

DOE/RW-0333P
Revision 4

by Rev. S

U.S. DEPARTMENT OF ENERGY

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

QUALITY ASSURANCE REQUIREMENTS AND DESCRIPTION

FOR THE

CIVILIAN RADIOACTIVE WASTE MANAGEMENT PROGRAM

**INFORMATION
ONLY**

Donald G. Horton, Director
OCRWM Office of Quality Assurance

7/31/95
Date

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7.31.95
Date

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Policy Statement

The U.S. Department of Energy (DOE) is authorized by the Nuclear Waste Policy Act, as amended, to site, construct, and safely operate a geologic repository and a monitored retrievable storage facility. The Act also instructs the DOE to provide for the safe transportation of spent fuel to either the MRS or the geologic repository and transportation of high level radioactive waste to the geologic repository.

The Act established the Office of Civilian Radioactive Waste Management (OCRWM) within the DOE to carry out this mission. Central to our mission is the protection of the health and safety of the public and workers, and the quality of the environment.

As the Director of OCRWM, I have established the quality assurance requirements necessary to ensure these vital protections. This document, the *Quality Assurance Requirements and Description*, embodies these requirements. These requirements apply to every level of every organization participating in this mission.

The quality assurance provisions described in the *Quality Assurance Requirements and Description* have my unqualified support. All organizations performing work for OCRWM will use and comply with the *Quality Assurance Requirements and Description* to develop and implement a quality assurance program.


Daniel A. Dreyfus, Director
Office of Civilian Radioactive
Waste Management

Date 7/11/94



Office of Civilian Radioactive Waste Management

Quality Assurance Requirements and Description

Title: REVISION HISTORY

Effective Date: 08/04/95

Section: i

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REVISION HISTORY

REVISION	REVISION DESCRIPTION
0	Initial issue. This document consolidates the <i>Quality Assurance Requirements Document</i> and the <i>Quality Assurance Program Description Document</i> into one document.
1	Revised Section 1.0, Organization, to reflect OCRWM reorganization.
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.
3	Revised Appendix B, Storage and Transportation to provide an exception to the <i>Quality Assurance Requirements and Description</i> for organizations working under the provisions of 10 CFR 71, Subpart C or 10 CFR 72, Subpart L.
4	Revised Appendix B, to reflect editorial change to correct 10 CFR Subpart reference.



Office of Civilian Radioactive Waste Management

Quality Assurance Requirements and Description

Title: INTRODUCTION

Effective Date: 12/18/92

Section No.: ii

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

The QARD applies to the following:

1. acceptance of spent nuclear fuel and high-level radioactive waste.
2. transport of spent nuclear fuel and high-level radioactive waste.
3. the Monitored Retrievable Storage (MRS) facility through application for an operating license.
4. Mined Geologic Disposal System (MGDS), including the site characterization activities (exploratory studies facility (ESF) and surface based testing), through application for an operating license.
5. the high-level-waste form from production through acceptance.

Section 2.0 defines in greater detail criteria for determining work subject to QARD requirements.

The QARD is organized into sections, supplements, appendices, and a glossary. The sections contain requirements that are common to all Program elements. The supplements contain requirements for specialized activities. The appendices contain requirements that are specific to an individual Program element. The glossary establishes a common vocabulary for the Quality Assurance Program.

The QARD provides for both the achievement and the 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 quality assurance program. The line organization and the quality assurance organization share responsibility for the verification of quality. The Program Director retains responsibility for the total quality assurance program; ensures its development, implementation, and verification; and retains ultimate review and approval authority on matters pertaining to the implementation of the quality assurance program requirements.

The line organizations need to 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.

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QARD requirements are derived from the regulatory and industry documents listed in Figure ii-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 quality assurance 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 quality assurance program. Guidance documents are reviewed upon revision, and changes are incorporated into the QARD on a case-by-case basis.

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Figure ii-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

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
- 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



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Office of Civilian Radioactive Waste Management

Quality Assurance Requirements and Description

Title: ORGANIZATION

Effective Date: 07/21/94

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1.1 GENERAL

This section establishes requirements for creating and maintaining an organizational structure to implement the Quality Assurance Program for the Civilian Radioactive Waste Management Program. This section also provides a description of the OCRWM organization and other affected organizations.

1.2 REQUIREMENTS

Each affected organization shall prepare controlled documents, accepted by the responsible organization with immediate authority over the affected organization (next-higher-level organization), that describe internal and external organizational interfaces, organizational structures, requirements, and responsibilities for its scope of work.

1.2.1 Line Management

Each affected organization shall identify the responsibilities and authorities of those organizations and management positions responsible for achieving and maintaining quality.

1.2.2 Quality Assurance Management

Each affected organization shall identify the management position within the organization responsible for performing quality assurance functions. This position shall be occupied by an individual with appropriate knowledge and experience in management and quality assurance. The position shall:

- A. Be at the same or higher organization level as the highest line manager directly responsible for performing work subject to QARD requirements.
- B. Be sufficiently independent from cost and schedule considerations.
- C. Have the organizational freedom to effectively communicate with other senior management positions.
- D. Be responsible for interpreting and approving quality assurance program requirements as they apply to the affected organization's scope of work.
- E. Have no other assigned responsibilities unrelated to the quality assurance program that would prevent full attention to quality assurance matters.
- F. Be responsible for identifying quality problems, initiating, recommending, or providing solutions to quality problems, and verifying solutions to quality problems.

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- G. Be responsible for verifying the proper establishment and execution of the quality assurance program.
- H. Have the authority to stop work when significant conditions adverse to quality warrant such action.

1.2.3 Responsibility for Quality

Quality shall be achieved and maintained by those who have been assigned responsibility for performing work. Quality achievement shall be verified by persons or organizations not directly responsible for performing the work.

1.2.4 Delegation of Work

Positions or organizations responsible for establishing and executing the quality assurance program may delegate work to other organizations. The positions or organizations making the delegation shall retain overall responsibility for the delegated work.

1.2.5 Resolution of Quality Disputes

Differences of opinion involving quality assurance program requirements shall be brought to the attention of the appropriate management and, if not resolved, shall be elevated progressively to successively higher levels of management.

1.3 DESCRIPTION

1.3.1 General Description of the Office of Civilian Radioactive Waste Management

- A. OCRWM is comprised of the Office of the Director; the Offices of Quality Assurance; Waste Acceptance, Storage and Transportation; Program Management and Integration; Human Resources and Administration; and the Yucca Mountain Site Characterization Office. The Yucca Mountain Site Characterization Office is headed by a Project Manager. The remaining offices are headed by Office Directors. The Project Manager and Office Directors report to the Director, OCRWM. The OCRWM organization is illustrated in Figure 1-1.
- B. OCRWM's functions are described in official mission and function statements, approved by the Assistant Secretary, Office of Human Resources and Administration.
 - 1. All references to OCRWM responsibilities and functions in the QARD are intended only as summarizations of those official functions and are in no way intended to replace or supplement the official statements.
 - 2. Any substantial OCRWM reorganization of descriptions or functions of the offices described herein, will require a revision to this document.

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1.3.2 Specific Civilian Radioactive Waste Management Offices

A. Office of the Director

The Office of the Director has been delegated overall responsibility for carrying out the functions of the Secretary of Energy as prescribed in the Nuclear Waste Policy Act, as amended.

B. Office of Quality Assurance (OQA)

1. The OQA is responsible for providing guidance and direction to the line organization on quality assurance matters relating to OCRWM activities, developing the OCRWM quality assurance program and managing the quality concerns program. The OQA is also responsible for the overview of work subject to QARD requirements and environmental, safety and health activities. This overview includes the verification of the OCRWM line organization's achievement and quality of work through audits, surveillances, or other means of verification, as appropriate.
2. The OQA is responsible for reporting the overview findings to senior management.

C. Office of Waste Acceptance, Storage and Transportation (OWAST)

The OWAST is responsible for managing the standard contracts for disposal of spent nuclear fuel and/or high level radioactive waste; collection of data to support the acceptance and transportation of spent nuclear fuel from contract holders; studies to determine technical waste acceptance criteria; environmental assessments; Nuclear Regulatory Commission (NRC) license application for OCRWM operated storage facilities; cask design, testing, certification and acquisition; economic and engineering analysis for transportation system development; and transportation operations support, including cask maintenance. The OWAST is also responsible for developing and coordinating the implementation of safeguards and security for the OCRWM program.

D. Office of Program Management and Integration (OPMI)

The OPMI is responsible for program control and project management system policy, requirements, and guidance; the overall OCRWM program Work Breakdown Structure (WBS); development of overall OCRWM budgets; OCRWM systems engineering activities and technical baselines at the program level; configuration management system and OCRWM Change Control Boards; supporting the system elements/project in identifying and resolving site suitability and licensing regulatory issues related to the Monitored Retrievable Storage (MRS) facility or Mined Geologic Disposal System (MGDS) license application, and cask/canister certifications; integrating the MGDS with the multipurpose canister (MPC) and transportation elements of the OCRWM program; program wide system to provide reporting on commitments made by or to OCRWM, to or from the NRC.

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E. Office of Human Resources and Administration (OHRA)

The OHRA is responsible for headquarters training program; verification of OCRWM personnel qualifications; program wide Total Quality Management (TQM) program; coordinating the OCRWM Ombudsman Program; OCRWM Information Systems; OCRWM Headquarters Records Management System, the Central Records Facility, and the Quality Records Center. In addition, the OHRA manages the procurement/business activities associated with the management and operating contract and all other OCRWM contracts program-wide and overseeing and administering the award fee process for the Management and Operating Contractor.

F. Yucca Mountain Site Characterization Office (YMSCO)

The YMSCO is responsible for directing the Yucca Mountain Site Characterization Project (YMP); scientific evaluations needed to determine whether the Yucca Mountain candidate site is suitable for a geologic repository; waste-package and repository design and development; integrating the MGDS with the waste acceptance storage and transportation elements of the OCRWM program; MGDS Environmental Impact Statement (EIS); and the preparation and submittal to the NRC of a license application for the MGDS should the Yucca Mountain Site be found suitable. The YMSCO is also responsible for YMP information resources management and records management programs; YMP training program; and the YMP radiological program.

1.3.3 Other Affected Organizations

A. DOE Operations Offices

1. The Idaho and Oak Ridge Operations Offices are responsible for overall line management and implementation of assigned tasks. These Operations Offices establish a management organization and delegate responsibility and authority for management and direction of Program tasks. These Operations Offices have direct, primary responsibility and accountability for the execution and implementation of Program work; are points of contact for the flow of information to and from the Director, OCRWM and other affected organizations; and are responsible for complying with the QARD requirements.
 - a. The Idaho Operations Office provides support for waste transportation cask development.
 - b. The Oak Ridge Operations Office provides geoscience, shielding, systems integration, operations, and public relations support.
2. The other Operations Offices are contract holders through management agreements and have administrative responsibility only. Technical direction is performed by OCRWM. These Operations Offices are:
 - a. Richland Operations Office - The Richland Operations Office provides administrative support for the work performed by Pacific Northwest Laboratories (PNL);

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- b. Albuquerque Operations Office - The Albuquerque Operations Office provides administrative support for work performed by Los Alamos National Laboratory (LANL) and Sandia National Laboratories (SNL);
- c. Oakland Operations Office - The Oakland Operations Office provides administrative support for work performed by Lawrence Livermore National Laboratory (LLNL) and Lawrence Berkeley Laboratory (LBL).

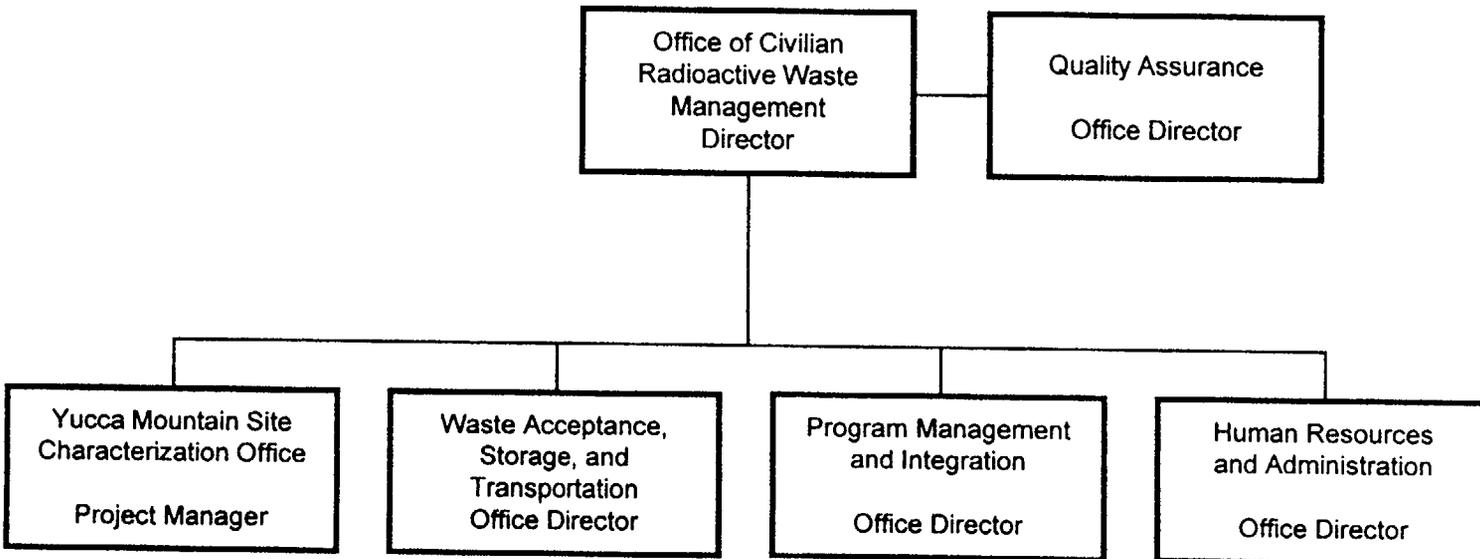
B. OCRWM-Managed Affected Organizations

OCRWM-managed affected organizations perform work subject to QARD requirements in accordance with the controls established in their respective implementing documents. The QARD requirements for each OCRWM-managed affected organization are identified in the appropriate procurement documents. OCRWM provides an overview of affected organization work subject to QARD requirements by using appropriate verification methods.

C. OCRWM Direct-Support Affected Organizations

OCRWM direct-support organizations perform work subject to QARD requirements in accordance with controls established in OCRWM implementing documents.

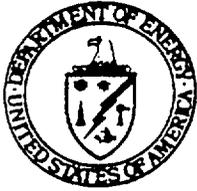
- D. For affected organizations performing work in accordance with Memoranda of Understanding (MOUs) or Memoranda of Agreement (MOAs) rather than in accordance with procurement documents, appropriate technical and Quality Assurance requirements shall be incorporated into the MOU or MOA.



OCRWMORG.136/6-27-94

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

Figure 1-1



Office of Civilian Radioactive Waste Management

Quality Assurance Requirements and Description

Title: QUALITY ASSURANCE PROGRAM

Effective Date: 12/18/92

Section No.: 2.0

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2.1 GENERAL

This section establishes requirements for planning, implementing, and maintaining the Quality Assurance Program. This section also establishes requirements for special topics related to the quality assurance program.

2.2 REQUIREMENTS

2.2.1 Quality Assurance Program Objective

The Quality Assurance Program establishes requirements to ensure that work meeting the criteria described in the subsection entitled *Classifying Items and 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.

2.2.2 Quality Assurance Program Documents

- A. Affected organizations shall issue a policy statement signed by senior line management directing mandatory compliance with the quality assurance program.
- B. Affected organizations shall establish quality assurance implementing documents applicable to their scope of work that translate QARD requirements into work processes. The following requirements apply to quality assurance implementing documents.
 1. Each affected organization shall establish a structured system of quality assurance implementing documents that provides for top down implementation of QARD requirements or, if stipulated in procurement documents, shall work to the quality assurance implementing documents of the next-higher-level 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. An interface exists when one organization prescribes an activity or requirement to, or shares an activity or requirement with, another organization.

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4. Each affected organization shall review revisions to the QARD and incorporate changes into their quality assurance 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 addressed.
 - b. Where they are not applicable including justification.
 - c. Where exceptions to requirements have been taken including justification.
 2. The next-higher-level affected organization shall accept the requirements matrix, and shall grant authorization to initiate work once readiness has been verified.
 3. QARD requirements matrices are controlled according to the requirements of Section 6.0. The quality assurance organizations shall ensure that, as changes are made to the implementing documents, the respective QARD requirements matrices are revised if necessary, and sent to the next-higher-level affected organization for acceptance.
- D. As an alternate to C above, for suppliers of items and services, organizations may determine if the supplier's Quality Assurance program meets necessary QARD requirements using the supplier qualification process described in Section 7.0. If the supplier's Quality Assurance program meets the necessary QARD requirements, a QARD requirements matrix is not required.

2.2.3 Classifying Items and Applying Quality Assurance Controls

- A. The quality assurance program shall apply to the following, which shall be included on the Q-List maintained by OCRWM.
1. Items important to radiological safety as described in 10 CFR Parts 60, 71, and 72.
 2. Items important to waste isolation as described in 10 CFR Part 60.
 3. Items required for the control and management of site-generated radioactive waste other than spent fuel and high-level radioactive waste.
 4. Items required for the protection of items important to safety and waste isolation from the hazards of fire.

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5. 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.
 6. Items required for physical protection as defined by 10 CFR Part 73.
 7. Natural barriers important to waste isolation.
- B. The quality assurance program shall apply to site characterization data and samples.
- Note: Site characterization for the purpose of quality assurance program applicability includes activities related to sample collection and the collection and analysis of data to support performance confirmation or performance assessments.
- C. The quality assurance program shall apply to activities related to the items on the Q-List (such as design, procurement, construction, fabrication, production, handling, packaging, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, modification, decontamination, dismantling, decommissioning, and permanent closure). An activity shall take on the same level of importance as the item to which it pertains.
- D. The quality assurance program shall apply to those activities that provide data used to assess the potential dispersion of radioactive materials from the licensed facility.
- E. The quality assurance program shall apply to activities related to the high-level waste form from production through acceptance.
- F. For items on the Q-List, related activities, and activities associated with site characterization data and samples, quality assurance controls (grading) shall be applied to the degree commensurate with the:
1. Function or end use of the item.
 2. Consequence of failure (risk).
 3. Importance of the data.
 4. Complexity of design or fabrication of the item or design or implementation of the activity.
 5. Reliability of the process.
 6. Reproducibility of the results.
 7. Uniqueness of the item or degree of standardization.
 8. History of the item or service quality.

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9. Necessity for special controls or processes.
10. Degree to which functional compliance can be demonstrated through inspection or test.

2.2.4 Planning Work

Planning shall be performed 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 quality assurance program verifications to overview the work performed or the product produced.
- H. Identification of prerequisites, special controls, environmental conditions, processes, or skills.
- I. Identification of computer software.

2.2.5 Surveillances

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

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2.2.6 Management Assessments

Senior management of an affected organization shall perform or direct the performance of management assessments by personnel outside the quality assurance organization.

A. Management assessments shall be planned and documented, and performed annually.

B. Management assessments shall evaluate the:

1. Adequacy of the organizational structure and staff.
2. Adequacy and effectiveness of the quality assurance program.
3. Adequacy of the personnel qualification and training program.
4. Effectiveness of the nonconformance and corrective action program.
5. Adequacy of the quality assurance program management information tracking, evaluation, and reporting system.

2.2.7 Readiness Reviews

The need for readiness reviews shall be identified by 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.

2.2.8 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 in 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.

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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 quality assurance 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.

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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.

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- 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.

2.2.9 Document Review

Documents 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. These 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 originator.
- D. Reviewers shall be technically competent in the subject area 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 quality assurance organization shall review quality assurance implementing documents that translate QARD requirements into work processes as described in the subsection entitled *Quality Assurance Program Documents*. The quality assurance organization shall also review changes to documents if they reviewed the previous version, regardless of whether the quality assurance organization is affected by the change.
- F. Mandatory comments resulting from the review shall be documented and resolved before approving the document.

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2.2.10 Quality Assurance Program Information Management

- A. Affected organizations shall establish and maintain a quality assurance information system to facilitate effective communication of the status of the quality assurance program; status of resolution of issues, trends, and significant conditions adverse to quality; and summary of quality assurance overview results.
- B. Each manager of a quality assurance organization shall report quality assurance program information to internal management and to the quality assurance organization of the next-higher-level affected organization.

2.2.11 Personnel Selection, Indoctrination, Training, and Qualification

Each affected organization shall establish a program for the evaluation, selection, indoctrination, training, and qualification of personnel performing work subject to QARD requirements. The program shall:

- A. Evaluate each job position to determine whether the responsibilities of the position include performing work subject to QARD requirements.
- B. Establish descriptions for those positions that include work subject to QARD requirements.
- C. Ensure personnel are indoctrinated and trained, as needed, to achieve initial proficiency; maintain proficiency; and adapt to changes in technology, methods, or job responsibilities.
- D. Establish minimum education and experience requirements for each position commensurate with the scope, complexity, and nature of the work.
- E. Ensure personnel have the experience, education, training, and proficiency commensurate with the minimum requirements established.
- F. Ensure minimum education and experience are verified or, when minimum education and experience cannot be specifically verified, provide a statement and justification for the personnel assignment.
- G. Ensure supervisors evaluate and assess the need for additional indoctrination and training as assignments, positions, and implementing documents change.
- H. Ensure the required indoctrination and training for a specified task is completed prior to performing the task.
- I. Ensure records on individuals generated by training and qualification programs are collected and maintained.

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- J. Ensure personnel are indoctrinated in the following topics as they relate to a particular function:
1. General criteria, including the QARD, applicable codes, regulations, and standards.
 2. Applicable implementing documents.
 3. Job responsibilities and authority.

2.2.12 Qualification of Personnel Performing Quality Assurance Functions

Personnel performing special quality assurance functions (such as inspecting, examining, testing, and auditing) shall be qualified according to the requirements of the applicable QARD Section.



Office of Civilian Radioactive Waste Management

Quality Assurance Requirements and Description

Title: DESIGN CONTROL

Effective Date: 12/18/92

Section No.: 3.0

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3.1 GENERAL

This section provides requirements to ensure that designs (from conceptual through final) are defined, controlled, and verified.

3.2 REQUIREMENTS

3.2.1 Design Input Control

Applicable design inputs (such as design bases, conceptual design reports, performance requirements, 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. Changes from approved design inputs and reasons for the changes shall be identified, approved, documented, and controlled.
- D. Design inputs based on assumptions that require reverification shall be identified and controlled.

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 the design process to be carried out in a correct manner.
- B. Design documents shall be adequate to support design, fabrication, construction, and operation.
- C. Appropriate standards shall be identified and documented, and their selection reviewed and approved.

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- D. Changes from specified standards, including the reasons for the change, shall be identified, approved, documented, and controlled.
- E. Controls for selecting and reviewing design methods, materials, parts, equipment, and processes that are essential to the function of an item for suitability of application shall be established.
- F. Applicable information derived from experience, as set forth in reports or other documentation, shall be made available to cognizant design personnel.
- G. Design 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 understand the documents and verify their adequacy without recourse to the originator.
- H. Controls for identifying assemblies or components that are part of the item being designed shall be established. If a commercial grade assembly or component is modified or selected by special inspection or testing to meet requirements that are more restrictive than the supplier's published product description, then the assembly or component shall be represented as different from the commercial grade item in a manner traceable to a documented description of the difference.
- I. Drawings, specifications, and other design output documents shall contain appropriate inspection and testing acceptance criteria.

3.2.3 Design Analyses

- A. Design analyses shall be planned, controlled, and documented.
- B. Design analysis documents shall be legible and in a form suitable for reproduction, filing, and retrieval.
- C. Calculations shall be identifiable by subject (including structure, system, or component to which the calculation applies), originator, reviewer, and date, or by other designators such that the calculations are traceable.
- D. Computer software used to perform design analyses shall be developed or qualified, and used according to the requirements of Supplement I.
- 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.

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4. Identification of assumptions and designation of those that must be verified as the design proceeds.
5. Identification of any computer calculation, including computer type, computer program (e.g., name), revision identification, inputs, outputs, and the bases (or reference thereto) supporting application of the computer program to the specific physical problem.
6. Identification of the reviewer and approver.

3.2.4 Design Verification

The following design control requirements shall be applied to verify the adequacy of design.

- A. Design verification shall be performed using one or a combination of the following methods:
 1. Design review.
 2. Alternate calculations.
 3. Qualification testing.
- B. The particular design verification method shall be identified and its use justified.
- C. The results of design verification shall be documented, including the identification of the verifier.
- D. Design verification shall be performed by competent individuals or groups other than those who performed the original design but may be from the same organization. If necessary, this verification may be performed by the originator's 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; or
 2. The supervisor is the only individual in the organization competent to perform the verification.
 3. The review is not hastily and superficially done.
 4. The determination to use the supervisor is documented and approved, in advance, with concurrence of the Quality Assurance organization.

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- E. Design verification shall be performed at appropriate times during the design process.
 - 1. Verification shall be performed before release for procurement, manufacture, or construction or release to another organization for use in other design work.
 - 2. In some cases (such as when insufficient data exists) it may be necessary to release unverified designs to other organizations to support schedule requirements. Unverified portions of the design shall be clearly identified and controlled.
 - 3. In all cases, design verification shall be completed before relying on the item to perform its function.
- F. The extent of the design verification required shall be a function of the importance to safety or waste isolation, complexity of design, degree of standardization, state of the art, and similarity with previously proven designs.
- G. Where the design has been subjected to a verification process in accordance with this QARD, the verification process need not be duplicated for identical designs.
- H. Use of previously proven designs shall be controlled according to the following requirements:
 - 1. The applicability of standardized or previously proven designs shall be verified with respect to meeting pertinent design inputs for each application.
 - 2. Known problems affecting standard 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.
 - 4. Changes in previously verified designs shall require reverification. Such verifications shall include the evaluation of the effects of those changes on the overall previously verified design and on any design analyses upon which the design is based.

3.2.5 Design Reviews

Design reviews shall be controlled and performed to ensure:

- A. The design inputs were correctly selected and incorporated.
- B. Assumptions necessary to perform the design work were adequately described, reasonable, and, where necessary, reverified.
- C. An appropriate design method was used.

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- D. The design output is reasonable compared to design inputs.
- E. The necessary design input and verification requirements for interfacing organizations were specified in the design documents or in supporting implementing documents.

3.2.6 Alternate Calculations

The appropriateness of assumptions, input data, and the computer program or other calculation method used shall be evaluated, and the results shall be checked through the use of alternate calculation methods to verify the correctness of the original calculations or analyses.

3.2.7 Qualification Testing

- A. If design adequacy is to be verified by qualification tests, the tests shall be identified.
- B. The test configuration shall be defined and documented.
- C. Testing shall demonstrate the adequacy of performance under conditions that simulate the most adverse design conditions. Operating modes and environmental conditions in which the item must perform satisfactorily shall be considered in determining the most adverse conditions.
- D. If the tests verify only specific design features, then the other features of the design shall be verified by other means.
- E. Test results shall be documented and evaluated to ensure that test requirements have been met.
- F. If qualification testing indicates that a modification to an item is necessary to obtain acceptable performance, then the modification shall be documented and the item modified and retested or otherwise verified to ensure satisfactory performance.
- G. Scaling laws shall be established and verified when tests are being performed on models or mockups.
- H. The results of model test work shall be subject to error analysis, where applicable, before using the results in final design work.

3.2.8 Design Change Control

Design changes shall be controlled according to the following requirements:

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

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- B. Design control measures for changes shall include provisions to ensure that the design analyses for the item are still valid.
- C. Changes shall be approved by the same affected groups or organizations that reviewed and approved the original design documents.
 - 1. If an organization that originally was responsible for approving a particular design document is no longer responsible, then a new responsible organization shall be designated.
 - 2. The designated design 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.
- D. The design process and design verification methods and implementing documents shall be reviewed and modified, as necessary, when a significant design change is necessary because of an incorrect design. These design deficiencies shall be documented according to Section 15.0.
- E. Field changes shall be incorporated into affected design documents when such incorporation is appropriate, and when a field change is approved other than by revision to the affected design documents.
- F. Design changes that impact related implementing documents or training programs shall be communicated to affected organizations.

3.2.9 Design Interface Control

- A. Design interfaces shall be identified and controlled.
- B. Design efforts shall be coordinated among participating organizations.
- C. Interface controls shall include the assignment of responsibility and the establishment of implementing documents among participating design organizations for the review, approval, release, distribution, and revision of documents involving design interfaces.
- D. Design information transmitted across interfaces shall be documented and controlled.
- E. The status of the design information or document provided shall be identified in transmittals. Where necessary, incomplete designs that require further evaluation, review, or approval shall be identified.
- F. Design information shall be promptly confirmed through a controlled implementing document when it is necessary to initially transmit the design information orally or by other informal means.



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Quality Assurance Requirements and Description

Title: PROCUREMENT DOCUMENT CONTROL

Effective Date: 12/18/92

Section No.: 4.0

Revision No.: 0

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4.1 GENERAL

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

4.2 REQUIREMENTS

4.2.1 Procurement Document Preparation

Procurement documents issued by each affected organization shall include the following provisions, as applicable to the item or service being procured:

- A. A statement of the scope of work to be performed by the supplier.
- B. Technical requirements including:
 - 1. Design bases shall be identified or referenced.
 - 2. Specific documents (such as drawings, codes, standards, regulations, procedures, or instructions) 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, or acceptance requirements that the purchaser will use to monitor and evaluate the performance of the supplier shall be specified.
- C. Quality Assurance Program Requirements including:
 - 1. A requirement for the supplier to have a documented quality assurance program that implements applicable QARD requirements prior to the initiation of work. The extent of the quality assurance program shall depend on the scope, nature, or complexity of the item or service being procured.
 - 2. A requirement for the supplier to incorporate the appropriate QARD requirements into any subtier supplier-issued procurement document.

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3. When deemed appropriate, the purchaser shall permit some or all supplier work to be performed under the purchaser's quality assurance program provided the work is adequately addressed. In these cases, procurement documents shall specify that the purchaser's implementing documents are applicable to the supplier and that the purchaser shall provide these applicable documents to them.
- D. Right of access to supplier facilities and records for inspection or audit by the purchaser, OCRWM, or other designee authorized by the purchaser.
- E. Provisions for establishing hold points beyond which work cannot proceed without purchaser authorization.
- F. Documentation required to be submitted to the purchaser for information, review, or acceptance.
 1. The document submittal schedule shall be identified.
 2. If the purchaser requires the supplier to maintain documentation that will become quality assurance records, the retention times and disposition requirements shall be identified.
- G. Purchaser requirements for the supplier to report nonconformances and the purchaser approval of the disposition of nonconformances.
- H. Identification of any spare and replacement parts or assemblies and the appropriate technical and quality assurance data required for ordering.

4.2.2 Procurement Document Review and Approval

- A. Procurement document reviews shall be performed and documented prior to issuance of the procurement documents to the supplier.
- 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 all applicable technical and quality assurance program requirements are included.
- 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.

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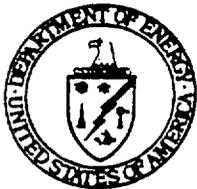
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- E. Procurement document reviewers shall include representatives from the technical and quality assurance organizations.
- F. Procurement documents shall be approved.

4.2.3 Procurement Document Change

- A. Changes to the scope of work, technical requirements, quality assurance program requirements, right of access, documentation requirements, nonconformances, hold points, and lists of spare and replacement parts delineated in procurement documents 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 precontract 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. This 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 the supplier 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.



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Quality Assurance Requirements and Description

Title: IMPLEMENTING DOCUMENTS

Effective Date: 12/18/92

Section No.: 5.0

Revision No.: 0

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5.1 GENERAL

This section establishes the requirements to ensure that work is prescribed by, and performed in accordance with, written implementing documents.

5.2 REQUIREMENTS

Work shall be performed according to controlled implementing 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.

5.2.2 Content of Implementing Documents

Implementing documents shall include the following information as appropriate to the work to be performed:

- A. Responsibilities of the organizations affected by the document.
- B. Technical and regulatory requirements.
- C. A sequential description of the work to be performed including controls for altering the sequence of required inspections, tests, and other operations. The organization responsible for preparing the document shall determine the appropriate level of detail.
- D. Quantitative or qualitative acceptance criteria sufficient for determining that activities were satisfactorily accomplished.
- E. Prerequisites, limits, precautions, process parameters, and environmental conditions.
- F. Quality verification points and hold points.
- G. Methods for demonstrating that the work was performed as required (such as provisions for recording inspection and test results, checkoff lists, or signoff blocks).
- H. Identification of the lifetime or nonpermanent quality assurance records generated by the implementing document.
- I. Identification of associated items and activities.

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5.2.3 Review and Approval of Implementing Documents

Implementing documents shall be reviewed, approved, and controlled according to the requirements of Section 6.0.

5.2.4 Compliance with Implementing Documents

Individuals shall comply with implementing documents, however:

- A. When work cannot be accomplished as described in the implementing document, or accomplishment of such work would result in an undesirable situation, the work shall be stopped.
- B. Work shall not resume until the implementing document is changed (according to Section 6.0) to reflect the correct work practices.



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Quality Assurance Requirements and Description

Title: DOCUMENT CONTROL

Effective Date: 12/18/92

Section No.: 6.0

Revision No.: 0

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6.1 GENERAL

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

6.2 REQUIREMENTS

6.2.1 Types of Documents

Documents that specify technical requirements, quality requirements, or prescribe work shall be controlled in accordance with this section.

6.2.2 Preparing Documents

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

6.2.3 Reviewing Documents

Documents that specify technical requirements, quality requirements or prescribe work shall be reviewed for adequacy, correctness, and completeness, according to the requirements of Section 2.0, prior to approval and issuance.

6.2.4 Approving Documents

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

6.2.5 Controlling the Distribution and Use of Documents

The distribution and use of documents, including changes and editorial corrections to documents, shall be controlled.

- A. Documents used to perform work shall be distributed to, and used at, the work location.
- B. Effective dates shall be established for approved implementing documents.
- C. The disposition of obsolete or superseded documents shall be controlled.

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- D. Lists shall be established to identify the current status of each document that is required to be controlled in accordance with this section.

6.2.6 Changes to Documents

Changes to documents shall be reviewed for adequacy, correctness, and completeness, according to the requirements of Section 2.0, prior to approval and issuance.

- A. Changes shall be reviewed by the organizations or disciplines affected by the change.
- B. The quality assurance organization shall review changes if the quality assurance organization was involved in the review of the previous version.
- C. Changes shall be approved for release by the designated organizational position that is responsible for the document.
- D. Implementing documents shall define the method used to incorporate changes. If the defined method is other than reissue of the entire controlled document, the implementing document shall define the maximum number of changes permitted prior to requiring reissue of the entire controlled document.
- E. Implementing documents shall require that a history of changes to Quality Assurance 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.

6.2.7 Expedited Changes

If an activity cannot be performed as listed in the implementing document, and the change process would cause unreasonable delays, then 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.

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6.2.8 Editorial Corrections

Editorial corrections may be made to documents without being subject to review requirements.

A. The following items are considered editorial corrections:

1. Correcting grammar or spelling.
2. Renumbering sections or attachments.
3. Changing the title or number of the document.
4. Updating organizational titles.

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

B. The organizational position responsible for the document shall approve editorial corrections.



Office of Civilian Radioactive Waste Management

Quality Assurance Requirements and Description

Title: CONTROL OF PURCHASED ITEMS AND SERVICES

Effective Date: 03/27/95

Section: 7.0

Revision No.: 1

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7.1 GENERAL

This section establishes requirements for planning and executing procurements to ensure that purchased items and services meet specified requirements. This section does not apply to direct-support services used for staff augmentation.

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.
- 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. Identify and document the sequence of actions and milestones needed to effectively complete the procurement.
- 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 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 quality assurance records.

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- E. Be accomplished as early as possible, and no later than at the start of those procurement activities which are required to be controlled.
- 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 the involvement of the quality assurance organization.

7.2.2 Source Evaluation and Selection

- A. Supplier selection shall be based on an evaluation, performed before the contract is awarded, of the supplier's capability to provide items or services in accordance with procurement document requirements.
- B. The organizational responsibilities for source evaluation and selection shall be identified and shall include the quality assurance organization. If a source evaluation board is established, then the quality assurance organization shall have a voting member.
- C. Measures for evaluating and selecting procurement sources shall include one or more of the following elements:
 - 1. Evaluation of the supplier's history for providing an identical or similar product which performs satisfactorily in actual use.
 - 2. Evaluation of supplier's current quality assurance records supported by any documented qualitative and quantitative information.
 - 3. Evaluation of the supplier's technical and quality capability based on an evaluation of supplier facilities, personnel, and quality assurance program implementation.
- 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 the procurement document requirements. This evaluation shall be performed by designated, technically qualified organizations including the quality assurance organization and shall include the following subjects consistent with the importance, complexity, and quantity of items or services being procured.
 - 1. Technical considerations.
 - 2. Quality assurance program requirements.
 - 3. Supplier personnel.

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4. Supplier production capability.
 5. Supplier past performance.
 6. Alternatives.
 7. Exceptions.
- B. Before the contract is awarded, the purchaser shall resolve, or obtain commitments to resolve, unacceptable quality conditions identified during the proposal/bid evaluation.
- C. Supplier quality assurance programs shall be evaluated either before or after contract placement, and any deficiencies that would affect quality shall be corrected before starting work subject to QARD requirements.
- D. Supplier quality assurance programs shall be accepted by the purchaser before the supplier starts work subject to QARD requirements.

7.2.4 Supplier Performance Evaluation

- A. The purchaser of items and services shall establish measures to interface with the supplier and to verify supplier's performance. The measures shall include:
1. Establishing an understanding between the purchaser and supplier of 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 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. The extent of verifications shall be a function of the relative importance, complexity, and quantity of items or services being procured, and the supplier's quality performance.

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- C. Verifications shall be conducted as early as practical and shall not relieve the supplier of the responsibility for the verification of quality achievement. Verifications shall include supplier audits used as a method of evaluating the supplier's performance, and evaluation of purchaser's documentation to aid in the determination of the effectiveness of the supplier's quality assurance program.

7.2.5 Control of Supplier Generated Documents

- A. Supplier generated documents shall be controlled, processed, and accepted in accordance with the requirements established in the procurement documents.
- B. Measures shall be implemented to ensure that the submittal of these documents is accomplished in accordance with the 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. Methods for accepting supplier furnished items or services shall include one or more of the following, as appropriate to the items or services being procured:
 - 1. Evaluating the supplier certificate of conformance.
 - 2. Performing one or a combination of source verification, receiving inspection, or post-installation test.
 - 3. Technical verification of the product produced.
 - 4. Surveillance or audit of the work.
 - 5. Review of objective evidence (such as certifications, stress reports, or personnel qualifications) for conformance to the procurement document requirements.
- B. The supplier shall verify that furnished items or services comply with the purchaser's procurement requirements before offering the items or services for acceptance.
- C. The supplier shall provide the purchaser objective evidence that items or services conform to procurement documents. The documentation shall be available at the purchaser's facility before the item is installed or before the service is accepted.

7.2.7 Certificate of Conformance

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

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

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- B. The certificate shall identify the specific procurement requirements met by the purchased item or service. The procurement requirements identified shall include any approved changes, waivers, or deviations applicable to the item or service.
- C. The certificate shall identify any procurement requirements that have not been met together with an explanation and the means for resolving the nonconformances.
- D. The certificate shall be signed or otherwise authenticated by a person who is responsible for this quality assurance function and whose responsibilities and position are described in the supplier's quality assurance 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 supplier's quality assurance program.
- F. Measures shall be identified to verify the validity of supplier certificates and the effectiveness of the certification process (such as by audit of the supplier or by an independent inspection or test of the item). Verifications shall be conducted 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 shall be implemented consistent with the supplier's planned inspections, examinations, or tests at predetermined points and performed at intervals consistent with the importance and complexity of the item.
- B. 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.
- C. Source verification shall be performed by personnel qualified in accordance with the applicable QARD requirements for the item or service being procured.

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 established inspection implementing documents.

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- C. The inspection shall verify, as applicable, 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. Receiving inspection shall be coordinated with a review for adequacy and completeness of any required supplier documentation submittals.

7.2.10 Post-installation Testing

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

7.2.11 Control of Supplier Nonconformances

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

- A. The supplier shall evaluate nonconforming items according to the requirements of Section 15.0.
- B. The supplier shall submit a report of nonconformance to the purchaser including supplier recommended disposition (for example, use-as-is or repair) and technical justification. Reports of nonconformances to procurement document requirements, or documents approved by the purchaser, shall be submitted to the purchaser for approval whenever one of the following conditions exists:
 - 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.

7.2.12 Commercial Grade Items

Where design specifies the use of commercial grade items, the following requirements are an acceptable alternative to other requirements of this section.

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- A. The commercial grade item shall be identified in an approved design output document. An alternate commercial grade item may be applied, provided the responsible design organization provides verification that the alternate commercial grade item will perform the intended function and will meet design requirements applicable to both the replaced item and the application.
- B. Supplier evaluation and selection, when determined necessary by the purchaser based on the complexity and importance to safety, shall be in accordance with the requirements of the subsection entitled *Source Evaluation and Selection*.
- C. Commercial grade items shall be identified in the procurement document by the manufacturer's published product description.
- D. After receipt of a commercial grade item, the purchaser shall ensure that:
 - 1. Damage was not sustained during shipment.
 - 2. The item received was the item ordered.
 - 3. Inspection or testing is accomplished, to the extent determined by the purchaser, to ensure conformance with the manufacturer's published requirements.
 - 4. Documentation, as applicable to the item, was received and is acceptable.



Office of Civilian Radioactive Waste Management

Quality Assurance Requirements and Description

Title: IDENTIFICATION AND CONTROL OF ITEMS

Effective Date: 12/18/92

Section No.: 8.0

Revision No.: 0

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8.1 GENERAL

This section establishes requirements 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 a manner which ensures that identification is established and maintained.
- B. Items shall be identified from the time of initial fabrication, or receipt, up to and including installation or end use.

8.2.2 Physical Markings

- A. Item identification methods shall include use of physical markings. If physical markings are either impractical or insufficient, other appropriate means shall be employed (such as 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 or coatings, or after installation unless other means of identification are substituted.

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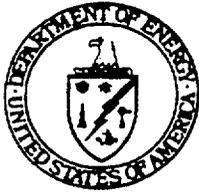
8.2.3 Traceability

- A. Item identification methods shall ensure that traceability is established and maintained in a manner that allows an item to be traced to applicable design or other specifying documents.
- B. Item traceability documentation shall ensure that the item can be traced at all times from its source through installation or end use.

8.2.4 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 (such as identification or traceability of the item to applicable specification or grade of material; heat, batch, lot, part, or serial number; or specified inspection, test, or other records), then identification and traceability methods shall implement the requirements specified.
- B. If items have a limited operating or shelf life specified, then methods shall be established that preclude using the item beyond the shelf or operating life.
- C. If item storage is required, then methods shall be established for the control of item identification that are 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.



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Quality Assurance Requirements and Description

Title: CONTROL OF SPECIAL PROCESSES

Effective Date: 12/18/92

Section No.: 9.0

Revision No.: 0

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9.1 GENERAL

This section establishes the requirements for the control of special processes (such as welding, weld overlay, heat treating, chemical cleaning, and nondestructive examinations).

9.2 REQUIREMENTS

9.2.1 Special Processes

- A. Special processes that control or verify quality shall be controlled according to the requirements of this section whether or not they are covered by existing codes and standards, or whether or not the quality requirements specified for an item exceed those of existing codes or standards.
- 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 product.
- C. Based on this criteria, a list of the special processes that each affected organization will perform, or be responsible for performing, shall be established and maintained.

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. Qualification requirements for personnel, implementing documents, and equipment.
- B. Conditions necessary for accomplishment of the special process. These conditions shall include proper equipment, controlled parameters of the process, and calibration requirements.
- C. Requirements of applicable codes and standards, including acceptance criteria for the special process.

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9.2.3 Qualification of Nondestructive Examination Personnel

- A. Nondestructive examination shall include radiography, magnetic particle, ultrasonic, liquid penetrant, eddy current, neutron radiography, and leak testing.
- B. Nondestructive examination shall be considered a special process and personnel that perform nondestructive examinations shall be qualified in accordance with the American Society for Nondestructive Testing Recommended Practice No. SNT-TC-1A, June 1980 Edition.
- C. The affected organization shall establish implementing documents for the control and administration for the training, examination, and certification of nondestructive examination personnel.



Office of Civilian Radioactive Waste Management

Quality Assurance Requirements and Description

Title: INSPECTION

Effective Date: 12/18/92

Section No.: 10.0

Revision No.: 0

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10.1 GENERAL

This section establishes requirements for planning and executing inspections.

10.2 REQUIREMENTS

10.2.1 Inspection Planning

Inspection planning shall be performed, documented and include:

- A. Identification of each work operation where inspection is necessary to ensure quality and implementing documents that will be used to perform the inspections.
- B. Identification of the characteristics to be inspected and the identification of when, during the work process, inspections are to be performed.
- C. Identification of inspection or process monitoring methods to be employed.
- D. The final inspection shall be planned to arrive at a conclusion regarding conformance of the item to specified requirements.
- E. Identification of the functional qualification level (category or class) of personnel performing inspections.
- F. Identification of acceptance criteria.
- G. Identification of sampling requirements.
- H. Methods to record inspection results.
- I. Selection and identification of the measuring and test equipment to be used to perform the inspection to ensure that the equipment is calibrated and is of the proper type, range, accuracy, and tolerance to accomplish the intended function.

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

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- C. The inspections shall be performed by personnel other than those who performed or directly supervised the item being inspected and are independent of the organization directly responsible for that item. These personnel shall not report directly to the immediate supervisor responsible for the item being examined.

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.

10.2.5 In-Process Inspections and Monitoring

- A. Items in-process 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.

10.2.6 Final Inspection

- A. 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.
- B. Documentation not previously examined shall be examined for adequacy and completeness.

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- C. Final inspections shall include a review of the results and resolution of nonconformances identified by earlier inspections.
- D. 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 an item 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 identify:

- A. The item inspected.
- B. The date of inspection.
- C. The name of the inspector, or the inspector's unique identifier, 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 indicating 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.

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10.2.9 Qualifications of Inspection and Test Personnel

A. Qualifications

Personnel performing inspections as described in this section and personnel performing tests as described in Section 11.0 shall be qualified according to the indoctrination and training, education and experience, and physical requirements of this Section. These personnel shall have experience or training commensurate with the scope, complexity, or special nature of the inspections or tests.

B. Determination of Initial Capabilities

The capabilities of a candidate for certification shall be initially determined by an evaluation of the candidate's education, experience, and training; and either examination results or capability demonstration. The evaluation shall be performed to the requirements of the applicable functional level, and education and experience requirements of this Section.

C. Indoctrination and Training of Inspection and Test Personnel

1. Inspection and test personnel shall be indoctrinated to the technical objectives and requirements of the applicable codes and standards and the quality assurance program requirements that are to be employed in executing their responsibilities.
2. The need for formal training shall be determined, and training shall be conducted as required to qualify personnel for performing inspections and tests.
3. On-the-job training, with emphasis on hands-on experience gained through actual performance of inspections and test, shall be included in the training program.
 - a. On-the-job training for personnel qualification shall be performed under the direct observation and supervision of a qualified person.
 - b. The documented verification of conformance shall be performed by the qualified person and not by the person being administered on-the-job training.

D. Functional Qualification Levels of Inspection and Test Personnel

Three levels of functional qualification shall be used depending on the complexity of the functions involved. The criteria for each level are not limiting with regard to organizational position or professional status but, rather, are limiting with regard to functional work.

1. Level I Personnel Capabilities

Level I personnel shall be capable of performing and documenting the results of designated inspections or tests.

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2. Level II Personnel Capabilities

Level II personnel shall have Level I capabilities for the corresponding category or class. Additionally, Level II personnel shall have demonstrated capabilities in:

- a. Inspection or test planning.
- b. Advanced preparation, including the preparation and setup of related equipment, as appropriate.
- c. Supervising or monitoring the inspections or tests.
- d. Supervising and certifying lower-level personnel.
- e. Evaluating the validity and acceptability of results.

3. Level III Personnel Capabilities

Level III personnel shall have Level II capabilities for the corresponding category or class. In addition, Level III personnel shall also be capable of evaluating the adequacy of specific programs used to train, qualify, and certify the personnel.

E. Education and Experience Requirements for Inspection and Test Personnel

The requirements for education and experience shall be considered with recognition that other factors commensurate with the scope, complexity, or special nature of the inspections or tests affect the assurance that a person can competently perform a particular task. Other factors that demonstrate capability in a given job and the basis for their equivalency shall be documented.

1. Level I Inspection Personnel shall meet the following education and experience requirements:
 - a. Two years of related experience in equivalent inspections or tests; or
 - b. High school graduation and six months of related experience in equivalent inspections or tests; or
 - c. Completion of college level work leading to an associate degree in a related discipline plus three months of related experience in equivalent inspections or tests.

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2. Level II Inspection personnel shall meet the following education and experience requirements:
 - a. One year of satisfactory performance as a Level I in the corresponding category or class; or
 - b. High school graduation plus three years of related experience in equivalent inspections or tests; or
 - c. Completion of college level work leading to an associate degree in a related discipline plus one year of related experience in equivalent inspections or tests; or
 - d. Graduation from a four-year college plus six months of related experience in equivalent inspections or tests.
3. Level III Inspection personnel shall meet the following education and experience requirements:
 - a. Six years of satisfactory performance as a Level II in the corresponding category or class; or
 - b. High school graduation plus ten years of related experience in equivalent inspections or tests; or high school graduation plus eight years of experience in equivalent inspections or tests with at least two years as a Level II and with at least two years associated with nuclear facilities; or, if not, at least sufficient training to be acquainted with the relevant quality assurance program aspects of a nuclear-related facility; or
 - c. Completion of college-level work leading to an associate degree and seven years of related experience in equivalent inspections or tests with at least two years of this experience associated with nuclear facilities -- or, if not, at least sufficient training to be acquainted with the relevant quality assurance program aspects of a nuclear-related facility; or
 - d. Graduation from a four-year college plus five years of related experience in equivalent inspections or tests with at least two years of this experience associated with nuclear facilities -- or, if not, at least sufficient training to be acquainted with the relevant quality assurance program aspects of a nuclear-related facility.

F. Physical Requirements for Inspection and Test Personnel

The responsible organization shall identify any special physical characteristics needed for performance in each functional level (categories or class) including identifying the need for initial and subsequent visual acuity and other physical examinations.

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G. Certifying the Qualifications of Inspection and Test Personnel

The qualifications of inspection and test personnel shall be certified in writing by the responsible organization. The certification shall document the:

1. Name of the certifying organization.
2. Identification of the person being certified.
3. Qualified inspection and test categories or class the individual is certified to perform.
4. Basis for certification (such as education, experience, indoctrination, training, examination results, and results of capability demonstration).
5. Results of periodic evaluations.
6. Results of visual acuity and physical examination when required.
7. Date of certification and date of certification expiration.
8. Signature of the organization's designated representative responsible for certification.

H. Periodic Evaluation of Qualification for Inspection and Test Personnel

1. The job performance of inspection and test personnel shall be reevaluated at periodic intervals not to exceed three years to ensure qualifications have been maintained.
 - a. Reevaluation shall be by evidence of continued satisfactory performance or redetermination of required capability in accordance with the qualification requirements specified for the job as described in this section.
 - b. If during this evaluation or at any other time the responsible organization determines that the capabilities of an individual are not in accordance with the qualification requirements specified for the job, that person shall be removed from the inspection or test until the required capability has been demonstrated.
2. Any person who has not performed inspections or tests in their qualified area for a period of one year shall be reevaluated by a redetermination of required capability in accordance with this section.

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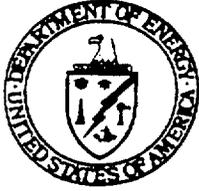
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I. Maintaining Qualification Documentation for Inspection and Test Personnel

1. Documentation of personnel qualification shall be established, kept current, and maintained by the responsible organization. This documentation shall contain the information required for the initial qualification and the maintenance of qualification.
2. Documentation for each person shall be maintained and updated according to the following requirements:
 - a. Removal of a person from performing in an area of certification when the responsible organization determines that the capabilities of the individual are not in accordance with the qualification requirements specified for the job as described in this section. This shall be documented at the time of removal.
 - b. Reinstatement of certifications for the qualified area when the required capability has been demonstrated as described in this section. This shall be documented at the time of reinstatement.
 - c. Continued performance in each certified area or redetermination of required capability as described in this section for each certified area shall be updated annually.
 - d. Reevaluation of job performance by evidence of continued satisfactory performance or redetermination of capability as described in this section. This shall be updated every three years.



Office of Civilian Radioactive Waste Management

Quality Assurance Requirements and Description

Title: TEST CONTROL

Effective Date: 12/18/92

Section No.: 11.0

Revision No.: 0

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11.1 GENERAL

This section establishes requirements for planning and executing tests that are used to verify conformance of an item to specified requirements, or to demonstrate satisfactory performance for service. Examples of such tests include prototype qualification tests, production tests, proof tests prior to installation, construction tests, and pre-operational tests.

Testing of computer software is performed in accordance with Supplement I.

Activities required to collect data (such as for siting or design input) are performed in accordance with Supplement III.

11.2 REQUIREMENTS

11.2.1 Test Planning

Test planning shall include:

- A. Identification of the implementing documents to be developed to control and perform tests.
- B. Identification of item to be tested and the test requirements and acceptance limits, including required levels of precision and accuracy.
- C. Identification of test methods to be employed and instructions for performing the test.
- D. Test prerequisites that address calibrated instrumentation, appropriate and adequate test equipment and instrumentation, trained personnel, condition of test equipment and the item to be tested, suitably controlled environmental conditions, and provisions for data acquisition.
- E. Mandatory hold points.
- F. Methods to record data and results.
- G. Provisions for ensuring that prerequisites for the given test have been met.
- H. Selection and identification of the measuring and test equipment to be used to perform the test to ensure that the equipment is of the proper type, range, accuracy, and tolerance to accomplish the intended function.
- I. Identification of the functional qualification level of personnel performing tests.

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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. Include or reference 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.
- E. Potential sources of uncertainty and error. Test parameters affected by potential sources of uncertainty and error shall be identified and controlled.

11.2.3 Use of Other Testing Documents

- A. Other testing documents (such as American Society for Testing and Materials (ASTM) specifications, supplier manuals, or other related documents containing acceptance criteria) may be used instead of preparing special test implementing documents. If used, then they shall incorporate the information directly into the approved test implementing document, or shall be incorporated by reference in the approved test implementing document.
- B. Implementing 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.

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11.2.5 Test Documentation

Test documentation shall identify the:

- A. Item or work product tested.
- B. Date of test.
- C. Name of the tester and data recorders.
- D. Type of observation and method of testing.
- 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 nonconformances noted.
- H. Name of the person evaluating the test results.
- I. Identification of the measuring and test equipment used during the test including the identification number and the most recent calibrated date.

11.2.6 Qualification of Test Personnel

Personnel who perform testing shall be qualified according to the requirements of Section 10.0.



Office of Civilian Radioactive Waste Management

Quality Assurance Requirements and Description

Title: CONTROL OF MEASURING AND TEST EQUIPMENT

Effective Date: 12/18/92

Section No.: 12.0

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12.1 GENERAL

This section establishes requirements to ensure measuring and test equipment is properly controlled, calibrated, and maintained.

12.2 REQUIREMENTS

12.2.1 Calibration

- A. Measuring and test equipment shall be calibrated, adjusted, and maintained at prescribed intervals or, prior to use, against reference calibration standards having traceability to nationally recognized standards. If no nationally recognized standards or physical constants exist, the basis for calibration shall be documented.
- B. Calibration standards shall have a greater accuracy than the required accuracy of the measuring and test equipment being calibrated.
 - 1. If calibration standards with a greater accuracy than required of the measuring and test equipment 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. The method and interval of calibration for each device shall be defined, based on the type of equipment, stability characteristics, required accuracy, intended use, and other conditions affecting measurement control. For measuring and test equipment used in one-time-only applications, the calibration shall be done both before and after use.
- D. A calibration shall be performed when the accuracy of calibrated measuring and test equipment is suspect.
- E. Calibrated measuring and test equipment shall be labeled, tagged, or otherwise suitably marked or documented to indicate due date or interval of the next calibration.
- F. Calibrated measuring and test equipment shall be uniquely identified to provide traceability to its calibration data.

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12.2.2 Documenting the Use of Measuring and Test Equipment

The use of measuring and test equipment shall be documented. As appropriate to equipment use and its calibration schedule, the documentation shall identify the processes monitored, data collected, or items inspected or tested since the last calibration.

12.2.3 Out-of-calibration Measuring and Test Equipment

- A. Measuring and test equipment shall be considered to be out-of-calibration and not be used 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 or suspected to be in error.
- B. Out-of-Calibration measuring and test equipment shall be controlled. The controls shall include the following requirements:
 - 1. Out-of-Calibration measuring and test equipment shall be tagged, segregated, or otherwise controlled to prevent use until they have been recalibrated.
 - 2. When measuring and test equipment is found out-of-calibration during recalibration, 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 any measuring and test equipment is consistently found to be out-of-calibration during the recalibration process, it shall be repaired or replaced.

12.2.4 Handling and Storage

Measuring and test equipment shall be properly handled and stored to maintain accuracy.

12.2.5 Commercial Devices

Calibration and control shall not be required for rulers, tape measures, levels, and other normal commercial equipment that provides adequate accuracy.

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12.2.6 Measuring and Test Equipment Documentation

Measuring and test equipment 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 measuring and test equipment including evaluation results, as appropriate.
- H. Identification of the implementing document (including revision level) used in performing the calibration.



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Quality Assurance Requirements and Description

Title: HANDLING, STORAGE, AND SHIPPING

Effective Date: 12/18/92

Section No.: 13.0

Revision No.: 0

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13.1 GENERAL

This section establishes requirements for the handling, storage, cleaning, packaging, shipping, and preservation of items 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 (such as containers, shock absorbers, and accelerometers) and special protective environments (such as inert gas and specific moisture 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.

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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.



Office of Civilian Radioactive Waste Management

Quality Assurance Requirements and Description

Title: INSPECTION, TEST AND OPERATING STATUS

Effective Date: 12/18/92

Section No.: 14.0

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14.1 GENERAL

This section establishes requirements to identify the inspection, test, and operating status of items.

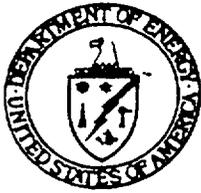
14.2 REQUIREMENTS

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 by-passing 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 status indicators (such as tags, markings, labels and stamps), or other means (such as travelers, inspection or test records).
- D. The authority for applying and removing status indicators shall be specified.
- E. Status indicators shall be used to provide an indication of the test or operating status of items or facilities to prevent inadvertent changes in operating status.



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Quality Assurance Requirements and Description

Title: NONCONFORMANCES

Effective Date: 12/18/92

Section No.: 15.0

Revision No.: 0

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15.1 GENERAL

This section establishes requirements for the control of items that do not conform to requirements in order to prevent inadvertent installation or use of the item.

15.2 REQUIREMENTS

15.2.1 Documenting and Evaluating Nonconformances

- A. Nonconformance documentation shall clearly identify and describe the characteristics that do not conform to specified criteria.
- B. Nonconformance documentation shall be reviewed, and recommended dispositions of nonconforming items shall be proposed. The review shall include determining the need for corrective action according to the requirements of Section 16.0. In addition, organizations affected by the nonconformance shall be notified.
- C. Recommended dispositions shall be evaluated and approved.
- D. Personnel performing evaluations of recommended dispositions shall have demonstrated competence in the specific area they are evaluating, an adequate understanding of the requirements, and access to pertinent background information.
- E. The responsibility and authority for reviewing, evaluating, approving the disposition, and closing nonconformances shall be specified.
- F. Further processing, delivery, installation, or use of a nonconforming item shall be controlled pending the evaluation and approval of the disposition.

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.

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15.2.3 Segregating Nonconforming Items

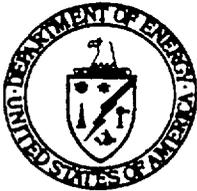
- A. Nonconforming items shall be segregated, when practical, by placing them in a clearly identified and designated hold area until properly dispositioned.
- B. If segregation is impractical or impossible due to physical conditions, then other precautions shall be employed to preclude inadvertent use.

15.2.4 Disposition of Nonconforming Items

- A. The disposition of "use-as-is," "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 "repair" or "use-as-is" shall be documented.
- C. Items that do not meet original design requirements that are dispositioned "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 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 (inspect, 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.

15.2.5 Trending

Nonconformance documentation shall be periodically analyzed by the quality assurance organization to identify quality trends in accordance with Section 16.0.



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Quality Assurance Requirements and Description

Title: CORRECTIVE ACTION

Effective Date: 12/18/92

Section No.: 16.0

Revision No.: 0

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16.1 GENERAL

This section establishes requirements for identifying and correcting conditions adverse to quality.

16.2 REQUIREMENTS

16.2.1 Identifying Conditions Adverse to Quality

A condition adverse to quality shall be identified when a QARD or an implementing document requirement is not met.

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. Two categories of classification shall be established:
 - 1. Conditions adverse to quality.
 - 2. Significant conditions adverse to quality.

16.2.3 Conditions Adverse to Quality

- A. Conditions adverse to quality shall be documented and reported to the appropriate levels of management responsible for the conditions and to the quality assurance organization for tracking.
- B. Responsible management shall investigate and document the investigation of conditions adverse to quality.
- C. Responsible management shall determine, document, and complete remedial action in a timely manner.
- D. The quality assurance organization shall concur with the proposed remedial action to ensure that quality assurance program requirements are satisfied.

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16.2.4 Significant Conditions Adverse to Quality

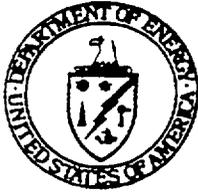
- A. Criteria for determining a significant condition adverse to quality shall be established.
- B. Significant conditions adverse to quality shall be documented and reported to management responsible for the condition, their upper management, and to the quality assurance organization for tracking.
- C. Significant conditions adverse to quality shall be evaluated for a stop work condition by the quality assurance organization to determine if stopping work is warranted.
 - 1. Quality assurance management shall issue stop work orders to responsible management after a stop work condition has been identified.
 - 2. Quality assurance management shall take appropriate action to lift and close (in part or total) the stop work issued by the quality assurance organization based on the resolution of the related significant condition adverse to quality.
- D. Responsible management shall perform investigative action to determine the extent of the condition, and document the results.
- E. Responsible management shall determine, document, and complete remedial action. Responsible management shall also determine the root cause of the problem and take corrective action to prevent recurrence in a timely manner.
- F. The quality assurance organization shall concur with the proposed corrective action including remedial action, the root cause, and actions taken to prevent recurrence to ensure that quality assurance program requirements are satisfied.

16.2.5 Follow-up and Closure Action

The quality assurance organization shall verify implementation of corrective actions taken for all reported conditions adverse to quality and close the related corrective action documentation in a timely manner when actions are complete.

16.2.6 Trending

- A. The quality assurance organization shall establish criteria for determining adverse quality trends.
- B. Reports of nonconformances and significant conditions adverse to quality shall be evaluated to identify adverse quality trends and help identify root causes.
- C. Trend evaluation shall be performed in a manner and at a frequency that provides for prompt identification of adverse quality trends.
- D. Identified adverse trends shall be reported to the organization responsible for corrective action.



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Quality Assurance Requirements and Description

Title: QUALITY ASSURANCE RECORDS

Effective Date: 12/18/92

Section No.: 17.0

Revision No.: 0

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17.1 GENERAL

This section establishes requirements to ensure that quality assurance records are controlled and maintained.

17.2 REQUIREMENTS

17.2.1 Classifying Quality Assurance Records

Quality assurance records shall be classified as lifetime or nonpermanent.

A. Documents that meet the following requirements shall be classified as lifetime quality assurance records:

1. Documents that provide evidence of the quality of items on the Q-List.
2. Documents that provide evidence of the quality of activities related to items on the Q-List.
3. Documents that provide evidence of the quality of site characterization data and samples.
4. Documents that provide evidence of those activities that provide data used to assess the potential dispersion of radioactive materials from the licensed facility.
5. Documents that provide evidence of the quality of the production process for the high-level waste form and acceptance of the high-level waste form itself.
6. Personnel training and qualification documents for individuals executing quality assurance program requirements.
7. Documents considered Implementing Documents as described in Section 5.0.

B. Documents that do not meet the requirements for lifetime quality assurance records, but provide objective evidence that the Quality Assurance Program has been properly executed shall be classified as nonpermanent quality assurance records.

17.2.2 Creating Valid Quality Assurance Records

A. Implementing documents shall:

1. Identify those documents that will become quality assurance records.

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2. Identify the organization responsible for submitting the quality assurance records to the records management system
 - B. Individuals creating quality assurance records shall ensure that the quality assurance records are legible, accurate, and complete.
 - C. Individuals handling quality assurance records shall protect them from damage or loss until the records are submitted to the records management system.
 - D. Records shall be considered quality assurance records when stamped, initialed, or signed and dated as complete. If the nature of the record (such as magnetic or optical media) precludes stamping or signing, then other means of authentication by authorized personnel are permitted.
 - E. Quality assurance records may be originals or copies.

17.2.3 Receiving and Indexing Quality Assurance Records

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

- A. An individual or organization shall be assigned the responsibility for receiving quality assurance records.
- C* B. Quality assurance records shall be protected from damage, deterioration, or loss when received.
- D* C. Legibility and completeness of quality assurance records shall be verified.
- E* D. The receipt control system shall permit a current and accurate assessment of the status of quality assurance records during the receiving process.
- F* E. Quality assurance records shall be indexed to ensure retrievability. The indexing system shall include:
 1. The location of the quality assurance records within the records management system.
 2. Identification of the item or related activity to which the quality assurance records pertain.
 3. The retention classification of the quality assurance record.
- G* F. Quality assurance records shall be submitted to storage after the receipt process has been completed.

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17.2.4 Correcting Information in Quality Assurance Records

- A. Corrections shall include the initials or signature of the person authorized to make the correction and the date the correction was made.
- B. Corrections to quality assurance records shall be approved by the originating organization.

17.2.5 Storing and Preserving Quality Assurance Records

- A. Quality assurance records shall be stored and preserved in predetermined storage facilities 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 quality assurance records received are in agreement with the transmittal document.
 - 17.2.3.B ← 4. A method for verifying that the quality assurance records are those designated.
 - ~~5. A method for verifying that the quality assurance records are legible and complete.~~
 6. A description of controls governing quality assurance record access, retrieval, and removal.
 7. A method for filing supplemental information and disposition of superseded quality assurance records.
- B. Storage methods shall be developed to preclude deterioration of quality assurance records in accordance with the following:
 1. Provisions shall be made in the storage arrangement to prevent damage from moisture, temperature, and pressure.
 2. Approved filing methods shall require quality assurance 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 record medium being stored.
 3. The storage arrangement shall provide adequate protection of special processed records (such as radiographs, photographs, negatives, microform, and magnetic media) to preclude damage from moisture, temperature, excessive light, electromagnetic fields, or stacking, consistent with the type of record being stored.
 4. The storage area shall be protected from unauthorized entry, larceny, and vandalism.

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17.2.6 Retrieval of Quality Assurance Records

- A. The records management system shall provide for retrieval of quality assurance records with planned retrieval times based on record type.
- B. Access to storage facilities shall be controlled. A list shall be maintained designating personnel who are permitted access to the quality assurance records.

17.2.7 Retention of Quality Assurance Records

- A. OCRWM or its designee shall retain and preserve lifetime quality assurance records for the operating life of the item or facility.
- B. Nonpermanent quality assurance records shall be retained for a minimum of three years or as specified by procurement documents. Nonpermanent quality assurance records shall not be disposed of until the following conditions are met:
 - 1. Regulatory requirements are satisfied.
 - 2. Operational status permits.
 - 3. Purchaser's requirements are satisfied.

17.2.8 Disposition of Quality Assurance Records

- A. Affected organizations shall submit, to OCRWM or the purchaser, those quality assurance records being temporarily stored by them that are subject to records turnover requirements. The timing of the submittal shall be as record packages become complete, or as items are released for shipment, or as prescribed by the purchaser.
- B. The OCRWM records management organization shall inventory the submittal, acknowledge receipt, and process the records in accordance with DOE OCRWM records management policy.
- C. The responsible OCRWM line organizations shall identify those quality assurance records in temporary storage to be submitted for long-term storage to the records management system.

17.2.9 Long-Term Storage Facility

- A. OCRWM's single storage facility for the storage of lifetime quality assurance records shall meet the following design and construction requirements:
 - 1. Reinforced concrete, concrete block, masonry, or equal construction.
 - 2. Floor and roof with drainage control. If a floor drain is provided, a check valve or equal shall be included.

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3. Doors, structure and frames, and hardware shall be designed to comply with the requirements of a minimum 2 hour fire rating.
4. Sealant applied over walls as a moisture or condensation barrier.
5. Surface sealant on floor providing a hard wear surface to minimize concrete dusting.
6. Foundation sealant and provisions for drainage.
7. Forced air circulation with filter system.
8. Fire protection system.
9. Only those penetrations that are used exclusively for fire protection, communication, lighting, or temperature and humidity control are allowed. All penetrations shall be sealed or dampered to comply with the minimum 2 hour fire protection rating.

- ^{17.2.5.B.1} B. The facility shall be constructed to minimize the risk of damage or destruction by natural disasters, extremes in environmental conditions, and infestations of pests or molds.
- C. If the facility is located within a building or structure, the environment and construction of that building can provide a portion or all of these criteria.
- D. 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.

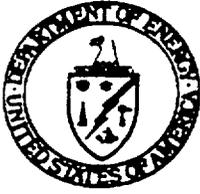
¹¹ 17.2.10 Temporary Storage Facility

OCRWM and affected organizations shall provide for temporary storage of quality assurance records during processing, review, or use until turnover to OCRWM for disposition, according to the following requirements:

- A. Quality assurance records shall be temporarily stored in a container or facility with a fire rating of 1 hour, or dual storage shall be provided.
- B. For 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.
- C. The maximum time limit for keeping quality assurance records in temporary storage shall be specified by OCRWM or the purchaser consistent with the nature or scope of work.

¹² 17.2.11 Replacement

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



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Quality Assurance Requirements and Description

Title: AUDITS

Effective Date: 12/18/92

Section No.: 18.0

Revision No.: 0

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18.1 GENERAL

This section establishes requirements for performing internal and external quality assurance audits to verify compliance with, and to determine the effectiveness of, the quality assurance program.

18.2 REQUIREMENTS

18.2.1 Scheduling Internal Audits

- A. Internal audits shall be 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 or effectiveness.
- E. Internal audits of work to verify quality assurance program compliance shall be performed annually or at least once during the life of the work, whichever is shorter.
- F. Internal audits to determine quality assurance program effectiveness (performance based audits) shall be performed on selected work products.

18.2.2 Scheduling External Audits

- A. The need for, and frequency of, external audits shall be determined after an affected organization has been selected to perform work for the CRWM Program. The determination is based on the complexity and nature of the items or services being procured.
- B. External audits shall not be required for procured items that are relatively simple and standard in design, manufacturing, and testing, or adaptable to standard or automated inspections or tests of the end product to verify quality characteristics after delivery. Rationale for not performing audits for these items shall be documented.

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- C. External audits for compliance shall be performed triennially as a minimum. Pre-award surveys, if applicable, may serve as the first triennial audit if the affected organization is implementing the same quality assurance program for other contracts that is proposed for the purchaser's contract.
- D. External audits to determine quality assurance program effectiveness (performance based audits) shall be performed on selected work products.
- E. Annual performance evaluations shall be performed on each affected organization to determine the need to schedule additional audits. This evaluation shall be documented and based on:
 - 1. Review of documentation furnished by the affected organization (such as certificates of conformance, nonconformance notices, and corrective actions).
 - 2. Results of previous source verifications, audits, management assessments, and receiving inspections including audits from other sources.
 - 3. Operating experience of identical or similar products furnished by the same affected organization.
 - 4. A review of procurement documents to determine what additional work the affected organization has received since the initial contract.
- F. The need to schedule additional external audits shall also be evaluated when a major change in the contract scope or work methodology occurs.

18.2.3 Audit Schedule

The audit schedule shall be developed annually and revised as necessary to ensure that coverage is maintained current.

18.2.4 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, type of audit personnel needed, 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 audit shall be based on an evaluation of the work to be audited, the results of previous audits and the impact of significant changes in personnel, organization, or the quality assurance program.

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18.2.5 Audit Team Independence

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

18.2.6 Audit Team Selection

- A. An audit team shall be identified before beginning each audit. The audit shall include representatives from the quality assurance organization and any applicable technical organizations.
- B. A lead auditor shall be appointed to supervise the team, organize and direct the audit, coordinate the preparation and issuance of the audit report, and evaluate responses.
- C. Lead auditors and auditors shall be qualified according to 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 qualified according to the requirements of this Section.
- 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 auditing organization 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.

18.2.7 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.

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F. Identified adverse audit findings (conditions adverse to quality) shall be documented and corrected according to the requirements of Section 16.0.

G. Nonconformances identified during an audit shall be controlled by the audited organization according to the requirements of Section 15.0.

18.2.8 Reporting Audit Results

The audit report shall be prepared by the audit team leader, and issued to management of the audited organization and affected organizations. The audit report shall include the following information:

- A. A description of the audit scope.
- B. Identification of the auditors.
- C. Identification of persons contacted during the audit.
- D. A summary of the documents reviewed, persons interviewed, and the specific results of the reviews and interviews, that is, a summary of the checklist contents.
- E. Statement of the Quality Assurance program effectiveness.
- F. A description of each reported adverse audit finding (condition adverse to quality) in sufficient detail to enable corrective action to be taken by the audited organization according to the requirements of Section 16.0.

18.2.9 Responding to Audits

Management of the audited organization shall: investigate adverse audit findings (conditions adverse to quality); determine and schedule corrective action, including measures to prevent recurrence; and notify the auditing organization in writing of the actions taken or planned according to the requirements of Section 16.0.

18.2.10 Evaluating Audit Responses

The adequacy of corrective actions for adverse audit findings (conditions adverse to quality) shall be evaluated by the auditing organization according to the requirements of Section 16.0.

18.2.11 Follow-up Action

Follow-up action shall be taken by the auditing organization to verify that corrective action is accomplished as scheduled according to the requirements of Section 16.0.

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18.2.12 Technical Specialist Qualifications

Technical specialists selected for auditing assignments shall be indoctrinated and trained according to the requirements of Section 2.0 and shall have the level of experience or training commensurate with the scope, complexity, or special nature of the work being audited.

18.2.13 Auditor Qualifications

Auditors shall have appropriate training or orientation to develop their competence for performing audits. Competence of personnel performing various audit functions shall be developed by one or a combination of the following methods:

- A. Quality assurance program orientation to provide a working knowledge and understanding of the QARD, and the implementing documents used to perform audits and report audit results.
- B. Training programs to provide general and specialized training in audit performance.
 - 1. General training shall include the fundamentals, objectives, and techniques of performing audits.
 - 2. Specialized training shall include methods of examining, questioning, evaluating, and documenting specific audit items and methods of closing out adverse audit findings (conditions adverse to quality) addressed by corrective action requests.
- C. On-the-job training, guidance, and counseling under the direct supervision of a lead auditor. Such training shall include planning, performing, reporting, and follow-up action involved in conducting audits.

18.2.14 Lead Auditor Qualifications

- A. A lead auditor shall be capable of organizing and directing audits, reporting audit findings, and evaluating planned and taken corrective action.
- B. A lead auditor shall be certified as meeting the requirements for education and experience, communication skills, training, audit participation, and passing the examination as provided in this Section.

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18.2.15 Lead Auditor Education and Experience

The prospective lead auditor shall have verifiable evidence that a minimum of ten credits have been accumulated under the following scoring system:

A. Education (four credits maximum)

1. An associate degree from an accredited institution: score one credit. If the degree is in engineering, physical sciences, mathematics, or quality assurance: score two credits; or
2. A bachelors degree from an accredited institution: score two credits or, if the degree is in engineering, physical sciences, mathematics, or quality assurance: score three credits. In addition, score one credit for a master's degree in engineering, physical sciences, business management, or quality assurance from an accredited institution.

B. Experience (nine credits maximum)

Technical experience in such areas as scientific investigation, site characterization, production, transportation, engineering, manufacturing, construction, operation, maintenance, or experience applicable to the auditing organization's area of responsibility: score one credit for each full year with a maximum of five credits for this aspect of experience.

1. If two years of this experience have been in the nuclear-related field: score one additional credit; or
2. If two years of this experience have been in quality assurance: score two additional credits; or
3. If two years of this experience have been in auditing: score three additional credits; or
4. If two years of this experience have been in nuclear-related quality assurance: score three additional credits; or
5. If two years of this experience have been in nuclear-related quality assurance auditing: score four additional credits.

C. Professional Competence (two credits maximum)

For certification of competency in engineering science or quality assurance specialties issued and approved by a state agency or national professional or technical society: score two credits.

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D. Rights of Management (two credits maximum)

When determined appropriate, the auditing organization may grant up to two credits for other performance factors applicable to auditing that are not explicitly called out in this section (such as leadership, sound judgment, maturity, analytical ability, tenacity, past performance, and completed quality assurance training courses).

18.2.16 Lead Auditor Communication Skills

The prospective lead auditor shall have the capability to communicate effectively, both in writing and orally. These skills shall be attested to in writing by the candidate's supervisor.

18.2.17 Lead Auditor Training

- A. Prospective lead auditors shall be trained to the extent necessary to ensure their competence in auditing skills as established by the organization responsible for performing audits.
- B. Training in the following areas shall be given based upon management evaluation of the particular needs of each prospective lead auditor.
 - 1. Knowledge and understanding of the QARD and other program related procedures, codes, standards, regulations, and regulatory guides.
 - 2. General structure of quality assurance programs as a whole and the specific elements of the QARD.
 - 3. Auditing techniques of examining, questioning, evaluating, and reporting. Methods of identifying, following up on, and closing corrective action items.
 - 4. Audit planning in functional areas (such as scientific investigation, design, purchasing, construction, fabrication, handling, shipping, storage, cleaning, inspection, testing, statistics, nondestructive examination, maintenance, repair, operation, modification, and safety) of nuclear facilities.
 - 5. On-the-job training to include applicable elements of the audit program.

18.2.18 Lead Auditor Audit Participation

The prospective lead auditor shall have participated in a minimum of five quality assurance audits or equivalent verifications (such as management assessments, pre-award surveys, or comprehensive surveillances, providing the parameters of the audit process are met) within a period of time not to exceed three years prior to the date of certification. One audit shall be a nuclear-related quality assurance audit or equivalent verification within the year prior to certification.

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18.2.19 Lead Auditor Examination

- A. The prospective lead auditor shall pass an examination that evaluates the comprehension of and ability to apply the audit knowledge described in this Section. The test shall be oral, written, practical, or any combination.
- B. The development and administration of the examination for a lead auditor is the responsibility of the auditing organization. The auditing organization shall:
 - 1. Maintain the integrity of the examination through confidentiality of files and, where applicable, proctoring of examinations.
 - 2. Develop and maintain objective evidence regarding the type and content of the examination.

18.2.20 Certification of Lead Auditor Qualifications

Each lead auditor shall be certified by the auditing organization as being qualified to lead audits. This certification shall document the:

- A. Name of the auditing organization.
- B. Name of the lead auditor.
- C. Date of certification or recertification.
- D. Basis of certification (such as education, experience, communication skills, and training).
- E. Signature of the designated representative of the auditing organization responsible for certification.

18.2.21 Maintaining Lead Auditor Proficiency

- A. Lead auditors shall maintain their proficiency through one or combination of the following:
 - 1. Regular and active participation in the audit process.
 - 2. Review and study of codes, standards, implementing documents, instructions, and other documents related to the quality assurance program and program auditing.
 - 3. Participation in training programs.

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- B. Management of the auditing organization shall evaluate the proficiency of lead auditors annually. Based on the evaluation, management may choose to extend the qualification, require retraining, or require requalification. Management evaluations shall be documented.

- C. Lead auditors who fail to maintain their proficiency for a two-year period shall require requalification to the requirements of this Section for a lead auditor.



Office of Civilian Radioactive Waste Management

Quality Assurance Requirements and Description

Title: SOFTWARE

Effective Date: 12/18/92

Section No.: SUPPLEMENT I

Revision No.: 0

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I.1 GENERAL

This Supplement establishes requirements for the development, acquisition, control, and use of scientific and engineering software. Software that is acquired as an integral part of measuring and test equipment is controlled by Section 12.0 of this QARD and is exempted from the requirements of this supplement.

Model validation is addressed in Section 3.0 and Supplement III.

I.2 REQUIREMENTS

I.2.1 Software Life Cycles, Baselines and Controls

- A. Each affected organization shall document and approve a specific life cycle plan for each software item prior to development or modification of software or the qualification of acquired software.
 - 1. Software life cycles shall be defined by control points at which software baseline elements shall be documented. Software life cycle activities may be performed in an iterative or sequential manner.
 - 2. For software developed within an affected organization, the documentation requirements of Section I.2.6 shall be established when the life cycle is defined.
- B. Reviews of software baselines shall be performed and documented at the software control points.

I.2.2 Software Verification and Software Validation

- A. Software verification and software validation of developed or modified software or qualification of acquired software shall be performed prior to release. In those cases where this requirement cannot be met prior to the release of the software, the portions of software that have not been verified and validated shall be identified and controlled, and written justification of the reason shall be documented.
- B. Software verification and software validation plans shall describe methods (such as review, inspection, analysis, demonstration and test) for verification and validation.

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- C. Software verification and software validation activities shall be accomplished or reviewed by an independent individual or organization, one who did not work on the original software development or modification. The person who directed the work may perform these activities with a higher level of management approval and documented justification.

I.2.3 Software Verification

The software verification shall be performed and documented to ensure that the products of a life cycle phase meet the requirements established for that phase.

I.2.4 Software Validation

- A. Software validation activities (such as the development of test plans and test cases) shall be integrated into the software life cycle.
- B. Testing shall be the primary method of software validation.
- C. Software validation of modifications to released software items shall include regression testing. The test plans and test cases shall be documented in a software validation plan.

I.2.5 Acquired Software

Acquired software shall be documented sufficiently to demonstrate the ability of the software to meet the needs of the affected organization.

- A. Qualification of acquired software not developed in accordance with this supplement or its predecessors shall include the following:
 - 1. Performing validation to an approved plan, to ensure that software meets the requirements for its intended use.
 - 2. Placing the software under the configuration controls of Section I.2.7 of this supplement.
- B. Qualification of acquired software that was developed or modified in accordance with this supplement or its predecessors shall include the following:
 - 1. Installation testing to ensure that software performs as required in the operational environment.
 - 2. Confirmation that documented information exists to support that appropriate requirements were met.
 - 3. Placing the software under the configuration controls of Section I.2.7 of this supplement.

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- C. Acquired software shall meet the documentation requirements of Section I.2.6 A, B, C, and D only.

I.2.6 Documentation

Software activities shall be documented sufficiently to demonstrate the ability of the software to meet the needs of the affected organization and shall include the following:

A. Requirements Information:

1. A description of the overall nature and purpose of the software.
2. Requirements for its intended use.

B. User Information:

1. A description of how to use the software item including:
 - a. Input and output options.
 - b. Data files, input and output data, defaults and file formats.
 - c. Anticipated errors and how the user can respond.
 - d. The hardware and software environments.
 - e. A description of the allowable and tolerable ranges for inputs and outputs.
2. Available sample problems.
3. Changes since the last release that affect the user.
4. Installation procedures.

C. Validation Information:

1. The validation plan shall include a description of the tasks, methods, implementing documents, and acceptance criteria for accomplishing the software validation.
2. A record of the results of the execution of planned software validation including the extent to which the results agree with the specified acceptance criteria.

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D. Information on Reviews:

1. Records of reviews of software baselines.

E. Requirements and Design Information:

1. Functional requirements.
2. Performance requirements and design constraints.
3. Interfaces with external data, hardware, or other software.
4. Applicable software and hardware operation issues to include programming languages and versions, portability, maintainability, reliability, and efficiency.
5. A description of the major software items as they relate to the functional requirements.
6. A description of the software structure including software internal interfaces, control logic, and data structure and flow.
7. A description of models and numerical methods.

F. Verification Information:

1. The verification plan shall include a description of the tasks, methods, implementing documents, and acceptance criteria for accomplishing the software verification.
2. A record of the results of the execution of planned software verification including the extent to which the results agree with the specified acceptance criteria.

1.2.7 Software Configuration Management

A software configuration management system shall be established to include configuration identification, configuration control and configuration status accounting. Software shall be placed under configuration management control as each baseline element is approved.

A. Configuration identification shall include:

1. A definition of the baseline elements of each software baseline.
2. A unique identification of the software items to be placed under software configuration management.

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- a. Each version or revision of a software item shall be uniquely identified and labeled.
 - b. The software version or revision identifier shall be included with the generated output, when feasible.
 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.
- B. Configuration control shall include:
1. A release and control process for baseline elements.
 2. Changes to baseline elements, including retirement and withdrawal, 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.
 - a. The change shall be formally evaluated and approved by the organization responsible for approving the baseline element.
 - b. Only approved changes shall be made to software baselines and information concerning approved changes shall be transmitted to all organizations affected by the changes.
 - c. Software verifications shall be performed for the changes as necessary to ensure the change is appropriately reflected in software documentation and to ensure that document traceability is maintained.
 - d. Software validation shall be performed as necessary for the change.
- C. Configuration status accounting shall include:
1. A listing of the approved baseline elements and unique identifiers.
 2. The status of proposed and approved changes to the baseline elements.
 3. A brief chronology of the software items, including descriptions of the changes made between versions of software items.

I.2.8 Defect Reporting and Resolution

A software defect reporting and resolution system shall be implemented.

- A. The defect reporting and resolution system shall be integrated with the software configuration management system to ensure formal processing of defect resolutions.

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- B. Software defect reporting and resolution systems shall include the following controls:
1. Defects shall be documented and resolved.
 2. Defects shall be assessed for their impact on previous applications.
 3. Resolutions shall be reviewed and approved before changes are made to baseline elements.
 4. Affected organizations shall be appropriately notified.
- C. If a defect is identified in software that adversely impacts previous applications, then the condition adverse to quality shall be documented and controlled in accordance with Section 16.0.

I.2.9 Media Control

Media containing a copy of the completed/released software items shall be controlled to prevent inadvertent damage or degradation.

I.2.10 Use of Software

- A. Affected organizations shall establish procedures for controlling and documenting the use of released software items sufficient to allow an independent repetition of the use of software.
- B. Software uses shall be approved and independently reviewed to ensure that the software selected is applicable to the problem being solved and that inputs and assumptions are valid and traceable.
- C. If use of a software item falls outside the range of validation, further validation shall be performed prior to use.



Office of Civilian Radioactive Waste Management

Quality Assurance Requirements and Description

Title: SAMPLE CONTROL

Effective Date: 12/18/92

Section No.: SUPPLEMENT II

Revision No.: 0

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II.1 GENERAL

This supplement establishes requirements for the control of physical samples.

II.2 REQUIREMENTS

II.2.1 General Requirements

- A. Samples shall be controlled and identified in a manner consistent with their intended use.
- B. These 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.

II.2.3 Identification

- A. Identification shall be maintained on the samples or in a manner which ensures that identification is established and maintained.
- B. Samples shall be identified from their initial collection through final use.
- C. Sample identification is documented and checked before released for use.
- D. Sample identification methods shall include use of physical markings. If physical markings are either impractical or insufficient, other appropriate means shall be employed (such as physical separation, labels or tags attached to containers, or procedural control).

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- E. 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 requirement documents (such as the Site Characterization Plan, test plans, study plans, or job packages) contain specific identification or traceability requirements (such as 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 are 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 work and inspection implementing documents or other specified documents.

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- 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. 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. Markings and labels shall indicate the presence of special environments or the need for special controls if necessary.
- D. If required for particular samples, special equipment (such as containers) and special protective environments (such as inert gas, and moisture and temperature limits) shall be specified and provided.
- E. 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 Disposition of Nonconforming Samples

- A. Samples that do not meet requirements specified in work controlling documents (such as Job Packages, Travelers, or Work Requests) shall be documented, evaluated, identified, and segregated in accordance with Section 15.0 of this QARD.
- B. The disposition for nonconforming samples shall be identified and documented and shall be limited to "use-as-is," "limited use," or "discard."



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Quality Assurance Requirements and Description

Title: SCIENTIFIC INVESTIGATION

Effective Date: 12/18/92

Section No.: SUPPLEMENT III

Revision No.: 0

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III.1 GENERAL

This supplement establishes requirements for scientific investigations.

III.2 REQUIREMENTS

III.2.1 Planning Scientific Investigations

- A. Scientific investigations shall be planned in accordance with Section 2.0 of the QARD.
- 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.
- D. Planning documents shall meet the requirements of Section 5.0 and Section 6.0.

III.2.2 Performing Scientific Investigations

- A. Scientific investigations shall be performed using scientific notebooks, technical implementing documents, or a combination of both.
- B. Scientific notebooks shall contain the following:
 - 1. Statement of objective and description of work to be performed, or reference to an approved plan that describes the work.
 - 2. Method(s) to be used.
 - 3. Identification of any samples or measuring and test equipment used.
 - 4. Description of the work 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.

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- C. Scientific notebooks shall be reviewed by an independent qualified individual to verify there is sufficient detail to retrace the investigation and confirm the results, if feasible, or repeat the investigation and achieve comparable results, without recourse to the original investigator.
- D. Technical implementing documents used to perform scientific investigations shall meet the requirements of Section 5.0 and Section 6.0.

III.2.3 Data Identification

- A. Data shall be identified to provide traceability, indicate usability, and document validation status.
- B. Identification and traceability shall be maintained throughout the lifetime of the data.

III.2.4 Data Validation and Qualification

- A. Data collected under the QARD shall be subject to validation, including:
 - 1. A review of associated documentation to establish technical adequacy, suitability for intended usage, and the satisfaction of quality assurance and documentation requirements.
 - 2. The results of the data review shall be documented.
 - 3. The reviewer shall be independent from the collector.
- B. Data considered as established fact by the scientific and engineering community do not require validation.
- C. Validation of existing data shall require documenting and subjecting to review, the known level of confidence associated with the data to establish the adequacy and suitability of the data for the intended use.
- D. Existing data relied upon to address safety and waste isolation issues shall be qualified as follows:
 - 1. One or a combination of the following methods shall be used:
 - a. Determination that the controls under which the data were generated are similar in scope, requirements and implementation to the QARD.
 - b. Corroborating Data - Inferences drawn to corroborate the existing data shall be clearly identified and justified.
 - c. Confirmatory Testing.

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- d. Peer Review in accordance with Section 2.0.
2. Qualification shall be planned and documented. The documentation shall include the following:
 - a. The factors used in arriving at the choice of qualification methods and also the acceptance criteria used to determine if the data is qualified.
 - b. Use of qualification methods (a), (b) and (c) shall include a documented review to validate data for usage.
3. The following attributes shall be considered in the qualification process as applicable:
 - a. Previous uses of the existing data and associated verification processes.
 - b. Previous professional reviews of the existing data and the results of those reviews.

III.2.5 Data Usage

- A. The selection and determination of suitability of data for use in individual applications shall be documented.
- B. Data reduction and transfer shall be controlled to permit independent reproducibility by another qualified individual.

III.2.6 Model Validation

- A. Use and validation of models of natural phenomena shall be performed and documented to provide adequate justification for the intended use.
- B. Model validation shall be accomplished by comparing analysis results against data acquired from laboratory or field experiments or observations. When data are not available from these sources, alternative approaches (such as peer review or comparisons with data from open literature) shall be documented and used for model validation.



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Quality Assurance Requirements and Description

Title: FIELD SURVEYING

Effective Date: 12/18/92

Section No.: SUPPLEMENT IV

Revision No.: 0

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IV.1 GENERAL

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.

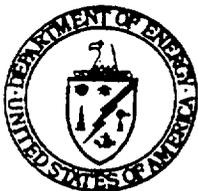
IV.2 REQUIREMENTS

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.



Office of Civilian Radioactive Waste Management

Quality Assurance Requirements and Description

Title: HIGH LEVEL RADIOACTIVE WASTE FORM PRODUCTION

Effective Date: 12/18/92

Section No.: APPENDIX A

Revision No.: 0

Page 1 of 2

A.1 GENERAL

This appendix contains amplifications of requirements and descriptions unique to waste form production. Amplifications provided relate to specific sections or supplements. In those cases when a section or supplement requires no amplification, reference to the section or supplement is omitted.

DOE's Office of Environmental Restoration and Waste Management (EM) has overall responsibility for processing high-level radioactive waste form. EM interfaces with the OCRWM Office of Systems and Compliance on matters pertinent to waste form production and acceptance.

A.2 REQUIREMENTS

A.2.1 Amplification of QARD Section 2 - Quality Assurance Program

Line management shall plan, schedule, and conduct readiness reviews at significant transitional events both leading up to and during waste form production.

A.2.2 Amplification of QARD Section 3 - Design Control

A. Waste Form Development

1. Line organizations shall control and document waste form development in a manner that ensures that resulting waste form qualification data is suitable for use and can be independently reconstructed and evaluated.
2. Implementing documents shall identify responsibilities for performing waste form development work and contain requirements for:
 - a. Selection and qualification of personnel.
 - b. Evaluation of results obtained from waste form development work.
 - c. Documentation of waste form development work including final results.

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B. Technical Modifications to Waste Form Production Process

1. Line management shall establish measures for controlling item and technical modifications to the waste form production process.
2. Items and technical documents subject to modification control include:
 - a. Waste form and canistered waste form.
 - b. Processing and process control plans and implementing documents.
 - c. Waste Form Compliance Plans (WCPs), Waste Form Qualification Reports (WQRs), and Production Records (PRs).



Office of Civilian Radioactive Waste Management

Quality Assurance Requirements and Description

Title: STORAGE AND TRANSPORTATION

Effective Date: 08/04/95

Section: APPENDIX B

Revision No.: 2

Page 1 of 1

B.1 GENERAL

- A. This appendix contains amplifications of requirements and descriptions unique to the work conducted for the storage of spent fuel and the transportation of spent fuel and high-level radioactive waste. Exceptions to the *Quality Assurance Requirements and Description* (QARD) requirements are given for organizations that design or fabricate transportation casks or multi-purpose canisters (MPCs) under the licensing provisions of 10 Code of Federal Regulations (CFR) 71, or design or fabricate storage casks or MPCs under the licensing provisions of 10 CFR 72.
- B. Activities associated with storage casks, transportation casks, and MPCs that are required to ensure future compliance with 10 CFR 60 are not covered by this appendix. For example, whereas work on translating Mined Geologic Disposal System design criteria into MPC design criteria would be subject to the applicable sections of this QARD, implementing approved MPC design criteria would only be subject to the requirements of this appendix.

B.2 REQUIREMENTS

B.2.1 General

Organizations that design or fabricate storage casks, transportation casks, or MPCs shall develop Quality Assurance (QA) programs that are accepted by the Nuclear Regulatory Commission and the procuring organization. The QA programs shall meet the following requirements.

B.2.2 Storage Casks, Transportation Casks, and MPCs

- A. The QA program shall meet the requirements of 10 CFR 71, Subpart H or 10 CFR 72, Subpart G, as applicable.
- B. The requirements of this appendix are the only QARD requirements that apply to organizations designing or fabricating storage casks, transportation casks, or MPCs under 10 CFR 71, Subpart H or 10 CFR 72, Subpart G, QA programs.



Office of Civilian Radioactive Waste Management

Quality Assurance Requirements and Description

Title: MINED GEOLOGIC DISPOSAL SYSTEM

Effective Date: 12/18/92

Section No.: APPENDIX C

Revision No.: 0

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C.1 GENERAL

This appendix contains amplifications of requirements and descriptions unique to work conducted for the Mined Geologic Disposal System. Amplifications provided relate to specific sections or supplements. In those cases when a section or supplement requires no amplification, reference to the section or supplement is omitted.

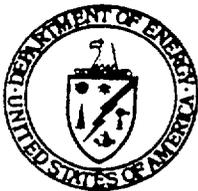
C.2 REQUIREMENTS

C.2.1 Amplification of QARD Section 10 - Inspections

If required by work controlling documents (such as Job Packages, Travelers or Work Requests) work products shall be subject to inspection in accordance with Section 10.0 of the QARD.

C.2.2 Amplification of QARD Section 15 - Nonconformances

Nonconforming products resulting from activities specified in work controlling documents (such as Job Packages, Travelers, or Work Requests) shall be documented, evaluated, identified, segregated, and dispositioned in accordance with Section 15.0 of this QARD.



Office of Civilian Radioactive Waste Management

Quality Assurance Requirements and Description

Title: GLOSSARY

Effective Date: 12/18/92

Section No.: GLOSSARY

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Acceptance (document): The documented determination by the receiving organization that a work product is suitable for the intended purpose.

Affected Organization: An organization (including OCRWM, other DOE offices, other government agencies, and suppliers) performing Program work subject to QARD requirements.

Alternate Calculations: Calculations that are made with alternate methods to verify correctness of the original calculation.

Approval: The documented determination by a responsible organization that a work product is suitable for the intended purpose and shall be used as required.

Audit: A planned and documented quality assurance program verification performed to determine by investigation of objective evidence the adequacy of and compliance with established implementing documents and the effectiveness of implementation.

Auditor: An individual who is qualified to perform assigned portions of an audit.

Audit Team Leader: A lead auditor who is assigned to direct the efforts of an audit team.

Baseline Element (Software): An individual component of a software baseline.

Certificate of Conformance: A document signed or otherwise authenticated by an authorized individual certifying the degree to which items or services meet specified requirements.

Certification: The act of determining, verifying, and attesting in writing to the achievement or compliance with specified requirements.

Characteristic: A property of a work product that is distinct, describable, and measurable.

Code Listing: An ordered display or printout of program statements.

Commercial Grade Item: An item that is (i) not subject to design or specification criteria unique to the Program or nuclear facilities, (ii) used in applications other than the nuclear industry, and (iii) ordered from the manufacturer or supplier on the basis of specifications set forth in the manufacturer's published product description.

Computer Program: A sequence of instructions suitable for processing by a computer.

Condition Adverse to Quality: A state of noncompliance with quality assurance program requirements.

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Confirmatory Testing: An evaluation subject to implementing documents that investigates the properties of interest of data in an attempt to confirm the quality of the data.

Controlled Document: A document that is prepared, reviewed, and approved in accordance with established implementing documents; subject to controlled distribution; and subject to a defined change process.

Corrective Action: Measures taken to rectify conditions adverse to quality and, where necessary, to preclude repetition.

Corroborating Data: Data that is used to support or substantiate other data that is being qualified.

Data Reduction: Processes that change the form of expression, quantity of data or values, or the number of data items.

Design Bases: Information that identifies the specific functions to be performed by items and the specific values or ranges of values chosen for controlling parameters as reference bounds for design.

Design Input: Those criteria, parameters, bases, or other design requirements upon which design output documents are based.

Design Output: Drawings, specifications and other documents resulting from the translation of design input requirements of items.

Design Process: Technical and management process that commences with identification of design input and ends with the issuance of design output documents.

Design Review: A documented evaluation of design output during the design process to determine design adequacy and conformance to specified acceptance criteria.

Document Control: The process for controlling documents that provides for adequacy review, approval for release by authorized personnel, and distribution for use at the prescribed work locations.

Existing Data: Data developed prior to the implementation of a quality assurance program that meets OCRWM requirements and data that are not information accepted by the scientific and engineering community as established fact.

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.

Implementing Document: A document that prescribes an approved process for accomplishing work in compliance with QARD requirements.

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Indoctrination: Method of training designed to familiarize personnel in fundamental criteria, program elements, responsibilities, and authority applicable to assigned tasks.

Inspection: A quality assurance program verification that is used to verify whether an item conforms to specified technical criteria.

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 that is identified in a design document.

Lead Auditor: An individual who is certified to organize, perform, and direct an audit; report audit results; and evaluate related corrective actions.

Management Assessment: A quality assurance program verification that is conducted by management above or outside the Quality Assurance organization and that evaluates the scope, status, adequacy, programmatic compliance, and implementation effectiveness of the quality assurance 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.

Model Validation: The process that demonstrates that the model is an acceptable representation of the process or system for which it is intended.

Nonconformance: A deficiency in characteristic or record that renders the quality of an item or sample unacceptable or indeterminate.

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.

Peer: A person having technical expertise in the subject matter to be reviewed to a degree at least equivalent to that needed for the original work.

Peer Review: A documented, in-depth critique of a work product by a group of peers.

Performance Confirmation: The program of tests, experiments and analyses which is conducted to evaluate the accuracy and adequacy of the information used to determine with reasonable assurance that the performance objectives for the period after permanent closure will be met.

Personnel Qualification: See Qualification (Personnel).

Process: A series of actions that achieves an end result or accomplishes work.

Procurement Document: Purchase orders, contracts, specifications, or other document used to define technical and quality assurance requirements for the procurement of items or services.

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Quality Assurance Record: A completed document (or other medium) that furnishes evidence that items or work comply with QARD requirements.

Quality Assurance (QA): All those planned and systematic actions necessary to provide adequate confidence that an item will perform satisfactorily in service.

Qualification of Data: A formal process that is intended to provide a desired level of confidence that data is suitable for its intended use.

Qualification Testing: A test that is intended to provide a desired level of confidence that an item meets specified criteria.

Qualification (Personnel): The capabilities gained through education, training, or experience that qualify an individual to perform a required function.

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.

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 an item 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.

Rework: The process by which an item is restored to original specifications by completion or correction.

Right of Access: The procurement requirement that permits the purchaser or designated representative to enter the premises of a supplier for verification purposes.

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 and Engineering Software: Software that uses numerical methods for complex scientific, engineering, and mathematical calculations.

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Scientific Investigation: Any observation, identification, description, experimental study, or analysis and explanation of natural phenomena.

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 a scope of work that does not involve the deliverance of an item to the purchaser.

Significant Condition Adverse to Quality: A significant condition adverse to quality is one which, if uncorrected, could have a serious affect on safety, or the ability to isolate waste.

Site Characterization: The program of exploration and research both in the laboratory and the field that is undertaken to establish the geologic conditions and the ranges of parameters of a particular site that are relevant to the implementing documents.

Software: A software item and associated documentation.

Software Baseline: (1) A specification or product that has been formally reviewed and agreed upon, that thereafter is the basis for further development, and that can be changed only through formal change procedures. (2) A document, a set of documents, or a product formally designated and controlled at a specific time during the software life cycle.

Software Control Point: Milestones in the software life cycle when controls are applied to the software baselines.

Software Item: Source code, object code, job control code, control data, or a collection of these items that function as a single unit.

Software Life Cycle: A series of activities that begins when a software product is conceived and ends when the software is no longer available for use.

Software Validation: The process of evaluating a system or component during or at the end of the development process to determine whether it satisfies specified requirements.

Software Verification: The process of determining whether the products of a given software life cycle phase satisfy the conditions imposed at the start of that phase.

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.

Stop Work Order: A formal directive issued by management that work must be stopped until resolution of the related significant condition adverse to quality.

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Supplier: Any individual or organization who furnishes items or services in accordance with a contract. An all-inclusive term used in place of any of the following: vendor, seller, participant, contractor, or subcontractor.

Surveillance: The act of observing real-time activities and/or reviewing documentation to verify conformance with specified requirements and to evaluate their adequacy and effectiveness.

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.

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.

Traceability: The ability to trace the history, application, or location of an item, data, or sample using recorded documentation.

Training: 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.

Use-As-Is: A disposition permitted for a nonconforming item when it can be established that the item is satisfactory for its intended use.

Verification: The process that is performed to determine by investigation of objective evidence the adequacy of and compliance with established implementing documents and the effectiveness of implementation.

Work: Activities that have been determined to be performed in accordance with QARD requirements.

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(QARD)

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

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