ENCLOSURE I

QARD APPROVED REVISION 2

U. S. DEPARTMENT OF ENERGY

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

QUALITY ASSURANCE REQUIREMENTS

for the

CIVILIAN RADIOACTIVE WASTE MANAGEMENT PROGRAM

Dwight Shelor, Acting Director
OCRWM Office of Quality Assurance

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Date

Approved
Samuel Rousso, Acting Director
Office of Civilian Radioactive
Waste Management

2/1/90
Date

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TABLE OF CONTENTS

TABLE OF CONTENTS (Continued)

TABLE OF CONTENTS (Continued)

TABLE OF CONTENTS (Continued)

TABLE OF CONTENTS (Continued)

TABLE OF CONTENTS (Continued)

TABLE OF CONTENTS (Continued)

TABLE OF CONTENTS (Continued)

TABLE OF CONTENTS (Continued)

FOREWORD

CGR/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 As a result of the reevaluation, these four documents have been superseded and replaced by DOE/RW-0214, Quality Assurance Requirements Document (QARD) and DOE/RW-0215, Quality Assurance Program Description (QAPD). CGR/B-14, Quality Assurance Requirements for High-Level Waste Form Production, February 1988, has been superseded and replaced by the QARD.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 valication 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 CCBM 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 inadvertant 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 review 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.

3.0 AMPLIFICATION OF QARD SECTION 3 - IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, COMPONENTS, AND SAMPLES

3.1 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.

3.2 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.

3.3 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.

3.4 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 instrument or chemical analysis, or both.

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

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

QUALITY ASSURANCE REQUIREMENTS DOCUMENT
QAR, REV. 2

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

Accession No.: HQO. 900208.0004

ENCLOSURE II

ANNOTATED VERSION OF QARD APPROVED REVISION 2

Annotated version of approved QARD,
Rev.2 dated January 17, 1990

U. S. DEPARTMENT OF ENERGY

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

QUALITY ASSURANCE REQUIREMENTS

for the

CIVILIAN RADIOACTIVE WASTE MANAGEMENT PROGRAM

~~Lake Barrett~~ Dwight Shelor, Acting Director — Date
OCRWM Office of Quality Assurance

Approved — Date
~~Charles E. Kay~~Samuel Rousso, Acting Director
Office of Civilian Radioactive
Waste Management

REVISION ~~1~~2

January 17, 1990

NOTES TO READER

This annotated version of the Revision 2 has been prepared to provide the reader an explanation of how the document has evolved to its present form.

Revision 2 of the QAR (now called "QARD") represents a change in format to QAR Revision 1 to accommodate the objective of creating a single generic baseline document that addresses quality assurance requirements for all OCRWM Program Elements. This revision does not deviate from the Quality Assurance requirements already approved for the Mined Geologic Disposal System (MGDS). Instead, the requirements unique to MGDS have been moved to Appendix A and requirements applicable to Waste Acceptance Process Activities are included as Appendix B. As quality assurance requirements for Transport of Spent fuel and High-Level Nuclear Waste and Monitored Retrieval Storage become further developed, they will be incorporated as Appendices C and D respectively.

For this reason, it is felt Revision 2 will provide a more uniform basis for program quality, will be more easily understood, and will facilitate more readily its implementation.

I. Explanation of Text Enhancements:

1) Strike out - i.e. "...~~A three tier~~..."
is used to denote the deletion of full text or partial content.

2) Shading - i.e. "...Verification Activities..."
is used to denote the addition of new text or content.

3) *Italics - i.e. "...Quality Level 1..."*
is used to denote the moving of text or content as written in the Revision 1 to another area of the Revision 2. This form of text enhancement is used in conjunction with a note typed in bold to inform the reader where the content or text has been moved, ie ... **"The following italicized text has been moved to Appendix A."**

4) Numbering of sections within the Appendices correlates to the major Sections of the QARD. Where no amplification is required, there is no correlative section number in the Appendices.

II. Explanation of Document Format Changes:

1) Section 2.5 "Quality Levels and Graded Quality Assurance" as stated in QAR Revision 1 has been amended because the level of detail was too restrictive for the PROGRAM Level.

2) The following is detailed explanation of editoral changes to incorporate comment resolutions and format changes for the incorporation of Appendix H "Requirements for Computer Software from NNWSI/88-9 "Quality Assurance Plan", Revision 1.

   a) Section 3.3.5(a); added the words "The program of validation of computer software shall be documented." to first sentence of first paragraph, and the words "Where validation of the software has been performed," to beginning of last sentence of first paragraph,

   b) Section 3.3.7(d); added the words "any plans for" to first sentence of first paragraph and the word "any" to second sentence of second paragraph.

   c) Section 3.3.12(a) the following stated in part was added "Validation of the software ... shall be validated and documented".

II. Explanation of Document Format Changes (continued):

d) Paragraph 3.3.2(d), (e) and (f); deleted the words "and validation".

e) Section 3.3.12(b) the following words stated in part; "and shall determine .... to these controls" were added.

These changes clarifies the requirement for validation of the models and software for specific applications. Specifically the requirement for validation is moved from subsection 3.3.2 to subsection 3.3.12. Since all design, site characterization and performance assessment application are not known at time of code development, it is not appropriate to mandate validation during development but to mandate it prior to any specific applications of the model/software. This is a clarification and not a reduction in requirements.

3) Original Appendix A, titled "Quality Assurance Program Documents listing," has been deleted.

4) Appendix A of QARD Revision 2 is the result of moving the Quality Assurance Program Requirements for the Mined Geologic Disposal System (MGDS) from the main body of the QAR, Revision 1 to a document that provides amplification of requirements unique to the MGDS and is subordinate to the main body of the QARD Revision 2.

5) Appendix B of QAR Revision 1 was titled "Rationale on the Applicability of NRC Requirements to Scientific Investigations." The content of this Appendix has been moved to Addendum A-1 of QARD Revision 2.

6) Appendix B of QARD Revision 2, contains amplifications of Quality Assurance Requirements previously contained in the March 1989, Revised Draft, OGR/B-14, "Quality Assurance Requirements for High-Level Waste Form Production," and is subordinate to the main body of the QARD.

7) Appendices C and D of Revision 2 have been added for format purposes to reserve space for future amplifications applicable to the Transport of Spent fuel and High-Level Nuclear Waste and Monitored Retrieval Storage.

8) The Glossary in QAR Rev.1 is now contained as Attachment I in QARD, Rev.2.

QUALITY ASSURANCE REQUIREMENTS
for the
CIVILIAN RADIOACTIVE WASTE MANAGEMENT PROGRAM

TABLE OF CONTENTS

TABLE OF CONTENTS (Continued)

TABLE OF CONTENTS (Continued)

TABLE OF CONTENTS (Continued)

TABLE OF CONTENTS (Continued)

TABLE OF CONTENTS (Continued)

TABLE OF CONTENTS (Continued)

TABLE OF CONTENTS (Continued)

TABLE OF CONTENTS (Continued)

FOREWORD

OGR/B-3, Quality Assurance Plan for High Level Radioactive Waste Repositories, August 1986; DOE/RW-0032, Quality Assurance Management Policies and Requirements, October 1985; DOE/RW-0103, Quality Assurance Directive, October 1986; and the "Director's Statements on Managing for Quality and Quality Assurance," July 14, 1987, were reevaluated in light of Congressional redirection of the Civilian Radioactive Waste Management Program in December 1987 and a major reorganization of the Office of Civilian Radioactive Waste Management in April 1988. As a result of the reevaluation, ~~the~~ these four documents have been superseded and replaced by DOE/RW-0214, Quality Assurance Requirements Document (QARD) ~~for the Civilian Radioactive Waste Management Program~~ and DOE/RW-0215, Quality Assurance Program Description ~~for the Civilian Radioactive Waste Management Program~~ (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 ~~ACRONYMS~~ABBREVIATIONS AND ~~ABBREVIATIONS~~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 Procedures
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
~~QAGG: Quality Assurance Coordinating Group~~
QAL: Quality Activities List
QAPD: DOE/RW-0215, Quality Assurance Program Description ~~for the Civilian~~ Radioactive Waste Management Program
QARD: DOE/RW-0214, Quality Assurance Requirements Document ~~for the Civilian Radioactive Waste Management Program~~
RD: Requirements Document
SEMP: Systems Engineering Management Plan
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: ~~Nevada Operations Office,~~ Yucca Mountain Project Office.

INTRODUCTION

GENERAL

Quality achievement is a continuing responsibility of management at all levels in the U.S. Department of Energy's Civilian Radioactive Waste Management Program (PROGRAM). Well defined quality assurance (QA) programs describing the ~~set of~~ 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 ~~Repository System~~ (MGDS), Waste Acceptance Process Activities of High-Level Waste Form Production, Transport of Spent Fuel and High-Level Nuclear Waste, and ~~the~~ Monitored Retrievable Storage. ~~facility, transportation and if required, the Federal Interim Storage Facility.~~

The amplifications ~~specified~~ identified in Sections 1 through 18 of this document are in addition to ANSI/ASME NQA-1-1986b (NQA-1) requirements and ~~apply only to the geologic repository. Amplifications specific to the monitored retrievable storage facility, transportation, and if required, the Federal Interim Storage will be provided in subsequent versions of this document.~~ to all PROGRAM elements.

~~The quality assurance requirements specified in OCRWB-14, Specification of Quality Assurance Requirements for the High-Level Waste Form Production are applicable to the PROGRAM's waste form producers.~~ **NOTE: The following italicized text has been moved to Appendix C, paragraph 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.*

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.

SECTION 1

ORGANIZATION

1.0 GENERAL

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

1.1 QUALITY ASSURANCE PROGRAM MANAGEMENT

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

(d) No other duties or responsibilities ~~that are~~ unrelated to quality assurance ~~and~~ 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 ~~a Project Office~~ 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. ~~directly to the PROGRAM Director without fear of reprisal. The provisions shall address allegations of inadequate quality from employees of PROGRAM participants and persons outside the PROGRAM. Allegations shall be investigated and resolved.~~

1.5 STOP WORK PROVISIONS

Provisions for issuing and lifting stop work orders/requests shall be developed and implemented. ~~The~~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 ~~(hereafter referred to as the QA PROGRAM)~~ shall consist of a quality assurance program description (sometimes referred to as a QA Plan) and detailed technical and quality assurance administrative procedures. The ~~QA Program~~quality assurance program shall meet the requirements established by this document. The quality assurance program descriptions ~~(or QA Plans)~~ shall be reviewed and ~~approved~~ acceptedin a timely manner by line management of the next higher ~~PROGRAM~~-organizational level ~~in a timely manner~~. PROGRAM-participants' quality assurance QA organizations shall review and make recommendations to line management concerning the ~~approval~~acceptance of lower-tier quality assurance program descriptions. ~~(or QA Plans).~~

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 ~~noted~~ 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 ~~of~~ 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 ~~of~~ 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) ~~Assignment of quality levels~~ Determination of the applicability of the quality assurance program to items and activities based on their

importance to ~~applicable radiological safety, waste isolation, or other~~ PROGRAM objectives

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

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

(e) Identification of the specific scientific or technical information to be collected, analyzed, or used ~~for design, performance assessment, or site characterization~~

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

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

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

2.4 READINESS REVIEWS

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

(a) Work activity prerequisites have been satisfied

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

(c) Personnel have been suitably trained and qualified.

2.5 ~~QUALITY LEVELS AND~~ GRADED QUALITY ASSURANCE PROGRAM

2.5.1 Method

NOTE: The following italicized text has been move to Appendix A Section 2.1 and Appendix B Section 2.3

~~The classification of quality levels shall be performed in accordance~~ A methodology shall be developed to identify those items and activities to which the quality assurance program applies, *with the guidance provided in NUREG-1318, Technical Position on Items and Activities in the High-Level Waste Geologic Repository Program Subject to Quality Assurance Requirements, April 1988,* ~~and the following amplifications.~~

~~2.5.1 Classification of Quality Levels~~

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

~~(a) Quality Level 1 (QL1). QL1 is the classification to be assigned to PROGRAM items and activities requiring application of the most stringent quality assurance requirements and procedural controls because of their importance to public radiological health and safety and waste isolation. The assignment of QL1 imposes the applicable quality assurance requirements of 10 CFR 60, Subpart G and ANSI/ASME NQA-1-1986b. OCRWM and each Project Office shall establish a Q-List and a Quality Activities List.~~

~~(b) Quality Level 2 (QL2). QL2 is the classification to be assigned to PROGRAM items and activities requiring application of additional quality assurance requirements and procedural controls because of their importance to the success of the PROGRAM. The assignment of QL2 imposes the appropriate quality assurance requirements of ANSI/ASME NQA-1-1986b. QL2 will be assigned as a minimum of the following categories.~~

~~(1) Items and activities designed to minimize nonradiological health and safety hazards to the public and PROGRAM workers.~~

~~(2) Items and activities designed to protect workers from radiological hazards exceeding the limits of 10 CFR 20~~

~~(3) Items whose failure, emission, or degradation could affect the operational reliability, maintainability, and performance of engineered structures, systems, and components~~

~~(4) Items and activities of special programmatic importance designated as such by the appropriate director or program manager~~

~~(c) Quality Level 3 (QL3). QL3 is the classification to be assigned to PROGRAM items and activities requiring routine quality assurance requirements and procedural controls to assure proper performance or service. The assignment of QL3 imposes the use of routine managerial, administrative, scientific, engineering, industry, and laboratory practices.~~

~~2.5.2 Graded Quality Assurance~~
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 of schedule or cost or both~~ 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 testing activities to verify conformance of an 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. ~~in process.~~

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

~~2.7.2~~ (b) Surveillance shall be conducted to accomplish the following objectives:

~~(a)~~ (1) Verify quality of ~~Monitor~~ work in progress

~~(b)~~ (2) Document compliance or noncompliance with requirements and procedures

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

~~(d) Promote prompt corrective action by cognizant management responsible for performing the work~~

~~(e)~~ (4) Provide management information on activities under surveillance

~~(f)~~ (5) Verify timely implementation of corrective action.

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

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

~~(a)~~ (1) Description of the activity or item under surveillance

~~(b)~~ (2) Identification of the persons conducting the surveillance

~~(c)~~ (3) Identification of the persons contacted during the surveillance

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

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

~~(f)~~ (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 ~~the~~ 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

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

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

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

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

~~2.9.2~~(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. ~~at least quarterly.~~

SECTION 3

DESIGN CONTROL

3.0 GENERAL

The provisions of NQA-1 Basic Requirement 3 and Supplement 3S-1 shall apply to design, from conceptual design through final design. The following 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.~~or Section 18 as applicable.~~

3.2 DESIGN CHANGES

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

~~3.3 COMPUTER SOFTWARE CONTROL~~

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

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

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

~~(a) Criteria for application of the requirements of this document~~

(b) Methods to be used to develop functional performance requirements, to translate those requirements into a detailed design, and to implement that design in computer software

(c) Documentation to be prepared, reviewed, and maintained during computer software design, development, implementation, test, and use

(d) Methodology for establishing computer software baselines and baseline changes and for tracking changes throughout the life of the computer software

(e) Process to be used for verification and validation of computer software

(f) Procedure for reporting and documenting computer software discrepancies, evaluating impacts of discrepancies on previous calculations, and determining appropriate corrective action

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

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

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

(a) A description of the computer software development history that identifies specific computer software versions and other basic information about the evolution of the computer software

(b) An explanation of the mathematical model(s) and derivation of the numerical methods used in the computer software design. Physical and mathematical assumptions on which the

~~computer software is based shall be listed along with an explanation of the capabilities and limitations inherent in the computer software.~~

~~(c) Instructions enabling users to run the computer software and a description of anticipated errors with user responses~~

~~(d) A description of formal reviews and of verification and validation testing~~

~~3.3.5 Computer software testing shall be performed for those inputs and conditions necessary to exercise the computer software to assure that unintended functions that would degrade the computer software will not be performed. The documentation shall include test boundary conditions and provide suitable benchmarks or sample problems.~~

~~3.3.6 If parameters that control experiments are not sufficiently defined to allow for validation, an independent assessment shall be performed to determine the degree of computer software validation achievable.~~

~~3.3.7 Computer software that was not developed under a documented quality assurance program meeting the requirements of Subsection 3.3.1 may be qualified for use provided that the computer software is verified and validated. A computer software baseline is to be established and controlled, and applicable documentation is to be prepared to support its use.~~

3.3 COMPUTER SOFTWARE DESIGN AND CONTROL

Note: The following text was taken from NNWSI/88-9 "Quality Assurance Plan", Appendix H, "Requirements for Computer Software," Revision 1, with only editorial changes made to properly integrate the material into the QARD.

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 and validation 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-and-validation 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-and-validation 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 shall become 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, ~~interactions~~ 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 ~~in support of site characterization or design, analysis, testing, developmental activities, performance assessment, and operation of engineered items.~~ 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

~~3.4.1~~(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.

~~3.4.2~~(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.

~~3.4.3~~(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.

~~3.4.4~~(d) The results of technical reviews shall be documented.

NOTE: The following italicized text is now contained in Appendices A and B of this revision.

3.5 PEER REVIEWS

3.5.1 Peer reviews shall be performed in accordance with the guidance provided in NUREG-1297, Peer Review for the High-Level Waste Repositories Generic Technical Position, February 29, 1988.

NOTE: The following italicized text is now contained in Appendix A of this Revision.

3.6 SCIENTIFIC INVESTIGATIONS

3.6.1 Control of Scientific Investigations

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

The scientific notebook system and the technical procedures system are two approaches that may be used to control scientific 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 shall control the activities.

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

3.6.2 Planning

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

(a) Description of work to be performed

(b) Rationale and justification for the information to be obtained

(c) Proposed methodology

(d) Rationale and justification for the proposed methodology

(e) References to applicable documents

(f) Identification, explanation, and justification for areas where scientific notebooks are to be used

(g) Description of constraints

(h) Description of the application of the results

(i) Description of schedules and milestones.

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

The range, accuracy, and precision of equipment used for scientific investigations shall be specified in order to be commensurate with requirements. In developing quality assurance 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 requirements are found to be necessary, special quality or performance verification requirements shall be established and described to govern the use of the equipment.

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

3.6.3 Data Collection and Analysis

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

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

3.6.4 Use of Data

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

3.6.5 Data Identification and Traceability

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

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

3.6.6 Data Recording, Storage, and Retrievability

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

Records shall, as appropriate, identify the following elements:

(a) Scientific investigation requirements, plans, and procedures including applicable revisions

(b) Item or sample investigated

(c) Date of scientific investigation

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

(e) Results and acceptability for intended use

(f) Action taken in connection with any deviations noted

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

(h) Identification of equipment used

3.6.7 Qualification of Data of Indeterminate Quality

Data that was not collected under the control of a quality assurance program meeting the quality assurance 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. This data may include information collected from such sources as professional journals, technical reports, and symposia proceedings but does not include design reference codes and standards (for example, ASME Boiler and Pressure Vessel Code, ASTM standards, and CRC Handbooks). The organization using the data shall define the data-qualification process that describes how data will be assessed for quality characteristics, such as accuracy, precision, completeness, representativeness, and comparability. Acceptable qualification methods include any one or a combination of peer review, corroborating data, or confirmatory testing. Consideration shall be given to the following factors when available and measurable:

(a) Qualifications of personnel or organizations generating the data

(b) Technical adequacy of the equipment and procedures used in the scientific investigation

(c) Environmental conditions

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

(e) Amount of corroborating data or confirmatory testing

(f) Extent to which data demonstrates properties of interest (for example: physical, chemical, geologic, mechanical)

(g) Extent to which conditions generating the data may partially meet requirements of this document

(h) Prior uses of the data and associated verification process

(i) Prior professional reviews of the data

(j) Extent and reliability of the documentation associated with the data

(k) Degree to which data-generating processes were independently audited

(l) Importance of the data to show that performance objectives were met

The results of data qualification activities shall be documented. The information to be found in peer review reports is addressed in Section 35. Reports of data qualification by use of corroborating data shall include the following elements:

(a) Identification of the corroborating data source

(b) Tabulation of the corroborating data

(c) Description of the corroborating data relationship to the data being qualified

(d) Technical justification for use of the corroborating data

(e) Identification of the corroborating data reviewers

(e) Test results.

SECTION 4

PROCUREMENT DOCUMENT CONTROL

4.0 GENERAL

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

4.1 REVIEW

Procurement documents shall be reviewed by PROGRAM-participants' QA technical and quality assurance organization representatives to assure that applicable quality assurance program requirements are included.

4.2 APPLICABILITY OF PURCHASER'S ~~QA~~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 ~~development~~ developing and ~~maintenance~~ maintaining ~~of~~ 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.

NOTE: The following italicized text has been moved to Appendix A, Section 5.0
The review shall consider whether the activities have the potential to impact the waste isolation capability of the site or interfere with other site characterization tests.

5.2 PROCEDURES LIST

PROGRAM participants shall maintain a 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

NOTE: The following italicized text has been moved to Appendix A Section 6.1

(e) Evaluation of changes for the potential impact on the waste isolation capability of the site or interfere with other site characterization activities.

6.3 CONTROLLED DOCUMENTS

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

SECTION 7

CONTROL OF PURCHASED ITEMS AND SERVICES

7.0 GENERAL

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

7.1 SUPPLIERS' QUALITY ASSURANCE PROGRAMS

When required by procurement documents, suppliers' ~~QA PROGRAMS~~ 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~~ AND

8.0 GENERAL

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

NOTE: The following italicized text is now contained in Appendix A Section 8.0:

8.1 SAMPLES

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

8.1.1 Sample Identification

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

8.1.2 Sample Traceability

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

8.1.3 Archival Samples

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

SECTION 9

CONTROL OF PROCESSES

9.0 GENERAL

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

NOTE: The following italicized text is now contained in Appendix A, Section 9.0:

9.1 APPLICABILITY

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

~~9.2~~9.1 LIST OF SPECIAL PROCESSES

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

~~9.3~~9.2 ~~QA~~ QUALITY ASSURANCE ORGANIZATION INVOLVEMENT IN QUALIFICATION ACTIVITIES

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

~~9.4~~9.3 EVIDENCE OF ACCOMPLISHMENT

~~Each~~ 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 amplifications.

NOTE: The following italicized text is now contained in Appendix A, Section 10.0:

10.1 APPLICABILITY

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

~~10.2~~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.

NOTE: The following italicized text is now contained in Appendix A, Section 11.0:

11.1 APPLICABILITY

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

~~11.~~211.1 UNCERTAINTY AND ERROR

Potential sources of uncertainty and error shall be identified in test plans and procedures. In addition, parameters ~~that must be controlled and measured~~ 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 ~~have to 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. ~~with the following amplifications.~~

Note: The following italicized text is now contained in Appendix A, Section 13.0:

13.1 SAMPLES

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

13.1.1 Sample Handling and Shipping

Samples shall be controlled during handling, storage, and shipment to preclude damage or loss and minimize deterioration. Controls shall be established for appropriate packaging, handling, and modes of transportation, with consideration being given to 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.

13.1.2 Sample Storing

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

SECTION 14

INSPECTION, TEST, AND OPERATING STATUS

14.0 GENERAL

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

NOTE: The following italicized text is now contained in Appendix A, Section 14.0:

14.1 APPLICABILITY

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

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. ~~QA~~ Quality assurance organizational concurrence with proposed corrective action and ~~QA~~ 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 ~~that are consistent with, and meet the requirements~~ Section 4, Subsection 5.5, and Appendices A, B, E, F, and G, of ~~in~~ 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 PROJECT OFFICE AUDITS~~

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

18.~~3~~2 ANALYSIS OF AUDITS ~~DATA~~

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

18.~~4~~3 INTERNAL AUDIT SCHEDULING

~~18.4.1~~ Internal audits of the adequacy ~~and implementation~~ effectiveness of the quality assurance program shall be performed at least once each year or at least once during the life of the activity affecting quality, whichever is shorter.

~~18.4.2~~ The 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) Results of previous extrinsic audits~~

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

18.54 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.

~~18.5.1~~ (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:

~~(a)~~ (1) Relatively simple and standard in design, manufacturing and testing; or

~~(b)~~ (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.

~~18.5.2 External audits of suppliers' quality assurance programs shall be conducted on at least a triennial basis. External audits of the suppliers' quality assurance programs may be performed by a third party for PROGRAM participants. The triennial period begins when an audit is performed. The need for more frequent external audits of a supplier shall be evaluated when major changes to contract scope or work methodology occurs. Preaward surveys may serve as the first triennial audit if the scope of the preaward survey is similar to the scope of other triennial audits.~~

~~18.5.3~~ (c) Audits conducted on a supplier by an external organization for the PROGRAM participant, or for a group of purchasers that includes the PROGRAM participant, are an acceptable alternative to a PROGRAM-participant conducted audit~~, provided that~~ However, the scope of the audit must meets the needs of the PROGRAM, and the audit report ~~is~~ must be provided to the PROGRAM participant. The PROGRAM participant remains responsible for the adequacy of these audits.

~~18.5.4 Annual evaluations of suppliers shall be performed or arranged forProgram participants shall perform or arrange for annual evaluation of suppliers. Evaluations shall be documented. These evaluations shall assess:~~

~~(a) Supplier furnished documents and records~~

~~(b) Previous verification results~~

~~(c) Supplier's experience with identical or similar products provided to others~~

~~(d) Extrinsic verification results.~~

APPENDIX A

QUALITY ASSURANCE PROGRAM DOCUMENTS LISTING

1. DOE ORDER 5700.6B, Quality Assurance, September 23, 1986 -- Provides policy, sets forth principles and designates responsibility for the implementation of DOE plans and actions to assure quality achievement and verification. DOE Order 5700.6 endorses NQA-1 as the preferred standard for DOE nuclear programs. The OCRWM quality assurance program is consistent with DOE Order 5700.6 with specific variances as defined in the QAR.

2. DOE ORDER 4700.1, Project Management System -- Establishes the Department of Energy project management system and provides implementing instructions, formats, and procedures, and sets forth the principles and requirements which govern the development, approval, and execution of DOE's outlay program acquisitions.

3. ANSI/ASME NQA-1-1986b, Quality Assurance Program Requirements For Nuclear Facilities -- Contains basic and supplementary requirements and non-mandatory guidance for establishing QA programs for nuclear facilities.

4. DOE/RW-0005, Mission Plan for the Office of Civilian Radioactive Waste Management Program, June 1985 -- Responds to the requirements of the Nuclear Waste Policy Act of 1982 by providing an overview of and correct plans for the PROGRAM and presents the detailed information required by section 301 (a) of the Act. Quality assurance for the PROGRAM is covered in Part 1, Section 5.6 of the Mission Plan. In addition, the following amendments to the Mission Plan are applicable:

   - DOE/RW-0128, OCRWM Mission Plan Amendment, June 1987 -- Amends the Mission Plan to apprise the Congress of significant recent achievements in the PROGRAM, the revised schedule for the first repository, the intent to postpone site specific work for the second repository and plans for continuing the technology development program for the second repository, and the proposal for the construction of a monitored retrievable storage (MRS) facility as an integral part of the waste management system.

   - DOE/RW-0187, Draft 1988 Mission Plan Amendment, June 1988 -- Amends the Mission Plan to inform the Congress of DOE's plans for implementing the new focus for the PROGRAM provided by the Nuclear Waste Policy Amendments Act of 1987.

5. DOE/RW-0043, Program Management System Manual (PMS), January 1986 -- Provides the Director, OCRWM, and his staff with a set of policies and procedures that are used in managing for quality and in integrating the various PROGRAM elements and projects into cohesive and cost effective program. The management system that is described in the PMS Manual, along with specific implementing plans or procedures, define the elements of the OCRWM approach to managing for quality.

~~6. DOE/RW-0051, Systems Engineering Management Plan (SEMP), October 1985 — Prescribes the Systems Engineering Procedures to be implemented by the PROGRAM and the minimum requirements for Systems Engineering at the Program Element (Repository, Transportation, and Monitored Retrievable Storage) levels.~~

~~7. DOE/RW-0068, Program Baseline Procedures Notebook (OGR/B-1), February 1988 — Provides a description of the baseline management concept, establishes the Repository Program Baseline itself, and provides procedures to be followed for controlling changes to that baseline.~~

~~8. DOE/RW-0090, Generic Requirements (GR) for a Mined Geologic Disposal System (OGR/B-2), March 1987 — Establishes the technical baseline of generic repository requirements that are controlled by OGRWM using baseline procedures and is based on statutory, regulatory, and other requirements.~~

~~9. DOE/RW-0101, Issues Hierarchy for a Mined Geologic Disposal System (OGR/B10), August 1987 — Presents the issues DOE will use to guide development of site characterization plans and conduct site characterization activities.~~

~~10. DOE/RW-0125, Waste Acceptance Preliminary Specifications for the West Valley Demonstration Project High-level Waste Form (OGR/B-8), December 1986 — Specifies the properties and requirements for high-level waste forms at West Valley, N.Y.~~

~~11. DOE/RW-0136, Waste Acceptance Preliminary Specifications for the Defense Waste Processing Facility High Level Waste Form (OGR/B-9), March 1987 — Specifies the properties and requirements for high-level waste forms to be produced by the Defense Waste Processing Facility at the Savannah River Plant, South Carolina.~~

~~12. DOE/RW-0142, Annotated Outline for Site Characterization Plans (OGR/B-5), August 1987 — Provides a standard format and guidance for the preparation of Site Characterization Plans (SCP).~~

~~13. DOE/RW-0147, Annotated Outline for the SCP Conceptual Design Report (OGR/B6), June 1987 — Provides a standard format and guidance for the preparation of the SCP Conceptual Design Report.~~

~~14. DOE/RW-0194, Records Management Policies and Requirements, July 1988 — Establishes policies and requirements and assigns responsibility for the identification, collection, organization, processing, and storage of records of the civilian radioactive waste management program in order to document and facilitate the review of program activities.~~

~~15. DOE/RW-0214, Quality Assurance Requirements for the Civilian Radioactive Waste Management Program — Defines the quality assurance requirements for the PROGRAM and establishes a basis for development of consistent quality assurance programs by OGRWM, the Project Office(s), and all other PROGRAM participants.~~

16. DOE/RW-0215, Quality Assurance Program Description for the Civilian Radioactive Waste Management Program, -- Defines responsibilities and describes means of implementation of the quality assurance requirements for the PROGRAM.

17. Office of Storage and Transportation Systems Quality Assurance Plan for the Transportation Casks Systems Development Program, Revision 0 -- Implements DOE/RW-0032, Quality Assurance Management Policies and Requirements and DOE/RW-0103, Quality Assurance Directive, promulgated requirements for the casks systems development program element, and provides supplementary QA guidance to the DOE Idaho Operations Office.

18. OGR/B-7, Systems Engineering Management Plan for the Office of Geologic Repositories, April 1986 -- The purpose of the Systems Engineering Management Plan is to prescribe how Repository Systems Engineering will be implemented at the OGRWM level and sets forth the minimum requirements for Repository Systems Engineering at the Project Office level.

19. OGR/B-12, Project Charter for the Nevada Nuclear Waste Storage Investigation Project, June 1987 -- Delineates management responsibility, authority, and accountability for the Nevada Nuclear Waste Storage Investigations Project. The project charter establishes the operational management relationships between Headquarters Office of Civilian Radioactive Waste Management and the Nevada Operations Office.

20. OGR/B-14, Specification of QA Requirements for High-Level Waste Form Production, February 1988 -- Identifies the basic and supplementary requirements for quality assurance programs applied to the waste acceptance process activities of high-level waste form production.

21. Appendix B, 10 CFR 50, Quality Assurance Criteria for Nuclear Power Plants -- Establishes general QA criteria for safety-related structures, systems, and components of nuclear power plants and fuel reprocessing plants.

22. 10 CFR 60, Disposal of High Level Radioactive Wastes in Geologic Repositories -- Establishes requirements for siting, designing, licensing, constructing, operating and closing geologic repositories for high-level waste. Subpart G specifies the general QA criteria of Appendix B, 10 CFR 50.

23. 10 CFR 71, Packaging and Transportation of Radioactive Material -- Subpart H establishes quality assurance requirements for packaging and transportation of radioactive materials which are similar to the general QA criteria of Appendix B, 10 CFR 50.

24. 10 CFR 72, Licensing Requirements for the Storage of Spent Fuel in an Independent Spent Fuel Storage Installation (ISFSI) -- Subpart G establishes QA requirements for siting, designing, licensing, constructing, operating, and decommissioning a fuel storage facility and specifies the general QA criteria of Appendix B, 10 CFR 50.

~~25. NRC REVIEW PLAN, Quality Assurance Programs for Site Characterization of High Level Nuclear Waste Repositories, June 1984 -- Defines the criteria and methods by which the DOE Quality Assurance Program for Site Characterization activities will be reviewed by the NRC staff during the prelicensing phase.~~

~~26. NUREG-0856, Final Technical Position on Documentation of Computer Codes for High Level Waste Management, June 1983 -- Describes the guidelines (identified by OCRWM as requirements for the PROGRAM) for documentation of the codes used by the applicant in performing the analyses submitted in support of a license application under 10 CFR 60.~~

~~27. NUREG 1318, Technical Position on Items and Activities in the High Level Waste Geologic Repository Program Subject to Quality Assurance Requirements, April 1988 -- Provides guidance (identified by OCRWM as requirements for the PROGRAM) on how to identify items and activities subject to quality assurance in the High Level Nuclear Waste Repository Program for pre-closure and post-closure phases of the repository.~~

~~28. NUREG 1297, Peer Review for High Level Waste Repositories Generic Technical Position, February 29, 1988 -- Provides guidance (identified by OCRWM as requirements for the PROGRAM) on the definition of peer reviews, the areas where peer reviews are appropriate, the acceptability of peers, and the conduct and documentation of a peer review.~~

~~29. NUREG 1298, Qualification of Existing Data for High Level Nuclear Waste Repositories Generic Technical Position, February 27, 1988 -- Provides guidance (identified by OCRWM as requirements for the PROGRAM) on the use and qualification of data that has not be initially collected under a 10 CFR 60, Subpart G, QA Program.~~

~~30. REGULATORY GUIDE 7.10, Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material, January 1983 -- Provides NRC guidance (identified by OCRWM as requirements for the PROGRAM) on the development of quality assurance programs for the packaging used to transport radioactive material.~~

APPENDIX 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 specified 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

~~3.5~~3.1 PEER REVIEWS (NOTE: Formerly Section 3.5 in Rev.1)

Peer Reviews shall be performed in accordance with the guidance provided in NUREG-1297, Peer Review for the High-Level Waste Repositories Generic Technical Position, February 1988.

~~3.6~~3.2 SCIENTIFIC INVESTIGATIONS (NOTE: Formerly Section 3.6 in Rev.1)

~~3.6.1~~3.2.1 Control of Scientific Investigations (Was Section 3.6.1 in Rev.1)

(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 ~~responsible~~ 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.~~of the procedures to collect data.~~

~~3.6.2~~3.2.2 Planning (Was section 3.6.2, Rev.1)

(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:

~~(a)~~ (1) Description of work to be performed

~~(b)~~ (2) Rationale and justification for the information to be obtained

~~(c)~~ (3) Proposed methodology

~~(d)~~ (4) Rationale and justification for the proposed methodology

~~(e)~~ (5) References to applicable documents

~~(f)~~ (6) Identification, explanation, and justification for areas where scientific notebooks are to be used

~~(g)~~ (7) Description of constraints

~~(h)~~ (8) Description of the application of the scientific investigation's results

~~(i)~~ (9) Description of schedules and milestones.

NOTE: The following italicized text has been moved to paragraph 3.2.3 of page (A-4).

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.

(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) ~~that~~Adequate instrumentation is available and used

(3) ~~that~~Necessary monitoring including witness or hold points ~~is~~ have been performed

(4) ~~and that~~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 acquisi ions and recordings of data;

(7) andDisposition of facilities after completion of scientific investigation activities.

~~3;6;~~23.2.3 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;6;~~23.2.4 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;6;~~23.2.5 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.

~~3.6.3~~3.3 DATA COLLECTION AND ANALYSIS (Was Section 3.6.3, Rev.1)

(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.

~~3.6.4~~3.4 ~~Use of~~DATA COLLECTION, ANALYSIS, AND REVIEW (Was Section 3.6.4, Rev.1)

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

~~3.6.5~~3.5 DATA IDENTIFICATION AND TRACEABILITY (Was Section 3.6.5, Rev.1)

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

~~3.6.6~~3.6 DATA RECORDING, STORAGE, AND RETRIEVABILITY (Was Section 3.6.3, Rev.1)

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.

~~3.6.7~~3.7 QUALIFICATION OF DATA OF INDETERMINATE QUALITY (Was Section 3.6.7, Rev.1)

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) ~~This~~ Data may include ~~data~~ information collected from such sources as professional journals, technical reports, and symposia proceedings; ~~but 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:

~~(a)~~ (1) Qualifications of personnel or organizations generating the data

~~(b)~~ (2) Technical adequacy of the equipment and procedures used in the scientific investigation

~~(e)~~ (3) Environmental conditions

~~(d)~~ (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

~~(e)~~ (5) Amount of corroborating data or confirmatory testing

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

~~(g)~~ (7) Extent to which conditions generating the data may partially meet requirements of this document

~~(h)~~ (8) Prior uses of the data and associated verification process

~~(i)~~ (9) Prior professional reviews of the data

~~(j)~~ (10) Extent and reliability of the documentation associated with the data

~~(k)~~ (11) Degree to which data-generating processes were independently audited

~~(l)~~ (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 ~~Section 3.5~~ 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

~~(e)~~ (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 ~~activities have 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.

~~8.1.1~~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.

~~8.1.2~~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.

~~8.1.3~~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.~~and from waste form qualification 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 ~~also~~ applicable to samples collected for site characterization.

~~13.1.11~~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.

~~13.1.21~~13.3 SAMPLE ~~STORING~~ 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.

QAR Revision 2.ANO

NOTE: The following italicized text has been moved entirely to Addendum A-1.

APPENDIX B

RATIONALE ON THE APPLICABILITY OF NRC REQUIREMENTS TO SCIENTIFIC INVESTIGATIONS

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

PURPOSE

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

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

DISCUSSION

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

For engineered items, the requirements of 10 CFR 50, Appendix B will be met by implementation of ANSI/ASME

NQA-1-1986b. These requirements are supplemented in the QAR Section 11, "Test Control," by the incorporation of guidance provided in the NRC Review Plan for QA Programs for Site Characterization of High Level Nuclear Waste Repositories (SIC).

The controls applied to scientific investigations are identified in Section 3 of the QAR. The following comparison with the NRC Review Plan, Chapter 11D depicts how the requirements for the controls that are applicable to scientific investigations have been incorporated. Where appropriate, the requirements of ANSI/ASME NQA-1-1986b for control of tests have also been incorporated.

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

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.

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

NRC Review Plan Requirement 11.1

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

Response

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

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

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

The QAR requires QA organization overview of activities affecting quality.

NRC Review Plan Requirement 11.2

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

Response

This requirement is stated in Section 3.6.1 of the QAR.

NRC Review Plan Requirement 11.3

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

Response

This requirement is stated in Section 3.6.2 of the QAR.

NRC Review Plan Requirement 11.4

"Test procedures or instructions provide the following:

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

Response

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

b. "Instruction for performing the test."

Response

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

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

Response

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

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

Response

This requirement is stated in Section 3.6.4 of the QAR.

f. "Methods of data analysis."

Response

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

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

Response

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

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

Response

This requirement is stated in Section 3.6.2 of the QAR.

NRC Review Plan Requirement 115

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

Response

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

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

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

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

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

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

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

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 ~~with the following additions~~ 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, ~~functions~~ processes, tasks, or work which influence the achievement or verification of ~~CRWM~~ PROGRAM quality requirements ~~or~~ and objectives. For the ~~geologic repository~~ 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 ~~are~~ under change and distribution control and ~~are~~ 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 ~~geologic repository~~, MRS facility, Transportation cask system, and Waste ~~form, and Federal interim storage facility~~.

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

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

Design Activities: Activities related to the design process, including data collection and ~~analyses~~ 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 ~~its~~ 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: A method used to identify QA program controls to be applied to items and activities consistent with their importance to safety, waste isolation, or achievement of quality objectives. The degree to which QA program controls are applied is commensurate with function, complexity, consequence of failure, reliability, replicability and economic considerations.~~

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).

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

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

Procurement Document: 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 Level 1 item).~~

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

Quality Activities List: In the ~~geologic repository~~ 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 ~~geologic repository~~Mined Geologic Disposal System, including the overall design of the facilities and waste package. This includes the various ~~studies of activities~~ that are performed for, or in support of, the investigation, exploration, site characterization, design bases development, licensing, construction, operation, monitoring, performance evaluation, or closure of the ~~geologic repository~~ 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 falls within the state of the art, conducted to verify or validate or both its applicability, correctness, adequacy, and completeness. Technical reviews are performed by qualified personnel with technical expertise at least equivalent to those who conducted the original work, and who are independent of those who conducted the work being reviewed.

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

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.

QAR Revision 2.ANO

NOTE: Formerly QAR Appendix B, Rev.1

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 for that the procedure to be used being subjected to added tests and that the individual being tested to provide additional confidence in that individual's skills of 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 paper 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 ones most likely to be interpreted as involving special processes.

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

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

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

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

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

Section 2: ~~QA~~ 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: ~~Scientific Investigations and~~ Design Control - Criteria for the planning, review/approval, and performance of scientific investigations are prescribed. Scientific notebooks or technical implementing procedures can be used for describing how the work is to be done and for documenting the activity. Surveillances of scientific investigations are conducted to ensure that procedures are followed and documented.

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

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

Section 7: Control of Purchased Items and Services - Measures ~~are~~ 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 ~~Control of Items, Samples, and Documents~~ -- Procedures shall be developed and implemented to ensure that samples are identified and controlled in a manner consistent with their intended use. 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 ~~specific~~ 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 ~~is defined~~ 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: ~~QA~~ Quality Assurance Records - Records that furnish documentinged 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 ~~then~~ that there are controlled processes governing the collection, preparation, and analysis of data in scientific investigations. The interest is not in the sample per se, but in physical or chemical parameters obtained from the sample. Data ~~is~~ 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 resultant 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 processes are mechanisms for qualifying processes. A review of a process must determine whether the process is adequate for the purpose of the SIPD. "Adequate," as used in scientific investigations, means that the process addresses the issues detailed in the SIPD and that there is sufficient confidence that the results generated by the process can be used in licensing. As part of the review process, the reviewers must determine if the controls specified in the 18 criteria of 10 CFR 50, Appendix B are adequately built into the technical procedures to produce quality results (that is, results in which there is a high degree of confidence that they are acceptable for use in licensing). Calibration of measuring equipment, confirmatory or corroborative measurements by independent processes, and use of the 18 criteria, exclusive of special processes, appear to be sufficient to ensure quality results in scientific investigations.

~~SUMMARY~~

Processes in scientific investigations are ~~oriented toward~~ 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 does not normally exist in scientific investigations. The main variable is the sample or material. It is the variability in some parameter or subset of parameters that is the object of an instrumental or chemical analysis, or both.

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

The results of all scientific investigation processes, including those used in the High-Level Waste Repository program, depend on the technical abilities of the scientists and technicians to apply the laws of physics, chemistry, engineering, and other sciences. This is supported by a very large volume of scientific data already in existence and accepted by the scientific community and regulatory bodies. The imposition of special process controls will not provide increased assurance that the results of a scientific investigation ~~is~~ 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 ~~is~~ 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 ~~of science~~ that aid in the explanation of the phenomena. It follows that the requirements of Criterion ~~10~~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 ~~paper~~ addendum is intended to document the rationale and approach to satisfy the intent of ~~criteria~~ 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 of the QAR~~ by requiring the preparation of ~~scientific investigation planning documents~~ 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 ~~e.y.~~ 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. ~~of the QAR~~. For both scientific notebooks and technical implementing procedures, it is required that

any special training or qualification requirements be clearly defined.

The 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 Section 3.6.1 of the QAR~~ 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 Section 3.6.2 of the QAR~~ 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 Section 3.6.2 of the QAR~~ 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 ~~is~~ are used to establish acceptance limits.

b. "Instruction for performing the test."

Response

This requirement is stated ~~in Sections 3.6.2 and 3.6.3 of the QAR~~ 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 Sections 3.6.2 and 3.6.3 of the QAR~~ 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 ~~of~~ or process is not established.

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

Response

This requirement is stated ~~in Section 3.6.4 of the QAR~~ QARD Appendix A, Section 3.0.

f. "Methods of data analysis."

Response

For technical implementing procedures this requirement is stated ~~in Section 3.6.3 of the QAR~~ QARD Appendix A, Section 3.0. This requirement is not applicable to scientific notebooks as ~~data is~~ are the end product.

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

Response

This requirement is stated ~~in Section 3.6.5 of the QAR~~ 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 Section 3.6.2 of the QAR~~ 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 Sections 3.6.1, 3.6.4 and 3.5.5 of the QAR~~ QARD Appendix A, Section 3.0.

IV. APPLICABILITY OF NRC 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 ~~14~~XIV (Criteria X and XI) are described in Sections II and III.

The operating status aspect of ~~this~~ 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 Section 3.6 of the~~ 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 ~~Criteria 14~~ 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 ~~14~~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.

ENCLOSURE III

MATRIX ILLUSTRATING THE INCORPORATION OF OGR/B-14 QA PROGRAM REQUIREMENTS INTO THE APPROVED QARD REVISION 2

ENCLOSEURE III

MATRIX ILLUSTRATING THE INCORPORATION OGR/B-14

QA PROGRAM REQUIREMENTS INTO THE APPROVED QARD REVISION 2

MATRIX ILLUSTRATING THE INCORPORATION OGR/B-14 QA PROGRAM REQUIREMENTS
INTO THE APPROVED QARD REVISION 2

OGR/B-14 QA Program Requirements	QARD Resolution
5.0 Requirements Quality assurance programs are to be established and implemented in waste Acceptance Process Activities of high-level waste form production. These programs shall contain the activities and meet the criteria for those activities as defined in the basic and supplementary requirements defined hereafter.	QARD Introduction contains this concept.
5.1 Basic Requirements The basic quality assurance requirements to be implemented in the quality assurance programs of major participants in Waste Acceptance Process Activities of high-level waste form production are defined in national consensus standards and DOE directives as identified in this section.	QARD specifies the national consensus standards and DOE directives that are the requirements.
5.1.1 National Consensus Standard	
(1) ANSI/ASME NQA-1, 1986, "Quality Assurance Program Requirements for Nuclear Facilities," Section I, II, and III and Appendix 2A-1 of Section IV. This standard contains basic and supplementary requirements and nonmandatory guidance for establishing and implementing quality assurance programs for nuclear facilities. (Note the nonmandatory guidance has not been invoked in the above reference except for Appendix 2A-1 of Section IV.)	QARD references and commits all NQA-1 Basic Requirements, Supplements and Appendix 2A-1 under criteria 1-18.
5.1.2 Department of Energy (DOE) Orders and Guidance	
(1) DOE 5000.3 "Unusual Occurrence Reporting System" This directive sets forth policy, responsibilities, criteria, and instructions for preparing, analyzing, and disseminating unusual occurrence reports.	OQA chose not to incorporate this reference into the QARD as a requirement of the QA Program. QARD Section 1.4 "Allegation and Quality Concerns Resolution" is the requirement. DOE 5000.3 is still a DOE order to be followed but not as a QA program requirement.

OCR/8-14 QA Program Requirements	QARD Resolution
(2) DOE 5700.68 "Quality Assurance"	
This directive provides policy, sets forth principles, and designates responsibility for the implementation of DOE plans and actions necessary to ensure quality achievement.	The QARD incorporates the requirements of DOE 5700.68.
(3) Guidance for Appliance of Readiness Reviews to Department of Energy Activities, January, 1987	
This document contains guidelines for planning, staffing and conducting readiness reviews for assuring that all necessary activities and actions have been satisfactorily completed before subsequent activity initiation is authorized.	This document is a draft DOE document. Readiness Reviews are covered in QARD paragraph 2.5.
5.1.3 Relationship to Other Requirements and Guidance	
(1) 10 CFR Part 60, "Disposal for High-Level Radioactive Waste in Geologic Repositories." Subpart G, "Quality Assurance," Defines basic and supplemental requirements for quality assurance programs for Program participants. Major participants in Waste Acceptance Process Activities of high-level waste form production will fulfill the applicable requirements of 10 CFR Part 60, Subpart G, through implementation of quality assurance programs that meet the basic and supplementary requirements defined herein.	QARD meets 10 CFR Part 60 requirements as the NRC has evaluated the QARD for use in the high-level waste program.

OCR/B-14 QA Program Requirements	QARD Resolution
(2) DOE/RW-0005, "Mission Plan for Civilian Radioactive Waste Management," Section 5.6, also identified the basic requirements for quality assurance programs for program participants. The quality assurance programs of major participants in Waste Acceptance Process Activities of high-level waste form production will implement the applicable requirements of Section 5.6 of DOE/RW-0005 as a consequence of implementing the basic requirements defined herein.	QARD Introduction states that QARD contains all information needed to implement QA requirements.
(3) DOE/RW-0214 Quality Assurance Requirements for the Civilian Radioactive Waste Management Program - Defines the quality assurance requirements for the PROGRAM and establishes a basis for development of consistent quality assurance programs by OCRWM, the Project Office(s), and all other PROGRAM participants. The quality assurance programs of major participants in waste acceptance process activities of high-level waste form production will implement the applicable requirements of DOE/RW-0214 as a consequence of implementing the basic and supplementary requirements defined herein.	This is the QARD.
(4) DOE/RW-0043, "Program Management System Manual," Chapter 5, also identifies basic and supplementary requirements for quality assurance programs for OCRWM program participants. The quality assurance programs of major participants in Waste Acceptance Process Activities of high-level waste form production will also implement the applicable requirements of Chapter 5 of DOE/RW-0043 as a consequence of implementing the basic and supplementary requirements defined herein.	QARD Introduction states that QARD contains all information to implement QA program.

OCR/B-14 QA Program Requirements	QARD Resolution
5.2 Supplemental Requirements	
There are several areas in Waste Acceptance Process Activities of high-level waste form production in which quality assurance activities are required in addition to those contained in the basic requirements identified in Section 5.1. These activities are identified in this section and the requirements for each activity are defined. These activities, as applicable, are to be developed and implemented as integral parts of the quality assurance programs of major participants in Waste Acceptance Process Activities of high-level waste form production.	QARD Sections 2.0, 2.1, and 2.1.1 addresses the applicability of the QARD requirements to PROGRAM participants. QARD Appendix B Section addresses the applications of the QA PROGRAM Requirements applicable to the Waste Acceptance Process Activities of high level waste form production.
5.2.1 Control of Essential Software	
Software that is essential to meeting the WAS is to be developed, implemented, documented and controlled as defined hereafter.	QARD Section 3.3 and Appendix B Section 3.3 addresses this requirement.
A. Software to be controlled shall be identified in the WCP and documented. The documentation of the software shall appropriately reflect the provision of NUREG-0856 (see Appendix C) including meeting the documentation guidelines contained within Section III.	QARD Section 3.3 identifies how computer software is designed and controlled. Section 3.3. also addresses NUREG-0856. Appendix B Section 3.3 also addresses this requirement.
NUREG/CR-4640, Handbook of Software Quality Assurance Techniques Applicable to the Nuclear Industry, may be used as a reference in developing software quality assurance programs. Compute software controls pertaining to the control of software that is essential to meeting the Waste Acceptance Specification shall be consistent with the requirements of the 11/2/88 Draft ANSI/ASME NQA-2, Part 2.7, Quality Assurance Requirements of Computer Software for Nuclear Facility Applications."	The computer controls established through the use of NWMSI 88-9 Appendix H has been incorporated into QARD Section 3.3 is sufficient guidance to control the development and use of computer software. These computer controls have been accepted by the NRC for the High-Level Waste Repository program.

OCR/B-14 QA Program Requirements	QARD Resolution
5.2.2 Peer Review	
Peer reviews are to be conducted for items or data significant to Waste Acceptance Process Activities of high-level waste form production. As a minimum, peer reviews shall include activities that go beyond the existing technology or where conclusions or assumptions have not been clearly validated (e.g., disagreement exists between experts) by conventional means. Such peer reviews are to be identified and are to be planned, conducted and controlled as defined hereafter. Peer review methods and procedures shall reflect the provisions of NUREG-1297, Generic Technical Position on Peer Review for High-Level Waste Repositories.	QARD Appendix B Section 3.1 stipulates that peer reviews will be done in accord with NUREG-1297.

OCR/B-14 QA Program Requirements	QARD Resolution
5.2.3 Control of Experiments and Developmental Activities Experiments and developmental activities to support Waste Acceptance Process Activities of high-level waste form production are to be controlled and documented in a manner which ensures that: (1) The data will be suitable for its intended use. (2) Independent reconstruction and evaluation of the activities can be performed. A. The controls for experiments and developmental activities shall address the following: (1) Responsibility for initiating experiments and developmental activity. (2) Selection and qualification of personnel. (3) Review and approval of procedures. (4) Surveillance and auditing of experiments and developmental activities. (5) Review and evaluation of the results of experiments and developmental activities. (6) Documentation of experiments and developmental activities and results. (7) Responsibility for preparation and retention of documentation. B. While in progress, experiments and developmental activities shall be documented on a day-to-day basis and be maintained in a retrievable form. C. The experimental or developmental record 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.	QARD Appendix B Section 3.2 (entire section) incorporates the requirements of OCR/B-14 paragraph 5.2.3 (entire section).

(2) The person(s) initiating the experiment or developmental activity.

(3) The person(s) performing the experiment or developmental activity.

D. The experimental or developmental record shall also identify equipment, materials, and procedures actually used in sufficient detail to allow an individual skilled in the technology to reproduce the results.

E. The experimental or developmental record shall also include original records of data or facsimiles of the original records.

F. The experimental or developmental records shall be signed by the person performing the experiment or developmental activity.

G. Any summaries, reports, or evaluation of the experiments, developmental activities or their results that are used for Waste Acceptance Process Activities shall clearly reference the experimental records.

H. The experimental or developmental records of Waste Acceptance Process Activities shall clearly reference the experimental records.

5.2.4 Qualification of Data

Data or data interpretations in support of Waste Acceptance Process Activities of high-level waste form production are to be acquired or produced under a quality assurance program that meets the requirements 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 reviews or other qualification activities to be conducted as specified in NUREG-1298, Qualification of Existing Data for High-Level Waste Repositories.

OARD Appendix B Section 3.2.5 incorporates the requirements of OCR/B-14 paragraph 5.2.4.

OCR/B-14 QA Program Requirements	QARD Resolution
5.2.5 Archival of Samples	
Archival samples used for waste form qualification or for certification of canistered waste forms are to be prepared and controlled as follows:	QARD Appendix B Section 13.1 addresses all the requirements of OCR/B-14 paragraph 5.2.5 (entire section).
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 used. These shall cover the following as a minimum:

(1) Sample taking or preparation.

(2) Logging and labeling or otherwise identifying.

(3) Packing, packaging and hauling.

(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 sampled as quality records.

OCR/B-14 QA Program Requirements	QARD Resolution
5.2.6 Control of Special Processes Production that have a significant effect on quality characteristics of the canistered waste form and that produce results that cannot be readily verified by inspection or testing of the final product are to be identified in the WCP and controlled. The controls to be established and implemented on such processes shall be performed by qualified personnel using qualified procedures in accordance with specified requirements and shall include: A. Process requirements shall be specified and maintained in controlled documentation. B. Process procedures or instructions shall be prepared and maintained as controlled documents with unique identification and revision status and be readily available in the work area when the process is being performed. These procedures or instructions shall consider the following as a minimum: (1) Identification of required equipment and instrumentation. (2) Identification of control parameters and the operating limits for those parameters. (3) Environmental conditions and requirements. (4) Instrument calibration frequency. (5) Reference to applicable codes, standards and specifications. These procedures or instructions may be included in other controlled documents, such as drawings, checklists, travelers, work orders, or specifications. C. Personnel shall be selected, trained, and indoctrinated in accordance with subsection 5.2.10.	QARD Section 9, "Control of Processes" addresses the requirements of OCR/B-14 paragraph 5.2.6.

OGR/B-14 QA Program Requirements	QARD Resolution
D. Copies of process requirements, procedures or instructions, and documentation of personnel qualifications shall be collected and maintained as quality record(s).	
5.2.7 Product Certification	
The waste form producers are to develop and provide for retention, the records necessary to provide evidence of the acceptability of the canister and waste form which includes the canistered waste form. The WCP and/or WOR are to identify the types of records that will be developed during the waste form production process. The WOR is to identify the quality records required to be a permanent part of the overall canistered waste form product certification package. These documents are to be identified, collected, managed and delivered in accordance with the requirements of subsection 5.2.12.	QARD Section 17.0 addresses the records requirements of OGR/B-14 paragraph 5.2.7. QARD Appendix B sections 17.0 (entire section) address the identification of QA records requirements of OGR/B-14 paragraph 5.2.7. QARD Appendix B Section 17.0 (entire section) addresses the requirements of OGR/B-14 subsection 5.2.12.
5.2.8 Readiness Review	
Readiness reviews are to 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 all necessary activities and actions have been satisfactorily completed before subsequent activity initiation is authorized. Readiness reviews shall be performed in accordance with DOE Guidelines for Application of Readiness Reviews to Department of Energy Activities, dated January, 1987.	QARD Section 2.4 addresses readiness reviews.
5.2.9 Selective Application of Program Activities (Quality Levels) A systematic method by which quality assurance activities are selected and applied to Waste Acceptance Process Activities of high-level waste form production is to be established and implemented.	QARD Sections 2.5 (entire section) addresses the requirements of OGR/B-14 paragraph 5.2.9. QARD Appendix B Section 2.3 addresses this requirement.

OCR/B-14 QA Program Requirements	QARD Resolution
The selective application method implemented shall be consistent with the provisions of NUREG-1318, Technical Position on Items and Activities in the High-Level Nuclear Waste Repository Program Subject to QA requirements, and be described in the WCP.	
5.2.10 Selection, Indoctrination, and Training of Personnel	
Personnel who perform or verify activities affecting quality in waste acceptance process activities of high-level waste form production are to be proficient in the activities that they perform. A systematic practice for achieving and assuring the required proficiency is to be established and implemented. Prior to assigning personnel to perform activities affecting quality, they shall receive appropriate training and indoctrination as defined in ANSI/ASME NQA-1, Supplement 2S-4.	QARD Section 2.0 addresses Basic Requirements of NQA-1 in the Supplement 2S-4 as appropriate.
A. Personnel who perform verification activities that require qualification (e.g., lead auditors, inspectors, testers, nondestructive examiners, etc.) are to be certified in accordance with the detailed requirements specified in ANSI/ASME NQA-1 and referenced codes and standards.	QARD Section 2.0 references NQA-1, Supplement 2S-3 which concerns auditors and lead auditors. Also QARD, Appendix B, Section 2.4.

OGR/B-14 QA Program Requirements	QARD Resolution
B. Other personnel who perform activities that require qualification are to have their qualification requirements defined and their qualifications determined and documented as follows.	
1. Types of positions or tasks requiring qualified personnel shall be identified and procedures established for the following:	QARD Section 2.0 references NQA-1, Supplement 2S-1 as a requirement. This Supplement addresses the requirements of OGR/B-14 Paragraph 5.2.10.B. Also QARD, Appendix B, Section 2.4.
(a) Selection of personnel.	
(b) Training and indoctrination of personnel.	
(c) Proficiency evaluation.	
(d) Recording of qualifications.	
2. Position or task descriptions shall be prepared which define the minimum education and experience requirements for each type of position or task requiring qualification.	
3. Personnel selected to fill positions or perform tasks requiring qualification shall be evaluated to determine that they are qualified. Such determinations shall be documented by manager or supervisors responsible for activities to be performed.	

OCR/B-14 QA Program Requirements	QARD Resolution
5.2.11 Overview of Quality Assurance Activities Each major participant in Waste Acceptance Process Activities of high-level waste form production is to establish and implement a systematic overview of quality assurance activities performed by organizations over which they have contractual or administrative overview responsibilities. Each organization's overview practice is to include an appropriate combination of the following activities: (1) The review and approval of participant quality assurance program description (or plans). (2) Surveillance of participant activities affecting quality to verify compliance with requirements. (3) Performance of quality assurance audits to verify the adequacy and effectiveness of participant quality assurance program activities.	QARD Sections 2.1, 2.7 and 18.0 (references NQA-1 Basic Reqt 18 and Supplement 18S-1.)

These activities are to be planned and performed in accordance with procedures as described hereafter:

A. Procedures shall be established for the review of participant quality assurance programs to verify adequacy, completeness and relevance. The overview procedures shall identify the types of documents to be submitted by the participant for review and approval; shall assign project responsibility for reviews; and shall identify the methods for documenting review and approval actions.

B. Procedures shall be established for planning, scheduling, performing, and documenting surveillance of participant activities related to quality. Surveillance activities shall be performed by personnel who are not directly responsible for performing the work to be monitored or observed in the surveillance activity. Surveillance actions shall be performed to written checklists or plans whenever practicable. All deficiencies, nonconformances, and potential quality problems identified during the surveillance shall be documented and monitored until verification of disposition or corrective action is accomplished.

C. Procedures shall be established for the planning, scheduling, performing and reporting of quality assurance audits of participant quality assurance programs. Audit schedules shall be developed annually and updated as changes occur. Audits of organizations common to more than one project shall be coordinated whenever practicable to conserve resources and maintain consistency.

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

D. Documentation of overview activities shall be retained as quality records.

5.2.12 Quality Records

Documentation sufficient to demonstrate canistered waste form compliance with the WAS and implementation of this specification is to be prepared and maintained as quality records. These records are to be collected and maintained as follows.

A. Documentation sufficient to demonstrate satisfactory implementation of the WCP shall be collected and maintained as lifetime quality records by the major participant that generated or caused to be generated the documentation. 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. Such records will be maintained by the Federal Repository Operator to satisfy any repository requirements. Other documentation generated during preparation and implementation of the WCP shall be collected and maintained as nonpermanent quality records.

B. Documentation sufficient to support preparation of the VOR shall be collected and maintained as lifetime quality records by the major participant that generated or caused to be generated the documentation. 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. Such records will be maintained by the Federal Repository Operator to satisfy any repository requirements. Other duality records.

C. Production documentation shall be identified in a manner that facilitates positive-direct correlation between documents and canistered waste forms to which they relate.

QARD Appendix B Section 17.0 incorporates the requirements of OCR/B-14 paragraph 5.2.12.

D. Production documentation shall be declared lifetime quality records and transferred to the Federal Repository Operator with the canistered waste forms to which they relate.

E. Copies of production documentation shall be kept and maintained by the waste form producer as non-permanent quality records. These records shall be kept for a minimum of 10 years after the canistered waste forms they represent are transferred to the Federal Repository Operator or as otherwise directed by DOE.

5.2.13 Modification Control

Controls are to be established and implemented by the appropriate major participant 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:

OCR/B-14 QA Program Requirements	QARD Resolution
A. 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.	QARD Appendix B Section 3.2.6 incorporates the requirements of OCR/B-14 paragraph 5.2.13.
(1) The waste form.	
(2) The waste canister.	
(3) The canister waster form.	
(4) The production process.	
(5) Processing equipment.	
(6) Processing supplies and consumables.	
(7) Processing plans and proced[illegible].	
(8) Maintenance plans and procedures.	
(9) Process control plans and procedures.	
B. A controlled listing of the documentation that defines items and activities under modification control.	
C. Procedures defining elements of the modification control process that address:	QARD Appendix B Section 3.2.6 incorporates the requirements of OCR/B-14 paragraph 5.2.13.C.
(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.	
D. Provisions for assessing the need for and accomplishing any needed requalification resulting from modifications.	QARD Section 3.2.6(e) addresses the requirements of OCR/B-14 paragraph 5.2.13.D.

OCR/B-14 QA Program Requirements	QARD Resolution
5.2.14 Effectiveness Evaluation Each major participant in Waste Acceptance Process Activities of high-level waste form production is to establish and implement methods and procedures for evaluating the effectiveness of its quality assurance program in ensuring conformance with the WAS. The effectiveness evaluation practice is to include the following: A. A clear identification of the quality characteristics to be achieved in meeting the requirements of the WAS. B. The identification of an appropriate set of performance indicators that reflect actual quality characteristics being achieved. C. A performance measuring process using review, surveillance, inspection, tests, audit or other techniques to monitor performance indicators. D. An analysis process in which performance data are trended and problem areas identified. E. A reporting practice in which program effectiveness information is prepared and fed back to top management.	QARD Section 2.8, "Management Assessment,"; Section 2.7, "Surveillance" and Section 18, "Audits", Section 16, "Corrective Action", and Appendix B Section 2.5 address the requirements of OCR/B-14 paragraph 5.2.14.

OCR/B-14 QA Program Requirements	QARD Resolution
5.3 Quality Assurance Program Description	
The quality assurance program applied to Waste Acceptance Process Activities of high-level waste form production is to be described in a document that provides guidance and direction for program implementation and a concise description of what the program contains and how it is to function.	QARD Sections 2.0, 2.1, 2.1.1 and Appendix B Section 2.0 (entire section) address the requirements of OCR/B-14 paragraph 5.3.
5.3.1 General	
A. The description shall cover the basic and supplementary requirements identified in Sections 5.1 and 5.2 of this specification in sufficient detail to provide a knowledgeable reviewer with confidence that an adequate response to all quality assurance requirements have been identified and fully developed in the quality assurance program.	
B. The description shall also provide a formal statement by the management of the organization of its commitment to:	
(1) Implement the quality assurance program activities for which it is responsible.	
(2) Review the program periodically and revise it as necessary to keep it current and effective.	

ENCLOSURE IV

Resolution of NRC Comments on OGR/B-14

The following Matrix identifies previous NRC comments on the February 1988 issue of OGR-14 submitted for NRC review on August 9, 1988 and the resolution of those comments are reflected in the QARD, Revision 2:

NRC COMMENT	DOE Resolution
Comments 1.0 and 2.0 and A.0 through AM.18.8 were on the Foreword and Appendices to the February 88 issue of OGR/B-14.	The content of these Sections and resolution of the NRC comments will be addressed, as appropriate in the Quality Assurance Program Descriptions of the Waste Form Producers. Those descriptions will be submitted to the NRC for review.

The following comments 3 through 10 were the NRC comments on Section 5, of "Requirements", of OGR/B-14 which has been incorporated into the QARD, Revision 2.

3.	NRC Criterion 2.2 states, in part, "The quality assurance program provides a commitment to comply with NQA-1... The provisions of Appendix 2A-1... should be met..." Section 5.1.1 of OGR/B-14 states that nonmandatory guidance (i.e. Appendix 2A-1) has not been invoked by the reference to NQA-1.	QARD Section 2.0 applies and invokes the requirements of Appendix 2A-1.

ENCLOSURE IV (CONTINUED)

4.	Item Nos. 3 and 5 of Section 5.1.3 identify documents DOE/RW-0032 and DOE/RW-0095, respectively. Since these documents have been superseded, they should be replace with "Quality Assurance Requirements for the Civilian Radioactive Waste Management Program" (QAR) and "OCRWM Quality Assurance Program Description" (QAPD).	Reference to DOE/RW-0032 is deleted with incorporation of OGR/B-14 requirements into the QARD, Revision 2. The QARD applies to all OCRWM Program participants. The QARD requires that each of the major participants in the Waste Form Producer Organization have their own Quality Assurance Program Description Document to be submitted to OCRWM for approval.
5.	Section 5.1.3 "Relationship to Other Requirements and Guidance" does not reference NUREG-1298, Generic Technical Position on Qualification of Existing Data (June 1987); NUREG-1297, Generic Technical Position on Peer Review for High-Level Waste Repositories (June 1987); and NUREG-1318, Technical Position on Items and Activities in the High-Level Nuclear Waste Repository Program Subject to QA Requirements (April 1988); nor state that the quality assurance programs of the major participants will implement the applicable requirements of these NUREG documents.	NUREG 1297, 1298 and 1318 have been incorporated as requirements in the QARD, Revision 2, Appendix B - Paragraphs 3.1, 3.2.5, and 2.3, respectively.

6.	The final version of NQA-2, Part 2.7 "Quality Assurance Requirements of Computer Software for Nuclear Facility Applications" will likely be endorsed and used by the NRC in the licensing process. Section 5.2.1 does not note that the activities pertaining to the control of software that is essential to meeting the WAS will be consistent with the requirements of NQA-2, Part 2.7 nor does it provide alternatives specifying how Appendix B of 10 CFR Part 50 will be applied to computer software. In addition NUREG/CR-4640 "Handbook of Software Quality Assurance Techniques Applicable to the Nuclear Industry" may be used as a reference for developing software QA programs.	Software QA requirements are now addressed in Section 3.3 of the QARD, Rev. 2 which makes no reference to NQA-2, draft Part 2.7. The Section 3.3 requirements have been previously accepted by the NRC as Appendix H to NNWSI/88-9.
7.	Paragraph 5.2.1 A of Section 5.2 "Supplemental Requirements" states, in part, "the documentation shall appropriately reflect the provisions of NUREG-0856..., "but does not indicate that the "documentation" will meet the applicable Section III Guidelines of NUREG-0856.	See resolution to comment #6 above. The QARD, Rev. 2 in paragraph 3.3.1(a) commits to the requirements of NUREG-0856 including the NUREG-0856 guidelines for documentation.

ENCLOSURE IV (CONTINUED)

8.	Section 5.2.2 "Peer Review" states, in part, "Peer reviews are to be conducted...," but it does not reference NUREG-1297.	The reference to NUREG-1297 has been incorporated See the QARD, Rev. 2, Appendix B, paragraph 3.1.
9.	Section 5.2.4 "Qualification of Data" does not indicate that reviews or other qualification activities are to be conducted in accordance with NUREG-1298.	The reference to NUREG-1298 has been incorporated See the QARD, Rev. 2, Appendix B, paragraph 3.2.5.
10.	Section 5.4 states that QA programs will be evaluated by DOE/RW against the applicable criteria of the "NRC Review Plan for... High-Level Nuclear Waste Repositories." Thc current NRC "Review Plan for High-Level Waste Repository Quality Assurance Program Descriptions" is dated December 1988.	DOE/RW (OCRWM) is reviewing OCRWM Program QA Requirements and Description Documents to the latest revision of the NRC Review Plan issued at the time of review. Note that the QARD, Revision 2 has been reviewed against the guidance of the latest revision of the NRC "Review Plan for High-Level Waste Repository Quality Assurance Program Description", Revision 2 (March 1989.)

ENCLOSURE V

NRC OPEN ITEM

Reference: Safety Evaluation of Quality Assurance Requirements for the Civilian Radioactive Waste Repository Program - Transmitted by NRC letter dated May 8, 1989

The Open Item concerns Quality Assurance being recognized as an interdisciplinary function, extending to all levels of participating organizations as stated in Paragraph 2 of ANSI/ASME NQA-1-1986, Nonmandatory Appendix 1A-1.

The following has been cited from the referenced document in order to provide a basis to resolve the Open Item:

From "3.1 ORGANIZATION (Criterion I)"

"...The QA organization's involvement is to provide assurance to senior line management of the line organization's achievement and verification of quality through conduct of overview activities such as audits, surveillances and assessments. Quality achievement is required to be a continuing responsibility of management at all levels of the program. It is required to be achieved through well-defined QA programs, with a set of management controls to be implemented by all program participants. Paragraph 2 of ANSI/ASME NQA-1-1986 Nonmandatory Appendix 1A-1 (see Ref.7) contains the following nonmandatory guidance on the functions of the QA organization and the line organization:

> "In structuring the organization and assigning responsibility, quality assurance should be recognized as an interdisciplinary function involving many organizational components and, therefore, should not be regarded as the sole domain of a single quality assurance group. The quality assurance group, however, should be designated to describe, integrate, and monitor the agreed-upon quality assurance activities of the various disciplines.
>
> Quality assurance encompasses many functions and extends to various levels in all participant organizations, from the top executive to workers, such as designers, welders, inspector,s facility operators, craftsmen, and auditors, who perform activities affecting quality.
>
> Difference organizational structures may be effective, depending on the portion of the project or job in which the implementing organization is involved."

ENCLOSURE V (CONTINUED)

The NRC staff recommends that DOE incorporate the above guidance into the QAR to help clarify the roles of the QA and line organizations. This is identified as an open item in Section 5 of this evaluation. With the inclusion of the above in the QAR, the QAR meets the ANSI/ASME NQA-1-1986 (See Ref.7) criteria for QA organization responsibilities and is acceptable to the NRC staff..."

From "4. CONCLUSION"

"...On the basis of its detailed review and evaluation of the QAR, the NRC staff concludes that the QAR contains adequate requirements and planned and systematic controls that address each of the appropriate criteria of Appendix B to 10 CFR Part 50 in an acceptable manner, with the exception of the open item listed below. With the resolution of this open item, the QAR can serve as an adequate framework for DOE and its project participants to develop specific policies, plans, and procedures to implement the QA Program for the high-level radioactive waste repository..."

From "5. OPEN ITEM"

"...In Section 3.1 of this SE, a discussion is provided pertaining to guidance on the role of the QA organization. DOE should incorporate the guidance from paragraph 2 of ANSI/ASME NQA-1-1986 Nonmandatory Appendix 1A-1 into the next revision of the QAR..."

RESOLUTION:

The concepts in Paragraph 2 of Appendix 1A-1 are adequately addressed in the INTRODUCTION of the QARD under QUALITY ASSURANCE PROGRAM BASIS (unchanged from QAR, Revision 1) and the following addition to Section 1.1, in part, incorporated into Revision 2:

> "The quality assurance organization is responsible for... that, as a minimum, include surveillances, audits, and assessments.

ENCLOSURE VI

EXPLANATION OF CHANGES REGARDING GRADED QA

Section 2.5 of the QARD, Revision 1, mandated a three level QA classification system for all OCRWM Program activities. In the QARD, Revision 2, that has been replaced by a more generic requirement that each PROGRAM participant define a method by which they determine those items and activities required to be controlled under an approved 10CFR60, Subpart G, QA Program consistent with NUREG-1318.

OCRWM found that mandatory implementation of the three level system was neither practicable or appropriate during implementation of the QA Program for the OCRWM-level activities. Furthermore, in developing the single, generic set of program requirements, it was determined that providing a specified level or grading system for all PROGRAM participants was not appropriate, desirable, nor required by NUREG-1318 "Technical Position on ITems and Activities in the High-Level Waste Geologic Repository Program Subject to 10 CFR Part 60 QA Requirements." The classification and grading approach implemented by OCRWM, and the new more generic requirement is consistent with both the NRC guidance provided in NUREG-1293, "Quality Assurance Guidance for Low-Level Radioactive Waste Disposal Facility", Section III, on quality levels and graded QA and the guidance provided in NUREG-1318.

ENCLOSURE VII

MATRIX COMPARING NRC STANDARD REVIEW PLAN, REVISION 2 TO THE APPROVED QARD, REVISION 2

ENCLOSURE VII

MATRIX COMPARING THE QARD, REVISION 2

TO THE NRC REVIEW PLAN (FOR REPOSITORY QA

PROGRAMS), REVISION 2 (March 1989)

MATRIX COMPARING NRC STANDARD REVIEW PLAN, REVISION 2 TO QARD, REVISION 2

	NRC REVIEW PLAN REVISION 2	OCRWM QARD REVISION 2
1.	The organization elements responsible for the QA program are acceptable to the NRC staff if:	
1.1	The responsibility for the establishment and execution of the overall QA program is retained and exercised by that organization or individual responsible for submitting the license application.	QARD Introduction: page (xiv) Responsibilities
1.2	The authorities and duties of persons and organizations performing activities important to safety or waste isolation * are clearly established and delineated in writing. * Hereafter referred to as "safety functions"	QARD Section 2.1 QUALITY ASSURANCE PROGRAM(entire section)
1.3	The QA program assures that activities affecting safety functions include both the performing functions of attaining quality objectives and the QA functions.	QARD Section 2.1(entire section)
1.4	The QA functions are those of: (a) assuring that an appropriate QA program is established and effectively executed; and (b) verifying, such as by checking, auditing, and inspection, that activities affecting the safety functions have been correctly performed.	QARD Section 1.0, 1.1
1.5	DOE and prime contractors describe major delegation of work involved in establishing and executing the QA program, or part thereof, to other organizations.	QARD Section 1.2, Delegation of Work (entire section) QARD Section 2.1.1 PROGRAM Participant's Quality Assurance Programs

1.6	DOE and prime contractors describe how responsibility is exercised for the overall QA program. The extent of management responsibility and authority from DOE headquarters and from the field office should be addressed.	QARD Introduction page(xiii) PURPOSE AND APPLICABILITY(entire section) QARD Section 1.1 (entire section) QARD Section 1.2 (entire section)
1.7	DOE and prime contractors evaluate the performance of work delegated to other organizations. This shall include audits of the prime contractors QA programs and audits of subcontractors, consultants, vendors, and laboratories furnishing equipment or services to the prime contractor or DOE. The frequency and method of evaluation should be specified.	QARD Section 1.1 QARD Section 2.2 QARD Section 7.1 QARD Sections 18.2, 18.3, and 18.4 (entire section)
1.8	Qualified individual(s) or organizational element(s) are identified within DOE's organization as responsible for the quality of the delegated work before initiation of activities.	QARD Section 1.2
1.9	Clear management controls and effective lines of communication exist, for QA activities, between DOE and its contractors, to assure direction of the QA program.	QARD Section 1.0 (entire section) QARD Section 2.1.1(a) QARD Section 3.0
1.10	Organization charts clearly identify all the "on-site" and "off-site" organizational elements which function under the cognizance of the QA.	QARD Section 2.1.1(b) QARD Section 1.0 , paragraphs 1.1 and 1.2 Note: Positions of Responsibility and Organization Charts are presented in the Quality Assurance Program Description(QAPD) - none are included in QARD.

1.11	The QA organization is involved in portions of the high-level waste repository program that affect safety and waste isolation. The extent of QA controls is determined by the QA staff, in combination with the line staff, and depends on the specific activity, its complexity, and its importance to safety or waste isolation, as defined in 10 CFR Part 60 Section 60.2.	QARD Section 2.0 QARD Section 2.3 QARD Section 2.5 (entire section) QARD Appendix A section 2.0 QARD Appendix B Section 2.0
1.12	DOE and its prime contractors describe the QA responsibilities of each of the organizational elements noted on the organization charts.	QARD Section 1.0 QARD Section 2.1.1(c)
1.13	DOE and its prime contractors identify a management position within each respective organization that retains overall authority and responsibility for the QA program. This position, occupied by an individual with appropriate management and QA knowledge and experience, has the following characteristics:	QARD Section 1.1(entire section)
	a. Is at the same of higher organization level as the highest line manager directly responsible for performing activities affecting quality (such as design, engineering, site investigations, procurement, manufacturing, etc.) and is sufficiently independent from cost and schedule.	QARD Section 1.1(a), (c), (e), and (f)
	b. Has effective communication channels with other senior management positions.	QARD Section 1.1(f)
	c. Has responsibility for approval of QA Manual(s), changes thereto, and interpretations thereof.	QARD Section 1.1(g) Responsibility for approval resides with PROGRAM Director.

	d. Has no other duties or responsibilities unrelated to QA that would prevent full attentions to QA matters.	QARD Section 1.1(d)
1.14	Persons and organizations performing QA functions have sufficient authority and organization freedom to: a. Identify quality problems b. Initiate, recommend, or provide solutions through designated channels. c. Verify implementation of solutions. d. Assure that further processing, delivery, installation, or operation is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred.	QARD Section 1.0 QARD Section 1.1, 1st paragraph QARD Section 1.5 QARD Section 2.2
	The persons and organizations with the above authority are identified, and a description of how those actions are carried out is provided.	QARD Sections 1.2, 1.4, and 1.5 QARD Section 2.1.1, (d), 2.2, 2.3, 2.4, 2.7, and 2.8, QARD Sections 15,16, and 18
1.15	Provisions are established for the resolution of disputes involving quality arising from a difference of opinion between QA personnel and other department personnel.	QARD Section 1.3 and 1.4
1.16	Policies on the implementation of the QA program are documented and made mandatory.	QARD Introduction: PROGRAM Director policy statement is included in QAPD.

1.17	Provisions are established for resolving allegations of inadequate quality. These allegations may originate within the responsible organization(s) or form outside the responsible organization(s).	QARD Section 1.4
2.	Activities related to the QA Program are acceptable to the NRC staff if:	QARD Introduction - Purpose and Applicability Section, 5th Paragraph
2.1	A QA program is established and documented which complies with the QA controls of 10 CFR Part 60, Subpart G; with 10 CFR Part 50, Appendix B; and with this Review Plan.	
2.2	The QA program provides a commitment to comply with NQA-1, "Quality Assurance Program Requirements for Nuclear Facilities" (see Ref. 2) and the following position, relative to the NQA-1 standard: Appendix 2A-1, "Nonmandatory Guidance on the Qualifications of Inspection and Test Personnel," provides guidance on the qualifications of inspection and test personnel. The provisions of Appendix 2A-1 (or acceptable alternative) should be met as part of Supplement 2S-1, "Supplementary Requirements for the Qualification of Inspection and Test Personnel."	QARD Section 2.0 and 2.6
2.3	The QA program is documented by written policies, procedures or instructions and carried out by qualified individual(s), in accordance with these program documents, before initiation of activities.	QARD Section 2.1 QARD Section 2.6 (entire section) QARD Section 5

2.4	Criteria are established and documented for determining and identifying structures, systems, components, software and activities which are to be controlled by the QA program. Guidance for determining these items and activities is provided in NUREG-1318, "Technical Position on Items and Activities in the High Level Waste Geologic Repository Program Subject to Quality Assurance Requirements." (See Ref. 4)	QARD Section 2.0 QARD Section 2.3 (entire section) QARD Section 2.5 (entire section) QARD Section 3.3 QARD Appendix A Section 2.0 (entire section) QARD Appendix B Section 2.0 (entire section)
2.5	Activities affecting quality are to be accomplished under suitably controlled conditions. Controlled conditions include the use of appropriate equipment; suitable environmental conditions for accomplishing the activity, such as adequate cleanness; and assurance that all prerequisites for the given activity have been satisfied.	QARD Section 2.0 QARD Section 5.0 QARD Section 9.0 QARD Section 11.0 QARD Section 13.0
2.6	The program takes into account the need for special controls, processes, test equipment, tools, and skills to attain the required quality, and the need for verification of quality by inspection and tests.	QARD Section 2.0 QARD Section 9 QARD Section 10 QARD Section 11 QARD Section 12 QARD Section 14
2.7	Provisions are established which demonstrate through a matrix system or other means that each criterion of Appendix B is properly documented and covered by implementing procedures and/or instructions.	Introduction (entire section) QARD Section 2.1, 1st paragraph QARD Section 2.1.1,(entire section) QARD Section 5.2
2.8	A policy statement signed by a senior management official renders the implementation of the QA program mandatory.	Policy Statement is found in QAPD.

2.9	The QA program includes a commitment that all development, control, and/or use of computer programs will be conducted in accordance with the QA program. Guidance for the content of documentation of computer codes is provided by NUREG-0856, "Final Technical Position on Documentation of Computer Codes for High-Level Waste Management." (See Ref.5.0 NUREG-CR-4740, "Handbook of Software Quality Assurance Techniques Applicable to the Nuclear Industry," (see Ref.6) may be used as a reference for developing software QA programs.	QARD Section 3.3 (entire section)
2.10	Provisions are established to assure that technical and quality assurance procedures required to implement the QA program are consistent with regulatory, licensing, and QA program requirements and are properly documented and controlled.	QARD Section 2.1 QARD Section 5.0 (entire section) QARD Section 6.0 (entire section) Appendix A, Section 5.1
2.11	The QA organization or other designated organizations knowledgeable in QA controls reviews and document concurrence with procedures pertaining to safety functions.	QARD Section 2.0 QARD Section 5.2 QARD Section 6.0 QARD Section 6.2 QARD Appendix A, Section 5.1
2.12	A description is provided of how management (above or outside the QA organization) regularly assesses the scope, status, adequacy, and compliance or the QA program to 10 CRF Part 50, Appendix B. These measures should include:	
	a. Frequent contact with program status through reports, meetings, and/or audits.	QARD Section 2.0 QARD Section 2.9
	b. Performance of an annual assessment which is preplanned and documented with corrective action identified and tracked.	QARD Section 2.0 QARD Section 2.1.1 QARD Section 2.8

2.13	Management of other organizations participating in the quality assurance program shall regularly review the status and adequacy of that part of the quality assurance program which they are executing.	QARD Section 2.1 and 2.1.1
2.14	Indoctrination, training, and qualification program are established for personnel performing activities affecting quality to assure that suitable proficiency is achieved and maintained and that:	QARD Section 2.6
	a. Personnel responsible for performing quality-related activities are instructed as to the purpose, scope, and implementation of the quality-related manuals, instructions, and procedures.	QARD Section 2.1.9(c) QARD Section 2.6
	b. Personnel verifying activities affecting quality are qualified in the principles, techniques, and requirements of the activity being performed.	QARD Section 2.0 QARD Section 2.6.2(a)
	c. For formal training and qualification programs, documentation includes the objective, content of the program, attendees, and date of attendance.	QARD Section 2.6.2(b)
	d. Appropriate management monitors the performance of individuals involved in activities affecting quality and determines the need for retraining and/or replacement. A system of annual appraisal and evaluation can satisfy this criterion.	QARD Section 2.0 QARD Section 2.6.2(b)

	e. Qualified personnel are certified in accordance with applicable codes and standards.	QARD Section 2.6
2.15	Measures are provided describing the extent a readiness review program will be established and executed at appropriate major milestones to complement the inspection program.	QARD Section 2.4 QARD Appendix B Section 2.2
3.	Activities related to Design Control are Acceptable to the NRC staff if:	QARD Section 3 QARD Attachment 1 Glossary - See definitions of "Design, Design Activities, and Design Review"
3.1	The definitions of design, design information, and design activities used in the design control program are defined as specifications, drawings, design criteria, and component performance requirements for the natural and engineered components of the repository system. It includes design inputs and outputs at each stage of design development (i.e., from conceptual design to final design). Design information and design activities refer to data collection and analyses activities and computer codes that are used in supporting design development and verification. This includes general plans and detailed procedures for data collection and analyses and related information such as test results and analyses. Data analyses includes the initial step of data reduction, as well as broad level systems analyses (such as performance assessments) which integrate many other data and analyses of individual parameters. The above is consistent with the definition and usage of these terms in 10 CFR Part 60 and the Atomic Energy Act of 1954.	
3.2	The design control program includes design and design activities as described in Section 3.1. It provides for the correct translation of applicable regulatory requirements and design bases into design, procurement, and procedural documents.	QARD Section 3.0 QARD Section 4.0 QARD Section 4.1 QARD Section 5.1 QARD Appendix A, Section 3.0, 5.0 QARD Appendix B. Section 3.0

3.3	Measures are established to assure that those applicable regulatory requirements, design bases and design features developed through the site characterization phase activities for those structures, systems, components, and software to which this appendix applies are correctly translated into specification, drawings, plans, procedures, and instructions.	QARD Section 3.0 QARD - Appendix A Section 3.0(entire section) QARD - Appendix B Section 3.0(entire section) QARD Section 5.1
3.4	Design control measures are established and applied to: (a) the design of engineered items important to safety or waste isolation; (b) the description of the geologic setting and plans for data collections and analysis activities that will generate information pertinent to the repository design and that will be relied on in licensing; and (c) computer codes. These design control measures apply to the design inputs, outputs, and implementation of the Site Characterization Plan into scientific investigation plans and study plans.	QARD Section 3.0 / NQA-1 Basic Requirements 3 and Supplement 3S-1 QARD Section 3.3 QARD Appendix A Section 2.1, 3.2
3.5	Design control measures are established and applied to conceptual design, or parts thereof, which may at a later time become part of the final design.	QARD Section 3.0 / NQA-1 Supplement 3S-1, Sections 2 and 3 QARD Attachment 1 "Glossary" See Definition of Design
3.6	Organizational responsibilities are described for preparing, reviewing, approving, verifying and validating design and design information documents.	QARD Section 3.0 / NQA-1 Basic Requirement 3 and Supplement 3S-1 QARD Section 3.3 QARD Sections 3.4 QARD Appendix A Sections 2.0 and 3.0 (entire section)
3.7	Errors and deficiencies in approved design and design information documents are documented, and action is taken to assure that all errors and deficiencies are corrected.	QARD Section 3.1 QARD Section 3.3.9 QARD Appendix A, Section 3.0 (entire section)

3.8	Design interfaces and interface controls among organizations or groups involved in design development and other design activities such as the review, approval, release, distribution and revisions of documents involving design interface are described and procedurally controlled.	QARD Section 3.0 (entire section)
3.9	Procedures require that design drawings, specifications, criteria, and analyses be reviewed by the QA and/or technical organization, to assure that the documents are prepared, reviewed, and approved in accordance with documented procedures and QA requirements and that the appropriate quality standards are specified and included in design documents.	QARD Section 3.0 (entire section) QARD Section 5.0
3.10	Procedural controls provided for verifying or checking the adequacy of design, such as by the performance of design reviews, by the use of alternate or simplified calculation methods, or by the performance of a suitable testing program.	QARD Section 3.0 (entire section) QARD Section 5.0
3.11	Procedures are established to assure that plans for data collection and analyses are completed before performing the data collection and analysis activities.	QARD Section 3.0 QARD Appendix A Section 3.2 thru 3.7.1. QARD Appendix B Section 3.2
3.12	Procedures for a design or technical review require, where applicable, the identification of the reviewers, the area or features reviewed, and the resolution methods for resolving comments.	QARD Sections 3.3.8 and 3.4 QARD Section 6.0

3.13	Design verification procedures assure the following:	QARD Section 3.0 QARD Section 3.3 QARD Section 3.4 QARD Appendix A, Section 3.1 QARD Appendix B, Section 3.1
	a. criteria for determining the method of verification are established;	
	b. the persons performing verification and validation are qualified and not directly responsible for the design;	QARD Section 3.3 QARD Section 3.4(c) QARD Appendix A, Section 3.1 QARD Appendix B, Section 3.1
	c. the verification and validation are completed before release for procurement, manufacturing, construction, or use;	QARD Section 3.0
	d. the responsibilities of the persons performing the verification or validation are defined;	QARD Section 3.3.3 QARD Section 3.4(c) QARD Appendix A, Section 3.1 QARD Appendix B, Section 3.1
	e. the areas and features to be verified are specified, and	QARD Section 3.4 QARD Appendix A, Section 3.1 QARD Appendix B, Section 3.1
	f. the extent of documentation is defined.	QARD Section 3.4(d) QARD Appendix A, Section 3.1 QARD Appendix B, Section 3.1

3.14	Procedures are established and described for verification of design and design activities. Individuals verifying designs should be qualified and not directly responsible for the design (i.e., not the performer or his immediate supervisor). In exceptional cases, the designer's immediate supervisor can, however, perform the verification provided: a. The supervisor is the only technically qualified individual.	QARD Section 3.3 QARD Section 3.4
	b. The need is individually documented and approved in advance, with concurrence of the QA manager.	NOTE: Approval by the QA Manager to allow the use of a designer's supervisor to perform design verification is not required by the QARD.
3.15	Where a test program is used to verify the adequacy of a specific engineering design feature in lieu of other verifying of checking processes, it shall include suitable qualification testing of a prototype unit under the most adverse design conditions.	QARD Section 3.?
3.16	Peer reviews which comply with the reference commitments in NUREG-1297, "Generic Technical Position on Peer Review for High-Level Waste Repositories," (see Ref.7) are conducted.	QARD Appendix A Section 3.1 QARD Appendix B Section 3.1
3.17	Design changes, including field changes, are subject to the same design controls that were applicable to the original design. Such a configuration control system is in place at the earliest practicable time. These changes area analyzed to assure that change is required. Associated changes to procedures and training should be considered and communicated to all affected groups or individuals.	QARD Section 3.0 QARD Section 3.1 QARD Section 3.2 QARD Section 3.3.7 QARD Appendix B, Section 3.2.6

3.18	Procedures are established to assure that verified computer codes are certified for use and that their uses are specified.	QARD Sections 3.3.1(a), (d), 3.3.3(b), 3.3.4, 3.3.8
3.19	Procedures are established describing methods of reviewing and qualifying data which was gathered without a fully implemented 10 CFR Part 60 QA Program. For guidance refer to NUREG-1298, "Generic Technical Position on Qualification of Existing Data for High-Level Nuclear Waste Repositories." (See Ref.8)	QARD Appendix A Section 3.7 QARD Appendix B Section 3.2.5
3.20	The design inputs are specified and approved on a timely basis and to the level of detail necessary to permit the design activity to be carried out in a correct manner and to provide a consistent basis for making design decisions, accomplishing design decisions, and accomplishing design verification measures, and evaluating design changes.	QARD Section 3.0(entire section)
4.	Activities related to Procurement Document Control are acceptable to the NRC staff if:	
4.1	Procedures are established to assure that applicable regulatory requirements, design bases, and other requirements are referenced or stated in procurement documents; there are adequate acceptance and rejection criteria, where appropriate; and that procurement documents have been prepared, reviewed, and approved to confirm that these requirements have been correctly carried out.	QARD Section 4.0 QARD Section 4.1
4.2	Procurement documents specify that contractors, subcontractors and consultants are to provide an acceptable QA program commensurate with the scope, complexity and safety of the activity.	QARD Section 4.0 QARD Section 7.0

4.3	Organizational responsibilities are described for: (1) procurement planning; (2) the preparation, review, approval, and control of procurement documents; (3) supplier selection; (4) bid evaluation; and (5) review and concurrence of supplier QA programs before initiation of activities affected by the program. The involvement of the QA organization is described.	QARD Section 4.1 QARD Section 7.0
5.	Activities related to Instructions, Procedures, and Drawings are acceptable to the NRC staff if:	QARD Section 5.0 QARD Appendix A Section 5.0
5.1	Activities affecting quality are prescribed by documented instructions, procedures, or drawings and accomplished in accordance with these instructions, procedures, or drawings.	
5.2	Organizational responsibilities are described for assuring that quality-related activities are: (1) specified in instructions, procedures, and drawings; and (2) accomplished through implementation of these documents.	QARD Section 1.0 QARD Section 2.1.1 (entire section) QARD Section 5.0
5.3	Procedures are established to assure that instructions, procedures, and drawings include or reference quantitative or qualitative acceptance criteria for determining that quality-related activities have been satisfactorily accomplished.	QARD Section 2.1.1(entire section) QARD Section 5.0
5.4	Provisions are described for controlling changes to field and laboratory procedures associated with exploratory investigations within the site characterization program to assure that such changes are subsequently documented and verified in a timely manner by authorized personnel.	QARD Appendix A Section 2.1 (entire section) QARD Appendix A Section 3.2 thru 3.7.1

6.	Activities related to Document Control are acceptable to the NRC staff if:	QARD Section 6.2 QARD Appendix A Section 6.1
6.1	The scope of the document control program is described, and the types of controlled documents are identified (e.g, instructions, procedures, drawings, as-builts, design and technical supporting documents, QA documents, and nonconformance and corrective action reports including changes thereto).	
6.2	Procedures for the review, approval, issuance, and revision of documents are established. These procedures assure that the technical and quality requirements are correctly included, before release, through reviews by qualified authorized personnel who did not provide input to the document.	QARD Section 6.0 QARD Section 6.2
6.3	Procedures are established to assure that correct and applicable documents are available at the location where the activity will be performed, before commencing the work.	QARD Section 6.1
6.4	Changes to documents shall be reviewed and approved by the same organizations that performed the original review and approval, unless the applicant designated another responsible organization.	QARD Section 6.0 QARD Section 6.2
6.5	Procedures are established and described to assure that obsolete or superseded documents are removed and replaced by applicable revision at work areas in a timely manner.	QARD Sections 6.1 and 6.3

6.6	A master list or equivalent document control system is established to identify the current revision of instructions, procedures, specification, drawings, and procurement documents.	QARD Sections 6.1 and 6.3
6.7	When documents which require verification are released before verification, they are so identified, controlled and authorized for release through signature approval, with the described bases for release.	QARD Section 6.2(d)
7.	Activities related to Control of Purchase Materials, Equipment, Items and Services and Software are acceptable to the NRC staff if:	QARD Section 7.0
7.1	Measures are established and described to assure that purchased items and services, including software, whether purchased directly or through contractors and subcontractors, conform to procurement documents.	
7.2	Organizational responsibilities are described for the control of purchased items, services and software.	QARD Section 2.1.1 QARD Section 3.3 QARD Section 7.0
7.3	Procedures governing procurement of items or services provide for: (a) evaluation and selection of suppliers; (b) objective evidence of quality furnished by suppliers; (c) inspections and audits of suppliers activities, items, services and software; and (d) receiving inspections.	QARD Section 7.0

7.4	The organization providing items, materials, equipment, services, or software furnishes the following records to the purchaser: a. Documentation that identifies the procurement and the specific procurement requirements met (e.g., codes, standards, and specifications). b. Documentation identifying any procurement requirements that have not been met. c. A description of those nonconformances from the procurement requirements dispositions "accept as is" or "repair". A procedure that assure that the review and acceptance of these documents, before installation or use of the procured item, should be described in the purchaser's QA program.	QARD Section 4.0 QARD Section 7.0
7.5	Documents attesting to the acceptability of procured items shall be sufficient to identify the specific requirements, such as codes, standards, or specifications, met by the purchased item, and retained in the records storage facilities for retrievability, as necessary.	QARD Section 7.0
7.6	Provisions are established by DOE or its designee to assess and ensure the control of quality by contractors and subcontractors. these assessments are performed at intervals consistent with the importance, complexity, and quantity of the product or services.	QARD Section 4.0, 4.1 QARD Section 7.0 QARD Section 18.4
7.7	Suppliers certificates of conformance for items, services and software are periodically evaluated by audits, independent inspection, or tests to assure that they are valid and the results documented.	QARD Section 7.0 QARD Section 18.4(b)

8.	Activities related to Identification and Control of Items (including samples), Services, and Software are acceptable to the NRC staff if:	QARD Section 3.3 QARD Section 8.0 QARD Appendix A Section 13 QARD Appendix B Section 13
8.1	Controls are established and described to identify and control items (including samples) and consumables, services, and software, to assure that the identity is maintained and traceable to technical and quality-related documents.	
8.2	Procedures are established which assure that identification is maintained either on the item, software and samples or on records and containers traceable thereto.	QARD Section 3.3.6 QARD Section 8.0 (entire section) QARD Appendix A, Section 13 QARD Appendix B, Section 13
8.3	Identification can be traced to the appropriate documentation such as drawings, specification, purchase orders, technical reports, drilling locations, logs, (including well bore and depth), test records, installation and use records, inspection documents, and nonconformence reports.	
8.4	Correct identification of samples is verified and documented before release for use or analysis.	
8.5	Controls are established to preclude the inadvertent use of incorrect or defective items, software, and samples.	

9.	Activities related to Control of Special Processes are acceptable to the NRC staff if:	QARD Section 9.0 QARD Appendix A Section 9.1 QARD Appendix B Section 9.1
9.1	The criteria for determining those processes that are controlled as special processes are described. As complete a listing as possible of special processes is provided, which generally are those processes where direct inspection is impossible or disadvantageous, such as heat treatment, welding, nondestructive testing, data collection, and other site characterization activities.	
9.2	Organizational responsibilities including those for the QA organization are described for qualification of special processes, equipment, and personnel.	QARD Section 9.2 QARD Appendix A Section 9.0(entire section)
9.3	Procedures, equipment, and personnel associated with special processes are qualified and are in conformance with applicable codes, standards, QA procedures, and specifications. Acceptable methods for qualifying those special processes associated with scientific investigation are: (1) the conduct of a prototype test, if possible, that demonstrates the process maintains quality or produces a quality product; or (2) a technical review; or (3) a peer review.	QARD Section 3.4 QARD Section 9.0 QARD Section 9.3 QARD Appendix A Section 3.1 QARD Appendix A Section 9.0 QARD Appendix B Section 3.1 QARD Appendix B Section 9.0 QARD Addendum A-1, Section I
9.4	Procedures are established for recording evidence of acceptable accomplishment of special processes, using qualified procedures, equipment, and personnel.	QARD Section 9.3 QARD Appendix A Section 9.1 QARD Appendix B Section 9.1 QARD Addendum A-1, Section I

9.5	Qualification records of procedures, equipment, and personnel associated with special processes are established and maintained.	QARD Section 9.0 QARD Section 9.3 QARD Appendix A, Section 9.0 QARD Appendix B, Section 9.0 QARD Addendum A-1, Section I
10.	Activities related to inspection are acceptable to the NRC staff if:	QARD Section 2.1.1(g) QARD Section 10.0 QARD Appendix A, Section 10.0
10.1	The scope of the inspection program is described that indicates an effective program has been established to verify that items and services conform to documented instructions, procedures, drawings, and specification. Program procedures provide criteria for determining when inspection of each work operation are to be performed.	
10.2	Organizational responsibilities for inspection are described. Individuals performing inspections are part of the QA organization or are qualified individuals independent of the organizational unit directly responsible for the activity being inspected.	QARD Section 2.1.1(g) QARD Section 2.2 QARD Section 2.6 QARD Addenda A-1, Section II
10.3	A qualification program for inspectors is established and documented, and the qualification and certification of inspectors are kept current.	QARD Section 2.6

10.4	Inspection procedures, instructions, or checklists provide for the following: a. Identification of characteristics and activities to be inspected. b. A description of the method of inspection. c. Identification of the individuals or groups responsible for performing the inspection operation. d. Acceptance and rejection criteria. e. Identification of required procedures, drawings, and specification and revisions. f. Recording inspector or data recorder and the results of the inspection operation. g. Specifying necessary measuring and test equipment, including accuracy requirements.	QARD Section 10 QARD Section 2.3 QARD Appendix A, Section 10 QARD Addenda A-1, Section 11
10.5	Procedures include identification of mandatory inspection hold points beyond which work may not proceed until inspected by a designated inspector.	QARD Section 2.1.1 QARD Section 10.0
10.6	Provisions are established to assure that when inspection of processed material or products is impossible or disadvantageous, indirect control by monitoring processing methods, equipment, and personnel is provided.	QARD Section 2.7 QARD Section 10.0
10.7	Provisions are established to assure that both inspection and process monitoring is provided when control is inadequate without both.	QARD Section 2.7 QARD Section 10.0

10.8	Inspection results are documented and evaluated, and their acceptability is determined by a responsible individual.	QARD 3.4(entire section) QARD Section 10.0
11.	Activities related to Test Control are acceptable to the NRC staff if:	QARD Section 3.3 QARD Section 11.0 QARD Appendix A QARD Appendix B Section 3.2 QARD Addenda A-1, Section III
11.1	A test program is established to assure that all testing associated with items, software, scientific investigations, and acquiring data from samples is identified and performed in accordance with written test procedures incorporating, as appropriate the requirements and acceptance limits contained in applicable design documents.	
11.2	Procedural controls are established to assure the test program includes, as appropriate, proof tests before installation, preoperational tests, and operational tests during site characterization, construction and operation of high level waste storage facilities.	QARD Section 11(entire section) QARD Appendix A Section 11.0 QARD Appendix B Section 3.0 QARD Addenda A-1, Section III
11.3	Program procedures for test control provide for: (a) determining when a test is required and how testing activities are performed; and (b) assurance that the test program is conducted by trained and appropriately qualified personnel.	11.3(a) QARD Sections 2.1.1 and 2.3 QARD Section 3.3 (entire section) QARD Section 11.0 QARD Appendix A Section 11.0 QARD Appendix B Sections 3.2.6 and 11.0 QARD Addenda A-1, Section III 11.3(b) QARD Section 2.6 QARD Section 11.0 Appendix A Section 11.0 Appendix B Section 2.4 QARD Addenda A-1, Section III

11.4	Test plans and procedures are reviewed in accordance with the verification requirements in Section 3.15 and 3.17.	QARD Section 11.0 QARD Appendix A Sections 3.2 and 11.0 QARD Addenda A-1, Section III
11.5	The potential sources of uncertainty and error in test plans, procedures, and parameters, which must be controlled and measures to assure that tests are well-controlled, are identified.	QARD Section 2.3(entire section) QARD Section 11 (entire section) QARD Appendix A Sections 3.1 and 11.0 QARD Appendix B Section 3.1 QARD Addenda A-1, Section III
11.6	Test procedures or instructions provide for the following: a. The requirements and acceptance limits, including required levels of precision and accuracy, as appropriate, are contained in applicable documents. b. Instructions for performing the test. c. Test prerequisites such as: calibrated instrumentation; adequate test equipment and instrumentation; completeness of item to be tested; suitable and controlled environmental conditions; and provisions for data collection and storage. d. Mandatory inspection hold points (as required). e. Acceptance and rejection criteria, including required levels of precision and accuracy. f. Methods of documenting or recording test data and results. g. Provisions for assuring test prerequisites have been met.	QARD Section 2.1 QARD Section 3 (entire section) QARD Section 11.0 QARD Appendix A, Section 3.2 QARD Addenda A-1, Section III

11.7	Test results are documented, evaluated, and their acceptability determined by a responsible individual or group, as described in Section 3.	QARD Section 3.3 (entire section) QARD Section 3.4 (entire section) QARD Section 11 QARD Appendix A Sections 3.1, 3.3.1, 3.4, 3.5 and 11.0 Appendix B Section 3 QARD Addenda A-1, Section III
11.8	Items tested should be identified, controlled, and ultimately dispositioned, and samples should be archived, as required by procedures.	QARD Section 11 QARD Section 2.3(g) QARD Section 8 Appendix A, Section 8 Appendix A, Section 13 Appendix B, Section 13
12.	Activities related to Control of Measuring and Test Equipment are acceptable to the NRC staff if:	QARD Section 2.1.1(i) QARD Section 12 (Inc. Supplement 12S-1) QARD Appendix A Section 3.2.4 QARD Addenda A-1, Section I (1st paragraph)
12.1	The scope of the program is described for assuring that tools, gauges, instruments and other measuring and testing devices are properly controlled, calibrated, and adjusted, at specified periods, to maintain accuracy with necessary limits.	
12.2	QA and other organizations' responsibilities are described for establishing, implementing, and assuring effectiveness of the calibration program.	
12.3	Procedures are established and described for calibration (technique and frequency), maintenance, and control of the measuring and test equipment (instruments, tools, gages, fixtures, reference and transfer standards, and nondestructive test equipment) used for measurement, inspection, and monitoring. The review and documented concurrence of these functions is identified.	

12.4 Measuring and test equipment is labeled, tagged or otherwise documented to indicate due date of next calibration and to provide traceability to calibration test data.

12.5 Measuring and test equipment is calibrated at specified intervals, based on required accuracy, precision, purpose, degree of use, stability, characteristics, and other conditions which could affect measurement.

12.6 Calibration standards are traceable to nationally recognized standards. Where national standards do not exist, provisions are established to document acceptability of the calibration standard used.

12.7 When measuring and test equipment is found to be out of calibration, evaluation are made and documented to determine the validity and acceptability of measurement performed since the last calibration. Inspections or tests are repeated on items determined to be suspect.

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

13. Activities related to Handling, Storage, and Shipping are acceptable to the NRC staff if:

13.1 Handling, preservation, storage, packaging, shipping, cleaning and preservation requirements and procedures are established to prevent damage or deterioration of items and samples and accomplished by suitably trained individual in accordance with predetermined work and inspection instructions.

13.2 Procedures are established and described to control cleaning, handling, storage, packaging, and shipping of items and samples in accordance with design and procurement requirements and manufacturer's recommendations to preclude damage, loss, or deterioration by environmental conditions such as temperature or humidity.

13.3 The methods of handling, storage and packaging of items and samples take into consideration controls, as appropriate, for limited life expectancy, and special cleanliness.

QARD Section 13
QARD Appendix A Sections 8 and 13
QARD Appendix B Section 13

14. Activities related to Inspection, Test and Operating Status are acceptable to the NRC staff if:

14.1 Procedures are established to indicate by the use of markings the status of inspections and tests, and the operating status of individual items and software.

14.2 Procedures are established for the identification of items which have passed required inspections and tests, where necessary to preclude inadvertent by passing of such inspections and tests.

14.3 Measures are established for indicating the test and/or operating status of items; for example, tagging, to prevent inadvertent operation or use.

QARD Section 3.3
QARD Section 14
QARD Appendix A Section 14.0
QARD Addenda A-1, Section IV

14.4	Procedures are established and described to control altering the sequence of required tests, inspections, and other operations important to safety. Such actions should be subject to the same controls as the original review and approval.	QARD Section 2.1.1 (entire section) QARD Section 2.3 (entire section) QARD Section 3.3 (entire section) QARD Section 5 QARD Section 14 QARD Appendix A Section 3.2.2 and 3.2.3 QARD Appendix B Section 3.2.6 (entire section) QARD Addenda A-1, Section IV
14.5	The status of nonconforming, inoperative, or malfunctioning structures, systems, and components is documented and identified to prevent inadvertent use. The organization responsible for this function is identified.	QARD Section 2.1.1 (entire section) QARD Section 3.3 (entire section) QARD Section 14.0 QARD Appendix A Section 14.0 QARD Addenda A-1, Section IV
15.	Activities related to Nonconformances are acceptable to the NRC staff if:	QARD Sections 3.1 and 3.3.9 QARD Section 15.0
15.1	Measures are established to control materials, parts, or components which do not conform to requirements in order to prevent their inadvertent use or installation.	
15.2	Procedures are established for identifying, documenting, tracking, segregating, reviewing, dispositioning, and notifying affected organization of nonconforming or defective items, software, procedures, records, and activities. The procedures identify positions authorized to dispose of and close out nonconformances.	
15.3	QA responsibilities related to nonconformance control are described.	QARD Section 2.1 (entire section) QARD Section 15.0
15.4	Documentation identifies and describes the dispositions, nonconformances, and includes authorized signature approval of the disposition.	

15.5 Nonconformance reports are periodically analyzed by the QA organization to show trends and to help identify root causes of nonconformances, and the significant results are reported to upper management for review and assessment.

QARD Section 2.8 and 2.9
QARD Section 16

16. Activities related to Corrective Action are acceptable to the NRC staff if:

QARD Section 2.8, 3.1 and 3.3.9
QARD Section 16

16.1 Procedures are established indicating that an effective corrective action program has been established to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, nonconforming and defective items, samples, procedures, and records are promptly identified and corrected. The QA organization reviews and documents concurrence with the procedures.

16.2 Corrective action is documented and initiated after a nonconformance to preclude recurrence. The QA organization concurs with the correction action to assure that QA requirements are satisfied.

16.3 Follow-up action is taken by the QA organization to verify proper implementation of corrective action and to close out the corrective action in a timely manner.

16.4 The cause of significant conditions adverse to quality is determined and the corrective action is taken to preclude repetition. These actions are documented and reported to immediate management and upper levels of management for review and assessment.

17.	Activities related to QA Records are acceptable to the NRC staff if:	QARD Section 17 QARD Appendix B Section 17
17.1	The scope of the records program is described which assures that sufficient records affecting quality are identifiable, retrievable, and maintained. QA records include scientific, engineering, and operational data and logs; geotechnical data; results of reviews, inspection, tests, audits, and material analyses; monitoring of work performance; qualification of personnel, procedures, and equipment; and other documentation such as drawings, specifications, procurement documents, calibration procedures and reports, design review reports, peer review reports, nonconformance reports, and corrective action reports.	
17.2	QA and other organizations are identified and their responsibilities are described for defining and implementing record activities, particularly in the retention, duration and safe storage or records.	QARD Section 1.1 and 1.2 QARD Section 2.1, 2.1.1 and 17.0 (entire sections) QARD Section 17 QARD Appendix B Section 17

17.3 Inspection and test records contain the following, where applicable:

a. Identification of procedure and item inspected or tested.

b. A description of the type of observation.

c. The date and results of the inspection or test.

d. Information related to conditions adverse to quality.

e. Inspector or data recorder identification.

f. Evidence as to the acceptability of the results, with signature and organization.

g. Action taken to resolve any discrepencies noted.

17.4 Criteria are established and described in procedures for determining when a document becomes a QA record, subject to the controls of this section and the retention periods for such records.

QARD Section 1.1 and 1.2
QARD Section 2.1.1
QARD Section 3.3.7
QARD Section 10.1
QARD Section 11.0
QARD Section 17
QARD Appendix A Section 3.6
QARD Appendix B 3.2.4
QARD Appendix B Section 17

17.5 Controls are established and described for controlling, protecting and maintaining those records before their being entered and stored in the quality record control storage area.

17.6 Procedures are established describing methods of documenting/recording, reviewing, and confirming accuracy of records, which include laboratory and field notebooks and log books, data sheets, data reduction documents, and software.

17.7 Suitable facilities for the storage and security of records are described and used to preclude deterioration, damage, loss and misuse of records.

QARD Section 17.0
QARD Appendix B Section 17

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18. Activities related to Audits are acceptable to the NRC staff if:

QARD Section 1.1 1st paragraph
QARD Section 18.0
QARD Appendix A Section 18
QARD Appendix B Section 18

18.1 Internal and external audits are carried out by DOE and its contractors to verify that procedures and activities comply with all aspects of the overall QA program and to determine the effectiveness of the program. DOE and its contractors should perform audits of the prime contractor and subcontractors, consultants, vendors, and laboratories.

18.2 An audit plan is prepared identifying audits to be performed, their frequencies, and schedules, taking into consideration the complexity, safety, importance and degree of previous audits, inspections and surveillance. Audits are regularly scheduled, based on the status and safety importance of the activities being performed, and are initiated early enough to assure effective QA during design, procurement, site characterization, manufacturing, construction, installation, inspection and testing.

18.3	Audits include technical evaluations of the applicable procedures, instructions, activities, and/or items. As applicable, they should include the review of documents and records, including software and test data from samples, to ensure they are acceptable.	
18.4	Audit results are documented and analyzed by the QA and technical staff organization, and the results are reported to responsible management for review, assessment, and appropriate action.	
18.5	Audits are performed in accordance with pre-established written approved procedures or checklists and conducted by trained, qualified, competent QA and technical personnel having expertise which encompasses the area being audited and having no direct responsibilities in the area being audited.	QARD Section 2.0 (Invokes Supplement 2S-3)
18.6	A tracking system for audit findings is established to help assure that all findings are appropriately addressed, prioritized and rended.	QARD Section 16.1 QARD Section 18.0
18.7	The audited organization describes in a formal report the corrective action to be taken to address findings. This report is submitted to the auditing organization and/or responsible management.	QARD Sections 18
18.8	Provisions are established and described to assure that the cause of each finding is also identified, the corrective action for it described, and follow-up action is accomplished to assure proper closeout of deficiencies.	QARD Sections 16 and 18