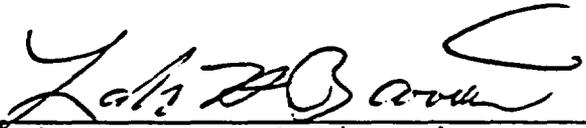


U. S. DEPARTMENT OF ENERGY
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

QUALITY ASSURANCE REQUIREMENTS

for the

CIVILIAN RADIOACTIVE WASTE MANAGEMENT PROGRAM



Lake Barrett, Acting Director
OCRWM Office of Quality Assurance

8/15/88
Date



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

8/22/88
Date

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QUALITY ASSURANCE REQUIREMENTS
for the
CIVILIAN RADIOACTIVE WASTE MANAGEMENT PROGRAM

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FOREWORD

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 As a result of the reevaluation, the four documents have been superseded and replaced by DOE/RW-YYYY, Quality Assurance Requirements for the Civilian Radioactive Waste Management Program (QAR) and DOE/RW-XXXX, Quality Assurance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

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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 were added from the NRC review plan for high level nuclear waste repositories and from NUREGs that have been adopted as requirements documents 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.

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

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 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

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.

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 and Supplements 2S-1, 2S-2, 2S-3, and 2S-4 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).

2.2 PLANNING

Participant's QA PROGRAMs shall include provisions for quality assurance program planning to be integrated and coordinated among participating organizations 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

2.3 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

2.4 QUALITY LEVELS AND GRADED QUALITY ASSURANCE

2.4.1 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. OCRM 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.

2.4.2 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

2.5 PERSONNEL SELECTION, INDOCTRINATION, TRAINING, AND QUALIFICATION

- 2.5.1 Supplement 2S-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.
- 2.5.2 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.

2.6 SURVEILLANCE

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

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

2.6.2 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

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

2.6.4 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

2.7 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

2.8 QUALITY ASSURANCE MANAGEMENT-INFORMATION REPORTING AND TRACKING

- 2.8.1 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.)
- 2.8.2 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. 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 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.

3.2.1 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
- 3.2.2 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.
- 3.2.3 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.
- 3.2.4 As applicable, computer software documentation 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
- 3.2.5 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.
- 3.2.6 If parameters that control experiments are too poorly defined to allow for validation, an independent assessment shall be

performed to determine the degree of computer software validation achievable.

- 3.2.7 Computer software that was not developed under a documented quality assurance program meeting the requirements of Subsection 3.2.1 may be qualified for use provided that the computer software is verified and validated. A computer software baseline is to be established and controlled, and applicable documentation is to be prepared to support its use.

3.3 TECHNICAL REVIEWS

- 3.3.1 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.
- 3.3.2 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.
- 3.3.3 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.
- 3.3.4 The results of technical reviews shall be documented.

3.4 PEER REVIEWS

- 3.4.1 A peer review shall be performed when the adequacy of information or the suitability of procedures and methods cannot otherwise be established through testing, alternate calculations, or reference to previously established standards and practices. A peer review shall be considered when:
- (a) Critical interpretations or decisions will be made in the face of significant uncertainty including the planning for data collection, research, or exploratory testing
 - (b) Decisions or interpretations will be made having significant impact on performance assessment conclusions
 - (c) Untried or unproven state-of-the-art testing, methods, procedures, or analyses are, or will be, used
 - (d) Detailed technical criteria or standard industry procedures do not exist or are being developed

- (e) Results of tests are not reproducible or repeatable
 - (f) Data or interpretations are ambiguous
 - (g) Data adequacy is questionable (for example, data may not have been collected in conformance with an established quality assurance program)
- 3.4.2 A peer review shall be used when the adequacy of a critical body of information can be established by alternate means, but there is disagreement within the cognizant technical community regarding the applicability or appropriateness of the alternate means.
- 3.4.3 A peer review plan shall be prepared prior to initiating a peer review. The peer review plan shall describe the work to be reviewed, the size and spectrum of the peer review group, and the suggested method and schedule necessary to produce the peer review report.
- 3.4.4 Peer reviews shall be performed by personnel having an appropriate spectrum of technical skills in the subject matter to be reviewed. Peer reviewers shall have comparable knowledge in the subject matter to the person who conducted the original work. Peer reviewers shall have no direct involvement as a performer, supervisor, technical reviewer, or advisor in the work being reviewed. Peer reviewers shall have sufficient freedom from outside influences to ensure the work is impartially reviewed.
- 3.4.5 The results of peer reviews shall be documented and, as a minimum, shall address the suitability of the work being reviewed for intended purpose and for conformance to specified requirements. Minority positions shall be documented. The peer review report shall identify the reviewers and document their qualifications and experience in a manner that provides sufficient information to demonstrate that the requirements for technical coverage and independence have been met. The investigators performing the work under review shall document their disposition of, and justify any departures from, the peer review group's conclusions and recommendations. When appropriate, peer review reports shall address the following subjects:
- (a) Validity of assumptions
 - (b) Alternate interpretations
 - (c) Uncertainty of results and consequences if wrong

- (d) Appropriateness and limitations of methodology and procedures
- (e) Adequacy of application
- (f) Accuracy of calculations
- (g) Validity of conclusions
- (h) Adequacy of requirements

3.5 SCIENTIFIC INVESTIGATIONS

3.5.1 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 for the task.

The technical procedures system shall be used by qualified personnel to perform repetitive work that does not include the use of professional judgment nor trial and error methods. Technical procedures are required when it is not possible to deviate from a strict 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 qualified persons familiar with the procedures and the purposes of the investigations to ensure that the objectives of the investigations are fulfilled. 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.

3.5.2 Planning

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.

3.5.3 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.

3.5.4 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.

3.5.5 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.

3.5.6 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

3.5.7 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 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 3.4. 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.

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SECTION 5

INSTRUCTIONS, PROCEDURES, AND DRAWINGS

5.0 GENERAL

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

5.1 REVIEWS

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

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

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.

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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.

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.

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

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SECTION 11

TEST CONTROL

11.0 GENERAL

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

11.1 APPLICABILITY

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

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SECTION 12

CONTROL OF MEASURING AND TEST EQUIPMENT

12.0 GENERAL

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

12.1 ACCURACY OF CALIBRATION STANDARDS

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

SECTION 13

HANDLING, STORAGE, AND SHIPPING

13.0 GENERAL

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

13.1 SAMPLES

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

13.1.1 Sample Handling and Shipping

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

13.1.2 Sample Storing

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

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SECTION 14

INSPECTION, TEST, AND OPERATING STATUS

14.0 GENERAL

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

14.1 APPLICABILITY

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

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SECTION 15
CONTROL OF NONCONFORMING ITEMS

15.0 GENERAL

The provisions of 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, OCRM Office of Quality Assurance. QA organizational concurrence with proposed corrective action and QA verification of corrective action implementation are required.

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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 and 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.

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 OCRM level and sets forth the minimum requirements for Repository Systems Engineering at the Project Office level.
19. OGR/B-12, Project Charter for the Nevada Nuclear Waste Storage Investigation Project, June 1987 - Delineates management responsibility, authority, and accountability for the Nevada Nuclear Waste Storage Investigations Project. The project charter establishes the operational management relationships between Headquarters Office of Civilian Radioactive Waste Management and the Nevada Operations Office.
20. OGR/B-14, Specification of QA Requirements for High-Level Waste Form Production, February 1988 - Identifies the basic and supplementary requirements for quality assurance programs applied to the waste acceptance process activities of high-level waste form production.
21. Appendix B, 10 CFR 50, Quality Assurance Criteria for Nuclear Power Plants - Establishes general QA criteria for safety-related structures, systems, and components of nuclear power plants and fuel reprocessing plants.
22. 10 CFR 60, Disposal of High Level Radioactive Wastes in Geologic Repositories - Establishes requirements for siting, designing, licensing, constructing, operating and closing geologic repositories for high-level waste. Subpart G specifies the general QA criteria of Appendix B, 10 CFR 50.
23. 10 CFR 71, Packaging and Transportation of Radioactive Material - Subpart H establishes quality assurance requirements for packaging and transportation of radioactive materials which are similar to the general QA criteria of Appendix B, 10 CFR 50.
24. 10 CFR 72, Licensing Requirements for the Storage of Spent Fuel in an Independent Spent Fuel Storage Installation (ISFSI) - Subpart G establishes QA requirements for siting, designing, licensing, constructing, operating, and decommissioning a fuel-storage facility and specifies the general QA criteria of Appendix B, 10 CFR 50.

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: Activities which influence or affect the achievement or verification of OCRM quality objectives or requirements. These activities include the collection and analysis of data to be used for, or in support of, performance assessment, site characterization, design, construction, and licensing.

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.

Corroborating Data: Information that may or may not have been obtained and controlled in a manner consistent with a 10 CFR 60 Subpart G quality assurance program and may be used to substantiate other existing data.

Design: (noun) The totality of the design outputs for a structure, system, or component. (verb) The act of defining technical requirements for a structure, system, or component.

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.

Document: (noun) Any written, printed, recorded, pictorial, or processed information describing, defining, specifying, prescribing, reporting, or certifying activities, requirements, procedures, data, or results.

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.

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

Peer Review: A documented, in-depth critique of work that goes beyond the state of the art or where potential uncertainty exists.

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

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

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

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

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

Readiness Review: A systematic, documented evaluation of the fitness and availability for start up or continued use of a facility, process, or activity.

Scientific Investigation: Any research, experiment, test, study, or activity that is performed for the purpose of investigating the natural barriers or man-

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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, critical evaluation of work that falls within the state of the art.

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

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.