Office of Civilian Radioactive Waste Management QA: QA

QUALITY ASSURANCE REQUIREMENTS AND DESCRIPTION

DOE/RW-0333P

Revision 14

Effective Date: 04/01/2004

R Dennis Brown

R. Dennis Brown, Director
Office of Civilian Radioactive Waste Management
Office of Quality Assurance

3/30/04
Date

Dr. Margaret S.Y. Chu, Director
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3/31/04
Date

DOE/RW-0333P
Revision 4

Quality Assurance Policy

Successful implementation of the Office of Civilian Radioactive Waste Management (OCRWM) Quality Assurance (QA) Program is essential for OCRWM to carry out its mission. Central to our mission is the protection of the health and safety of the public and workers, the quality of the environment, and meeting the regulatory basis for the licensing of a Monitored Geologic Repository.

The *Quality Assurance Requirements and Description* document establishes the minimum requirements for the OCRWM QA Program. *The Quality Assurance Requirements and Description* defines the organizational responsibilities related to implementation and oversight of the OCRWM QA Program.

As the Director of OCRWM, I endorse the QA requirements necessary to fulfill our mission. This document, the *Quality Assurance Requirements and Description*, embodies these requirements. These requirements, as applicable, apply to every level of every organization participating in this mission.

The QA provisions described in the *Quality Assurance Requirements and Description* have my unqualified support. All organizations performing work for, or to be accepted by, OCRWM shall comply with the *Quality Assurance Requirements and Description*.

Margaret S.Y. Chu, Director
Office of Civilian Radioactive
Waste Management

3/31/04
Date

REVISION HISTORY

REVISION	REVISION DESCRIPTION	EFFECTIVE DATE
0	Initial issue. This document consolidates the *Quality Assurance Requirements Document* and the *Quality Assurance Program Description Document* into one document	12/18/92
1	Revised Section 1.0, Organization, to reflect OCRWM reorganization.	07/21/94
2	Revised Section 7.0, Control of Purchased Items and Services, to accommodate the transfer of responsibility for the performance of audits from Affected Organizations to OCRWM OQA.	03/27/95
3	Revised Appendix B, Storage and Transportation to provide an exception to the *Quality Assurance Requirements and Description* for organizations working under the provisions of 10 CFR 71, Subpart C or 10 CFR 72, Subpart L.	07/13/95
4	Revised Appendix B, to reflect editorial change to correct 10 CFR Subpart reference.	08/04/95
5	Revised the following sections to incorporate changes requested by various Affected Organizations. • Section RevHist, Revision History • Section TOC, Table of Contents • Section Policy, Quality Assurance Policy • Section Intro, Introduction • Section 1.0, Organization • Section 2.0, Quality Assurance Program • Section 3.0, Design Control • Section 4.0, Procurement Document Control • Section 5.0, Implementing Documents • Section 6.0, Document Control • Section 7.0, Control of Purchased Items and Services • Section 8.0, Identification and Control of Items • Section 9.0, Control of Special Processes • Section 12.0, Control of Measuring and Test Equipment • Section 14.0, Inspection, Test and Operating Status • Section 15.0, Nonconformances • Section 16.0, Corrective Action • Section 17.0, Quality Assurance Records	10/31/95

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

REVISION	REVISION DESCRIPTION	EFFECTIVE DATE
	• Section 7.0, Revised 7.2.2B to allow for the transition of QA functions • Appendix B, Revised to clarify applicability of 10 CFR 72 to ancillary equipment • Appendix C, Revised to clarify MGDS requirements for procurement of analytical services in support of scientific investigations	
8	Revised the following sections to incorporate changes as noted: • Section RevHist, Revision History. • Section TOC, Table of Contents. • Section Intro, Introduction - Modified Figure Intro-1 (Source Documents) to add NUREG-1563 as a guidance document for the use of expert elicitation. • Section 2.0, Quality Assurance Program - Revised Subsection 2.2.11, Quality Assurance Program Information Management to correct typographical error. Revised Subsection 2.2.12, Personnel Qualification to incorporate a graded approach to training and qualification. Revised Subsection 2.2.13, Qualification of Personnel Who Perform Inspection, Nondestructive Examination, Testing, and Auditing to explicitly state the special QA functions. • Supplement I, Software-Modified Subsection I.1 to clarify applicability of Supplements I and V. Deleted "baseline" in I.2.1.C.1. • Supplement III, Scientific Investigation - Subsection III.2.4, Data Review, Adequacy, and Usage and Subsection III.2.5, Technical Report Review were rewritten. This establishes new categories (qualified, accepted, and existing) for data and adds technical assessment as an alternative method for qualification of data. • Appendix C, Mined Geologic Disposal System - Added new Subsection C.2.1, to define requirements for conducting expert elicitation. • Glossary - Added definitions of special terms used in Appendix C, Expert Elicitation (i.e., expert elicitation, generalist, normative expert, and subject-matter expert). Added definitions of special terms used in Supplement III (i.e., accepted data, acquired data, developed data, existing data and technical report). Modified definition of “qualified data.”	06/05/98

REVISION	REVISION DESCRIPTION	EFFECTIVE DATE
	• This revision was initiated by Document Action Request Number 2054.	
9	Revised the following sections to incorporate changes as noted: • Policy, Quality Assurance Policy • Section RevHist, Revision History • Section TOC, Table of Contents • Section Intro, Introduction - Modified Figure Intro-1 (Source Documents) to add NUREG-1636 as a guidance document for use in model validation. • Section 1.0, Organization - Revised Subsections 1.3.1, 1.3.2, 1.3.3, and Figure 1-1 to reflect OCRWM organizational changes and minor clarification. • Sections TOC, Table of Contents; Intro, Introduction; 1.0, Organization; Appendix B, Storage and Transportation; and Appendix C, Mined Geologic Disposal System - Changed "Mined Geologic Disposal System" to "Monitored Geologic Repository." • Section 2.0, Quality Assurance Program - Deleted Subsection 2.2.2.F, requirement for items required for physical protection as defined by 10 CFR Part 73 to be included on a Q-List. Added Subsection 2.2.2.B to address physical protection items. Revised Subsection 2.2.12.B to clarify applicability of position descriptions and action taken for personnel that do not meet minimum education and experience requirements. • Supplement I, Software - Enhanced life cycle description and general rewrite. • Supplement III, Subsection III.2.6 - Enhanced modeling process due to commitment in LVMO-C-99-010. Subsection III.2.4 - Changed existing data to unqualified data. • Supplement V - Rewrite to be consistent with changes made to Supplement I. • Appendix C, Subsection C.2.1 - Changed existing data to unqualified data. Subsection C.2.3 - Clarified traceability of quality control samples to recognized national standards. • Glossary – Various definitions added, deleted, or changed. • Various editorial changes. • This revision was initiated by Document Action Request	02/07/2000

REVISION	REVISION DESCRIPTION	EFFECTIVE DATE
	numbers 21075, 2329, and 20020.	
10	Revised the following sections to incorporate changes as noted: • Section RevHist, REVISION HISTORY • Section TOC, TABLE OF CONTENTS • Section 7.0, CONTROL OF PURCHASED ITEMS AND SERVICES–Deleted second sentence in Paragraph 7.2.2B (i.e., voting membership in procurement evaluation board). • This revision incorporates Document Action Request D-49.	04/28/2000
11	Revised the following sections to incorporate changes as noted: • Section RevHist, Revision History • Section TOC, Table of Contents • Section 1.0, Organzation–Revised Paragraph 1.3.1B to reflect correct approval authority for Office of Civilian Radioactive Waste Management mission and function statements. Revised Paragraphs 1.3.2B and 1.3.2E to reflect current responsibility for managing the Office of Civilian Radioactive Waste Management Concerns Program. Revised Paragraph 1.3.2B to clarify that the Office of Quality Assurance is responsible for developing the *Quality Assurance Requirements and Description* not the Office of Civilian Radioactive Waste Management Quality Assurance Program. • Supplement III, Scientific Investigation–Revised Subsection III.2.4B3.a to clarify that U.S. Department of Energy owned high-level waste and spent nuclear fuel is actually U.S. Department of Energy-Office of Environmental Restoration and Waste Management managed high-level waste and spent nuclear fuel. Revised Paragraph III.2.6 to provide additional guidance on model development and use. • Glossary–Revised definition for Model Validation, added definitions for Model, Abstraction; Model, Conceptual; Model, Mathematical; Model, Process; Model, System; and Transparent. Incorporated Document Action Request D766.	05/03/2002

REVISION	REVISION DESCRIPTION	EFFECTIVE DATE
12	Revised the following sections to incorporate changes, as noted: • Section RevHist, Revision History • Section TOC, Table of Contents • Section 1.0, Organization–Revised Paragraph 1.2.2C to clarify responsibility. Revised Paragraph 1.3.2B to delineate the quality assurance functions for the Office of Civilian Radioactive Waste Management Program that are the responsibility of the Office of Quality Assurance. Revised Paragraph 1.3.3A to identify the evaluation and verification activities that are performed by Office of Civilian Radioactive Waste Management Affected Organizations' Quality Assurance organizations; to specify the requirements imposed on the Office of Civilian Radioactive Waste Management Affected Organizations' Quality Assurance organizations' position responsible for evaluation and verification activities; and to incorporate Paragraph 1.3.3C for clarification purposes. Revised Paragraph 1.3.3B to change the wording to be compatible with the wording used in the revised Paragraph 1.3.3A.	08/20/2002
13	Revised the following sections to incorporate changes as noted: • Editorial changes in 1.2.2, 1.3.3A.5e, 1.3.3A.5g, 2.2.1C.2, 2.2.3D, I.2.6, and III.2.6E.2. • Section Policy, Quality Assurance Policy–Revised to incorporate current Director, Office of Civilian Radioactive Waste Management Quality Assurance Policy Statement. • Section RevHist, Revision History. • Section TOC, Table of Contents. • Section 1.0, Organization–Revised organization to be consistent with Office of Civilian Radioactive Waste Management Organization realignment. • Section 2.0, Quality Assurance Program–Deleted waiver of education and experience in 2.2.12B.3. Revised 2.2.1C.4 to require Office of Quality Assurance review of requirements identified as not applicable and exceptions to *Quality Assurance Requirements and Description* requirements per commitment made in U.S. Nuclear Regulatory Commission Observer Inquiry.	04/22/2003

REVISION	REVISION DESCRIPTION	EFFECTIVE DATE
	• Supplement III, Scientific Investigation–Revised III.2.4 and III.2.6 to clarify qualification of data. • Appendix B, Storage and Transportation–Clarified the applicability of *Quality Assurance Requirements and Description* for 10 CFR 71 and 10 CFR 72 licensees per U.S. Nuclear Regulatory Commission request. • Appendix C, Monitored Geologic Repository– Deleted "accepted data" from C.2.1B.4 to be consistent with changes made in III.2.4. Deleted C.2.6 to address comment resulting from Independent Review of *Quality Assurance Requirements and Description* per Management Improvement Initiatives Action: Nonconformances will be processed in accordance with Section 15.0 and will be limited to nonconforming items. • Glossary–Added definition of Quality Assurance (QA) Organization to address comment resulting from Independent Review of *Quality Assurance Requirements and Description* per Management Improvement Initiatives Action. Modified definition of Item to be consistent with NQA-1, 1989, and accommodate deletion of C2.6. Deleted definitions of Accepted Data, Acquired Data, and Developed Data. Revised the definitions of Confirmatory Testing, Corroborating Data, Data, Qualified Data, Technical Assessment, and Unqualified Data. Incorporated new definition of Established Fact. Incorporated Document Action Requests D1807, D5990, D6033, D6168, and D6169.	
14	Revised Section 1.0 as follows: • Revised Subsection 1.3.2 to address ORD reorganization. • Revised Figure 1-1 to reflect ORD reorganization. • Revised the Glossary definitions for Performance Assessment and Performance Confirmation to be consistent with 10 CFR 63.2. These terms are used in the Office of License Application and Strategy responsibilities.	04/01/2004

REVISION	REVISION DESCRIPTION	EFFECTIVE DATE
	Incorporated Document Action Request D11228.	

TABLE OF CONTENTS

Section	Title	Revision
Title Page		**14**
Policy	**QUALITY ASSURANCE POLICY**	**4**
RevHist	**REVISION HISTORY**	**14**
TOC	**TABLE OF CONTENTS**	**14**
Intro	**INTRODUCTION**	**3**
1.0	**ORGANIZATION**	**8**
1.1	GENERAL	
1.2	REQUIREMENTS	
1.2.1	Line Management	
1.2.2	Quality Assurance Management	
1.2.3	Responsibility for Quality	
1.2.4	Delegation of Work	
1.2.5	Resolution of Quality Disputes	
1.3	DESCRIPTION	
1.3.1	General Description of the OCRWM	
1.3.2	Specific Civilian Radioactive Waste Management Offices	
1.3.3	OCRWM Affected Organizations	
Fig. 1-1	Office of Civilian Radioactive Waste Management	
2.0	**QUALITY ASSURANCE PROGRAM**	**5**
2.1	GENERAL	
2.2	REQUIREMENTS	
2.2.1	QA Program Documents	
2.2.2	Classifying Items	
2.2.3	Controlling Activities	
2.2.4	Applying QA Controls	
2.2.5	Planning Work	
2.2.6	Surveillances	
2.2.7	Management Assessments	
2.2.8	Readiness Reviews	
2.2.9	Peer Reviews	
2.2.10	Document Review	
2.2.11	QA Program Information Management	
2.2.12	Personnel Qualification	
2.2.13	Qualification of Personnel Who Perform Inspection, Nondestructive Examination, Testing, and Auditing	

TABLE OF CONTENTS (Continued)

Section	Title	Revision
3.0	**DESIGN CONTROL**	**3**
3.1	GENERAL	
3.2	REQUIREMENTS	
3.2.1	Design Input Control	
3.2.2	Design Process	
3.2.3	Design Analyses	
3.2.4	Design Verification	
3.2.5	Design Reviews	
3.2.6	Alternate Calculations	
3.2.7	Qualification Testing	
3.2.8	Design Change Control	
3.2.9	Design Interface Control	
4.0	**PROCUREMENT DOCUMENT CONTROL**	**1**
4.1	GENERAL	
4.2	REQUIREMENTS	
4.2.1	Procurement Document Preparation	
4.2.2	Procurement Document Review and Approval	
4.2.3	Procurement Document Change	
5.0	**IMPLEMENTING DOCUMENTS**	**1**
5.1	GENERAL	
5.2	REQUIREMENTS	
5.2.1	Types of Implementing Documents	
5.2.2	Content of Implementing Documents	
5.2.3	Review and Approval of Implementing Documents	
5.2.4	Compliance with Implementing Documents	
6.0	**DOCUMENT CONTROL**	**2**
6.1	GENERAL	
6.2	REQUIREMENTS	
6.2.1	Types of Documents	
6.2.2	Preparing Documents	
6.2.3	Reviewing Documents	
6.2.4	Approving Documents	
6.2.5	Distribution and Use of Documents	
6.2.6	Changes to Documents	
6.2.7	Expedited Changes	
6.2.8	Editorial Corrections	

TABLE OF CONTENTS (Continued)

Section	Title	Revision
7.0	**CONTROL OF PURCHASED ITEMS AND SERVICES**	**4**
7.1	GENERAL	
7.2	REQUIREMENTS	
7.2.1	Procurement Planning	
7.2.2	Source Evaluation and Selection	
7.2.3	Proposal/Bid Evaluation	
7.2.4	Supplier Performance Evaluation	
7.2.5	Control of Supplier Generated Documents	
7.2.6	Acceptance of Items or Services	
7.2.7	Certificate of Conformance	
7.2.8	Source Verification	
7.2.9	Receiving Inspection	
7.2.10	Post-installation Testing	
7.2.11	Control of Supplier Nonconformances	
7.2.12	Commercial Grade Items	
8.0	**IDENTIFICATION AND CONTROL OF ITEMS**	**1**
8.1	GENERAL	
8.2	REQUIREMENTS	
8.2.1	Identification	
8.2.2	Physical Markings	
8.2.3	Traceability	
8.2.4	Conditional Requirements	
9.0	**CONTROL OF SPECIAL PROCESSES**	**1**
9.1	GENERAL	
9.2	REQUIREMENTS	
9.2.1	Special Processes	
9.2.2	Personnel, Implementing Documents, and Equipment Qualifications	
9.2.3	Qualification of Nondestructive Examination Personnel	
10.0	**INSPECTION**	**0**
10.1	GENERAL	
10.2	REQUIREMENTS	
10.2.1	Inspection Planning	
10.2.2	Selecting Inspection Personnel to Perform Inspections	
10.2.3	Inspection Hold Points	
10.2.4	Statistical Sampling	
10.2.5	In-process Inspections and Monitoring	
10.2.6	Final Inspection	
10.2.7	Accepting Items	

TABLE OF CONTENTS (Continued)

Section	Title	Revision
10.2.8	Inspection Documentation	
10.2.9	Qualifications of Inspection and Test Personnel	
11.0	**TEST CONTROL**	**0**
11.1	GENERAL	
11.2	REQUIREMENTS	
11.2.1	Test Planning	
11.2.2	Performing Tests	
11.2.3	Use of Other Testing Documents	
11.2.4	Test Results	
11.2.5	Test Documentation	
11.2.6	Qualification of Test Personnel	
12.0	**CONTROL OF MEASURING AND TEST EQUIPMENT**	**1**
12.1	GENERAL	
12.2	REQUIREMENTS	
12.2.1	Calibration	
12.2.2	Documenting the Use of Measuring and Test Equipment	
12.2.3	Out-of-Calibration Measuring and Test Equipment	
12.2.4	Lost Measuring and Test Equipment	
12.2.5	Handling and Storage	
12.2.6	Commercial Devices	
12.2.7	Measuring and Test Equipment Documentation	
13.0	**HANDLING, STORAGE, AND SHIPPING**	**0**
13.1	GENERAL	
13.2	REQUIREMENTS	
13.2.1	Controls	
13.2.2	Special Equipment, Tools, and Environments	
13.2.3	Marking and Labeling	
14.0	**INSPECTION, TEST AND OPERATING STATUS**	**1**
14.1	GENERAL	
14.2	REQUIREMENTS	
14.2.1	Identifying Items	
14.2.2	Indicating Status	
15.0	**NONCONFORMANCES**	**1**
15.1	GENERAL	
15.2	REQUIREMENTS	
15.2.1	Documenting and Evaluating Nonconforming Items	

TABLE OF CONTENTS (Continued)

Section	Title	Revision
15.2.2	Identifying Nonconforming Items	
15.2.3	Segregating Nonconforming Items	
15.2.4	Disposition of Nonconforming Items	
15.2.5	Quality Trending	
16.0	**CORRECTIVE ACTION**	**1**
16.1	GENERAL	
16.2	REQUIREMENTS	
16.2.1	Identifying Conditions Adverse to Quality	
16.2.2	Classification of Conditions Adverse to Quality	
16.2.3	Conditions Adverse to Quality	
16.2.4	Significant Conditions Adverse to Quality	
16.2.5	Follow-up and Closure Action	
16.2.6	Quality Trending	
17.0	**QUALITY ASSURANCE RECORDS**	**2**
17.1	GENERAL	
17.2	REQUIREMENTS	
17.2.1	Classifying Quality Assurance Records	
17.2.2	Creating Valid Quality Assurance Records	
17.2.3	Receiving and Indexing Quality Assurance Records	
17.2.4	Correcting Information in Quality Assurance Records	
17.2.5	Storing and Preserving Quality Assurance Records	
17.2.6	Retrieval of Quality Assurance Records	
17.2.7	Retention of Quality Assurance Records	
17.2.8	Turnover of Quality Assurance Records	
17.2.9	Long Term Single Storage Facility	
17.2.10	Dual Storage Facilities	
17.2.11	Temporary Storage Facility	
17.2.12	Replacement of Quality Assurance Records	
18.0	**AUDITS**	**1**
18.1	GENERAL	
18.2	REQUIREMENTS	
18.2.1	Scheduling Internal Audits	
18.2.2	Scheduling External Audits	
18.2.3	Audit Schedule	
18.2.4	Audit Planning	
18.2.5	Audit Team Independence	
18.2.6	Audit Team Selection	
18.2.7	Performing Audits	

TABLE OF CONTENTS (Continued)

Section	Title	Revision
18.2.8	Reporting Audit Results	
18.2.9	Responding to Audits	
18.2.10	Evaluating Audit Responses	
18.2.11	Follow-up Action	
18.2.12	Technical Specialist Qualifications	
18.2.13	Auditor Qualifications	
18.2.14	Lead Auditor Qualifications	
18.2.15	Lead Auditor Education and Experience	
18.2.16	Lead Auditor Communication Skills	
18.2.17	Lead Auditor Training	
18.2.18	Lead Auditor Audit Participation	
18.2.19	Lead Auditor Examination	
18.2.20	Certification of Lead Auditor Qualifications	
18.2.21	Maintaining Lead Auditor Proficiency	
SUPPLEMENT I SOFTWARE		**4**
I.1	GENERAL	
I.2	REQUIREMENTS	
I.2.1	General Software Requirements	
I.2.2	Software Planning	
I.2.3	Software Life Cycle Requirements	
I.2.4	Software Configuration Management	
I.2.5	Defect Reporting and Resolution	
I.2.6	Software Procurement	
I.2.7	Software Previously Developed Not Using This Supplement	
I.2.8	Control of the Use of Software	
SUPPLEMENT II SAMPLE CONTROL		**1**
II.1	GENERAL	
II.2	REQUIREMENTS	
II.2.1	General Requirements	
II.2.2	Traceability	
II.2.3	Identification	
II.2.4	Conditional Requirements	
II.2.5	Archiving Samples	
II.2.6	Handling, Storage, and Shipping	
II.2.7	Disposition of Nonconforming Samples	

TABLE OF CONTENTS (Continued)

Section	Title	Revision
SUPPLEMENT III SCIENTIFIC INVESTIGATION		**6**
III.1	GENERAL	
III.2	REQUIREMENTS	
III.2.1	Planning Scientific Investigations	
III.2.2	Performing Scientific Investigations	
III.2.3	Data Identification	
III.2.4	Data Review, Adequacy, and Usage	
III.2.5	Technical Report Review	
III.2.6	Model Development and Use	
SUPPLEMENT IV FIELD SURVEYING		**0**
IV.1	GENERAL	
IV.2	REQUIREMENTS	
IV.2.1	Field Survey System	
IV.2.2	Field Survey Documentation	
SUPPLEMENT V CONTROL OF THE ELECTRONIC MANAGEMENT OF DATA		**1**
V.1	GENERAL	
V.2	REQUIREMENTS	
V.2.1	Control of the Electronic Management of Data	
APPENDIX A HIGH-LEVEL WASTE FORM PRODUCTION		**1**
A.1	GENERAL	
A.2	REQUIREMENTS	
A.2.1	Amplification of QARD Section 2.0, Quality Assurance Program	
A.2.2	Amplification of QARD Supplement III, Scientific Investigation	
APPENDIX B STORAGE AND TRANSPORTATION		**5**
B.1	GENERAL	
B.2	REQUIREMENTS	
B.2.1	General	
B.2.2	Storage Casks, Transportation Casks, MPCs, and Ancillary Equipment	
APPENDIX C MONITORED GEOLOGIC REPOSITORY		**5**
C.1	GENERAL	
C.2	REQUIREMENTS	
C.2.1	Modification of QARD Section 2.0, Quality Assurance Program	
C.2.2	Modification of QARD Section 4.0, Procurement Document Control	
C.2.3	Modification of QARD Section 7.0, Control of Purchased Items and Services	

TABLE OF CONTENTS (Continued)

Section	Title	Revision
C.2.4	Modification of QARD Section 9.0, Control of Special Processes	
C.2.5	Modification of QARD Section 10.0, Inspections	
Glossary	**GLOSSARY**	**7**

INTRODUCTION

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

The QARD applies to the following:

A. Acceptance of spent nuclear fuel and high-level waste.

B. Transport of spent nuclear fuel and high-level waste.

C. Storage of spent nuclear fuel through receipt of storage cask certification or a facility operating license.

D. Monitored Geologic Repository, including the site characterization activities [Exploratory Studies Facility (ESF) and surface based testing], through receipt of an operating license.

E. High-level waste form development through qualification, production, and acceptance.

F. Characterization of DOE spent nuclear fuel, and conditioning through acceptance of DOE spent nuclear fuel.

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

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

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

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

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

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

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

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

FIGURE INTRO–1

SOURCE DOCUMENTS

Regulatory Documents

10 CFR 50, Appendix B (Current) -	Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants
10 CFR 60, Subpart G (Current) -	Quality Assurance
10 CFR 71, Subpart H (Current) -	Quality Assurance
10 CFR 72, Subpart G (Current) -	Quality Assurance
10 CFR 73, (Current) -	Physical Protection of Plants and Materials

Commitment Documents

NQA-1 (1989) -	Quality Assurance Program Requirements for Nuclear Facilities
- Basic Requirements:	1 through 18
- Supplements:	1S-1, 2S-1, 2S-2, 2S-3, 2S-4, 3S-1, 4S-1, 6S-1, 7S-1, 8S-1, 9S-1, 10S-1, 11S-1, 12S-1, 13S-1, 15S-1, 17S-1, and 18S-1
- Appendices:	2A-1 and 2A-3
NRC Review Plan (Revision 2) -	U. S. Nuclear Regulatory Commission Review Plan for High-Level Waste Repository Quality Assurance Program Descriptions
NUREG-1297 (2/88) Staff Position-	Peer Review for High-Level Nuclear Waste Repositories
NUREG-1298 (2/88) Staff Position-	Qualification of Existing Data for High-Level Nuclear Waste Repositories

Guidance Documents

NQA-2 (1989) -	Quality Assurance Requirements for Nuclear Facility Applications
NQA-3 (1989) -	Quality Assurance Program Requirements for the Collection of Scientific and Technical Information for Site Characterization of High-Level Nuclear Waste Repositories

FIGURE INTRO–1 (Continued)

NUREG-0856 (1983) -	Final Technical Position on Documentation of Computer Codes for High-Level Waste Management
NUREG-1318 (1988) Staff Position -	Technical Position on Items and Activities in the High-Level Waste Geologic Repository Program Subject to Quality Assurance Requirements
NUREG-1563 (1996) -	Branch Technical Position on the Use of Expert Elicitation in the High-Level Radioactive Waste Program
NUREG-1636 (1999)	Regulatory Perspectives on Model Validation in High-Level Radioactive Waste Management Programs: A Joint NRC/SKI White Paper
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

1.0 ORGANIZATION

1.1 GENERAL

This section establishes requirements for creating and maintaining an organizational structure to implement the Quality Assurance (QA) program for the Civilian Radioactive Waste Management Program. This section also provides a description of the Office of Civilian Radioactive Waste Management (OCRWM) organization and other Affected Organizations.

1.2 REQUIREMENTS

Each Affected Organization shall prepare one or more controlled documents, accepted by the OCRWM Office of Quality Assurance (OQA), that describes 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

The Director, OQA, is the management position responsible for performing the QA function for the OCRWM program. Authority to execute this responsibility may be delegated to the Affected Organization. This position shall be occupied by an individual with appropriate knowledge and experience in management and QA. The position shall:

A. Be at the same or higher organization level as the highest line manager directly responsible for performing work subject to the *Quality Assurance Requirements and Description* (QARD).

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 the approval and the documented interpretations of the QA program requirements.

E. Have no other assigned responsibilities unrelated to the QA program that would prevent full attention to QA matters.

F. Be responsible for identifying quality problems, initiating, recommending, or providing solutions to quality problems, and verifying solutions to quality problems.

G. Be responsible for verifying the proper establishment and execution of the QA 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 QA 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 QA 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. The Director, OCRWM, has ultimate resolution authority.

1.3 DESCRIPTION

1.3.1 General Description of the OCRWM

A. OCRWM is comprised of the Office of the Director, the OQA, the Office of Repository Development (ORD), and the Office of Strategy and Program Development (OSPD). The ORD and OSPD report to the Director, OCRWM. The OCRWM organization, including organizations reporting directly to the ORD and OSPD, are illustrated in Figure 1-1.

B. OCRWM's functions are described in the official OCRWM Mission and Function Statement, approved by the Director, OCRWM.

   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.

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. The Office of the Director is responsible for providing leadership in developing and implementing strategies to accomplish the Program's mission in a manner that ensures public and worker health and safety, protects the environment, merits public confidence, and is economically viable. The Director reports to the Secretary of Energy through the Under Secretary.

B. Office of Quality Assurance

1. The OQA is responsible for the QA functions for the OCRWM program. The QA functions are:

   a. Ensuring that a QA program that meets regulatory and management requirements is established, maintained, and effectively executed.

   b. Verifying that activities subject to the QARD have been correctly performed by reviews, surveillance, and audits (compliance and performance based), or other means of verification, as appropriate.

2. The OQA is responsible for providing guidance and direction to organizations responsible for performing activities subject to the QARD on QA matters relating to OCRWM activities; performing overview of OCRWM Affected Organizations' activities subject to the QARD, including verification and evaluation activities, using appropriate verification methods; ensuring lines of communication with the other OCRWM Affected Organizations' QA organizations are established and maintained; and reporting the overview results to senior management.

C. Office of Repository Development

1. The Deputy Director, ORD reports directly to the Director, OCRWM and has delegating authority as the Head of Contracting Activity (HCA) for OCRWM. The Deputy Director, ORD is responsible for licensing, design, procurement, construction, and pre-operational testing for the Yucca Mountain Project (YMP). The Deputy Director, ORD is also responsible for directing the day-to-day YMP activities and has authority to stop unsatisfactory work performed by Affected Organizations and suppliers performing quality-affecting work on

the YMP. Specific duties and responsibilities of the Deputy Director, ORD include:

- Chief Nuclear Office and signature authority for the DOE YMP License Application
- Certification Official for the Licensing Support Network (LSN)
- Direction and administration of ORD staff
- Development, organization, and maintenance of control and oversight of the technical and quality functions of Affected Organizations in their support of the Project
- Development of overall plans and schedules for licensing, design, procurement, construction, and testing activities
- Development and implementation of technical and administrative controls to ensure quality objectives are met
- Direction, coordination, and review of OCRWM Management and Operating Contractor (M&O) activities including design, procurement, license application preparation, and on-site construction testing activities
- Review and acceptance of contract required quality-related deliverables submitted by the Affected Organizations and suppliers.

2. The following functional organizations report to the Deputy Director, ORD:

   a. Office of License Application and Strategy

      The Director, Office of License Application and Strategy is responsible for:

      - Developing the License Application
      - Regulatory strategy regarding U.S. Nuclear Regulatory Commission (NRC) licensing
      - NRC interaction
      - Post-closure performance assessment
      - Performance confirmation.

b. Office of Facility Operations

The Director, Office of Facility Operations is responsible for:

- Managing site operations
- Managing site support infrastructure
- Ensuring that site construction and operations activities comply with applicable federal, state, local, and Indian tribe statutes
- Managing the construction of facilities and structures associated with the Project, including underground construction of the Exploratory Studies Facility, surface-based testing facilities, and general support facilities and drilling operations
- Managing and integrating all aspects of field operations including engineering, design, construction, and site testing activities
- Ensuring ORD compliance with radiological protection standards and regulations
- Managing the ORD Safeguards and Physical Security Program.

c. Office of Business Support

The Director, Office of Business Support is responsible for:

- Ensuring execution of procurement documents
- Developing the ORD federal employee training program
- Overseeing contractor training programs
- Verifying education and experience of applicable ORD employees
- Overseeing contractor records management system.

d. Office of Project Management and Engineering

The Director, Office of Project Management and Engineering is responsible for:

- Establishing requirements to ensure that the design meets all repository nuclear safety and performance requirements
- Monitoring contractor design activities including the development of designs for individual features as well as adequacy of design products
- Providing overall direction and approving the basis for placement of items on the classification list

- Pre-closure safety
- Managing the YMP technical baseline.

e. Office of Performance Management and Improvement

The Office of Performance Management and Improvement is responsible for:

- Coordinating the development of ORD procedures
- Overseeing contractor document development and control system
- Development and oversight of the ORD document hierarchy and the document management system
- Identification, dissemination, and maintenance of ORD programmatic requirements
- Management and oversight of ORD Corrective Action Program activities.

D. Office of Strategy and Program Development

The OSPD is responsible for broad, comprehensive analysis of Program policies, systems, and activities; managing the overall strategy for the direction of Program resources; delegating authority for Head of Contracting Activity (HCA); providing direction in the development of a strategy for an integrated transportation program; managing scientific investigations and analyses of current and developing technologies; and managing the OCRWM Information Technology (IT) program.

The following functional organizations report to the OSPD:

1. Office of Systems Analysis and Strategy Development

The Office of System Analysis and Strategic Development (OSASD) is responsible for establishing waste acceptance requirements for repository and transportation projects; coordinating and maintaining Program interface with EM, Naval Nuclear Propulsion Program (NNPP), NNSA, and other DOE offices on waste management disposal activities; developing waste acceptance criteria for DOE spent nuclear fuel and high-level waste; reviewing applicable nuclear regulatory requirements for impact and incorporating into Program plans and activities; establishing, implementing, and overseeing Safeguards policy; managing the OCRWM Security Program; managing the standard contracts for disposal of spent nuclear fuel an/or high-level radioactive waste with owners and generators; administratively managing responses to

Congressional questions; and providing central focus within OCRWM for program policy formulation and guidance.

2. Office of National Transportation

   The Office of National Transportation is responsible for establishing strategy, defining requirements, and developing integrated policies and plans for the transportation program; establishing Nevada transportation policy/requirements; developing and coordinating technology activities involving cask design, testing, and certification; managing national transportation service and integration contracts; managing the program's transportation service contracts, including acquisition planning, Request for Proposal development, evaluations, award, cost and schedule, and work plans; monitoring contractor performance of activities supporting the National Transportation Program; managing the regional transportation analyses required as input to the Environmental Impact Statement and related studies for analysis of impacts for sabotage and terrorism; and coordinating issues with the NRC, DOE/EM, U.S. Air Force, U.S. Department of Transportation, and NNPP, as appropriate, related to transportation alternatives and options.

3. Office of Science and Technology and International

   The Office of Science and Technology and International is responsible for identifying, evaluating, and supporting scientific investigations and analyses of current and developing technologies.

4. Office of Program Management

   The Office of Program Management is responsible for managing the Program Change Control process and implementing the Program Change Control Board; establishing procedures and training materials and coordinating the implementation of a configuration management system for the cost and schedule baseline and OCRWM Change Control Boards; establishing policy for training of DOE and contractor personnel on the OCRWM program (including QA training); overseeing the verification of qualifications of OCRWM personnel to ensure compliance with program QA requirements; managing the HQ training program; preparing the OCRWM Training Plan; developing an OCRWM orientation program for HQ employees; developing and managing the OCRWM Information Management (IM) Program; monitoring contractor development and implementation of information management activities; and issuing policy and procedural guidance on IT Strategic Planning, Network and Telecommunications, and Information Architecture Baseline Configuration Management.

1.3.3 OCRWM Affected Organizations and Direct Support Organizations

A. OCRWM Affected Organizations

1. OCRWM Affected Organizations include: OCRWM, specific programs within the DOE that have material planned for disposition at a monitored geologic repository (i.e., EM High-Level Waste Vitrification Program and EM Management National Spent Nuclear Fuel Program), U.S. Geological Survey (USGS), OCRWM Management and Operating Contractor (M&O), and National Laboratories performing work for OCRWM (i.e., Los Alamos National Laboratory, Lawrence Berkeley National Laboratory, Lawrence Livermore National Laboratory, and Sandia National Laboratories).

2. The QARD requirements for each OCRWM Affected Organization are identified in the appropriate procurement documents. When a Memorandum of Understanding, Memorandum of Agreement, Program Guidance Memorandum, or other document serves as a procurement document, it shall include the scope of work and appropriate technical and QA requirements.

3. OCRWM Affected Organizations perform work subject to the QARD in accordance with implementing documents developed and maintained by OCRWM Affected Organizations. For certain tasks and when agreed to by involved organizations, an implementing document may apply to more than one OCRWM Affected Organization.

4. OCRWM Affected Organizations, with the exception of the USGS and National Laboratories, evaluate and verify implementation of their activities through reviews; surveillance; audits (compliance and performance based) and inspection of systems, structures and components; or other means of verification, as appropriate. The M&O QA organization performs the evaluation and verification of the M&O, M&O subcontractors and suppliers, USGS, and National Laboratories' activities.

5. The OCRWM Affected Organization's position responsible for evaluation and verification activities shall be occupied by an individual with appropriate knowledge and experience in management and QA. The position shall:

   a. Be at the same or higher organization level as the highest line manager directly responsible for performing work subject to the QARD.

   b. Be sufficiently independent from cost and schedule considerations.

   c. Have the organizational freedom to effectively communicate with other senior management positions.

d. Have no other assigned responsibilities that would prevent full attention to QA matters.

e. Be responsible for identifying quality problems; initiating, recommending, or providing solutions to quality problems; and verifying solutions to quality problems.

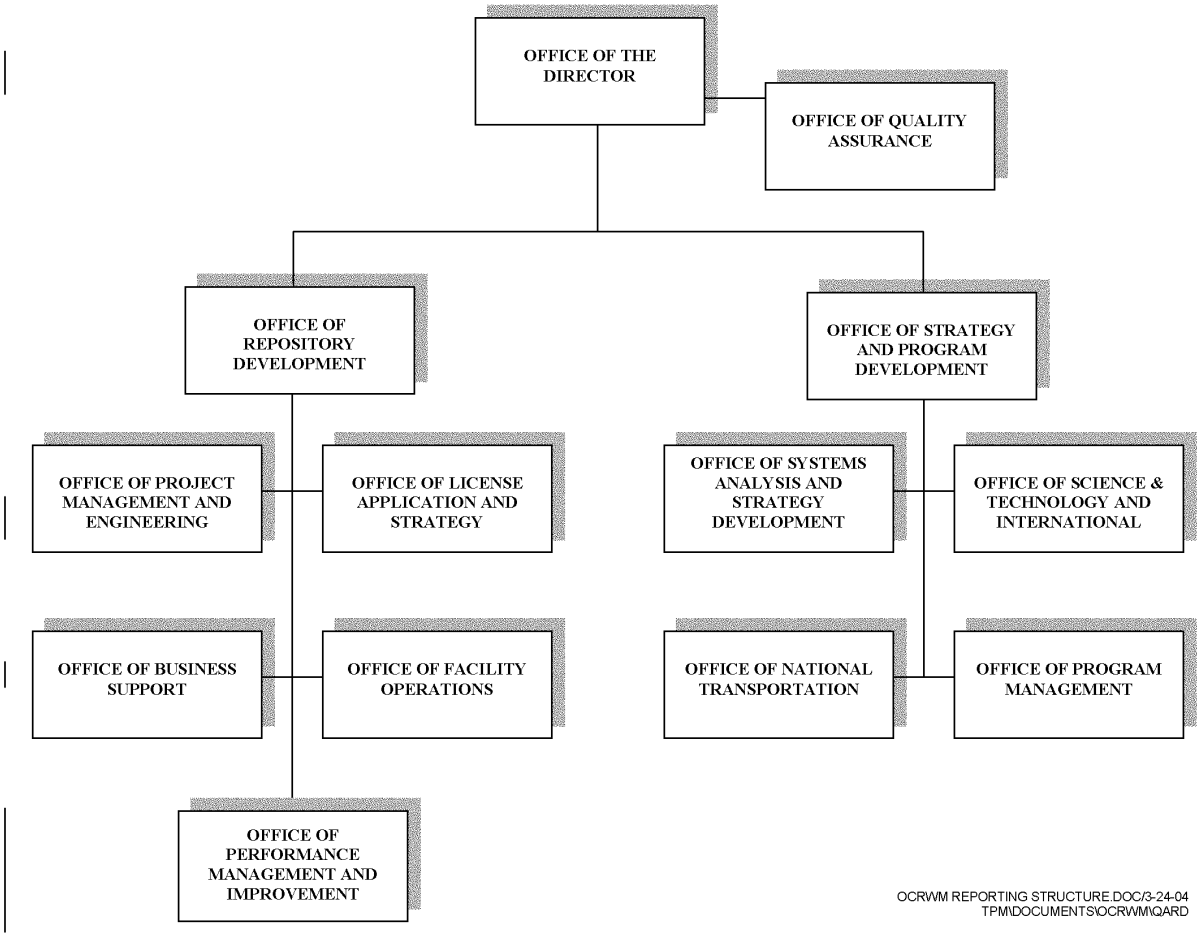
f. Have the authority to stop work when significant conditions adverse to quality warrant such action.

g. Be responsible for providing guidance and direction to organizations responsible for performing activities subject to the QARD on QA matters relating to the OCRWM Affected Organization's activities.

6. OCRWM Affected Organizations ensure lines of communication are established and maintained between their QA organizations and the OQA.

B. OCRWM Direct Support Organizations

OCRWM Direct Support Organizations perform work subject to the QARD in accordance with the appropriate OCRWM Affected Organization's implementing documents. OCRWM Direct Support Organizations are not required to develop and maintain implementing documents.



OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

FIGURE 1-1

2.0 QUALITY ASSURANCE PROGRAM

2.1 GENERAL

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

2.2 REQUIREMENTS

2.2.1 QA Program Documents

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

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

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

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

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

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

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

1. The matrix shall identify:

a. Where the QARD requirements are directly addressed.

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

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

2. Initial QARD requirements matrices shall be reviewed by the Office of Quality Assurance (OQA) in accordance with QARD Subsection 2.2.10, Document Review.

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

4. Changes to QARD requirements matrices shall be reviewed by the QA organization in accordance with Subsection 2.2.10. Changes delineated in Paragraph 2.2.1C.1b and 2.2.1C.1c shall be reviewed by the OQA in accordance with Subsection 2.2.10.

2.2.2 Classifying Items

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

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

2. Items and natural barriers 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 waste.

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

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 to control occupational radiological exposure.

B. The QA Program shall apply to the items required for physical protection as defined by 10 CFR Part 73.

2.2.3 Controlling Activities

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

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

B. The QA program shall apply to activities related to the items listed in Section 2.2.2 (such as design, procurement, construction, fabrication, production, handling, packaging, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, modification, and decontamination).

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

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

E. The QA program shall apply to activities associated with characterization of U.S. Department of Energy (DOE) spent nuclear fuel, and conditioning through acceptance of DOE spent nuclear fuel.

2.2.4 Applying QA Controls

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

A. Function or end use of the item.

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

C. Importance of the data being collected or analyzed.

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

E. Reliability of the process.

F. Reproducibility of the results.

G. Uniqueness of the item or degree of standardization.

H. History of the item or service quality.

I. Necessity for special controls or processes.

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

2.2.5 Planning Work

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

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

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

C. Identification of applicable standards and criteria.

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

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

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

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

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

I. Identification of computer software.

2.2.6 Surveillances

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

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

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

C. Documented in a report to appropriate management.

2.2.7 Management Assessments

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

A. Be planned and documented, and performed annually.

B. Evaluate the:

1. Adequacy of resources and personnel provided to achieve and assure quality.
2. Adequacy of the QA program.
3. Effectiveness of the QA program.

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

2.2.8 Readiness Reviews

The need for readiness reviews shall be identified by Affected Organization management for major scheduled or planned work to ensure program objectives are met. Where needed, readiness reviews shall be conducted for the planned scope of work to ensure that objective evidence exists demonstrating that:

A. Work prerequisites have been satisfied.

B. Personnel have been suitably trained and qualified.

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

2.2.9 Peer Reviews

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

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

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

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

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

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

5. Results of tests are not reproducible or repeatable.

6. Data or interpretations are ambiguous.

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

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

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

1. Number of the peer reviewers is commensurate with the complexity of work to be reviewed, its importance to Program objectives, the number of technical disciplines involved, the degree to which uncertainties in the data or technical approach exist, and the extent to which differing viewpoints are strongly held within the applicable technical and scientific community concerning issues under review.

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

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

4. Potential for technical or organizational partiality is minimized.

5. Peer review group chairperson is identified.

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

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

2. Technical credentials that are recognized and verifiable.

3. Independence from the work under review. Independence means that the individual was not involved as a participant, supervisor, technical reviewer or

advisor in the work under review and is, to the extent practical, free from any funding considerations.

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

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

1. Specifies the work to be reviewed.

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

3. Describes the expected method and reporting schedule.

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

   a. Validity of the assumptions.

   b. Alternate interpretations.

   c. Adequacy of requirements and criteria.

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

   e. Adequacy of application.

   f. Accuracy of calculations.

   g. Validity of conclusions.

   h. Uncertainty of results and impact if wrong.

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

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

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

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

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

2.2.10 Document Review

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

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

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

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

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

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

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

   2. The QA organization shall review implementing documents and changes thereto that translate the QARD into work processes as described in Subsection 2.2.1, QA Program Documents. The QA organization also shall review changes to other documents if they were required to review the previous version, unless the QA organization has concurred that its review is no longer required.

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

2.2.11 QA Program Information Management

Affected Organization management shall on a continuing basis be apprised of the status, adequacy and compliance aspects of the QA Program. Appropriate management

shall receive, as a minimum, audit reports, surveillance reports, trend reports and management assessment reports.

2.2.12 Personnel Qualification

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

1. Determine required indoctrination and training.

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

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

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

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

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

   b. Applicable implementing documents.

   c. Job responsibilities and authority.

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

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

2. Minimum education and experience requirements are established for each position commensurate with the scope, complexity, and nature of the work.

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

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

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

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

3.0 DESIGN CONTROL

3.1 GENERAL

This section provides requirements to ensure that designs 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 confirmation shall be identified and controlled as the design proceeds.

3.2.2 Design Process

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

A. Design work shall be prescribed and documented on a timely basis and to the level of detail necessary to permit 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.

D. Changes from specified standards, including the reasons for the change, shall be identified, approved, documented, and controlled.

E. Design methods, materials, parts, equipment, and processes that are essential to the function of an item shall be selected and reviewed for suitability of application.

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. The final design shall identify assemblies or components that are part of the item being designed. 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, Software.

E. Documentation of design analyses shall include:

1. Definition of the objective of the analyses.

2. Definition of design inputs and their sources.

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

4. Identification of assumptions.

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 originator, reviewer, and approver.

3.2.4 Design Verification

In addition to reviewing completed design analyses and design output in accordance with QARD Subsection 2.2.10, Document Review, the following design control requirements shall be applied:

A. Design verification shall be performed to determine the adequacy of design by 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 verification is not hastily and superficially done.

   4. The determination to use the supervisor is documented and approved, in advance, with concurrence of the QA organization.

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. In some cases (such as when insufficient data exists) it may be necessary to release unverified designs to support schedule requirements. Unverified portions of the design shall be clearly identified and controlled

2. 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 *Quality Assurance Requirements and Description*, 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.

I. Changes in previously verified designs shall require reverification. Such verification shall include the evaluation of the effects of those changes on the overall previously verified design and on any design analysis 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 were adequately described, reasonable and where applicable, identified as requiring confirmation as the design proceeds.

C. Appropriate design methods, and computer programs when applicable, were used.

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

E. The necessary design input for interfacing organizations were specified in the design documents.

3.2.6 Alternate Calculations

The appropriateness of assumptions, input data, and the computer program or other calculation method used shall be reviewed, 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 in accordance with Section 11.0, Test Control.

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

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.

B. Design control measures for changes shall include provisions to assess the effect of the changes on the overall previously verified design and ensure that the design analyses for the item are still valid.

C. Changes shall be approved by the same affected groups or organizations that 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; and

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

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 in accordance with Section 16.0, Corrective Action. Additionally, if the incorrect design causes constructed or partially constructed systems, structures, or components to be nonconforming, the affected items shall be controlled in accordance with Section 15.0, Nonconformances.

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 organizations affected by the change.

3.2.9 Design Interface Control

A. Design interfaces shall be identified and controlled.

B. Design efforts shall be coordinated among participating organizations and groups.

C. Interface controls shall include the assignment of responsibility and the establishment of implementing documents among participating design

organizations and groups 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. Designs or portions of designs that require further development, analysis, review, or approval shall be identified.

F. When it is necessary to initially transmit design information orally or by other informal means, the design information shall be promptly confirmed with formal documentation initiated in accordance with the initiating organizations approved implementing document.

4.0 PROCUREMENT DOCUMENT CONTROL

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, and 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 (QA) program that implements applicable *Quality Assurance Requirements and Description*, (QARD) requirements prior to the initiation of work. The extent of the QA 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.

3. When deemed appropriate, the purchaser shall permit some or all supplier work to be performed under the purchaser's or another Affected Organization's QA program provided the work is adequately addressed. In these cases, procurement documents shall specify that the purchaser's or another Affected Organization'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 QA 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 QA data required for ordering.

4.2.2 Procurement Document Review and Approval

A. Procurement document reviews in accordance with Subsection 2.2.10, Document Review, 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 QA 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.

E. Procurement document reviewers shall include representatives from the technical and QA organizations.

F. Procurement documents shall be approved.

4.2.3 Procurement Document Change

A. Changes to the scope of work, technical requirements, QA 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.

5.0 IMPLEMENTING DOCUMENTS

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 in accordance with 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. Implementing documents include documents such as procedures, instructions, and drawings, with the exception of drawings governed by Section 3.0, Design Control.

5.2.2 Content of Implementing Documents

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

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

B. 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 and nonpermanent quality assurance records generated by the implementing document.

I. Identification of associated items and activities.

5.2.3 Review and Approval of Implementing Documents

Implementing documents shall be reviewed, approved, and controlled in accordance with Section 6.0, Document Control.

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 (in accordance with Section 6.0, Document Control) to reflect the correct work practices.

6.0 DOCUMENT CONTROL

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

Implementing documents and documents that specify technical requirements or quality requirements 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 shall be reviewed in accordance with the requirements of Subsection 2.2.10, Document Review.

6.2.4 Approving Documents

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

6.2.5 Distribution and Use of Documents

The distribution and use of documents, including changes and editorial corrections to documents, shall include the following:

A. Documents, either in hardcopy or electronic media, used to perform work shall be distributed to, or made available 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 to ensure that they are not used to perform work.

D. A method 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

A. Changes to documents shall be reviewed in accordance with the requirements of Subsection 2.2.10, Document Review, prior to approval for release.

B Changes shall be approved for release by the designated organizational position that is responsible for the document.

C. 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.

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

6.2.7 Expedited Changes

If an activity cannot be performed as listed in a 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.

6.2.8 Editorial Corrections

Editorial corrections may be made to documents without being subject to review requirements, but such corrections shall be distributed as a revision or change to the document.

A. The following items are considered editorial corrections:

1. Correcting grammar or spelling.

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

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 approving the document for release shall approve editorial corrections.

7.0 CONTROL OF PURCHASED ITEMS AND SERVICES

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. The supplier selection and bid/proposal evaluation requirements of this section do not apply to situations where the Office of Civilian Radioactive Waste Management obtains the services of other Department of Energy offices or Federal agencies through Memoranda of Understanding, Memoranda of Agreement, Program Guidance Memoranda, Interagency Agreement or other documents containing appropriate technical and Quality Assurance (QA) requirements. Technical and QA requirements specified in these documents shall be verified to be satisfactorily incorporated into the applicable program prior to starting work subject to the Quality Assurance Requirements and Description (QARD).

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, Procurement Document Control.

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 QA records.

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 QA 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, including provisions for input from the QA organization.

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 QA 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 QA 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 QA organization.

B. The evaluation shall include the following subjects consistent with the importance, complexity, and quantity of items or services being procured:

1. Technical considerations.
2. QA program requirements.
3. Supplier personnel.
4. Supplier production capability.
5. Supplier past performance.
6. Alternatives.
7. Exceptions.

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

D. Supplier QA 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 the QARD.

E. Supplier QA programs shall be accepted by the purchaser before the supplier starts work subject to the QARD.

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 document requirements.

4. Identifying and processing necessary change information.

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

6. Establishing the extent of source surveillance and inspection.

B. 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.

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 QA 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. The supplier shall verify that furnished items or services comply with the purchaser's procurement document requirements before offering the items or services for acceptance.

B. 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.

C. 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 item or service.

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.

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.

B. The certificate shall identify the specific procurement document requirements met by the purchased item or service. The procurement document requirements identified shall include any approved changes, waivers, or deviations applicable to the item or service.

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

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

E. The certification process, including the implementing documents to be followed in filling out a certificate and the administrative implementing documents for review and approval of the certificates, shall be described in the supplier's QA 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 Section 2.0, Quality Assurance Program.

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.

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, Inspection.

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

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

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

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, Nonconformances.

B. The supplier shall submit a report of nonconformance to the purchaser including supplier recommended disposition (e.g., use-as-is or repair) and technical justification. Reports of nonconformances related 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.

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 7.2.2, 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.

8.0 IDENTIFICATION AND CONTROL OF ITEMS

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.

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

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.

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, or standards 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 be specified in specifications.

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

C. If items have a limited operating or shelf life specified, then methods shall be established that preclude using the item beyond the shelf or operating life.

D. 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.

9.0 CONTROL OF SPECIAL PROCESSES

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 item.

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, calibration requirements, and traceability between the item or product, and individual performing the special process.

C. Requirements of applicable codes and standards, including acceptance criteria for the special process.

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. 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. In lieu of the three year recertification interval specified in SNT-TC-1A, June 1980 edition, Level III Nondestructive examination personnel may be recertified on a five year interval.

C. The Affected Organization shall establish implementing documents for the control and administration for the training, examination, and certification of nondestructive examination personnel.

10.0 INSPECTION

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.

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.

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.

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.

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.

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.

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.

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.

11.0 TEST CONTROL

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.

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.

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.

12.0 CONTROL OF MEASURING AND TEST EQUIPMENT

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 including equipment that contains software or programmable hardware, shall be calibrated, adjusted, and maintained as a unit at prescribed intervals, or prior to use, against reference calibration standards having traceability to nationally recognized standards. Software developed or modified by the user shall be controlled in accordance with Supplement I, Software. 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 or calibration check 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.

G. Updates to software contained in measuring and test equipment that effect calibration, require recalibration of the equipment prior to use.

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 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 Lost Measuring and Test Equipment

When measuring and test equipment is lost, 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.

12.2.5 Handling and Storage

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

12.2.6 Commercial Devices

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

12.2.7 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.

13.0 HANDLING, STORAGE AND SHIPPING

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.

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.

14.0 INSPECTION, TEST AND OPERATING STATUS

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 legible and easily recognizable 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.

15.0 NONCONFORMANCES

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 Nonconforming Items

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, Corrective Action. 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.

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 Quality Assurance 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 Quality Trending

Nonconformance documentation shall be periodically analyzed by the Quality Assurance organization to identify quality trends in accordance with Section 16.0, Corrective Action.

16.0 CORRECTIVE ACTION

16.1 GENERAL

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

16.2 REQUIREMENTS

16.2.1 Identifying Conditions Adverse to Quality

A condition adverse to quality shall be identified when the *Quality Assurance Requirements and Description* (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 (QA) organization for tracking.

B. Responsible management shall determine the extent of the adverse condition and complete remedial action as soon as practical.

C. The QA organization shall concur with the proposed remedial action to ensure that QA program requirements are satisfied.

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 QA organization for tracking.

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

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

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

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

E. Responsible management shall determine, document, and complete remedial action. Responsible management shall also determine the root cause of the problem and take corrective action to prevent recurrence as soon as practical.

F. The QA organization shall concur with the proposed corrective action including remedial action, the root cause, and actions taken to prevent recurrence to ensure that QA program requirements are satisfied.

16.2.5 Follow-up and Closure Action

The QA 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 Quality Trending

A. The QA organization shall establish criteria for determining adverse quality trends.

B. Reports of nonconformances and 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. Trend evaluations shall be distributed to Affected Organization management.

E. Identified adverse trends shall be reported to the management of the organization responsible for corrective action.

17.0 QUALITY ASSURANCE RECORDS

17.1 GENERAL

This section establishes requirements to ensure that Quality Assurance (QA) records are specified, prepared and maintained.

17.2 REQUIREMENTS

17.2.1 Classifying Quality Assurance Records

QA records shall be classified as lifetime or nonpermanent.

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

1. Documents that provide evidence of the quality of items on a *Q-List*.

2. Documents that provide evidence of the quality of activities related to items on a *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. Documents that provide evidence of the quality of those activities associated with the characterization of DOE spent fuel, and conditioning through acceptance of DOE spent fuel.

7. Personnel training and qualification documents for individuals executing QA program requirements.

8. Documents which are implementing documents as described in Section 5.0, Implementing Documents.

B. Documents that do not meet the requirements for lifetime QA records, but provide objective evidence that the QA program has been properly executed shall be classified as nonpermanent QA records.

17.2.2 Creating Valid Quality Assurance Records

A. Implementing documents shall:

1. Identify those documents that will become QA records.

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

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

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

D. Records shall be considered QA records when stamped, initialed, or signed and dated as complete. If the nature of the record (such as magnetic or optical media) precludes stamping, initialing or signing, then other means of identifying the record as complete by authorized personnel are permitted.

E. QA records may be originals or copies.

17.2.3 Receiving and Indexing Quality Assurance Records

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

A. An individual or organization shall be assigned the responsibility for receiving QA records.

B. A method for verifying that the QA records are those designated.

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

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

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

F. QA records shall be indexed to ensure retrievability. The indexing system shall include:

1. The location of the QA records within the records management system.
2. Identification of the item or related activity to which the QA records pertain.
3. The classification of the QA record.

G. QA records shall be submitted to storage after processing has been completed.

17.2.4 Correcting Information in Quality Assurance Records

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

B. Corrections to QA records shall be approved by the originating organization. If an organization that was originally responsible for approving a particular document is no longer responsible, the new responsible organization shall be identified.

17.2.5 Storing and Preserving Quality Assurance Records

A. QA 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 QA records received are in agreement with the transmittal document.

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

5. A method for filing supplemental information.

6. A method for disposition of superseded QA records.

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

1. The storage area shall minimize the risk of damage or destruction by natural disasters, extremes in environmental conditions and infestations of pests or molds.

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

3. The storage arrangement shall provide adequate protection of special processed QA records (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 QA record being stored.

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

17.2.6 Retrieval of Quality Assurance Records

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

17.2.7 Retention of Quality Assurance Records

A. OCRWM or its designee shall retain and preserve lifetime QA records for the operating life of the item or facility.

B. Nonpermanent QA records shall be retained for a minimum of three years or as specified by procurement documents, whichever is longer. Nonpermanent QA 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 Turnover of Quality Assurance Records

A. Affected Organizations shall submit, to the Office of Civilian Radioactive Waste Management (OCRWM) or the purchaser, those QA records being temporarily stored by them that are subject to records turnover requirements. The timing of the submittal shall be as records packages become complete, or as items are released for shipment, or as prescribed by the purchaser.

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

C. The responsible OCRWM line organizations shall identify those QA records in temporary storage to be submitted for long-term storage to the records management system.

17.2.9 Long Term Single Storage Facility

A. OCRWM's single storage facility for the storage of lifetime QA 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.

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.

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

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

17.2.10 Dual Storage Facilities

A. The OCRWM's dual storage facilities for the storage of lifetime QA records shall provide facilities for copies of each record at locations sufficiently remote from each other to eliminate the chance of exposure to a simultaneous hazard.

B. Dual storage facilities are not required to meet the design and construction requirements specific for a long term single storage facility.

17.2.11 Temporary Storage Facility

The OCRWM and Affected Organizations shall provide for temporary storage of QA records during processing, review, or use until turnover to the OCRWM for disposition, according to the following requirements:

A. QA 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 QA records in temporary storage shall be specified by the OCRWM or the purchaser consistent with the nature or scope of work.

17.2.12 Replacement of Quality Assurance Records

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

18.0 AUDITS

18.1 GENERAL

This section establishes requirements for performing internal and external Quality Assurance (QA) audits to verify compliance with, and to determine the effectiveness of, the QA 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 QA program compliance shall be performed annually or at least once during the life of the work, whichever is shorter.

F. Internal audits to determine QA program effectiveness (performance based audits) shall be performed on selected work.

18.2.2 Scheduling External Audits

A. The need for, and frequency of, external audits shall be determined after a supplier has been selected to perform work for the Office of Civilian Radioactive Waste Management. The determination shall be 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 item to verify quality characteristics after delivery. Rationale for not performing audits for these items shall be documented.

C. External audits for compliance shall be performed triennially as a minimum with the initial audit to occur as early in the life of the activity as practical.

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

1. The supplier is implementing the same QA program for other contracts that is proposed for the purchasers contract, and

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

E. External audits to determine QA program effectiveness (performance based audits) shall be performed on selected work.

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

1. Review of documentation furnished by the supplier (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 work furnished by the same supplier.

4. A review of procurement documents to determine what additional work the supplier has received since the initial contract.

. G. The need to schedule additional external audits shall also be evaluated when a major change in the contract scope, work methodology, or organization occurs.

18.2.3 Audit Schedule

The audit schedule shall be developed annually and revised periodically 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 evaluation of implementing documents, activities, and items to be audited, the results of previous audits and the impact of significant changes in personnel, organization, or the QA program.

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 team shall include representatives from the QA organization and when appropriate 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 in accordance with the requirements of this section.

D. Technical specialists may be used by the auditing organization to assist in assessing the adequacy of technical processes. Technical specialists, when used, shall be qualified in accordance with 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 lead auditor shall, before starting the audit, ensure that the assigned personnel collectively have experience or training commensurate with the scope, complexity, or special nature of the work to be audited.

18.2.7 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.

F. Identified conditions adverse to quality shall be documented and corrected in accordance with of Section 16.0, Corrective Action.

G. Nonconforming items identified during an audit shall be controlled by the audited organization in accordance with Section 15.0, Nonconformances.

18.2.8 Reporting Audit Results

The audit report shall be prepared and signed 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 on the effectiveness of the QA program elements which were audited.

F. A description of each reported 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, Corrective Action.

18.2.9 Responding to Audits

Management of the audited organization shall investigate 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 in accordance with Section 16.0, Corrective Action.

18.2.10 Evaluating Audit Responses

The adequacy of corrective actions for conditions adverse to quality shall be evaluated by the auditing organization in accordance with the requirements of Section 16.0, Corrective Action.

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 in accordance with the requirements of Section 16.0, Corrective Action.

18.2.12 Technical Specialist Qualifications

Technical specialists selected for auditing assignments shall be indoctrinated and trained in accordance with Section 2.0, Quality Assurance Program, 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. QA program orientation to provide a working knowledge and understanding of the *Quality Assurance Requirements and Description* (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 conditions adverse to quality addressed by corrective action documents.

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.

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 QA: score two credits; or

2. A bachelor's degree from an accredited institution: score two credits or, if the degree is in engineering, physical sciences, mathematics, or QA: score three credits. In addition, score one credit for a master's degree in engineering, physical sciences, business management, or QA 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 QA: 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 QA: score three additional credits; or

5. If two years of this experience have been in nuclear-related QA auditing: score four additional credits.

C. Professional Competence (two credits maximum)

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

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 QA 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 QA 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 QA audits within a period of time not to exceed three years prior to the date of certification. One audit shall be a nuclear-related QA audit within the year prior to certification.

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 QA program and program auditing.

3. Participation in QA training programs.

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 period of two years or more shall require requalification. Requalification shall include retraining and re-examination in accordance with this section, and participation as an auditor in at least one nuclear QA audit.

SUPPLEMENT I SOFTWARE

I.1 GENERAL

This supplement establishes requirements for the acquisition, development, modification, control, and use of software. Acquired software that is integral to the operations, maintenance, or calibration of measuring and test equipment, and has not been developed or modified by the Affected Organization, is controlled by Section 12.0, Control of Measuring and Test Equipment, and is exempt from the requirements of this supplement. Requirements for electronic management of data are addressed in Supplement V, Control of the Electronic Management of Data.

The following types of software are not required to be qualified using this supplement: operating systems; system utilities; compilers and their associated libraries; word processors; spreadsheets; database managers; e-mail; and other types of automated office support systems. Any applications, other than software routines and macros, developed using these types of commercially available software shall meet the requirements of this supplement. Software routines and macros shall meet the requirements of Paragraph I.2.1.C.

I.2 REQUIREMENTS

I.2.1 General Software Requirements

A. Software acquisition, development, modification, and maintenance shall proceed in a planned, traceable, and orderly manner utilizing a defined software life cycle methodology.

1. A defined software life cycle methodology shall address the following phases: requirements, design, implementation, testing, installation and checkout, operations and maintenance, and retirement. The number of phases and relative emphasis placed on each phase of the software life cycle will depend on the nature and complexity of the software. Software life cycle activities may be performed in an iterative or sequential manner.

2. Acquired software or software previously developed not using this supplement must either be: a) acquired through a procurement activity in accordance with Section I.2.6 with appropriate quality controls, or b) be controlled and qualified in accordance with Section I.2.7 of this supplement. In either case, software planning in accordance with I.2.2 and a defined software life cycle methodology, excluding a design document and code development, shall be applied.

3. Software life cycles shall contain control points that, when reached, shall ensure specified software is documented, reviewed, and baselined.

B. Software verification and validation activities shall be planned, documented, and performed for each software, for software changes, or for those system configurations that are determined to impact the software.

1. Software verification shall be performed at the end of the Requirements, Design, Implementation, and Testing life cycle phases to ensure that the products of a given life cycle phase are traceable and fulfill the requirements of the previous phase and/or previous phases.

2. Verification reviews shall identify the reviewer(s) and their specific responsibilities during the review.

3. Software verification and validation activities shall be performed by individuals not associated with the development of the software. In those instances where this level of independence may not be achieved, an individual associated with the development of the software may perform these activities with a higher level of management approval and documented justification.

C. Software routines or macros that are documented in each product in which they are used and independently verified by visual inspection or hand calculation without recourse to the originator shall have limited requirements applied as follows:

1. Identification, including version of the software routine or macro.

2. Documentation that includes inputs, computer program generated correct results for a specified range of input parameters, computer program generated evidence of the programmed algorithms or equations (e.g., computer programs listings and spreadsheet cell contents), and verification results.

3. Identification, including version of the commercially available software used to develop the routine and macro.

I.2.2 Software Planning

A. A plan addressing software quality assurance (QA) shall be in existence for each new software project at the start of the software life cycle.

B. The plan(s) may be prepared individually for each software project, or may exist as a generic document to be applied to software prepared within or procured by an organization, or may be incorporated into the overall QA program.

C. The plan for software shall identify:

1. A description of the overall nature and purpose of the software.

2. The software products to which it applies.

3. The organizations responsible for performing the work and achieving software quality and their tasks and responsibilities.

4. Required documentation.

5. Standards, conventions, techniques, or methodologies that shall guide the software activity.

6. Required software reviews.

7. Methods for error reporting and corrective action.

I.2.3 Software Life Cycle Requirements

A. Requirement Phase

1. Software requirements that address functionality, performance, design constraints, attributes, and external interfaces shall be specified, documented, and reviewed.

   a. Functionality–The functions the software is to perform.

   b. Performance–The time-related issues of software operation such as speed, recovery time, response time, etc.

   c. Design constraints imposed on implementation phase activities–Any elements that will restrict design options.

   d. Attributes–Non-time-related issues of software operation such as portability, acceptance criteria, access control, maintainability, etc.

   e. External interfaces–Interactions with people, hardware, and other software.

2. A software requirement shall only be specified if its achievement can be verified and validated.

3. Software requirements shall be traceable throughout the remaining stages of the software life cycle.

4. Software requirements shall provide enough detail to either design the software or make an acquisition decision.

B. Design Phase

1. The software design shall be developed, documented, and reviewed based on the requirements depicted in the requirements document.

2. The design documentation shall specify:

   a. A description of the major components of the software design as they relate to the software requirements.

   b. A technical description of the software with respect to the theoretical basis, mathematical model, control flow, data flow, control logic, and data structure.

   c. A description of the allowable or defined ranges for inputs and outputs.

   d. The design described in a manner that can be translated into code.

   e. The generation of design-based test cases.

   f. The generation of test plans/cases, based on the requirements and design, shall provide for acceptance criteria and verification of results. Alternative methods to evaluate technical adequacy may be used, such as:

      1) Analysis without computer assistance (hand calculations).
      2) Other validated computer programs.
      3) Experiments and tests.
      4) Standard problems with known solutions.
      5) Comparisons to confirmed published data correlations.

C. Implementation Phase

1. The design shall be translated into source code and resulting executables necessary to perform the functions required.

2. The source code and resulting executables shall adhere to the design specifications.

3. User information shall be developed, documented, and reviewed in accordance with the design to delineate how to use the software, including the following, as applicable:

   a. Instructions that contain an introduction (e.g., purpose, scope, etc.), description of the user's interaction with the software, and a description of any required training necessary to use the software.

   b. Input and output specifications.

   c. Data files, input and output data, defaults, and file formats.

   d. A description of the allowable and tolerable ranges for inputs and outputs.

e. Anticipated errors and how the user can respond.

f. The hardware and software environments.

g. Available sample problems.

h. Installation procedures.

D. Testing Phase

1. Software validation activities shall be performed, documented, and verified at the end of the implementation phase to ensure that the software installs properly and satisfies the requirements for its intended use.

2. Testing, to an approved plan or process, shall be the primary method of software validation to ensure adherence to the requirements, and to ensure that the software produces correct results for the test cases.

3. Software validation documentation shall describe the task and criteria for accomplishing the validation of the software at the end of the development cycle. The documentation shall:

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a. Specify the hardware and software configurations.

b. Be organized in a manner that allows traceability to both software requirements and design.

c. Contain the results of the execution of the validation activity.

d. Include the results of reviews and tests along with a summary of the status of the software (e.g., indication of incomplete design performance and application requirements).

4. Failure to successfully execute the test cases shall be documented and reviewed to determine if modifications to the requirements, design, implementation, or test plans and cases are required.

5. Software validation of modifications to released software shall be subjected to regression testing to detect errors introduced during the modification of the software, to verify that the modifications have not caused unintended adverse affects, or to verify that a modified software still meets specified requirements.

E. Operations and Maintenance Phase

1. Upon acceptable validation of the software, in accordance with I.2.3.D, the software shall be baselined and placed under Configuration Management controls in accordance with section I.2.4.

2. Further operations and maintenance activities shall consist of maintenance of the software:

   a. To remove latent errors (corrective maintenance).

   b. To respond to new or revised requirements (perfective maintenance).

   c. To adapt the software to changes in the operating environment (adaptive maintenance).

3. Software modifications shall be approved, documented, verified and validated, and controlled.

4. In-use tests shall be developed, performed, documented, and verified to provide confirmation of acceptable performance of software that is performing continuous data acquisition or process control functions. Periodic manual or automatic self-check in-use tests shall be defined and performed for those software where computer program errors, data errors, computer hardware failures, or instrument drift can affect the required performance.

F. Installation and Checkout Phase

1. Software installation and checkout activities shall be performed and documented when the software is installed on a computer, or when there are changes in the operating system, to ensure that the software installs properly and satisfies the requirements for its intended use.

2. The software validation activities for the installation and checkout shall consist of:

   a. The execution of tests for installation.

   b. The documentation that the software was successfully installed and ready for operational use.

G. Retirement Phase

During the retirement phase, the support for a software product is terminated and use of the software shall be prevented.

I.2.4 Software Configuration Management

A software configuration management system shall be established to include configuration identification, configuration change control, and status accounting. Software shall be placed under configuration management control as each baseline element is approved. Software shall not be used in activities identified under Section 2.2.2 or 2.2.3 of this document unless it is obtained, and limited to received copies, from software configuration management.

A. Configuration identification shall include:

1. A definition of the baseline elements of each software baseline.

2. A unique identification of each software item, including version or revision, to be placed under software configuration management.

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 change control shall include:

1. A release and control process for baseline elements.

2. Changes to baseline elements shall be formally controlled and documented. This documentation shall contain a description of the change, the rationale for the change, and the identification of affected baseline elements.

3. A formal evaluation of the baseline element or change to the baseline element and approval by the organization responsible for approving the baseline element.

4. The transmission of information concerning approved changes to all organizations affected by the changes.

5. Software verifications performed for the changes as necessary to ensure the changes are appropriately reflected in software documentation and to ensure that document traceability is maintained.

6. Software validation performed as necessary for the change.

C. Configuration status accounting shall include:

1. A listing of the approved baseline elements and unique identifiers.

2. The status of proposed, in-process, or approved changes to the baseline elements.

3. A history of changes to the software items, including descriptions of the changes made between versions of software items.

I.2.5 Defect Reporting and Resolution

A. A software defect reporting and resolution system shall be implemented for software errors and failures to assure that problems are promptly reported to Affected Organizations and to assure formal processing of problem resolutions.

B. The defect reporting and resolution system shall be integrated with the software configuration management system.

C. Software defect reporting and resolution systems shall include the following controls:

1. Problems are identified, evaluated, documented, and, if required, corrected.

2. Problems are assessed for impact on past and present applications of the software by the responsible organization.

3. Corrections and changes shall be controlled in accordance with applicable configuration change control requirements.

4. Notification along with preventive actions and corrective actions are provided to the user organizations.

D. 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, Corrective Action.

I.2.6 Software Procurement

A. Individuals or organizations developing and supplying software under contract shall be required to have policies and procedures that meet the applicable requirements of this Supplement as specified in procurement documents.

1. Documentation as required by this Supplement shall be delivered or made available by the supplier to the purchaser.

2. Upon receipt of the software from the supplier, the purchaser assumes responsibility of the applicable requirements as specified in this supplement.

3. Software errors and failures shall be reported between the supplier and purchaser in accordance with I.2.5.

B. For procured software services, the organization providing the services shall have plan(s) for software QA, in accordance with I.2.2.A, that meets the requirements of I.2.6.A, and the user organization shall determine the adequacy of this plan.

I.2.7 Software Previously Developed Not Using This Supplement

This section shall apply only to unqualified software in which the history of the software is not known, but the software is required to be used in quality affecting activities.

A. Software that was previously developed not using this supplement shall be placed under configuration controls prior to use.

B. The user organization shall perform, document, and provide for an independent review and evaluation to:

1. Determine its adequacy to support software operation and maintenance.

2. Identify the activities to be performed and documents required in order for the software to be placed under configuration management. As a minimum, these activities shall include:

   a. User application requirements.
   b. Test plans and test cases required to validate the software for acceptability.
   c. User documentation required in accordance with I.2.3.C.3.

C. Upon independent review and approval of the above activities, the software shall be placed under configuration control in accordance with I.2.4.

I.2.8 Control of the Use of Software

A. Affected Organizations shall control and document the use of released software items such that comparable results can be obtained, with any differences explained, through independent replication of the process.

B. Use of software shall be independently reviewed and approved to ensure that the software selected is suitable to the problem being solved.

C. If the intended use of a software item falls outside the range of validation as baselined, changes shall be made to the appropriate baseline elements prior to continuing use.

D. Documentation for the receipt of software obtained from Software Configuration Management in accordance with Section I.2.4 shall be provided and maintained for all software in operation or use.

SUPPLEMENT II SAMPLE CONTROL

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.

E. 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).

F. Physical markings, when used, shall:

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

2. Not detrimentally affect the sample content or form.

3. Be transferred to each identified sample part when the sample is subdivided.

4. Not be obliterated or hidden by surface treatments or sample preparations unless other means of identification are substituted.

II.2.4 Conditional Requirements

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

A. If documents (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 implementing documents or other specified documents.

B. If required for critical, sensitive, perishable, or high-value samples, specific measures for handling, storage, cleaning, packaging, shipping, and preservation shall be identified and used.

C. 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.

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

E. 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.

F. 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, Nonconformances.

B. The disposition for nonconforming samples shall be identified and documented and shall be limited to “use-as-is,” “limited use,” or “discard.”

REFER TO QUALITY ASSURANCE PROGRAM CLARIFICATION LOCATED BEHIND QARD GLOSSARY

No. 99-001 Quality Assurance Program Clarification–Clarification of QARD Supplement III, Section III.2.4.3

SUPPLEMENT III SCIENTIFIC INVESTIGATION

III.1 GENERAL

This supplement establishes requirements for scientific investigations, including data identification, data reduction, and model development and use. Requirements for electronic management of data are addressed in Supplement V, Control of the Electronic Management of Data. Development of software including database applications or software that performs functions of analysis or calculation shall be controlled in accordance with Supplement I, Software.

III.2 REQUIREMENTS

III.2.1 Planning Scientific Investigations

A. Scientific investigations shall be planned in accordance with Section 2.0, Quality Assurance Program.

B. Planning shall be coordinated with organizations providing input to or using the results of the investigation.

C. Planning shall address provisions for determining the accuracy, precision, and representativeness of results.

III.2.2 Performing Scientific Investigations

A. Scientific investigations shall be performed using scientific notebooks, 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 planning document or implementing document that addresses those topics.

2. Identification of method(s) and computer programs to be used.

3. Identification of any samples or measuring and test equipment used.

4. Description of the work as it was performed and results obtained, names of individuals performing the work, and dated initials or signature, as appropriate, of individuals making the entries.

5. Description of changes made to methods used, as appropriate.

C. Scientific notebooks shall be reviewed by an independent qualified individual to verify there is sufficient detail to:

1. Retrace the investigations and confirm the results, or

2. Repeat the investigation and achieve comparable results, without recourse to the original investigator.

III.2.3 Data Identification

A. Data shall be identified in a manner that facilitates traceability to associated documentation.

B. Data shall be identified in a manner that facilitates traceability to its qualification status.

C. Identification and traceability shall be maintained throughout the lifetime of the data.

III.2.4 Data Review, Adequacy, and Usage

A. Data reduction shall be described to permit independent reproducibility by another qualified individual.

B. Data directly relied upon to address safety and waste isolation issues shall be qualified data or established fact, except as allowed in Subsection III.2.4B.2.

1. Data shall be reviewed by individuals other than those who collected or reduced the data to ensure technical correctness.

2. Unqualified data may be used in scientific investigation and design activities, provided traceability to its status as unqualified data is maintained. Unqualified data directly relied upon to address safety and waste isolation issues shall be qualified in accordance with III.2.4.C at appropriate times during the scientific investigations and design process and before:

a. OCRWM acceptance of DOE-EM managed high-level waste or spent nuclear fuel;

b. Submittal of the License Application;

c. Relying on the item for which the data were used as design input, to perform its function; or

d. Data are relied upon to resolve safety or waste isolation issues.

C. Unqualified data directly relied upon to address safety and waste isolation issues shall be qualified by one or a combination of the methods that follow:

1. Determination that the controls under which the data were generated are similar in scope, requirements, and implementation to the QARD.

2. Evaluation of corroborating data - Rationale for selecting one set of data to corroborate another set of data shall be clearly explained and justified.

3. Confirmatory testing.

4. Peer review in accordance with Section 2.0, Quality Assurance Program.

5. Technical Assessment to independently evaluate data which includes one or a combination of the following:

   a. Determination that the employed methodology is acceptable;

   b. Determination that confidence in the data acquisition or developmental results is warranted; or

   c. Confirmation that the data have been used in similar applications.

Methods 1, 2, and 3 above shall include a review to determine the technical correctness of the data in accordance with established review criteria. The qualification process shall be planned and documented. Documentation shall include the acceptance criteria used to determine if the data are qualified, and rationale for discontinuing any qualification methods abandoned after the initiation of the qualification process.

III.2.5 Technical Report Review

Technical reports shall be reviewed in accordance with the requirements of Subsection 2.2.10, Document Review.

III.2.6 Model Development and Use

A. Model development and approaches to validation shall be planned, controlled, and documented. Planning for model validation shall identify the validation methods and the validation criteria used. If model validation activities will be completed after documentation of the model (for example, using new confirmation test data gathered in the field or laboratory), describe these activities in the work-planning document.

B. Documentation of models shall be in accordance with QARD Section 17.0, Quality Assurance Records; shall be transparent; and shall include:

   1. Definition of the objective (intended use) of the model.

   2. Description of conceptual model and scientific basis, as well as alternatives for the selected conceptual model. Include rationale for not selecting alternatives.

   3. Results of literature searches and other applicable background information.

4. Identification of inputs and their sources.

5. Identification of and rationale for assumptions that are made to develop or apply the model, including model idealizations as well as those assumptions that support the input to the model and impact model results.

6. Discussion of mathematical and numerical methods that are used in the model, including governing equations, formulas, and algorithms, and their scientific and mathematical bases.

7. Identification of any associated software used, computer calculations performed, and basis to permit traceability of inputs and outputs.

8. Discussion of initial and/or boundary conditions.

9. Discussion of model limitations (e.g., data available for model development, valid ranges of model application, spatial and temporal scaling).

10. Discussion of model uncertainties (conceptual model, mathematical model, process model, abstraction model, system model, parameters) and how they affect the model.

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

C. Computer software used to develop or execute the model shall be qualified in accordance with the requirements of the QARD, Supplement I, Software.

D. The intended use of the model and the importance of the model for assessing repository system performance shall determine the appropriate level of confidence for a model (i.e., models of system components most relied upon shall be validated with the highest levels of confidence to the extent practical).

E. Criteria for model validation shall be established to reduce, to the extent practical, the uncertainties inherent in the model and to demonstrate that the phenomenon, process, or system being represented by the model is sufficiently well understood to support the model's intended use. Model validation criteria shall address the following:

1. Criteria used to establish the adequacy of the scientific basis for the model shall be consistent with the model application and justified in the model documentation.

2. Criteria used to demonstrate that the model is sufficiently accurate for its intended use shall be consistent with parameter uncertainties and justified in the model documentation.

3.. Define the importance of the model for assessing repository system performance.

4. Describe the relative level of confidence for the model.

5. Define the supporting information needed to substantiate validation.

F. A model progression exists (usually from conceptual model to mathematical model to process model to abstraction model to system model). A conceptual model is validated when its implementation as a mathematical, process, abstraction, or system-level model is validated. Technical review through publication in a refereed professional journal or review by an external agency may be used to corroborate model validation when used in conjunction with one or more of the following:

1. Corroboration of model results with data acquired from field experiments, analogue studies, laboratory experiments, or subsequent relevant observations (e.g., refereed journals or literature). Data used to develop and calibrate a model shall not be used to validate a model.

2. Peer review (QARD Paragraph 2.2.9) and independent technical review (QARD Paragraph 2.2.10)

3. Performance confirmation studies using validation-test model predictions prior to comparison with field or laboratory data.

4. Comparison of model results with other model results obtained from the implementation of an alternative model.

5. Calibration with experimental data sets, including the review of model calibration parameters for reasonableness and consistency in explanation of all relevant data.

SUPPLEMENT IV FIELD SURVEYING

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.

SUPPLEMENT V CONTROL OF THE ELECTRONIC MANAGEMENT OF DATA

V.1 GENERAL

This supplement applies to the processes and controls for the management of data that either exist or are used in an electronic format. This includes electronic formatted data used in design input, developed as design output, or developed as an output of scientific investigation or performance assessment modeling and analysis.

Development of software including database applications or software that performs functions of analysis or calculation shall be controlled in accordance with Supplement I, Software. The acquisition, development and use of data are controlled by the requirements of Section 3.0, Design Control, or Supplement III, Scientific Investigation.

V.2 REQUIREMENTS

V.2.1 Control of the Electronic Management of Data

The Affected Organization shall establish process controls to ensure:

A. Data are suitably protected from damage and destruction during their prescribed lifetime and are readily retrievable.

B. A description is prepared of how data will be stored with respect to media, conditions, location, retention time, security, and access.

C. Storage and transfer media are properly identified as to source, physical and logical format, and relevant date (i.e., date written).

D. The completeness and accuracy of the data input and any subsequent changes to the data are maintained.

E. The security and integrity of the data are maintained.

F. Data transfers are error free, or within a defined permissible error rate, to ensure no information is lost in transfer and that the input is recoverable from the output. Examples of data transfer include copying raw data from a notebook to a computerized data form, copying from computer tape to disk, etc.

APPENDIX A HIGH-LEVEL WASTE FORM PRODUCTION

A.1 GENERAL

A. This appendix contains amplifications of requirements and descriptions unique to waste form development through qualification, production, and acceptance. 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.

B. The Department of Energy's Office of Environmental Management has overall responsibility for developing, qualifying, and producing an acceptable high-level waste form.

A.2 REQUIREMENTS

A.2.1 Amplification of QARD Section 2.0, Quality Assurance Program

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

B. Line management shall establish measures for controlling technical modifications to the waste form production process. Technical modifications subject to control shall include:

1. Waste form and canistered waste form.

2. Process control plans and other implementing documents.

3. Waste Acceptance Product Specifications, Waste Form Compliance Plans, and Waste Form Qualification Reports.

A.2.2 Amplification of QARD Supplement III, Scientific Investigation

Implementing documents shall contain requirements for evaluating development and qualification results including final results within Waste Form Qualification Reports.

APPENDIX B STORAGE AND TRANSPORTATION

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, multi-purpose canisters (MPCs), or ancillary equipment under the licensing provisions of 10 Code of Federal Regulations (CFR) 71, or design or fabricate storage casks, MPCs, or ancillary equipment under the licensing provisions of 10 CFR 72.

B. Activities associated with storage casks, transportation casks, MPCs, and ancillary equipment that are required to ensure future compliance with 10 CFR 60 are not covered by this appendix. For example, whereas work on translating Monitored Geologic Repository 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, MPCs, or ancillary equipment shall develop Quality Assurance (QA) programs that are accepted by the Nuclear Regulatory Commission and docketed in their license, and accepted by the procuring organization. The QA programs shall meet the following requirements.

B.2.2 Storage Casks, Transportation Casks, MPCs, and Ancillary Equipment

A. The NRC licensee/certificate holder's QA program shall meet the requirements of 10 CFR 71, Subpart H or 10 CFR 72, Subpart G, as applicable.

B. With the exception of the requirements specified in this Appendix, the QARD does not apply to NRC licensee/certificate holders that design or fabricate storage casks, transportation casks, MPCs, or ancillary equipment in accordance with 10 CFR 71, Subpart H, or 10 CFR 72, Subpart G, QA programs. This appendix does not exempt OCRWM from implementing the QARD relative to activities it performs as a prospective licensee.

APPENDIX C MONITORED GEOLOGIC REPOSITORY

C.1 GENERAL

This appendix contains modifications of requirements and descriptions unique to work conducted for the Monitored Geologic Repository. Modifications provided relate to specific sections or supplements. In those cases when a section or supplement requires no modification, reference to the section or supplement is omitted.

C.2 REQUIREMENTS

C.2.1 Modification of QARD Section 2.0, Quality Assurance Program

A. The use of expert elicitation may be considered when one or more of the following conditions exist:

1. Empirical data are not reasonably obtainable, or the analyses are not practical to perform;

2. Uncertainties are large and significant to a demonstration of regulatory compliance;

3. More than one conceptual model is permitted by the available data; or

4. Technical interpretations are required to properly assess the knowledge and uncertainty in data, processes, and models.

B. In conducting an expert elicitation, a systematic process for its conduct shall be implemented, including appropriate issue-focused workshops, so that the results of the elicitation accurately reflect data, process, and model uncertainty.

The systematic elicitation process shall consist of the following steps:

1. The objectives are explicitly defined to reflect a clear understanding of how the judgments will be used.

2. Potential conflicts of interest and criteria used to select subject-matter experts are documented.

3. The generalist and normative experts work with the subject-matter experts or expert teams to decompose the objectives of the assessment into focused subissues.

4. Background information, including qualified and unqualified data, is assembled and provided to the subject-matter experts without bias before the elicitation.

5. Pre-elicitation training is provided to the subject-matter experts.

6. The elicitation interviews are structured in a consistent manner, considering the specific issues for which assessments are required.

7. Post-elicitation feedback is provided before the subject-matter experts complete the final documentation of their assessments.

8. The process of aggregating expert assessments is clearly described, including the individual expert's uncertainties and the aggregate uncertainty of multiple experts.

9. Documentation of the elicitation process is assembled.

C. New data shall be reviewed to determine relevance with respect to the experts' assessments, including the need for reassessment.

D. Software that has not been qualified in accordance with Supplement I and unqualified data may be used in the expert elicitation process. The results of the expert elicitation are considered qualified; however, the expert elicitation process is not considered a method for the qualification of software or unqualified data used as input.

C.2.2 Modification of QARD Section 4.0, Procurement Document Control

As an alternative to requiring a documented QA program (see Subsection 4.2.1C) for suppliers of analytical services (measurement of properties or other characterization of samples) supporting scientific investigations, these procurements may be controlled in accordance with Appendix C.2.3

C.2.3 Modification of QARD Section 7.0, Control of Purchased Items and Services

Where analytical services in support of scientific investigation are obtained, the following requirements are an acceptable alternative to the requirements of Section 7.0. The purchaser shall:

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

1. The number of quality control samples and approach to be used for submitting these (blind, duplicate, spike, etc.).

2. The preparation and analysis of quality control samples, or identification of the source of the preparation and analysis method. Standards used in the preparation of quality control samples shall be traceable to nationally

recognized standards. If no nationally recognized standard exists, the basis for use shall be documented.

3. Acceptance criteria.

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

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

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

C.2.4 Modification of QARD Section 9.0, Control of Special Processes

Special processes associated with work products specified in work controlling documents (such as job packages or work requests) shall comply with the requirements specified in Section 9.0, Control of Special Processes.

C.2.5 Modification of QARD Section 10.0, Inspections

If required by work controlling documents (such as job packages or work requests) work products shall be subject to inspection in accordance with Section 10.0 of the QARD.

GLOSSARY

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

Affected Organization–An organization performing Program work subject to QARD requirements whose organizational relationships are defined in OCRWM Program documents.

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

Application (Software)–1) Software designed to fulfill the specific needs of a user. 2) Software that are written where the user prescribes one or more instructions to generate data, manipulate data, or perform calculations.

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

Audit–A planned and documented 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.

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

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

Baseline Element (Software)–An individual software component (e.g., requirements document, design document, source code, etc.) that is under configuration management control.

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 or attribute of an item, process or service 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.

Conceptual Model–A set of hypotheses consisting of assumptions, simplifications, and idealizations that describe the essential aspects of a system, process, or phenomenon.

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

Confirmatory Testing–Testing conducted under a 10 CFR Part 60, Subpart G QA program that investigates the properties of interest (e.g., physical, chemical, geologic, or mechanical) of an unqualified database.

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 are used to support or substantiate other data.

Data (collected)–Factual information obtained from investigation activities such as sample collection, physical measurements, testing, and analyses, both in the field and the laboratory.

Database–A collection of previously distinct data (not created by the database) which have been logically organized to facilitate data access.

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

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 Change–Any revision or alteration of the technical requirements defined by approved and issued design output documents and approved and issued changes thereto.

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.

Established Fact–Information accepted by the scientific and engineering community as established fact (e.g., engineering handbooks, density tables, gravitational laws, etc.).

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.

Expert Elicitation–A formal, structured and documented process for obtaining the judgements of multiple experts.

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.

Generalist–An individual with technical background in one or more disciplines needed to address the problem of interest and who has a general understanding of the technical aspects of the problem.

Implementation (Software)–The process of translating the software design into a computer program.

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.

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

Macro–Single computer instructions invoked by a symbol, name, or key that represents commands, actions, or keystrokes.

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–A representation of a process, system, or phenomenon, along with any hypotheses required to describe the process or system or explain the phenomenon, often mathematically.

Model, Abstraction–A product of the abstraction process that meets the definition of a mathematical model.

Model, Conceptual–A set of hypotheses consisting of assumptions, simplifications, and idealizations that describes the essential aspects of a system, process, or phenomenon.

Model, Mathematical–A mathematical representation of a conceptual model (system, process, or phenomenon) that is based on established scientific and engineering principles and from which the approximate behavior of a system, process, or phenomenon can be calculated within determinable limits of uncertainty.

Model, Process–A mathematical model that represents an event, phenomenon, process, component, etc., or series of events, phenomena, processes, or components, etc. A process model may undergo an abstraction for incorporation into a system model.

Model, System–A collection of interrelated mathematical models that represents the overall geologic repository or overall component subsystem of the geologic repository.

Model Validation–A process used to establish confidence that a mathematical model and its underlying conceptual model adequately represents with sufficient accuracy the phenomenon, process, or system in question.

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

Normative Expert–An individual with a theoretical and conceptual knowledge of probability and practical experience in the elicitation of judgements from individuals.

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.

Organizational Interface–The relationship between organizations when one organization prescribes an activity or requirement to, or shares an activity or requirement with, another organization.

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 work by a group of peers independent from the work being reviewed.

Performance Assessment–An analysis that:

1. Identifies the features, events, processes (except human intrusion), and sequences of events and processes (except human intrusion) that might affect the Yucca Mountain disposal system and their probabilities of occurring during 10,000 years after disposal;

2. Examines the effects of those features, events, processes, and sequences of events and processes upon the performance of the Yucca Mountain disposal system; and

3. Estimates of the dose incurred by the reasonably maximally exposed individual, including the associated uncertainties, as a result of releases caused by all significant features, events, processes, and sequences of events and processes, weighted by their probability of occurrence.

Performance Confirmation–The program of tests, experiments, and analyses that is conducted to evaluate the accuracy and adequacy of the information used to demonstrate compliance with the performance objectives in subpart E of 10 CFR 63.

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.

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

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.

Qualified Data–Data collected under an approved Quality Assurance program that meets the requirements of 10 CFR Part 60, Subpart G (i.e., qualified from origin), or unqualified data that have undergone the qualification process.

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

Quality Assurance (QA) Organization–The OQA organization for activities performed by OCRWM and reviews of OCRWM-owned documents; the M&O QA organization for activities performed by the M&O and reviews of M&O-owned documents; and the OQA organization and the M&O QA organization for documents implemented by both OCRWM and the M&O.

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

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 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 activities such as design, fabrication, inspection, nondestructive examination, repair or installation.

Significant Condition Adverse to Quality–A condition adverse to quality which, if uncorrected, could have a serious effect 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–Computer programs, procedures, rules, and associated documentation pertaining to the operation of a computer system.

Software Baseline–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.

Software Control Point–Milestones in the software life cycle when controls are applied to the software in which they are baselined prior to proceeding with the software project.

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 the software product is conceived and ends when the software product is no longer available for routine use.

Software Routine–A collection of computer macros or script files, a spreadsheet application, or other stand-alone software application (either acquired or developed) that generally operates within another program, such as a spreadsheet, and must be independently verified by visual inspection and/or hand calculation.

Software Validation–The test and evaluation of completed software to ensure compliance with software requirements.

Software Verification–The process of determining whether or not the product(s) of a given phase of the software development cycle fulfills the requirements imposed by the previous phase.

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.

Subject-Matter Expert–An individual recognized by his or her peers as an authority on a specific topic.

Supplier–Any individual or organization who furnishes items or services in accordance with a procurement document. An all-inclusive term used in place of any of the following: vendor, seller, contractor, 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 Assessment–Used for data qualification purposes, a technical assessment is an evaluation of the technical merit of unqualified data against established criteria.

Technical Report–As it pertains to scientific investigation, a document that presents scientific information such as data, analyses, interpretations, or conclusions.

Technical Specialist–An individual who is assigned to an audit team when the scope, complexity, or special nature of the work to be audited warrants assistance from a technical standpoint.

Test Case–A specific set of test data and associated procedures developed for a particular objective, such as to exercise a particular program path or to verify compliance with a specific requirement.

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.

Transparent–A document is transparent if it is sufficiently detailed as to purpose, method, assumptions, inputs, conclusions, references and units such that a person technically qualified in the subject can understand the document and ensure its adequacy without recourse to the originator.

Unqualified Data–Data not collected under an approved Quality Assurance program that meets the requirements of 10 CFR Part 60, Subpart G.

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 act of reviewing, inspecting, testing, checking, auditing, or otherwise determining and documenting whether items, processes, services, or documents conform to specified requirements.

Work–Activities that are subject to the *Quality Assurance Requirements and Description*.

TABLE OF CONTENTS

Number	Subject
99-001	Quality Assurance Program Clarification–Clarification of QARD Supplement III, Section III.2.4.3

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
OFFICE OF QUALITY ASSURANCE

QUALITY ASSURANCE PROGRAM CLARIFICATION NUMBER 99-001

DESCRIPTION OF CONDITION

The DOE National Spent nuclear Fuel Program (NSNFP) has interpreted Supplement III, Section III.2.4.B.3 of the Quality Assurance Requirements and Description (QARD) as not requiring any NSNFP unqualified data to be qualified for OCRWM submittal of a License Application (LA) to construct a repository.

CLARIFICATION

The QARD Supplement III, Section III.2.4.B.3 states:

"Unqualified data directly relied upon to address safety and waste isolation issues shall be qualified in accordance with III.2.4(C) at appropriate times during the scientific investigations and design process and **before**:

a. OCRWM acceptance of DOE-owned high-level waste or spent nuclear fuel;

b. Submittal of the License Application;

c. Relying on the item for which the data were used as design input, to perform its function; or

d. Data are relied upon to resolve safety or waste isolation issues."

The timing of data qualification is dependent on the intended use of the data. For example:

1. With respect to Items b and d above, DOE High-Level Waste or Spent Nuclear Fuel unqualified data used to support our safety case for a license to construct a repository must be qualified **prior** to submittal of the LA; whereas unqualified data that requires the results of confirmatory testing (beyond LA) may be identified as unqualified going into LA, with a commitment to the Nuclear Regulatory Commission to qualify the data at the appropriate time.

2. With respect to Items a and c above, these time frames were meant for unqualified data relating to our license to operate a repository, not our license to construct a repository.

This Quality Assurance program clarification will remain in effect until a future revision of QARD Supplement III, SectionIII.2.4.B.3 is issued.

Robert W. Clark,

R.W. Clark (signature on file)	*10/25/99*
Acting Director	Date
Office of Quality Assurance	