U. S. DEPARTMENT OF ENERGY

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

QUALITY ASSURANCE REQUIREMENTS

for the

CIVILIAN RADIOACTIVE WASTE MANAGEMENT PROGRAM

Lake Barrett, Director
OCRWM Office of Quality Assurance

10/27/88
Date

~~Approved~~
Charles E. Kay, Acting Director
Office of Civilian Radioactive
Waste Management

11/3/88
Date

REVISION 1

QUALITY ASSURANCE REQUIREMENTS
for the
CIVILIAN RADIOACTIVE WASTE MANAGEMENT PROGRAM

TABLE OF CONTENTS

FOREWORD

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 As a result of the reevaluation, the four documents have been superseded and replaced by DOE/RW-YYYY, Quality Assurance Requirements for the Civilian Radioactive Waste Management Program (QAR) and DOE/RW-XXXX, Quality Assurance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

LIST OF ACRONYMS AND ABBREVIATIONS

ANSI: American National Standards Institute
ASME: American Society of Mechanical Engineers
ASNT: American Society for Nondestructive Testing
ASTM: American Society for Testing and Materials
CAR: Corrective Action Report
CRC: Chemical Rubber Company
CFR: Code of Federal Regulations
DOE: United States Department of Energy
DWPF: Defense Waste Prossing Facility
ILP: Implementing Line Procedures
ISFSI: Independent Spent Fuel Storage Installation
MRS: Monitored Retrievable Storage
NQA-1: ANSI/ASME Standard NQA-1-1986b
NCR: Nonconformance Report
NRC: United States Nuclear Regulatory Commission
NWPA: Nuclear Waste Policy Act
OCRWM: DOE, Office of Civilian Radioactive Waste Management
OGR: Office of Geologic Repositories
Q-List: Quality List
QA: Quality Assurance
QAAP: Quality Assurance Administrative Procedure
QACG: Quality Assurance Coordinating Group
QAL: Quality Activities List
QAPD: DOE/RW-XXXX, Quality Assurance Program Description for the Civilian Radioactive Waste Management Program
QAR: DOE/RW-YYYY, Quality Assurance Requirements for the Civilian Radioactive Waste Management Program
SEMP: Systems Engineering Management Plan
RD: Requirements Document
SIP: Scientific Investigation Planning Document
WBS: Work Breakdown Structure
WVDP: West Valley Demonstration Project
YMP: Yucca Mountain Project
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 management controls needed to achieve PROGRAM objectives are to be established and effectively implemented by all PROGRAM participants. These participants include the Office of Civilian Radioactive Waste Management (OCRWM), Operations Offices, Project Offices, contractors, subcontractors, national laboratories, and other government agencies performing activities affecting quality for the PROGRAM.

PURPOSE AND APPLICABILITY

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

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

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

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

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

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

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

RESPONSIBILITY

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

QUALITY ASSURANCE PROGRAM BASIS

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

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

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

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

SECTION 1

ORGANIZATION

1.0 GENERAL

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

1.1 QUALITY ASSURANCE PROGRAM MANAGEMENT

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

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

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

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

(c) The authority and responsibility to verify the adequacy and implementation effectiveness of the organizations and subtier organizations' quality assurance program

(d) No other duties or responsibilities that are unrelated to quality assurance and that could prevent full attention to quality assurance matters

(e) Sufficient freedom from cost and schedule considerations when opposed to quality considerations

(f) Access to senior management and management at the next higher PROGRAM organizational level to identify, and obtain resolution to, unresolved quality concerns

(g) Review and approval recommendation authority for quality assurance programs, revisions to, and interpretations thereof

1.2 DELEGATION OF WORK

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

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

1.3 DISPUTE RESOLUTION

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

1.4 ALLEGATION RESOLUTION

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

1.5 STOP WORK PROVISIONS

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

(a) Criteria for stopping work and for lifting stop work orders

(b) Authorities and responsibilities

(c) Methodology for lifting stop work orders

SECTION 2

QUALITY ASSURANCE PROGRAM

2.0 GENERAL

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

2.1 QUALITY ASSURANCE PROGRAM

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

PROGRAM participants' quality assurance program documents shall include:

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

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

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

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

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

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

(g) Description of the inspection program including organizational responsibilities

(h) Description of the test control program scope

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

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

2.2 REPORTING INDEPENDENCE OF PERSONNEL

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

2.3 PLANNING

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

(a) Definition of activities

(b) Assignment of quality levels to items and activities based on their importance to radiological safety, waste isolation, or other PROGRAM objectives

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

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

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

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

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

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

2.4 READINESS REVIEWS

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

(a) Work activity prerequisites have been satisfied

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

(c) Personnel have been suitably trained and qualified

2.5 QUALITY LEVELS AND GRADED QUALITY ASSURANCE

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

2.5.1 Classification of Quality Levels

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

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

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

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

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

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

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

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

2.5.2 Graded Quality Assurance

Quality assurance requirements and procedural controls shall be selectively applied. The selective application and the degree of application of the quality assurance requirements assigned to

each item and activity shall be commensurate with the following factors:

(a) Consequence of failure

(b) Importance of data

(c) Complexity of function

(d) Reliability of process

(e) Reproducibility of results

(f) Uniqueness of product

(g) Degree of functional product demonstration

(h) Degree of standardization

(i) History of quality

(j) Impact of schedule or cost or both

(k) Necessity of special controls or processes

(l) Significance to licensing process

2.6 PERSONNEL SELECTION, INDOCTRINATION, TRAINING, AND QUALIFICATION

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

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

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

(b) Personnel selected to perform or verify activities affecting quality shall have education, experience, and training commensurate with the minimum requirements specified. Relevant education and experience shall be

verified. The capabilities of an individual shall be based upon an evaluation of education and experience and compared to those qualification requirements established for the position. Management shall monitor the performance of personnel doing work affecting quality and, at least annually, determine the need for retraining or reassignment.

2.7 SURVEILLANCE

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

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

2.7.2 Surveillance shall be conducted to accomplish the following objectives:

(a) Monitor work in progress

(b) Document compliance or noncompliance with requirements and procedures

(c) Identify actual and potential deficiencies and deviations promptly

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

(e) Provide management information on activities under surveillance

(f) Verify timely implementation of corrective action

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

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

(a) Description of the activity or item under surveillance

(b) Identification of the persons conducting the surveillance

(c) Identification of the persons contacted during the surveillance

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

(e) Summary of the surveillance results that identifies deficiencies, deviations, or exemplary practice noted during the surveillance

(f) Summary of any immediate corrective actions taken

2.8 MANAGEMENT ASSESSMENT

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

(a) Effectiveness of the quality assurance program

(b) Adequacy of planning and procedural controls

(c) Effectiveness of the corrective action system

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

(e) Adequacy of the indoctrination and training program

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

2.9 QUALITY ASSURANCE MANAGEMENT-INFORMATION REPORTING AND TRACKING

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

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

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

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

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

SECTION 3

DESIGN CONTROL

3.0 GENERAL

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

3.1 DESIGN ERROR AND DEFICIENCY CONTROL

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

3.2 DESIGN CHANGES

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

3.3 COMPUTER SOFTWARE CONTROL

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

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

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

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

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

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

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

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

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

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

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

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

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

(b) An explanation of the mathematical model(s) and derivation of the numerical methods used in the computer software design. Physical and mathematical assumptions on which the computer software is based shall be listed along with an explanation of the capabilities and limitations inherent in the computer software.

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

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

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

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

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

3.4 TECHNICAL REVIEWS

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

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

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

3.4.4 The results of technical reviews shall be documented.

3.5 PEER REVIEWS

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

3.6 SCIENTIFIC INVESTIGATIONS

3.6.1 Control of Scientific Investigations

Scientific investigations shall be defined, controlled, and verified. Process variables affecting scientific investigations

shall be measured and controlled. Variables that affect interrelated scientific investigations shall be identified, documented, and controlled in each investigation.

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

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

3.6.2 Planning

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

(a) Description of work to be performed

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

(c) Proposed methodology

(d) Rationale and justification for the proposed methodology

(e) References to applicable documents

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

(g) Description of constraints

(h) Description of the application of the results

(i) Description of schedules and milestones

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

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

special quality or performance verification requirements shall be established and described to govern the use of the equipment.

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

3.6.3 Data Collection and Analysis

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

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

3.6.4 Use of Data

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

3.6.5 Data Identification and Traceability

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

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

3.6.6 Data Recording, Storage, and Retrievability

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

Records shall, as appropriate, identify the following elements:

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

(b) Item or sample investigated

(c) Date of scientific investigation

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

(e) Results and acceptability for intended use

(f) Action taken in connection with any deviations noted

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

(h) Identification of equipment used

3.6.7 Qualification of Data of Indeterminate Quality

Data that was not collected under the control of a quality assurance program meeting the quality assurance requirements of 10 CFR 60 Subpart G or this document shall be qualified in accordance with NUREG-1298, Qualification of Existing Data for High-Level Nuclear Waste Repositories Generic Technical Position, February 27, 1988 prior to use. This may include data collected from such sources as professional journals, technical reports, and symposia proceedings but does not include design reference codes and standards (for example, ASME Boiler and Pressure Vessel Code, ASTM standards, and CRC Handbooks). The organization using the data shall define the data-qualification process that describes how data will be assessed for quality characteristics, such as accuracy, precision, completeness, representativeness, and comparability. Acceptable qualification

methods include any one or a combination of peer review, corroborating data, or confirmatory testing. Consideration shall be given to the following factors when available and measurable:

(a) Qualifications of personnel or organizations generating the data

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

(c) Environmental conditions

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

(e) Amount of corroborating data or confirmatory testing

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

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

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

(i) Prior professional reviews of the data

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

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

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

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

(a) Identification of the corroborating data source

(b) Tabulation of the corroborating data

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

(d) Technical justification for use of the corroborating data

(e) Identification of the corroborating data reviewers

(e) Test results

SECTION 4

PROCUREMENT DOCUMENT CONTROL

4.0 GENERAL

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

4.1 REVIEW

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

4.2 APPLICABILITY OF PURCHASER'S QA PROGRAM

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

SECTION 5

INSTRUCTIONS, PROCEDURES, AND DRAWINGS

5.0 GENERAL

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

5.1 REVIEWS

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

5.2 PROCEDURES LIST

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

SECTION 6

DOCUMENT CONTROL

6.0 GENERAL

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

6.1 CONTROL

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

6.2 CONTROL SYSTEM

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

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

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

(c) Documentation and maintenance of review comments and resolutions

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

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

6.3 CONTROLLED DOCUMENTS

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

SECTION 7

CONTROL OF PURCHASED ITEMS AND SERVICES

7.0 GENERAL

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

7.1 SUPPLIERS' QUALITY ASSURANCE PROGRAMS

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

SECTION 8

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

8.0 GENERAL

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

8.1 SAMPLES

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

8.1.1 Sample Identification

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

8.1.2 Sample Traceability

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

8.1.3 Archival Samples

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

SECTION 9

CONTROL OF PROCESSES

9.0 GENERAL

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

9.1 APPLICABILITY

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

9.2 LIST OF SPECIAL PROCESSES

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

9.3 QA INVOLVEMENT IN QUALIFICATION ACTIVITIES

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

9.4 EVIDENCE OF ACCOMPLISHMENT

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

SECTION 10

INSPECTION

10.0 GENERAL

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

10.1 APPLICABILITY

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

10.2 RECORDS

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

(a) Inspection procedure

(b) Characteristics inspected

(c) Inspection criteria or reference documents used to determine acceptance

(d) Equipment used during the inspection

(e) Special expertise used

SECTION 11

TEST CONTROL

11.0 GENERAL

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

11.1 APPLICABILITY

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

11.2 UNCERTAINTY AND ERROR

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

11.3 PRECISION AND ACCURACY

Precision and accuracy considerations shall be identified in test procedures.

SECTION 12

CONTROL OF MEASURING AND TEST EQUIPMENT

12.0 GENERAL

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

12.1 ACCURACY OF CALIBRATION STANDARDS

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

SECTION 13

HANDLING, STORAGE, AND SHIPPING

13.0 GENERAL

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

13.1 SAMPLES

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

13.1.1 Sample Handling and Shipping

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

13.1.2 Sample Storing

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

SECTION 14

INSPECTION, TEST, AND OPERATING STATUS

14.0 GENERAL

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

14.1 APPLICABILITY

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

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 organizational concurrence with proposed corrective action and QA verification of corrective action implementation are required.

SECTION 17

QUALITY ASSURANCE RECORDS

17.0 GENERAL

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

17.1 COMPLIANCE WITH OCRWM RECORDS-MANAGEMENT PROGRAM

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

SECTION 18

AUDITS

18.0 GENERAL

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

18.1 TECHNICAL CONSIDERATIONS

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

18.2 PROJECT OFFICE AUDITS

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

18.3 ANALYSIS OF AUDIT DATA

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

18.4 INTERNAL AUDIT SCHEDULING

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

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

(a) Results of previous internal audits

(b) Results of previous extrinsic audits

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

18.5 EXTERNAL AUDIT SCHEDULING

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

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

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

18.5.4 Annual evaluations of suppliers shall be performed or arranged for. Evaluations shall be documented. These evaluations shall assess:

(a) Supplier-furnished documents and records

(b) Previous verification results

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

(d) Extrinsic verification results

APPENDIX A

QUALITY ASSURANCE PROGRAM DOCUMENTS LISTING

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

16. DOE/RW-XXXX, 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 OCRWM level and sets forth the minimum requirements for Repository Systems Engineering at the Project Office level.

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

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

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

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

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

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

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

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

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

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

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

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

APPENDIX B

RATIONALE ON THE APPLICABILITY OF NRC REQUIREMENTS TO SCIENTIFIC INVESTIGATIONS

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

PURPOSE

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

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

DISCUSSION

Scientific investigations involve a large number of different processes, both laboratory and field, directed to the collection and analysis of data 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 include a wide range of activities some of which are:

1. Cutting and retrieving core from boreholes
2. Waxing core
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 because 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-YYYY, Quality assurance Requirements (QAR) which are applicable to the topic of this report are:

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

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

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

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

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

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

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

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

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

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

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

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

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

It is important to recognize then that there are controlled processes governing the collection, preparation, and analysis of data in scientific investigations.

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

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

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

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

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

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

operator through some established requirements (for example, a written certification test or a performance test).

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

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

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

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

SUMMARY

Processes in scientific investigations are oriented toward the collection and the analysis of data, not toward preparing an item for use as part of a permanent structure. Pre-established acceptance criteria for samples or for the results of data collection and analysis does not normally exist in scientific

investigations. The main variable is the sample or material. It is the variability in some parameter or subset of parameters that is the object of an instrumental or chemical analysis or both.

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

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

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

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

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

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

- A thorough plan of the investigation is prepared and approved.
- A technical review of the plan is completed by the participant.

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

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

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

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

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

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

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

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

NRC Review Plan Requirement 11.1

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

Response

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

It is not appropriate in most cases for individual procedures to address when a test or testing activities are performed. Scientific investigation activities cannot necessarily be scheduled as construction activities (for example, take one concrete cylinder 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 11.5

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

Response

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

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

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

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

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

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

In summary, since Criteria 14 focuses on the safe operation of equipment and systems (engineered items) being tested and inspected and scientific investigations are prior to repository construction and operation, an exception

has been taken in the QAR such that Criterion 14 applies only to engineered items and not to scientific investigations. The controls established in the QAR for scientific investigations are sufficient to assure the proper conduct of scientific investigations and their impact on site characterization activities.

GLOSSARY

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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