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OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

QUALITY ASSURANCE REQUIREMENTS

for the

CIVILIAN RADIOACTIVE WASTE MANAGEMENT PROGRAM

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REVISION 2

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FOREWORD

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 As a result of the reevaluation, these four documents have been superseded and replaced by DOE/RW-0214, Quality Assurance Requirements Document (QARD) and DOE/RW-0215, Quality Assurance Program Description (QAPD). OGR/B-14, Quality Assurance Requirements for High-Level Waste Form Production, February 1988, has been superseded and replaced by the QARD.

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
CRC:	Chemical Rubber Company
CFR:	Code of Federal Regulations
DOE:	United States Department of Energy
DP:	DOE, Assistant Secretary for Defense Programs
DWPF:	Defense Waste Processing Facility
HLWF:	High-Level Waste Forms
ILP:	Implementing Line Procedure
ISFSI:	Independent Spent Fuel Storage Installation
MGDS:	Mined Geologic Disposal System
MRS:	Monitored Retrievable Storage
NQA-1:	ANSI/ASME Standard NQA-1-1986b - Quality Assurance Program Requirements for Nuclear Facilities
NCR:	Nonconformance Report
NE:	DOE, Assistant Secretary for Nuclear Energy
NRC:	United States Nuclear Regulatory Commission
NUREG:	Nuclear Regulation
NWPA:	Nuclear Waste Policy Act
OCRWM:	DOE, Office of Civilian Radioactive Waste Management
OGR:	Office of Geologic Repositories
PR:	Production Record
Q-List:	Quality List
QA:	Quality Assurance
QAAP:	Quality Assurance Administrative Procedure
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
RD:	Requirements Document
SIPD:	Scientific Investigation Planning Document
WAC:	Waste Acceptance Committee
WAS:	Waste Acceptance Specification
WBS:	Work Breakdown Structure

LIST OF ABBREVIATIONS AND ACRONYMS (Continued)

WCP:	Waste-Form Compliance Plan
WQR:	Waste-Form Qualification Report
WVDP:	West Valley Demonstration Project
YMP:	Yucca Mountain Project
YMPO:	Yucca Mountain Project Office.

INTRODUCTION

GENERAL

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

PURPOSE AND APPLICABILITY

This document defines the quality assurance requirements governing activities affecting quality of all PROGRAM participants unless specifically stated otherwise herein. These 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 18 of this document are in addition to ANSI/ASME NQA-1-1986b (NQA-1) requirements and apply to all PROGRAM elements.

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.

PROGRAM participants 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 technical implementation requirements and criteria of Regulations, DOE Orders, and applicable NUREGs that are to be used when implementing the OCRWM quality assurance program.

NQA-1 has been chosen as the basic document for the OCRWM quality assurance program requirements because DOE Order 5700.6B, Quality Assurance, has endorsed NQA-1 as the preferred standard for quality assurance requirements for the nuclear area and the United States Nuclear Regulatory Commission (NRC) in Regulatory Guide 1.28 has found that the requirements of NQA-1 are acceptable for use in quality assurance programs for reactor design and construction.

Together, DOE/RW-0214, Quality Assurance Requirements Document (QARD) and approved Quality Assurance Program Descriptions (QAPDs) represent the "quality assurance plan" for the Civilian Radioactive Waste Management Program.

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

RESPONSIBILITY

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

QUALITY ASSURANCE PROGRAM BASIS

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

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

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

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

SECTION 1

ORGANIZATION

1.0 GENERAL

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

1.1 QUALITY ASSURANCE PROGRAM MANAGEMENT

The quality assurance organization is responsible for describing, integrating, and monitoring agreed upon quality assurance activities within the scope of the quality assurance program. The quality assurance organization is responsible for ensuring the quality assurance program is described in a quality assurance program description document, integrating quality assurance requirements with line management through review and concurrence of the quality assurance program detailed technical and quality assurance administrative procedures, and monitoring the quality assurance program activities through verification activities that, as a minimum, include surveillances, audits, and assessments.

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

(a) An organizational position at the same or higher organizational level as the highest equivalent manager responsible for performing activities affecting quality

(b) Knowledge and experience in the areas of quality assurance and management

(c) The authority and responsibility to verify the adequacy and implementation effectiveness of 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 responsible for the quality of the delegated work. PROGRAM participants shall describe the major delegations of work involved in establishing the quality assurance program or any part thereof to any other organizations.

1.3 DISPUTE RESOLUTION

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

1.4 ALLEGATION AND QUALITY CONCERN RESOLUTION

Provisions shall be established for individuals to express allegations and quality concerns as outlined or specified in the OCRWM Quality Concerns Directive.

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 for stopping work and for lifting stop work orders/requests

(b) Authorities and responsibilities

(c) Methodology for lifting stop work orders/requests.

SECTION 2

QUALITY ASSURANCE PROGRAM

2.0 GENERAL

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

2.1 QUALITY ASSURANCE PROGRAM

PROGRAM participants shall develop quality assurance program documents that address quality assurance program requirements applicable to their respective PROGRAM scope of work. Quality assurance program documents shall consist of a quality assurance program description (sometimes referred to as a QA Plan) 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 line management of the next higher organizational level. PROGRAM-participants' quality assurance organizations shall review and make recommendations to line management concerning the acceptance of lower-tier quality assurance program descriptions.

2.1.1 PROGRAM Participants' Quality Assurance Programs

PROGRAM participants' quality assurance program description documents shall include:

(a) Descriptions of the management controls and lines of communication that exist with their contractors to assure direction of the quality assurance program

(b) Descriptions of all onsite and offsite organizational elements that function under the cognizance of the quality assurance program and the lines of responsibility

(c) Descriptions of the quality assurance program responsibilities of each of the organizational elements shown on the organizational charts

(d) Descriptions of persons and organizations that have authority to identify and resolve quality problems and of programs that will implement these actions

(e) Identification of existing or proposed quality assurance program administrative procedures

(f) Description of the organizational responsibilities for reviewing, approving, verifying, and validating design criteria and design documents

(g) Description of the inspection program, including organizational responsibilities

(h) Description of the test control program scope

(i) Description of the scope and types of measuring and test equipment to be controlled by the quality assurance program

(j) Description of the method for control of erroneous, rejected, superseded, or otherwise unsuitable data.

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

2.2 REPORTING INDEPENDENCE OF PERSONNEL

If verification personnel are not part of the formal quality assurance organization, they shall have sufficient authority, access to work areas, and organizational freedom to (1) identify quality problems; (2) initiate, recommend, or provide solutions to quality problems through designated channels; (3) verify implementation of solutions; and (4) assure that further processing, delivery, installation, or use is controlled until proper disposition to resolve a nonconformance, deficiency, or unsatisfactory condition has occurred. When verification personnel are not part of the formal quality assurance organization (that is, part of the line organization), then the quality assurance organization shall overview the verification activities.

2.3 PLANNING

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) Determination of the applicability of the quality assurance program to items and activities based on their importance to applicable PROGRAM objectives

(c) Selective application of appropriate quality assurance program requirements and procedural controls (that is, a graded approach) to items and activities

(d) Assignment of responsibilities for quality assurance program control and verification activities

(e) Identification of the specific scientific or technical information to be collected, analyzed, or used

(f) Identification of applicable technical and quality assurance program management control and verification activities

(g) Identification of field, laboratory, and engineering procedures for sampling, testing, and analysis activities

(h) Provisions for the identification of required quality assurance records.

2.4 READINESS REVIEWS

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

(a) Work activity prerequisites have been satisfied

(b) Detailed technical and quality assurance 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 PERSONNEL SELECTION, INDOCTRINATION, TRAINING, AND QUALIFICATION

2.6.1 Supplement 2S-1 and Appendix 2A-1 shall only apply to personnel who conduct inspections and 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.

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

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

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

2.7 SURVEILLANCE

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

(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) Document compliance or noncompliance with requirements and procedures

(3) Identify actual and potential deficiencies and deviations and promote prompt corrective action by cognizant management responsible for performing the work

(4) Provide management information on activities under surveillance

(5) 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) Description of the activity or item under surveillance

(2) Identification of the persons conducting the surveillance

(3) Identification of the persons contacted during the surveillance

(4) List of the requirements governing the activity or item

(5) Summary of the surveillance results that identifies deficiencies, deviations, or exemplary practices observed

(6) Summary of any immediate corrective actions taken.

2.8 MANAGEMENT ASSESSMENT

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

(a) Effectiveness of quality assurance program implementation

(b) Adequacy of planning and procedural controls

(c) Effectiveness of the corrective action system

(d) Adequacy of organizational structure and staffing to implement the quality assurance program

(e) Adequacy of the indoctrination and training program

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

2.9 QUALITY ASSURANCE PROGRAM MANAGEMENT-INFORMATION REPORTING AND TRACKING

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

(1) Status of development and implementation of the quality assurance program

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

(3) Summary of management overview results (exemplary practices shall be reported but need not be tracked).

(b) Quality assurance program management information shall be reported at least quarterly to the appropriate level of management and the next higher PROGRAM-participant 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 ERROR AND DEFICIENCY CONTROL

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

3.2 DESIGN CHANGES

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

3.3 COMPUTER SOFTWARE DESIGN AND CONTROL

3.3.1 Application of Requirements

(a) A computer software design 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.

(b) PROGRAM participants 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 and complexity 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 PROGRAM-participant'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.

3.3.2 Computer Software QA Plan

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

(a) A computer software QA plan 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 software QA plan 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

The computer software QA plan should reference any standards, conventions, techniques, or methodologies which guide the computer software development and describe methods to assure compliance to the computer software QA plan.

(b) Within the computer software QA plan, computer software life-cycle management shall be described. Each PROGRAM participant shall present the specific computer software life-cycle controls for their organization in their computer software QA plan. The following life-cycle elements shall apply, as appropriate, for the specific life-cycle model defined, interpreted, and described in each PROGRAM-participant's computer software QA plan.

(c) 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.

(d) 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.

(e) Implementation Phase

The design shall be translated into a programming language and the implemented computer software shall be debugged. 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.

(f) 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.

(g) 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.

(h) Operations 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 (perfective 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 3.3.3.

3.3.3 Computer Software Verification and Validation

(a) The responsible PROGRAM-participant 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.

(b) 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 shall be accomplished by an independent individual or organization, one who did not work on the original software. The results of verification and validation activities shall be documented.

(c) Verification and/or validation of computer software should be performed in two stages:

(1) By the individual generating or modifying the computer software

(2) By an independent individual or organization (one who did not work on the original computer software).

The first stage 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.

3.3.4 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 implemented in code. Appropriate methods such as inspection, analysis, test, or demonstration shall be applied to accomplish verification objectives.

3.3.5 Validation

(a) The program of validation 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 validation of the software 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 used shall be documented. Alternative approaches may include peer review and comparisons with the results of similar analyses performed with verified computer software. The results of computer software validation shall be documented.

3.3.6 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 baseline changes.

(a) Configuration Identification

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 number

(2) Identifies changes to configuration items by revision

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

(b) Configuration Change Control

Changes to baselined computer software configuration items shall be formally documented. This documentation shall contain a description of the changes, the identification of the originating organization, the rationale for the changes, 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.

(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, and information to support the functions of configuration identification and configuration control.

3.3.7 Documentation

Minimum acceptable computer software life-cycle documentation that has been developed or modified shall be specified in each PROGRAM-participant's computer software QA plan. The documentation provided shall meet the requirements of Subsections 3.3.7.a through 3.3.7.e, as applicable. Additional documentation may also be identified in the computer software QA plan for each PROGRAM-participant's computer software project.

(a) Computer Software Requirements Specification

A specific capability of computer software can be called a requirement only if its achievement can be verified by a prescribed method. 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 requirements 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

(6) Continuing documentation, code listings, and computer software summary forms as required by NUREG-0856.

(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 should be the basis for the computer software verification and validation plans.

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

Computer software verification and 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 validation of the computer software. 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 computer software verification and any 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

3.3.8 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 Validation Review

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

3.3.9 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.

3.3.10 Media Control and Security

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

3.3.11 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 Subsection 3.3 requirements and the needs of the PROGRAM-participant'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.

3.3.12 Computer Software Application

(a) Technical calculations using computer software shall be performed with applicable computer codes and with computer software operating procedures defined sufficiently to allow independent repetition of the entire computation. Validation of the software shall be performed for the specific application. If the software has not been validated previously, the software shall be validated and documented.

(b) PROGRAM participants shall establish procedures for controlling the application of verified or validated computer software to technical calculations and shall determine which technical calculations are subject to these controls.

(c) PROGRAM participants 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 should include documentation of technical calculations performed and should include independent review as part of the calculations.

(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.

3.4 TECHNICAL REVIEWS

(a) A technical review shall be performed when the information or document under review is within the state of the art and is based on accepted standards, criteria, principles, and practices.

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

(c) Technical reviews shall be performed by individuals with sufficient technical knowledge of the area under review to be able to render an opinion. Individuals shall be independent of those who performed the work.

(d) The results of technical reviews 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 PROGRAM-participants' technical and quality assurance organization representatives to assure that applicable 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, AND DRAWINGS

5.0 GENERAL

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

5.1 REVIEWS

An independent review of instructions, procedures, and drawings shall be performed by the originating organization to assure technical adequacy, including the correct translation of design requirements, and inclusion of quality requirements.

5.2 PROCEDURES LIST

PROGRAM participants shall maintain a controlled list of QA Administrative Procedures and detailed technical procedures that are applicable to the quality assurance program.

SECTION 6

DOCUMENT CONTROL

6.0 GENERAL

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

6.1 CONTROL

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

6.2 CONTROL SYSTEM

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

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

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

(c) Documentation and maintenance of review comments and resolutions

(d) Identification and control of documents released prior to completing the approval process

6.3 CONTROLLED DOCUMENTS

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

SECTION 7

CONTROL OF PURCHASED ITEMS AND SERVICES

7.0 GENERAL

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

7.1 SUPPLIERS' QUALITY ASSURANCE PROGRAMS

When required by procurement documents, suppliers' Quality Assurance programs shall be reviewed and accepted prior to initiation of activities affected by their quality assurance programs.

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

PROGRAM participants' QA Program documents shall provide a list of special processes that the PROGRAM participant will perform or be responsible for.

9.2 QUALITY ASSURANCE ORGANIZATION INVOLVEMENT IN QUALIFICATION ACTIVITIES

The quality assurance organization shall be involved in qualification activities to help assure satisfactory performance. 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

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

SECTION 10

INSPECTION

10.0 GENERAL

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

10.1 RECORDS

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

(a) Inspection procedure

(b) Characteristics inspected

(c) Identification of the inspection criteria or reference documents used to determine acceptance

(d) Identification of the specific equipment used during the inspection

(e) Identification of special expertise used.

SECTION 11

TEST CONTROL

11.0 GENERAL

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

11.1 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 PRECISION AND ACCURACY

Precision and accuracy considerations shall be identified in test procedures.

SECTION 12

CONTROL OF MEASURING AND TEST EQUIPMENT

12.0 GENERAL

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

12.1 ACCURACY OF CALIBRATION STANDARDS

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

SECTION 13

HANDLING, STORAGE, AND SHIPPING

13.0 GENERAL

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

SECTION 14

INSPECTION, TEST, AND OPERATING STATUS

14.0 GENERAL

The provisions of NQA-1 Basic Requirement 14 shall apply.

SECTION 15

CONTROL OF NONCONFORMING ITEMS

15.0 GENERAL

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

SECTION 16

CORRECTIVE ACTION

16.0 GENERAL

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

16.1 TREND ANALYSIS

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

16.2 SIGNIFICANT CONDITIONS ADVERSE TO QUALITY

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

SECTION 17

QUALITY ASSURANCE RECORDS

17.0 GENERAL

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

17.1 COMPLIANCE WITH OCRWM RECORDS-MANAGEMENT PROGRAM

Each PROGRAM participant shall develop quality assurance records programs or procedures appropriate for their scope of work. These programs and procedures shall meet the requirements of Section 4, Subsection 5.5, and Appendices A, B, E, F, and G, of DOE/RW-0194, Records Management Policies and Requirements as they apply to the Program participants.

SECTION 18

AUDITS

18.0 GENERAL

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

18.1 TECHNICAL CONSIDERATIONS

The audit program shall address the quality of products and technical work as well as programmatic compliance. Audit team members selected for technical consideration purposes to participate in audits shall have technical expertise or experience in the work being audited and shall be indoctrinated in audit techniques as a minimum. Management at all levels within each PROGRAM-participant'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 overall quality assurance program adequacy and effectiveness and the results reported to responsible management for review, assessment, and appropriate action.

18.3 INTERNAL AUDIT SCHEDULING

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.

The schedule for 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 internal and extrinsic audits

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

18.4 EXTERNAL AUDIT SCHEDULING

(a) PROGRAM participants shall annually audit implementation of quality assurance programs of the next lower-tier PROGRAM participants for which they are responsible. A preaward survey may serve as the first annual audit if the scope of the survey is similar to the scope of other audits where the scope of work is comparable.

(b) After award of the contract and based on the determination of the quality assurance program applicability to classification of each item or service to be procured, the need for external audits shall be evaluated. A determination may be made that external audits are not necessary for procuring items that are:

(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.

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

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 18. 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 GRADED 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.

3.2 SCIENTIFIC INVESTIGATIONS

3.2.1 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) The scientific notebook system and the technical procedures system are two approaches that may be used to control scientific investigation activities. The scientific notebook system may be used by qualified individuals who are required to use a high degree of professional judgment or trial-and error-methods or who are developing the methodology by which an activity will be accomplished. When the scientific notebook system is used, the scientific investigation planning document (SIPD) shall control the 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) Technical procedures are required when it is not possible to deviate from a prescribed sequence of actions without endangering the validity of the results.

(e) Technical procedures shall be reviewed for technical adequacy and approved by qualified persons other than those who prepared the procedures. Changes to technical procedures for conducting scientific investigations shall be reviewed and approved by the same organizations that performed the original review and approval unless the PROGRAM participant designates the responsibility in writing to another organization.

(f) The technical aspects of procedures may be modified with the approval of an appropriately qualified reviewer if the change is within the scope of the scientific investigation planning document, the activity can be repeated, and the activity does not potentially impact the waste isolation capability of the site or interfere with other site characterization activities.

(g) 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.

3.2.2 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) Planning shall assure the compatibility of scientific investigations with any conceptual or mathematical models used at each applicable stage. Planning shall establish provisions for the evaluation of data quality to assure that generated data is valid, comparable, complete, representative, precise, and accurate. Known sources of error and uncertainty and input data that is suspect or whose quality is beyond the control of the performing organizations shall be identified. These 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 environmental conditions are maintained.

(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.

3.2.3 Use of Data

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.

3.2.4 Accuracy of Data

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

3.2.5 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.

3.3 DATA COLLECTION AND ANALYSIS

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

(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.

3.4 DATA COLLECTION, ANALYSIS, AND REVIEW

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. Collected data shall be reported so as to relate it to information needs and issue resolution.

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

3.6 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, and procedures including applicable revisions

(b) Item or sample investigated

(c) Date of scientific investigation

(d) Identification of the persons performing the scientific investigation and the performers' organizations

(e) Results and acceptability for intended use

(f) Action taken in connection with any deviations noted

(g) Persons evaluating scientific investigation results and evaluators' organizations

(h) Identification of equipment used.

3.7 QUALIFICATION OF DATA OF INDETERMINATE QUALITY

Data that was 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.

(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) Environmental 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.

3.7.1 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.

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

5.1 REVIEWS

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

6.0 AMPLIFICATION OF QARD, SECTION 6 - DOCUMENT CONTROL

6.1 DOCUMENT PREPARATION

The document control system for document preparation, review, approval, and issuance 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 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 source, requirement, or use document. Traceability of samples from initial acquisition through final disposition is required. Measures shall be taken to preclude the use of samples that cannot be identified.

8.4 ARCHIVAL SAMPLES

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

9.0 AMPLIFICATION OF QARD SECTION 9 - CONTROL OF PROCESSES

9.1 APPLICABILITY

The requirements of this Section 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 and do not apply 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 SAMPLES

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

13.2 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 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 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 and do not apply to scientific investigation activities.

18.0 AMPLIFICATIONS OF QARD SECTION 18 - QUALITY ASSURANCE AUDITS

18.1 AUDIT SCHEDULE

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

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 18. 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 2.6. 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 of QARD Section 2.8, management assessments shall evaluate conformance to the WAS.

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 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) The waste form

(2) The waste canister

(3) The canistered waste form

(4) The 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 WAS shall be controlled in accordance with QARD Section 3.3.

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

1.1 The quality assurance requirements specified in the Office of Storage and Transportation Systems Quality Assurance Plan for the Transportation Casks Systems Development Program are applicable to the PROGRAM's radioactive material transportation cask systems. The quality assurance programmatic guidance of REGULATORY GUIDE 7.10 - Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material amplify the quality assurance program requirements for the packaging used in radioactive material transportation systems.

APPENDIX D

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

[RESERVED]

ATTACHMENT I

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.

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.

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

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

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.

Confirmatory Testing: For the Mined Geologic Disposal System, 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.

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

Design Activities: Activities related to the design process, including data collection and 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.

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

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

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

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

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

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

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

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.

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.

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 barriers 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, design bases development, licensing, construction, operation, monitoring, performance evaluation, or closure of the Mined Geologic Disposal System.

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

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

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

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 (10CFR60.2).

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.

ADDENDUM A-1

RATIONALE ON THE APPLICABILITY OF NRC REQUIREMENTS TO SCIENTIFIC INVESTIGATIONS

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

PURPOSE

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

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

DISCUSSION

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

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

1. Cutting and retrieving core specimens from boreholes
2. Waxing core specimens
3. Identifying the minerals in a sample of tuff through X-ray diffraction analysis of a powdered specimen
4. Identifying minerals in a sample of tuff using thin-section analysis
5. Preparing and analyzing geophysical logs from a borehole
6. Determining ground water level through monitored boreholes
7. Determining the chemistry of pore waters extracted from a core
8. The shaping of a piece of core for resistivity or induced polarization measurements.

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

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

The criteria in 10 CFR 50, Appendix B represents an adequate set of controls for the analysis used in scientific investigations without the need to categorize such processes as "special". Sections of the QARD which are applicable to the topic of this report are:

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

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

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

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

Section 6: Document Control - Applicable controlled, current quality and design documents shall be available at the location where they are to be used.

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

Section 8: Identification and Control of Materials, Parts, and Components - Procedures shall be developed and implemented to ensure that samples are identified and controlled in a manner consistent with their intended use. Further amplification of these requirements for the MGDS are addressed in Appendix B.

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

Section 13: Handling, Shipping, and Storage - Measures shall be established to control packaging, handling, storage, shipping, cleaning, and preservation of material and equipment to prevent damage, loss, or deterioration. Further amplifications of these requirements for the Mined Geologic Disposal System and the waste acceptance process activities of High-Level Waste Form production are addressed in Appendices A and B respectively.

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

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

Section 17: Quality Assurance Records - Records that furnish documented evidence of quality shall be specified, prepared, and maintained in accordance with Administrative Procedures. Further amplifications of the requirements for the waste acceptance process activities of the High-Level Waste Form Production are addressed in Appendix B.

Section 18: Audits - All activities affecting quality will be subject to planned and scheduled internal and external audits to assure that procedures and activities comply with the overall QA program and to determine their effectiveness. The audit program will be supplemented by independent surveillance activities. Amplifications of these requirements applicable to Mined Geologic Disposal System and the waste acceptance process activities of High-Level Waste Form Production are addressed in Appendices A and B, respectively.

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

While it is true that standards are included in the analysis of materials (for example, standard tables for the identification of minerals from X-ray diffraction data), there are no standards for the sample itself. That is to say there may or may not be clay in the sample, and one or more clay mineral species may be present. Similarly a technician may use standard solutions (National Bureau of Standards [NBS]) to calibrate the recording instrument prior to a chemical analysis. This calibration indicates that the instrument is reading values within an acceptable range and sensitivity.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

It is important to note that the QARD allows at least two basic kinds of documentation which can be used for quality assurance, documentation, and control of scientific work. These are the scientific notebook system and the technical implementing procedure system. The scientific notebook system will generally be used by qualified individuals who are using a high degree of professional judgment or trial-and-error methods or who are developing the methodology by which an activity will be accomplished. The technical implementing procedure system will generally be used when qualified technicians are performing repetitive work which does not include the use of a high degree of professional judgment or trial-and-error methods in the performance of the work.

Detailed technical implementing procedures are required when it is not possible to deviate from a prescribed sequence of actions, without endangering the validity of the results that will be obtained from the work. Logbooks or appropriate forms or both are used, particularly in repetitive work, to document the performance of the work according to the technical implementing procedure, and to maintain absolute control over all other aspects of the work. The following indicates where the NRC Review Plan requirements are implemented for procedures and scientific notebooks.

NRC Review Plan Requirement 11.1

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

Response

The work is controlled in QARD Section 3 by requiring the preparation of SIPDs for individual activities.

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

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

The QARD requires QA organization overview of activities affecting quality.

NRC Review Plan Requirement 11.2

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

Response

This requirement is stated in QARD Appendix A, Section 3.0.

NRC Review Plan Requirement 11.3

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

Response

This requirement is stated in QARD Appendix A, Section 3.0.

NRC Review Plan Requirement 11.4

"Test procedures or instructions provide the following:

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

Response

This requirement is stated in QARD Appendix A, Section 3.0. These requirements are not applicable to scientific notebooks since the end product of research or experiment is data which are used to establish acceptance limits.

b. "Instruction for performing the test."

Response

This requirement is stated in QARD Appendix A, Section 3.0. This requirement is not applicable to scientific notebooks since the purpose of experiment or research is to establish methodology.

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

Response

This requirement is stated in QARD Appendix A, Section 3.0. Inspections are not applicable to scientific investigation. This requirement is not applicable to scientific notebooks since, at that phase of research, the methodology or process is not established.

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

Response

This requirement is stated in QARD Appendix A, Section 3.0.

f. "Methods of data analysis."

Response

For technical implementing procedures this requirement is stated in QARD Appendix A, Section 3.0. This requirement is not applicable to scientific notebooks as data are the end product.

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

Response

This requirement is stated in QARD Appendix A, Section 3.0. It is not applicable to scientific notebooks as the activity methodology has not been established at this point. Therefore, the data or its format cannot be readily determined.

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

Response

This requirement is stated in QARD Appendix A, Section 3.0.

NRC Review Plan Requirement 11.5

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

Response

This requirement is stated in QARD Appendix A, Section 3.0.

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

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

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

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

The controls placed on scientific investigations by QARD Appendix A, Section 3.0 require scientific investigations to be planned. The planning requirements of QARD Section 2.3 provide for sufficient controls to preclude inadvertent interruption of the investigations and to ensure operational compatibility with other site characterization activities.

In summary, since Criterion XIV focuses on the safe operation of equipment and systems (engineered items) being tested and inspected and scientific investigations are prior to repository construction and operation, an exception has been taken in the QARD such that Criterion XIV applies only to engineered items and not to scientific investigations. The controls established in the QARD Appendix A, Section 3.0 for scientific investigations are sufficient to assure the proper conduct of scientific investigations and their impact on site characterization activities.

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