

# UNCONTROLLED COPY



## OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT QUALITY ASSURANCE ADMINISTRATIVE PROCEDURE

Title:

**ESTABLISHING QUALITY ASSURANCE PROGRAM CONTROLS**

Procedure No.:

**QAAP 2.3**

Revision:

**1**

Date:

**10/10/90**

Page

**1 of 12**

Concurrence

Date:

*R. Blahotis* 10/10/90

Approval

Date:

*John W. Benthitt* 10/11/90

### 1.0 PURPOSE

The purpose of this procedure is to delineate the process for determining whether requirements of the Quality Assurance Requirements Document (QARD) are applicable to work performed by OCRWM and for specifying the quality assurance (QA) program controls that are to be implemented for all work.

### 2.0 SCOPE

This procedure applies to and shall be used to plan and manage all work within OCRWM. OCRWM-managed PROGRAM participants who perform work in accordance with their respective QA programs shall establish QA program controls as specified in documents prepared by OCRWM in accordance with QAAP 4.2, *Establishing Procurement Quality Assurance Controls*.

### 3.0 REFERENCES AND DEFINITIONS

#### 3.1 REFERENCES

3.1.1 *Quality Assurance Requirements Document (QARD), DOE/RW-0214.*

3.1.2 *Quality Assurance Program Description (QAPD), DOE/RW-0215.*

#### 3.2 DEFINITIONS

3.2.1 The definitions of standard terms may be found in the Glossary contained in reference 3.1.1.

3.2.2 PROGRAM - U.S. Department of Energy's Civilian Radioactive Waste Management Program.



- 3.2.3 Function - An OCRWM office responsibility directed towards satisfying **PROGRAM** objectives consistent with those approved by the Director, Office of Administration and Human Resource Management in accordance with DOE orders and procedures.
- 3.2.4 Work - An activity or set of activities having clearly defined products or expected results that are undertaken by an OCRWM office to satisfy a function.
- 3.2.5 Task - A work supplement assigned to or expected of OCRWM or other **PROGRAM** participants.
- 3.2.6 Design Activities - Activities related to the design process including data collection and analyses that are used to support design development and verification.
- 3.2.7 QA Program Controls - QAAPs, ILPs, and other DOE documents that are related to the applicable QAPD sections and are identified to be implemented in the conduct of work to assure the achievement of quality.
- 3.2.8 Radiological Safety - For the purposes of this procedure, the safety of workers or the public from exposure to radiation from high-level radioactive waste and associated non-fuel components.
- 3.2.9 Work Breakdown Structure (WBS) - A structure which logically defines the relationships of work products or elements to each other and to the total radioactive waste management system.

#### 4.0 RESPONSIBILITIES

##### 4.1 DIRECTOR, OCRWM

The Director, OCRWM is responsible for function definitions and, if necessary, work definitions and associated QA Controls Matrices and QA Controls Basis Sheets for the Office of the Director. The Director, OCRWM is also responsible for approval of the *QA Controls Document* that will be developed in accordance with Section 6.0.

##### 4.2 ASSOCIATE AND OFFICE DIRECTORS

The Associate and Office Directors are responsible for function definitions, and, if necessary, work definitions and associated QA Controls Matrices and QA Controls Basis Sheets for their Offices.



#### **4.3 DIRECTOR, OQA**

The Director, OQA is responsible for function definitions and, if necessary, work definitions and associated QA Program Controls Matrices and QA Program Controls Basis Sheets for the Office of Quality Assurance. The Director, OQA is also responsible for reviewing the *QA Controls Document*, concurring with the QA Program Controls Basis Sheets, and issuing and controlling the *QA Controls Document*. The Director, OQA is also responsible for preparing and maintaining this QAAP.

#### **4.4 ASSOCIATE DIRECTOR FOR PROGRAM AND RESOURCE MANAGEMENT**

The Associate Director for Program and Resource Management is responsible for developing, coordinating, securing approval of, and maintaining current OCRWM mission and function statements.

#### **5.0 GENERAL**

- 5.1 Planning for the application of appropriate QA program controls to assure the quality of items and activities required for the achievement of **PROGRAM** objectives is required by the QARD and QAPD. To effectively plan and selectively apply QA program controls for work (also known as *grading*), work products must be clearly defined. Only then can a determination be made whether or not the work needs to be conducted in accordance with the QARD requirements and which procedural controls are applicable.
- 5.2 Determining whether QA program requirements must be applied to work and the specific procedural controls to be applied is a management responsibility. The most important decision is whether the work is subject to QARD requirements and the most difficult decisions involve the selection of appropriate QA program controls. As a minimum, the following OCRWM work shall be considered subject to the QARD requirements:
  - 5.2.1 Design activity work or site characterization work for those elements directly related to radiological safety or waste isolation and directly associated with siting, design, or construction of items and activities for processing, handling, transportation, storage, or disposal of spent nuclear fuel or high-level radioactive waste; and
  - 5.2.2 Work that is direct input into the license application or the radiological safety sections of the environmental impact statement or indirectly supports the technical arguments in the license application or the radiological safety sections of the environmental impact statement.



5.3 The selective application of QA program controls (grading) shall depend upon the type of work being conducted and its purpose or use. The following factors may be considered when specifying QA program controls:

- a) Consequence of failure
- b) Importance of data
- c) Complexity of function
- d) Reliability of data or product
- e) Reproducibility of data
- f) Uniqueness of product
- g) Degree of functional product demonstration
- h) Degree of standardization in industry
- i) History of quality
- j) Impact on schedule or cost or both
- k) Impact on environmental quality
- l) Impact on occupational health and safety
- m) Impact on public health and safety
- n) Impact on safety and waste isolation
- o) Need for special controls or processes
- p) Significance to the licensing process.

#### 6.0 PROCEDURE

OCRWM Program activities and associated QA program controls shall be identified in a QA controls document. The *QA Controls Document* shall provide descriptions of each Office's applicable function or work definitions and identify the applicable QA program controls to be implemented. The *QA Controls Document* shall be formatted as outlined in Attachment I, Format for QA Controls Document and prepared in accordance with the following subsections.



### **6.1 RESPONSIBILITY DEFINITION**

The Director, OCRWM; the Director, OQA; and the Associate and Office Directors shall develop descriptions of their assigned responsibilities at a function and, if necessary, a work level. These descriptions shall be at the level of detail required to 1) define the purpose and outputs and 2) identify the applicable QA program controls that are necessary to assure the achievement and verification of quality requirements. These descriptions shall be consistent with approved mission and function statements.

### **6.2 QA PROGRAM APPLICABILITY**

For each description that shall have applicable QA program requirements and QA program controls specified, a determination of the applicability of the QARD shall be made in accordance with Subsection 5.2. The results of, and the basis (that is justification) for, the determination shall be documented on Attachment II, QA Program Controls Matrix and Attachment III, QA Program Controls Basis Sheet, respectively.

### **6.3 APPLICABLE QA PROGRAM CONTROLS**

The QA program controls applicable to each description shall be identified and documented as follows:

#### **6.3.1 QARD REQUIREMENTS ARE APPLICABLE**

When the QARD is applicable, the QAPD shall be implemented. This shall be documented on the associated QA Program Controls Matrix sheet. The applicability of QAPD Subsections are established as follows:

- a) QAPD Sections 1, 2, 4, 5, 6, 7, 16, 17, and 18 are always applicable.
- b) The applicability of QAPD Subsections 3, 8-15, 19, and 20 and Appendices A, B, and C is dependent on the scope of the defined function or work and must be separately evaluated in accordance with Subsection 5.3. The applicability of these Subsections shall be documented on the associated QA Program Controls Matrix sheet.
- c) In those cases where QAPD Sections 3, 8-15, 19, or 20 and Appendices A, B, and C are not applicable, a justification shall be documented on Attachment III, QA Program Controls Basis Sheet.



**6.3.2 QARD REQUIREMENTS ARE NON-APPLICABLE**

When the QARD is non-applicable, the implementation of the QAPD is not required. This is documented on the associated QA Program Controls Matrix sheet. The QAPD subsections and the considerations in Subsection 5.3 may be used as guidance to determine if any QAPD sections are necessary. These are documented on the associated QA Controls Matrix sheet.

**6.4 QA CONTROLS DOCUMENT PREPARATION**

Each Associate or Office Director shall submit function or work definitions; associated QA Program Controls Matrices; and QA Program Controls Basis Sheets to the Director, OQA for incorporation into the QA Controls Document.

**6.5 QA CONTROLS DOCUMENT REVIEW AND APPROVAL**

6.5.1 The Associate Director for Program and Resource Management shall review and concur with the function work definitions for conformance to approved mission and function statements.

6.5.2 The Director, OQA shall review the QA Controls Document in accordance with QAAP 2.5, *Quality Assurance Program Document Review*. The Director, OQA shall concur with and sign the QA Program Controls Basis Sheets. OQA concerns with the QA Controls Basis Sheets shall be resolved as specified in QAAP 2.5.

6.5.3 The Director, OCRWM shall review and approve the QA Controls Document prior to issuance.

**6.6 QA CONTROLS DOCUMENT CONTROL**

6.6.1 The QA Controls Document shall be maintained as a controlled document by OQA in accordance with QAAP 6.1, *Document Control*.

6.6.2 Revisions to the QA Controls Document shall be accomplished in accordance with Subsections 6.1 through 6.5. QA Program Controls Basis Sheets shall be prepared for those revisions to the QA Program Controls Matrices where the identified QAPD sections are found to be not applicable.



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**7.0** RECORDS

- 7.1 Documentation generated as a result of this procedure shall be maintained in accordance with requirements specified in QAAP 17.1, *QA Records Management*. The *QA Controls Document* is a QA record.

**8.0** ATTACHMENTS

- 8.1 Attachment I - Format for the QA Controls Document
- 8.2 Attachment II - QA Program Controls Matrix
- 8.3 Attachment III - QA Program Controls Basis Sheet
- 8.4 Attachment IV - Flow Diagram for QAAP 2.3



ATTACHMENT I  
FORMAT FOR QA CONTROLS DOCUMENT

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Table of Contents

Section 1.0 - Office of the Director

1.1 Function Definition #1

1.1.1 Work Definition #1 (Related to Function Definition #1)

1.1.2 Work Definition #2 (Related to Function Definition #1)

1.2 Function Definition #2

Figure 1.1 - QA Controls Matrix sheets (Attachment II)

Figure 1.2 - QA Controls Basis sheets (Attachment III)

Section 2.0 - Office of Quality Assurance

Section 3.0 - Office of Strategic Planning and International Programs

Section 4.0 - Office of External Relations

Section 5.0 - Office of Program and Resource Management

Section 6.0 - Office of Geologic Disposal

Section 7.0 - Office of Systems and Compliance

Section 8.0 - Office of Storage and Transportation

Section 9.0 - Office of Contract Business Management

Appendices and Attachments





ATTACHMENT II  
QA PROGRAM CONTROLS MATRIX

FUNCTION OR WORK	SUBSECTION NO. / TITLE	APPLICABLE QA PROGRAM CONTROLS			
		QAPD REQUIREMENTS APPLY? (YES/NO)	QAPD REQUIRED? (YES/NO)		
				QAPD SECTION 1.0	
				QAPD SECTION 2.0	
				QAPD SECTION 3.0	
				QAPD SECTION 4.0	
				QAPD SECTION 5.0	
				QAPD SECTION 6.0	
				QAPD SECTION 7.0	
				QAPD SECTION 8.0	
				QAPD SECTION 9.0	
				QAPD SECTION 10.0	
				QAPD SECTION 11.0	
				QAPD SECTION 12.0	
				QAPD SECTION 13.0	
				QAPD SECTION 14.0	
				QAPD SECTION 15.0	
				QAPD SECTION 16.0	
				QAPD SECTION 17.0	
				QAPD SECTION 18.0	
				QAPD SECTION 19.0	
				QAPD SECTION 20.0	
				APPENDIX A	
				APPENDIX B	
				APPENDIX C	

QA PROGRAM CONTROLS MATRIX (EXAMPLE)

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**ATTACHMENT III  
QA PROGRAM CONTROLS BASIS SHEET**



OFFICE OF CIVILIAN  
RADIOACTIVE WASTE MANAGEMENT  
U.S. DEPARTMENT OF ENERGY  
WASHINGTON, D.C.

SHEET \_\_\_\_\_ OF \_\_\_\_\_

**QA PROGRAM CONTROLS BASIS SHEET**

APPLICABLE FUNCTION/WORK: \_\_\_\_\_  
SUBSECTION NUMBER AND TITLE \_\_\_\_\_ REV. NO. \_\_\_\_\_

QARD APPLICABILITY? YES \_\_\_\_\_ NO \_\_\_\_\_

JUSTIFICATION:

JUSTIFICATION FOR NOT SPECIFYING QAPD REQUIREMENTS:

APPROVAL SIGNATURE: \_\_\_\_\_ DATE: \_\_\_\_\_

OQA CONCURRENCE: \_\_\_\_\_ DATE: \_\_\_\_\_

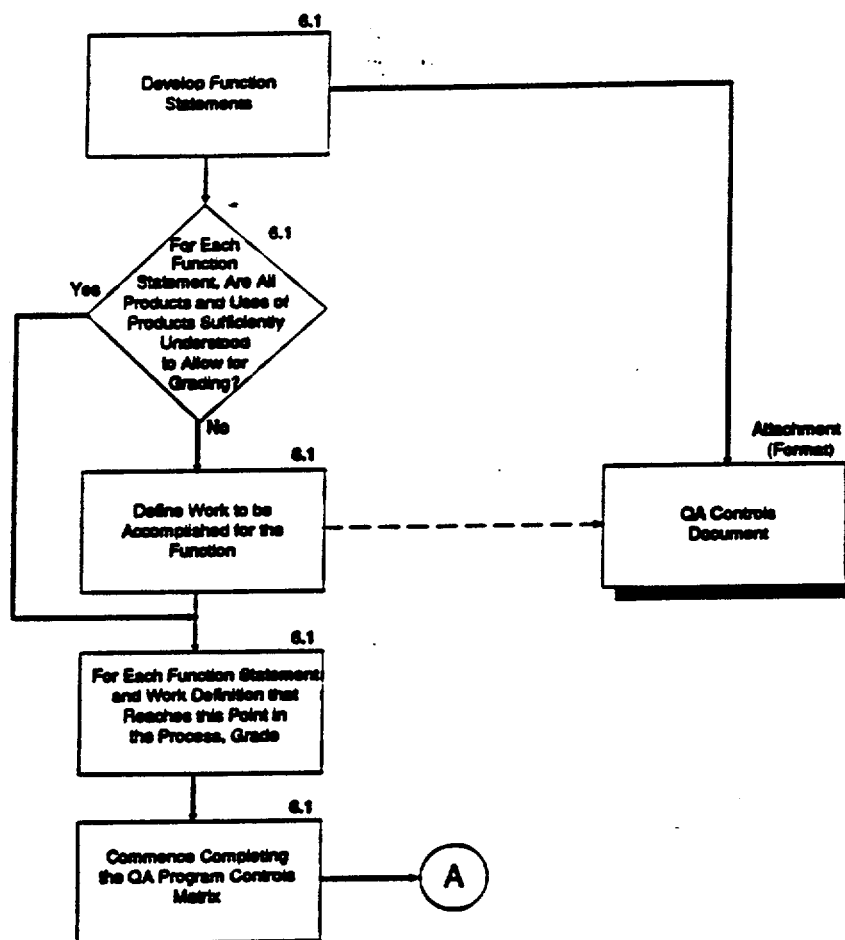
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WASHINGTON, D.C.

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ATTACHMENT IV  
FLOW DIAGRAM FOR QAAP 2.3

These steps are performed by the Director, OCRWM  
and the Associate and Office Directors





**ATTACHMENT IV (CONTINUATION)  
FLOW DIAGRAM FOR QAAP 2.3**

