

# UNCONTROLLED COPY



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

Title:

**PREPARATION AND REVISION OF QUALITY ASSURANCE ADMINISTRATIVE PROCEDURE**

Procedure No.:

**QAAP 5.1**

Revision:

**3**

Date:

**12/28/90**

Page

**1 of 20**

Concurrence

Date:

Approval

Date:

### 1.0 PURPOSE

The purpose of this procedure is to establish responsibilities, identify requirements, and prescribe instructions for the uniform preparation, review, approval, issuance, and revision of Quality Assurance Administrative Procedures (QAAPs) for the Office of Civilian Radioactive Waste Management (OCRWM).

### 2.0 SCOPE

This procedure applies to the development and revision of OCRWM QAAPs.

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

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



- 3.2.3 Mandatory Comment - A comment requiring resolution that identifies and describes a conflict with, or deviation from, an existing OCRWM (a) policy, (b) quality assurance program requirement, or (c) external commitment or (d) provides a substantive change in the process.
- 3.2.4 Minor Revision - QAAP changes that are an alteration to an approved document such as an organizational title change; a change to the alpha-numeric identifier of the document; minor wording changes for clarity; editorial, typographical, grammar, punctuation, or spelling corrections, where the basic content of the document does not change.
- 3.2.5 QAAP - Quality Assurance Administrative Procedure which implements the QARD and QAPD by prescribing specific measures, methods, or systems to be used to assure quality assurance program compliance and defines the specific individuals or organizations responsible for implementation.

#### 4.0 RESPONSIBILITIES

##### 4.1 DIRECTOR, OCRWM

The Director, OCRWM or designee has responsibility for approving the initial issue of QAAPs and major QAAP revisions.

##### 4.2 ASSOCIATE AND OFFICE DIRECTORS, OCRWM

The Associate and Office Directors, OCRWM or designees are responsible for:

- 4.2.1 Identifying the need for development of new QAAPs and preparing QAAP revisions within their functional areas of responsibility.
- 4.2.2 Reviewing assigned QAAPs and subsequent revisions and providing comments.
- 4.2.3 Providing concurrence of assigned QAAPs through the review process.
- 4.2.4 Evaluating a proposed QAAP revision in their area of responsibility to determine if the revision constitutes a major or minor revision.
- 4.2.5 Assuring that their staff and direct-support personnel who perform activities covered by a new or revised QAAP receive appropriate indoctrination and training.
- 4.2.6 Assuring the implementation of requirements delineated in QAAPs in their functional areas of responsibility.



#### **4.3 OCRWM PERSONNEL**

OCRWM personnel are responsible for:

- 4.3.1 Identifying the need or possible need for a QAAP or a revision to a QAAP to the Director, OQA or to the Associate or Office Director having responsibility for the maintenance of the affected QAAP.
- 4.3.2 Developing, reviewing, or resolving comments on QAAPs as assigned in accordance with requirements of this QAAP.
- 4.3.3 Completing assigned indoctrination and training upon the issue of a new or revised QAAP.

#### **4.4 DIRECTOR, OFFICE OF QUALITY ASSURANCE (OQA)**

The Director, OQA or designee is responsible for:

- 4.4.1 Preparing and maintaining this QAAP.
- 4.4.2 Coordinating the development and maintenance of QAAPs.
- 4.4.3 Establishing specific review and acceptance criteria (See Paragraph 5.1.5) for the review of QAAPs and subsequent revisions.
- 4.4.4 Determining the need for new QAAPs or revisions to existing QAAPs within OQA's areas of responsibility in accordance with Paragraphs 4.2.1 through 4.2.6.
- 4.4.5 Interpreting quality assurance program requirements for inclusion into appropriate QAAPs.
- 4.4.6 Reviewing QAAPs to assure the existence of adequate qualitative and quantitative instructions for compliance.
- 4.4.7 Evaluating proposed QAAP revisions to determine if the change represents a major or minor revision.
- 4.4.8 Informing the OCRWM QA Training Officer of any newly developed or revised QAAPs so that appropriate training may be identified and implemented.



4.4.9 Providing signatory concurrence on new QAAPs and QAAP revisions.

4.4.10 Providing signatory approval on QAAP minor revisions.

4.4.11 Issuing and distributing approved QAAPs and QAAP revisions in accordance with QAAP 6.1, *Document Control*.

#### 4.5 OCRWM QA TRAINING OFFICER

The OCRWM QA Training Officer is responsible for identifying and implementing appropriate training for each newly developed or revised QAAP.

#### 5.0 GENERAL

Any OCRWM participant may suggest the subject for a new QAAP or a change to an existing QAAP by transmitting the request to the Director, OQA or to the Associate or Office Director having responsibility for the maintenance of an existing QAAP. (The responsibility for maintenance is defined in Section 4.0 of each QAAP.) The Director, OQA or the responsible Associate or Office Director shall evaluate the proposed action for suitability and initiate the appropriate activities as necessary. A flow chart depicting these activities is provided as Attachment VIII.

#### 5.1 QAAP PREPARATION AND REVIEW

5.1.1 QAAPs and QAAP revisions shall be prepared in accordance with this QAAP and shall be distributed and controlled in accordance with QAAP 6.1, *Document Control*.

5.1.2 Preliminary QAAP drafts may be developed and informally reviewed as necessary to adequately define the proposed process prior to drafting the QAAP for formal review and comment resolution.

5.1.3 Each formal draft of an initial-issue QAAP or major QAAP revision shall be reviewed by the Director, OQA and the responsible Associate or Office Directors affected by or with defined responsibility within the document.

5.1.4 The formal QAAP review process shall be documented on Attachment III, "Document Review Record" and Attachment IV, "Document Review Record Continuation Sheet."



- 5.1.5 Review criteria specified on the Document Review Record shall be specific and detailed. Reviewers shall be provided with sufficient information to evaluate the QAAP being reviewed. The review and acceptance criteria shall include the requirement for Associate or Office Directors affected by or with defined responsibility within the document to evaluate the document or changes relative to their respective external commitments.
- 5.1.6 Reviewers shall evaluate each of their comments provided on the Document Review Record to determine if the comment meets one of the mandatory comment criteria provided in Paragraph 3.2.3. For comments that meet the mandatory comment criteria, the reviewers shall mark the comments in the SECTION/PARAGRAPH block with an asterisk (\*) and a letter (a through d) corresponding to the applicable criterion. The mandatory comment designations shall be reviewed and evaluated further by the QAAP preparer and the Director, OQA.
- 5.1.7 Mandatory comments shall be resolved by the reviewer and the QAAP preparer and the resolution shall be documented in the RESPONSE block of the DRR. The reviewer shall initial and date the appropriate DRR block next to the mandatory comment resolution response. The resolution of mandatory comments may be accomplished via a mandatory comment resolution meeting or individual consultations that produce an acceptable end result.
- 5.1.8 Mandatory comments that cannot be resolved shall be brought to the attention of appropriate management and, if not resolved, shall be elevated progressively to the Director, OQA and the responsible Associate or Office Director and, if necessary, to the Director, OCRWM.
- 5.1.9 Non-mandatory comments shall require no formal resolution or resolution documentation although the QAAP preparer shall review non-mandatory comments for possible inclusion into the QAAP.

**5.2 QAAP FORMAT AND CONTENT**

- 5.2.1 To maintain uniformity, QAAPs shall be developed in the format described in Attachment V, "QAAP Standard Arrangement Format" and Attachment VI, "Standard Block Paragraph Format."



5.2.2 QAAPs shall be prepared using Attachment I, "Procedure Title Page" and Attachment II, "Procedure Continuation Page." The required information follows:

- a) Title - The subject of the QAAP
- b) Procedure Number - The appropriate alphanumeric identification for the QAAP as assigned by the Director, OQA
- c) Revision - The appropriate sequential revision number of the QAAP with zero being the first issue
- d) Date - The effective date of the QAAP
- e) Page - The specific page and total pages ("Page 1 of \_\_\_\_")
- f) Approval - The authorizing approval signature and the date signed (The Director, OCRWM for initial-issued QAAPs and major QAAP revisions or the Director, OQA for minor revisions)
- g) Concurrence - The authorizing concurrence signature and the date signed by the Director, OQA.

5.2.3 Each QAAP shall contain a flow chart depicting the process described in Section 6.0. It is not necessary that the flow chart depict each individual step in the process described in Section 6.0. The flow chart should depict the materials or documents that are used in the process and the products developed as a result of implementing the process.

5.2.4 Attachments shall be contained within the border confines of Attachment II and shall be identified as *Sample*, *Example*, or *Typical*.

5.2.5 The QAAP preparer shall use the following conventions within the QAAP:

- a) *Shall* expresses a mandatory requirement directed towards an action/activity in the QAAP.
- b) *Should* denotes expectation relative to desired results.
- c) *May* denotes permission.



### 5.3 QAAP REVISIONS

- 5.3.1 QAAP revisions shall be uniquely identified.
- 5.3.2 When an existing QAAP is revised, the entire QAAP shall be reissued.
- 5.3.3 Revisions to QAAPs shall be classified as *Major* or *Minor* in accordance with the definitions provided in Paragraphs 3.2.2 and 3.2.4.
- 5.3.4 Major revisions shall require a formal review and comment resolution process for specified major changes. Minor revisions do not require a formal review and comment resolution process and shall require only the approval of the Director, OQA prior to issuance.
- 5.3.5 QAAP changes shall be identified in the issued QAAP revision by a change bar (vertical line in the margin adjacent to the lines or sections that were revised).

### 5.4 ISSUANCE

- 5.4.1 For QAAP revisions, the OCRWM QA Training Officer shall identify the recommended training on the Attachment VII, "Revision Record" in accordance with QAAP 2.1, *Indoctrination and Training*.
- 5.4.2 Approved QAAPs and approved revisions to QAAPs shall be included in the OCRWM QAAP Manual.

## 6.0 PROCEDURE

### 6.1 NEW QAAP PREPARATION

- 6.1.1 When a valid need for a QAAP has been identified, the Director, OQA shall prepare or shall assign the QAAP preparation to a specific Associate or Office Director.
- 6.1.2 The Director, OQA or the responsible Associate or Office Director shall prepare the QAAP or assign the development of the QAAP to a preparer.
- 6.1.3 The QAAP preparer shall develop the QAAP in accordance with Subsections 5.1 and 5.2.



## 6.2 NEW QAAP REVIEW

- 6.2.1 A formal draft QAAP prepared by an Associate or Office Director shall be submitted to the Director, OQA.
- 6.2.2 The Director, OQA shall initiate the formal review process by completing the top portion of Attachment III, "Document Review Record" (DRR) including the identification of the review and acceptance criteria in accordance with Paragraph 5.1.6; identification of the reviewing Associate or Office Directors in accordance with Paragraph 5.1.3; and the establishment of a realistic comment-due date. The Director, OQA then shall forward the draft QAAP to the affected Associate or Office Directors.
- 6.2.3 The Director, OQA or the affected Associate or Office Directors shall review the draft QAAP or assign the reviews to their staff.
- 6.2.4 The reviewers shall perform their reviews using the specified review and acceptance criteria referenced on the DRR and shall identify their mandatory comments in accordance with Paragraph 5.1.6.
- 6.2.5 Each affected Associate or Office Director shall provide to the Director, OQA a consolidated set of comments on a single set of DRRs for subsequent resolution.
- 6.2.6 The Director, OQA shall review the DRR to determine the extent of the comments. If no comments exist, the Director, OQA shall complete the steps identified in Subsection 6.7. If comments exist, the Director, OQA shall initiate the steps identified in Subsection 6.3.

## 6.3 NEW QAAP COMMENT RESOLUTION

- 6.3.1 The Director, OQA shall forward the DRRs to the QAAP preparer for comment resolution.
- 6.3.2 Prior to resolving comments, the QAAP preparer shall evaluate each identified mandatory comment specified by the reviewer on the DRR. Where the comment does not meet the mandatory comment criterion of Paragraph 3.2.3, the QAAP preparer may, with concurrence of the Director, OQA, change the designation and document the justification for the change in the RESPONSE block. The change shall be concurred with by the reviewer. If there is disagreement between the preparer and reviewer, it shall be elevated to appropriate management.



- 6.3.3 Once an acceptable response to a mandatory comment is reached in accordance with Paragraphs 5.1.6 through 5.1.8, the QAAP preparer shall indicate acceptable resolution by signing and dating the space provided on the DRR.
- 6.3.4 Following completion of the mandatory comment resolution process, the QAAP preparer shall revise the document as necessary and shall forward the completed draft QAAP along with the completed DRR package to the Director, OQA.
- 6.3.5 The Director, OQA shall process the draft QAAP in accordance with Subsection 6.7.

#### 6.4 QAAP REVISION PREPARATION

- 6.4.1 The Director, OQA or the Associate or Office Director who is responsible for the maintenance of the QAAP shall evaluate the need for a QAAP revision.
- 6.4.2 If a QAAP requires revision, the Responsible Associate or Office Director shall assign the revision of the QAAP to a preparer.
- 6.4.3 The QAAP preparer shall complete the draft QAAP revision in accordance with Subsections 5.1 and 5.2 and identify all changes. For drafts issued for comment, changes shall be identified by annotation, such as redline strikeout. For draft issued for approval signature, changes shall be identified by vertical side bar marking. A Revision Record (Attachment VII) shall be prepared describing proposed major changes and identifying the reason for the changes. For revisions that contain only minor changes, this fact shall be stated on the Revision Record.
- 6.4.4 The QAAP preparer shall sign the Revision Record and transmit the draft QAAP revision and the Revision Record to the Responsible Associate or Office Director.
- 6.4.5 The Responsible Associate or Office Director shall evaluate if the proposed revision is *Major* or *Minor* in accordance with the definitions provided in Paragraphs 3.2.2 and 3.2.4, document the decision and justification on the Revision Record, and sign in the block provided.
- 6.4.6 The Responsible Associate or Office Director shall forward the draft QAAP revision and the Revision Record to the Director, OQA.



**6.5 MINOR REVISION REVIEW AND APPROVAL**

6.5.1 If the Revision Record indicates that the QAAP revision is a minor revision, the Director, OQA shall review the draft QAAP and informally resolve any concerns with the QAAP preparer before concurring and approving the QAAP revision by signing the appropriate blocks on the title page.

6.5.2 The Responsible Associate or Office Director shall complete the RECOMMENDED TRAINING block of the Revision Record in accordance with Paragraphs 5.4.1.

6.5.3 The minor revision is then processed and distributed in accordance with Subsection 6.8.

**6.6 MAJOR REVISION REVIEW AND APPROVAL**

6.6.1 If the Revision Record indicates that the draft QAAP change constitutes a major revision, the Director, OQA shall initiate the formal review and comment resolution process in accordance with Subsections 6.2 and 6.3

**6.7 APPROVAL OF INITIAL-ISSUE AND MAJOR REVISIONS**

6.7.1 Mandatory comments for initial-issue or major revisions shall be resolved prior to submitting to the Director, OQA. The Director, OQA shall obtain the concurrence of the Associate Directors affected by or with defined responsibility within the document and shall sign the Concurrence block on the QAAP title page and forward the QAAP (by memorandum) to the Director, OCRWM soliciting the Director's approval signature on the QAAP title page.

6.7.2 If the Director, OCRWM has comments, the Director, OQA shall resolve the comments as necessary and shall resubmit the QAAP to the Director, OCRWM for an approval signature.

6.7.3 Upon obtaining QAAP approval, the Director, OQA shall require the OCRWM QA Training Officer to complete the RECOMMENDED TRAINING block of the Revision Record in accordance with Paragraph 5.4.1 and shall distribute the QAAP in accordance with Subsection 6.8.

**6.8 CONTROL AND DISTRIBUTION**

6.8.1 The Director, OQA shall process approved QAAPs and approved QAAP revisions in accordance with QAAP 6.1, *Document Control*.



## 7.0 RECORDS

7.1 Documentation generated as a result of this QAAP shall be collected and maintained in accordance with requirements specified in QAAP 17.1, *QA Records Management*. At a minimum, each approved QAAP revision with the corresponding Attachments III, IV, and VII shall be considered QA Records.

## 8.0 ATTACHMENTS

- 8.1 Attachment I - Procedure Title Page
- 8.2 Attachment II - Procedure Continuation Page
- 8.3 Attachment III - Document Review Record
- 8.4 Attachment IV - Document Review Record Continuation Sheet
- 8.5 Attachment V - QAAP Standard Arrangement Format
- 8.6 Attachment VI - Standard Block Paragraph Format
- 8.7 Attachment VII - Revision Record
- 8.8 Attachment VIII - QAAP 5.1 Flow chart



**ATTACHMENT I (Example)**



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

Title:

Procedure No.:

Revision:

Date:

Page

of

Concurrence

Date:

Approval

Date:



OCRWM QA  
ADMINISTRATIVE  
PROCEDURE

Procedure No.:  
**QAAP 5.1**

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**ATTACHMENT II (Example)**



OCRWM QA  
ADMINISTRATIVE  
PROCEDURE

Procedure No.:

Revision:

Page:  
of

U.S. DEPARTMENT OF ENERGY  
WASHINGTON, D.C.

REV. 6/90

U.S. DEPARTMENT OF ENERGY  
WASHINGTON, D.C.

REV. 6/90



**ATTACHMENT III (Example)**

<p><b>OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT U.S. DEPARTMENT OF ENERGY WASHINGTON, D.C.</b></p>		<p>SHEET <u>1</u> OF _____ WBS NO. _____</p>	
<p><b>DOCUMENT REVIEW RECORD</b></p>			
<p>DOCUMENT NAME REVISION DATE</p>			
<p>REVIEW INSTRUCTIONS/ACCEPTANCE CRITERIA</p>			
<p>REVIEW INSTRUCTIONS/CRITERIA PREPARED BY</p> <p>_____ Signature _____ Date</p>		<p>REVIEW INSTRUCTIONS/CRITERIA APPROVED BY</p> <p>_____ Signature _____ Date</p>	
<p>FORWARD RESULTS TO</p>			
<p><b>COMMENTS THAT ARE ANNOTATED WITH AN (*) ARE MANDATORY AND REQUIRE RESPONSE AND RESOLUTION.</b></p>			
<p>SECT./ PARA.</p>	<p>COMMENT</p>	<p>RESPONSE</p>	<p>ACCEPT/ REJECT</p>
<p>REVIEWED BY</p> <p>_____ Signature _____ Date</p>		<p>RESPONSE BY</p> <p>_____ Signature _____ Date</p>	

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**ATTACHMENT IV (Example)**

<b>OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT U.S. DEPARTMENT OF ENERGY WASHINGTON, D.C.</b>			SHEET ____ OF ____ #BS NO. _____
<b>DOCUMENT REVIEW RECORD (continuation sheet)</b>			
DOCUMENT NAME REVISION DATE			
<b>COMMENTS THAT ARE ANNOTATED WITH AN (*) ARE MANDATORY AND REQUIRE RESPONSE AND RESOLUTION.</b>			
SECT/ PARA.	COMMENT	RESPONSE	ACCEPT/ REJECT
REVIEWED BY  _____ Signature		RESPONSE BY  _____ Signature	
Date		Date	

REV. 1/89



**ATTACHMENT V (Example)**  
**QAAP STANDARD ARRANGEMENT FORMAT**

**1.0 PURPOSE**

This section should be a description of the objective of the procedure.

**2.0 SCOPE**

Identify the specific application of the procedure and to which OCRWM activities it will apply. Include any restrictions on the procedure application.

**3.0 REFERENCES AND DEFINITIONS**

**3.1 REFERENCES**

List those documents used in the preparation that will interface with the procedure being written.

**3.2 DEFINITIONS**

Reference the Glossary for general terms. Define here the terms that are unique to the procedure being written.

**4.0 RESPONSIBILITIES**

Identify the individuals or organizations who have the major responsibility for the implementation of the procedure. Restrict this to OCRWM personnel who have direct involvement in the subject activity.

**5.0 GENERAL**

Delineate requirements and provide leading information which brings the reader up to the step-by-step details of the procedure section.

**6.0 PROCEDURE**

Provide the detailed methodology to implement the requirements of the QA Program and include reference in the text to any attachments.

**7.0 RECORDS**

**7.1** State the following: "Documentation generated as a result of this QAAP is collected and maintained in accordance with the requirements specified in QAAP 17.1, *Records Management*. At a minimum, attachments (list the attachments by number, for example, I, II) are considered QA Records.

**8.0 ATTACHMENTS**

List exhibits, illustrations, forms, appendices, etc. described in the procedure text.



**ATTACHMENT VI (Example)**  
**STANDARD BLOCK PARAGRAPH FORMAT**

**1.0 FIRST LEVEL INDENTURE**

(The first level indenture shall be titled in upper case letters and underscored.)

**1.1 SECOND LEVEL INDENTURES**

(The second level indentures shall be titled, as appropriate, in upper case letters and underscored.)

1.1.1 (Third level indentures shall be written in sentence or paragraph format in lower case letters and shall not bear titles.)

- a) Itemization or delineation beneath any indented paragraphs shall be typed in lower case letters and identified by a letter a), b), etc.
- b) Paragraph titles, when used, shall always be on a separate line.
- c) There shall always be a double space between indentures: except for fourth level indentures, for example, a), b), shall be single spaced between indentures when the text does not exceed one line.



**ATTACHMENT VII (Example)**

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

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

**REVISION RECORD**

TITLE:	PROCEDURE NO.	REV. NO. (current)
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DESCRIPTION OF PROPOSED REVISION AND RATIONALE:

PREPARER OF PROPOSED REVISION \_\_\_\_\_ DATE \_\_\_\_\_

TYPE OF REVISION (Check One): MAJOR \_\_\_\_ MINOR \_\_\_\_

SIGNATURE TO AUTHORIZE REVISION \_\_\_\_\_ DATE \_\_\_\_\_  
Responsible Associate or Office Director

TYPE OF REVISION (Check One): MAJOR \_\_\_\_ MINOR \_\_\_\_

CONCURRENCE SIGNATURE \_\_\_\_\_ DATE \_\_\_\_\_  
Director, OQA

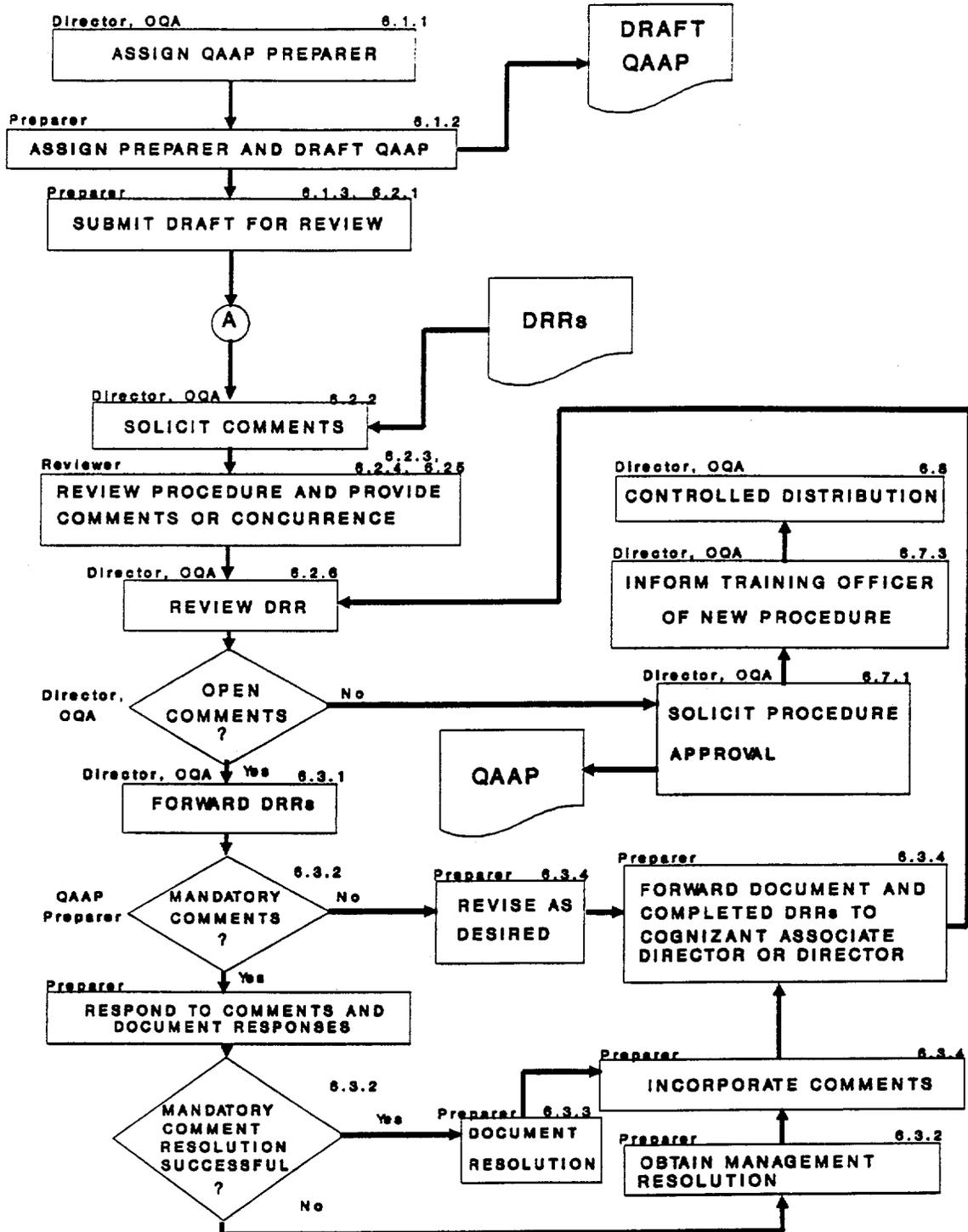
RECOMMENDED TRAINING: READ \_\_\_\_ CLASSROOM \_\_\_\_ OTHER \_\_\_\_

\_\_\_\_\_  
RESPONSIBLE ASSOCIATE OR OFFICE DIRECTOR OR QA TRAINING OFFICER DATE \_\_\_\_\_

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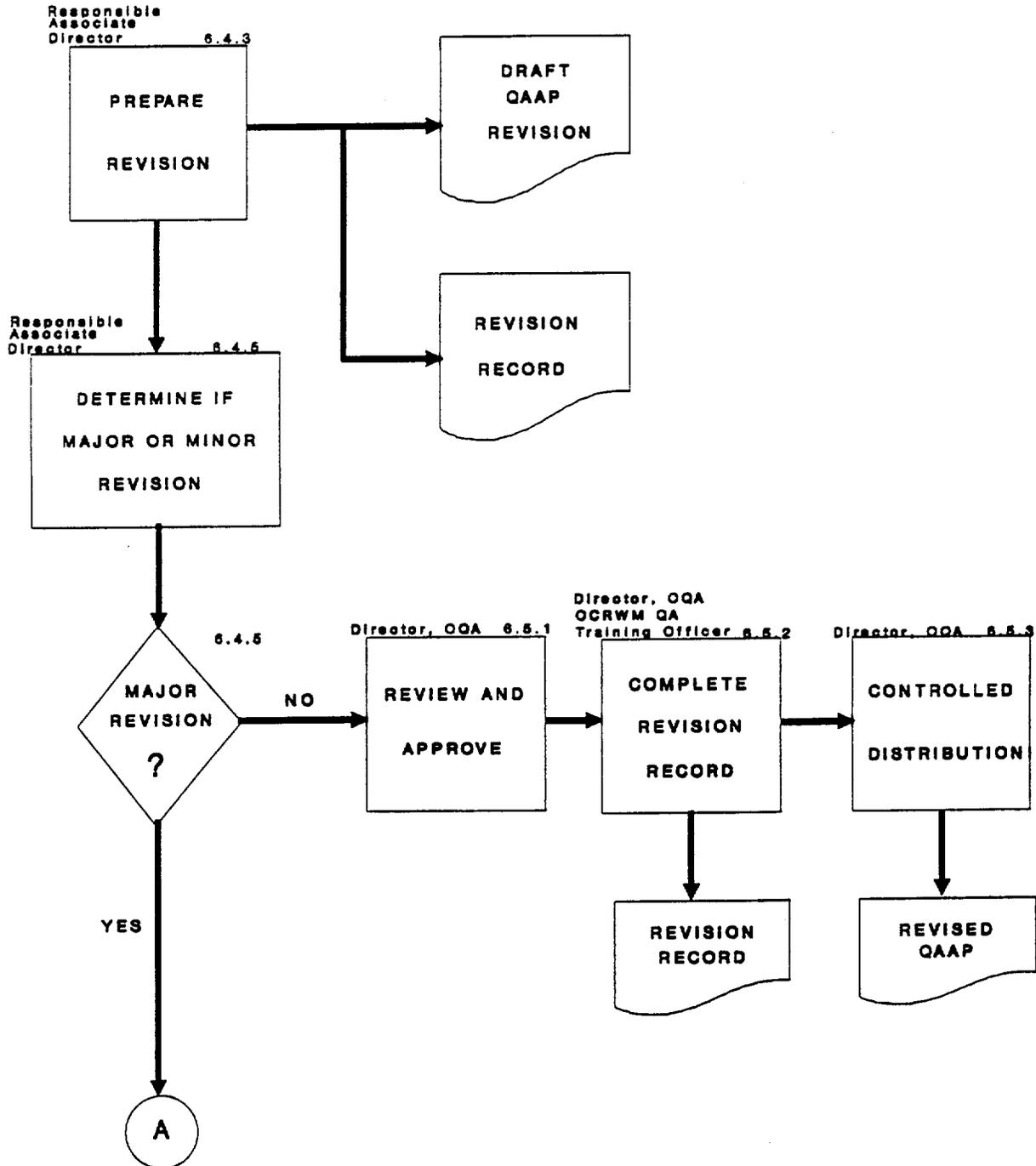


ATTACHMENT VIII (Example)





ATTACHMENT VIII Continued (Example)



(Continue processing Revision per page 1 of Attachment VIII)