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Revision 8

U.S. DEPARTMENT OF ENERGY

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

QUALITY ASSURANCE REQUIREMENTS AND DESCRIPTION

FOR THE

CIVILIAN RADIOACTIVE WASTE MANAGEMENT PROGRAM

EFFECTIVE DATE: 06/05/98

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Enclosure 2

REVISION HISTORY

REVISION	REVISION DESCRIPTION	EFFECTIVE DATE
0	Initial issue. This document consolidates the *Quality Assurance Requirements Document* and the *Quality Assurance Program Description Document* into one document.	12/18/92
1	Revised Section 1.0, Organization, to reflect OCRWM reorganization.	07/21/94
2	Revised Section 7.0, Control of Purchased Items and Services, to accommodate the transfer of responsibility for the performance of audits from Affected Organizations to OCRWM OQA.	03/27/95
3	Revised Appendix B, Storage and Transportation to provide an exception to the *Quality Assurance Requirements and Description* for organizations working under the provisions of 10 CFR 71, Subpart C or 10 CFR 72, Subpart L.	07/13/95
4	Revised Appendix B, to reflect editorial change to correct 10 CFR Subpart reference.	08/04/95
5	Revised the following sections to incorporate changes requested by various Affected Organizations. • Section RevHist, Revision History • Section TOC, Table of Contents • Section Policy, Quality Assurance Policy • Section Intro, Introduction • Section 1.0, Organization • Section 2.0, Quality Assurance Program • Section 3.0, Design Control • Section 4.0, Procurement Document Control • Section 5.0, Implementing Documents • Section 6.0, Document Control • Section 7.0, Control of Purchased Items and Services • Section 8.0, Identification and Control of Items • Section 9.0, Control of Special Processes • Section 12.0, Control of Measuring and Test Equipment • Section 14.0, Inspection, Test and Operating Status • Section 15.0, Nonconformances	10/31/95

REVISION	REVISION DESCRIPTION	EFFECTIVE DATE
	• Section 16.0, Corrective Action • Section 17.0, Quality Assurance Records • Section 18.0, Audits • Supplement I, Software • Supplement II, Sample Control • Supplement III, Scientific Investigation • Supplement V, Control of the Electronic Management of Data • Appendix A, High-Level Waste Form Production • Appendix C, Mined Geologic Disposal System • Glossary New section added to incorporate Supplement V, Control of the Electronic Management of Data	
6	Revised the following sections to incorporate changes as noted: • Section RevHist, Revision History. • Section TOC, Table of Contents. • Section 3.0, Design Control - Revised to reinstate requirement addressing design calculations. • Section 6.0, Document Control - Revised to eliminate inconsistency with Section 2.2.10. • Section 17.0, Quality Assurance Records - Revised to delete the term authentication from the QARD. • Supplement III, Scientific Investigation - Revised to clarify that data shall be identified in a manner that facilitates traceability to the qualification status, clarify requirement for data review, establish requirement for review of technical reports, clarify when unqualified data relied upon to address safety and waste isolation issues must be qualified, and clarify model validation requirements. • Glossary - Deleted term and definition of authentication.	03/03/97
7	Revised the following sections to incorporate changes as noted: • Section RevHist, Revision History • Section TOC, Table of Contents • Section 1.0, Organization - Revised to reflect transition of QA functions and reorganization of OCRWM • Section 2.0, Quality Assurance Program - Revised to reflect transition of QA functions • Section 3.0, Design Control - Revised to reflect transition of QA functions • Section 7.0, Revised 7.2.2B to allow for the transition of QA functions • Appendix B, Revised to clarify applicability of 10 CFR 72 to ancillary equipment • Appendix C, Revised to clarify MGDS requirements for procurement of analytical services in support of scientific investigations	06/02/97

REVISION	REVISION DESCRIPTION	EFFECTIVE DATE
8	Revised the following sections to incorporate changes as noted: • Section RevHist, Revision History. • Section TOC, Table of Contents. • Section Intro, Introduction - Modified Figure Intro-1 (Source Documents) to add NUREG-1563 as a guidance document for the use of expert elicitation. • Section 2.0, Quality Assurance Program - Revised Subsection 2.2.11, Quality Assurance Program Information Management to correct typographical error. Revised Subsection 2.2.12, Personnel Qualification to incorporate a graded approach to training and qualification. Revised Subsection 2.2.13, Qualification of Personnel Who Perform Inspection, Nondestructive Examination, Testing, and Auditing to explicitly state the special QA functions. • Supplement I, Software-Modified Subsection I.1 to clarify applicability of Supplements I and V. Deleted "baseline" in I.2.1.C.1. • Supplement III, Scientific Investigation - Subsection III.2.4, Data Review, Adequacy, and Usage and Subsection III.2.5, Technical Report Review were rewritten. This establishes new categories (qualified, accepted, and existing) for data and adds technical assessment as an alternative method for qualification of data. • Appendix C, Mined Geologic Disposal System - Added new Subsection C.2.1, to define requirements for conducting expert elicitation. • Glossary - Added definitions of special terms used in Appendix C, Expert Elicitation (i.e., expert elicitation, generalist, normative expert, and subject-matter expert). Added definitions of special terms used in Supplement III (i.e., accepted data, acquired data, developed data, existing data and technical report). Modified definition of "qualified data." • This revision was initiated by Document Action Request Number 2054.	06/05/98

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The *Quality Assurance Requirements and Description* (QARD) is the principal Quality Assurance (QA) document for the Civilian Radioactive Waste Management Program (Program). It establishes the minimum requirements for the QA program. The QARD contains regulatory requirements and program commitments necessary for the development of an effective QA program. Implementing documents must be based on, and be consistent with the QARD.

The QARD applies to the following:

1. Acceptance of spent nuclear fuel and high-level waste.
2. Transport of spent nuclear fuel and high-level waste.
3. Storage of spent nuclear fuel through receipt of storage cask certification or a facility operating license.
4. Mined Geologic Disposal System (MGDS), including the site characterization activities [Exploratory Studies Facility (ESF) and surface based testing], through receipt of an operating license.
5. High-level waste form development through qualification, production, and acceptance.
6. Characterization of DOE spent nuclear fuel, and conditioning through acceptance of DOE spent nuclear fuel.

Section 2.0, Quality Assurance Program, defines in greater detail criteria for determining work subject to the QARD.

The QARD is organized into sections, supplements, appendices, and a glossary. The sections contain requirements that are common to all Program activities. The supplements contain requirements for specialized activities. The appendices contain requirements that are specific to high-level waste form production, storage and transportation, and Mined Geologic Disposal System. The glossary establishes a common vocabulary for the QA program.

The QARD provides for both the achievement and verification of quality. The line organization has total responsibility for meeting the quality requirements, and individuals are responsible for the quality of their work. Therefore the line organization is responsible for the implementation of the QA program. The line organization and the QA organization share responsibility for the verification of quality. The Director, OCRWM retains responsibility for the total QA program; ensures its development, implementation, and verification; and retains ultimate review and approval authority on matters pertaining to the implementation of the QA program.

The line organizations develop implementing documents that translate applicable QARD requirements into work processes. In addition, each Affected Organization must develop a matrix that identifies where QARD requirements are contained in their implementing documents.

QARD requirements are derived from the regulatory and industry documents listed in Figure Intro-1. These source documents fall into one of three categories: regulatory documents, commitment documents, or guidance documents.

A. Regulatory documents define the requirements necessary for obtaining licenses issued by the Nuclear Regulatory Commission. Regulatory documents are reviewed upon revision, and changes are appropriately incorporated into the QARD.

B. Commitment documents are imposed by management because they are necessary for the development and implementation of an effective QA program. Commitment documents are reviewed upon revision, and changes are incorporated into the QARD on a case-by-case basis.

C. Guidance documents provide additional information useful in developing a QA program. Guidance documents are reviewed upon revision, and changes are incorporated into the QARD on a case-by-case basis.

Figure Intro-1
SOURCE DOCUMENTS

Regulatory Documents	
10 CFR 50, Appendix B (Current) -	Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants
10 CFR 60, Subpart G (Current) -	Quality Assurance
10 CFR 71, Subpart H (Current) -	Quality Assurance
10 CFR 72, Subpart G (Current) -	Quality Assurance
10 CFR 73, (Current) -	Physical Protection of Plants and Materials
Commitment Documents	
NQA-1 (1989) -	Quality Assurance Program Requirements for Nuclear Facilities
- Basic Requirements:	1 through 18
- Supplements:	1S-1, 2S-1, 2S-2, 2S-3, 2S-4, 3S-1, 4S-1, 6S-1, 7S-1, 8S-1, 9S-1, 10S-1, 11S-1, 12S-1, 13S-1, 15S-1, 17S-1, and 18S-1
- Appendices:	2A-1 and 2A-3
NRC Review Plan (Revision 2) -	U. S. Nuclear Regulatory Commission Review Plan for High-Level Waste Repository Quality Assurance Program Descriptions
NUREG-1297 (2/88) Staff Position -	Peer Review for High-Level Nuclear Waste Repositories
NUREG-1298 (2/88) Staff Position -	Qualification of Existing Data for High-Level Nuclear Waste Repositories
Guidance Documents	
NQA-2 (1989) -	Quality Assurance Requirements for Nuclear Facility Applications
NQA-3 (1989) -	Quality Assurance Program Requirements for the Collection of Scientific and Technical Information for Site Characterization of High-Level Nuclear Waste Repositories
NUREG-0856 (1983) -	Final Technical Position on Documentation of Computer Codes for High-Level Waste Management
NUREG-1318 (1988) Staff Position -	Technical Position on Items and Activities in the High-Level Waste Geologic Repository Program Subject to Quality Assurance Requirements
NUREG-1563 (1996) -	Branch Technical Position on the Use of Expert Elicitation in the High-Level Radioactive Waste Program
Regulatory Guide 1.28 (Revision 3) -	Quality Assurance Program Requirements (Design And Construction)
Regulatory Guide 7.10 (Revision 1) -	Establishing Quality Assurance Programs for Packaging Used in the Transportation of Radioactive Material

2.1 GENERAL

This section establishes requirements for planning, implementing, and maintaining the Quality Assurance (QA) program. This section also establishes requirements for special topics related to the QA program. The QA program establishes requirements to ensure that work meeting the criteria described in Subsection 2.2.2, Classifying Items, Subsection 2.2.3, Controlling Activities, and Subsection 2.2.4, Applying Quality Assurance Controls, is performed under suitably controlled conditions including the use of appropriate equipment, suitable environmental conditions for accomplishing the activity, and assurance that prerequisites for a given activity have been satisfied.

2.2 REQUIREMENTS

2.2.1 Quality Assurance Program Documents

A. Affected Organizations shall issue a policy statement signed by senior line management directing mandatory compliance with this QA program.

B. Affected Organizations shall establish implementing documents applicable to their scope of work that translate *Quality Assurance Requirements and Description* (QARD) requirements into work processes. The following requirements apply to implementing documents.

1. Each Affected Organization shall establish a structured system of implementing documents that provides for top down implementation of the QARD or, if stipulated in procurement documents, shall work to the implementing documents of another Affected Organization.

2. The system 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 system shall provide positive control over external interfaces between Affected Organizations and internal interfaces within an organization.

4. Each Affected Organization shall review revisions to the QARD and incorporate changes into their implementing documents, as appropriate.

C. Each Affected Organization shall complete a QARD requirements matrix for the portion of the QARD which they are implementing.

1. The matrix shall identify:

a. Where the QARD requirements are directly addressed.

b. Where QARD requirements are not applicable based on scope of work.

c. Where exceptions to QARD requirements have been taken including justification.

2. Initial QARD requirements matrices shall be reviewed by OQA in accordance with QARD Subsection 2.2.10, Document Review.

3. As changes are made to implementing documents each Affected Organization shall ensure that respective QARD requirements matrices are revised if necessary.

4. Changes to QARD requirements matrices shall be reviewed by the QA organization in accordance with Subsection 2.2.10.

2.2.2 Classifying Items

The QA program shall apply to the following, which shall be included on a *Q-List*.

A. Items important to public radiological safety as described in 10 Code of Federal Regulations (CFR) Parts 60, 71, and 72.

B. Items and natural barriers important to waste isolation as described in 10 CFR Part 60.

C. Items required for the control and management of site-generated radioactive waste other than spent fuel and high-level waste.

D. Items required for the protection of items important to safety and waste isolation from the hazards of fire.

E. Items not intended to perform a safety function but whose failure could impair the capability of other items to perform their intended safety or waste isolation function.

F. Items required for physical protection as defined by 10 CFR Part 73.

G. Items required to control occupational radiological exposure.

2.2.3 Controlling Activities

A. The QA program shall apply to site characterization data and samples.

Note: Site characterization for the purpose of QA program applicability includes activities related to sample collection and the collection and analysis of data to support performance confirmation or performance assessments.

B. The QA program shall apply to activities related to the items on a *Q-List* (such as design, procurement, construction, fabrication, production, handling, packaging, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, modification, and decontamination).

C. The QA program shall apply to those activities that provide data used to assess the potential dispersion of radioactive materials from the licensed facility.

D. The QA program shall apply to activities related to the high-level waste form development through qualification, production, and acceptance.

E. The QA program shall apply to activities associated with characterization of DOE spent nuclear fuel, and conditioning through acceptance of DOE spent nuclear fuel.

2.2.4 Applying Quality Assurance Controls

QA controls (grading) shall be applied to the degree commensurate with the:

A. Function or end use of the item.

B. Consequence of failure (risk) of the item.

C. Importance of the data being collected or analyzed.

D. Complexity of design or fabrication of the item or design or implementation of the activity.

E. Reliability of the process.

F. Reproducibility of the results.

G. Uniqueness of the item or degree of standardization.

H. History of the item or service quality.

I. Necessity for special controls or processes.

J. Degree to which functional compliance can be demonstrated through inspection or test.

2.2.5 Planning Work

Planning shall be documented to ensure work is accomplished under suitably controlled conditions. Planning elements shall include, as appropriate:

A. Definition of the work scope, objectives, and a listing of the primary tasks involved.

B. Identification of scientific approach or technical methods used to collect, analyze, or study results of applicable work.

C. Identification of applicable standards and criteria.

D. Identification and selective application, or development, of appropriate implementing documents.

E. Identification of field and laboratory testing equipment, or other equipment.

F. Identification of, or provisions for the identification of, required records and the recording of objective evidence of the results of the work performed.

G. Identification of QA program verifications of the work performed.

H. Identification of prerequisites, special controls, environmental conditions, processes, or skills.

I. Identification of computer software.

2.2.6 Surveillances

Surveillances shall be conducted to evaluate the quality of selected work subject to the QARD. Surveillances shall be:

A. Conducted to verify the quality of work in progress; to identify conditions adverse to quality; to ensure that prompt corrective action is taken by management responsible for performing the work; and to verify the timely implementation, adequacy, and effectiveness of corrective action.

B. Performed by personnel who are knowledgeable about, and not directly responsible for, the work under surveillance.

C. Documented in a report to appropriate management.

2.2.7 Management Assessments

The Office of Civilian Radioactive Waste Management shall perform or direct the performance of management assessments of Affected Organizations by personnel outside the QA organization. Management Assessment shall:

A. Be planned and documented, and performed annually.

B. Evaluate the:

1. Adequacy of resources and personnel provided to achieve and assure quality.

2. Adequacy of the QA program.

3. Effectiveness of the QA program.

C. Be documented and results shall be distributed to Affected Organization management.

2.2.8 Readiness Reviews

The need for readiness reviews shall be identified by Affected Organization management for major scheduled or planned work to ensure 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. Detailed implementing documents and management controls are available and approved.

2.2.9 Peer Reviews

A. Peer reviews shall be conducted when the adequacy of information or the suitability of implementing documents and methods essential to meet specified objectives cannot be established through testing, alternate calculations, or reference to previously established standards and practices.

The following conditions are situations for which a peer review shall be considered:

1. Critical interpretations or decisions will be made in the face of significant uncertainty, including the planning for data collection, research, or exploratory testing.

2. Decisions or interpretations having significant impact on performance assessment results will be made.

3. Novel or beyond the state-of-the-art testing, plans and procedures, or analyses will be utilized.

4. Detailed technical criteria or standard industry procedures are not available.

5. Results of tests are not reproducible or repeatable.

6. Data or interpretations are ambiguous.

7. Data adequacy is questionable (e.g., the data may not have been collected in conformance with an established QA program).

B. Management shall determine the need for and, as appropriate, shall initiate peer reviews when the adequacy of a critical body of information can be established by alternate means, but there is significant disagreement regarding the applicability or appropriateness of the alternate means.

C. In conducting a peer review, management shall ensure that the:

1. Number of the peer reviewers is commensurate with the complexity of work to be reviewed, its importance to Program objectives, the number of technical disciplines involved, the degree to which uncertainties in the data or technical approach exist, and the extent to which

differing viewpoints are strongly held within the applicable technical and scientific community concerning issues under review.

2. Collective technical expertise and qualifications of the peer reviewers span the technical issues and areas involved in the work to be reviewed, including differing bodies of scientific thought.

3. Technical areas central to the work to be reviewed receive appropriate proportional representation among the peer reviewers.

4. Potential for technical or organizational partiality is minimized.

5. Peer review group chairperson is identified.

D. Peer reviews shall be performed by individuals that have:

1. Technical qualifications in the review area at least equivalent to that needed for the work under review.

2. Technical credentials that are recognized and verifiable.

3. Independence from the work under review. Independence means that the individual was not involved as a participant, supervisor, technical reviewer or advisor in the work under review and is, to the extent practical, free from any funding considerations.

Note: In those cases where total independence cannot be met, the rationale as to why someone of equivalent technical qualification and greater independence was not selected shall be documented in the peer review report.

E. Initiation of the peer review shall require the development of a planning document that:

1. Specifies the work to be reviewed.

2. Identifies the size and spectrum of the peer review group.

3. Describes the expected method and reporting schedule.

4. Establishes review criteria that shall include, as appropriate:

a. Validity of the assumptions.

b. Alternate interpretations.

c. Adequacy of requirements and criteria.

d. Appropriateness and limitations of the methods and implementing documents used to complete the work under review.

e. Adequacy of application.

f. Accuracy of calculations.

g. Validity of conclusions.

h. Uncertainty of results and impact if wrong.

F. The peer review chairperson shall provide a report that:

1. Is signed by each peer reviewer or contains information detailing which peer reviewers have chosen not to sign and why.

2. States the work or issue that was reviewed and the conclusions of the review.

3. Includes individual statements by the peer reviewers reflecting dissenting views or additional comments, as appropriate.

4. Includes a listing of the peer reviewers and a statement that the qualifications and experience of each reviewer have been evaluated and are acceptable.

2.2.10 Document Review

Implementing documents and documents that specify technical or quality requirements shall be reviewed to the following requirements and for any additional requirements specified by the applicable section of the QARD.

A. Review criteria shall be established before performing the review. The criteria shall consider applicability, correctness, technical adequacy, completeness, accuracy, and compliance with established requirements.

B. Pertinent background information or data shall be made available to the reviewers by the organization requesting the review if the information is not readily available to the reviewer.

C. The review shall be performed by individuals other than the preparer.

D. Reviewers shall be technically competent for the subject area of the document being reviewed.

E. The scope of the review shall consider all aspects of the document.

1. Each organization or technical discipline affected by the document shall review the document according to the established review criteria. Changes to the document shall be reviewed by those organizations or technical disciplines affected by the change.

2. The QA organization shall review implementing documents and changes thereto that translate the QARD into work processes as described in Subsection 2.2.1, Quality Assurance Program Documents. The QA organization also shall review changes to other documents if

they were required to review the previous version, unless the QA organization has concurred that its review is no longer required.

F. Mandatory comments resulting from the review shall be documented and resolved before approving the document.

2.2.11 Quality Assurance Program Information Management

Affected Organization management shall on a continuing basis be apprised of the status, adequacy and compliance aspects of the QA Program. Appropriate management shall receive, as a minimum, audit reports, surveillance reports, trend reports and management assessment reports.

2.2.12 Personnel Qualification

A. Each Affected Organization shall indoctrinate and train personnel as follows:

1. Determine required indoctrination and training.

2. 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.

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

4. Ensure indoctrination and training are completed prior to performing the work.

5. 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. Applicable implementing documents.

   c. Job responsibilities and authority.

B. For personnel who perform or manage design, scientific investigation, software development activities and for personnel who verify or manage the verification of design, scientific investigation, software development activities, or items, Affected Organizations shall ensure that:

1. Descriptions are established for the positions those personnel occupy.

2. Minimum education and experience requirements are established for each position commensurate with the scope, complexity, and nature of the work or documented justification is provided for positions for which no specific minimum education and experience is required.

3. Personnel have experience and education commensurate with the minimum requirements established.

4. Minimum education and experience are verified or, when minimum education and experience cannot be verified, documented justification is provided for the personnel assignment.

2.2.13 Qualification of Personnel Who Perform Inspection, Nondestructive Examination, Testing, and Auditing

Personnel who perform inspection, nondestructive examination, testing, and auditing shall be qualified in accordance with the requirements of the applicable QARD section covering the activity and QARD Subsection 2.2.12, Personnel Qualification.