

**U.S. DEPARTMENT OF ENERGY**

**OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT**

**QUALITY ASSURANCE REQUIREMENTS AND DESCRIPTION**

**FOR THE**

**CIVILIAN RADIOACTIVE WASTE MANAGEMENT PROGRAM**



Donald G. Horton, Director  
OCRWM Office of Quality Assurance

7/31/95  
Date



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

7.31.95  
Date



# Office of Civilian Radioactive Waste Management

## *Quality Assurance Requirements and Description*

Title: STORAGE AND TRANSPORTATION

Effective Date: 08/04/95

Section: APPENDIX B

Revision No.: 2

Page 1 of 1

### **B.1 GENERAL**

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

### **B.2 REQUIREMENTS**

#### **B.2.1 General**

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

#### **B.2.2 Storage Casks, Transportation Casks, and MPCs**

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



# Office of Civilian Radioactive Waste Management

## *Quality Assurance Requirements and Description*

Title: **REVISION HISTORY**

Effective Date: **08/04/95**

Section: **i**

Revision No.: **4**

Page **1** of **1**

### REVISION HISTORY

REVISION	REVISION DESCRIPTION
0	Initial issue. This document consolidates the <i>Quality Assurance Requirements Document</i> and the <i>Quality Assurance Program Description Document</i> into one document.
1	Revised Section 1.0, Organization, to reflect OCRWM reorganization.
2	Revised Section 7.0, Control of Purchased Items and Services, to accommodate the transfer of responsibility for the performance of audits from Affected Organizations to OCRWM OQA.
3	Revised Appendix B, Storage and Transportation to provide an exception to the <i>Quality Assurance Requirements and Description</i> for organizations working under the provisions of 10 CFR 71, Subpart C or 10 CFR 72, Subpart L.
4	Revised Appendix B, to reflect editorial change to correct 10 CFR Subpart reference.



# Office of Civilian Radioactive Waste Management

## *Quality Assurance Requirements and Description*

Title: TABLE OF CONTENTS

Effective Date: 08/04/95

Section: iii

Revision No.: 4

Page 1 of 6

<u>Section</u>	<u>Title</u>	<u>Revision</u>
	Title Page	3
	Policy Statement	1
i	Revision History	3
ii	Introduction	0
iii	Table of Contents	3
1.0	Organization	1
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 OCRWM	
1.3.2	Specific CRWM Offices	
1.3.3	Other Affected Organizations	
Fig. 1-1	OCRWM Organization	
2.0	Quality Assurance Program	0
2.1	General	
2.2	Requirements	
2.2.1	Quality Assurance Program Objective	
2.2.2	Quality Assurance Program Documents	
2.2.3	Classifying Items and Applying Quality Assurance Controls	
2.2.4	Planning Work	
2.2.5	Surveillances	
2.2.6	Management Assessments	
2.2.7	Readiness Reviews	
2.2.8	Peer Reviews	
2.2.9	Document Review	
2.2.10	Quality Assurance Program Information Management	
2.2.11	Personnel Selection, Indoctrination Training, and Qualification	
2.2.12	Qualification of Personnel Performing Quality Assurance Functions	

# Quality Assurance Requirements and Description

Section: iii

Revision No.: 4

Page 2 of 6

<u>Section</u>	<u>Title</u>	<u>Revision</u>
<b>3.0</b>	<b>Design Control</b>	<b>0</b>
3.1	General	
3.2	Requirements	
3.2.1	Design Input Control	
3.2.2	Design Process	
3.2.3	Design Analysis	
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	
<b>4.0</b>	<b>Procurement Document Control</b>	<b>0</b>
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	
<b>5.0</b>	<b>Implementing Documents</b>	<b>0</b>
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	
<b>6.0</b>	<b>Document Control</b>	<b>0</b>
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	Controlling the Distribution and Use of Documents	
6.2.6	Changes to Documents	
6.2.7	Expedited Changes	
6.2.8	Editorial Corrections	
<b>7.0</b>	<b>Control of Purchased Items and Services</b>	<b>1</b>
7.1	General	
7.2	Requirements	
7.2.1	Procurement Planning	
7.2.2	Source Evaluation and Selection	
7.2.3	Bid Evaluation	
7.2.4	Supplier Performance Evaluation	
7.2.5	Control of Supplier Generated Documents	
7.2.6	Acceptance of Items or Services	

# Quality Assurance Requirements and Description

Section: iii

Revision No.: 4

Page 3 of 6

<u>Section</u>	<u>Title</u>	<u>Revision</u>
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	
<b>8.0</b>	<b>Identification and Control of Items</b>	<b>0</b>
8.1	General	
8.2	Requirements	
8.2.1	Identification	
8.2.2	Physical Markings	
8.2.3	Traceability	
8.2.4	Conditional Requirements	
<b>9.0</b>	<b>Control of Special Processes</b>	<b>0</b>
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	
<b>10.0</b>	<b>Inspection</b>	<b>0</b>
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	Inprocess Inspections and Monitoring	
10.2.6	Final Inspection	
10.2.7	Accepting Items	
10.2.8	Inspection Documentation	
10.2.9	Qualifications of Inspection and Test Personnel	
<b>11.0</b>	<b>Test Control</b>	<b>0</b>
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	

# Quality Assurance Requirements and Description

Section: iii

Revision No.: 4

Page 4 of 6

<u>Section</u>	<u>Title</u>	<u>Revision</u>
12.0	<b>Control of Measuring and Test Equipment</b>	0
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	Handling and Storage	
12.2.5	Commercial Devices	
12.2.6	Measuring and Test Equipment Documentation	
13.0	<b>Handling, Storage, and Shipping</b>	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	<b>Inspection, Test and Operating Status</b>	0
14.1	General	
14.2	Requirements	
14.2.1	Identifying Items	
14.2.2	Indicating Status	
15.0	<b>Nonconformances</b>	0
15.1	General	
15.2	Requirements	
15.2.1	Documenting and Evaluating Nonconformances	
15.2.2	Identifying Nonconforming Items	
15.2.3	Segregating Nonconforming Items	
15.2.4	Disposition of Nonconforming Items	
15.2.5	Trending	
16.0	<b>Corrective Action</b>	0
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	Trending	
17.0	<b>Quality Assurance Records</b>	0
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	

# Quality Assurance Requirements and Description

Section: iii

Revision No.: 4

Page 5 of 6

<u>Section</u>	<u>Title</u>	<u>Revision</u>
17.2.8	Disposition of Quality Assurance Records	
17.2.9	Long-Term Storage Facility	
17.2.10	Temporary Storage Facility	
17.2.11	Replacement	
<b>18.0</b>	<b>Audits</b>	<b>0</b>
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	
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 Qualification	
18.2.21	Maintaining Lead Auditor Proficiency	
<b>Supplement I</b>	<b>Software</b>	<b>0</b>
I.1	General	
I.2	Requirements	
I.2.1	Software Life Cycles, Baselines, and Controls	
I.2.2	Software Verification and Software Validation	
I.2.3	Software Verification	
I.2.4	Software Validation	
I.2.5	Acquired Software	
I.2.6	Documentation	
I.2.7	Software Configuration Management	
I.2.8	Defect Reporting and Resolution	
I.2.9	Media Control	
I.2.10	Use of Software	

# Quality Assurance Requirements and Description

Section: iii

Revision No.: 4

Page 6 of 6

<u>Section</u>	<u>Title</u>	<u>Revision</u>
<b>Supplement II</b>	<b>Sample Control</b>	<b>0</b>
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	
<b>Supplement III</b>	<b>Scientific Investigation</b>	<b>0</b>
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 Validation and Qualification	
III.2.5	Data Usage	
III.2.6	Model Validation	
<b>Supplement IV</b>	<b>Field Surveying</b>	<b>0</b>
IV.1	General	
IV.2	Requirements	
IV.2.1	Field Survey System	
IV.2.2	Field Survey Documentation	
<b>Appendix A</b>	<b>High Level Radioactive Waste Form Production</b>	<b>0</b>
A.1	General	
A.2	Requirements	
A.2.1	Amplification of QARD Section 2	
A.2.2	Amplification of QARD Section 3	
<b>Appendix B</b>	<b>Storage and Transportation</b>	<b>2</b>
B.1	General	
B.2	Requirements	
B.2.1	General	
B.2.2	Storage Casks, Transportation Casks, and MPCs	
<b>Appendix C</b>	<b>Mined Geologic Disposal System</b>	<b>0</b>
C.1	General	
C.2	Requirements	
C.2.1	Amplification of QARD Section 10	
C.2.2	Amplification of QARD Section 15	
<b>Glossary</b>	<b>Glossary</b>	<b>0</b>