OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
QUALITY ASSURANCE ADMINISTRATIVE PROCEDURE

rec'd with ltr dtd 9/1/91

Title: QUALITY ASSURANCE PROGRAM DOCUMENT REVIEW			
Procedure No.: QAAP 2.5	Revision: 1	Date: 10/01/90	Page 1 of 12
Concurrence: R B Lahoti Date: 8-21-90		Approval: John W. Bartlett Date: 8/27/90	

1.0 PURPOSE

The purpose of this procedure is to establish the responsibilities and methods for the acceptance, approval, or concurrence of QA program documents for the Civilian Radioactive Waste Management Program.

2.0 SCOPE

This procedure applies to the approval or concurrence of internal QA program documents and subsequent revisions and for the acceptance of QA program documents and subsequent revisions submitted to OCRWM by OCRWM-managed PROGRAM participants in accordance with procurement documents. OCRWM Quality Assurance Administrative Procedures (QAAPs) are governed by QAAP 5.1, *Preparation of Quality Assurance Administrative Procedures*, and Implementing Line Procedures (ILPs) are governed by *QAAP 5.2, Preparation of Implementing Line Procedures.*

3.0 REFERENCES AND DEFINITIONS

3.1 REFERENCES

3.1.1 Quality Assurance Requirements for the Civilian Radioactive Waste Management Program, (QARD) DOE/RW-0214.

3.1.2 Quality Assurance Program Description for the Civilian Radioactive Waste Management Program, (QAPD) DOE/RW-0215.

3.2 DEFINITIONS

Definitions of standard terms may be found in the Glossary contained in reference 3.1.1.

3.2.1 Acceptance - Act of determining that an external document may be used for the purpose intended.

3.2.2 Approval - The documented act of a designated representative of the organization responsible for the development of a document indicating acceptance of the document and mandating its implementation as required.

3.2.3 Concurrence - This term is used to indicate agreement that an internal document is suitable for use and that review of the document has been satisfactorily completed.

3.2.4 Mandatory Comment - Comment requiring resolution that identifies and describes a conflict with, or deviation from, an existing OCRWM (a) policy, (b) quality assurance program requirement, (c) technical position, (d) licensing commitment or (e) provides a substantive change in the process.

3.2.5 Major Change - A modification to a QA program document that constitutes a change from a previously established OCRWM; (a) policy, (b) quality assurance program requirement, (c) technical requirement, or (d) licensing commitment or that (e) provides a substantive change in the level of control previously established in the document.

3.2.6 Minor Change - A change to a QA program document that is not considered to be a Major Change as defined in Subsection 3.2.5.

3.2.7 Quality Assurance Program Review - An examination of a document to determine compliance with quality assurance program requirements and to evaluate the ability of the program or process to achieve quality.

3.2.8 Quality Assurance Program Documents - QA program description documents, such as QA plans and manuals, and detailed technical and quality assurance administrative procedures (ref. QARD Section 2). Also, refers to documents such as the QA Controls Document developed in accordance with QAAP 2.3, *Establishing Quality Assurance Controls*.

3.2.9 *Responsible Associate Director* - As used in this procedure, the Associate Director and Office Director who has responsibility for initiating, revising, maintaining, or reviewing QA Program documents and who have the OCRWM line responsibility for the work of another **PROGRAM** participant required to submit QA program documents for OCRWM acceptance.

3.2.10 *Responsible Accepting-Authority Representative (RAAR)* - The individual designated authority to approve or accept a **PROGRAM** participant's QA Program documents. For Contractors, the RAAR shall be the Contracting Officer's Technical Representative. For other participants, such as those whose work is directed through Project or Field Offices with the use of program guidance letters, the RAAR shall be designated by the *Responsible Associate Director* for the particular **PROGRAM** participant.

4.0 RESPONSIBILITIES

4.1 DIRECTOR, OCRWM

The Director, OCRWM has overall responsibility for:

4.1.1 Approving internal QA program documents and subsequent revisions.

4.2 *RESPONSIBLE ASSOCIATE DIRECTORS, OCRWM*

The *Responsible Associate Directors*, OCRWM are responsible for:

4.2.1 Concurring with internal QA program documents and subsequent revisions and for OCRWM-managed, **PROGRAM**-participant QA program documents within their area of responsibility.

4.2.2 Accepting those external QA program documents and subsequent revisions within their area of responsibility that are specified in procurement documents requiring OCRWM review and acceptance prior to implementation by **PROGRAM** participants.

4.3 DIRECTOR, OFFICE OF QUALITY ASSURANCE (OQA)

The Director, OQA is responsible for:

4.3.1 Preparing and maintaining this QAAP;

4.3.2 Reviewing and commenting on QA program documents and subsequent revisions to assure that QA program requirements are adequately addressed and can be effectively implemented to achieve quality;

4.3.3 Maintaining and tracking concurrence and approval status of internal QA program documents and subsequent revisions;

4.3.4 Assigning responsibility for coordinating the review of internal QA program documents and subsequent revisions;

4.3.5 Establishing specific review and acceptance criteria (see Subsection 5.1) for the review of internal QA program documents and subsequent revisions;

4.3.6 Reviewing QA program documents and subsequent revisions prepared by OCRWM-managed **PROGRAM** participants;

4.3.7 Accepting external QA program documents and subsequent revisions within the area of responsibility specified in procurement documents for OCRWM review and acceptance prior to implementation by **PROGRAM** participants;

4.3.8 Maintaining a list of participants QA Program Description Documents reviewed and accepted by OCRWM.

4.4 ***RESPONSIBLE ACCEPTING-AUTHORITY REPRESENTATIVE***

The *Responsible Accepting-Authority Representative* (RAAR) is responsible for taking the following actions with respect to QA program documents prepared by OCRWM-managed **PROGRAM** participants:

4.4.1 Reviewing and commenting on QA program documents and subsequent revisions to assure that proper QA program requirements are adequately addressed and can be effectively implemented to achieve quality;

4.4.2 Maintaining and tracking concurrence and approval status of QA program documents and subsequent revisions;

4.4.3 Assigning responsibility for review coordination of QA program documents and subsequent revisions;

4.4.4 Establishing in conjunction with the Director, OQA specific review and acceptance criteria (see Subsection 5.1) using the QA program requirements specified in the applicable procurement documents as the base requirements for the review of QA program documents and subsequent revisions;

4.4.5 Accepting QA program documents and subsequent revisions after successful completion of the comment resolution and document update process and communicating that acceptance to the affected **PROGRAM** participants.

5.0 GENERAL

5.1 Review criteria provided on the Document Review Record (DRR) shall be explicit. Reviewers shall be provided with the details of the work being conducted for which the QA program document was generated. The review and acceptance criteria shall include the requirement for the Director, OQA or *Responsible Associate Directors* to evaluate the document changes relative to the their respective external licensing commitments. For OCRWM-managed **PROGRAM** participants, the procurement documents shall provide the detailed evaluation criteria for use in the review process.

5.2 Major internal QA program document changes (see Subsection 3.2.5) shall be identified by change bars (vertical lines in the margin adjacent to the lines or sections that have been revised).

5.3 The Director, OQA acceptance of external QA program documents is signified by the resolution of the Director, OQA's mandatory comments on the DRR that was submitted by the Director, OQA and the acceptance by OQA of the resolution of the mandatory comments provided by other designated reviewers.

6.0 PROCEDURE

6.1 INTERNAL QA PROGRAM DOCUMENT ISSUE AND REVISION APPROVAL

6.1.1 Upon development of a draft internal QA program document or subsequent revision, the Director, OQA shall coordinate the concurrence and approval process.

6.1.2 The Director, OQA shall initiate the formal review process by completing the top portion of Attachment I and II, DRR including the identification of the review and approval criteria in accordance with Subsection 5.1; identification of the reviewing Offices; and the establishment of a realistic comment-due date. The Director, OQA shall forward a copy of the draft document to each reviewing Office along with the DRR.

6.1.3 The *Responsible Associate Director* shall assign one or more reviewers to perform the review for their Offices.

6.1.4 The assigned reviewers shall perform the review following the specified review and acceptance criteria identified on the DRR.

6.1.5 The reviewers shall document comments or annotate "No Comments" on a DRR.

6.1.6 Reviewers shall evaluate each of their comments to determine if a comment meets one of the mandatory comment criteria provided in Subsection 3.2.4. Reviewers shall identify mandatory comments in the SECTION/PARAGRAPH block with an asterisk (*) and a letter (a through e) corresponding to the applicable criterion. The reviewer shall forward the DRR to the *Responsible Associate Director*.

6.1.7 Upon completion of the review, the *Responsible Associate Director* shall forward the signed DRR to the Director, OQA for further action. If a *Responsible Associate Director* has assigned more than one reviewer, the *Responsible Associate Director* shall ensure that the reviewers' comments are consolidated onto a single set of DRRs and shall resolve any conflicting comments before sending DRRs to the Director, OQA.

6.1.8 The Director, OQA shall collect the DRR and shall forward the DRRs to the preparer for comment resolution.

6.1.9 The preparer shall review and evaluate mandatory comment designations. This review shall determine if the comment was correctly identified as mandatory by the reviewer. For incorrectly identified mandatory comments, the preparer with concurrence of the Director, OQA shall change the designation and document the justification for the change in the RESPONSE block on the DRR. This change shall be concurred with by the reviewer. If there is a disagreement between the preparer and reviewer it shall be elevated to the appropriate management.

6.1.10 The reviewer and the preparer shall resolve each mandatory comment and document the resolution 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.

6.1.11 The preparer shall bring mandatory comments that cannot be resolved to the attention of the preparer's immediate supervisor and, if not resolved internally, shall progressively elevate the disagreement to the Director, OQA and the *Responsible Associate Director* and, if necessary, to the Director, OCRWM.

6.1.12 The preparer shall review non-mandatory comments for possible inclusion into the document although non-mandatory comments shall require neither formal resolution nor documentation.

6.1.13 If no mandatory comments exist or remain unresolved, the preparer shall update the draft document with the accepted changes; submit the document to the Director, OQA who shall obtain concurrence of the *Responsible Associate Directors*; and solicit the approval signature of the Director, OCRWM.

6.2 EXTERNAL QA PROGRAM DOCUMENT ACCEPTANCE

6.2.1 Upon receipt of an OCRWM-managed PROGRAM-participant (external) QA document for acceptance, the *Responsible Accepting-Authority Representative* shall coordinate the review and acceptance process.

6.2.2 The *Responsible Accepting-Authority Representative* shall initiate the formal review process by completing the top portion of Attachments I and II, DRR including the identification of the review and acceptance criteria; identification of the reviewing Offices including Director, OQA; and the establishment of a realistic comment-due date.

6.2.3 The *Responsible Accepting-Authority Representative* shall forward a copy of the QA program document to each reviewing Responsible Associate Director along with the DRR.

6.2.4 The *Responsible Associate Directors* shall assign one or more reviewers to perform the review for their respective Offices.

6.2.5 The assigned reviewers shall perform the review following the specified review and acceptance criteria identified on the DRR.

6.2.6 The reviewers shall document comments on the DRR and annotate "No Comments" on a DRR if they have no comments on the review document.

6.2.7 Reviewers shall evaluate each of their comments provided on the DRR to determine if a comment meets any of the mandatory comment criteria provided in Subsection 3.2.4. 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 e) corresponding to the applicable criterion.

6.2.8 Upon completion of the review, the *Responsible Associate Director* shall forward the signed DRR to the *Responsible Accepting-Authority Representative* (RAAR) for further action. If *Responsible Associate Directors* have assigned more than one reviewer within their offices, the *Responsible Associate Director* shall ensure that the reviewers' comments are consolidated onto a single set of DRRs and shall resolve any conflicting comments before sending DRRs to the RAAR.

6.2.9 The *Responsible Accepting-Authority Representative* (RAAR) shall prepare a transmittal to the OCRWM-managed **PROGRAM** participant detailing the mandatory comments and any non-mandatory comments requiring resolution. The RAAR shall consider non-mandatory comments for possible inclusion into the transmittal although non-mandatory comments shall require neither formal resolution nor documentation.

6.2.10 The *Responsible Accepting-Authority Representative* (RAAR) in conjunction with the responsible reviewer and the Director, OQA shall resolve mandatory comments with the OCRWM-managed **PROGRAM** participant and shall document the resolution in the RESPONSE block of the DRR. The RAAR, reviewer, and the Director, OQA shall initial and date the appropriate DRR block next to the mandatory comment resolution response signifying acceptance.

6.2.11 The *Responsible Accepting-Authority Representative* shall forward mandatory comments that cannot be resolved to the attention of appropriate management and, if not resolved, shall progressively elevate the disagreement to the Director, OQA and the involved *Responsible Associate Director* and, if necessary, to the Director, OCRWM.

6.2.12 Upon receipt of the revised document and verifying that all accepted mandatory responses have been incorporated, the *Responsible Accepting-Authority Representative* shall transmit OCRWM formal acceptance of the document.

7.0 RECORDS

7.1 Documentation prepared 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, a copy of the document reviewed and completed Attachments I and II shall be considered QA Records.

8.0 ATTACHMENTS

8.1 Attachment I - OCRWM Document Review Record.

8.2 Attachment II - OCRWM Document Review Record Continuation Sheet.

8.3 Attachment III - QAAP 2.5 Flowchart (Internal QA Program Review).

8.4 Attachment IV - QAAP 2.5 Flowchart (External QA Program Review).

ATTACHMENT I (EXAMPLE)

OCRWM DOCUMENT REVIEW RECORD

SHEET 1 OF _____
WBS NO. _____

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

DOCUMENT REVIEW RECORD

DOCUMENT NAME
REVISION
DATE

REVIEW INSTRUCTIONS/ACCEPTANCE CRITERIA

REVIEW INSTRUCTIONS/CRITERIA PREPARED BY		REVIEW INSTRUCTIONS/CRITERIA APPROVED BY	
Signature	Date	Signature	Date

FORWARD RESULTS TO

COMMENTS THAT ARE ANNOTATED WITH AN (*) ARE MANDATORY AND REQUIRE RESPONSE AND RESOLUTION.

SECT./ PARA.	COMMENT	RESPONSE	ACCEPT/ REJECT

REVIEWED BY		RESPONSE BY	
Signature	Date	Signature	Date

REV. 1/89

ATTACHMENT II (EXAMPLE)

OCRWM DOCUMENT REVIEW RECORD CONTINUATION SHEET

SHEET ____ OF ____
WBS NO. _____

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

DOCUMENT REVIEW RECORD (continuation sheet)

DOCUMENT NAME
REVISION
DATE

COMMENTS THAT ARE ANNOTATED WITH AN (*) ARE MANDATORY AND REQUIRE RESPONSE AND RESOLUTION.

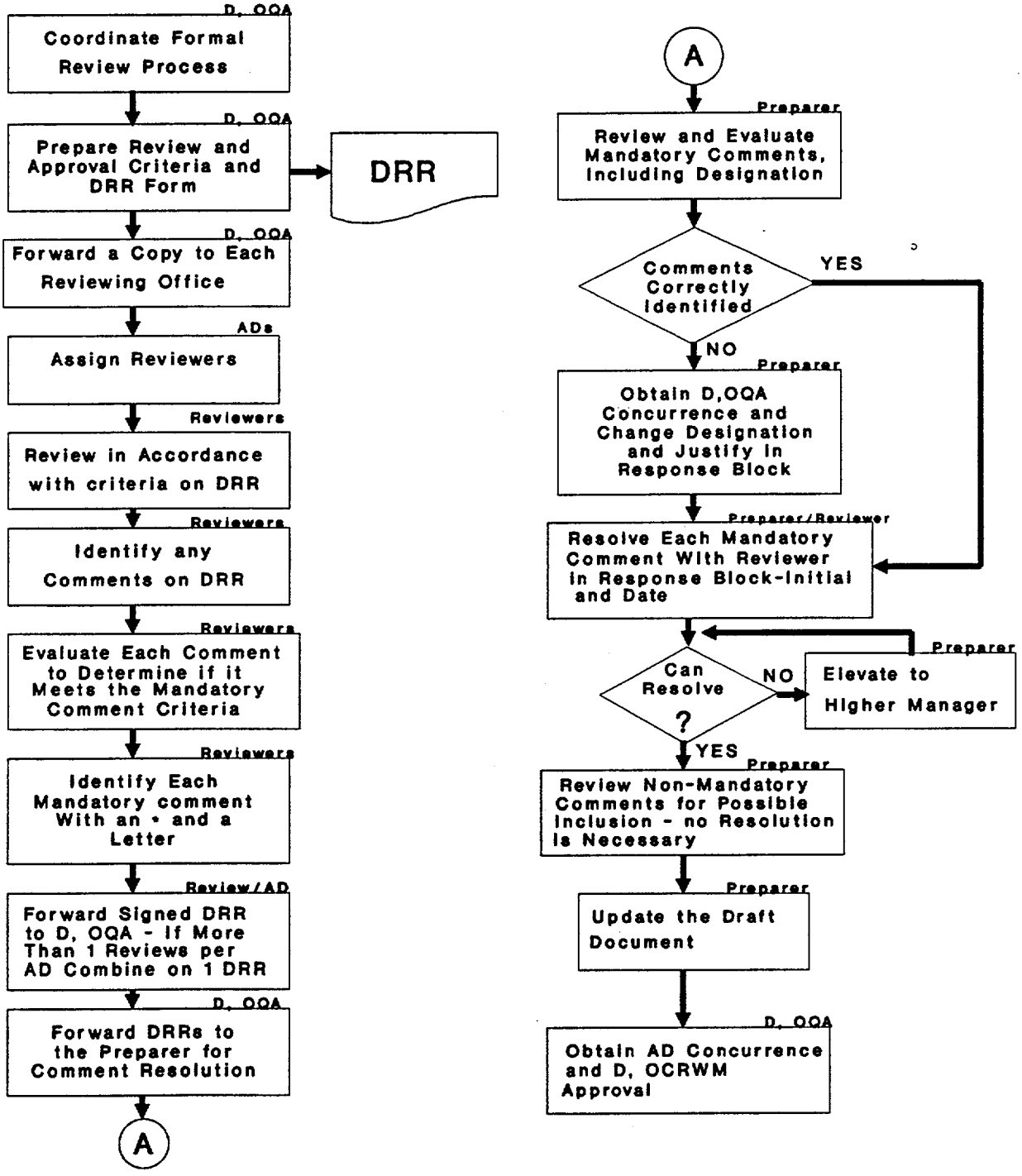
SECT./ PARA.	COMMENT	RESPONSE	ACCEPT/ REJECT

REVIEWED BY		RESPONSE BY	
Signature	Date	Signature	Date

REV. 1/89

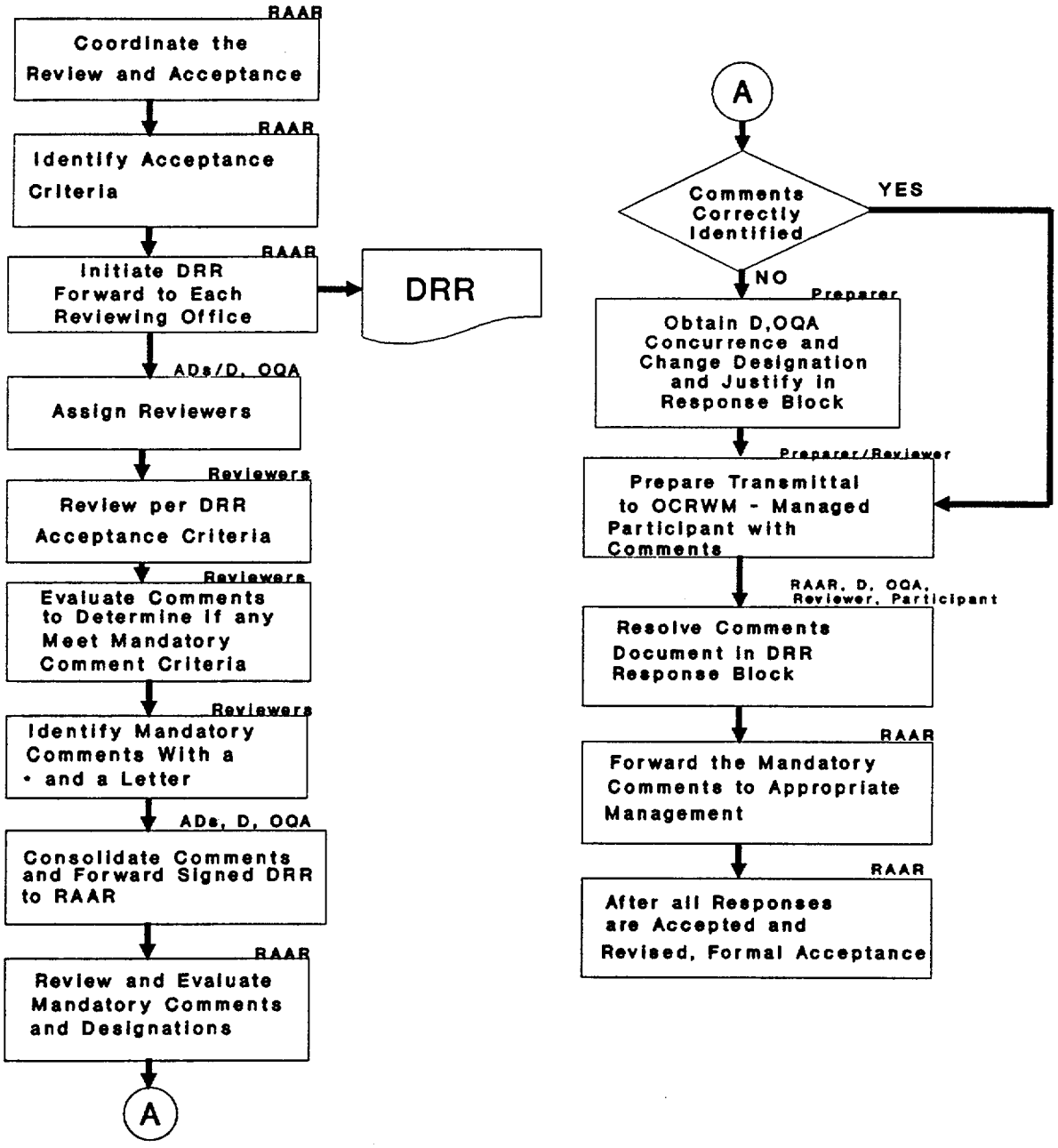
ATTACHMENT III (EXAMPLE)

INTERNAL QA PROGRAM DOCUMENT REVIEW FLOWCHART



ATTACHMENT IV (EXAMPLE)

EXTERNAL QA PROGRAM DOCUMENT REVIEW FLOWCHART



LEGEND

RAAR • Responsible Accepting-Authority Representative