

UNCONTROLLED COPY



OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT QUALITY ASSURANCE ADMINISTRATIVE PROCEDURE

Title: **DOCUMENT CONTROL**

Procedure No.:
QAAP 6.1

Revision: **2**

Date: **04/12/91**

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Concurrence

R.W. O'Leary

Date: **3/13/91**

Approval

R.W. O'Leary

Date: **3/13/91**

1.0 PURPOSE

The purpose of this procedure is to establish the responsibilities and methods for the distribution and control of OCRWM documents that specify quality requirements or prescribe quality affecting activities, and for ensuring that only current and approved documents are available and in use during the performance of quality affecting activities.

2.0 SCOPE

- 2.1 This procedure shall be implemented for the control and distribution of Office of Civilian Radioactive Waste Management (OCRWM) Quality Assurance Program documents as specified in the *OCRWM QA Controls Document* for OCRWM quality related work. Quality Assurance Program documents specifically included are the *Quality Assurance Requirements (QARD)*, the *Quality Assurance Program Description (QAPD)*, the *Quality Assurance Controls Document (QACD)*, the *OCRWM Quality Assurance Administrative Procedures (QAAPs)*, and the *OCRWM Implementing Line Procedures (ILPs)*.
- 2.2 The OCRWM Program Change Control Procedure (PCCP) and the OCRWM baselines and other controlled documents that fall within the scope of the PCCP are specifically excluded from the controls of this procedure.
- 2.3 The distribution of additional copies of controlled OCRWM quality assurance program documents issued to affected organizations may, at the discretion of the Director, OQA be conducted by the affected organization in accordance with their approved QA Program.

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 Controlled Document - Written information that is prepared, reviewed, and approved in accordance with established procedures, has controlled distribution, and is subject to revision and voidance control.

3.2.2 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, OFFICE OF QUALITY ASSURANCE (DOQA)

The Director, OQA or designee is responsible for:

4.1.1 Preparing and maintaining this QAAP;

4.1.2 Monitoring activities covered by this procedure;

4.1.3 Designating those documents under OQA cognizance that are to be controlled (based upon the criteria listed in Section 5);

4.1.4 Administering quality assurance document control functions for OCRWM;

4.1.5 Approving the initial distribution of those controlled quality assurance program documents;

4.1.6 Establishing and maintaining a controlled document index for those OCRWM documents covered within the scope of this procedure;

4.1.7 Maintaining controlled document distribution lists for quality assurance program documents;

4.1.8 Distributing all controlled OCRWM documents covered within the scope of this procedure;

4.1.9 Approving changes to the distribution list of controlled quality assurance program documents under OQA cognizance; and



- 4.1.10 Maintaining and controlling the QARD, QAPD, QACD, QAAP manual, and OCRWM ILP Manual or Manuals.

4.2 ASSOCIATE OR OFFICE DIRECTORS

The Associate or Office Directors are responsible for:

- 4.2.1 Designating appropriate documents under their cognizance as controlled (based upon the criteria listed in Section 5);
- 4.2.2 Approving the initial distribution of those controlled documents;
- 4.2.3 Providing the Director, OQA with their minimum required distribution list for QAAPs and ILPs under their cognizance; and
- 4.2.4 Requesting changes to the distribution list of those controlled documents.

4.3 ORIGINATORS OF A CONTROLLED DOCUMENT

Originators of draft or revised controlled documents (see criteria in Section 5) are responsible for:

- 4.3.1 Providing the Director, OQA with the materials listed in Paragraph 6.2.2.

4.4 RECIPIENTS OF A CONTROLLED DOCUMENT

Recipients of controlled documents are responsible for:

- 4.4.1 Maintaining their assigned copies;
- 4.4.2 Providing receipt acknowledgement and disposing of obsolete documents as instructed;
- 4.4.3 Ensuring that users of controlled documents, within their area of responsibility, are using the latest version of controlled documents; and
- 4.4.4 Notifying the Director, OQA of changes in name, position address, or employment status.

5.0 GENERAL

- 5.1 Documents that specify quality requirements or prescribe activities that affect quality shall be controlled.



- 5.2 A document shall satisfy one or both of the following criteria before being designated as controlled, issued, and maintained in accordance with this procedure:
- 5.2.1 The document's users require a current copy of the document to properly conduct their work.
- 5.2.2 The use of a non-current version of the document could adversely impact quality.
- 5.3 Controlled documents, including changes, shall be approved for release by authorized personnel and shall be distributed to and used at the location where the prescribed activity is being performed.
- 5.4 Documents must be identifiable by unique title or number, revision number, and effective date.
- 5.5 Controlled copies of documents, including revisions and Interim Change Notices (ICNs), covered by this procedure shall be clearly identified as controlled copies by either:
- a) Being printed on white paper with the word "CONTROLLED" printed diagonally across each sheet in a color other than black; or
 - b) Having a "Controlled Copy" stamp imprinted in red ink on the first page of the document; or
 - c) Where secondary distribution by another organization has been approved by the DOQA, being identified in accordance with the approved document control procedure for that organization.
- 5.6 Copies of documents covered by this procedure not identified as controlled copies in accordance with paragraph 5.5 shall not be used in the performance of quality affecting work.
- 5.7 An archival copy of each controlled document, and revision, shall be maintained.

6.0 PROCEDURE

6.1 DESIGNATING A DOCUMENT FOR CONTROLLED ISSUE

- 6.1.1 The responsible manager shall, prior to issuing documents, designate documents for controlled issue in accordance with the criteria identified in Subsection 5.2.



6.2 ISSUING A CONTROLLED DOCUMENT

- 6.2.1 The responsible Associate or Office Director shall approve controlled distribution of documents within their primary area of responsibility.
- 6.2.2 The following shall be submitted to the Director, OQA for documents covered by this procedure:
- a) One approved (signed) document original;
 - b) The required distribution list for initial issue of the document or requested changes, if any, to the existing distribution list for the document or Manual; and
 - c) Special instructions for distribution, if any, required or recommended.
- 6.2.3 The Director, OQA shall ensure that:
- a) Each controlled document has a unique title or number and effective date identified on the document;
 - b) Each controlled copy is identified in accordance with paragraph 5.5;
 - c) Each controlled copy is assigned a unique copy number; and
 - d) Records indicate the assigned copy holder of each controlled copy by copy number.
- 6.2.4 The Director, OQA shall establish and maintain a controlled document index. The index shall consist of one or both of the following:
- a) A table of contents for each controlled manual that identifies each document in the manual by number, title, revision or ICN number, and effective date. A new table of contents shall be issued each time a document is added or revised.
 - b) For documents not controlled as part of a controlled manual, a list identifying each such individually controlled document. The list shall identify each document by number and title, revision or ICN number, and effective date. This index, if required, shall be updated annually or as major changes occur and distributed to the document recipients.



6.3 TRANSMITTAL OF A CONTROLLED DOCUMENT

- 6.3.1 The Director, OQA shall prepare a Document Transmittal (Attachment I) for each distribution of a controlled document and distribute a copy of the Document Transmittal with the controlled copy to all personnel on the approved distribution list. The Document Transmittal shall contain any necessary instructions, to include action to be taken with superseded documents and for acknowledging receipt.
- 6.3.2 The Director, OQA shall forward one uncontrolled copy of each controlled document to the OCRWM Central Records Facility for inclusion in the Records Information System.
- 6.3.3 The recipient shall ensure that the controlled document is updated in compliance with the instructions provided and then shall sign and date the Document Transmittal and return it to the OQA.
- 6.3.4 The Director, OQA shall make a record of the return of the Document Transmittal including the document number, revision number, date the recipient signed the acknowledgement, controlled copy number, and recipient that acknowledges receipt.
- 6.3.5 If the Document Transmittal has not been returned, signed, to the OQA by the acknowledgement required date specified, The Director, OQA shall issue a reminder using the Document Transmittal to the controlled document holder (assignee).
- 6.3.6 If the Document Transmittal has not been returned, signed, to the OQA by the acknowledgement date specified, the Director, OQA will formally request that the controlled document be updated or the OQA will take appropriate action.

6.4 ISSUING REVISIONS TO OR DELETING A CONTROLLED DOCUMENT

- 6.4.1 Revisions and ICNs to controlled documents shall be controlled in the same manner as the original controlled document. The effective date and revision number shall be plainly visible on the document cover sheet.
- 6.4.2 The Document Transmittal shall instruct the recipient to destroy or return superseded material or clearly label it "SUPERSEDED" and shall inform the recipient that signing the acknowledgement so attests that the action was taken.



6.5 **MAINTAINING AND REVISING CONTROLLED DOCUMENT DISTRIBUTION LISTS**

- 6.5.1 The Director, OQA shall maintain a controlled distribution list for each document or manual covered by this procedure. The distribution list includes each controlled copy holder or location and the copy number.
- 6.5.2 Requests for changes to the controlled distribution lists shall be made by memorandum and directed to the Director, OQA.
- 6.5.3 When a document holder is removed from a distribution list, the Director, OQA shall notify the person, via a Document Transmittal, to destroy the document, mark it "SUPERSEDED", or return it to the OQA. The document holder or other responsible person shall sign and return the Document Transmittal to verify that the document has been removed from use.
- 6.5.4 At least annually copies of the distribution list for each controlled document or group of controlled documents shall be transmitted by the Director, OQA to the Director, OCRWM, and the Associate or Office Directors for review and updating (if appropriate).

7.0 **RECORDS**

- 7.1 Documents generated as a result of this procedure are to be maintained in accordance with the requirements contained in QAAP 17.1, *QA Records Management*. At a minimum, the completed Document Transmittal(s) (Attachment I) and copy of the distribution list for controlled distributions are to be considered QA records.

8.0 **ATTACHMENTS**

Attachment I - Document Transmittal

Attachment II - QAAP 6.1 Flowchart



ATTACHMENT 1

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT U.S. DEPARTMENT OF ENERGY WASHINGTON, D.C.		DATE OF TRANSMITTAL
		PAGE 1 OF ____ QA
SECTION A DOCUMENT TRANSMITTAL		
TO:	FROM:	
DOCUMENT(S) TRANSMITTED:		
INSTRUCTIONS TO RECIPIENT:		RESPONSE DUE DATE:
SECTION B ACKNOWLEDGEMENT		
COMMENTS:	ACKNOWLEDGEMENT:	
	_____ SIGNATURE	
	_____ DATE	

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ATTACHMENT I (Cont'd)

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

DATE OF TRANSMITTAL

PAGE ____ OF ____
QA

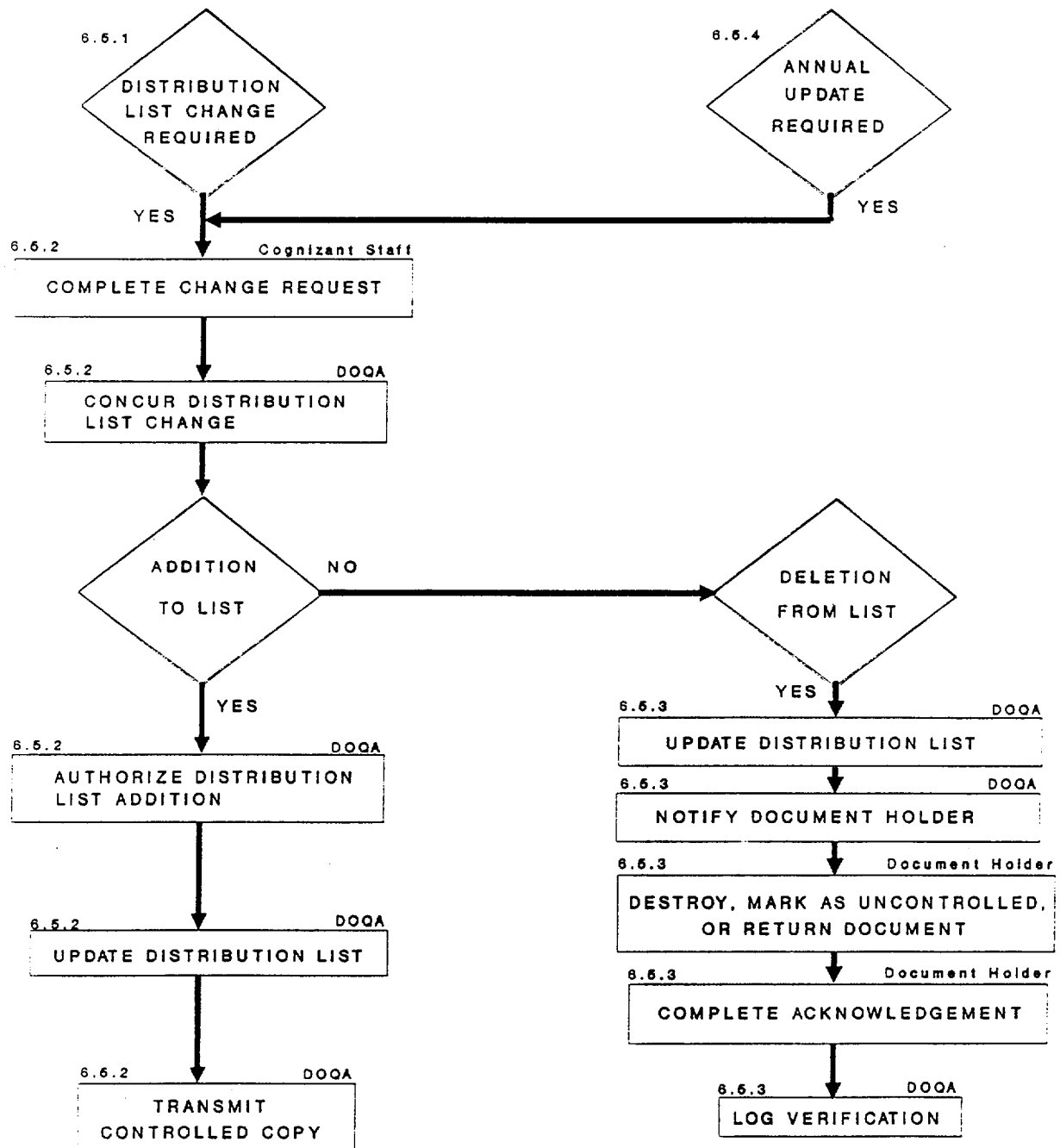
DOCUMENT TRANSMITTAL (Continuation Page)

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ATTACHMENT II

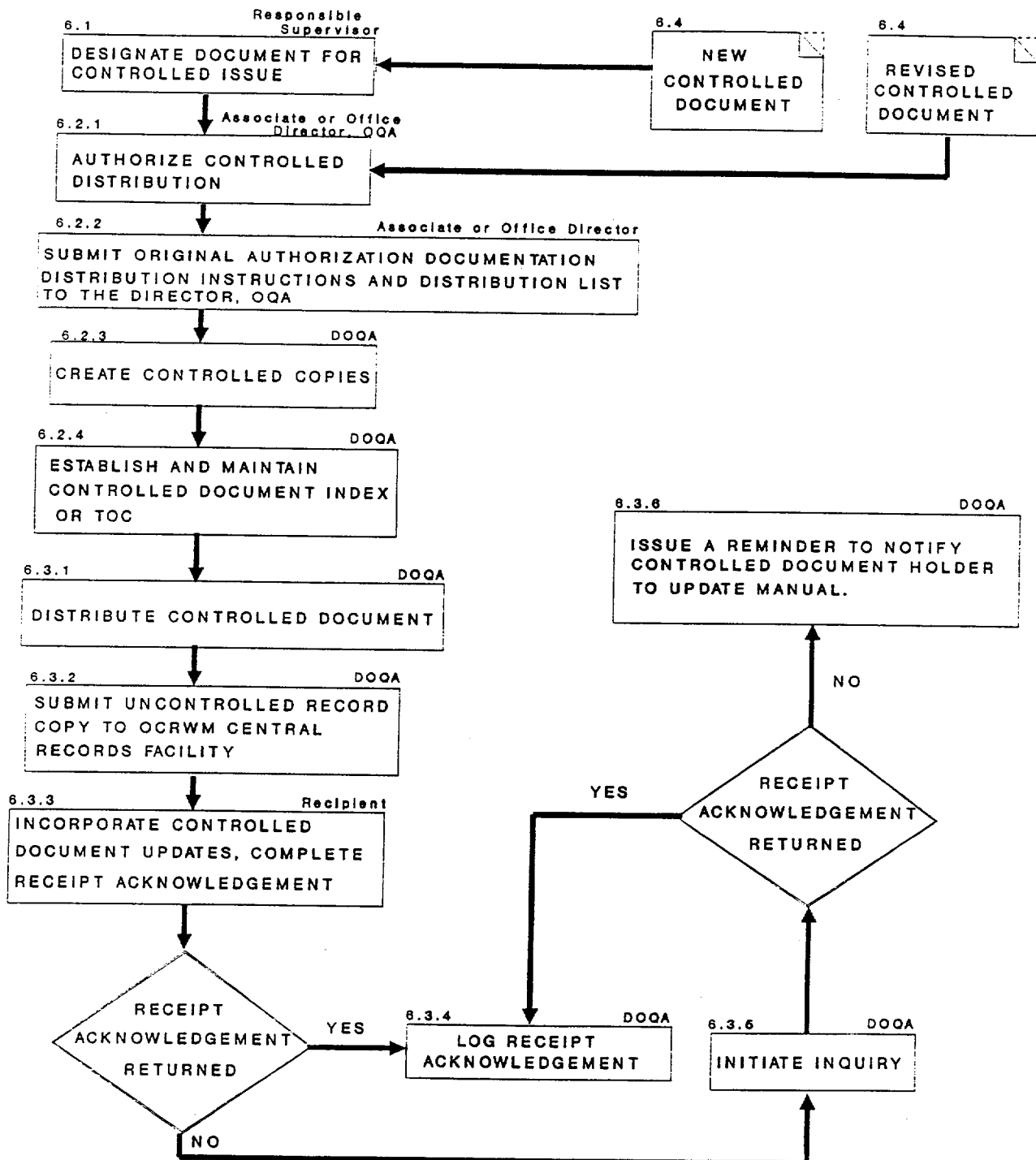
MAINTENANCE OF CONTROLLED DOCUMENT DISTRIBUTION LISTS (FLOWCHART)





ATTACHMENT II (Cont'd)

ISSUANCE OF CONTROLLED DOCUMENTS (FLOWCHART)



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

REVISION RECORD

TITLE:

Control of Procured Services

PROCEDURE NO.

QAAP 7.1

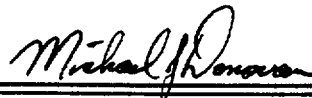
REV. NO. (current)

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DESCRIPTION OF PROPOSED REVISION AND RATIONALE:

Procedure completely rewritten and retitled to consolidate QAAPs 4.1, 4.2 and 7.1 while removing the document review process that has been replaced by QAAP 6.2. The entire process has been rewritten to more clearly address the DOE procurement process relative to QA program requirements.

PREPARER OF PROPOSED REVISION Michael J. Donovan



DATE 11/12/91

TYPE OF REVISION (Check One):

MAJOR ☒MINOR ☐

SIGNATURE TO AUTHORIZE REVISION


Responsible Associate or Office Director

DATE 12/18/91

TYPE OF REVISION (Check One):

MAJOR ☒MINOR ☐

CONCURRENCE SIGNATURE


for Director, OQA

DATE 12/30/91

RECOMMENDED TRAINING:

READ ☒CLASSROOM ☒OTHER ☐

- Classroom training required on this revision for individuals whose I&T Matrix required classroom training for QAAP 4.1, 4.2 or 7.1.



RESPONSIBLE ASSOCIATE OR OFFICE DIRECTOR OR QA TRAINING OFFICER

DATE 12/30/91