Office of Civilian Radioactive Waste Management QA: QA

QUALITY ASSURANCE REQUIREMENTS AND DESCRIPTION

DOE/RW-0333P

Revision 21

Effective Date: 01-04-2009

Larry Newman, Director
Office of Quality Assurance

12/30/08
Date

Edward F. Sproat III, Director
Office of Civilian Radioactive Waste Management

12/30/08
Date

Office of Civilian Radioactive Waste Management
Quality Assurance Policy

Successful implementation of the Office of Civilian Radioactive Waste Management (OCRWM) Quality Assurance (QA) program is essential for the OCRWM to carry out its mission.

Our mission is to manage and dispose of high-level radioactive waste and spent nuclear fuel in a manner that protects health, safety, and the environment; enhances national and energy security; and merits public confidence.

The *Quality Assurance Requirements and Description* (QARD) document establishes the requirements for the OCRWM QA program, and is designed to meet 10 CFR 63.142, Quality assurance criteria, and DOE O 414.1C, *Quality Assurance*. The QARD also defines the organizational responsibilities related to implementation and oversight of the OCRWM QA program.

The QARD provides the framework for both the achievement and verification of quality. The members of the line organization are responsible for implementing the OCRWM QA program requirements within their areas of responsibility. Individuals are responsible for the quality of their work. The line organization and the QA organization share responsibility for the verification of quality. Quality must be an integral part of everything that we do on the OCRWM program. Quality must be planned up-front to ensure that quality requirements are adequately incorporated into the implementing documents. Additionally, we need to hold ourselves to the high standards that are required of a U.S. Nuclear Regulatory Commission licensee of a nuclear facility, to objectively assess our performance against these standards, and to take prompt and aggressive corrective action when we find divergence. We must learn from our mistakes, never be satisfied with our performance, and always have a questioning attitude about our work. It is only then that the QARD becomes a living document, where quality lives in the organization and becomes part of our culture.

As the Director, OCRWM, I am responsible for the OCRWM QA program, including its development, implementation, and verification. I retain ultimate review and approval authority on matters pertaining to the implementation of the OCRWM QA program. Organizations performing quality-affecting work for the OCRWM shall comply with the applicable requirements from the QARD.

for Edward F. Sproat III, Director
Office of Civilian Radioactive Waste Management

12/30/08
Date

REVISION HISTORY

Revision	Revision Description	Effective Date
21	Revised the following Subsections to incorporate changes as noted: • Revision History—Revised to reflect changes made in QARD Rev. 21 • Table of Contents—Revised to reflect QARD Rev. 21 subsection structure • Section 1.3—Revised section 1.3 to incorporate a reference to the *OCRWM Mission and Functions Statement*, reflect the OCRWM 2010 organization; delete excessive detail relative to the responsibilities and authorities of OCRWM Offices, incorporate generic organization descriptions, and remove the requirement in 1.3C to revise the QARD solely to reflect organization changes • Section 2.1—Revised to clarify that a graded QA approach will be applied only to non-ITS/ITWI SSCs • Subsection 2.2.2—Revised to remove the note regarding characterization measurements of spent nuclear fuel • Subsection 4.2.1—Revised to clarify that procurement documents at all tiers include appropriate quality provisions and procurement documents identify the documentation required to be submitted for information, review, or approval by the Purchaser • Subsection 7.2.12A—Revised to correct the reference to 7.2.14B.1 • Subsection 11.2.6—Revised to clarify that requirements are applicable to personnel who either direct or perform tests • Subsection 16.2.1A—Revised to include “deviation” in the list of conditions that constitute a condition adverse to quality • Subsection 16.2.4F— Revised to clarify that root cause determinations for significant conditions adverse to quality will be documented • Subsection A.2.3B.2—Revised to correct applicability of some requirements to EM and their contractors	01-04-2009

- Appendix C—Revised Subsection C.1 to clarify OCRWM position on QA programs developed under other parts of 10 CFR Chapter 1
- Glossary- Revised the definition of conditions adverse to quality to incorporate “deviations” in the definition

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INTRODUCTION

The OCRWM Quality Assurance (QA) program for the Yucca Mountain repository consists of the QARD (DOE/RW-0333P) and those documents that implement the QARD.

The QA program applies to structures, systems, and components (SSCs) important to safety (ITS), to design and characterization of barriers important to waste isolation (ITWI), and to related activities. Title 10 of the Code of Federal Regulations, Section 63.142, *Quality assurance criteria*, does not require that the QARD address non-ITS/ITWI SSCs and related activities. However OCRWM is applying this QA program, with the exception of QARD Supplements II through V and appendices, to SSCs important to worker and public safety, or to the environment (non-ITS/ITWI) and related activities. OCRWM applies a graded approach to the use of the QA program for non-ITS/ITWI SSCs and related activities that are outside the scope of 10 CFR 63.142 requirements.

The OCRWM QA program provides reasonable assurance that SSCs will perform satisfactorily in service. This document primarily describes the commitment of OCRWM, its contractors, and waste custodians commitment to implement the quality assurance (QA) requirements of 10 CFR 63.142 and integrates the requirements of 10 CFR 63.142 and DOE O 414.1C. In most respects, satisfaction of 10 CFR 63.142 also results in satisfaction of DOE O 414.1C which the U.S. Department of Energy (DOE) has determined is applicable to this project. However, if duplicate or conflicting requirements exist, 10 CFR 63.142 shall govern. When the content of this program document refers only to the DOE Order requirement, it is identified as such. DOE Order-only requirements are not considered to be within the scope of 10 CFR 63.142. Day-to-day work is governed by implementing documents developed based on the requirements of this program.

This QARD applies to design, procurement, and construction activities occurring prior to receipt of high-level radioactive waste (HLW) and spent nuclear fuel (SNF) for disposal in the Yucca Mountain repository. This QARD will be revised prior to the receipt of a license to receive and possess HLW/SNF to address activities associated with facility operation.

The QA measures and administrative controls established by this QARD revision are comparable to those implemented during the site characterization phase of the Yucca Mountain repository conducted prior to the effective date of this QARD. QARD changes are performed in accordance with 10 CFR 63.144, *Quality assurance program change.*

BASIS

The QARD is based on 10 CFR 63.142, and DOE O 414.1C. The requirements of 10 CFR 63.44; 10 CFR 63.73, *Reports of deficiencies*; 10 CFR 63.141-63.144; 10 CFR 21, *Reporting of Defects and Noncompliance*; 10 CFR 71, Subpart H, *Quality Assurance*; and 10 CFR 72, Subpart G, *Quality Assurance* are applicable and are also included in the development and application of the OCRWM QA program. OCRWM commitments are identified in the relevant QARD sections/supplements.

1.0 ORGANIZATION

1.1 GENERAL

A. The OCRWM organizational structure encompasses those positions responsible for establishing, managing, verifying, and interpreting the OCRWM Quality Assurance program. The QARD describes the relationships of organizations within OCRWM, and between OCRWM and principal contractors and waste custodians with overall responsibilities and authority for performing activities within the scope of the QARD.

B. The QARD identifies organizational structure, functional responsibility levels of authority and lines of communication.

C. The OCRWM organization and its description in this document will evolve to that described in the Yucca Mountain repository safety analysis report prior to the commencement of construction activities (i.e., prior to the issuance of the Construction Authorization).

1.2 REQUIREMENTS

The OCRWM and principal contractors shall prepare one or more controlled documents that describe their responsibilities and authorities, including the management positions responsible for achieving and maintaining quality, internal and external organizational interfaces, organizational structures, and responsibilities for their scope of work. These documents shall be revised upon any reorganization that impacts responsibilities associated with the implementation of QARD-related activities.

1.2.1 Responsibility for Quality

The organizational structure and the responsibility assignments shall be such that the quality is achieved and maintained by those who have been assigned responsibility for performing work; and quality achievement is verified by persons or organizations not directly responsible for performing the work.

1.2.2 Resolution of Quality Disputes

Differences of opinion between the QA organization and other personnel involving the OCRWM QA program requirements shall be brought to the attention of the appropriate management and, if not resolved, shall be elevated to higher levels of management. The Director, OCRWM, has ultimate resolution authority.

1.3 DESCRIPTION

A. Organization charts that clearly identify OCRWM organizational elements that function under the cognizance of the OCRWM QA program are developed, maintained and controlled in the *OCRWM Mission and Functions Statement*. PGM-CRW-AD-000003. Figure 1, *OCRWM Organization*, identifies the general

reporting relationships of the OCRWM organizations responsible for the implementation of activities affecting quality. Figure 2, *OCRWM External Interfaces*, identifies the OCRWM interface with the principal contractors and waste custodians.

B. Section 1.3.1 below describes those major organizations within OCRWM that are responsible for activities affecting quality.

C. Additional organizational functions are described in the *OCRWM Mission and Functions Statement*.

1.3.1 OCRWM Organization Descriptions

A. Office of the Director

The Office of the Director is responsible for, and has the authority for, the implementation of activities that ensure quality, including public and worker health and safety, and protection of the environment, establishing the OCRWM QA policy. Several programmatic and technical authorities of the Director, OCRWM, are delegated to OCRWM office directors and principal contractors as reflected in this document.

The following responsibilities and authorities are not delegable:

1. Ensuring effective implementation of the OCRWM QA program
2. Approving the QARD in coordination with the Director, OQA
3. Resolving disputes relative to the OCRWM QA program
4. Establishing the OCRWM organizational structure, including the organizational roles, responsibilities, authority and accountability
5. Ensuring a sufficient number of trained personnel are available to implement activities described in this QARD before the initiation of the activities
6. Integrating QA program activities
7. Monitoring key performance indicators.

B. Office of Quality Assurance

1. Ensure that an appropriate QA program is established and verify that activities affecting quality have been correctly performed. This program

shall be established at the earliest time consistent with the schedule for accomplishing the activities.

2. Verify the adequacy and implementation (i.e., completeness, compliance and effectiveness) of the QA program and report the results to senior management.

3. Have sufficient authority, access to work areas, and organizational freedom to (i) identify quality problems; (ii) initiate, recommend, or provide solutions through designated channels; (iii) verify implementation of solutions to quality problems and; (iv) ensure that further processing, delivery, installation, or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred.

4. Report to a management level such that the required authority and organizational freedom are provided, including sufficient independence from cost and schedule when opposed to safety considerations.

5. Have direct access to responsible management at a level where appropriate action can be effected.

6. Ensure that QA staff are involved in day-to-day activities such as work and scheduling meetings.

7. Have no other assigned duties that would prevent full attention to QA related responsibilities.

8. Develop, approve in coordination with the Director, OCRWM, and maintain the QARD, and interpret requirements, as necessary.

9. Ensure adequate QA coverage relative to procedural and inspection controls, acceptance criteria, and staffing and qualification of personnel to carryout QA assignments. Qualification of QA personnel shall be in accordance with Subsection 2.2.11.

10. Have the authority to stop work when significant conditions adverse to quality warrant such action.

C. Technical Management

The manager of this office serves as the Chief Nuclear Officer during the design and construction phases of the Program. Technical management is comprised of the following organizations that are responsible for science, regulatory affairs and engineering.

C.1 Science

Science is responsible for developing and maintaining the postclosure safety analysis and the associated technical basis, planning and implementing the performance confirmation program, directing and coordinating scientific investigation activities among participating organizations, serving as the approval authority for scientific investigation products, and providing scientific technical support to participating organizations.

C.2 Engineering

Engineering is responsible for design and preclosure safety analysis of repository SSCs, establishing and maintaining nuclear safety design bases for repository SSCs, monitoring contractor performance of design and preclosure safety analysis activities, configuration management, project-level systems engineering activities, procedure document hierarchy, document control, and records management.

C.3 Regulatory Affairs

Regulatory affairs is responsible for providing regulatory compliance and licensing support through NRC communications, initiating and maintaining agreement documents with regulatory agencies, and integrating design, scientific investigation, preclosure and postclosure safety analyses into coherent systematic descriptions.

D. Construction

Construction is responsible for construction management of the Yucca Mountain repository and associated facilities including site testing, SSC acceptance and turnover activities, construction project authorizations, construction, facility maintenance, verification of installation in accordance with design requirements, as-built/as-constructed design, environmental safety and health, event reporting, emergency preparedness, safeguards and security.

E. Operations

Operations is responsible for the nonconformance and corrective action program, trending, performance improvement, radiological protection, lessons learned and repository startup programs.

F. Project Management

Project Management is responsible for: functioning as the Head of Contracting Activity; administration of program-wide contracts, grants, cooperative agreements, and interagency agreements; providing guidance on acquisition regulatory requirements including maintenance of contractual documents required for major system acquisitions; acquisition planning, Request for Proposal (RFP) development, RFP evaluation, award for OCRWM acquisition instruments; and establishing acquisition strategies.

G. Logistics Management

Logistics Management is responsible and has the authority for waste acceptance and developing and operating the transportation system and related infrastructure. This includes integrating startup programs for the transportation system and acquiring and maintaining NRC-certified transportation casks and their ancillary equipment.

H. Business Management

Business management is responsible for setting program and budget guidance; developing workforce planning strategies; providing oversight of the OCRWM Training Program; providing information technology support to OCRWM entities; and overseeing the software QA management program.

I. Line Management Functions (All Managers)

All organization managers are responsible for the implementation of this QARD within their areas of responsibility and have the authority for managing their functions and resources and providing leadership, evaluating contractor technical products against quality requirements and directing corrective actions when necessary, and coordinating and integrating their activities with other OCRWM offices.

1.3.2 Delegation of Authority

A. The Director, OCRWM, retains ultimate responsibility for the adequacy and effectiveness of the OCRWM QA program. Individuals or organizations responsible for establishing and executing the QA program may delegate any or all of the work to others but shall retain responsibility for the delegated work.

B. The QA requirements applicable to OCRWM contractors shall be established and delineated in appropriate procurement documents. The QA interface between the OCRWM and waste custodians shall be established and delineated in appropriate agreement documents. The OCRWM has delegated to OCRWM contractors and EM waste custodians the authority to establish and execute an effective QA

program to be applied to the items and activities specified in Subsection 2.2.2, as applicable to their scope of work.

1.3.3 Principal Contractors

A. Management and Operating Contractor

The Management and Operating Contractor **(**M&O) is responsible for fulfilling the function of Design Authority, the preclosure safety analysis, and the design and construction of the Yucca Mountain repository. These functions are performed in accordance with the M&O QA program. Specific M&O responsibilities are identified in the contract between the OCRWM and the M&O.

B. Lead Laboratory

The Lead Laboratory is responsible for the postclosure safety analysis and the performance confirmation program. These functions are performed in accordance with the Lead Laboratory QA program. The Lead Laboratory is supported by other organizations (e.g., other national laboratories subcontractors, federal agencies, and universities). Specific Lead Laboratory responsibilities are identified in the agreement document between the OCRWM and the Lead Laboratory.

C. Principal Contractors' QA Function

Duties, responsibilities, and qualifications of the principal contractors' QA Manager are the same as those of the Director, OQA, as delineated in Subsection 1.3.1B, with the exception of developing, approving, and maintaining the QARD, and interpreting QARD requirements.

1.3.4 Waste Custodians

Waste custodian agreements describe the interface with commercial nuclear utilities and federal waste custodians (i.e., the EM and the Naval Nuclear Propulsion Program (NNPP)). These agreements shall identify scope, specify appropriate quality and technical requirements, and describe responsibilities and interfaces that apply to these entities. Appendix A describes the measures taken to ensure that information supplied by waste custodians is suitable for use in the license application, and that waste forms are suitable for acceptance.

1.3.5 Commitment Document Positions

A. OCRWM commits to the following documents:

1. NQA-1a-1983, Basic Requirement 1, *Organization.*

2. NQA-1a-1983, Supplement 1S-1, *Supplementary Requirements for Organization.*

3. DOE O 414.1C, Section 4b (1) (a).

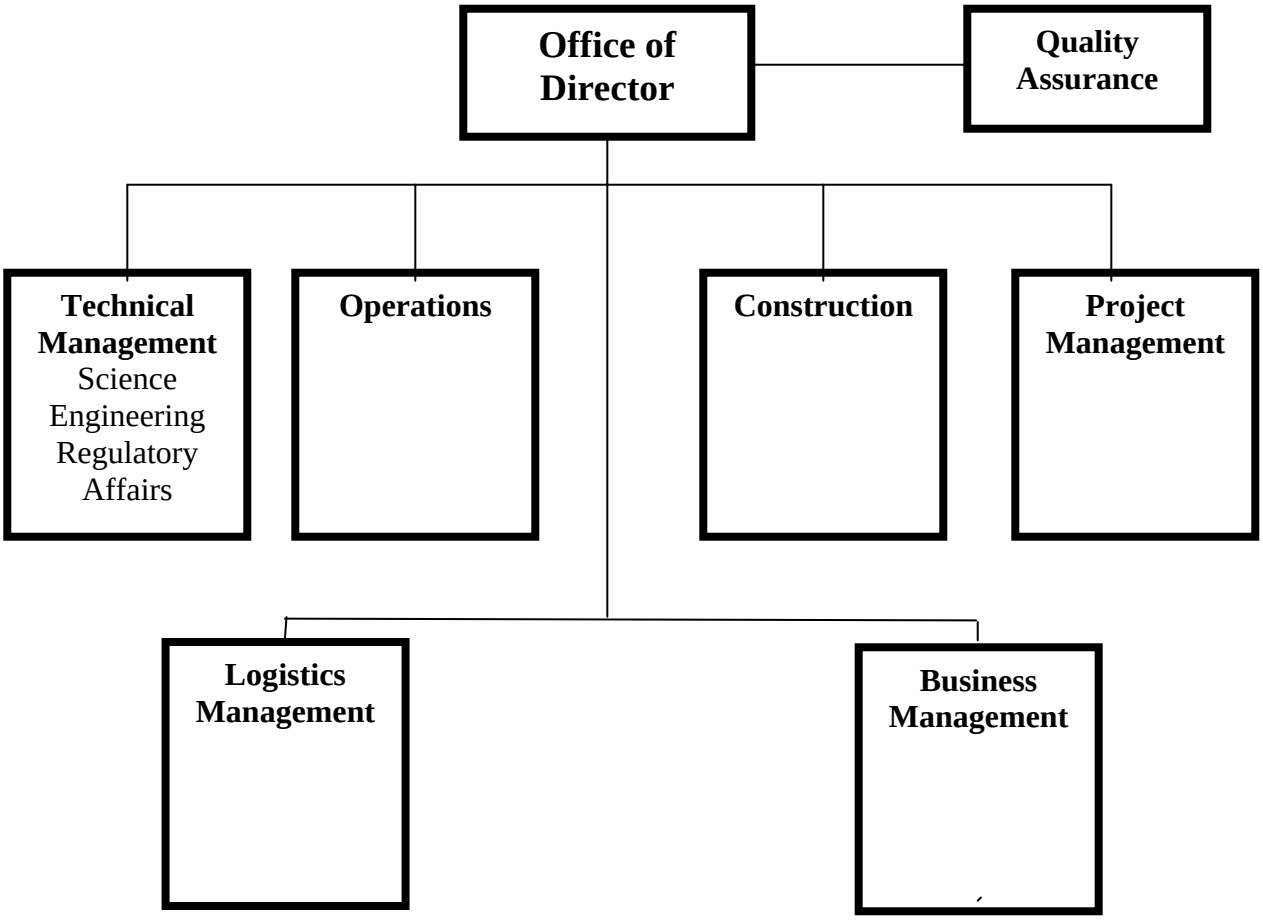

Figure 1. OCRWM Organization

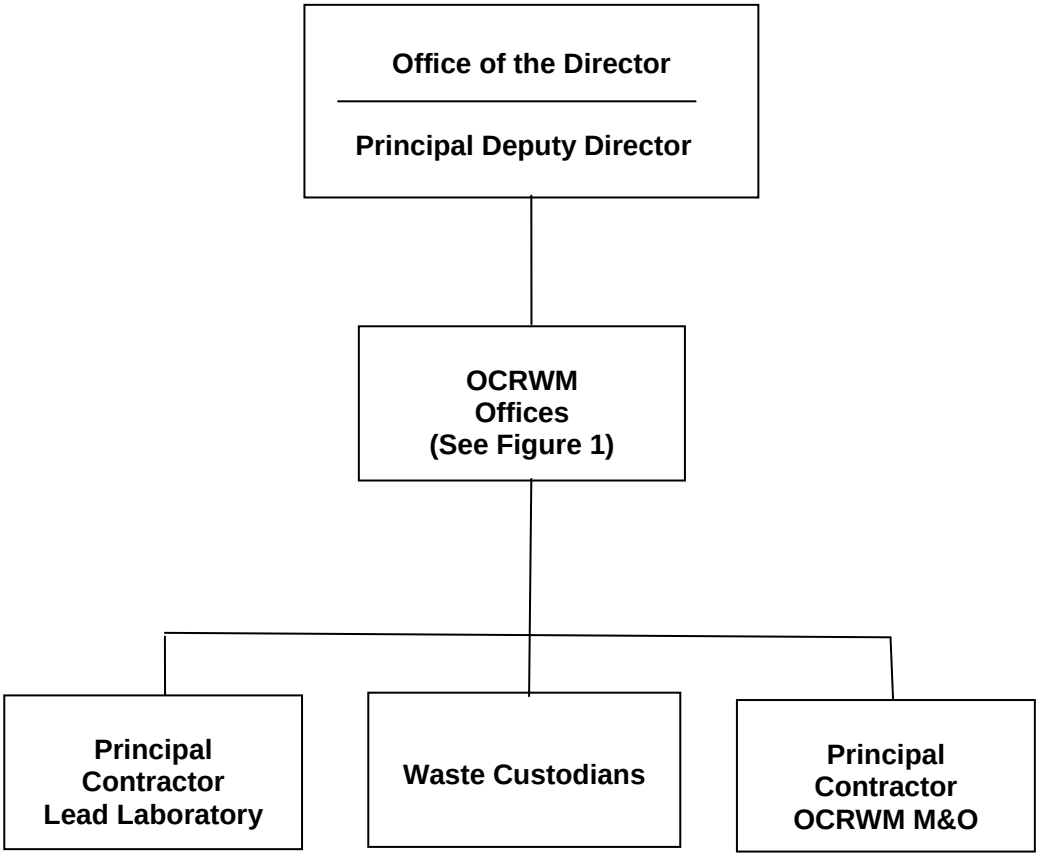

Figure 2. OCRWM External Interfaces

2.0 QUALITY ASSURANCE PROGRAM

2.1 GENERAL

This section establishes the scope of the OCRWM QA program and identifies requirements for planning and special topics related to the OCRWM QA program. The OCRWM QA Program is applied uniformly to ITS/ITWI SSCs and related activities. DOE will apply the QARD to non-ITS/ITWI SSCs and related activities using a graded approach, commensurate with the SSCs' importance to worker and public safety, or the environment. The OCRWM QA program establishes requirements to provide reasonable assurance that activities related to SSCs described in Subsection 2.2.2 are performed under suitably controlled conditions.

2.2 REQUIREMENTS

2.2.1 Quality Assurance Program Documents

A. The Director, OCRWM, shall issue a policy statement directing mandatory compliance with the QARD. The QA program description document of principal contractors shall have a similar requirement.

B. The following requirements apply to implementing documents:

1. A structured process of implementing documents shall provide for top-down implementation of upper tier requirements.

2. The process shall accommodate the size and location(s) of the organization, the organizational structure, and the nature of the work such that management processes will be carried out efficiently and effectively.

3. The process shall provide for the control of internal and external organizational interfaces.

4. QARD revisions shall be reviewed by organizations that implement the QARD as delineated in OCRWM procurement/agreement documents. Changes which impact their work scope shall be incorporated into their QA program documents.

C. The OCRWM and principal contractors maintain a matrix or other similar cross-reference, consistent with their scope of work, which provides the relationship between the QARD to implementing documents.

2.2.2 Quality Assurance Program Applicability and Related Activities

The OCRWM QA program shall be applied to:

A. SSCs important to safety (ITS).

B. Design and characterization of barriers important to waste isolation (ITWI).

C. SSCs important to worker and public safety, or the environment (non-ITS/ITWI).

D. Activities related to SSCs and barriers described in Subsections 2.2.2A and 2.2.2B which include site characterization; acquisition, control, and analysis of samples and data; tests and experiments; scientific studies; performance of the preclosure safety analysis, total system performance assessment (postclosure safety analysis), and qualification of their inputs; and performance confirmation.

E. Activities related to SSCs and barriers described in Subsections 2.2.2A, 2.2.2B, and 2.2.2C which include facility and equipment design and construction (i.e., designing, purchasing, fabricating, handling, packaging, shipping, receiving, storing, cleaning, erecting, installing, inspecting, testing, maintaining, repairing, and modifying).

F. The controls applied to activities related to SSCs described in Subsection 2.2.2C using a graded approach. These SSCs and related activities are not within the scope of 10 CFR 63.142. However, if duplicate or conflicting requirements exist between 10 CFR 63.142 and DOE O 414.1C, 10 CFR 63.142 shall govern.

G. Activities related to DOE HLW waste forms (i.e., waste form development through qualification, waste form production, and waste form acceptance).

H. Activities related to DOE SNF (i.e., SNF characterization, conditioning, treatment, and/or canisterization and acceptance).

2.2.3 Classifying Structures, Systems, and Components

The SSCs or barriers, and constituent consumables that are ITS or ITWI shall be identified as ITS or ITWI and documented on a "Q-List."

2.2.4 Planning Work

When required, planning establishes the systematic, sequential progression of actions to meet the defined requirements.

A. Planning activities shall be performed and documented prior to the start of work to ensure that work is accomplished under suitably controlled conditions, which includes the use of appropriate equipment, suitable environmental conditions for accomplishing the activity, and assurance that prerequisites for the given activity have been satisfied.

B. Planning shall provide for any special controls, processes, test equipment, tools, and skills needed to attain the required quality/verification of quality and the need for verification of quality by inspection and test.

2.2.5 Surveillances

Surveillances shall be:

A. Scheduled to provide coverage, consistency, and coordination of ongoing work at a frequency commensurate with the status and importance of work.

B. Performed by personnel from an organization independent of the task who are knowledgeable of the work under surveillance.

C. Documented in a report to appropriate management.

2.2.6 Management Assessments

The Director, OCRWM, shall perform or direct the performance of management assessments of the OCRWM organizations and principal contractors supporting the OCRWM Program. Management assessments shall:

A. Be performed by personnel above and/or outside the QA organization

B. Be planned and documented and performed biennially

C. Evaluate:

1. The adequacy of resources and personnel provided to achieve and ensure quality.

2. The scope, status, and adequacy of the OCRWM QA program.

3. The effectiveness of the OCRWM QA program.

4. The programmatic compliance with the OCRWM QA program.

D. Identify conditions adverse to quality and recommend corrective actions.

2.2.7 Readiness Reviews

The need for readiness reviews shall be identified by the OCRWM management or OCRWM contractor's management for major programmatic, organizational or process changes to ensure OCRWM Program objectives are met. Where needed, readiness reviews shall be conducted for the planned scope of work to ensure that objective evidence exists demonstrating that:

A. Work prerequisites have been satisfied.

B. Personnel have been suitably trained and qualified.

C. Appropriate implementing documents and management controls are available and approved.

2.2.8 Peer Reviews

Peer reviews shall be conducted in accordance with NUREG-1297, *Peer Review for High-Level Nuclear Waste Repositories* (February 1988), as delineated in Subsection 2.2.13B.6.

2.2.9 Expert Elicitation

Expert elicitation shall be conducted in accordance with NUREG-1563, *Branch Technical Position on the Use of Expert Elicitation in the High-Level Radioactive Waste Program* (November 1996), as delineated in Subsection 2.2.13B.7.

2.2.10 Quality Assurance Program Self Assessments

Management of each organization regularly assesses the scope, status, adequacy, and compliance aspects of the QA program they are executing to ensure its effective implementation. These assessments shall include frequent reviews of the QA program status through reports, meetings, audits, surveillance, and observations. Management shall receive, as a minimum, audit reports, surveillance reports, trend reports, and management assessment reports. Self Assessments are documented. Identified conditions adverse to quality shall be documented in accordance with Section 16.0.

2.2.11 Personnel Indoctrination, Training, Qualification, and Certification

Personnel indoctrination, training, and qualification processes shall be implemented in a manner that ensures the appropriate indoctrination, training, and qualification have been provided prior to independently performing activities within the scope of the QA program. Personnel performing these activities are indoctrinated, trained, qualified, and certified.

A. Personnel shall be indoctrinated and trained as follows:

1. Determine the necessary required indoctrination and training.

2. Document formal training including the objective, content of the training, attendees, and date of attendance.

3. Ensure personnel are indoctrinated and trained, as needed, to achieve initial proficiency; maintain proficiency; and to adapt to changes in technology, methods, or job responsibilities.

4. Personnel that require certification are given proficiency tests. Acceptance criteria are developed to determine whether individuals are properly trained and qualified.

5. Evaluate and assess the need for additional indoctrination and training as assignments, positions, or implementing documents change.

6. Ensure that personnel are indoctrinated in the following topics as they relate to a particular function:

   a. General criteria, including the QARD, applicable codes, regulations, and standards

   b. QA practices, concepts, and requirements

c. Applicable implementing documents

d. Job responsibilities and authority.

B. Personnel performing inspections or tests shall be trained, qualified, and certified in accordance with the following QARD Subsections:

1. Subsection 2.2.13B.1, Regulatory Guide 1.28, Revision 3, *Quality Assurance Program Requirements (Design and Construction),* Position C.1.

2. Subsection 2.2.13A.1, ANSI/ASME NQA-1-1983 Edition, *Quality Assurance Program Requirements for Nuclear Facilities,* with ANSI/ASME NQA-1a, 1983 Addenda, Basic Requirement 2, *Quality Assurance Program.*

3. Subsection 2.2.13A.2, Supplement 2S-1, *Supplementary Requirements for the Qualification of Inspection and Test Personnel.*

4. Subsection 2.2.13A.3, Appendix 2A-1, *Nonmandatory Guidance on the Qualification of Inspection and Test Personnel*.

C. Personnel performing as auditors and technical specialists shall be trained and qualified, and lead auditors shall be trained, qualified, and certified in accordance with the following QARD subsections:

1. Subsection 2.2.13A.1, ANSI/ASME NQA-1-1983 Edition, with ANSI/ASME NQA-1a, 1983 Addenda, Basic Requirement 2.

2. Subsection 2.2.13B.3, Supplement 2S-3, *Supplementary Requirements for the Qualification of Quality Assurance Program Audit Personnel.*

3. Subsection 2.2.13A.4, Appendix 2A-3, *Nonmandatory Guidance on the Education and Experience of Lead Auditors*.

D. Personnel performing nondestructive examinations shall be trained, qualified, and certified in accordance with QARD Subsection 2.2.13B.2, Supplement 2S-2, *Supplementary Requirements for the Qualification of Nondestructive Examination Personnel.*

E. When required by codes, standards, and specifications, personnel who perform inspections shall be certified in accordance with the pertinent codes, standards, and specifications, (e.g., American Welding Society [Certified Welding Inspector], National Electric Code [Certified Electrical Inspector], and American Concrete Institute [Concrete Construction Inspector, Concrete Transportation Inspector]). These certifications shall be verified prior to performing inspections.

F. Qualifications for the Director, OQA, M&O QA Manager, and Lead Laboratory QA Manager include:

1. Management experience through assignments to responsible supervisory positions.

2. In-depth knowledge of QA regulations, policies, practices, and standards.

3. Appropriate experience working in QA or related activity in nuclear-related design, construction, or operation or a similar technically based industry.

4. Meeting or exceeding the qualification requirements for the Quality Assurance position specified in ANSI/ANS-3.1-1993, Paragraph 4.3.7, as modified by Regulatory Guide 1.8, *Qualification and Training of Personnel for Nuclear Power Plants*, Revision 3 (5/2000), Regulatory Position C.2.1.1.

2.2.12 Scheduled Frequency Tolerance

Activities addressed in this QARD that specify a scheduled frequency for the performance of an activity may be extended by 25% at the discretion of the manager responsible for performing the activity. This flexibility shall not be used to circumvent the next scheduled performance.

2.2.13 Commitment Document Positions

A. OCRWM commits to the following documents:

1. NQA-1a-1983, Basic Requirement 2, *Quality Assurance Program.*

2. NQA-1a-1983, Supplement 2S-1, *Supplementary Requirements for the Qualification of Inspection and Test Personnel.*

3. NQA-1a-1983, Appendix 2A-1, *Nonmandatory Guidance on the Qualifications of Inspection and Test Personnel.*

4. NQA-1a-1983, Appendix 2A-3, *Nonmandatory Guidance on the Education and Experience of Lead Auditors.*

5. Regulatory Guide 1.189, Rev. 0 (4/2001), Subsection 1.7, *Quality Assurance.*

6. DOE O 414.1C, Section 4b (1) (b).

7. DOE O 414.1C, Section 4b (2).

8. DOE O 414.1C, Section 4b (9).

B. OCRWM commits to the following documents with the associated modifications:

1. Regulatory Guide 1.28, Revision 3 (8/85), *Quality Assurance Program Requirements (Design and Construction)*, Position C.1.

The QARD will be revised prior to the receipt of a license to receive and possess HLW/SNF to address activities associated with facility operation, permanent closure, and decontamination and dismantling of surface facilities.

2. NQA-1a-1983, Supplement 2S-2, *Supplementary Requirements for the Qualification of Nondestructive Examination Personnel.*

   - This supplement requires the implementation of American Society of Nondestructive Testing *Recommended Practice No. SNT–TC-1A* (6/1975) and applicable supplements for nondestructive examination personnel. In lieu of this requirement, the OCRWM will implement requirements of the SNT-TC-1A (6/1980) edition with one additional exception. In lieu of the three (3) year recertification interval specified in the SNT-TC-1A (6/1980) edition, Level III nondestructive examination personnel may be recertified on a five year interval. The qualification and certification will include a performance demonstration as part of the practical examination.

3. NQA-1a-1983, Supplement 2S-3, *Supplementary Requirements for the Qualification of Quality Assurance Program Audit Personnel.*

   - This supplement requires that personnel selected for QA auditing assignments shall have experience or training commensurate with the scope, complexity, or special nature of the activities to be audited. In lieu of this requirement the lead auditor shall, before starting the audit, ensure that the assigned personnel collectively have experience or training commensurate with the scope, complexity, or special nature of the work to be audited.

4. Regulatory Guide 1.8, Revision 3 (5/2000), *Qualification and Training of Personnel for Nuclear Power Plants*, Revision 3.

   - Commitment to this guide is limited to Regulatory Position; C.2.1.1.

5. ANSI/ANS 3.1-1993, *Selection, Qualification, and Training of Personnel for Nuclear Power Plants.*

   - Commitment to this standard is limited to Paragraph 4.3.7.

6. NUREG 1297 (1988), *Peer Review for High-Level Nuclear Waste Repositories.*

   - Commitment to this NUREG is limited to Section III, Definitions, and Section IV, Staff Position.

7. NUREG 1563 (1996), *Branch Technical Position on the Use of Expert Elicitation in the High-Level Radioactive Waste Program.*

   - Commitment to this NUREG is limited to Section 3, Branch Technical Position, and Appendix A, Glossary, with the following exception:

     Step 7 recommends documenting the rationale for any revisions to elicited evaluations after the experts receive feedback on their initial evaluations. OCRWM does not require documentation of the rationale for revisions to an expert's initial assessment in the expert elicitation report.

3.0 DESIGN CONTROL

3.1 GENERAL

A. This section provides requirements to ensure that designs are defined, controlled, and verified. The scope of the design control program includes design activities associated with the preparation and review of design documents, including the correct translation of applicable regulatory requirements, design bases, and site characteristics into design, procurement, and procedural documents (e.g., drawings, calculations, specifications, plans, and procedures). Included in the scope are activities such as field design engineering; physics (including criticality physics); seismic, stress, thermal, hydraulic, and preclosure and postclosure analyses; radiation shielding; compatibility of materials; delineation of acceptance criteria for inspections and tests; safety analysis report event sequence analyses and associated computer software; features to facilitate decontamination; suitability; and accessibility for in-service inspection, maintenance, repair, and quality standards.

B. Design control measures are established and applied to: (i) the design of items that are ITS; (ii) engineered and natural barriers that are ITWI; (iii) the description of the geologic setting and the plans for data collection and analysis activities that will generate information pertinent to the repository design and that will be relied on in site characterization, licensing, and performance confirmation; (iv) computer software used in such activities; and (v) development of as-built drawings and related documentation. These design measures shall apply to the design inputs, outputs, and performance confirmation activities.

C. Computer software used in design activities shall be developed or procured, qualified, and used in accordance with Supplement I, Software.

D. Activities related to postclosure analysis are performed in accordance with Supplement III, Scientific Investigation.

3.2 REQUIREMENTS

3.2.1 Design Input Control

Applicable design inputs such as design bases, conceptual design reports, performance requirements (including those resulting from postclosure analyses), regulatory requirements, codes, and standards shall be controlled by those responsible for the design according to the following requirements:

A. Design inputs shall be identified and documented, and their selection reviewed and approved, by those responsible for the design.

B. Design inputs shall be specified and approved on a timely basis and to the level of detail necessary to permit the design work to be carried out in a correct manner

that provides a consistent basis for making design decisions, accomplishing design verification, and evaluating design changes.

C. Data from scientific investigation activities used as design input shall be qualified in accordance with Supplement III, Scientific Investigation. If not qualified prior to use in a design product, it shall be identified as such and tracked until qualified. Unqualified data directly relied on to address safety or waste-isolation issues shall be qualified or it shall not be used in the license application.

D. Changes from approved design inputs and reasons for the changes shall be identified, approved, documented, and controlled.

E. Design inputs based on assumptions that require confirmation shall be identified and controlled as the design proceeds.

3.2.2 Design Process

The design process shall be controlled according to the following requirements:

A. Design work shall be prescribed and documented on a timely basis and to the level of detail necessary to permit (i) the design process to be carried out in a correct manner and (ii) verification that the design meets requirements.

B. Design documents shall be adequate to support design, fabrication, construction, and operation. The documentation shall include not only the final design documents, such as drawings, specifications, and their revisions, but also documentation that identifies the important steps, including sources of design inputs supporting the final design.

C. Appropriate technical and QA standards shall be identified and documented, and their selection reviewed and approved.

D. Changes or deviations from specified QA and technical standards, including the reasons for the changes or deviations, shall be identified, evaluated, approved, documented, and controlled.

E. Measures shall be established for selection and review for suitability of application of materials, parts, equipment, and processes that are ITWI or ITS functions of SSCs.

F. Applicable information derived from experience, as set forth in reports or other documentation, shall be made available to cognizant design personnel.

G. The final design (approved design documents and approved changes thereto) shall:

1. Be relatable to the design input by documentation in sufficient detail to permit design verification; and

2. Identify assemblies and/or components that are part of the item being designed.

H. If prior to installation, a commercial grade item is modified or selected by special inspection and/or testing to meet requirements that are more restrictive than the supplier's published product description, then the item shall be represented as different from the commercial grade item in a manner traceable to a documented description of the difference.

I. The dimensional accuracy and completeness of design drawings and specifications shall be checked and documented.

J. Design drawings, specifications, and other design output documents shall contain appropriate inspection and testing acceptance criteria.

K. When specified by controlling procedures, design drawings and specifications are reviewed by individuals or groups other than the one who generated the document that are trained and qualified in QA practices and concepts, to ensure that the documents (i) are prepared, reviewed, and approved in accordance with applicable implementing documents and (ii) contain the necessary QA requirements such as inspection and test requirements, acceptance requirements, and the extent to which inspection and test results are required to be documented. Training and qualification of individuals or groups performing reviews shall be in accordance with Subsection 2.2.11.

3.2.3 Design Analyses

A. Design analyses shall be performed in a planned, controlled, and documented manner.

B. Design analysis documents shall be legible and in a form suitable for reproduction, filing, and retrieval.

C. Design analysis documents shall be sufficiently detailed as to purpose, method, assumptions, design input, references, and units such that a person technically qualified in the subject can review and understand the analyses and verify the adequacy of the results without recourse to the originator.

D. Calculations shall be identifiable by subject (including SSC to which the calculation applies), originator, reviewer, and date, or by other designators such that the calculations are traceable and retrievable.

E. Documentation of design analyses shall include:

1. Definition of the objective of the analyses.

2. Definition of design inputs and their sources.

3. Results of literature searches or other applicable background data.

4. Identification of assumptions and indication of those that must be verified as the design proceeds.

5. Identification of any computer calculation, including computer type, computer program (i.e., name), revision identification, inputs, outputs, evidence of or reference to computer program verification, and the bases (or reference thereto) that support application of the computer program to the specific physical problem.

6. Computer programs may be utilized for design analysis without individual verification of the program for each application, provided:

   a. The computer program has been verified to show that it produces correct solutions for the encoded mathematical model within defined limits for each parameter employed; and

   b. The encoded mathematical model has been shown to produce a valid solution to the physical problem associated with the particular application.

7. Computer programs shall be controlled to ensure that changes are documented and approved by authorized personnel. Where changes to previously verified computer programs are made, verification shall be required and documented for the change, including evaluation of the effects of these changes to Paragraph 3.2.3E.6.a and 3.2.3E.6.b.

8. Identification of the originator, reviewer, and approver.

3.2.4 Design Verification

A. Design verification shall be performed to determine the adequacy of design, such as by one or a combination of the following methods:

   1. Design review (see Paragraph 3.2.5A).

   2. Alternate or simplified calculations (see Paragraph 3.2.5B).

   3. Qualification testing (see Paragraph 3.2.5C).

B. The extent of design verification required is a function of the importance to ITS/ITWI SSCs under consideration, the complexity of the design, the degree of standardization, the state of the art, and the similarity with previously proven designs.

C. Guidelines or criteria shall be established and described for determining the method of design verification. The particular design verification method used shall be identified and documented.

D. Procedural controls shall provide criteria for determining when design documents that reflect the commitments of the safety analysis report receive formal design verification by interdisciplinary or multi-organizational teams or by a single individual (a signature and date are acceptable documentation). Design documents subject to procedural controls include, but are not limited to, specifications, calculations, associated computer software supporting a safety or waste isolation function, system descriptions, parts of the safety analysis report when used as a design document, and drawings, including flow diagrams, piping and instrument diagrams, control logic diagrams, electrical single line diagrams, structural systems for major facilities, site arrangements, and equipment locations. Specialized reviews should be used when uniqueness or special design considerations warrant.

E. The results of design verification shall be documented, including the identification of the verifier.

F. Responsibilities of the verifier, areas and features to be verified, pertinent considerations to be verified, and the extent of documentation shall be identified in procedures.

G. Design verification shall be performed by competent individuals or groups other than those who performed the original design but who may be from the same organization. In exceptional circumstances, this verification may be performed by the originator's immediate supervisor, provided:

1. The supervisor did not specify a singular design approach or rule out certain design considerations and did not establish the design inputs used in the design.

2. The supervisor is the only individual in the organization competent to perform the verification.

3. The verification is not a cursory review.

4. The determination to use the supervisor is documented and approved in advance by the supervisor's management.

5. QA audits are conducted to evaluate the frequency and effectiveness of the use of supervisors as design verifiers.

H. Design verification shall be performed in a timely manner.

1. Design verification, for the level of design activity accomplished, shall be performed prior to release for procurement, manufacture, construction, or release to another organization for use in other design work. In those cases where this timing cannot be met, such as when insufficient data exists, the unverified portion of the design shall be identified and controlled. Justification for this action is documented.

2. In all cases, design verification shall be completed before relying on the SSC to perform its safety function.

I. Where the design has been subjected to a previous verification process in accordance with the QARD, the verification process need not be duplicated for identical designs.

J. Use of previously proven designs shall be controlled in accordance with the following requirements:

1. The applicability of standardized or previously proven designs, with respect to meeting pertinent design inputs, shall be verified and documented.

2. Known problems affecting standardized or previously proven designs and their effects on other features shall be considered.

3. The original design and associated verification measures shall be adequately documented and referenced in the files of subsequent application of the design.

K. Where changes to previously verified designs have been made, design verification shall be required for the changes, including evaluation of the effects of those changes on the overall design. Design changes are controlled in accordance with Subsection 3.2.6.

3.2.5 Design Verification Methods

A. Design Review

Design reviews shall be controlled and performed to ensure:

1. The design inputs were correctly selected and incorporated.

2. The assumptions necessary to perform the design were adequately described, reasonable, and where applicable, identified as requiring confirmation as the design proceeds.

3. Appropriate design methods, and computer programs where applicable, were used.

4. Design inputs were correctly incorporated into the design.

5. The design outputs are reasonable compared to design inputs.

6. The necessary design input and verification requirements for interfacing organizations were specified in the design documents or in supporting implementing documents.

B. Alternate or Simplified Calculations

These are calculations or analyses that are made with alternate methods to verify correctness of the original calculations or analyses. The appropriateness of assumptions, input data used, and the computer program or other calculation method used shall also be reviewed.

C. Qualification Testing

1. Where design adequacy is to be verified by qualification tests, the test method shall be identified.

2. Prototype, component, or feature testing shall be performed as early as possible before the installation would become irreversible.

3. The test configuration shall be defined and documented.

4. Testing shall demonstrate the adequacy of SSC performance under conditions that simulate the full range, including the most adverse anticipated design conditions as determined by analysis. Operating modes and environmental conditions in which the item must perform satisfactorily shall be considered in determining the most adverse conditions.

5. Where the test is intended to verify only specific design features, the other features of the design shall be verified by other means.

6. Test results shall be documented and evaluated by the responsible design organization to ensure that test requirements have been met.

7. If qualification testing indicates that modifications to an item are necessary to obtain acceptable performance, the modification shall be documented and the item modified and retested or otherwise verified to ensure satisfactory performance.

8. When tests are being performed on models or mockups, scaling laws shall be established, verified, and approved.

9. The results of model test work shall be subject to error analysis, where applicable, before using the results in the final design.

3.2.6 Design Change Control

Design changes, including field changes, shall be controlled in accordance with the following requirements:

A. Changes to final designs, field changes, and nonconforming items dispositioned as use-as-is or repair shall be justified and shall be subject to design control measures commensurate with those applied to the original design.

B. Changes shall be approved by the same affected groups or organizations which reviewed and approved the original design documents.

   1. Except where an organization which originally was responsible for approving a particular design document is no longer responsible, the OCRWM or its designee shall designate a new responsible organization.

   2. The designated approving organization shall have demonstrated competence in the specific design area of interest and have an adequate understanding of the requirements and intent of the original design.

C. Where a significant design change is necessary because of an incorrect design, the design process and verification implementing documents shall be reviewed and modified as necessary.

D. Errors and deficiencies in approved design documents, including design methods (e.g., computer software supporting a safety or waste isolation function), that could adversely affect ITS SSCs or ITWI barriers shall be documented and action taken to ensure all errors and deficiencies are corrected.

E. Deviations from specified quality standards shall be identified and formally documented. Procedures shall be established to ensure control of these deviations.

F. Measures shall be provided to ensure personnel are notified of design changes/modifications that may affect the performance of their duties.

G. Design change initiated prior to the issuance of the Construction Authorization shall be evaluated pursuant to applicable regulatory requirements. Subsequent to the issuance of the Construction Authorization, design changes shall be evaluated in accordance with 10 CFR 63.44.

3.2.7 Design Interface Control

A. Design interfaces shall be identified and controlled.

B. Design efforts shall be coordinated among participating design organizations and across technical disciplines. Interface controls shall include the assignment of responsibility and the establishment of implementing documents among participating design organizations and technical disciplines for the review, approval, release, distribution, and revision of documents involving design interfaces to ensure that SSCs are compatible geometrically, functionally, and with processes and environment.

C. Design information transmitted across interfaces shall be documented and controlled.

D. The status of the design information or document provided shall be identified in transmittals.

E. When it is necessary to initially transmit design information orally or by other informal means, the transmittal of design information shall be promptly confirmed and controlled with formal documentation initiated in accordance with the initiating organization's approved implementing document.

3.2.8 Sampling Plans

The basis, including any supporting analyses for the use of sampling plans for SSCs and barriers, and activities thereto, such as inspection and commercial dedication shall be documented. The following apply to the use of sampling plans:

A. Sampling plans used for high-safety-risk-significant activities shall use a criterion that provides at least a 95% confidence that there are only 5% defective items in a lot (95/5).

B. Reduced sampling plans may be used for low-safety-risk significant activities.

C. Lots sampled shall be essentially homogeneous.

3.2.9 Commitment Document Positions

A. OCRWM commits to the following documents:

1. NQA-1a-1983, Basic Requirement 3, *Design Control.*

2. NQA-1a-1983, Supplement 3S-1, *Supplementary Requirements for Design Control.*

3. DOE O 414.1C, Section 4b (6).

B. OCRWM commits to the following documents with the associated modifications:

1. NQA-1-2000, Part II, *Quality Assurance Requirements for Nuclear Facility Applications*, Subpart 2.1, *Quality Assurance Requirements for Cleaning of Fluid Systems and Associated Components for Nuclear Power Plants.*

   - Subsection 302.2, *Class B* refers to use of ASTM A 380-78, *Practice for Cleaning and Descaling Stainless Steel Parts, Equipment, and Systems*, Subsection 7.2.1, for performance of a visual inspection. ASTM A 380-78, Subsection 7.2.1, indicates visual inspection should be carried out under a lighting level of at least 100 foot candles and preferably 250 foot candles on the surface being examined. As an alternative, OCRWM may use a neutral 18% gray card with a 1/32 inch black line placed at 24 inches from the eye at an angle no less than 30 degrees to the surface of the card to determine appropriate illumination. Refer to NRC Inspection Procedure 57050.

   - Subsection 304.1, pH measurements will not be required for conductivity values less than or equal to 1micromho/cm.

2. NQA-1-2000, Part II, *Quality Assurance Requirements for Nuclear Facility Applications*, Subpart 2.2, *Packaging, Shipping, Receiving, Storage, and Handling of Items for Nuclear Power Plants.*

   - Subsection 202.2(d) permits weld electrodes hermetically sealed in metal containers to be stored under level "C", unless other storage requirements are specified by the manufacturer. Storage conditions for Level "C" may also apply to bare filler wire and consumable inserts unless specified otherwise by the manufacturer.

   - Subsection 202.4, (m) lists aggregates to be classified and stored under Level D requirements. Aggregates will be stored in outside locations, however, the requirements for marking, protection, etc. described in 302.4 will not be adhered to for piles of aggregate.

   - As an alternate to the requirements in Subsection 302.1(d) (e) (g), 302.2, 302.3(1), and 302.4(2), controlling the manner in which the items are stored may require control of the storage atmosphere such that it is free of harmful contaminants in concentration that could produce damage to the stored item, and protecting weld end preparations and threads.

   - Subsection 307.1, (a) limits cleated, sheathed boxes to 500 lb maximum net weight, however, a safe capacity of up to 1000 lb net weight will be utilized since this capacity is recognized within the industry.

- Requirements outlined in subsection 403 are understood to apply to over the road shipments to initial receipt at the facility warehouse.
- Personnel performing inspections required by subsection 502.1 will be trained to perform this function, but may not be certified as an inspector.
- Subsection 502.2(a) requires receiving inspections to be performed in an area equivalent to the level of storage requirement for the item. Receiving inspections will be performed in a manner and in an environment that does not endanger the requisite quality of an item, not necessarily with all requirements for the required storage level.
- Subsection 502.2(b) requires six additional inspection activities if an item was not inspected at the source. OCRWM will consider that inspections of these attributes have been conducted by the supplier if the supplier's QA program is required to comply with NQA 1-2000 and has been audited and found acceptable.
- Subsection 502.3 requires any special inspection procedure to be attached to the package or item. Any special inspection procedure required may not be attached to the package or item, but will be readily available to inspection personnel.
- Replace subsection 602.4 with the following: The use or storage of food, drinks, and salt tablet dispensers in any storage area shall be controlled, and shall be limited to designated areas where such use or storage is not deleterious to stored items.
- Replace subsection 602.5 with the following: Exterminators or other appropriate measures shall be used to control animals or insects to minimize the possible contamination and damage to stored material. If evidence of animal or insect activity is detected, a survey or inspection will be undertaken to determine the extent of possible contamination or damage.
- Subsection 604.2(e) requires space heaters to be energized during storage. Subsection 202.2(g) requires motors to be stored in level B storage. The combination of level B environment and energized space heaters negate the requirement to perform routine insulation resistance tests as required in subsection 604.2(f), and routine insulation resistance tests will not be applied to electrical equipment less than 50 HP. Subsection 604.2(g) requirement to rotate shafts of rotating equipment will not be applied to any rotating equipment weighing less than 50 pounds unless specifically recommended by the manufacturer or a documented engineering evaluation determines otherwise.

3. NQA-1-2000, Part II, *Quality Assurance Requirements for Nuclear Facility Applications*, Subpart 2.3, *Quality Assurance Requirements for Housekeeping for Nuclear Power Plants.*

   - In lieu of Subsection 302.3, *Fire Protection and Prevention*, Regulatory Guide 1.189, Rev. 0 (4/2001) shall be implemented.

   - Subsection 202 five level zone designation may not be used. Control of personnel, tools, equipment and supplies will be established when major portions of Geologic Repository Operations Area (GROA) systems or facilities are opened for inspection, maintenance or repair. Additional housekeeping requirements will be implemented, as required, to minimize radiation contamination.

4. NQA-1-2000, Part II, *Quality Assurance Requirements for Nuclear Facility Applications*, Subpart 2.4, *Quality Assurance Requirements for Installation, Inspection, and Testing Requirements for Power, Instrumentation, and Control Equipment at Nuclear Facilities*.

   - The requirements of this subpart will only be specified when Class 1E, i.e. ITS, is identified in the design.

   - OCRWM will implement the applicable Quality Assurance/Quality Control guidance found in IEEE-336-2005, *IEEE Guide for Installation, Inspection, and Testing for Class 1E Power Instrumentation, and Control Equipment at Nuclear Facilities* in lieu of implementing ANS/IEEE STD. 336-1985.

5. NQA-1-2000, Part II, *Quality Assurance Requirements for Nuclear Facility Applications*, Subpart 2.5, *Quality Assurance Requirements for Installation, Inspection, and Testing of Structural Concrete, Structural Steel, Soils, and Foundations for Nuclear Power Plants.*

   - In Subsection 402, other appropriate industry codes and standards may be invoked in lieu of ACI 359 as specified by the responsible design organization so long as they comply with the requirements of the defined work scope.

   - In Subsection 707, ASTM C1315 is added to the first paragraph as an applicable standard for test methods for curing compounds. Also other appropriate industry codes and standards may also be invoked as specified by the responsible design or supplier organizations.
   - For Subsection 804.1, paragraph 1, torque wrench inspections will not be required for completed connections installed by either the turn-of-nut method or by direct-tension indicator method.

6. NQA-1-2000, Part II, *Quality Assurance Requirements for Nuclear Facility Applications*, Subpart 2.8, *Installation, Inspection, and Testing of Mechanical Equipment and Systems for Nuclear Power Plants.*

   - Subsection 202(e) requires documents listed in (2), (5), (6), (7), (8), and (9) to be available at the work site. The referenced documents do not control the installation work processes, rather, the documents provide evidence the items are acceptable to be released for installation. The referenced documents will be electronically available on PC workstations in the Document Management System, not necessarily at the equipment work site.
   - Subsections 503.1 and 504 do not apply.

7. Regulatory Guide 1.54, Rev 1 (7/2000), *Service Level I, II, and III Protective Coatings Applied to Nuclear Power Plants.*

   Regulatory Guide Position C is incorporated into design and construction considerations for Service Level II and III protective coatings (GROA design has no Service Level I coatings) as described below:

   Regulatory Guide Position C.1, *Guidance in ASTM Standards.*

   - Guidance in ASTM standards is met by use of ASTM D 5144-00 to ensure that the coatings are suitable for the specific service environment to which the coatings will be exposed.

   Regulatory Guide Positions C.2, C3, C4, and C5.

   - Criteria are met by adopting the practices specified in the ASTM standards noted therein, as necessary, to ensure that the coatings are suitable for the specific service environment to which the coatings will be exposed.

   Regulatory Guide Position C.6, *Additional Information.*

   - Additional information is met by using as a reference, as necessary, the guidance available in the EPRI document noted therein.

   - Regulatory Guide 1.54 is not invoked for:

   1. Surfaces to be insulated
   ~~1.~~2. Inner surfaces of cabinets or enclosures
   ~~1.~~3. Field repair on any coated item of less than 30 square inches surface area
   ~~1.~~4. Small "production line items" such as small motors, hand wheels, electrical cabinets, control panels, loudspeakers, etc. where special painting would not be practical
   5. Stainless steel or galvanized surfaces

6. Coatings used for banding of piping
7. Strippable coatings used for cleanup.

4.0 PROCUREMENT DOCUMENT CONTROL

4.1 GENERAL

A. This section establishes requirements to ensure that procurement documents, and any changes thereto, contain appropriate technical and QA requirements.

B. When an Interagency Agreement or other document serves as a procurement document between the OCRWM and other federal agencies, the requirements of this section shall apply.

C. The requirements of this section that are applicable to suppliers are also applicable to OCRWM contractors unless otherwise noted.

4.2 REQUIREMENTS

4.2.1 Procurement Document Preparation

Procurement documents at all tiers of procurement shall include the following provisions to ensure quality as applicable to the item (including spare parts and replacements) or service being procured:

A. A statement of the scope of work to be performed.

B. Technical requirements, including:

1. Design bases and other applicable requirements shall be included or referenced in documents for procurement of items and services.

2. Specific documents (e.g., drawings, specifications, codes, standards, regulations, procedures, instructions), including revisions thereto, that describe the technical requirements of the items or services to be furnished shall be specified. The revision level or change status of these documents shall also be identified.

3. Tests, inspections, and acceptance requirements that the purchaser will use to monitor and evaluate the performance of the supplier shall be specified.

C. QA program requirements, including:

1. To the extent necessary, procurement documents shall require suppliers to have a QA program consistent with the applicable requirements of this document. The extent of the program shall depend upon the type and use of the item or service being procured. A principal contractor QA program description document shall comply with the QARD. A supplier QA program description document shall comply with the purchaser QA program description document. The extent of the QA program shall depend on the

scope, nature, type and use, or complexity of the item or service being procured.

2. A requirement for supplier to incorporate the appropriate QA requirements into any supplier procurement document issued to a sub tier supplier.

3. When deemed appropriate, the purchaser may permit some or all supplier work to be performed under the OCRWM QA program or the purchaser's QA program. In these cases, procurement documents shall specify that the OCRWM or purchaser's implementing documents are applicable to the supplier and that the purchaser shall provide these applicable documents to the supplier.

4. As an alternative (see Subsection 4.2.4B.1) to requiring a documented QA program for the procurement of analytical services to support scientific investigation, procurement of data, or commercial calibration services, the procurement may be controlled in accordance with Subsection 7.2.12B, 7.2.12C, and 7.2.12D, respectively.

D. Provisions for right of access to supplier facilities shall be granted at each tier of procurement for the purpose of inspection, verification, audit, or surveillance by the purchaser or other designee authorized by the purchaser. Procurement documents issued by OCRWM contractors shall also include a provision to provide right of access to the OQA for the purpose of inspection, verification, audit, or surveillance by the OQA.

E. Provisions for establishing hold points beyond which work cannot proceed without purchaser authorization.

F. The procurement documents at all tiers shall identify the documentation required to be submitted for information, review, or approval by the Purchaser. The time of submittal shall also be established. When the purchaser requires the supplier to maintain specific QA records, the retention times and disposition shall be prescribed.

G. Purchaser requirements for the supplier to report nonconformances dispositioned as use-as-is or repair to the purchaser for approval of the disposition.

H. Identification of any spare and replacement parts or assemblies and the appropriate technical and QA information required for ordering. Spare parts shall be subject to QA program controls, codes and standards, and technical requirements equal to or greater than the original requirements, or as required to preclude repetition of defects.

I. Instructions relative to the performance of special processes.

J. A requirement for suppliers to establish controls to mitigate the procurement and installation of counterfeit or fraudulent items.

K. Provisions for identifying that the procurement is subject to the provisions of 10 CFR 21.

4.2.2 Procurement Document Review and Approval

A. Procurement document reviews shall be performed and documented prior to issuance of the procurement documents.

B. A review of the procurement documents and any changes thereto shall be made to verify that documents include appropriate provisions to ensure that items or services will meet the governing requirements.

C. Reviews shall ensure that applicable requirements delineated in Subsection 4.2.1 are correctly stated, inspectable, and controllable; there are adequate acceptance and rejection criteria; and the procurement document has been prepared, reviewed, and approved in accordance with the requirements of this section.

D. Reviews shall be performed by personnel who have access to pertinent information and who have an adequate understanding of the requirements and scope of the procurement.

E. When specified by controlling procedures, procurement documents shall be reviewed by individuals or groups other than the one who generated the document that are trained and qualified in QA practices and concepts and concur with these documents with respect to the QA-related aspects. The training and qualification of individuals or groups performing reviews shall be in accordance with Subsection 2.2.11.

F. Procurement documents shall be approved.

4.2.3 Procurement Document Change

A. Changes shall be subject to the same degree of control as used in the preparation of the original documents.

B. Changes made as a result of proposal/bid evaluations or pre-contract negotiations shall be incorporated into the procurement documents. The evaluation of these changes and the resulting impact shall be completed before the contract is awarded. The evaluation shall consider:

1. Appropriate requirements as specified in this section.

2. Additional or modified design criteria.

3. Analysis of exceptions or changes requested or specified by suppliers and a determination of the impact such changes have on the intent of the procurement documents or quality of the item or service to be furnished.

4.2.4 Commitment Document Positions

A. OCRWM commits to the following documents:

1. NQA-1a-1983, Basic Requirement 4, *Procurement Document Control.*

2. DOE O 414.1C, Section 4b (7) (a).

B. OCRWM commits to the following document with the associated modification:

1. NQA-1a-1983, Supplement 4S-1, *Supplementary Requirements for Procurement Document Control.*

- Subsection 2.3 of this standard requires suppliers to have a QA program. When purchasing analytical services to support scientific investigation, data to support scientific investigation or commercial calibration services from calibration laboratories accredited by a nationally-recognized accrediting body, a QA program is not required to be imposed. These procurements shall be controlled in accordance with Subsections 7.2.12B, 7.2.12C, and 7.2.12D, respectively.

5.0 PROCEDURES, INSTRUCTIONS, AND DRAWINGS

5.1 GENERAL

This section establishes the requirements to ensure that work is prescribed by, and performed in accordance with, implementing documents (i.e., approved procedures, instructions, and drawings).

5.2 REQUIREMENTS

A. Work shall be prescribed by controlled implementing documents of a type appropriate to the circumstance and shall be accomplished in accordance with these implementing documents.

B. Work shall be suspended if it cannot be accomplished as described in controlled implementing documents.

C. OCRWM contractors may work to OCRWM or principal contractor implementing documents when stipulated in procurement documents, in accordance with Section 4.0.

D. Suppliers to a principal contractor may work to OCRWM or principal contractor implementing documents if permitted by the principal contractor QA program description document and if stipulated in procurement documents.

5.2.1 Types of Implementing Documents

The type of document to be used to perform work shall be appropriate to the nature and circumstances of the work being performed. Design drawings, including as-built drawings, are developed and controlled in accordance with the requirements of Section 3.0.

5.2.2 Content of Implementing Documents

Implementing documents shall be consistent with requirements delineated in the QA program description document applicable to the implementing organization and shall include the following information as appropriate to the work to be performed:

A. Responsibilities and organizational interfaces of the organizations affected by the document.

B. Quantitative and/or qualitative acceptance criteria for determining that prescribed activities have been satisfactorily accomplished and that prescribed results have been satisfactorily attained.

C. Identification of the QA records generated by the implementing document.

5.2.3 Commitment Document Positions

A. OCRWM commits to the following documents:

1 NQA-1a-1983, Basic Requirement 5, *Instructions, Procedures and Drawings.*

2. DOE O 414.1C, Section 4b (4).

3. DOE O 414.1C, Section 4b (5) (a).

6.0 DOCUMENT CONTROL

6.1 GENERAL

This section establishes requirements to ensure that documents within the scope of the QARD, including changes thereto, are reviewed for adequacy, approved for release, distributed for use at the location where the work is being performed, and used at the work location.

6.2 REQUIREMENTS

6.2.1 Controlled Documents

Controlled documents include, but are not limited to, documents that specify quality or technical requirements or prescribe activities that are governed by the QARD (e.g., design documents; procurement documents; procedures, instructions and drawings; QA program description documents; and safety analysis reports for distribution and use, and changes thereto).

6.2.2 Preparing Documents

The responsibility for preparing documents shall be assigned to the appropriate organization.

6.2.3 Reviewing Documents

A. Implementing documents and documents that specify technical or QA requirements or prescribe activities that are governed by the QARD, including changes thereto, shall be reviewed prior to approval and issuance for correctness, adequacy, completeness, accuracy, and compliance with established requirements.

B. When specified by controlling procedures, the review shall be performed by individuals other than the preparer who are trained and qualified in QA practices and concepts.

C. OQA shall review principal contractor procedures that direct the development and maintenance of their quality-affecting procedures. Review shall be performed and acceptance documented prior to initiation of the activity governed by the procedure.

D. Comments resulting from the reviews shall be documented and resolved to the satisfaction of the organization responsible for the document before approving the document.

6.2.4 Approving Documents

The organizational position responsible for approving the document for release shall be identified.

6.2.5 Distribution and Use of Documents

A. A process shall be established to identify the current status of each document that is required to be controlled in accordance with this section. This process shall be made accessible to document users.

B. The disposition of cancelled or superseded documents shall be controlled to ensure that they are not used to perform work.

C. Effective dates shall be established for approved implementing documents.

D. The latest version (revision or change) of documents, either in hardcopy or electronic media, shall be available for use prior to the start of work at the location where the activity is performed. These documents shall be adhered to in the performance of work.

6.2.6 Changes to Documents

A. Changes to documents shall be reviewed in accordance with the requirements of Subsection 6.2.3 prior to approval for release.

B. Implementing documents shall define the method used to incorporate changes. If the defined method is other than reissue of the entire revised controlled document as a revision, the implementing document shall define the maximum number of changes permitted prior to requiring reissue of the entire controlled document as a revision.

C. Implementing documents shall require that a history of changes to QA program documents, including the reasons for the changes, be documented and maintained. This document history shall be reviewed each time additional changes to the document are proposed.

D. Changes to documents, other than editorial corrections as delineated in Subsection 6.2.8, shall be reviewed and approved by the same organizations that performed the original review and approval (if these organizations are affected by the change) unless OCRWM designates another responsible organization. The reviewing organizations shall have access to pertinent background data or information upon which to base their approval.

6.2.7 Expedited Changes

If an activity cannot be performed as prescribed in a document and the change process would cause unreasonable delays, an expedited change may be made at the work location by responsible management.

A. After the expedited change has been authorized, the changes shall be processed through the normal change process. This processing shall occur in a timely manner consistent with the type and nature of the document being changed.

B. Implementing documents shall describe the process to control expedited changes according to the following requirements.

1. The level of management with the authority to make expedited changes shall be identified.

2. The time limits for processing expedited changes through the normal change process shall be specified.

3. An evaluation of the work shall be performed if the normal review process results in a change that is different from the expedited change.

6.2.8 Editorial Corrections

Editorial corrections that do not have a material impact on the document requirements may be made to documents without being subject to review requirements, but such corrections shall be distributed as a revision or change to the document.

A. The following items are considered editorial corrections:

1. Correcting grammar or spelling.

2. Renumbering sections or attachments that do not affect the chronological sequence of work.

3. Changing the title or number of the document or the title or number of documents referenced in the procedure.

4. Updating organizational titles.

B. A change in an organizational title accompanied by a change in responsibilities is not considered an editorial correction.

C. The organizational position responsible for approving the document for release shall approve editorial corrections.

6.2.9 Commitment Document Positions

A. OCRWM commits to the following documents:

1. NQA-1a-1983, Basic Requirement 6, *Document Control.*

2. DOE O 414.1C, Section 4b (4).

B. OCRWM commits to the following document with the associated modifications:

NQA-1a-1983, Supplement 6S-1, *Supplementary Requirements for Document Control.*

- Subsection 3.1 requires that changes to documents other than those defined in Subsection 3.2 are considered as major changes and shall be reviewed and approved by the same organizations that performed the original review and approval unless other organizations are specifically designated. In lieu of defining changes as Major or Minor, the OCRWM will implement the following alternative:

- The OCRWM will limit the scope of the Minor Changes category to the inconsequential editorial corrections described in QARD, Subsection 6.2.8. Controlled document changes outside the scope of Subsection 6.2.8 will be treated as Major Changes and will be reviewed and approved as described in QARD, Subsection 6.2.6.

7.0 CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

7.1 GENERAL

A. This section establishes requirements for planning and executing quality affecting procurements to ensure that purchased items and services meet specified requirements. This section does not apply to the procurement of direct support contractor services. The supplier selection and bid/proposal evaluation requirements of this section do not apply to situations where the OCRWM obtains the services of other federal agencies through an Interagency Agreement or other such document. When an Interagency Agreement or other such document serves as a procurement document between the OCRWM and other federal agencies, the technical and quality requirements, responsibilities, and interfaces specified in these documents shall be verified to be satisfactorily incorporated into the applicable federal agency's QA program description document prior to starting work subject to the QARD.

B. The requirements of this section that are applicable to suppliers are also applicable to OCRWM contractors unless otherwise noted.

7.2 REQUIREMENTS

7.2.1 Procurement Planning

Procurements shall be planned and documented to ensure a systematic approach to the procurement process. Procurement planning shall:

A. Identify procurement methods and organizational responsibilities (e.g., interfaces between design and procurement).

B. Identify what is to be accomplished, who is to accomplish it, how it is to be accomplished, and when it is to be accomplished.

C. Prior to the initiation of each individual activity identified in Paragraph 7.2.1D, identify and document the sequence of actions and milestones, indicating the completion of these activities and the preparation of applicable procedures.

D. Provide for the integration of the following activities:

1. Procurement document preparation, review, and change control according to the requirements of Section 4.0.

2. Selection of procurement sources.

3. Proposal/bid evaluation and award.

4. Evaluation of OCRWM contractor/supplier performance.

5. Verifications, including any hold and witness point notifications.

6. Control of nonconformances.

7. Corrective action.

8. Acceptance of the item or service.

9. Identification of QA records.

E. Be accomplished as early as practicable, and no later than the start of those procurement activities that are required to be controlled, to ensure interface compatibility and a uniform approach to the procurement process.

F. Be performed relative to the level of importance, complexity, and quantity of the item or service being procured and the supplier's quality performance.

G. Include participation of representatives from the technical organizations and individuals that are trained and qualified in QA practices and concepts.

7.2.2 Source Evaluation and Selection

A. Supplier selection shall be based on an evaluation, performed by or for the purchaser before the contract is awarded, to determine the supplier's capability to provide items or services in accordance with procurement document requirements.

B. The organizational responsibilities of the purchaser for source evaluation and selection to identify supplier's capability shall be identified.

C. The purchaser's measures for evaluating and selecting procurement sources shall be documented and shall include one or more of the following elements:

1. Evaluation of the supplier's history for providing an identical or similar product that performs satisfactorily in actual use. This evaluation shall reflect current capability.

2. Evaluation of the supplier's current QA records, supported by documented qualitative and quantitative information that can be objectively evaluated.

3. Evaluation of the supplier's technical and quality capability are determined by a direct evaluation of supplier's facilities and personnel, and implementation of the supplier's QA program.

D. The results of procurement source evaluation and selection shall be documented.

7.2.3 Proposal/Bid Evaluation

A. The proposal/bid evaluation process shall include a determination of the extent of conformance to procurement document requirements. This evaluation shall be performed by designated, technically-qualified individuals or organizations, including individuals that are trained and qualified in QA practices and concepts.

B. The evaluation shall include the following subjects, as applicable to the type of procurement:

1. Technical considerations.

2. QA program requirements.

3. Supplier personnel.

4. Supplier production capability.

5. Supplier past performance.

6. Alternatives.

7. Exceptions.

C. Before the contract is awarded, the purchaser shall resolve, or obtain commitments to resolve, unacceptable quality conditions identified during the proposal/bid evaluation.

D. Any deficiencies that would affect quality shall be corrected before starting quality affecting work.

E. The supplier's QA program description document shall be accepted by the purchaser prior to the start of work.

7.2.4 Supplier Performance Evaluation

A. The purchaser of items and services shall establish measures to interface with the supplier to verify performance as deemed necessary by the purchaser. The measures shall include:

1. Establishing an understanding between the purchaser and supplier regarding the requirements and specifications identified in the procurement documents.

2. Requiring the supplier to identify planning techniques and processes to be used in fulfilling procurement document requirements.

3. Reviewing supplier documents that are prepared or processed during work performed to fulfill procurement document requirements.

4. Identifying and processing necessary change information.

5. Establishing the method to be used to document information exchanges between purchaser and supplier.

6. Establishing the extent of source surveillance and inspection.

B. Annual performance evaluations shall be performed on each supplier to determine the need to schedule additional audits. This evaluation shall be documented and based on:

1. Review of supplier furnished documents and records (e.g., certificates of conformance, the American Society of Mechanical Engineers [ASME] Certificate of Authorization, ASME Quality System Certificate, nonconformance notices, and corrective actions).

2. Results of previous source verifications, audits, management assessments, and receiving inspections, including results of audits from other sources (e.g., other customers, ASME and NRC).

3. Operating experience of identical or similar products furnished by the same supplier.

C. The extent of verifications, including planning, shall be a function of the relative importance, complexity, and quantity of items or services being procured and supplier quality performance.

D. Verification activities shall be accomplished by qualified personnel assigned to check, inspect, audit, or witness supplier activities.

E. Verifications shall be conducted as early as practical and shall not relieve suppliers of their responsibility for the verification of quality achievement.

F. Verifications shall include (i) the use of audits to evaluate supplier performance and (ii) evaluation of purchaser documentation to aid in the determination of the effectiveness of the supplier QA program. This documentation shall include documentation of source surveillance and inspections, audits, receiving inspections, nonconformances, dispositions, waivers, and corrective actions.

7.2.5 Control of Supplier Generated Documents

A. Supplier generated documents shall be controlled, processed, and accepted in accordance with established methods.

B. Measures shall be implemented to ensure that the submittal of these documents is accomplished in accordance with procurement document requirements. These measures shall provide for the acquisition, processing, and recorded evaluation of technical, inspection, and test data compared against the acceptance criteria.

7.2.6 Acceptance of Items or Services

A. Suppliers shall verify that furnished items or services comply with purchaser procurement document requirements before offering the items or services for acceptance.

B. When required by code, regulation, or procurement document requirement, documentary evidence that items or services conform to procurement documents shall be available at the purchaser's facility before the item is installed or before the service is used.

C. Methods for accepting supplier-furnished items or services shall ensure that items or services comply with purchaser procurement document requirements and include one or more of the following, as appropriate to the items or services being procured:

1. Evaluation of the supplier certificate of conformance (items and related services).

2. Performance of one or a combination of: source verification, receiving inspection, or post-installation test (items and related services).

3. Technical verification of data produced (services only).

4. Surveillance and/or audit of the activity (services only).

5. Review of objective evidence (e.g., certifications and test reports) for conformance to procurement document requirements (services only).

D. Purchaser shall accept items and services prior to installation or use.

7.2.7 Certificate of Conformance

When a certificate of conformance is used to accept an item or related service:

A. The certificate shall identify the purchased item or service to the specific procurement document.

B. The certificate shall identify the specific procurement document requirements met by the purchased item or service, such as codes, standards and other specifications. The procurement document requirements identified shall include any approved changes, waivers, or deviations applicable to the item or service.

C. The certificate shall identify any procurement document requirements that have not been met, together with an explanation and the means for resolving the nonconformances.

D. The certificate shall be attested to by a person who is responsible for this QA function and whose responsibilities and position are described in the supplier's QA program.

E. The certification process, including the implementing documents to be followed in filling out a certificate and the administrative implementing documents for review and approval of the certificates, shall be described in the purchaser's or supplier's QA program description document.

F. Measures shall be identified to verify the validity of certificates and the effectiveness of the certification process (i.e., by audit of the supplier or by an independent inspection or test of the item). Verifications shall be conducted by the purchaser at intervals commensurate with the past quality performance of the supplier.

7.2.8 Source Verification

The purchaser may accept an item or service by monitoring, witnessing, or observing activities performed by the supplier. This method of acceptance is called source verification.

A. Source verification is planned and performed by individuals that are trained and qualified in QA practices and concepts in accordance with written procedures to ensure conformance to procurement requirements. Procedures applicable to the method of procurement provide for:

1. Specification of the characteristics or processes to be witnessed, inspected, or verified and the method of surveillance and the extent of documentation required.

2. Audits, surveillance, or inspections to verify the effectiveness of the supplier QA program and quality control activities and to ensure that the supplier complies with QA and technical requirements.

B. Source verification shall be implemented to inspect, monitor, witness, or observe activities consistent with the supplier's planned fabrication, inspections, examinations, or tests, and shipments of items at predetermined points and performed at intervals consistent with the importance and complexity of the item.

C. Documented evidence of acceptance of source verified items or services shall be furnished to the receiving destination of the item, to the purchaser, and to the supplier.

7.2.9 Receiving Inspection

When receiving inspection is used to accept an item:

A. The inspection shall consider the results of source verifications and audits and the demonstrated quality performance of the supplier.

B. The inspection shall be performed in accordance with inspection implementing documents.

C. The inspection shall verify by objective evidence such features as proper configuration; identification; dimensional, physical, and other characteristics; freedom from shipping damage; and cleanliness.

D. The inspection shall be planned and executed according to the requirements of Section 10.0.

E. The receiving inspection shall be coordinated with a review of supplier documentation when procurement documents require such documentation be furnished prior to receiving inspection.

7.2.10 Post-Installation Testing

A. When post-installation testing is used as a method of acceptance, the post-installation test requirements and acceptance documentation shall be mutually established by the purchaser and supplier.

B. The test shall be in accordance with the requirements of Section 11.0.

7.2.11 Control of OCRWM Contractor/Supplier Nonconformances

The purchaser and supplier shall establish and document methods for disposition of items and services that do not meet procurement document requirements according to the following requirements:

A. OCRWM contractors, other than principal contractors, shall evaluate nonconforming items according to the requirements of Section 15.0. Principal contractors shall evaluate nonconforming items according to the requirements of their QA program description document.

B. Suppliers/principal contractors shall submit a report of nonconformance to the purchaser, including recommended disposition for use-as-is or repair, and technical justification. Reports of nonconformances related to procurement document requirements or documents approved by the purchaser, which consist of one or more of the following shall be submitted to the purchaser for approval of the recommended disposition:

1. Technical or material requirements are violated.

2. A requirement in supplier documents, which have been approved by the purchaser, is violated.

3. The nonconformance cannot be corrected by continuation of the original manufacturing process or by rework.

4. The item does not conform to the original requirement even though the item can be restored to a condition such that the capability of the item to function is unimpaired.

C. The purchaser shall disposition the supplier's recommendation.

D. The purchaser shall verify implementation of the disposition.

E. The purchaser shall maintain records of supplier submitted nonconformances.

7.2.12 Commercial Procurement

A. Commercial Grade Items

Where specific QA controls appropriate for nuclear applications cannot be imposed in a practicable manner, commercial grade items may be substituted for basic components, subject to the following to provide the necessary assurance that the dedicated item will perform its intended safety or waste isolation function: (see Subsection 7.2.14B.1).

1. The item's critical characteristics shall be specified in approved design and procurement documents.

2. Verification of the item's critical characteristics shall be achieved by application of a dedication process to be performed by a specified dedicating entity.

3. Implementing processes shall be developed to be consistent with Electric Power Research Institute (EPRI) *Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications* (NCIG-07), EPRI NP-5652 (6/88 as endorsed and modified by NRC Generic Letters 89-02, *Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products* (3/89) and 91-05, *Licensee Commercial-Grade Procurement and Dedication Programs* (4/91).

B. Commercial Procurement of Analytical Services

For analytical services in support of scientific investigation, the following requirements shall be an acceptable alternative to all other requirements of Section 7.0 (see Subsection 7.2.14B.1). The purchaser shall:

1. Prior to issuing the procurement document, develop a documented quality control sample plan that describes:

    a. The number of quality control samples and the approach to be used for submitting the samples (e.g., blind, duplicate, or spike).

    b. The preparation and analysis of quality control samples or the identification of the source of the preparation and analysis method. Standards used in the preparation of quality control samples shall be traceable to nationally recognized standards. If no nationally recognized standard exists, the basis for use shall be documented.

    c. Acceptance criteria.

    d. How the number of quality control samples, the approach, and the acceptance criteria provide confidence in the accuracy/precision of the data.

2. Ensure that quality control analytical results are received and evaluated against acceptance criteria prior to use of data.

3. Ensure that data, quality control analytical results, the quality control sample plan, and evaluation documentation are submitted as QA records.

C. Commercial Procurement of Data

When required data cannot be obtained from any external source through a procurement process that involves the imposition of applicable QA program requirements, the data may be obtained through a non-Q procurement action, provided (see Subsection 7.2.14B.1):

1. Prior review and approval by the responsible OCRWM line organization director and the Director, OQA, is obtained.

2. Planning for data acquisition and use is performed in accordance with Supplement III, Subsection III.2.1.

3. The data produced by the procurement is identified, controlled, and qualified as described in Supplement III, Subsections III.2.3 and III.2.4.

D. Commercial Procurement of Calibration Services

1. For suppliers of commercial calibration services with accreditation by a nationally-recognized accrediting body, a documented review of the supplier's accreditation may be used in lieu of external audits, inspections or tests following delivery, or in-process surveillances during the performance of the service (see Subsection 7.2.14B.1 and 18.2.14B.1). The review shall include as a minimum:

a. Accreditation to ANSI/ISO/IEC 17025, *General Requirements for the Competence of Testing and Calibration Laboratories* (2005).

b. Accreditation by the National Voluntary Laboratory Accreditation Program (NVLAP), administered by the National Institute of Standards and Technology or an accrediting body recognized by the NVLAP through a mutual recognition agreement.

c. Published scope of accreditation for the calibration laboratory covering the needed measurement parameters, ranges, and uncertainties.

2. Procurement documents shall impose additional technical and administrative requirements, as necessary, to satisfy the requirements of the OCRWM QA program and/or technical requirements.

3. The critical characteristics associated with the calibration shall be specified in approved design and/or procurement documents.

4. Verification of the critical characteristics shall be achieved by application of a dedication process to be performed by a specified dedicating entity.

5. The procurement documents shall require reporting as-found and as-left calibration data when calibrated items are found to be out of calibration.

6. The calibration certificate/report shall include identification of the laboratory equipment/standards used.

7.2.13 American Society of Mechanical Engineers Section III Code Items

The following requirements relative to suppliers of ASME Section III Code items apply only to items designed and fabricated in accordance with ASME Section III, *Rules for Construction of Nuclear Power Plant Components*, and do not apply to noncode items that may be supplied by ASME Section III Code suppliers.

A. For the purchase of ASME Section III Code items, editions of ANSI/ASME NQA-1 identified in NRC endorsed or otherwise approved by the NRC versions of the Code may be used for the construction of ASME Section III Code items when the referenced edition of ANSI/ASME NQA-1 is used in conjunction with other QA, administrative, and reporting requirements contained in the Code. Further, applicable requirements contained in the QARD or supplier QA program description document shall also be met in conjunction with the ASME Section III Code.

B. When assessing whether a company has an acceptable QA program to enable it to become a supplier, credit may be taken for the fact that ASME has surveyed the ASME Code supplier and issued a Certificate of Authorization or Quality System Certification of the appropriate scope and for the desired location, without performing any additional evaluation of the supplier QA program.

C. Audits of ASME Code suppliers shall confirm that the suppliers are satisfactorily implementing:

1. Their accredited ASME Code QA program.

2. The technical and quality provisions specified in the purchase order.

3. The applicable provisions of the QARD or principal contractor QA program description document.

4. Applicable requirements contained in the regulations.

7.2.14 Commitment Document Positions

A. OCRWM commits to the following documents:

1. Regulatory Guide 1.28, Revision 3 (8/85), Regulatory Position C 3.2.2.

2. NQA-1a-1983, Basic Requirement 7, *Control of Items and Services.*

3. DOE O 414.1C, Section 4b (7) (b).

4. DOE O 414.1C, Section 4b (7) (c).

5. DOE O 414.1C, Attachment 3, *Suspect/Counterfeit Items Prevention.*

6. NRC Information Notice 86-21 (3/31/1986), *Recognition of American Society of Mechanical Engineers Accreditation Program for N Stamp Holders*, including Supplement 1 (12/04/1986), and Supplement 2 (4/16/1991).

B. OCRWM commits to the following documents with the associated modifications:

1. NQA-1a-1983, Supplement 7S-1, *Supplementary Requirements for Control of Purchased Items and Services.*

- Section 10, Commercial Grade Items, provides requirements for the commercial grade procurement of items. In lieu of the requirements specified in this section, OCRWM implements a commercial grade item dedication program in accordance with QARD Subsection 7.2.12A.

- As an alternative to the imposition of all otherwise applicable requirements of this supplement for the procurement of analytical services in support of scientific investigations, the procurement of data in support of scientific investigation, or the procurement of commercial calibration services, OCRWM may implement the purchaser related requirements described in QARD, Subsections 7.2.12B, 7.2.12C, or 7.2.12D, respectively.

2. EPRI NP-5652 (6/88), *Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications* (NCIG-07), as endorsed and modified by NRC Generic Letters 89-02 (3/89) and 91-05 (4/91).

   - If a commercial grade item dedication process as defined in 10 CFR 21.3, Definitions, is implemented, the implementing processes shall be developed with the guidance contained in EPRI NP-5652 and NRC Generic Letters 89-02 and 91-05.

8.0 IDENTIFICATION AND CONTROL OF MATERIAL, PARTS, AND COMPONENTS

8.1 GENERAL

This section establishes requirements for the identification and control of items (including consumables and partially fabricated assemblies) to ensure that only correct and accepted items are used or installed.

8.2 REQUIREMENTS

8.2.1 Identification

A. Identification shall be maintained on the items or in documents traceable to the items.

B. Items shall be identified from the time of initial fabrication, or receipt, up to and including installation or end use.

C. Identification shall relate an item to an applicable design or other pertinent specifying document.

D. Correct identification of items shall be verified and documented prior to release for fabrication, assembly, shipping, or installation.

8.2.2 Physical Markings

A. Item identification methods shall include use of physical markings to the maximum extent possible. If physical markings are either impractical or insufficient, other appropriate means shall be employed (e.g., physical separation, labels, or tags attached to containers or procedural control).

B. Physical markings, when used, shall:

1. Be applied using materials and methods that provide a clear and legible identification.

2. Not detrimentally affect the function or service life of the item.

3. Be transferred to each part of an identified item when the item is subdivided.

4. Not be obliterated or hidden by surface treatments, coatings, or after installation unless other means of identification are substituted.

8.2.3 Conditional Requirements

The controls for items shall address the following requirements, as applicable:

A. If codes, standards, or specifications include specific identification or traceability requirements (e.g., identification or traceability of the item to applicable specification and grade of material; heat, batch, lot, part, or serial number; specified inspection, test, or other records), the program shall be designed to provide such identification and traceability control.

B. If codes or standards do not include specific identification or traceability requirements, specifications shall specify identification and traceability methods appropriate to the item.

C. If items, including consumables, have a limited calendar (shelf) life, operating life, or operating cycles, their use shall be controlled to:

1. Uniquely identify them.

2. Establish records identifying the calendar (shelf) life, operating life, and/or operating cycles remaining.

3. Prevent the further use of such items, including consumables, which have reached the end of their calendar (shelf) life, operating life, or operating cycles.

D. If item storage is required, methods shall be established for the control of item identification that is commensurate with the planned duration and conditions of storage. These methods shall provide for, as applicable:

1. Maintenance or replacement of markings and identification tags damaged during handling or aging.

2. Protection of identification on items subject to excessive deterioration resulting from environmental exposure or adverse storage conditions.

3. Update of existing program records.

8.2.4 Commitment Document Positions

A. OCRWM commits to the following documents:

1. NQA-1a-1983, Basic Requirement 8, *Identification and Control of Items.*

2. NQA-1a-1983, Supplement 8S-1, *Supplementary Requirements for Identification and Control of Items.*

3. DOE O 414.1C, Section 4b (5) (b).

9.0 CONTROL OF SPECIAL PROCESSES

9.1 GENERAL

A. Processes affecting the quality of items or services shall be controlled. Special processes that control or verify quality, such as welding, heat treating, chemical cleaning, and nondestructive examination are controlled and accomplished by qualified personnel using qualified procedures in accordance with applicable codes, standards, specifications, criteria, and other requirements.

B. Processes performed to acquire or analyze data for scientific investigations (i.e., siting or design input) are performed in accordance with Supplement III.

9.2 REQUIREMENTS

9.2.1 Special Processes

A. For special processes not covered by existing codes and standards or where quality requirements specified for an item exceed those of existing codes or standards, the necessary requirements for qualification of personnel, procedures, or equipment shall be specified or referenced in implementing documents.

B. Processes to be controlled as special processes shall meet the following criteria:

1. The results are highly dependent on the control of the process; or

2. The results are highly dependent on the skill of the operator; and

3. Quality of the results cannot be readily determined by inspection or test of the item.

9.2.2 Personnel, Implementing Documents, and Equipment Qualifications

Implementing documents shall be used to ensure that process parameters are controlled and that the specified environmental conditions are maintained. Special process implementing documents shall include or reference:

A. Organizational responsibilities, including those for individuals or groups that are trained and qualified in QA practices and concepts, for the qualification of special process equipment and personnel.

B. Records to be maintained for each special process method.

C. Provisions for recording evidence of acceptable accomplishment of special processes using qualified procedures, equipment, and personnel.

D. Qualification requirements for personnel, implementing documents, and equipment which comply with specified requirements. Certificates of qualification shall clearly delineate the specific processes that personnel are qualified to perform and the criteria used to qualify personnel in each process.

E. Conditions necessary for accomplishment of the special process shall be included in implementing documents. These conditions shall include proper equipment, controlled parameters of the process, calibration requirements, and traceability between the item and the individual performing the special process.

F. Requirements of applicable codes, standards, and specifications, including acceptance criteria for the special process shall be referenced or specified in implementing documents.

9.2.3 Qualification and Certification of Nondestructive Examination Personnel

A. Nondestructive examination shall include radiography, magnetic particle, ultrasonic, liquid penetrant, eddy current, neutron radiography, acoustic emission, and leak testing.

B. Personnel who perform nondestructive examinations shall be qualified and certified in accordance with Subsection 2.2.11D. The qualification and certification shall include a performance demonstration as part of the practical examination.

C. Suppliers other than principal contractors may qualify their nondestructive examination personnel to other editions of SNT-TC-1A provided other editions are reconciled to the 1980 edition of SNT-TC-1A and found acceptable to the OQA.

D. Implementing documents shall be established for the control and administration of nondestructive examination personnel training, examination, and certification.

9.2.4 Commitment Document Positions

A. OCRWM commits to the following documents:

1. NQA-1a-1983, Basic Requirement 9, *Control of Processes.*

2. NQA-1a-1983, Supplement 9S-1, *Supplementary Requirements for Control of Processes.*

3. DOE O 414.1C, Section 4b (8) (a).

10.0 INSPECTION

10.1 GENERAL

This section establishes requirements for developing an effective inspection program. Inspections required to verify conformance of items and activities to specified requirements shall be planned and executed.

10.2 REQUIREMENTS

10.2.1 Inspection Planning

A. Inspection planning shall be performed and documented. Inspection plans may be separate documents governed by procedural controls, or an integral part of approved implementing documents.

B. Representatives of the interested technical organizations and individuals that are trained and qualified in QA practices and concepts shall participate in planning activities.

C. Applicable codes, standards, specifications, and design documents shall be used to develop inspection plans.

D. The elements of inspection plans identify:

1. Characteristics to be inspected.

2. Description of inspection or process monitoring that will be used.

3. Identification of the organization responsible for performing the inspection.

4. Identification of mandatory hold points, when required.

5. Acceptance criteria.

6. Measuring and test equipment to be used to perform the inspection to ensure the equipment is of the proper type, range, accuracy, and tolerance to accomplish the intended function.

7. If applicable, identification of a sampling plan in accordance with Subsection 10.2.4.

8. Methods to record inspection results.

10.2.2 Selecting Inspection Personnel to Perform Inspections

A. The individual who performs an inspection to verify conformance of an item to specified acceptance criteria shall be qualified to the requirements of this section.

B. Inspections performed by personnel during on-the-job training shall be performed under the direct observation and supervision of a qualified person and verification of conformance shall be by the qualified person until proper certification is achieved.

C. Data recorders, equipment operators, or other inspection or test team members who are supervised by a qualified inspector shall not be required to be a qualified inspector.

D. Inspections for acceptance shall be performed by individuals other than those who performed or directly supervised the work being inspected, and those individuals shall not report directly to the supervisor immediately responsible for performance of the work.

10.2.3 Inspection Hold Points

A. When mandatory hold points are used to control work that shall not proceed without the specific consent of the organization placing the hold point, then the specific hold points shall be indicated in implementing documents.

B. Consent to waive specified hold points shall be documented before continuing work beyond the designated hold point.

10.2.4 Statistical Sampling

When statistical sampling is used to verify the acceptability of a group of items, the statistical sampling method shall be based on recognized standard practices and shall comply with the sampling plan requirements delineated in Section 3.2.8.

10.2.5 In-Process Inspections and Monitoring

A. Items in-process or under construction shall be inspected when necessary to verify quality. If inspection of processed items is impossible or disadvantageous, indirect control by monitoring of processing methods, equipment, and personnel shall be provided.

B. Inspection and process monitoring both shall be conducted when control is inadequate with only one method.

C. A combination of inspection and process monitoring methods, when used, shall be performed in a systematic manner to ensure that the specified requirements for

control of the process and the quality of the item are met throughout the duration of the process.

D. Controls shall be established and documented for the coordination and sequencing of the work at established inspection points during successive stages of the process or construction.

10.2.6 Final Inspection

A. Final inspection shall be planned to arrive at a conclusion regarding conformance of the item to specified requirements.

B. Finished items shall be inspected for completeness, markings, calibration, adjustments, protection from damage, or other characteristics, as required to verify the quality and conformance of the item to specified requirements.

C. Quality records not previously examined shall be examined for adequacy and completeness.

D. Final inspections shall include a review of the results and resolution of nonconformances identified by earlier inspections.

E. Modifications, repairs, or replacements of items performed subsequent to final inspection shall require reinspection or retest, as appropriate, to verify acceptability.

10.2.7 Accepting Items

A. The acceptance of inspection results shall be documented and approved by qualified and authorized personnel.

B. The inspection status of an item shall be identified according to Section 14.0.

10.2.8 Inspection Documentation

Inspection documentation shall, at a minimum, identify:

A. The item inspected.

B. The date of inspection.

C. The name or unique identifier of the inspector who documented, evaluated, and determined acceptability.

D. The name of the data recorder, as applicable.

E. The type of observation or method of inspection.

F. The inspection criteria, sampling plan, or reference documents (including revision levels) used to determine acceptance.

G. Results or acceptability of characteristics inspected.

H. Measuring and test equipment used during the inspection, including the identification number and the most recent calibration date.

I. Reference to information on actions taken in connection with nonconformances, as applicable.

10.2.9 Qualification and Certification of Inspection Personnel

Personnel who perform inspections shall be qualified and certified in accordance with Subsection 2.2.11B and 2.2.11E.

10.2.10 Commitment Document Positions

A. OCRWM commits to the following documents:

1. Regulatory Guide 1.28, Revision 3 (8/85), Regulatory Position C.1.

2. NQA-1a-1983, Basic Requirement 10, *Inspection.*

3. NQA-1a-1983, Appendix 2A-1, *Nonmandatory Guidance on the Qualifications of Inspection and Test Personnel.*

4. DOE O 414.1C, Section 4b (8) (a).

B. OCRWM commits to the following document with the associated modifications:

1. NQA-1a-1983, Supplement 10S-1, *Supplementary Requirements for Inspection.*

- In lieu of the qualification requirement of Section 2.2, Qualifications, inspections may be performed by trainees during on-the-job training. These inspections shall be performed under the direct observation and supervision of a qualified person, and verification of conformance shall be by the qualified person until proper certification is achieved.

- In lieu of the qualification requirement of Section 2.2, Qualifications, data recorders, equipment operators, or other inspection or test team members who are supervised by a qualified inspector shall not be required to be a qualified inspector.

11.0 TEST CONTROL

11.1 GENERAL

A. This section establishes requirements for planning and executing tests required to demonstrate that items will perform satisfactorily in service.

1. Tests shall be performed in accordance with implementing documents that incorporate requirements and acceptance criteria contained in applicable design documents.

2. Examples of such tests include prototype qualification tests, component or feature qualification tests, production tests, proof tests prior to installation, construction tests, and preoperational tests (i.e., the test program before the start of preclosure operations).

B. Testing of computer software supporting a safety or waste isolation function shall be performed in accordance with Supplement I.

C. Tests supporting the acquisition of data from samples for scientific investigation, and scientific investigation shall be performed in accordance with Supplement III.

11.2 REQUIREMENTS

11.2.1 Test Planning

Test planning shall require that test implementing documents provide for the following:

A. Identification of the implementing documents to be developed to control and perform tests and provide criteria for (i) determining the accuracy requirements of test equipment and (ii) determining when tests are required and defining how and when testing activities are performed.

B. Provisions for performing prototype, component, or feature qualification testing, including design verification testing, as early as possible before the installation would become irreversible.

C. Identification of the item to be tested and the test requirements and acceptance limits contained in applicable design and procurement documents.

D. Identification of test methods to be employed and instructions for performing the test.

E. Test prerequisites that address the following: calibrated instrumentation; appropriate and adequate test equipment and instrumentation, including accuracy requirements, trained personnel, condition of test equipment, and the

completeness of the item to be tested; suitably controlled environmental conditions; and provisions for data acquisition and storage.

F. Mandatory inspection hold points for witnessing by the organization placing the hold point.

G. Methods to record data and results.

H. Provisions for ensuring that test prerequisites have been met.

I. Selection and identification of the measuring and test equipment (M&TE) to be used to perform the test to ensure that the M&TE is of the proper type, range, accuracy, and tolerance to accomplish the intended function.

11.2.2 Performing Tests

Tests shall be performed in accordance with implementing documents that address the following requirements, as applicable:

A. Provisions for determining when a test is required, describing how tests are performed, and ensuring that testing is conducted by trained and appropriately qualified personnel.

B. Inclusion of or reference to test objectives and provisions for ensuring that prerequisites for the given test have been met, adequate calibrated instrumentation is available and used, necessary monitoring is performed, and suitable environmental conditions are maintained.

C. Test requirements and acceptance criteria provided or approved by the organization responsible for the design of the item to be tested, unless otherwise designated.

D. Test requirements and acceptance criteria based upon specified requirements contained in applicable design or other pertinent technical documents.

11.2.3 Use of Other Testing Documents

A. Other testing documents (e.g., American Society for Testing and Materials specifications, supplier manuals, equipment maintenance instructions, controlled drawings, or other related documents containing acceptance criteria) may be used instead of preparing special test implementing documents. If used, these documents shall incorporate the information directly into the approved test document governing the test.

B. Other testing documents shall include adequate supplemental instructions, as required, to ensure the required quality of the testing work.

11.2.4 Test Results

A. Test results shall be documented, and their conformance with acceptance criteria shall be evaluated, by a qualified individual within the responsible organization to ensure that test requirements have been satisfied.

B. The test status of an item shall be identified in accordance with Section 14.0.

11.2.5 Test Documentation

Test documentation shall, as a minimum, identify the following:

A. Item or work product tested.

B. Date of test.

C. Name of the tester and data recorders.

D. Type of observation.

E. Identification of test criteria or reference documents used to determine acceptance.

F. Results and acceptability of the test.

G. Actions taken in connection with any deviations noted.

H. Name of the person evaluating and accepting the test results.

I. Identification of the M&TE used during the test, including the identification number and the next calibration due date.

11.2.6 Qualification and Certification of Test Personnel

Personnel who direct or perform tests shall be trained, qualified, and certified according to the requirements of Subsection 2.2.11B.

11.2.7 Commitment Document Positions

A. OCRWM commits to the following documents:

1. Regulatory Guide 1.28, Revision 3 (8/85), Regulatory Position C.1.

2. NQA-1a-1983, Basic Requirement 11, *Test Control.*

3. NQA-1a-1983, Supplement 11S-1, *Supplementary Requirements for Test Control.*

4. NQA-1a-1983, Appendix 2A-1, *Nonmandatory Guidance on the Qualifications of Inspection and Test Personnel.*

5. DOE O 414.1C, Section 4b (8) (a).

12.0 CONTROL OF MEASURING AND TEST EQUIPMENT

12.1 GENERAL

This section prescribes requirements applicable to the establishment of measures that ensure tools, gages, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits.

12.2 REQUIREMENTS

12.2.1 Calibration

A. M&TE, including equipment that contains embedded software or programmable hardware, shall be calibrated, adjusted, and maintained as a unit at prescribed intervals, or prior to use, against certified equipment, including reference and transfer standards having known valid relationship to nationally recognized standards. If no nationally recognized standards or physical constants exist, the basis for calibration shall be documented. Embedded software developed or modified by the user shall be controlled in accordance with Supplement I. Data acquisition and control applications, integral to the operations, maintenance, or calibration of scientific investigation testing apparatus, shall be verified or validated, and documented, in conjunction with the controlling test plan(s) and in conjunction with the M&TE or test hardware as an operating unit.

B. Calibration standards shall have a greater accuracy than the required accuracy of standards being calibrated.

   1. If calibration standards with a greater accuracy than required of the standard being calibrated do not exist or are unavailable, calibration standards with accuracy equal to the required calibration accuracy may be used if they can be shown to be adequate for the requirements.

   2. The basis for the calibration acceptance shall be documented and authorized by responsible management. The level of management authorized to perform this function shall be identified.

C. Calibration standards used for the calibration of M&TE shall have an accuracy of at least four times the required accuracy of the equipment being calibrated or, when this is not possible, shall have an accuracy that ensures the equipment being calibrated will be within required tolerance. The basis of acceptance shall be approved by responsible management. The level of management authorized to perform this function shall be identified.

D. The method and interval of calibration for each device shall be defined based on the type of equipment, stability characteristics, required accuracy, precision,

intended use, degree of use, and other conditions affecting measurement control. For M&TE used in one-time-only applications, the calibration shall be done both before and after use.

E. A calibration or calibration check shall be performed:

1. When the accuracy of the M&TE is suspect.

2. When M&TE has passed its calibration due date or interval and has been used since its last calibration and is removed from service (i.e., retired or surplus).

F. Calibrated M&TE shall be labeled, tagged, or otherwise suitably marked or documented to indicate the due date of the next calibration.

G. Calibrated M&TE shall be uniquely identified to provide traceability to its calibration data.

H. Updates to software contained in M&TE that affect calibration shall require recalibration of the equipment prior to use.

12.2.2 Documenting the Use of Measuring and Test Equipment

A. The use of M&TE shall be documented.

B. Selection of M&TE shall be controlled to ensure that such items are of proper type, range, accuracy, and tolerance to accomplish the function of determining conformance to specified requirements.

C. Documentation shall identify the processes monitored, the data collected, or items inspected or tested since the last calibration as appropriate to equipment use and its calibration schedule.

12.2.3 Out-of-Calibration Measuring and Test Equipment

A. M&TE shall be considered to be out-of-calibration and shall not be issued for use until calibrated if any of the following conditions exist:

1. The calibration due date or interval has passed without recalibration.

2. The device produces results known to be in error.

3. The calibration status cannot be determined.

B. Out-of-calibration M&TE shall be controlled. The controls shall include the following requirements:

1. Out-of-calibration M&TE shall be tagged, segregated and not used, or otherwise controlled to prevent reissue until it has been recalibrated (see Subsection 12.2.8B.1.

2. When M&TE is found to be out-of-calibration, the validity of results obtained using that equipment since its last valid calibration shall be evaluated.

   a. The evaluation shall include the determination of acceptability for previously collected data, processes monitored, or items previously inspected or tested.

   b. The evaluation shall be documented.

   c. If evaluation determines that processes monitored or items inspected or tested are suspect, it shall be documented in accordance with Section 15.0.

C. If M&TE is consistently found to be out-of-calibration during the recalibration process, it shall be repaired or replaced.

12.2.4 Lost or Abandoned–in-Place Measuring and Test Equipment

When M&TE is lost or abandoned in place, the validity of results obtained using that equipment since its last valid calibration shall be evaluated.

A. The evaluation shall include the determination of acceptability for previously collected data, processes monitored, or items previously inspected or tested.

B. The evaluation shall be documented.

C. If evaluation determines that processes monitored or items inspected or tested are suspect, it shall be documented in accordance with Section 15.0.

12.2.5 Handling, Storage, and Use

A. M&TE shall be properly handled and stored to maintain accuracy.

B. Selection of M&TE shall be controlled to ensure that such items are the proper type for the intended use.

12.2.6 Commercial Devices

Calibration and control shall not be required for commercial devices when normal commercial device accuracy is adequate for the intended use of the commercial device.

12.2.7 Measuring and Test Equipment Documentation

M&TE calibration documentation shall include the following information:

A. Identification of the measuring or test equipment calibrated.

B. Traceability to the calibration standard used for calibration.

C. Calibration data.

D. Identification of the individual performing the calibration.

E. Identification of the date of calibration and the recalibration due date or interval, as appropriate.

F. Results of the calibration and statement of acceptability.

G. Reference to any actions taken in connection with out-of-calibration or nonconforming M&TE, including evaluation results and repeated inspections or tests, as appropriate.

H. Identification of the implementing document (including revision level) used in performing the calibration.

12.2.8 Commitment Document Positions

A. OCRWM commits to the following documents.

1. NQA-1a-1983, Basic Requirement 12, *Control of Measuring and Test Equipment.*

2. DOE O 414.1C, Section 4b (5) (d).

3. DOE O 414.1C, Section 4b (8) (b).

B. OCRWM commits to the following document with the associated modifications:

1. NQA-1a-1983, Supplement 12S-1, *Supplementary Requirements for Control of Measuring and Test Equipment.*

- In lieu of the requirement in Section 3.2, which states "Out-of-calibration devices shall be tagged or segregated and not used until they have been recalibrated," OCRWM will implement the requirement as delineated in Subsection 12.2.3B.1. This methodology permits the continued use of M&TE that has passed its calibration due-date but does not permit the M&TE to be reissued until it has been recalibrated.

13.0 HANDLING, STORAGE, AND SHIPPING

13.1 GENERAL

This section establishes requirements for the handling, storage, cleaning, packaging, shipping, and preservation of items and consumables, in accordance with design and procurement requirements, to prevent damage or loss and to minimize deterioration.

13.2 REQUIREMENTS

13.2.1 Controls

A. Handling, storage, cleaning, packaging, shipping, and preservation of items shall be conducted in accordance with established work and inspection implementing documents, shipping instructions, or other specified documents.

B. If required for critical, sensitive, perishable, or high-value articles, specific implementing documents for handling, storage, cleaning, packaging, shipping, and preservation shall be prepared and used.

13.2.2 Special Equipment, Tools, and Environments

A. If required for particular items, special equipment (e.g., containers, shock absorbers, and accelerometers) and special protective environments (i.e., inert gas atmosphere and specific moisture content levels and temperature levels) shall be specified and provided.

B. If special equipment and environments are used, provisions shall be made for their verification.

C. Special handling tools and equipment shall be used and controlled, as necessary, to ensure safe and adequate handling.

D. Special handling tools and equipment shall be inspected and tested at specified time intervals and in accordance with implementing documents to verify that the tools and equipment are adequately maintained.

E. Operators of special handling and lifting equipment shall be experienced or trained to use the equipment.

13.2.3 Marking and Labeling

A. Measures shall be established for marking and labeling for the packaging, shipping, handling, and storage of items as necessary to adequately identify, maintain, and preserve the item.

B. Markings and labels shall indicate the presence of special environments or the need for special controls if necessary.

13.2.4 Commitment Document Positions

A. OCRWM commits to the following documents:

1. NQA-1a-1983, Basic Requirement 13, *Handling, Storage, and Shipping.*

2. NQA-1a-1983, Supplement 13S-1, *Supplementary Requirements for Handling, Storage, and Shipping.*

3. DOE O 414.1C, Section 4b (5) (c).

14.0 INSPECTION, TEST, AND OPERATING STATUS

14.1 GENERAL

This section establishes requirements to identify the inspection, test, and operating status of items throughout fabrication, construction, installation, and testing.

14.2 REQUIREMENTS

14.2.1 Identifying Items

A. Items that have satisfactorily passed required inspections and tests shall be identified.

B. The identification methods shall preclude the inadvertent installation, use, or operation of items that have not passed required inspections and tests.

14.2.2 Indicating Status

A. The status of required inspection and tests of items shall be indicated when necessary to preclude inadvertent bypassing of such inspections and tests.

B. The status of inspections and tests shall be identified either on the items or in documents traceable to the items.

C. Status shall be maintained through the use of legible and easily recognizable status indicators (e.g., tags, markings, labels, and stamps) or other means (e.g., travelers, inspection, or test records).

D. The authority for applying and removing status indicators shall be specified.

E. To prevent the inadvertent use or operation of an item that is out of service (e.g., a nonconforming, inoperative, or malfunctioning item), status indicators such as tags or markings shall be placed at all locations where operation of the item can be initiated (e.g., control panels, switches, breakers, valves, or systems).

14.2.3 Commitment Document Positions

A. OCRWM commits to the following documents:

1. NQA-1a-1983, Basic Requirement 14, *Inspection, Test, and Operating Status.*

2. DOE-O-414.1C, Section 4b (b).

15.0 NONCONFORMING MATERIALS, PARTS, OR COMPONENTS

15.1 GENERAL

A. This section establishes requirements for the control of items (including samples, boreholes, services, etc.) that do not conform to requirements in order to prevent inadvertent installation or use of the items.

B. Computer software nonconformances shall be controlled in accordance with Subsection I.2.5.

15.2 REQUIREMENTS

15.2.1 Documenting, Reporting, and Evaluating Nonconforming Items

A. Nonconformances shall be documented and reported to the appropriate levels of management responsible for the conditions. In addition, organizations affected by the nonconformance shall be notified in writing.

B. Nonconformances shall be tracked and trended in accordance with the requirements of Section 16.0.

C. Nonconformance documentation shall clearly identify and describe the characteristics that do not conform to specified criteria.

D. Nonconforming characteristics shall be reviewed, and recommended dispositions of nonconforming items shall be proposed and approved. The review shall include determining the need for corrective action according to the requirements of Section 16.0 and the need for reporting in accordance with 10 CFR 21 and 10 CFR 63.73.

E. Recommended dispositions shall be evaluated and approved by individuals who are independent of the work that produced the disposition.

F. Personnel performing evaluations to determine a disposition shall have demonstrated competence in the specific area being evaluated, have an adequate understanding of the requirements, and access to pertinent background information.

G. The responsibility and authority for reviewing, evaluating, and approving the disposition, and closing nonconformances shall be specified.

H. Further processing, delivery, installation, or use of a nonconforming item shall be controlled pending the evaluation and approval of the disposition.

I. Nonconformances shall be corrected or dispositioned before initiation of the preoperational test program on the item.

15.2.2 Identifying Nonconforming Items

A. Nonconforming items shall be identified by marking, tagging, or other methods that do not adversely affect their end use. The identification shall be legible and easily recognizable.

B. If the identification of a nonconforming item is not practical, then the container, package, or segregated storage area, as appropriate, shall be identified.

15.2.3 Segregating Nonconforming Items

A. Nonconforming items shall be segregated, when practical, by placing them in a clearly identified and designated hold area until properly dispositioned.

B. If segregation is impractical or impossible due to physical conditions, other precautions shall be employed to preclude inadvertent use.

15.2.4 Disposition of Nonconforming Items

A. The disposition of use-as-is, limited use (this disposition is limited to Supplement II nonconforming samples), reject, repair, or rework for nonconforming items shall be identified and documented.

B. The technical justification for the acceptability of a nonconforming item that has been dispositioned as repair, limited use or use-as-is shall be documented.

C. Items that do not meet original design requirements that are dispositioned as use-as-is or repair shall be subject to design control measures commensurate with those applied to the original design.

1. If changes to the specifying document are required to reflect the as-built condition, then the disposition shall require action to change the specifying document to reflect the accepted nonconformance.

2. Any document or QA record change required by the disposition of the nonconformance shall be identified in the nonconformance documentation, and when each document or record is changed, the justification for the change shall identify the nonconformance documentation.

D. The disposition of an item to be reworked or repaired shall contain a requirement to reexamine (e.g., by inspection, test, or nondestructive examination) the item to verify acceptability. Repaired or reworked items shall be reexamined using the original process and acceptance criteria unless the nonconforming item disposition has established alternate acceptance criteria.

E. Replacement items shall be inspected and tested in accordance with the original inspection and test requirements or acceptable alternatives.

15.2.5 Commitment Document Positions

A. OCRWM commits to the following documents:

1. NQA-1a-1983, Basic Requirement 15, *Control of Nonconforming Items.*

2. DOE O 414.1C, Section 4b (3).

B. OCRWM commits to the following document with the associated modification:

1. NQA-1a-1983, Supplement 15S-1, *Supplementary Requirements for the Control of Nonconforming Items.*

   - Subsection 4.4 of this standard provides for four types of disposition. OCRWM will use an additional disposition, limited use. This disposition will be only be used for samples governed by QARD Supplement II.

16.0 CORRECTIVE ACTION

16.1 GENERAL

This section establishes requirements to ensure conditions adverse to quality are promptly identified and corrected as soon as practical.

16.2 REQUIREMENTS

16.2.1 Identifying Conditions Adverse to Quality

A. A condition adverse to quality shall be identified and documented when a failure, malfunction, deficiency, deviation, defective item, or nonconformance is identified.

16.2.2 Classification of Conditions Adverse to Quality

A. Conditions adverse to quality shall be classified in regard to their significance, and corrective actions shall be taken accordingly.

B. Categories of classification shall be established to distinguish between:

1. Conditions adverse to quality.

2. Significant conditions adverse to quality.

C. Conditions adverse to quality shall be evaluated for reportability in accordance with 10 CFR 21 and 10 CFR 63.73.

16.2.3 Reporting Conditions Adverse to Quality

A. Conditions adverse to quality shall be documented, tracked, and reported to the appropriate levels of management responsible for the conditions.

B. Responsible management shall complete remedial action as soon as practical.

16.2.4 Significant Conditions Adverse to Quality

A. Criteria for determining a significant condition adverse to quality shall be established and documented.

B. Significant conditions adverse to quality shall be documented and reported to management responsible for the condition and their upper management in a prompt manner.

C. Significant conditions adverse to quality shall be evaluated for a stop work condition by the QA organization to determine whether stopping work is warranted.

1. QA management shall issue stop work orders to responsible management after a stop work condition has been identified.

2. QA management shall take appropriate action to lift and close (in part or total) the stop work issued by the QA organization based on the resolution of the related significant condition adverse to quality.

D. Responsible management shall perform investigative action to determine the extent and impact of the condition, and document the results.

E. Responsible management shall determine, document, and complete remedial action.

F. Responsible management shall determine and document the root cause of the problem and take corrective action to prevent recurrence as soon as practical.

16.2.5 Follow-up

Processes shall be established to verify the implementation of corrective actions associated with significant conditions adverse to quality.

16.2.6 Quality Trending

A. Criteria shall be established for determining adverse quality trends.

B. Reports of nonconformances and conditions adverse to quality shall be evaluated to identify adverse quality trends.

C. Trend evaluation shall be performed in a manner and at a frequency that provides for prompt identification of adverse quality trends and assists in identifying root cause.

D. Trend evaluations shall be promptly distributed to OCRWM and OCRWM contractor management for review and appropriate corrective action.

16.2.7 Commitment Document Positions

A. OCRWM commits to the following documents:

1. NQA-1a-1983, Basic Requirement 16, *Corrective Action.*

2. DOE O 414.1C, Section 4b (3).

17.0 QUALITY ASSURANCE RECORDS

17.1 GENERAL

A. This section establishes requirements to ensure that QA records that furnish documentary evidence of quality are specified, prepared, and maintained. The records system shall be established by the organization responsible at the earliest practicable time consistent with the schedule for accomplishing activities affecting quality.

B. The requirements of this section that are applicable to suppliers are also applicable to OCRWM contractors unless otherwise noted.

17.2 REQUIREMENTS

17.2.1 Quality Assurance Records

A. Specific QA record types include, but are not limited to:

1. Scientific, engineering, and operational data and logs; laboratory and field notebooks and logbooks; and data reduction documents.

2. Results of reviews, inspections, tests, audits, and material analysis.

3. Monitoring of work performance.

4. Maintenance and modification procedures and related inspection results.

5. Reportable occurrences.

6. QA program changes that reduce commitments.

7. Computer software supporting a safety or waste isolation function.

8. Qualification of personnel and equipment.

9. Qualification of special process procedures.

10. Documentation such as design records, drawings, specifications, procurement documents, calibration procedures and reports, design review reports, peer review reports, nonconformance reports, corrective action reports, and as-built drawings.

11. Documents that provide evidence of the quality of items and activities associated with the characterization of SNF and conditioning through OCRWM acceptance of the SNF.

12. Documents that provide evidence of the quality of HLW waste forms (i.e., waste form development through qualification, waste form production, and waste form acceptance by OCRWM).

13. Other records required by preclosure and postclosure operating conditions.

14. Construction records required by 10 CFR 63.72, *Construction records*.

15. Records required by 10 CFR 71.91, *Records*, and 10 CFR 71.135, *Quality assurance records.*

16. Records required by 10 CFR 72, Subpart D, *Records, Reports, Inspections, and Enforcement*, and 10 CFR 72.174, *Quality assurance records.*

B. Additional guidance relative to the types of documents considered to be QA records is provided in ANSI/ASME NQA-1-1983 and Appendix 17A-1, NRC Regulatory Guide 1.28, Revision 3.

17.2.2 Creating Valid Quality Assurance Records

A. Implementing documents shall:

1. Identify those documents that will become QA records.

2. Identify the organization responsible for submitting the QA records to the records management system.

B. Individuals creating QA records shall ensure that the QA records are legible, accurate, complete, appropriate to the work accomplished, and identifiable to the item(s) or activity(s) to which they apply.

C. Individuals handling QA records shall protect them from damage or loss until the records are submitted to the records management system.

D. Documents shall be considered valid records when stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated. This authentication may take the form of a statement by the reporting individual or organization. If the nature of the record (e.g., magnetic or optical media) precludes stamping, initialing, or signing, then other means of identifying the record as complete by authorized personnel are permitted.

E. Handwritten signatures shall not be required if the document is clearly identified as a statement of the reporting individual or organization.

F. QA records may be originals or copies.

17.2.3 Submission of Quality Assurance Records

QA records shall be submitted to the records management system for receipt, processing, and storage.

17.2.4 Receiving and Indexing Quality Assurance Records

A receipt control system shall be established for QA records according to the following requirements:

A. An individual or organization shall be assigned the responsibility for receiving QA records. The designee shall be responsible for organizing and implementing a system of receipt control of records for permanent and temporary storage.

B. A method shall be established for verifying that the QA records received are in agreement with the transmittal document.

C. QA records shall be protected from damage, deterioration, or loss when received.

D. Legibility and completeness of QA records shall be verified.

E. The receipt control system shall permit a current and accurate assessment of the status of QA records during processing.

F. QA records shall be indexed. The indexing system shall include, as a minimum:

1. The location of the QA records within the records management system.

2. Identification of the item or related activity to which the QA records pertain.

3. The record retention times.

17.2.5 Correcting Information in Quality Assurance Records

A. Corrections to QA records, including documents that will become QA records, shall include the initials or signature of the person authorized to make the correction and the date the correction was made.

B. Corrections to QA records shall be reviewed and approved by the originating organization. If the organization responsible for generating the record is no longer available, a new responsible organization shall be identified and documented.

17.2.6 Storing and Preserving Quality Assurance Records

A. QA records shall be stored and preserved in predetermined storage facilities that meet the requirements of applicable standards, codes, and regulatory agencies in accordance with an approved implementing document that provides:

1. A description of the storage facility.

2. A description of the filing system to be used.

3. A method for verifying that the QA records received are in agreement with the transmittal document and that the records are legible.

4. A description of controls governing QA record access, retrieval, and removal.

5. A method for filing supplemental information.

6. A method for disposition of superseded QA records.

B. Storage methods shall be developed to preclude deterioration of QA records in accordance with the following:

1. The storage area shall be constructed and maintained in a manner which minimizes the risk of damage or destruction from disasters such as wind, floods, or fires; environmental conditions such as high and low temperatures and humidity; and infestations of insects, molds, or rodents.

2. Approved filing methods shall require QA records to be firmly attached in binders or placed in folders or envelopes for storage in steel file cabinets or on shelving in containers appropriate for the QA record medium being stored.

3. The storage arrangement shall provide adequate protection of special processed QA records (e.g., radiographs, photographs, negatives, microform, and electronic and magnetic media) to preclude damage from moisture, temperature, excessive light, electromagnetic fields, or stacking, consistent with the type of QA record being stored. The guidance provided in NRC Regulatory Issue Summary 2000-18, *Guidance on Managing Quality Assurance Records in Electronic Media*, shall be complied with in the development of procedures governing the management of electronic media records.

4. The storage area shall be protected from unauthorized entry, larceny, and vandalism.

17.2.7 Retrieval of Quality Assurance Records

A. The records management system shall provide for retrieval of QA records.

B. Access to storage facilities shall be controlled. A list shall be maintained designating personnel who are permitted access to the QA records.

17.2.8 Retention of Quality Assurance Records

A. Lifetime QA Records

Lifetime QA records shall be retained and maintained until the license is amended for permanent closure. Lifetime QA records are those that meet one or more of the following criteria:

1. Those that would be of significant value in demonstrating capability for safe operation;

2. Those that would be of significant value in maintaining, reworking, repairing, replacing, or modifying an item;

3. Those that would be of significant value in determining the cause of an accident or malfunction of an item;

4. Those which provide required baseline data for in-service inspection.

B. Nonpermanent QA Records

Nonpermanent QA records are those required to show evidence that an activity was performed in accordance with the applicable requirements but need not meet the criteria for lifetime QA records.

1. Nonpermanent QA records shall be retained until the issuance of a license to receive and possess SNF/HLW. At a minimum, nonpermanent QA records shall be retained for 10 years or the life of the item if less than 10 years.

2. For programmatic nonpermanent QA records, the retention period shall be considered to begin on completion of the activity.

3. For product nonpermanent QA records, the retention period shall be considered to commence upon completion of delivery.

C. Retention of supplier QA records shall be in accordance with Subsection 17.2.8A and Subsection 17.2.8B. Records shall be made available to the OCRWM or its designee upon request.

17.2.9 Turnover of Quality Assurance Records

A. Suppliers shall submit to the OCRWM those QA records being temporarily stored by supplier that are subject to records turnover requirements. The timing of the submittal shall be as records packages become complete or, as items are released for shipment, or as prescribed by the purchaser.

B. The records management organization shall inventory the submittal, acknowledge receipt, and process the QA records.

C. The responsible line organizations shall identify those QA records in temporary storage to be submitted for long-term storage to the records management system in accordance with Subsection 17.2.10, or Subsection 17.2.11.

17.2.10 Long-Term Single Storage Facility

A. Single storage facilities for the storage of QA records shall meet the following design and construction requirements:

1. Reinforced concrete, concrete block, masonry, or equal construction.

2. Drainage control for the floor and roof. If a floor drain is provided, a check valve or equal shall be included.

3. Minimum 2-hour fire-rated structure, doors, frames, and hardware.

4. Sealant applied over walls as a moisture or condensation barrier.

5. Surface sealant on the floor providing a hard wear surface to minimize concrete dusting.

6. Foundation sealant and provisions for drainage.

7. Forced air circulation with a filter system.

8. A fire protection system.

9. Penetrations limited to fire protection, communication, lighting, and temperature and humidity controls. Seal or damper penetrations to meet 2-hour fire protection rating.

B. If the facility is located within a building or structure, the environment and construction of that building can provide a portion or all of the criteria in Paragraph 17.2.10A.

C. Construction details shall be reviewed for the adequacy of record protection by a person competent in the technical field of fire protection and fire extinguishing.

17.2.11 Dual Storage Facilities

If dual storage is used in lieu of implementing Subsection 17.2.10, the following requirements apply:

A. Dual storage facilities for the storage of QA records shall provide facilities for copies of each record at locations sufficiently remote from each other to eliminate the chance of exposure to a simultaneous hazard.

B. Dual storage facilities shall not be required to meet the design and construction requirements specific for a long-term single storage facility, but shall meet the other requirements of this QARD section.

17.2.12 Temporary Storage Facility

Temporary storage shall provide for the storage of QA records during processing, review, or use until turnover to the OCRWM for disposition according to the requirements specified in Subsection 17.2.14B.1.

17.2.13 Replacement of Quality Assurance Records

Organizations originating QA records shall develop implementing documents that identify means for replacement, restoration, or substitution of lost or damaged QA records.

17.2.14 Commitment Document Positions

A. OCRWM commits to the following documents:

1. Regulatory Guide 1.28, Revision 3 (8/85), Regulatory Position C.2.

2. NQA-1a-1983, Basic Requirement 17, *Quality Assurance Records.*

3. Regulatory Issue Summary 2000-18.

4. DOE O 414.1C, Section 4b (4).

B. OCRWM commits to the following document with the associated modifications:

1. NQA-1a-1983, Supplement 17S-1, *Supplementary Requirements for Quality Assurance Records.*

a. This supplement addresses the requirements and recommendations for the storage of records that are determined to be QA records, but it does not include a provision for the temporary storage of QA records. The following requirements shall apply to the temporary storage of QA records:

- QA records shall be temporarily stored in a container or facility with a 1-hour fire rating, or dual storage shall be provided.

- Single storage, containers or facilities shall bear an Underwriters' Laboratories label (or equivalent) certifying 1-hour fire protection or be certified by a person competent in the technical field of fire protection.

- The period of time allowed for records to be in temporary storage will be specified in appropriate procedures.

b. Subsection 4.4.2, *Alternate Single Facility*—OCRWM will not be using an alternate facility.

c. Section 5, *Retrieval*—The OCRWM records retrieval system is not configured in such a manner as to provide retrieval times based on the type of record. The retrieval times for all record types are the same regardless of record type.

d. Section 6, *Disposition*- Specifies certain conditions and events prior to which supplier's nonpermanent records shall not be disposed of. In addition to these requirements, OCRWM shall implement the requirements specified in QARD, Subsection 17.2.8B.

18.0 AUDITS

18.1 GENERAL

A. This section establishes requirements for performing a comprehensive system of planned and periodic internal and external QA audits to verify compliance with all aspects of the OCRWM QA program, and to determine the effectiveness of the OCRWM QA program.

B. The requirements of this section that are applicable to suppliers are also applicable to OCRWM contractors unless otherwise noted.

18.2 REQUIREMENTS

18.2.1 Audit Scheduling

Audits shall be performed in areas where the requirements of the QARD or supplier QA program description document are applicable. The following areas shall also be considered when scheduling audits:

A. The determination of site features that effect site suitability (e.g., site characterization, performance confirmation, core sampling, site and foundation preparation, and methodology).

B. The preparation, review, approval, and control of early procurements.

C. Indoctrination and training programs.

D. Interface control between the OCRWM and suppliers.

E. Corrective action, calibration, and nonconformance control systems.

F. Safety analysis report commitments.

G. Development and control of computer software supporting a safety or waste isolation function.

H. The purchase of ASME Code items.

I. Audits of ASME Code suppliers.

18.2.2 Scheduling Internal Audits

A. Internal audits (i.e., audits of OCRWM and principal contractors) shall be coordinated with the responsible line manager and scheduled in a manner to provide coverage, consistency, and coordination with ongoing work.

B. Internal audits shall be scheduled at a frequency commensurate with the status and importance of the work.

C. Internal audits shall be scheduled to begin as early in the life of the work as practical and shall be scheduled to continue at intervals consistent with the schedule for accomplishing the work.

D. Regularly scheduled internal audits shall be supplemented by additional audits of specific subjects, when necessary, to provide an adequate assessment of compliance and effectiveness.

E. Internal audits of applicable QARD elements to verify OCRWM QA program compliance and effectiveness shall be performed at intervals not to exceed 12 months or at least once during the life of the work, whichever is shorter.

F. Performance-based internal audits shall be performed on selected work to determine OCRWM QA program effectiveness.

18.2.3 Scheduling External Audits

A. External audits (audits of suppliers) shall be coordinated with responsible supplier management and scheduled in a manner to provide coverage, consistency, and coordination with ongoing work.

B. External audits shall be scheduled:

1. To begin as early in the life of the work as practical.

2. To continue at intervals consistent with the schedule for accomplishing the work.

3. At a frequency commensurate with the status and importance of the work.

C. External audits for compliance and effectiveness shall be performed triennially or at least once during the life of the work, whichever is shorter. Regularly scheduled external audits shall be supplemented by additional audits of specific subjects when necessary to provide an adequate assessment of compliance or effectiveness (performance based).

1. The audit period (triennial or annual) shall begin when the audit is performed.

2. Annual external audits shall be performed by the purchaser on suppliers or other external organizations when the supplier or external organization does not maintain a purchaser accepted audit program.

3. The initial audit shall be performed when the supplier has completed sufficient work to demonstrate that its organization is implementing a QA program that has the required scope for purchases placed during the audit period (triennial or annual).

4. An audit of the modified requirements shall be performed when a major change in the contract scope, work methodology, or organization occurs. This audit shall start a new audit period (triennial or annual).

D. Regularly scheduled audits shall be supplemented by additional audits of specific subjects when necessary to provide adequate coverage.

E. External audits may not be required for procured items that are relatively simple and standard in design, manufacturing, and testing, and adaptable to standard or automated inspections or tests of the end item to verify quality characteristics after delivery. The rationale for not performing audits for these items shall be documented.

F. Pre-award surveys, if applicable, may serve as the first triennial audit, provided:

1. The supplier is implementing the same QA program for other contracts that are proposed for the purchaser's contract.

2. The pre-award survey satisfies the same audit elements and criteria as those used in the performance of a triennial audit.

G. OCRWM purchasers include the OCRWM and OCRWM contractors. If more than one OCRWM purchaser buys from a single supplier, the OCRWM purchaser may either perform or arrange for an audit of the supplier on its own behalf and other OCRWM purchasers to reduce the number of external audits of the supplier.

1. The scope of this audit shall satisfy the needs of all OCRWM purchasers having a need to use the supplier.

2. The audit report shall be distributed to OCRWM purchasers for whom the audit was conducted.

3. Each OCRWM purchaser relying on the results of the audit shall be responsible for the adequacy of the audit.

H. Subsection 7.2.1.2D provides an alternative to performing an audit or a supplier survey for calibration services procured from certain accredited suppliers of those services.

18.2.4 Audit Schedule

The audit schedule(s) shall be developed annually, reviewed periodically, and revised as necessary to ensure that coverage is maintained current.

18.2.5 Audit Planning

A. The auditing organization shall develop and document an audit plan for each scheduled audit. This plan shall identify the audit scope, requirements for performing the audit, audit personnel, work to be audited, organizations to be notified, applicable documents, audit schedule, and implementing documents or checklists to be used. Audits shall include technical evaluations of the applicable procedures, instructions, activities, and items.

B. The scope of each internal audit shall be based on evaluation of implementing documents, activities, and items to be audited; results of previous audits; nature and frequency of previously identified deficiencies; and impact of significant changes in personnel, organization, or the QA program.

18.2.6 Audit Team Independence

The auditing organization shall select and assign auditors who are independent of any direct responsibility for performance of the activity being audited. Audit personnel shall have sufficient authority and organizational freedom to make the audit process meaningful and effective.

18.2.7 Audit Team Selection

A. An audit team shall be identified before beginning each audit. The audit team shall include representatives from the QA organization, and when appropriate, applicable technical specialists.

B. A lead auditor shall be appointed to supervise the team, organize and direct the audit, and coordinate the preparation and issuance of the audit report.

C. Lead auditors and auditors shall be qualified in accordance with the requirements of this section.

D. Technical specialists may be used by the auditing organization to assist in assessing the adequacy of technical processes. Technical specialists, when used, shall be indoctrinated and trained in accordance with Subsection 2.2.11C.

E. In the case of internal audits, personnel having direct responsibility for performing the work being audited shall not be involved in the selection of the audit team.

F. The lead auditor shall, before starting the audit, ensure that the assigned personnel collectively have experience or training commensurate with the scope, complexity, or special nature of the work to be audited.

18.2.8 Performing Audits

A. The audit team leader shall ensure that the audit team is prepared before starting the audit.

B. Audits shall be performed in accordance with written procedures or checklists.

C. Elements that have been selected for audit shall be evaluated against specified requirements.

D. Objective evidence shall be examined to the depth necessary to determine if these elements are being implemented effectively.

E. Audit results shall be documented by auditing personnel and reported to, and reviewed by, management having responsibility for the area audited. Conditions requiring prompt corrective action shall be reported immediately to management of the audited organization.

F. Identified conditions adverse to quality shall be documented and corrected in accordance with Section 16.0.

18.2.9 Reporting Audit Results

The audit report shall be prepared and signed by the audit team leader and issued to management of the audited organization. The audit report shall include the following information:

A. Description of the audit scope.

B. Identification of the auditors.

C. Identification of persons contacted during the audit.

D. Summary of the audit results including a statement on the effectiveness of the QA program elements that were audited.

E. A description of each reported condition adverse to quality, including those conditions identified as audit findings in sufficient detail to enable corrective action to be taken by the audited organization according to the requirements of Section 16.0.

18.2.10 Responding to Audits

A. Management of the internal audited organization or activity, including principal contractors, shall investigate conditions adverse to quality and determine and schedule corrective action in accordance with Section 16.0.

B. Management of the external audited organization or activity (other than principal contractors) shall investigate conditions adverse to quality, determine and schedule corrective action in accordance with Section 16.0, and notify the auditing organization in writing of the actions taken or planned.

C. For audit findings, management of the audited organization or activity shall also identify measures to prevent recurrence.

18.2.11 Evaluating Audit Finding Responses

The adequacy of corrective actions for audit finding responses shall be evaluated and accepted by the auditing organization prior to closure.

18.2.12 Follow-up Action

Follow-up action shall be taken by the auditing organization to verify that audit finding corrective action is accomplished in a timely manner.

18.2.13 Audit Team Qualification and Certification

Personnel performing audits, including auditors, technical specialists, and lead auditors, shall be qualified and certified in accordance with Subsection 2.2.11C.

18.2.14 Commitment Document Positions

A. OCRWM commits to the following documents:

1. NQA-1a-1983, Basic Requirement 18, *Audits.*

2. NQA-1a-1983, Supplement 18S-1, *Supplement Requirements for Audits.*

3. DOE O 414.1C, Section 4b (10).

B. OCRWM commits to the following document with the associated modification:

1. Regulatory Guide 1.28, Revision 3 (8/85), Regulatory Positions C.3, C.3.1, C.3.2, C.3.2.1, and C.3.2.3.

- When purchasing commercial calibration services from calibration laboratories accredited by a nationally-recognized accrediting body, the accreditation process and accrediting body may be credited with

carrying out a portion of the purchaser's duties of verifying acceptability and effective implementation of the calibration service supplier's QA program. In lieu of the requirements specified in Regulatory Position C.3.2.1 of this guide, OCRWM will implement the requirements of QARD Subsection 7.2.12 when purchasing commercial calibration from accredited calibration laboratories.

SUPPLEMENT I
SOFTWARE

I.1 GENERAL

A. This supplement establishes requirements for the acquisition, development, modification, control, and use of software.

B. Requirements of this supplement shall be implemented through policies, procedures, plans, specifications, work practices, etc, that provide the framework for software engineering activities. Software engineering elements must define the baseline documents that are to be maintained as records. The scope of software engineering activities includes the following elements, as appropriate:

1. Software acquisition method(s) for controlling the acquisition process for software and software services.

2. Software engineering method(s) used to manage the software life cycle activities.

3. Application of standards, conventions, and other work practices that support the software life cycle.

4. Controls for support software used to develop, operate, and maintain computer programs.

C. Embedded software that is integral to the operations, maintenance, or calibration of M&TE that is verified or validated in conjunction with the hardware as a unit and has not been developed or modified by the user organization is controlled by Section 12.0, and is outside the scope of this supplement.

D. The following types of commercial off-the-shelf (COTS) software are not required to be qualified using this supplement: word processors, spreadsheets, database managers, e-mail, and other types of automated office support systems. Applications developed using these types of COTS software shall meet the requirements of this supplement. Data acquisition and control software that is integral to the operations, maintenance, or calibration of M&TE and is verified or validated in conjunction with the M&TE or hardware as a unit is controlled by Section 12.0, and is exempt from the requirements of this supplement.

E. COTS support software, such as software tools or system software, shall, at a minimum, be evaluated, reviewed, tested, accepted for use, and placed under configuration control as part of the supported software development. Changes to the software tool and system software shall be evaluated for impact on the software product to determine the level of reviews and retesting that will be required.

F. The requirements of this supplement that are applicable to suppliers are also applicable to OCRWM contractors unless otherwise noted.

I.2 REQUIREMENTS

I.2.1 General Software Requirements

A. Software acquisition, development, modification, and maintenance shall proceed in a planned, traceable, and orderly manner utilizing a defined software life cycle methodology.

1. A defined software life cycle methodology shall address the following phases: requirements, design, implementation, testing, installation and checkout, operations and maintenance, and retirement. The number of phases and relative emphasis placed on each phase of the software life cycle depend on the nature and complexity of the software. The number of life cycle phases may be combined for documentation purposes; however, the combining of phases does not eliminate the requirement for addressing each life cycle element of the life cycle phase. Software life cycle activities may be performed in an iterative or sequential manner.

2. Acquired software or software previously developed not using this supplement shall be either:

   a. Acquired through a procurement activity in accordance with Subsection I.2.6, or

   b. Be controlled and qualified in accordance with Subsection I.2.4.

   In either case, software planning in accordance with Subsection I.2.2, and a defined software life cycle methodology, excluding a design document and code development, shall be applied.

3. Software life cycles shall contain control points that, when reached, shall ensure specified software is documented, reviewed, and baselined.

B. Software verification and validation activities shall be planned, documented, and performed for software, software changes, or system configurations that are determined to impact the software. The validation test plans, test cases, and test results shall be documented, reviewed, and approved prior to use of the software.

1. Software verification shall be performed at the end of the requirements, design, implementation, and testing life cycle phases to ensure that the products of a given life cycle phase are traceable and fulfill the requirements of the previous phase and/or previous phases.

2. Software verification shall evaluate the technical adequacy of the design approach and ensure internal completeness, consistency, clarity, and correctness of the software, and shall verify that software is traceable to the software design requirements.

    a. Tests and test results from reviews and verifications shall be included in the acceptance test documentation.

    b. Tests conducted as reviews or verifications do not substitute for performing comprehensive, end-of-development acceptance tests.

3. Software verification shall include review of the test results.

4. Software verification shall be completed prior to approval of the computer program for use.

5. Verification reviews shall identify the reviewer(s) and each reviewer's specific responsibilities during the review.

6. Documentation of all review comments and their disposition shall be retained as part of the records package.

7. Software verification and validation activities shall be performed by individuals not associated with the development of the software. In those instances where this level of independence may not be achieved, an individual associated with the development of the software may perform these activities with management approval and documented justification.

I.2.2 Software Planning

A. A plan addressing software QA shall be in existence for each new software project at the start of the software life cycle.

B. The plan for software QA shall identify:

1. A description of the overall nature and purpose of the software.

2. The software products to which it applies.

3. The organizations responsible for performing the work and achieving software quality and their tasks and responsibilities.

4. Required documentation.

5. Standards, conventions, techniques, or methodologies that shall guide the software activity.

6. Required software reviews.

7. Methods for error reporting and corrective action.

I.2.3 Software Life Cycle Requirements

A. Requirement Phase

1. Software requirements that address functionality, performance, design constraints, attributes, and external interfaces shall be specified, documented, and reviewed.

   a. Functionality–The functions the software is to perform.

   b. Performance–The time-related issues of software operation such as speed, recovery time, and response time.

   c. Design constraints imposed on implementation phase activities–Elements that will restrict design options.

   d. Attributes–Non-time-related issues of software operation such as portability, acceptance criteria, access control, and maintainability.

   e. External interfaces–Interactions with people, hardware, and other software.

2. A software requirement shall only be specified if its achievement can and will be verified and validated.

3. Software requirements shall be traceable throughout the remaining stages of the software life cycle (i.e., design, installation, and validation test cases, and user manual). Traceability shall be documented.

4. Software requirements shall provide enough detail to either design the software or make an acquisition decision.

B. Design Phase

1. The software design shall be developed, documented, and reviewed based on the requirements depicted in the requirements document.

2. The software design shall consider the computer software operating environment.

3. Measures to mitigate the consequences of potential problems shall be an integral part of the design. These potential problems include external and

internal abnormal conditions and events that can affect the computer program.

4. The software design documentation shall specify:

   a. A description of the major components of the software design as they relate to the software requirements.

   b. A technical description of the software with respect to the theoretical basis, mathematical model, control flow, data flow, control logic, and data structure.

   c. A description of the allowable or defined ranges for inputs and outputs.

   d. The design, described in a manner that can be translated into code.

   e. The generation of design-based test cases.

   f. The generation of test plans/cases, based on the requirements and design, shall provide for acceptance criteria and verification of results.

   g. For those computer programs used in design activities, the test plans shall provide for ensuring that the software produces correct results. For those computer programs used for operational control, computer test plans shall provide for demonstrating required performance over the range of operation of the controlled function or process.

C. Implementation Phase

1. The design shall be translated into source code and resulting executables necessary to perform the functions required.

2. The source code and resulting executables shall adhere to specified coding standards, conventions, and design specifications.

3. User information shall be developed, documented, and reviewed in accordance with the design to delineate how to use the software, including the following, as applicable:

   a. Instructions that contain an introduction (e.g., purpose, and scope), description of the user's interaction with the software, and a description of required training necessary to use the software.

   b. Input and output specifications.

   c. Data files, input and output data, defaults, and file formats.

d. A description of the allowable and tolerable ranges for inputs and outputs.

e. Anticipated errors and how the user can respond.

f. The hardware and software environments.

g. Available sample problems.

h. Installation procedures.

D. Testing Phase

1. Configuration items shall be under configuration change control prior to acceptance testing.

2. Software validation activities shall be planned, performed, documented, and verified at the end of the implementation phase to ensure that the software installs properly and satisfies the requirements for its intended use.

3. Testing to an approved plan or process and on a different computer with the same operating environment in which the software will be used shall be the primary method of software validation to ensure adherence to the requirements and to ensure the software produces correct results for the test cases.

4. Testing shall demonstrate, as appropriate, that the computer program:

a. Properly handles abnormal conditions and events as well as failures.

b. Does not perform adverse unintended functions. Observations of unexpected or unintended results shall be documented and dispositioned prior to test result approval.

c. Does not unexpectedly degrade the system either by itself or in combination with other functions or configuration items.

5. To evaluate technical adequacy, the software test case results may be compared to results from alternative methods, such as:

a. Analysis without computer assistance (hand calculations).

b. Other validated computer programs.

c. Experiments and tests.

d. Standard problems with known solutions.

e. Comparisons to confirmed published data correlations.

6. Software validation documentation shall describe the task and criteria for accomplishing the validation of the software at the end of the development cycle. The documentation shall:

   a. Specify the hardware and software configurations.

   b. Be organized in a manner that allows traceability to both software requirements and design.

   c. Contain the results of the execution of the validation activity.

   d. Include the results of reviews and tests along with a summary of the status of the software (i.e., indication of incomplete design performance and application requirements).

7. Failure to successfully execute the test cases shall be documented and reviewed to determine if modifications to the requirements, design, implementation, or test plans and cases are required.

8. Software validation of modifications to released software shall be subjected to selective testing (i.e., regression) to detect unintended adverse effects introduced during the modification of the software, to verify that the modifications have not caused unintended adverse affects, and to verify that a modified software still meets specified requirements.

E. Installation and Checkout Phase

1. Software installation and checkout activities shall be performed and documented when the software is installed on a computer or when there are changes in the operating system to ensure that the software installs properly and satisfies the requirements for its intended use.

2. The software validation activities for the installation and checkout shall consist of:

   a. The execution of tests for installation.

   b. The documentation that the software was successfully installed and ready for operational use.

F. Operations and Maintenance Phase

1. Upon acceptable validation of the software, in accordance with Paragraph I.2.3.D, Testing Phase, the software shall be baselined and placed

under Configuration Management controls in accordance with Subsection I.2.4.

2. After the software is approved for use and installed in the operating environment, the use of the software shall be controlled, in accordance with Subsection I.2.8, within approved procedures and instructions.

3. Continuing software maintenance activities consist of:

   a. Removal of latent errors (corrective maintenance).

   b. Responding to new or revised requirements (perfective maintenance).

   c. Adapting the software to changes in the operating environment (adaptive maintenance).

4. Software modifications shall be approved, documented, verified and validated, and controlled.

5. In-use tests shall be developed, performed, documented, and verified to provide confirmation of acceptable performance of software that is performing continuous data acquisition or process control functions. Periodic manual or automatic self-check in-use tests shall be defined and performed for that software where computer program errors, data errors, computer hardware failures, or instrument drift can affect the required performance.

G. Retirement Phase

During the retirement phase, the support for a software product is terminated and continued routine use of the software shall be prevented.

I.2.4 Software Configuration Management

A. A software configuration management (SCM) process shall be established to include configuration identification, configuration change control, and status accounting. Software shall be placed under configuration management control as each baseline element is approved.

B. Software shall not be used in activities identified under Subsection 2.2.2 unless it has been qualified and baselined. Software used in activities affecting quality is limited to copies obtained from SCM.

C. Support software (i.e., systems software and software tools) is not qualified or baselined. However, such software shall be placed under configuration management control (including change control) by SCM (see Subsection I.1.D).

D. Configuration items to be controlled shall include the following, at a minimum, and as appropriate:

1. Documentation (e.g., plans requirements, designs, user manuals, test reports, user information).

2. Computer program(s) e.g., source, object, backup files, media).

3. Support software.

E. Configuration identification shall include:

1. A definition of the baseline elements of each software baseline.

2. A unique identifier of each software item, including version or revision, to be placed under SCM.

3. Assignment of unique identifiers that relate baseline documents to their associated software items. Cross-references between baseline documents and associated software shall be maintained.

F. Configuration change control shall include:

1. A release and control process for baseline elements.

2. Changes to baseline elements. These changes shall be formally controlled and documented. This documentation shall contain a description of the change, the rationale for the change, and the identification of affected baseline elements.

3. A formal evaluation of the baseline element or change to the baseline element and approval by the organization responsible for approving the baseline element.

4. The transmission of information concerning approved changes to all organizations affected by the changes.

5. Software verifications performed for the changes, as necessary, to ensure the changes are appropriately reflected in software documentation and to ensure that document traceability is maintained.

6. Software validation performed as necessary for the change.

G. Configuration status accounting shall include:

1. A listing of the approved baseline elements and unique identifiers.

2. The status of proposed, in-process, or approved changes to the baseline elements.

3. A history of changes to the software items, including descriptions of the changes made between versions of software items.

I.2.5 Problem Identification, Reporting and Resolution

A. A software problem reporting and resolution system shall be implemented for software errors and failures to ensure problems are promptly reported to impacted organizations and to ensure formal processing of problem resolutions.

B. The problem reporting and resolution system shall be integrated with the SCM process.

C. Software problem reporting and resolution systems shall provide methods to ensure that:

1. Problems are identified, evaluated, documented, and, if required, corrected.

2. Description of the evaluation process for determining if the problem is an error or other type of problem (i.e., user mistake) is provided, and the responsibilities for disposition of the problem reports, including notification to the originator of the results of the evaluation, are defined. .

3 Problems are assessed for impact, which includes:

a. How the error relates to appropriate software engineering elements.

b. Impact on past and present use of the software by an organization.

c. How the corrective action impacts previous development activities.

4. Corrections and changes shall be controlled in accordance with applicable configuration change control requirements.

5. Notification of the error, its impacts, and how to avoid the error, pending implementation of corrective actions, are provided to the user organizations.

D. If a problem that constitutes a condition adverse to quality is identified in software, the condition adverse to quality shall be documented and controlled in accordance with Section 16.0.

I.2.6 Software Procurement

A. Individuals or organizations developing and supplying software under contract shall be required to have policies and procedures that meet the applicable requirements of this supplement. Software shall be procured as specified in Sections 4.0 and 7.0.

1. Documentation as required by this supplement shall be delivered or made available by the supplier to the purchaser.

2. Upon receipt of the software, the purchaser shall assume responsibility of the applicable requirements as specified in this supplement.

3. Software errors and failures shall be reported between the supplier and purchaser in accordance with Subsection I.2.5.

B. For procured software services, the organization providing the services shall have plan(s) for software QA, in accordance with Paragraph I.2.2.A, that meets the requirements of Subsection I.2.7. The purchaser organization shall determine the adequacy of this plan.

I.2.7 Otherwise Acquired Software

Software that has not been previously approved under a program consistent with this supplement for use in its intended application (e.g., freeware, shareware, procured COTS, or otherwise acquired software), other than software described in Paragraphs I.1C and I.1D, shall be qualified in accordance with the requirements of this supplement. The software shall be identified and controlled in accordance with Subsection I.2.4 prior to qualification.

I.2.8 Control of the Use of Software

A. User organizations control and document the use of issued software items such that comparable results can be obtained, with differences explained, through independent replication of the process.

B. Use of software shall be independently reviewed and approved to ensure that the software selected is suitable to the problem being solved.

C. If the intended use of the software item will require the use of inputs outside the ranges verified during validation testing, the appropriate baseline elements shall be reverified and revalidated for the expected range of inputs prior to continuing use.

D. Documentation for the receipt of software obtained from SCM in accordance with Subsection I.2.4 shall be provided and maintained for software in operation or use.

E. Controls shall be established to permit authorized access and prevent unauthorized access to operating environment.

I.2.9 Commitment Document Positions

A. OCRWM commits to the following documents:

1. ASME NQA-1 (2000), Part II, Subpart 2.7, *Quality Assurance Requirements for Computer Software for Nuclear Facility Applications.*

2. DOE O 414.1C, Attachment 5, *Safety Software Quality Requirements.*

Note: All references in ASME NQA-1-2000, Part II to ASME NQA-1 (2000) Part I requirements are understood to be referring to the appropriate criteria of ANSI/ASME NQA-1a-1983, as supplemented or modified by regulatory positions cited in Section C of Regulatory Guide 1.28, Rev.3.

SUPPLEMENT II
SAMPLE CONTROL

II.1 GENERAL

A. This supplement establishes requirements for the control of YMP site collected physical samples.

B. Procured samples shall be controlled in accordance with Section 8.0, and Section 13.0.

II.2 REQUIREMENTS

II.2.1 General Requirements

A. Samples shall be controlled and identified in a manner consistent with their intended use.

B. Controls shall identify responsibilities, including interfaces between organizations, for documenting and tracking sample possession from sample collection and identification through handling, preservation, shipment, transfer, analysis, storage, and final use.

C. Controls shall include specifics on orientation relative to the location that was sampled, as appropriate.

II.2.2 Traceability

A. Sample identification methods shall ensure that traceability is established and maintained from the samples to applicable implementing documents or other specifying documents.

B. Sample traceability shall ensure that the sample can be traced at all times from its collection through final use and any post-test retention that may be appropriate.

II.2.3 Identification

A. A unique identifier shall be maintained on the samples or in a manner that ensures that identification is established and maintained.

B. Samples shall maintain their same unique identifier from their initial collection through final use.

C. Sample identification shall be documented and verified before the sample is released for use or analysis.

D. Sample identification methods shall include use of physical markings.

E. If physical markings are either impractical or insufficient, other appropriate means shall be employed (e.g., physical separation, labels or tags attached to containers, or other procedural control).

F. Physical markings, when used, shall:

1. Be applied using materials and methods that provide a clear and legible identification.

2. Not detrimentally affect the sample content or form.

3. Be transferred to each identified sample part when the sample is subdivided.

4. Not be obliterated or hidden by surface treatments or sample preparations unless other means of identification are substituted.

II.2.4 Conditional Requirements

The controls for samples shall address the following requirements, as applicable:

A. If documents contain specific identification or traceability requirements (e.g., identification or traceability of the sample to applicable study plan, site characterization activity, or other records), those specified controls shall be implemented.

B. If samples have limited use or storage life, then methods shall be established that preclude using the sample beyond its intended use or storage life.

C. If sample storage is required, then methods shall be established for the control of sample identification that is commensurate with the planned duration and conditions of storage. These methods shall provide for, as applicable:

1. Maintenance or replacement of markings and identification tags damaged during handling or aging.

2. Protection of identification markings subject to excessive deterioration resulting from environmental exposure.

3. Updating related documentation.

II.2.5 Archiving Samples

Implementing documents shall specify the representative samples to be archived if the need to archive samples is identified.

II.2.6 Handling, Storage, and Shipping

A. Handling, storage, cleaning, packaging, shipping, and preservation of samples shall be conducted in accordance with established implementing documents or other specified documents.

B. If required for critical, sensitive, perishable, or high-value samples, specific measures for handling, storage, cleaning, packaging, shipping, and preservation shall be identified and used.

C. If required for particular samples, special equipment (i.e., containers) and special protective environments (i.e., inert gas and moisture and temperature limits) shall be specified and provided.

D. Special handling tools and equipment shall be used and controlled as necessary to ensure safe and adequate handling.

1. Special handling tools and equipment shall be inspected and tested in accordance with implementing documents and at specified time intervals to verify that the tools and equipment are adequately maintained.

2. Operators of special handling and lifting equipment shall be experienced or trained to use the equipment.

II.2.7 Identification

A. Measures shall be established for the marking and labeling for packaging, shipping, handling, and storage of samples, as necessary, to adequately identify, maintain, and preserve the sample.

B. Markings and labels shall indicate the presence of special environments or the need for special controls, if necessary.

II.2.8 Disposition of Nonconforming Samples

Nonconforming samples shall be processed in accordance with Section 15.0.

SUPPLEMENT III
SCIENTIFIC INVESTIGATION

III.1 GENERAL

This supplement establishes requirements for scientific investigations, including data identification, data reduction, and model development and use.

III.2 REQUIREMENTS

III.2.1 Planning Scientific Investigations

A. Scientific investigations shall be planned in accordance with Section 2.0.

B. Planning shall be coordinated with organizations providing input to or using the results of the investigation.

C. Planning shall address provisions for determining the accuracy, precision, and representativeness of results.

III.2.2 Performing Scientific Investigations

A. All documentation resulting from scientific investigation shall be transparent, identify principal lines of investigation considered, and be legible and in a form suitable for reproduction, filing, and retrieval.

B. Scientific investigations shall be performed using scientific notebooks, implementing documents, or a combination of both.

C. Scientific notebooks shall contain the following:

1. Statement of objective and description of work to be performed, or reference to an approved planning document or implementing document that addresses those topics.

2. Identification of method(s) and computer software used.

3. Identification of any samples or M&TE used.

4. Description of the work as it was performed and results obtained, names of individuals performing the work, and dated initials or signature, as appropriate, of individuals making the entries.

5. Description of changes made to methods used, as appropriate.

D. Scientific notebooks shall be reviewed by an independent qualified individual to verify there is sufficient detail to:

1. Retrace the investigations and confirm the results, or

2. Repeat the investigation and achieve comparable results, independent of the original investigator.

E. Software utilized in the performance of scientific investigations shall be controlled as follows:

1. Computer software used to develop or execute models shall be controlled in accordance with Section III.2.6 C.

2. Data acquisition and control applications, integral to the operation, maintenance, or calibration of a scientific investigation testing apparatus and verified or validated in conjunction with the M&TE or hardware as a unit, is controlled by Section 12.2.1 A.

III.2.3 Data Identification

A. Data shall be identified in a manner that facilitates traceability to associated documentation.

B. Data shall be identified in a manner that facilitates traceability to its qualification status.

C. Identification and traceability shall be maintained throughout the lifetime of the data.

III.2.4 Data Review, Adequacy, and Usage

A. Data reduction shall be described to permit independent reproducibility by another qualified individual.

B. Data from scientific investigation activities that are used as direct input to site characterization, and scientific analysis or performance modeling that address safety and waste isolation issues shall be qualified from origin, except as allowed in Paragraph III.2.4B.2. External source data that are not identified as established fact and are used as direct input to scientific analysis or performance modeling must be qualified for its intended use.

1. Data shall be reviewed by qualified individuals other than those who collected or reduced the data to ensure technical correctness.

2. Unqualified data may be used in scientific investigation provided traceability to its status as unqualified data is maintained. Unqualified data that are used as direct input to scientific analysis or performance modeling that address safety and waste isolation issues shall be qualified in

accordance with Paragraph III.2.4C at appropriate times during the scientific investigations and before:

a. Relying on the data to support the license application (i.e., prior to submittal of the application to the NRC),

b. Relying on the item for which the data were used as design input to perform its function, or

c. Relying on the data to resolve safety or waste isolation issues.

C. Unqualified data developed from scientific investigation activities that are used as direct input to site characterization, scientific analysis or performance modeling that address safety and waste isolation issues shall be qualified. External source data that are not identified as established fact and are used as direct input to scientific analyses or performance modeling shall be qualified. One or a combination of the following methods shall be used in performing qualification activities:

1. Determination that the controls under which the data were generated are similar in scope and implementation to the QARD.

2. Evaluation of corroborating data-Rationale for selecting one set of data to corroborate another set of data shall be clearly explained and justified.

3. Confirmatory testing.

4. Peer review in accordance with Section 2.0.

5. Technical assessment to independently evaluate data, which includes one or a combination of the following:

a. Determination that the employed methodology is acceptable.

b. Determination that confidence in the data acquisition or developmental results is warranted.

c. Confirmation that the data have been used in similar applications.

D. The methods in Paragraphs III.2.4C.1, III.2.4C.2, and III.2.4C.3 shall include a review to determine the technical correctness of the data in accordance with established review criteria.

E. The qualification basis shall be documented. Documentation shall include:

1. The factors used in arriving at the choice of the qualification method(s).

2. The decision as to the qualification of the data.

F. When data is acquired as non-ITS/ITWI data and is subsequently identified as necessary to support an activity in which the QARD applies, that data may be used provided:

1. Prior review and approval by the responsible OCRWM line organization director and the Director, OQA is obtained.

2. Planning for data use is performed in accordance with Subsection III.2.1.

3. The data to be used is identified, controlled, and qualified as described in Subsections III.2.3 and III.2.4.

III.2.5 Technical Report Review

Technical reports shall be reviewed in accordance with the requirements of Subsection 6.2.3.

III.2.6 Model Development and Use

A. Model development and approaches to validation shall be planned, controlled, and documented. Planning for model validation shall identify the validation methods and the validation criteria used. If model validation activities will be completed after documentation of the model (i.e., using new confirmation test data gathered in the field or laboratory), these activities shall be described in the work-planning document.

B. Documentation of models shall be in accordance with Section 17.0, shall be transparent, and shall include:

1. Definition of the objective (intended use) of the model.

2. Description of conceptual model and scientific basis, as well as alternatives for the selected conceptual model. Rationale for not selecting alternatives shall also be included.

3. Results of literature searches and other applicable background information.

4. Identification of inputs and their sources.

5. Identification of, and rationale for, assumptions that are made to develop or apply the model, including model idealizations, as well as those assumptions that support the input to the model and impact model results.

6. Discussion of mathematical and numerical methods that are used in the model, including governing equations, formulas, and algorithms, and their scientific and mathematical bases.

7. Identification of any associated software used, computer calculations performed, and basis to permit traceability of inputs and outputs.

8. Discussion of initial and/or boundary conditions.

9. Discussion of model limitations (i.e., data available for model development, valid ranges of model application, spatial and temporal scaling).

10. Discussion of model uncertainties (e.g., conceptual model, mathematical model, process model, abstraction model, system model, parameters) and how they affect the model.

11. Identification of the originator, reviewer, and approver.

C. Computer software used to develop or execute the model shall be qualified in accordance with the requirements of Supplement I.

1. Unqualified software may be used to produce preliminary output that may be used in preliminary technical products (see Supplement I.2.9B.1), subject to the following controls:

a. Unqualified software used to produce preliminary output shall be identified to SCM for the purpose of tracking the preliminary application of in-process software that is anticipated to be controlled per SCM procedures once it is qualified.

b. Use of all outputs from unqualified software shall be documented and tracked.

c. Outputs from unqualified software shall be appropriately identified as To Be Verified (TBV) or TBV-Temp.

d. When unqualified software has been qualified and baselined in accordance with appropriate software management life cycle procedures, one of the following steps shall be taken:

i. Rerun the software product outputs with the same inputs using the qualified software and update or replace the preliminary software product outputs with the qualified software product outputs.

ii. Compare the unqualified software with the qualified software using one of the following methods:

- Compare the qualified software media to the unqualified media using a hashing algorithm (e.g., n-bit check sums, Cyclic Redundancy Check, and Message Digest 5).

- Compare the qualified software media to the unqualified media software media using a file comparison utility (e.g., File Compare and diff).

iii. If the unqualified software and qualified software are shown to be identical by one of the methods above, update the status of the preliminary software product output from unqualified to qualified.

iv. If the unqualified software and qualified software are not identical as determined by one of the methods above, rerun the software product outputs using the qualified software and update or replace the preliminary software product outputs with the qualified software product outputs.

e. Responsible managers, leads, checkers, and quality engineering representatives for technical products shall ensure that all software used within the technical product has been qualified and baselined prior to final approval of the technical product in accordance with the governing technical product procedure.

2. Use of unqualified software under these provisions is strictly limited to use within preliminary technical products in direct support of OCRWM activities related to obtaining a license to construct a repository, including rework in support of the license application. No other use of these provisions shall be permitted for any other purpose.

D. The intended use of the model and the importance of the model for assessing repository system performance shall determine the appropriate level of confidence for a model (i.e., models of system components most relied upon shall be validated with the highest levels of confidence to the extent practical).

E. Model validation criteria shall address the following:

1. Criteria used to establish the adequacy of the scientific basis for the model shall be consistent with the model application and justified in the model documentation.

2. Criteria used to demonstrate that the model is sufficiently accurate for its intended use. Model documentation shall provide an accounting for uncertainties and variabilities in parameter values and provide the technical basis for parameter ranges, probability distributions, or bounding values used in process, abstraction, and system models used in (or supporting) the postclosure performance assessment.

3. The importance of the model for assessing repository system performance shall be defined.

4. The relative level of confidence for the model shall be described.

5. The supporting information needed to substantiate validation shall be defined.

F. The usual progression of a model is from conceptual model to mathematical model to process model to abstraction model to system model. A conceptual model shall be validated when its implementation as a mathematical, process, abstraction, or system-level model is validated. Technical review through publication in a refereed professional journal or review by an external agency may be used to corroborate model validation when used in conjunction with one or more of the following:

1. Corroboration of model results with data acquired from field experiments, analogue studies, laboratory experiments, or subsequent relevant observations (i.e., refereed journals or literature). Data used to develop and calibrate a model shall not be used to validate a model.

2. Peer review (Subsection 2.2.8) or independent technical review (Subsection 6.2.3).

3. Performance confirmation studies using validation test model predictions prior to comparison with field or laboratory data.

4. Comparison of model results with other results obtained from the implementation of an alternative validated model.

III.2.7 Commitment Document Positions

A. OCRWM commits to the following documents with the associated modifications:

1. NUREG 1298 (1988), *Qualification of Existing Data for High-Level Nuclear Waste Repositories.*

- Section IV, Staff Position 2, identifies four alternative or combinations of methods that are acceptable for the process of qualifying data. In addition to the four methods listed, OCRWM uses a fifth method, Technical Assessment, which includes one or a combination of the following:

  - Determination that the employed methodology is acceptable;

  - Determination that confidence in the data acquisition or developmental results is warranted; or

  - Confirmation that the data have been used in similar applications.

- The QA program that is discussed in Staff Position IV.1 is understood to mean 10 CFR 60, Subpart G, Quality Assurance, or 10 CFR 63.142, depending at the point in time when the data was required to be qualified.

- In those instances when data cannot be obtained from any external source through a procurement process that involves the imposition of applicable QA program requirements, the data may be obtained through a non-Q procurement in accordance with QARD Subsection 7.2.12C.

- In those instances when required data is shown to already exist in the form of a product of a non-Q acquisition, the OCRWM will permit use of that data in an activity to which the QA program applies provided such data is be subjected to the approval and data qualification process specified in QARD Subsection 7.2.12C.

2. NUREG-1636 (1999), *Regulatory Perspectives on Model Validation in High-Level Radioactive Waste Management Programs: A Joint NRC/SKI White Paper.*

- The OCRWM commits to the requirements and recommendations in Section 3, *Model Validation Approach from a Regulatory Perspective*, to the extent presented in QARD Supplement III, Scientific Investigation, Subsection III.2.6.

SUPPLEMENT IV
FIELD SURVEYING

IV.1 GENERAL

A. This supplement establishes requirements for field surveying. Examples of work that have the potential to require field surveying services for location determination include site characterization, explorations, and installations.

B. Other applicable sections of the QARD also apply to field surveying activities.

IV.2 REQUIREMENTS

IV.2.1 Field Survey System

A. A permanent system of horizontal and vertical controls shall be established and maintained.

B. This system shall be used in accordance with implementing documents to obtain the accurate location and relocation of designated features, including locations of sample or data collection.

IV.2.2 Field Survey Documentation

Pertinent survey documents shall be identified, maintained, and verified for completeness as the work progresses.

SUPPLEMENT V
CONTROL OF THE ELECTRONIC MANAGEMENT OF INFORMATION

V.1 GENERAL

This supplement applies to the processes and controls for the management of information that either exists or is used in an electronic format. This includes electronically formatted information used in design input, developed as design output, or developed as an output of scientific investigation or performance assessment modeling and analysis.

Development, acquisition, and modification of software, including database applications or software that performs functions of analysis or calculation, shall be controlled in accordance with Supplement I. The acquisition, development, and use of information shall be controlled by the requirements of Section 3.0 or Supplement III.

V.2 REQUIREMENTS

V.2.1 Control of the Electronic Management of Information

Controls shall be established to ensure that:

A. Information is suitably protected from damage and destruction during its prescribed lifetime and is readily retrievable.

B. A description is prepared of how information will be stored with respect to media, conditions, location, retention time, security, and access.

C. Storage and transfer media are properly identified as to source, physical and logical format, and relevant date (i.e., date written).

D. The completeness and accuracy of the information input and any subsequent changes to the information are maintained.

E. The security and integrity of the information is maintained.

F. Transfers of information are error free or (where applicable) within a defined permissible error rate, to ensure that no information is lost in transfer and the input is recoverable from the output. Examples of information transfers include copying raw information from a notebook to a computerized form, copying from computer tape to disk, and writing to a compact disk.

APPENDIX A
WASTE CUSTODIANS

A.1 GENERAL

The purpose of this Appendix is to define the roles, responsibilities and relationships between the OCRWM and the waste custodians, who in this instance is EM, NNPP, and commercial nuclear utilities.

A.1.1 Commercial Nuclear Utilities

A. This section contains clarification of requirements unique to the work associated with acceptance of SNF and/or HLW. The QA program requirements in 10 CFR 50, 71, and 72 include provisions that are generally comparable to 10 CFR 63.142. Those programs provide controls comparable to those in the QARD.

B. The QARD does not apply to non-OCRWM commercial licensees/certificate holders licensed pursuant to the provisions of 10 CFR 50, 71, or 72 that manage SNF and/or HLW in accordance with an approved QA program.

C. Commercial nuclear utilities shall prepare and ship to the Yucca Mountain repository, appropriate nuclear waste that has been packaged pursuant to a nuclear waste program that satisfies 10 CFR 50, Appendix B, that also addresses loading and (possibly) storage of transportation, aging, and disposal canisters. If OCRWM identifies specific technical or quality assurance requirements for loading/storage of disposable canisters that need to be met by the utilities, these requirements will be addressed in the standard contract between OCRWM and commercial nuclear facilities.

D. Additional QA-related requirements governing the interface between commercial nuclear utilities and the OCRWM will be addressed in greater detail in future QARD revisions when OCRWM deems such an action to be necessary.

A.1.2. Federal Waste Custodians

A. The OCRWM interfaces directly with federal waste custodians and their contractors to obtain information and/or data to support activities subject to the QARD (e.g., scientific document development and design). The OCRWM has developed the requirements described in this appendix to ensure that appropriate QA controls are implemented by federal waste custodians and their contractors.

B. Federal waste custodians and their contractors shall perform activities to ensure and document that their HLW and SNF will meet OCRWM waste acceptance criteria. In some cases federal waste custodians and/or their contractors also design and fabricate items that will be considered ITS SSCs or ITWI barriers

(e.g., SNF disposal canisters). Federal waste custodians and their contractors must have a QA program that meets the applicable QA requirements of 10 CFR 63.142. The applicable requirements of these QA programs shall be flowed down to respective contractors by the federal waste custodians.

C. Interfaces between the OCRWM and federal waste custodians shall be defined in formal agreement documents (e.g., Memoranda of Agreement). Agreement documents also shall identify requirements that the federal waste custodians will need to meet for OCRWM to use their work products (i.e.., license application input items that will be considered ITS or ITWI) and accept their HLW or SNF for disposal. The OCRWM will verify the implementation of these requirements through audits, surveillance, reviews, or observations prior to accepting their work products or accepting HLW or SNF.

D. Federal waste custodians normally contract some or all of the work addressed in this appendix to their contractors. Agreement documents shall be executed between the OCRWM and senior management of the DOE office that encompasses the federal waste custodians. Federal waste custodians are responsible for passing the appropriate provisions of the agreement document down to their contractors.

E. Agreement documents are not procurement documents; however, for the purpose of providing the appropriate level of control over OCRWM and federal waste custodian interface, the appropriate requirements of QARD Section 4.0 and Section 7.0 for EM waste custodians and 10 CFR 63.142 for the NNPP will be applied to the development, control, and revision of agreement documents.

A2. SPECIFIC DISCUSSION OF OCRWM INTERFACE WITH FEDERAL WASTE CUSTODIANS

A.2.1 Interface with the Naval Nuclear Propulsion Program

A. The NNPP is a joint U.S. Department of the Navy/DOE organization and, as promulgated under Executive Order 12344, *Naval Nuclear Propulsion Program*, (42 U.S.C., Section 7158 and 50 U.S.C., Section 2406), is responsible for all matters pertaining to naval nuclear propulsion. Within DOE, the NNPP is known as the Office of Naval Reactors and is considered a federal waste custodian. The NNPP's QA program has been a key contributor to the success of the NNPP throughout its history of more than 50 years. The QA program validates that the fundamental quality necessary for a successful naval nuclear program shall be built into all components and processes.

B. The NNPP QA program applies to all aspects of design, operation, construction, and maintenance of naval nuclear propulsion plants, including work to support

emplacement of naval SNF in the geologic repository. NNPP QA requirements embody the 18 quality criteria of 10 CFR 63.142.

C. An agreement document defines the interface between the NNPP and the OCRWM for the purpose of the OCRWM acceptance of naval SNF for disposal. This agreement specifies that the NNPP QA program shall be defined and administered solely by the NNPP in accordance with its statutory obligations and that the NNPP is responsible for conducting all oversight of NNPP activities related to acceptance of naval SNF. Under the agreement, OCRWM is responsible for reviewing NNPP QA practices regarding naval SNF and for determination of the sufficiency of these practices for disposal at the repository. The agreement provides for OCRWM observations of NNPP QA practices and periodic discussion and updates regarding these practices so that the OCRWM can fulfill its responsibilities under the agreement.

D. Interactions between the OCRWM and NNPP regarding the NNPP QA program started in the mid-1990s and led to a comprehensive OQA review and acceptance of the NNPP QA program as it applies to disposal of naval SNF in the geologic repository.

E. The OCRWM monitors the NNPP QA program to ensure it remains acceptable to the OCRWM. Monitoring activities include periodic observations of NNPP QA program oversight of various NNPP QA program elements and contractor QA program activities, as well as annual reviews of NNPP QA audits, surveillance, inspection reports, implementing document revisions, compliance matrices, and organizational changes.

A.2.2 Interface with the Office of Environmental Management

A. The OCRWM agreement with EM identifies the interfaces between OCRWM, EM waste custodians, and their contractors.

B. The agreement addresses the technical and quality requirements that apply to work associated with HLW and SNF and identifies that the QARD is applicable to EM federal custodians and their contractors. Subsection A.2.3 of this Appendix contains general clarification of QARD requirements as they apply to EM waste custodians and their contractors.

C. The agreement between the OCRWM and EM shall describe the oversight of EM waste custodians and their contractors performing work covered in the agreement. EM and the OCRWM jointly perform audits of EM waste custodians and their contractors. For example, QA teams auditing EM activities must include at least one OCRWM OQA team member. Audits shall be performed in accordance with approved OCRWM implementing documents or equivalent.

D. The EM National Spent Nuclear Fuel Program provides the OCRWM with information related to DOE SNF and HLW, and as such it is treated as a waste custodian even though it does not actually possess SNF or HLW.

A.2.3 QARD Amplifications and Clarifications Applicable to Environmental Management Waste Custodians and their Contractors

A. General

This section contains general amplifications and clarifications of specific QARD sections or supplements related to implementation of the QARD by EM waste custodians and their contractors. If a section or supplement requires no amplification or clarification, reference to the QARD section or supplement is omitted.

B. Amplifications and Clarifications

The requirements delineated in the QARD that are related to the implementation of DOE O 414.1C (i.e., non-ITS/ITWI SSCs and related activities) are not applicable to EM waste custodians or their contractors.

1. Section 1.0

a. Subsection 1.2—The requirements of this subsection are applicable to EM waste custodians and their contractors as well as to OCRWM and its principal contractors.

b. Subsection 1.3A—EM waste custodians and their contractors are required to document their organizational structure in accordance with this paragraph, but are not required to do so using organization charts (e.g., written description of the organization would be acceptable).

c. Subsection 1.3.1B—Replace this subsection with the following:

B. The QA position responsible for the QA functions of the EM waste custodians and their contractors shall:

1. Ensure that a QA program that complies with regulatory and management requirements is established and effectively implemented consistent with the schedule for accomplishing the activities.

2. Verify the adequacy and implementation (i.e., compliance and effectiveness) of the QA program and report the results to senior management.

3. Have sufficient authority, access to work areas, and organizational freedom to identify quality problems; to initiate, recommend, or provide solutions through designated channels; to verify implementation of solutions to quality problems; and ensure that further processing, delivery, installation, or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred.

4. Report to a management level so that the required authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations, are provided.

5. Have direct access to responsible management at a level where appropriate action can be effected.

6. Ensure that QA staff are involved in day-to-day activities such as work and schedule meetings.

7. Have no other assigned duties that would prevent full attention to QA-related responsibilities.

8. Develop, approve, and maintain their QA program description document.

9. Ensure adequate QA coverage relative to procedural and inspection controls, acceptance criteria, and QA staffing and qualification of personnel to carry out QA assignments. Qualification of QA personnel shall be in accordance with Subsection 2.2.11.

10. Have the authority to stop work when significant conditions adverse to quality warrant such action.

2. Section 2.0

a. Subsection 2.2.2 C and Subsection 2.2.2 F—The requirements of these subsections are not applicable to EM waste custodians and their contractors.

b. Subsection 2.2.3—EM waste custodians and their contractors shall identify their items and/or activities that are subject to the QARD. This identification does not have to be in the form of a Q-list (e.g., it may be more appropriate for some EM waste custodians or their contractors to maintain an items and activities list).

c. Subsection 2.2.7—The requirements of this subsection are not applicable to EM waste custodians and their contractors.

d. Subsection 2.2.11F—The requirements of this subsection are not applicable to EM waste custodians and their contractors.

e. Subsection 2.2.13A.5- The requirement of this subsection is not applicable to EM waste custodians and their contractors.

3. Section 3.0

a. Subsection 3.2.9B.1 through Subsection 3.2.9B.7 are not applicable to EM waste custodians and their contractors.

4. Section 16.0

a. Subsection 16.2.6D—Replace this subsection with the following:

D. Trend evaluations shall be distributed in a timely manner to EM waste custodian and their contractor's management for review and appropriate corrective action.

5. Section 17.0

a. Subsection 17.2.8—Replace this subsection with the following:

A. Lifetime QA records shall be retained and maintained until the license is amended for permanent closure. Lifetime QA records include those directly related to waste form or other items that will be supplied to OCRWM (such as the standard canister). These records shall be transferred to OCRWM for retention and maintenance.

B. QA records shall be classified as lifetime as follows:

- Documents that provide evidence of the quality of items on a items/activities list.
- Documents that provide evidence of the quality of activities related to items on a items/activities list.
- Documents that provide evidence of the quality of site characterization data and samples.
- Documents that provide evidence of those activities that provide data used to assess the potential dispersion of radioactive materials from the licensed facility.

- Documents that provide evidence of the quality of the production process for the HLW waste form and acceptance of the HLW waste form product.

- Documents that provide evidence of the quality of those activities associated with the characterization of SNF, and conditioning of SNF through acceptance of DOE SNF.

- Personnel training and qualification documents for individuals executing QA program requirements.

- Documents that are implementing documents as described in Section 5.0.

6. Section 18—General clarification of audit scheduling is as follows:

   Joint EM/RW audits at each EM SNF or HLW site shall be conducted annually, unless a decrease in the frequency of oversight activities is determined jointly between EM and OCRWM, based on the scope and complexity of work. In no case will the frequency be less than once every three years for a site performing work under an accepted QARD-compliant QA program.

APPENDIX B

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APPENDIX C
STORAGE AND TRANSPORTATION

C.1 GENERAL

This appendix contains clarification of requirements unique to the work conducted by commercial licensees/certificate holders for the storage of spent nuclear fuel and the transportation of SNF and HLW. The QA program requirements in 10 CFR 50, 71, and 72 include provisions that are generally comparable to 10 CFR 63.142. Those programs provide controls comparable to those in the QARD.

The QARD does not apply to non-OCRWM commercial licensees/certificate holders licensed pursuant to the provisions of 10 CFR Parts 50, 71, or 72 that design, fabricate, acquire, or use storage casks, transportation casks, canisters, or ancillary equipment in accordance with an approved QA program.

DOE will, as appropriate, perform reviews of documentation to verify that quality-affecting work performed by commercial licensees/certificate holders and their contractors is performed in a manner that complies with applicable QA requirements and, where applicable, the DOE Standard Contract.

C.2 REQUIREMENTS

The activities executed and products produced under the above mentioned QA programs have QA provisions applied to them that are comparable to the provisions of 10 CFR 63.142. Those activities and products used to satisfy the applicable licenses or certifications are acceptable for OCRWM to use as a basis for demonstrating compliance with 10 CFR 63, *Disposal of High-Level Radioactive Waste in a Geologic Repository at Yucca Mountain, Nevada*. For example:

1. Transportation/Storage System vendor design and safety analysis calculations performed under a 10 CFR 71 or 10 CFR 72 approved QA program are acceptable for use, by OCRWM, in demonstrating compliance with 10 CFR 63.

2. Where vendor work is procured by OCRWM, and such work is used to demonstrate compliance with 10 CFR 63, OCRWM oversight of such vendor work will be performed in accordance with the QARD.

3. Development of cask/canister loading operation requirements to meet 10 CFR 63 safety analysis design bases for disposal at the Yucca Mountain repository, and the imposition of those requirements by OCRWM on vendors/utilities will be in accordance with the provisions of the QARD.

4. Handling, loading, verification, and maintenance of casks/canisters to be accomplished by utilities, vendors, or others will be subject to the provisions of their 10 CFR 50, 71 or 72 QA programs, or the QARD if the former programs are not available.

The requirements of this Appendix do not relieve OCRWM of the need to implement the requirements of the QARD.

GLOSSARY

Abandoned–in-Place Measuring and Test Equipment–Measuring and test equipment that cannot or will not be retrieved upon the completion of a test or experiment.

Acceptance (Document)–The documented determination by the receiving organization that work is suitable for the intended purpose.

Acceptance Testing (Software)–The process of exercising or evaluating a system or system component by manual or automated means to ensure that it satisfies the specified requirements and to identify differences between expected and actual results in the operating environment. (NQA-1-2000, Subpart 2.7, Section 102).

Application (Software)–Includes software designed to fulfill the specific needs of a user and software that are written where the user prescribes one or more instructions to generate data, manipulate data, or perform calculations. (IEEE Std. 610.12-1990, *Standard Glossary of Software Engineering Terminology*).

Approval–The documented determination by a responsible organization that work is suitable for the intended purpose and shall be used as required.

Audit–A planned and documented activity performed to determine by investigation, examination, or evaluation of objective evidence the adequacy of and compliance with established procedures, instructions, drawings, and other applicable documents and the effectiveness of implementation. An audit should not be confused with surveillance or inspection activities performed for the sole purpose of process control or product acceptance. Compliance elements include the flowdown of requirements into approved implementing documents and implementation of the implementing documents. Performance-based elements address an evaluation of the end-products, services, and processes to determine whether the process produces the desired results (effectiveness). (NQA-1-1983, Supplement S-1-Modified).

Audit Finding–An issue or a collection of issues (non-significant and/or significant) that represent a performance, process, or programmatic weakness or breakdown, such that the QA organization's involvement is necessary to ensure that the analysis and resolution of the issue(s) is addressed effectively.

Audit Team Leader–A lead auditor who is assigned to direct the efforts of an audit team.

Auditor–An individual who is qualified to perform assigned portions of an audit.

Baseline Element (Software)–An individual software component (e.g., requirements document, design document, and source code) that is under configuration management control.

Basic Component–When applied to facilities or activities licensed pursuant to 10 CFR 63, a structure, system, or component or part thereof that affects their safety or waste isolation function, that is directly procured by the licensee of a facility or activity subject to the

regulations in 10 CFR 21, and in which a defect or failure to comply with any applicable regulation in Title 10, Chapter I, order, or license issued by the U.S. Nuclear Regulatory Commission could create a substantial safety hazard. The term includes activities important to safety or important to waste isolation such as design, analysis, inspection, testing, fabrication, replacement of parts, or consulting services that are associated with the component hardware whether these services are performed by the component supplier or others. (10 CFR 21.3)

Cancelled Document–A document that is removed from active use when the process is no longer needed.

Certificate of Conformance–A document signed by an authorized individual certifying the degree to which items or services meet specified requirements. (NQA-1-1983, Supplement S-1)

Certification–The act of determining, verifying, and attesting in writing to the qualifications of personnel, processes, procedures, or items in accordance with specified requirements. (NQA-1-1983, Supplement S-1)

Characteristic–A property or attribute of an item, process, or service that is distinct, describable, and measurable. (NQA-1-1983, Supplement S-1)

Code Data Report (ASME Section III)–A report required by the ASME Boiler and Pressure Vessel Code, such as Form N-1, Certificate Holders' Data Report For Nuclear Vessels, or Form N-3, Owners' Data Report for Nuclear Power Plant Components.

Commercial Devices- Commercially available tools and laboratory equipment such as rulers, tape measures, levels, laboratory glassware, and other normal commercial equipment that provides adequate accuracy.

Commercial Grade Item–An item that is not subject to design or specification requirements that are unique to nuclear facilities or activities, is used in applications other than nuclear facilities or activities, and is to be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturers published product description (i.e., catalog). (10 CFR 21.3)

Commercial Grade Survey–Activities conducted by the purchaser or its agent to verify that a principal contractor/supplier of commercial grade items controls, through quality activities, the critical characteristics of specifically designated commercial grade items, as a method to accept those items for ITS or ITWI use. (EPRI NP-5652, 6/88-Modified)

Commercial Off-The-Shelf Software–Software items that can be purchased, ready-made, from a principal contractor's/supplier's/retailer's store shelf or manufacturer's virtual store shelf (e.g., through a catalog or from a price list) on the basis of specifications set forth in the manufacturer's published product description (e.g., a catalog or other published specification).

Computer Program–A combination of computer instructions and data definitions that enable computer hardware to perform computational or control functions. Computer programs covered

by this document are those used in quality affecting activities. (NQA-1-2000, Part I, Section 400, Modified)

Conceptual Model–A set of qualitative assumptions used to describe a system or subsystem for a given purpose. Assumptions for the model are compatible with one another and fit the existing data within the context of the given purpose of the model. (NUREG-1804, *Yucca Mountain Review Plan*, Section 3, Glossary)

Condition Adverse to Quality–An all-inclusive term used in reference to any of the following: failures, malfunctions, deficiencies, defective items, and nonconformances. (NQA-1-1983, Supplement S-1). Included with the list of items above are deviations.

Configuration Item (Software)–A collection of hardware or software elements treated as a unit for the purpose of configuration control. (NQA-1-2000, Subpart 2.7, Section 102)

Configuration Management (Software)–The process of identifying and defining configuration items in a system (i.e., software and hardware), controlling the release and change of these items throughout the system's life cycle, and recording and reporting the status of configuration items and change requests. (NQA-1-2000, Subpart 2.7, Section 102)

Confirmatory Testing–Testing conducted under a 10 CFR 60, Subpart G, or 10 CFR 63, Subpart G, QA program that investigates the properties of interest (e.g., physical, chemical, geologic, or mechanical) of an unqualified database.

Consumables–Items that in the process of being used are consumed (e.g., weld rods).

Control Point (Software)–A point in the software life cycle at which specified agreements or controls (typically a test or review) are applied to the software configuration items being developed (e.g., an approved baseline or release of a specified document or computer program). (NQA-1-2000, Subpart 2.7, Section 102)

Corrective Action–Measures taken to rectify conditions adverse to quality and, where necessary, to preclude repetition. (NQA-1-1983, Supplement S-1)

Corroborating Data–Unqualified or qualified data used to support or substantiate other unqualified data. (NUREG-1298 [2/88]-Modified)

Critical Characteristics–The important design, material, and performance characteristics of a commercial grade item that, once verified, will provide reasonable assurance that the item will perform its intended safety function, or reasonable expectation that the item will perform its intended waste isolation function. (NUREG-1804, AC-7[8][b])

Data–Information measured or derived from scientific investigation activities both in the field and the laboratory. Parameters that have been derived from raw data are sometimes themselves considered to be data.

Database–A collection of previously distinct data (not created by the database) that have been logically organized to facilitate data access.

Data Reduction–Processes that change the form of expression, quantity of data or values, or the number of data items.

Dedicating Entity–The organization that performs the dedication process. Dedication may be performed by the manufacturer of the item, a third-party dedicating entity, or the Department of Energy itself. The dedicating entity pursuant to 10 CFR 21.21(c) is responsible for identifying and evaluating deviations, reporting defects and failures to comply for the dedicated item, and maintaining auditable records of the dedication process. (10 CFR 21.3)

Dedication–An acceptance process undertaken to provide (i) reasonable assurance that a commercial grade item to be used as a basic component will perform its intended safety function or (ii) reasonable expectation that the item will perform its intended waste isolation function and, in this respect, is deemed equivalent to an item designed and manufactured under a 10 CFR 63, Subpart G, quality assurance program. This assurance is achieved by identifying the critical characteristics of the item and verifying their acceptability by inspections, tests, or analyses performed by a purchaser or third-party dedicating entity after delivery, supplemented as necessary by one or more of the following:

(1) Commercial grade surveys

(2) Product inspections or witnessing at hold points at the manufacturer's facilities, and

(3) Analyses of historical records for acceptable performance.

In all cases, the dedication process shall be conducted in accordance with the applicable requirements of 10 CFR 63, Subpart G. Final dedication of an item occurs after receipt inspection and final acceptance by the U.S. Department of Energy or its contractor, when the item is designated for use as a basic component. (10 CFR 21.3)

Defect–

(1) A deviation in a basic component delivered to a purchaser for use in a facility or activity subject to the regulation in 10 CFR 21 if, on the basis of an evaluation, the deviation could create a substantial safety hazard; or

(2) The installation, use, or operation of a basic component containing a defect; or

(3) A deviation in a portion of a facility subject to the Construction Authorization or licensing requirements of 10 CFR 63, provided the deviation could, on the basis of an evaluation, create a substantial safety hazard and the portion of the facility containing the deviation has been offered to the purchaser for acceptance; or

(4) A condition or circumstance involving a basic component that could contribute to the exceeding of a safety limit, as defined in the technical specifications of a license for operation issued pursuant to part 63 of this chapter. (10 CFR 21.3)

Design–The term "design" includes specifications; drawings; design criteria; design bases; structures, systems, and components performance requirements for preclosure; and natural and engineered barriers of the repository system. It also includes inputs and outputs at each stage of design development (e.g., from conceptual design to final design). Design information and design activities also refer to data collection and analyses and computer software that are used in supporting design development and verification. Design information and activities include general plans and detailed procedures for data collection and analyses and related information such as test and analyses results. Data analyses include the initial step, data reduction, as well as broad system analyses (i.e., performance assessments) that integrate other data and analyses for individual parameters. (NUREG 1804, AC-3 [2])

Design Bases–Information that identifies the specific functions to be performed by a structure, system, or component of a facility and the specific values or ranges of values chosen for controlling parameters as reference bounds for design. These values may be constraints derived from generally accepted state-of-the-art practices for achieving functional goals or requirements derived from analysis (based on calculation or experiments) of the effects of a postulated event under which the structure, system, or component must meet its functional goals.

The values for controlling parameters for external events include:

(1) Estimates of severe natural events to be used for deriving design bases that will be based on consideration of historical data on the associated parameters, physical data, or analysis of upper limits of the physical processes involved, and

(2) Estimates of severe external human-induced events to be used for deriving design bases that will be based on analysis of human activity in the region, taking into account the site characteristics and the risks associated with the event. (10 CFR 63.2)

Design Change–Any revision or alteration of the technical requirements defined by approved and issued design output documents and approved and issued changes thereto. (NQA-1-1983, Supplement S-1)

Design Documents–Include, but are not limited to, specifications, calculations, associated computer software, system descriptions, and drawings, including flow diagrams, piping and instrument diagrams, control logic diagrams, electrical single line diagrams, structural systems for major facilities, site arrangements, and equipment locations. (NUREG-1804, AC-3[13][c])

Design Input–Those criteria, parameters, bases, or other design requirements upon which detailed final design is based. (NQA-1-1983, Supplement S-1)

Design Output–Documents, such as drawings, specifications, and other documents defining technical requirements of structures, systems, and components. (NQA-1-1983, Supplement S-1)

Design Process–Technical and management processes that commence with identification of design input and that lead to and include the issuance of design output documents. (NQA-1-1983, Supplement S-1)

Design Review–A critical review to provide assurance that the final design is correct and satisfactory. (NQA-1-1983, Supplement 3S-1, Paragraph 4.2.1)

Deviation–A departure from specified requirements. (NQA-1-1983, Supplement S-1)

Direct Input-Those inputs that are directly relied upon to support the results or conclusions of technical products.

Effective Date–The date after approval that the document is required to be fully implemented.

Embedded Software–Software that is a part of a larger system and performs some of the functions of that system, such as keypad controls or function and control capabilities. (IEEE Std. 610.12-1990, Modified)

Error (Software)–A condition deviating from an established baseline, including deviations from the current approved computer program and its baseline requirements. (NQA-1-2000, Subpart 2.7, Section 102)

Established Fact–Information accepted by the scientific and engineering community as established fact (e.g., engineering handbooks, density tables and gravitational laws).

Event Sequence–A series of actions and/or occurrences within the natural and engineered components of a geologic repository operations area that could potentially lead to exposure of individuals to radiation. An event sequence includes one or more initiating events and associated combinations of repository system component failures, including those produced by an action or inaction of operating personnel. Those event sequences that are expected to occur one or more times before permanent closure of the geologic repository operations area are referred to as Category 1 event sequences. Other event sequences that have at least 1 chance in 10,000 of occurring before permanent closure are referred to as Category 2 event sequences. (10 CFR 63.2)

Expedited Change–An abbreviated method of revising a document at the work location where the document is used, when the normal change process would cause unnecessary delays. The management responsible for the work makes the expedited change.

Field Surveying–The process of determining the boundaries, area, elevation, and location of land, structures, reference points, or other designated features either on, above, or below the earth surface relative to a permanent system of horizontal and vertical controls.

Hold Point–A step in a document that requires witnessing or inspection by the requesting individual or organization and beyond which work shall not proceed without the written consent of the requesting individual or organization. (NQA-1-1983, Supplement 10S-1, Paragraph 3)

Implementation (Software)–The process of translating the software design into a computer program. (IEEE Std. 610.12-1990)

Important to Safety (ITS)–With reference to structures, systems, and components, means those engineered features of the geologic repository operations area whose function is:

(1) To provide reasonable assurance that high-level waste can be received, handled, packaged, stored, emplaced, and retrieved without exceeding the requirements of 10 CFR 63.111(b)(1) for Category 1 event sequences; or

(2) To prevent or mitigate Category 2 event sequences that could result in radiological exposures exceeding the values specified at 10 CFR 63.111(b)(2) to any individual located on or beyond any point on the boundary of the site. (10 CFR 63.2)

Important to Waste Isolation (ITWI)–With reference to design of the engineered barrier system and characterization of natural barriers, means those engineered and natural barriers whose function is to provide reasonable expectation that high-level waste can be disposed of without exceeding the requirements of 10 CFR 63.113(b) and (c). (10 CFR 63.2)

Indoctrination–A method of training designed to familiarize personnel in fundamental criteria, program elements, responsibilities, and authority applicable to assigned tasks. (NQA-1-1989, Supplement 2S-4, Paragraph 3)

Information–A representation of data, facts, concepts, or instructions in a manner suitable for communication, interpretation, or processing by individuals or by automatic means.

Inspection–Examination or measurement to verify whether an item or activity conforms to specified requirements. (NQA-1-1983, Section II, Basic Requirement 10)

Item–An all-inclusive term used in place of any of the following: appurtenance, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, or unit. (NQA-1-1983, Supplement S-1)

Lead Auditor–An individual who is certified to organize, perform, and direct an audit; report audit results; and evaluate related corrective actions.

Limited Use–A disposition permitted for a nonconforming sample when it can be established that a sample has potential value to the project even though the sample has been determined to be nonconforming in respect to its original obtained condition. For example, samples contaminated by water may still hold value for rock mechanic studies, but hold no value for water infiltration investigations. Conditions for Limited Use will be established and set forth in the disposition of the nonconforming sample.

Management Assessment–An OCRWM QA program verification that is conducted by management above or outside the OCRWM QA organization and that evaluates the scope, status, adequacy, programmatic compliance, and implementation effectiveness of the OCRWM QA program.

Measuring and Test Equipment–Devices or systems used to calibrate, measure, gage, test, or inspect in order to control or acquire data to verify conformance to specified requirements. (NQA-1-1983, Supplement S-1)

Model–A depiction of a system, phenomenon, or process including any hypotheses required to describe the system or explain the phenomenon or process. (NUREG-1804, Section 3, Glossary)

Model, Abstracted–A model that reproduces, or bounds, the essential elements of a more detailed process model and captures uncertainty and variability in what is often, but not always, a simplified or idealized form. (NUREG-1804, Section 3, Glossary)

Model, Conceptual–A set of qualitative assumptions used to describe a system or subsystem for a given purpose. Assumptions for the model are compatible with one another and fit the existing data within the context of the given purpose of the model. (NUREG-1804, Section 3, Glossary)

Model, Mathematical–A mathematical description of a conceptual model. (NUREG-1804, Section 3, Glossary)

Model, Process–A depiction or representation of a process, along with any hypotheses required to describe or to explain the process. (NUREG-1804, Section 3, Glossary)

Model, System–A collection of interrelated mathematical models that represents the overall geologic repository or overall component subsystem of the geologic repository.

Model Validation–A process used to establish confidence that a mathematical model and its underlying conceptual model adequately represent with sufficient accuracy the phenomenon, process, or system in question.

Nonconformance–A deficiency in characteristic, documentation, or procedure that renders the quality of an item, sample, or activity unacceptable or indeterminate. (NQA-1-1983, Supplement S-1)

Objective Evidence–Any documented statement of fact, other information, or record, either quantitative or qualitative, pertaining to the quality of an item or activity, based on observations, measurements, or test which can be verified. (NQA-1-1983, Supplement S-1)

OCRWM Contractor-Suppliers and principal contractors that are contracted to OCRWM. The requirements of the QARD that are applicable to suppliers are also applicable to OCRWM contractors unless otherwise noted.

Organizational Interface–The relationship between organizations in which one organization prescribes an activity or requirement to, or shares an activity or requirement with, another organization.

Performance Assessment (Total System Performance Assessment)–An analysis that:

(1) Identifies the features, events, processes (except human intrusion), and sequences of events and processes (except human intrusion) that might affect the Yucca Mountain disposal system and their probabilities of occurring during 10,000 years after disposal;

(2) Examines the effects of those features, events, processes, and sequences of events and processes upon the performance of the Yucca Mountain disposal system; and

(3) Estimates of the dose incurred by the reasonably maximally exposed individual, including the associated uncertainties, as a result of releases caused by all significant features, events, processes, and sequences of events and processes, weighted by their probability of occurrence. (10 CFR 63.2)

Performance Confirmation–The program of tests, experiments, and analyses that is conducted to evaluate the adequacy of the information used to demonstrate compliance with the performance objectives in 10 CFR 63, Subpart E. (10 CFR 63.2)

Personnel Qualification–See Qualification (Personnel).

Postclosure Safety Analysis-A systematic analysis of the potential hazards associated with the repository after it has been closed and sealed. A postclosure safety analysis quantifies the overall level of performance, analyzes the associated uncertainties, and thereby allows comparison with relevant design requirements and safety standards.

Preclosure Safety Analysis–A systematic examination of the site; the design; and the potential hazards, initiating events, and event sequences and their consequences (e.g., radiological exposure to workers and the public). The analysis identifies structures, systems, and components important to safety. (10 CFR 63.2)

Principal Contractors–Organizations that provide items or services in accordance with an appropriate contractual document and that perform the functions of Management and Operating contractor, Management and Integration contractor, Construction contractor or Lead Laboratory.

Process–A series of actions that achieves an end result or accomplishes work.

Procurement Document–Purchase requisitions, purchase orders, drawings, contracts, specifications, or instructions used to define requirements for purchase. (NQA-1-1983, Supplement S-1)

Purchaser–The organization responsible for establishment of procurement requirements and for issuance, administration, or both, of procurement documents. (NQA-1-1983, Supplement S-1)

Qualification (Personnel)–The characteristics or abilities gained through education, training, or experience, as measured against established requirements, such as standards or tests, that qualify an individual to perform a required function. (NQA-1-1983, Supplement S-1)

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

Qualification Testing–A test that is intended to provide a desired level of confidence that an item meets specified criteria.

Qualified Data–Data collected under an approved QA program that meets the requirements of 10 CFR 63.142 (or previously implemented 10 CFR 60 QA program) (i.e., qualified from origin) or unqualified data that have undergone the qualification process. (NUREG-1298, 2/88)

Quality Assurance (QA)–All those planned and systematic actions necessary to provide adequate confidence that the geologic repository and its structures, systems, and components important to safety, the design and characterization of engineered and natural barriers important to waste isolation, and activities related thereto will perform satisfactorily in service. Quality assurance includes quality control, which comprises those quality assurance actions related to the physical characteristics of a material, structure, system, or component that provide a means to control the quality of the material, structure, system, or component to predetermined requirements. (10 CFR 63.141, Scope)

Quality Assurance (QA) Organization–The OQA organization for activities performed by the OCRWM and reviews of OCRWM owned documents, the Management and Operating contractor (M&O) QA organization for activities performed by the M&O and reviews of M&O owned documents; the Lead Laboratory QA organization for activities performed by the Lead Laboratory and reviews of Lead Laboratory owned documents; and the OQA organization, the M&O QA organization, and the Lead Laboratory QA organization for the review of documents implemented by the OCRWM, the M&O, and/or the Lead Laboratory jointly.

Quality Assurance (QA) Record–A completed document (or other medium) that furnishes evidence of the quality of items and/or activities affecting quality. (NQA-1-1983, Supplement S-1)

Readiness Review–A systematic assessment of the preparedness of an organization to start or continue a process or project phase.

Regression Testing–Selective retesting of a system or component to verify that modifications have not caused unintended effects and that the system or component still complies with its specified requirements. (IEEE Std. 610.12-1990)

Related Activities-Those activities that, if not properly controlled, could affect the quality of SSCs.

Release (Software)–The formal notification and distribution of approved software.

Remedial Action–The actions taken to correct specifically identified conditions adverse to quality.

Repair–The process of restoring a nonconforming characteristic to a condition such that the capability of an item to function reliably and safely is unimpaired even though that item still does not conform to the original requirement. (NQA-1-1983, Supplement S-1)

Rework–The process by which an item is made to conform to original requirements by completion or correction. (NQA-1-1983, Supplement S-1)

Right of Access–The right of a purchaser or designated representative to enter the premises of a principal contractor/supplier for the purposes of inspection, surveillance, or quality assurance audit. (NQA-1-1983, Supplement S-1)

Root Cause–The identified cause of a condition adverse to quality that, if corrected, will preclude recurrence or greatly reduce the probability of recurrence of the same or a similar condition adverse to quality.

Sample (Physical)–A physical part of a whole whose properties are studied to gain information about the whole.

Scientific Investigation–An analysis consisting of an explanation, observation, identification, description, or experimental study either of natural phenomena or of engineered materials that describe the postclosure repository system or its performance.

Scientific Notebook–A record of the methodology and results of scientific investigations that is used when the work involves a high degree of professional judgment or trial and error methods or both.

Service–The performance of activities such as design, fabrication, inspection, nondestructive examination, repair, or installation. (NQA-1-1983, Supplement S-1)

Significant Condition Adverse to Quality–A condition adverse to quality that, if uncorrected, could have a serious effect on safety, operability, or the ability to isolate waste. Significant conditions adverse to quality include, but are not limited to (1) loss, or potential loss, of a safety or waste-isolation function to the extent that there is a reduction in the degree of protection provided to the public health and safety; (2) loss, or potential loss, of a safety or waste-isolation function to the extent that there is a reduction in the degree of protection provided for worker safety; (3) common-cause failures; and (4) any adverse quality trends. Additionally, repetitive conditions that are less significant but when taken collectively (1) indicate programmatic failure to properly implement the QA program, (2) may be precursors for a significant technical deficiency or problem or, (3) may reduce the margin of safety are considered to be significant conditions adverse to quality. (NQA-1-1983, Supplement S-1, Modified)

Site Characterization–The program of exploration and research, both in the laboratory and in the field, undertaken to establish the geologic conditions and the ranges of those parameters of the

Yucca Mountain site, and the surrounding region to the extent necessary, relevant to the procedures under 10 CFR 63. Site characterization includes borings, surface excavations, excavation of the exploratory shafts and/or ramps, limited subsurface lateral excavations and borings, and in situ testing at a depth needed to determine the suitability of the site for a geologic repository. (10 CFR 63.2)

Software–Computer programs and associated documentation, and data pertaining to the operation of a computer system. (NQA-1-2000, Part I, Section 400)

Software Baseline–A specification or product that (1) has been formally reviewed and agreed upon, (2) thereafter is the basis for further development, and (3) can be changed only through formal change procedures.

Software Design Verification–The process of determining if the product of the software design activity fulfills the software design requirements. (NQA-1-2000, Subpart 2.7, Section 102)

Software Development Cycle–The activities that begin with the decision to develop a software product and end when the software is delivered. The software development cycle typically includes the following activities: (1) software design requirements, (2) software design, (3) implementation, (4) test, and sometimes (5) installation. (NQA-1-2000, Subpart 2.7, Section 102)

Software Engineering–(a) The application of a systematic, disciplined, quantifiable approach to the development, operation, and maintenance of software, that is, the application of engineering to software; and (b) the study of the approaches as in (a). (NQA-1-2000, Subpart 2.7, Section 102)

Software Item–Source code, object code, job control code, control data, or a collection of these items that function as a single unit. (IEEE Std. 610.12-1990)

Software Life Cycle–The activities that comprise the evolution of software from conception to retirement. The software life cycle typically includes the software development cycle phases and the activities associated with operation, maintenance, and retirement. (NQA-1-2000, Subpart 2.7, Section 102)

Software Life Cycle Element–A fundamental, constituent part of a life cycle phase. For example, the requirements phase consists of the individual requirements, the design phase consists of the individual design elements and the individual test cases, the implementation phase consists of source code and user instructions, and the testing phase consists of documented test results.

Software Operating Environment–A collection of software, firmware, and hardware elements that provide for the execution of computer programs. (NQA-1-2000, Subpart 2.7, Section 102)

Software Tool–A computer program used in the development, testing, analysis, or maintenance of a program or its documentation. Examples include comparators, cross-reference generators,

compilers, Computer Aided Software Engineering (CASE) tools, configuration and code management software, decompilers, disassemblers, editors, flowcharts, monitor test case generators, and timing analyzers. (NQA-1-2000, Subpart 2.7, Section 102)

Software Validation–The testing and evaluation of completed software to ensure compliance with specified software requirements.

Software Verification–The process of determining whether or not the product(s) of a given phase of the software development cycle fulfills the requirements imposed by the previous phase. (IEEE Std. 610.12-1990, Modified)

Special Process–A process, the results of which are highly dependent on the control of the process or the skill of the operators, or both, and in which the specified quality cannot be readily determined by inspection or test of the product. (NQA-1-1983, Supplement S-1)

Stop Work Order–A formal directive issued by management that work must be stopped until resolution of the related significant condition adverse to quality.

Substantial Safety Hazard–A loss of safety function to the extent that there is a major reduction in the degree of protection provided to public health or safety for any facility or activity licensed pursuant to 10 CFR 63. (10 CFR 21.3)

Superseded Document–A document that has been replaced by a revised or new document.

Supplier–Any individual or organization (except principal contractors) that furnishes items or services in accordance with a procurement document. An all-inclusive term used in place of any of the following: vendor, seller, contractor, subcontractor, fabricator, consultant, and their subtier levels.

Support Software–Software that aids in the development and maintenance of other software (e.g., compilers, loaders, and other utilities), including software tools and system software. (IEEE Std. 610.12-1990)

Surveillance–The act of monitoring or observing to verify whether an item or activity conforms to specified requirements. (NQA-1-1983, Supplement S-1)

System Software–Software designed to enable the operation and maintenance of a computer system and its associated computer programs (e.g., operating systems, assemblers, and utilities). (NQA-1-2000, Subpart 2.7, Section 102)

Technical Assessment–When used for data qualification, an evaluation of the technical merit of unqualified data against established criteria.

Technical Report–As it pertains to scientific investigation, a document that presents scientific information such as data, analyses, interpretations, or conclusions.

Technical Specialist–An individual who is assigned to an audit team when the scope, complexity, or special nature of the work to be audited warrants assistance from a technical standpoint.

Test Case–A set of test inputs, execution conditions, and expected results developed for a particular objective, such as to exercise a particular program path or to verify compliance with a specific requirement. (NQA-1-2000, Subpart 2.7, Section 102)

Test Plan (procedure)–A document that describes the approach to be followed for testing a system or component. Typical contents identify items to be tested, tasks to be performed, and responsibilities for the testing activities. (NQA-1-2000, Subpart 2.7, Section 102)

Testing–An element of verification for the determination of the capability of an item to meet specified requirements by subjecting the item to a set of physical, chemical, environmental, or operating conditions. (NQA-1-1983, Supplement S-1)

Testing (Software)–The process of operating a system (i.e., software and hardware) or system component under specified conditions, observing and recording the results, and making an evaluation of some aspect of the system (i.e., software and hardware) or system component in order to verify that it satisfies specified requirements and to identify errors. (NQA-1-2000, Subpart 2.7, Section 102)

Traceability–The ability to trace the history, application, or location of an item and like items or activities by means of recorded identification. (NQA-1-1983, Supplement S-1)

Training–A systematic process provided to personnel so that they achieve proficiency, maintain proficiency, and adapt to changes in technology, methods, processes, or responsibilities as necessary to perform assigned tasks. (NQA-1-1989, Supplement 2S-4, Paragraph 4)

Transparent–A document sufficiently detailed as to purpose, method, assumptions, inputs, conclusions, references, and units such that a person technically qualified in the subject can understand the document and ensure its adequacy without recourse to the originator.

Unqualified Data (Existing Data)–

A. Unqualified data includes:

(i) Data developed prior to the implementation of a 10 CFR 60, Subpart G, or 10 CFR 63, Subpart G, Quality Assurance program, or

(ii) Data developed outside the Yucca Mountain Project, such as by oil companies, national laboratories, or universities, or

(iii) Data published in technical or scientific publications. (NUREG-1298, 2/88).

B. Unqualified data does not include established fact.

Use-As-Is–A disposition permitted for a nonconforming item when it can be established that the item is satisfactory for its intended use. (NQA-1-1983, Supplement S-1)

Verification–The act of reviewing, inspecting, testing, checking, auditing, or otherwise determining and documenting whether items, processes, services, or documents conform to specified requirements. (NQA-1-1983, Supplement S-1).

Waste Custodian–The term waste custodian refers to an organizational entity that is in possession of HLW or SNF planned for disposition at the geologic repository. The term includes commercial nuclear utilities, and federal waste custodians (e.g., the DOE EM and the NNPP).

Witness Point–A step in a document that requires notification to the specifying individual or organization that the activity is scheduled to take place. Work may proceed after notification.

Work–Activities related to SSCs that are within the scope of the QARD.

Commitment Document Positions

A. OCRWM commits to the following documents with the associated modifications:

1. NQA-1-1983, Supplement S-1, *Terms and Definitions*–In lieu of the terms and definitions provided in this supplement, OCRWM will utilize the terms and definitions as delineated in this glossary. The terms and definitions in this glossary are consistent with Supplement S-1.

2. DOE O 414.1C, Section 7, *Definitions*–In lieu of the terms and definitions provided in this Order, OCRWM will utilize the terms and definitions as delineated in this glossary.