OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT QUALITY ASSURANCE ADMINISTRATIVE PROCEDURE

Title: PREPARATION AND REVISION OF IMPLEMENTING LINE PROCEDURES			
Procedure No.: QAAP 5.2	Revision: 2	Date: 12/28/90	Page 1 of 22
Concurrence R.W. Clark	Date: 12/3/90	Approval R.W. Clark	Date: 12/3/90

1.0 PURPOSE

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

2.0 SCOPE

This procedure applies to the development and revision of OCRWM ILPs developed in accordance with the implementation of QAAP 2.3, *Establishing 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 Document* (QAPD), DOE/RW-0215.

3.1.3 *Program Change Control Procedure* (PCCP), DOE/RW-0223.

3.2 DEFINITIONS

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

3.2.2 Implementing Line Procedure (ILP) - A procedure that provides instructions for OCRWM personnel performing activities subject to quality assurance program controls. ILPs include technical, management, and operating instructions necessary for performing work including implementation of the quality assurance program controls.

3.2.3 Major Revision - A modification to a ILP 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 ILP; or (e) provides a substantive change in the process.

3.2.4 Minor Revision - ILP 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 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.

3.2.6 *Responsible Associate Director* - The Associate Director and or Office Director who is responsible for the initiating, revising, and maintenance of an ILP. For the purpose of simplicity, this term will be used throughout this procedure.

4.0 RESPONSIBILITIES

4.1 RESPONSIBLE ASSOCIATE DIRECTORS, OCRWM

The *Responsible Associate Directors* are responsible for:

4.1.1 Identifying and evaluating the need for development of new ILPs and preparing ILP revisions within their functional areas of responsibility.

4.1.2 Evaluating a proposed ILP revision in their area of responsibility to determine if the revision constitutes a major or minor revision.

4.1.3 Establishing within their functional areas of responsibility specific review and acceptance criteria (see Section 5.1) for ILP preparation and review.

4.1.4 Providing approval of ILPs through the review and signatory process.

4.1.5 Issuing and distributing the PCCP ILP.

4.1.6 Assuring that their staff and direct-support contractor personnel who perform activities covered by an ILP are appropriately indoctrinated and trained.

4.1.7 Assuring implementation of requirements delineated in ILPs in their functional areas of responsibility.

4.1.8 Reviewing assigned ILPs and subsequent revisions and providing comments.

4.2 OCRWM PERSONNEL

OCRWM personnel are responsible for:

4.2.1 Identifying to the *Responsible Associate Director* the need to initiate or revise an ILP.

4.2.2 Developing, reviewing, or resolving comments on ILPs as assigned in accordance with requirements of this QAAP.

4.2.3 Completing assigned indoctrination and training upon the issuance of a new or revised ILP.

4.3 DIRECTOR, OFFICE OF QUALITY ASSURANCE (OQA)

The Director, OQA or designee is responsible for:

4.3.1 Preparing and maintaining this QAAP.

4.3.2 Interpreting quality assurance program requirements for inclusion into the appropriate ILPs.

4.3.3 Reviewing ILPs to assure the existence of adequate qualitative and quantitative instructions for compliance.

4.3.4 Informing the OCRWM QA Training Officer of newly developed or revised ILPs so that appropriate training may be identified and implemented.

4.3.5 Providing signatory concurrence on new ILPs and ILP major revisions.

4.3.6 Issuing and distributing approved ILPs and ILP revisions.

4.3.7 Developing and issuing ILPs for OQA use in accordance with Section 4.1.

4.4 **OCRWM QA Training Officer**

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

5.0 GENERAL

OCRWM personnel may suggest the subject for a new ILP or a revision to an existing ILP by transmitting the request to the *Responsible Associate Director*. The *Responsible Associate Director* shall evaluate the proposed draft for suitability and initiate the appropriate activities as necessary.

5.1 ILP PREPARATION AND REVIEW

5.1.1 With the exceptions of the PCCP, new ILPs and ILP revisions shall be prepared in accordance with this QAAP and shall be maintained and controlled in accordance with QAAP 6.1, *Document Control*. The PCCP ILP shall be prepared and revised in accordance with the direction provided within those ILPs.

5.1.2 Preliminary drafts of new or revised ILPs may be developed and informally reviewed as necessary to adequately define the proposed process prior to drafting the ILP for formal review and comment resolution.

5.1.3 Each formal draft of a new ILP or major ILP revision shall be reviewed by the Director, OQA and each *Responsible Associate Director* affected by or with defined responsibility within the document.

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

5.1.5 Review criteria specified on the DRR shall be explicit. Reviewers shall be provided with sufficient information to evaluate the ILP being reviewed. The review and acceptance criteria shall include the requirement for the Director, OQA, and *Responsible Associate Directors* 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 DRR to determine if the comment meets one of the mandatory comment criteria provided in Paragraph 3.2.5. 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.

5.1.7 Mandatory comments shall be resolved by the reviewer and the ILP preparer. The agreed resolution shall be documented in the RESPONSE block of the DRR. The reviewer shall initial, date, and approve the agreed resolution in 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 the appropriate management and, if not resolved, shall be elevated progressively to the Director, OQA and the *Responsible Associate Director* and, if necessary, to the Director, OCRWM.

5.1.9 Non-mandatory comments shall not require a formal review and comment resolution process although the ILP preparer shall review and consider non-mandatory comments for possible inclusion into the ILP.

5.2 ILP FORMAT AND CONTENT

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

5.2.2 The PCCP ILPs shall comply with the format and content requirements described within those ILPs.

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

a) Title Block - The title or subject of the ILP

b) Procedure No. - The appropriate alphanumeric identification for the ILP as assigned by the *Responsible Associate Director*

c) Revision - The appropriate revision number with zero being the first issue

d) Date - The effective date of the ILP

e) Page - The specific page and total pages ("Page 1 of _____")

f) Approval Block - The authorizing approval signature and the date signed *(by the Responsible Associate Director)*

g) Concurrence Block - The authorizing concurrence signature and the date signed by the Director, OQA.

5.2.4 Each ILP 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 that is described in Section 6.0 of the ILP. 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.

5.2.5 Attachments shall be contained within the border confines of Attachment II and shall be identified as *Example*.

5.2.6 The ILP preparer shall use the following conventions within the ILP:

a) *Shall* expresses a mandatory requirement directed towards an action/activity in the ILP.

b) *Should* denotes expectation relative to desired results.

c) *May* denotes permission.

5.3 ILP NUMBERING SYSTEM

5.3.1 Unique number designation shall be assigned by the *Responsible Associate Director*.

5.3.2 The unique number designation assigned to an ILP shall be alphanumeric with digits separated by periods (.) in the following format:

ILP 10.3.1

ILP Implementing Line Procedure

"10" these two digits reflect the originating OCRWM Office; RW-10 in this example

".3" Section of QAPD reference that the ILP relates to; Section 3, *Design Control* in this example

".1" the first ILP prepared by RW-10 relative to Section 3 of QAPD

5.4 ILP REVISIONS

5.4.1 ILP revisions shall be uniquely identified. The initial issuance of a ILP shall be identified as Revision 0 and subsequent revisions shall be sequentially numbered.

5.4.2 When an existing ILP is revised, the entire ILP shall be reissued.

5.4.3 Revisions to ILPs shall be classified as *Major* or *Minor* in accordance with the definitions provided in Paragraph 3.2.3 and 3.2.4.

5.4.4 Major revisions shall require a formal review and comment resolution process for mandatory comments (see Paragraph 5.1.7). Minor revisions do not require a formal review and comment resolution process and shall require only the concurrence of the Director, OQA and the approval of the *Responsible Associate Director* prior to issuance.

5.4.5 ILP changes shall be identified by a change bar (vertical line in the margin adjacent to the lines or sections that were revised).

5.5 ISSUANCE

5.5.1 For new and major ILP revisions, the OCRWM QA Training Officer shall identify the recommended training on the Revision Record in accordance with QAAP 2.1, *Indoctrination and Training*.

5.5.2 Approved new ILPs and revisions, except the PCCP ILPs, shall be included in the OCRWM ILP Manual.

5.5.3 The PCCP ILPs shall be identified by reference in the OCRWM ILP Manual table of contents. The PCCP ILPs are issued and controlled as separate documents in accordance with the direction provided in those ILPs.

6.0 PROCEDURE

6.1 NEW ILP PREPARATION

6.1.1 When a valid need for a new ILP has been identified, the *Responsible Associate Director* shall initiate the development of the ILP.

6.1.2 The *Responsible Associate Director* shall prepare a formal draft ILP or assign the development of the formal draft to a preparer.

6.1.3 The preparer shall develop the formal draft ILP in accordance with Sections 5.1, 5.2, and 5.3.

6.2 NEW ILP REVIEW

6.2.1 Upon completion of the formal draft ILP, the preparer shall submit the formal draft to the *Responsible Associate Director*.

6.2.2 The *Responsible Associate Director* shall initiate the formal review process for the new draft ILP by completing the top portion of Attachment III, DRR including the identification of the review and acceptance criteria in accordance with Paragraph 5.1.5; identification of the reviewing *Responsible Associate Directors* in accordance with Paragraph 5.1.3; and the establishment of a realistic comment due date and then shall forward the new draft ILP to the identified reviewing Responsible Associate Directors.

6.2.3 The Director, OQA and *Responsible Associate Directors* assigned review responsibility shall review the new draft ILP or delegate the review to their staff.

6.2.4 The reviewers shall perform their review 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 The Director, OQA and the *Responsible Associate Directors* reviewing the ILP shall provide to the *Responsible Associate Director* a consolidated set of comments on a single set of DRRs for subsequent resolution.

6.2.6 The *Responsible Associate Director* shall review the DRR to determine the extent of the comments. If no comments exist, the *Responsible Associate Director* shall complete the steps identified in Section 6.8. If comments exist, the *Responsible Associate Director* shall initiate the steps identified in Section 6.3.

6.3 NEW ILP COMMENT RESOLUTION

6.3.1 The *Responsible Associate Director* shall forward the DRRs to the ILP preparer for comment resolution.

6.3.2 Prior to resolving comments, the ILP preparer shall evaluate each identified mandatory comment specified by the reviewer on the DRR to assure that the comment qualifies as a mandatory comment in accordance with the specified criterion of Paragraph 3.2.5. For incorrectly identified mandatory comments the preparer, with concurrence of the *Responsible Associate Director*, shall change the designation and document the justification for the change in the RESPONSE block of the DRR. This 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 the requirements of Paragraph 5.1.6 through 5.1.8, the reviewer and the ILP preparer shall indicate acceptable resolution by signing and dating the space provided on the DRR.

6.3.4 Following completion of the resolution of mandatory comments, the ILP preparer shall revise the document to address comment resolutions and shall forward the revised draft ILP along with the completed DRR package to the *Responsible Associate Director*.

6.3.5 The *Responsible Associate Director* shall process the ILP in accordance with Subsection 6.8.

6.4 ILP REVISION PREPARATION

6.4.1 The *Responsible Associate Director* shall evaluate the need for an ILP revision.

6.4.2 If an ILP requires revision, the *Responsible Associate Director* shall assign the revision of the ILP to a preparer.

6.4.3 The ILP preparer shall complete the draft ILP revision in accordance with paragraphs 5.4 and 5.5. For draft revisions issued for comment, changes shall be identified by annotations, such as redline strikeout. For final draft issued for signature of approval, changes shall be identified by vertical side bar marking. A Revision Record (Attachment VII) shall be initiated describing proposed major ILP changes and identifying the reason for the changes. For revisions that contain only minor changes, that fact shall be stated on the Revision Record.

6.4.4 The ILP preparer shall evaluate if the proposed revision is *major* or *minor* in accordance with the definitions provided in Paragraphs 3.2.3 and 3.2.4, document the decision and justification on the Revision Record, and sign the Revision Record.

6.4.5 The ILP preparer shall forward the formal draft ILP and the Revision Record to the *Responsible Associate Director*.

6.4.6 The *Responsible Associate Director* shall review the Revision Record and concur with the major or minor revision evaluation by signing the Revision Record or shall initiate changes to the Revision Record prior to signing the Revision Record.

6.5 MINOR REVISION REVIEW AND APPROVAL

6.5.1 The *Responsible Associate Director* shall review the draft ILP and informally resolve any minor revisions with the ILP preparer before approving the ILP minor revision. The *Responsible Associate Director* shall approve the minor revision by signing the APPROVAL block on the title page and forwarding the draft ILP to the Director, OQA for concurrence.

6.5.2 The Director, OQA shall review and concur with the ILP by signing the CONCURRENCE block on the title page.

6.5.3 The *Responsible Associate Director* shall complete the RECOMMENDED TRAINING block of the Revision Record in accordance with Paragraph 5.5.1.

6.5.4 The minor revision is then processed and distributed in accordance with Paragraph 6.8.4.

6.6 MAJOR REVISION REVIEW

6.6.1 If the Revision Record indicates that the draft ILP change constitutes a major revision, the *Responsible Associate Director* shall initiate the formal review process in accordance with Paragraphs 6.2.2 through 6.3.4.

6.7 UNRESOLVED COMMENTS

6.7.1 Mandatory comments for initial-issue or major ILP revisions that cannot be resolved by the preparer and the reviewer shall be resolved by the *Responsible Associate Director* in accordance with Paragraph 5.1.8.

6.8 APPROVAL AND DISTRIBUTION

6.8.1 The *Responsible Associate Director* shall sign the APPROVAL block on the ILP title page and forward the ILP to the Director, OQA soliciting the Director, OQA's concurrence signature on the ILP title page.

6.8.2 If the Director, OQA has comments, the *Responsible Associate Director* shall resolve the comments as necessary and shall resubmit the ILP to the Director, OQA for a signature in the CONCURRENCE block.

6.8.3 Upon obtaining ILP concurrence, the *Responsible Associate Director* shall complete the RECOMMENDED TRAINING block of the Revision Record in accordance with Paragraph 5.5.1 and shall forward the ILP to the Director, OQA.

6.8.4 The Director, OQA shall process ILP revisions in accordance with QAAP 6.1, *Document Control* except for the PCCP ILPs that are controlled and distributed in accordance with the directions provided within those ILPs.

7.0 RECORDS

7.1 As a minimum, each approved ILP revision and the corresponding Attachments III, IV and VII shall be processed as QA records in accordance with the requirements of QAAP 17.1, *QA RECORDS MANAGEMENT*.

8.0 ATTACHMENTS

8.1 Attachment I - Procedure Title Page

8.2 Attachment II - Procedure Continuation Page

8.3 Attachment III - Document Review Record (DRR)

8.4 Attachment IV - Document Review Record (DRR) Continuation Sheet

8.5 Attachment V - ILP Standard Arrangement Format

8.6 Attachment VI - Standard Block Paragraph Format

8.7 Attachment VII - Revision Record

8.8 Attachment VIII - QAAP 5.2 Flowchart

ATTACHMENT I (Example)

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT IMPLEMENTING LINE PROCEDURE

TITLE:			
Procedure No.:	Revision:	Date:	Page: of
Associate Director, OCRWM Date:		Director, OQA Date:	

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

ATTACHMENT II (Example)

OCRWM QA IMPLEMENTING LINE PROCEDURE	Procedure No.:	Revision:	Page: of

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

REV. 6/90

ATTACHMENT III (Example)

SHEET ___ 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 IV (Example)

SHEET ___ OF ___
ABS 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 _____ Signature _____ Date

RESPONSE BY _____ Signature _____ Date

REV 1/89

ATTACHMENT V (Example)

ILP 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 procedure is collected and maintained in accordance with the requirements specified in QAAP 17.1, *QA Records Management*. At a minimum, the documents generated using attachments (list the attachments by number, i.e., I, II) are considered QA Records.

8.0 ATTACHMENTS

List all 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 **SECTION 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 indentured 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, e.g., 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)

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 ____

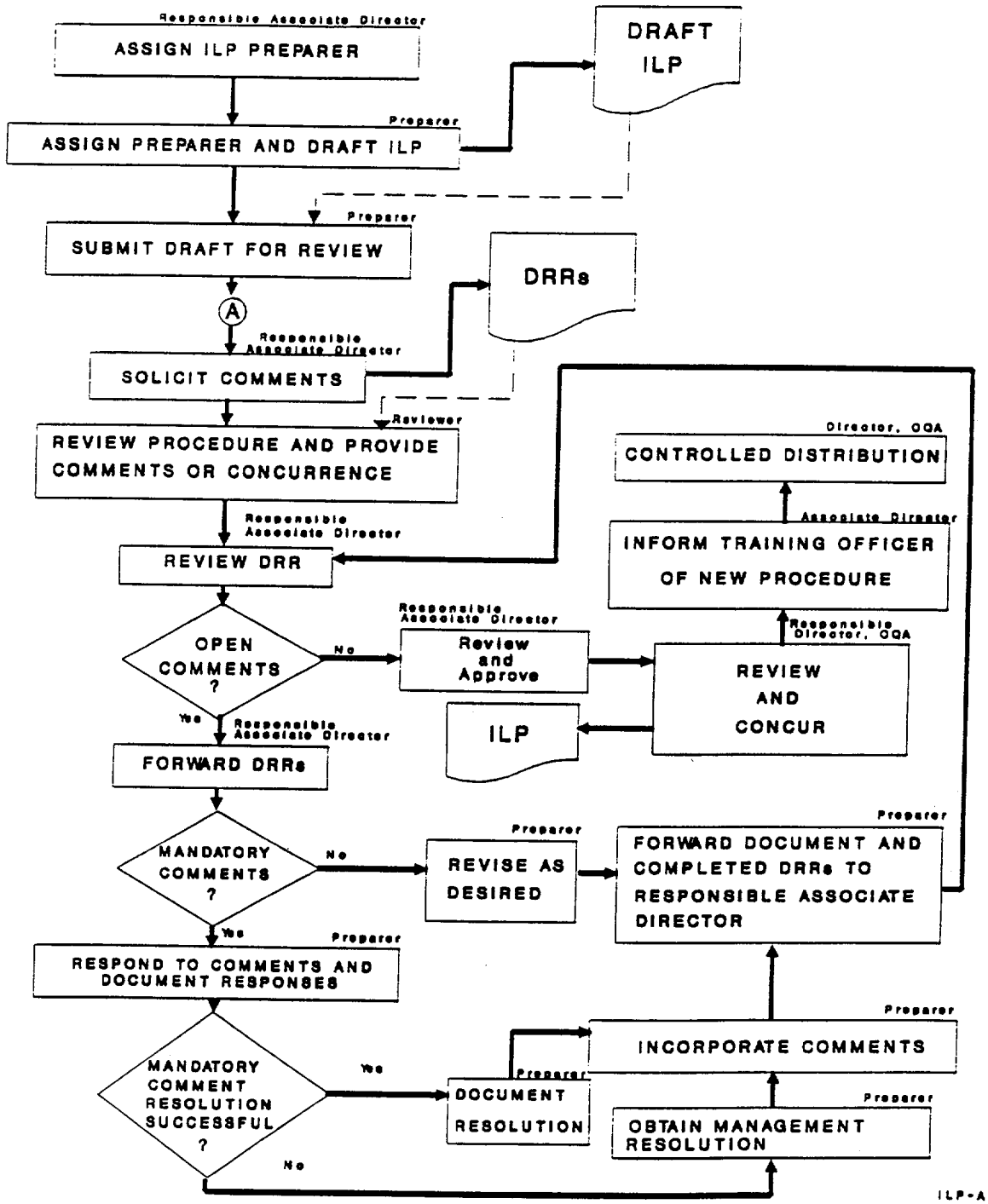
CONCURRENCE SIGNATURE _____ DATE _____
Director, OQA

RECOMMENDED TRAINING: READ ____ CLASSROOM ____ OTHER ____

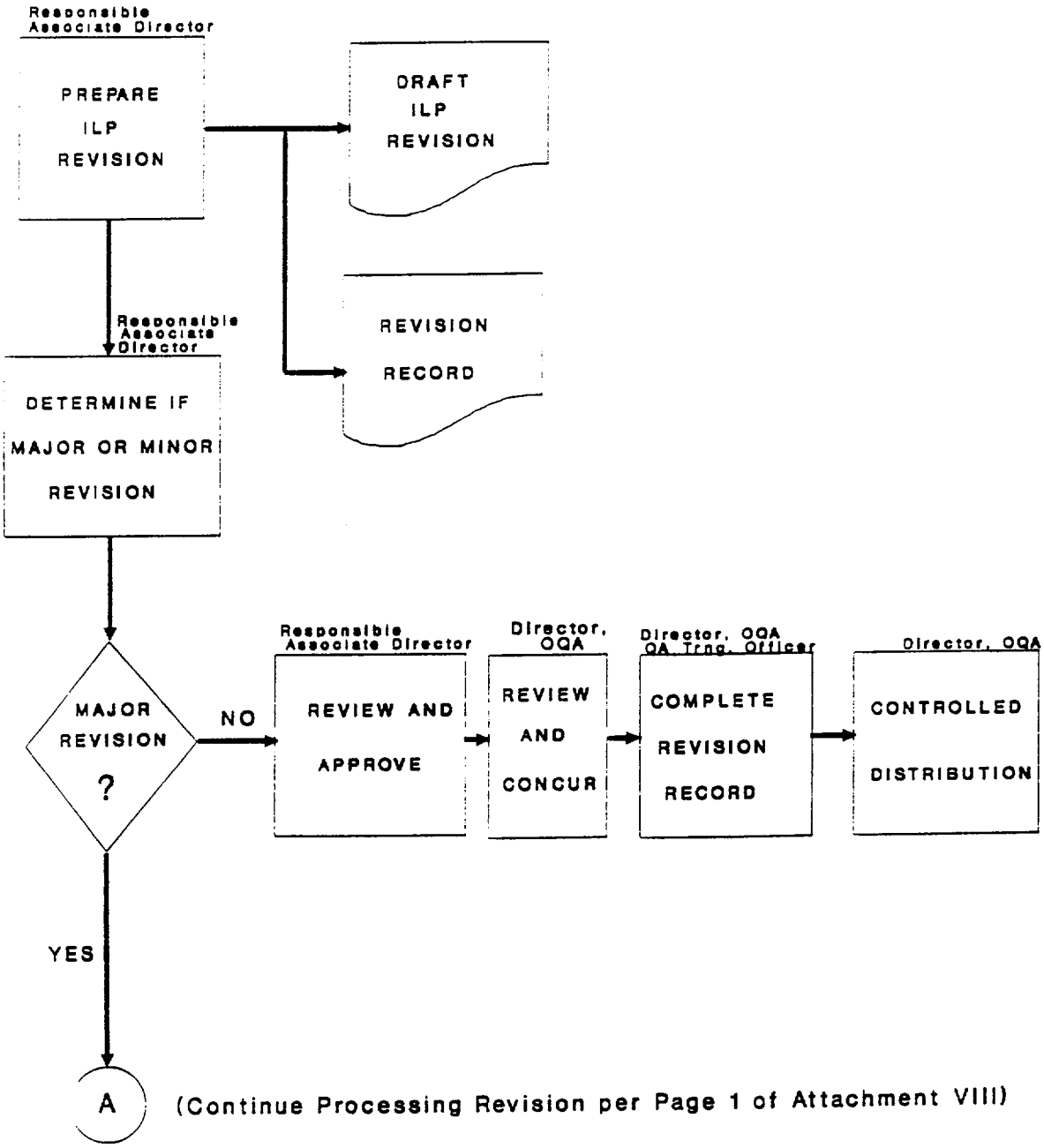
_____ DATE _____
RESPONSIBLE ASSOCIATE OR OFFICE DIRECTOR OR QA TRAINING OFFICER

REV. 8/90

ATTACHMENT VIII (Example)



ATTACHMENT VIII Continued (Example)



ILP-B