include the following:

b. Application to items and activities that are essential to canistered waste form certification and acceptance as defined in the WAS, including the following as appropriate:

1. Waste form.

2. Waste canister.

3. Canistered waste form.

4. Production process.

5. Processing equipment.

6. Processing supplies and consumables.

7. Processing plans and procedures.

8. Process control plans and procedures.

c. A controlled listing of the documentation that defines items and activities under modification control.

d. Procedures defining elements of the modification control process that address:

1. Change proposals (including deviation requests and waiver request.

2. Change review and approval.

3. Change implementation.

4. Change incorporation and issue of changed documentation and records.

e. Provisions for assessing the need for and accomplishing any needed requalification resulting from modifications.

3.3 COMPUTER SOFTWARE DESIGN AND CONTROL

Computer software that is essential to meeting the Waste Acceptance Specification (WAS) shall be controlled in accordance with QARD Section 19.

9.0 AMPLIFICATION OF QARD SECTION 9 - CONTROL OF PROCESSES

9.1 PROCESS CONTROL

Production processes are special processes and shall meet Section 9 requirements pertaining to process control and special processes.

13.0 AMPLIFICATION OF QARD SECTION 13 - HANDLING, STORAGE, AND SHIPPING

13.1 ARCHIVAL OF SAMPLES

Archival samples used for waste form qualification or for certification of canistered waste forms shall be prepared and controlled as follows:

a. Sample preparation and use shall be planned and documented.

The planning shall identify the following:

1. What samples are to be used (number, size, origin, or other characteristics).

2. Where and when they are to be taken or prepared.

3. Where and how they are to be kept.

4. Where and how they are to be analyzed.

5. When and how the results are to be used.

b. Methods and procedures for sample preparation, maintenance, and use shall be prepared and shall include the following:

1. Sample taking or preparation.

2. Logging and labeling or otherwise identifying.

3. Packing, packaging, and handling.

4. Locating, storage, and monitoring.

5. Retrieval.

6. Analysis.

7. Treatment of data and results.

c. Documentation and other forms of evidence necessary to demonstrate the performance of activities essential to the integrity of sample use shall be collected and maintained as QA records.

17.0 AMPLIFICATION OF QARD SECTION 17 - QUALITY ASSURANCE RECORDS

17.1 PRODUCT CERTIFICATION

The WCP and/or WQR are to identify the types of records that will be developed during the waste form production process. The WQR is to identify the quality records required to be a permanent part of the overall canistered waste form product certification package. These documents shall be delivered in accordance with the requirements of QARD Section 17.

17.2 DETERMINATION OF QA RECORDS

Documentation sufficient to demonstrate canistered waste form compliance with the WAS, WCP, and WQR shall be prepared and maintained as lifetime QA Records. Copies of these records shall be made available to the Federal Repository Operator at the time the repository is ready to begin accepting canistered waste forms from the waste form producer. Other documentation generated during preparation and implementation of the WCP, WAS, and WQR shall be collected and maintained as nonpermanent records.

17.3 PRODUCTION DOCUMENTATION

Production documentation shall be traceable to the canister and shall become lifetime quality assurance records that are transferred to the Federal Repository Operator with the canistered waste forms to which they relate.

18.0 AMPLIFICATION OF QARD SECTION 18 - AUDITS

18.1 PLANNING AND SCHEDULING

Audit schedules shall be developed annually and updated as changes occur.

18.2 AUDIT TEAM SELECTION

Audit teams should include, whenever possible, a representative that is trained and/or qualified in the technology being audited.

APPENDIX C

AMPLIFICATIONS OF QUALITY ASSURANCE PROGRAM REQUIREMENTS FOR THE TRANSPORT OF SPENT FUEL AND HIGH-LEVEL NUCLEAR WASTE

There are no amplifications to the applicable requirements of Sections 1 through 19 of the main body of this document.

APPENDIX D

AMPLIFICATIONS OF QUALITY ASSURANCE PROGRAM REQUIREMENTS FOR THE MONITORED RETRIEVABLE STORAGE (MRS) SYSTEM

There are no amplifications to the applicable requirements of Sections 1 through 19 of the main body of this document.

APPENDIX E

GLOSSARY

The terms and definitions of NQA-1 Supplement S-1 shall apply to all PROGRAM activities. The NQA-1 supplement S-1 definitions are supplemented and replaced by the definitions contained in this Glossary. Where differences exist between this document and others, the definitions in this document shall take precedence.

Accessible Environment: (1) the atmosphere; (2) the land surface; (3) surface water; (4) oceans; and (5) the portion of the lithosphere that is outside the controlled areas.

Activities Affecting Quality: Deeds, actions, processes, tasks, or work which influence the achievement or verification of PROGRAM quality requirements and objectives. For the MGDS, 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, operations, maintenance, repairing, modifying, performance confirmation, permanent closure, decontamination, and dismantling.

Activity: Any time-consuming effort (operation, task, function, or service) which influences or affects the achievement or verification of the objectives.

Affected Organization: Organization performing activities affecting quality for the PROGRAM that are subject to the requirements of the QARD. These organizations include OCRWM, EM, operations offices, project offices, contractors, subcontractors, national laboratories, and other government agencies or program participants.

Authentication (QA Records): Authentication is the act of attesting that the information contained within a document is accurate, complete, and appropriate to the work accomplished. Authentication is accomplished by one of the following methods: (1) a stamped, initialed, or signed, and dated document; (2) a statement by the responsible individual or organization; or (3) issuing a document which is clearly identified as a statement by the reporting individual or organization. A document cannot become a Quality Assurance (QA) record until it has been authenticated.

Auxiliary Software: (1) Software that may be easily and exactly verified, and that performs a simple function such as conversion of units, change in data format, or plotting of data in support of primary analysis software. (2) A stream of commands or sequence of streams of commands executed to utilize system maintained software in which the system maintained software generates reportable results. Auxiliary software does not generate primary data.

Barrier: Any material or structure that prevents or substantially delays the movements of water or radionuclides.

Canistered Waste Form: The waste form and the surrounding canister as well as any secondary canisters applied by the producer.

Computer Software Application: The act of putting computer software to use.

Computer Software Validation: 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.

Computer Software Verification: The process that demonstrates that the computer software correctly performs its stated capabilities and functions.

Configuration Management: As used for computer software (1) A system for orderly control of software, including methods used for labeling, changing, and storing software and its associated documentation. (2) The systematic evaluation, coordination, approval or disapproval, and implementation of all approved changes in an item of software after establishment of its configuration.

Confirmatory Testing: For the MGDS, an evaluation conducted under a 10 CFR 60, Subpart G or equivalent quality assurance program that investigates the properties of interest of an existing data base.

Consequence Analysis: A method by which the consequence of an event are calculated and expressed in some quantitative way, e.g., money loss, deaths, or quantities of radionuclides released to the accessible environment.

Containment: The confinement of radioactive waste within a designated boundary.

Containment, Period of: Known as the period during the first several hundred years following permanent closure of the geologic repository in which radiation and thermal levels are high and the uncertainties of ensuring repository performance are great. During this time, special emphasis is placed upon the ability to contain the wastes by waste packages with an engineered barrier system.

Contractor: An organization under contract to provide supplies, products, construction, or services.

Conversion Report: A written description of all modifications made to the original code or an externally available existing code after it is acquired.

Corroborative Data: Existing data used to support or substantiate other existing data.

Credible Event or Credible Accident: An event or accident scenario which needs to be considered in the design of a geologic repository.

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 MGDS , MRS facility, Transportation cask system, and Waste form. 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: This includes 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 analysis 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 adequacy of the design and the extent to which the design conforms to stated requirements.

Disposition: The action taken to resolve a nonconforming condition and to restore acceptable conditions.

DOE: The U.S. Department of Energy or its duly authorized representatives.

Engineered Barrier System: The waste package and the underground facility.

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

Existing Data: Data developed prior to the implementation of a 10 CFR 60, Subpart G QA program by DOE and its contractors, or data developed outside the DOE repository program, such as by oil companies, national laboratories, universities, or data published in technical or scientific publications. Existing data does not include information which is accepted by the scientific and engineering community as established facts (e.g., engineering handbooks, density tables, gravitational laws, etc.).

Functional Characteristics: Those attributes of a repository or its structures, systems, and components that determine its performance with respect to safety, reliability, operability, and other design criteria established in the OCRWM Program or other Federal regulatory documents.

Geologic Repository: A system that is either intended to be used for or may be used for the disposal of radioactive wastes in excavated geologic media. A geologic repository includes the geologic repository operations area and the portion of the geologic setting that provides isolation of the radioactive waste.

Geologic Repository Operations Area: A high-level radioactive waste facility that is part of a geologic repository, including both surface and subsurface areas, in which waste handling activities are conducted.

Graded Quality Assurance Program: The selective application of quality assurance program requirements and controls to items and activities commensurate with their importance to PROGRAM objectives.

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.

Internal Audit: An audit of those portions of an organization's QA program that is retained under its direct control and within its organizational structure.

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

Isolation: Inhibiting the transport of radioactive materials so that amounts and concentrations of this material entering the accessible environment will be kept with in prescribed limits.

Lifetime Records: Quality Assurance Records that furnish evidence of the quality and completeness of data, items, and activities affecting quality.

Material: A term that includes items plus any hardware or geologic samples either used in or resulting from research and development or site investigations. Hardware and geologic specimens include but are not limited to test apparatus or equipment, special nuclear material, cores, geologic samples, water, and gas samples, etc.

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

Non-Mechanistic Failures: Postulated failures which are not based on previously observed models or mechanisms but which are assumed to provide conservatism in safety assessments.

NTS: Nevada Test Site.

Operations, Period of: Includes the time during which emplacement of wastes occurs; any subsequent period before permanent closure during which the emplaced wastes are retrievable; and permanent closure, which includes sealing of shafts.

Overview: An analysis and assessment by management of the scope, status, adequacy and effectiveness of Program quality achievement and assurance activities. Overview encompasses effectiveness assessments, technical reviews, readiness reviews, audits, and surveillances, as appropriate.

Owner: The person, group, company, agency, or corporation that has or will have title to the repository.

Peer: A peer is a person having technical expertise in the subject matter to be reviewed (or a critical subset of the subject matter to be reviewed) to a degree at least equivalent to that needed for the original work.

Peer Review: A documented critical review performed by personnel who are independent of those who performed the work, but who have technical expertise at least equivalent to those who performed the original work. Peer reviews are in-depth, critical reviews and evaluations of documents, material or data that require interpretation of judgment to verify or validate assumptions, plans, results or conclusions or when the conclusions, material or data contained in a report go beyond the existing state-of-the-art.

Peer Review Group: A peer review group is an assembly of peers representing an appropriate spectrum of knowledge and experience in the subject matter to be reviewed and should vary in size based on the subject matter and importance of the subject matter to safety or waste isolation.

Peer Review Report: A documented in-depth report of the proceedings and findings of a peer review.

Performance Allocation: This term applies to the process of deriving subsystem and component performance goals from performance objectives. A systematic process of assigning confidence levels with their desired, associated performance goals for the mined geologic disposal systems, subsystems,and components.

Performance Assessment: The process of quantitatively evaluating component and system behavior, relative to containment and isolation of radioactive waste, to determine compliance with the numerical criteria associated with 10 CFR Part 60.

Permanent Closure: The sealing of shafts and boreholes. Permanent closure represents the end of active human intervention with respect to the engineered barrier system.

Performance Confirmation: The program of tests, experiments, and analyses that is conducted to evaluate the accuracy and adequacy of the information used to determine with reasonable assurance that the performance objectives for the period after permanent closure will be met.

Principal Investigator (PI): The individual who has the technical responsibility for a particular technical task. This responsibility includes, but is not limited to, planning and cost control, the day-to-day technical direction and control of the item or activity, and the assembly of a support team to accomplish the item or activity. This term may be synonymous with task leader or project engineer.

Primary Data: Information that can be shown to have been acquired and controlled in a manner consistent with all applicable Quality Assurance requirements and is necessary for the resolution of the NRC performance objectives of 10 CFR 60.

Procurement Document: Procurement requests, purchase requisitions, purchase orders, drawings, contracts, specifications, or instructions used to define requirements for purchase and broadly interpreted by OCRWM to include program guidance letters, work orders, work authorization letters, store orders, memoranda of understanding, field task proposals/agreements, and interagency agreements. Procurement documents or revisions thereto which do not modify the scope of an item or activity to which the QA program is applied are not subject to procurement controls delineated in the QA program. Where modifications to procurement documents include the addition of quality assurance or technical requirements and the item or activity is subject to quality assurance program controls, the procurement documents are subject to review by the quality assurance and affected technical organization.

PROGRAM: U.S. Department of Energy's Civilian Radioactive Waste Management Program

Q-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.

Qualification (of Data): A formal process intended to provide a desired level of confidence that data are suitable for their intended use.

Qualification Testing: Demonstration that an item meets design requirements.

Qualified Data: Data initially collected under a 10 CFR 60, Subpart G quality assurance program or existing data qualified in accordance with Appendix A Section 20 of this document.

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

Quality Activities List: In the MGDS 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 system or man-made aspects of the Mined Geologic Disposal System, including the overall design of the facilities and waste package. This includes the various studies that are performed for, or in support of, the investigation, exploration, site characterization (including radiological and meteorological), design bases development, licensing, construction, operation, monitoring, performance evaluation, or closure of the Mined Geologic Disposal System or activities related thereto.

Scientific Notebook: A document which may be used to provide a written record of the methodology and 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.

Site Characterization: The program of exploration and research both in the laboratory and in the field that is undertaken to establish the geologic conditions and the ranges of parameters of a particular site that are relevant to the procedures under 10 CFR Part 60. Site characterization includes borings, surface excavations, excavation or exploratory shafts, limited subsurface lateral excavations and borings, and in-situ testing at depth as needed to determine the suitability of the site for a geologic repository. It does not include preliminary borings and geophysical testing needed to decide whether or not site characterization should be undertaken.

Technical Review: A documented, traceable, in-depth, critical review, of documents, materials, or data that fall within the state of the art, conducted to evaluate 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 provided to personnel to develop and demonstrate initial proficiency in the application of selected requirements, methods, and procedures, and to adapt to changes in technology, methods, or job responsibilities.

Underground Facility: The underground structure, including openings and backfill materials, but excluding shafts, boreholes, and their seals.

Waste Acceptance Process Activities: The activities through which documentation and data are collected and prepared to support compliance with the Waste Acceptance Preliminary Specification. This includes activities associated with research and development that is essential to qualification of the waste form: control of materials, equipment, facilities, and processes that are essential to the certification of canistered waste forms.

Waste Acceptance Specification (WAS): The document that identifies the properties and requirements the high-level waste form must meet in order to be accepted for disposal in a Federal Repository.

Waste Form: The radioactive waste materials and any encapsulating or stabilizing matrix (10 CFR 60.2).

Waste Form Compliance Plan (WCP): The document that describes the producer's plan for demonstrating compliance with each Waste Acceptance Specification.

Waste Form Qualification Report (WQR): A compilation of results from waste form testing and analysis that develops, in detail, the case for compliance with each Waste Acceptance Specification.

Waste Package: The waste form and any containers, shielding, packing, and other absorbent materials immediately surrounding an individual waste container.

Validation (QA Records): Validation is the act of reviewing a document or document package to ensure it is complete, authenticated, reproducible, and microfilmable.

QUALITY ASSURANCE REQUIREMENTS DOCUMENT

(QARD)

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