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OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT QUALITY ASSURANCE ADMINISTRATIVE PROCEDURE

Title: **PREPARATION AND MAINTENANCE OF THE QARD AND QAPD**

Procedure No.:
QAAP 2.4

Revision: **0**

Date: **03/29/91**

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Concurrence *[Signature]* Date: **3/12/91**

Approval *[Signature]* Date: **3/12/91**

1.0 PURPOSE

The purpose of this procedure is to establish the responsibilities and methods for the preparation and maintenance of the QARD and QAPD for the Office of Civilian Radioactive Waste Management (OCRWM).

2.0 SCOPE

This procedure applies to the *Quality Assurance Requirements Document* and the *Quality Assurance Program Description Document*.

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 Document (QAPD)*, DOE/RW-0215.

3.2 DEFINITIONS

3.2.1 Interim Change Notice (ICN) - A method for issuing modifications to portions of the QARD or QAPD that does not require revising and reissuing the entire document.

3.2.2 Major Change - A modification that constitutes a change from a previously established OCRWM (a) policy, (b) quality assurance program requirement, or (c) external commitment or that (d) provides a substantive change in the level of control previously established in the document.

3.2.3 Minor Change - A modification that is not considered to be a major change as defined in Paragraph 3.2.2, such as editorial changes for clarity or correction of typographical, grammatical, punctuation, or spelling errors.



3.2.4 Revision - A method for issuing modifications to the QARD or QAPD that requires reissue of the entire document.

3.2.5 The definitions of other quality assurance related terms may be found in the Glossary contained in reference 3.1.1.

4.0 RESPONSIBILITIES

4.1 DIRECTOR, OCRWM

The Director, OCRWM has overall responsibility for approving the QARD and QAPD, subsequent revisions and ICNs containing major changes.

4.2 DIRECTOR, OFFICE OF QUALITY ASSURANCE (OQA)

The Director, OQA is responsible for:

4.2.1 Preparing and maintaining this QAAP;

4.2.2 Assigning individuals to prepare the QARD and QAPD, revisions, and interim changes;

4.2.3 Coordinating the review and approval of the QARD and QAPD, revisions, and ICNs containing major changes;

4.2.4 Approving and issuing the QARD and QAPD, revisions, and interim changes.

5.0 GENERAL

5.1 FORMAT AND CONTENT OF THE QARD AND QAPD

5.1.1 The QARD and QAPD shall contain numbered sections. The first eighteen sections shall follow the sequence of ASME NQA-1. Lettered appendices that indicate exceptions or additions to the individual sections specific to individual Program Elements may be added at the end of each document. The QARD shall contain an additional appendix that provides a glossary of standard terms.

a) The first page of each section shall include the title and section number centered at the top of the page. Each section shall be divided into subsections, these subsections shall be titled and numbered in the format aa.b, where "aa" is the section number and "b" is the sequential number of the subsection. Subsections shall be further broken down into paragraphs and subparagraphs as needed; each paragraph and subparagraph shall be uniquely identified.



- b) Each page of the QARD and QAPD shall be identified in the upper left hand corner by the abbreviation for the document (QARD or QAPD), the effective date and the revision number. Page numbers shall be indicated at the bottom center of each page, using the format "x-y", where "x" is the number of the section or letter of the appendix, and "y" is the sequential page number within that section or appendix. Page numbers for preliminary sections of the document shall be lower case roman numerals.

- 5.1.2 Each document shall include a Table of Contents that lists the number, title, and page number for each section and subsection of the document. Preliminary sections such as forewords, introductions, and policy statements, appendices, and figures appearing within the document shall also be listed in the Table of Contents.

5.2 METHODS OF MODIFYING THE QARD AND QAPD

- 5.2.1 The QARD and QAPD may be modified using revisions or interim changes. Revisions require reprinting and reissuing the entire document. ICNs are used to issue approved changes without revising the document.
- 5.2.2 A maximum of five ICNs may be issued against a single revision of the QARD or QAPD. The QARD or QAPD shall be revised when additional changes are required and five ICNs have been issued. The Director, OQA may request revision of the QARD or QAPD when fewer than five ICNs have been issued. Revisions to the QARD or QAPD shall incorporate any previously issued interim changes. A vertical line shall be placed in the margin of the revised document adjacent to any lines changed since the prior revision.

5.3 INTERIM CHANGE NOTICE

- 5.3.1 Interim changes shall be documented on Attachment I, "Interim Change Notice". The ICN shall include the text of each change, the rationale for the change, and instructions for incorporating the change (example: "Change Paragraph 1.2.3 to read ..." or "Delete paragraph 7.8.9 in its entirety.") Each change described on the ICN shall include a listing of the affected pages. The ICN shall also identify the document and revision to which the changes apply, the effective date of the changes, and the ICN number. The ICN shall also contain approval signatures and an indication of training required as a result of the changes.



5.3.2 Each ICN shall be uniquely numbered in the format "x.y" where "x" is the current revision of the document to which the ICN applies, and "y" is the sequential number of the ICN. For example, the first ICN against Revision 5 of the QARD would be ICN 5.1 and the next would be ICN 5.2.

5.3.3 ICNs shall be issued to holders of controlled copies of the QARD and QAPD in accordance with QAAP 6.1, *Document Control*. Document transmittals shall include instructions that recipients mark affected pages in their controlled copy with a reference to the ICN.

6.0 PROCEDURE

6.1 PREPARATION OF THE QARD AND QAPD

6.1.1 The Director, OQA shall assign individuals to prepare the QARD and QAPD.

6.1.2 The assigned individual shall prepare the document using the format described in Subsection 5.1.

6.1.3 The preparer shall submit the document to the Director, OQA.

6.1.4 The Director, OQA shall coordinate the review, resolution of comments, and approval of the document in accordance with QAAP 2.5, *Quality Assurance Program Document Review*.

6.1.5 The Director, OQA shall direct the preparation of appropriate training in accordance with QAAP 2.1, *Indoctrination and Training*.

6.1.6 The Director, OQA shall distribute the approved document in accordance with QAAP 6.1, *Document Control*.

6.2 MODIFICATION OF THE QARD AND QAPD

6.2.1 The Director, OQA shall determine if a revision is required in accordance with Paragraph 5.2.2. If a revision is required, it shall be processed in accordance with Subsection 6.1.

6.2.2 If a revision is not required, the Director, OQA shall assign individuals to prepare interim changes.

6.2.3 The assigned individual shall complete Attachment I, "Interim Change Notice", in accordance with Subsection 5.3.

6.2.4 The preparer shall indicate the type of change and submit the completed ICN to the Director, OQA.



- 6.2.5 The Director, OQA shall coordinate the review, resolution of comments, and approval of major changes in accordance with QAAP 2.5, *Quality Assurance Program Document Review*. Upon completion the Director, OQA shall approve the ICN and obtain the approval signature of the Director, OCRWM.
- 6.2.6 The Director, OQA shall review ICNs containing minor changes only and resolve any concerns with the preparer. Upon resolution of any concerns, the Director, OQA shall approve the ICN and mark "N/A" in the Director, OCRWM APPROVAL block.
- 6.2.7 The Director, OQA shall determine whether reading or classroom training is necessary for the approved changes and document the requirements on the ICN. If classroom training is required, the Director, OQA shall direct the preparation of appropriate training in accordance with QAAP 2.1, *Indoctrination and Training*.
- 6.2.8 The Director, OQA shall indicate the effective date on the ICN and distribute the approved ICN in accordance with Subsection 5.3.

7.0 RECORDS

Documentation generated as a result of this procedure shall be collected and maintained in accordance with the requirements specified in QAAP 17.1, *QA Records Management*. At a minimum, copies of each approved QARD or QAPD revision and approved Interim Change Notices shall be considered QA Records.

8.0 ATTACHMENTS

- 8.1 Attachment I - Interim Change Notice
- 8.2 Attachment II - QAAP 4.2 Flowchart



ATTACHMENT I (Example)

PAGE _____ OF _____ QA	
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT U.S. DEPARTMENT OF ENERGY WASHINGTON, D.C.	
INTERIM CHANGE NOTICE	
AFFECTED DOCUMENT (Including Revision):	EFFECTIVE DATE:
ICN NO.	
INTERIM CHANGE AND RATIONALE:	PAGES AFFECTED
TYPE OF CHANGE: Major _____ Minor _____	REQUIRED TRAINING: Read _____ Classroom _____
_____ PREPARER OF ICN	_____ DIRECTOR, OQA
_____ DATE	_____ DATE
APPROVAL:	APPROVAL:
_____ DIRECTOR, OQA	_____ DIRECTOR, OCRWM
_____ DATE	_____ DATE

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ATTACHMENT I (Continued)

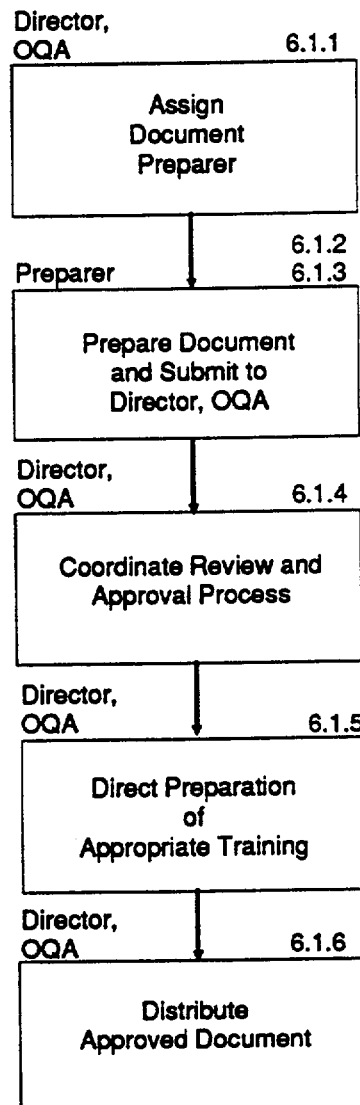
<p>OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT U.S. DEPARTMENT OF ENERGY WASHINGTON, D.C.</p>		
PAGE _____ OF _____ QA		
INTERIM CHANGE NOTICE (Continuation Sheet)		
AFFECTED DOCUMENT (Including Revision):	EFFECTIVE DATE:	ICN NO.
INTERIM CHANGE AND RATIONALE:		PAGES AFFECTED

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ATTACHMENT II (Example)

PREPARATION OF QA PROGRAM DOCUMENTS





ATTACHMENT II (Continued)

MODIFICATION OF QA PROGRAM DOCUMENTS

