



Department of Energy
Washington, DC 20585

February 24, 1989

Licensing Assistant
Repository Licensing and Quality Assurance
Project Directorate
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Enclosed is a Controlled Copy of RW-0197, Quality Assurance Administrative Procedures Manual, Revision 0. This is the initial issuance of the QAAP Manual, which contains the first 11 approved OCRWM QAAPs applicable to OCRWM headquarters activities. Additional QAAPs are planned and will be issued in the near future.

This document, along with the OCRWM Quality Assurance Manual (DOE/RW-0214 and DOE/RW-0215), supersedes and cancels OGR/B-3, Quality Assurance Plan for High-Level Radioactive Waste Repositories, August 1986; DOE/RW-0032, Quality Assurance Policies and Requirements, October 1985; DOE/RW-0103, Quality Assurance Directive, October 1986; and the "Director's Statements on Managing for Quality and Quality Assurance," July 14, 1987.

The individual QAAPs become effective on the dates listed in the index, contained in the front of the manual.

Please identify to the Office of Quality Assurance in writing any additional personnel in your area who require Controlled Copies of the QAAPs.

Please complete the actions requested on the Document Transmittal Record, also enclosed, and acknowledge receipt by the response due date indicated.

Sincerely,

Larry H. Barrett
Lake H. Barrett, Director *fc*
Office of Quality Assurance
Office of Civilian Radioactive
Waste Management

Enclosures

Received w/Ltr Dated

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PDR WASTE
WM-1 PDC

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

ORIGINATING ORGANIZATION
RW-3
DATE OF TRANSMITTAL
2/24/89

SECTION A DOCUMENT TRANSMITTAL

TO:
TANA, EILEEN
LICENSING ASSISTANT
REPOSITORY, LICENSING & QA PROJECT DIRECTORATE, NRC
US NUCLEAR REGULATORY COMMISSION
WASHINGTON DC 20555-0000

DOCUMENT(S) TRANSMITTED:

Initial Issue, Controlled Copy # 00278, DOE/RW-0197, Quality Assurance Administrative Procedures Manual, Rev. 0.

INSTRUCTIONS TO RECIPIENT:

RESPONSE DUE DATE

3/24/89

Please acknowledge receipt of the above documents by signing and dating in the appropriate block of Section B below and return as indicated below by the response due date indicated above.

SECTION B ACKNOWLEDGMENT

COMMENTS:

ACKNOWLEDGEMENT SIGNATURE:

DATE:

RETURN SIGNED TRANSMITTAL TO:

OCRWM RW-3
US Department of Energy
1000 Independence Avenue, S.W.
Washington, D.C. 20585-0000
Attention: Ms. Jennings

SECTION C DISTRIBUTION

OCRWM QA Manual Distribution List

Office of Civilian Radioactive Waste Management



**Quality Assurance
Administrative Procedures**

U.S. Department of Energy
Office of Civilian Radioactive Waste Management
Washington, DC



OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
QUALITY ASSURANCE ADMINISTRATIVE PROCEDURE

TITLE: TABLE OF CONTENTS

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2.6	Readiness Review	0	3/27/89
3.1	Technical Document Review	0	3/27/89
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3.3	Peer Review	0	3/27/89
5.1	Preparation of Quality Assurance Administrative Procedures	0	3/27/89
16.1	Corrective Action	0	3/27/89
18.1	Certification of Audit Personnel	0	3/27/89
18.2	Audit Program	0	3/27/89
18.3	Surveillance Program	0	3/27/89

Received w/Ltr Dated 2/24/89
4105



OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
QUALITY ASSURANCE ADMINISTRATIVE PROCEDURE

TITLE: INDOCTRINATION AND TRAINING

Procedure No.: QAAP 2.1	Revision: 0	Date: 3/27/89	Page: 1 of 16
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Director, OCRWM <i>[Signature]</i>	Date: 12/1/88	Director, OQA <i>[Signature]</i>	Date: 12/1/88
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1.0 PURPOSE

The purpose of this procedure is to establish specific responsibilities and directions for indoctrination and training of personnel working to the OCRWM Quality Assurance Program.

2.0 SCOPE

This procedure applies to the Quality assurance indoctrination and training of OCRWM personnel, including consultants and contract support personnel working to the OCRWM Quality Assurance Program.

3.0 REFERENCES AND DEFINITIONS

3.1 REFERENCES

- 3.1.1 "Quality Assurance Requirements for the Civilian Radioactive Waste Management Program", (QAR) DOE/RW-0214, 1988.
- 3.1.2 "Quality Assurance Program Description for the Civilian Radioactive Waste Management Program", (QAPD) DOE/RW-0215, 1988.

3.2 DEFINITIONS

- 3.2.1 The definitions of standards terms may be found in the Glossary contained in reference 3.1.1.
- 3.2.2 Job and Task Analysis - A systematic method of obtaining an indepth understanding of a specific position by breaking the job into finite tasks and elements.
- 3.2.3 Supervisor - As used in this procedure, a person who directs the activities of one or more subordinates.
- 3.2.4 Training Matrix - A document used to identify indoctrination and training requirements for a specific individual or job position.
- 3.2.5 Training Officer - That person who is directly responsible for the development and coordination of the OCRWM Indoctrination and Training Program.



3.2.6 Non-Permanent Personnel - Persons whose job assignment in support of OCRWM is expected to be less than three months.

4.0 RESPONSIBILITIES

4.1 ASSOCIATE DIRECTOR, OFFICE OF PROGRAM ADMINISTRATION AND RESOURCES MANAGEMENT (OPARM)

The Associate Director, OPARM, or designee has responsibility for:

- 4.1.1 Preparation and maintenance of this QAAP;
- 4.1.2 Overall development and coordination of an OCRWM indoctrination and training program; and
- 4.1.3 Implementation of supervisory duties in Section 4.3, below, including general supervision of the OCRWM Training Officer.

4.2 DIRECTOR, OFFICE OF QUALITY ASSURANCE (OQA)

The Director, OQA, or designee is responsible for:

- 4.2.1 Development and implementation of specific indoctrination and training requirements in coordination with the OCRWM Training Officer;
- 4.2.2 Review of and concurrence of this QAAP; and
- 4.2.3 Implementation of supervisory duties outlined in Section 4.3, below.

4.3 SUPERVISORS

Supervisory personnel, or designees, are responsible for:

- 4.3.1 Establishment of indoctrination and training requirements for applicable quality-affecting positions within their respective organizations;
- 4.3.2 Assuring that personnel within their organizations are identified for appropriate indoctrination and training;
- 4.3.3 Assuring that personnel within their respective organization receive appropriate indoctrination and training; and
- 4.3.4 Providing classroom instructors on subject matter within the supervisor's area of technical responsibility.



4.4 TRAINING OFFICER

The OCRWM Training Officer, or designee, is responsible for:

- 4.4.1 Assuring that indoctrination and training requirements are identified;
- 4.4.2 Developing an indoctrination and training schedule;
- 4.4.3 Overseeing the development of indoctrination and training materials;
- 4.4.4 Providing reports to the Associate Director, OPARM, Director, OQA and other OCRWM management on the status of reading assignments, classroom instruction and implementation of the indoctrination and training program; and
- 4.4.5 Entering indoctrination and training documentation into the OCRWM records management system.

4.5 INSTRUCTORS

Instruction personnel are responsible for:

- 4.5.1 Developing indoctrination and training materials;
- 4.5.2 Conducting classroom instruction and recording attendance; and
- 4.5.3 Assessing the assimilation of information presented and evaluating this with the Training Officer.

5.0 GENERAL

5.1 INDOCTRINATION AND TRAINING

- 5.1.1 Individuals performing activities affecting quality shall be indoctrinated and trained, as appropriate, to assure a thorough understanding of the OCRWM QA Program and implementing procedures.
- 5.1.2 Indoctrination and training shall be required upon initial implementation of this procedure and whenever personnel are initially assigned to OCRWM Headquarters.
- 5.1.3 Indoctrination and training shall be required whenever a new QAAP or new implementing line procedure is issued.



5.2 INDOCTRINATION SUBJECT MATTER

5.2.1 Personnel shall be indoctrinated in the following subjects as they relate to the individual's assigned responsibilities:

- a) General criteria, including any applicable codes, standards and regulations; and the purpose, scope and implementation of quality-related manuals, instructions and procedures;
- b) Applicable quality assurance program elements; and
- c) Job responsibilities and authority.

5.3 TRAINING

5.3.1 Training shall involve classroom instruction and shall be provided, as necessary, to:

- a) Achieve initial proficiency;
- b) Maintain proficiency; and
- c) Accommodate changes in QA program, procedures or methods, job responsibility, or technology.

5.3.2 The extent of training shall be commensurate with the following:

- a) The scope, complexity and nature of the activities; and
- b) The education, experience and initial proficiency of the person.

5.4 MINIMUM INDOCTRINATION REQUIREMENTS

5.4.1 Individuals assigned to perform activities affecting quality shall be familiar with the following applicable OCRWM documents, as a minimum:

- a) Quality Assurance Requirements document;
- b) Quality Assurance Program Description document;
- c) Quality Assurance Administrative Procedures appropriate for their scope of work and responsibilities;
- d) Applicable codes, national consensus standards, and Federal regulations commensurate with their scope of work and responsibilities; and



e) Other job-specific documents, as may be identified by their supervisor.

5.4.2 Non-permanent personnel shall receive indoctrination and training appropriate to their specific tasks. Indoctrination and training requirements shall be documented on the individual's Training Matrix. Non-permanent personnel are not subject to position Training Matrix requirements.

5.5 INDOCTRINATION METHODS

5.5.1 Indoctrination shall be accomplished by one or more of the following, as appropriate:

- a) Reading PROGRAM documents associated with their job responsibility; and/or
- b) Classroom instruction.

6.0 PROCEDURE

6.1 ESTABLISHING REQUIREMENTS

6.1.1 Supervisors, with assistance from the OCRWM Training Officer, shall establish basic indoctrination and training requirements for each job position. Minimum requirements for the position shall be documented on Attachment I.

6.1.2 Supervisors shall establish specific indoctrination and training requirements for each person on their staff. This shall be accomplished by entering the employee's name and any additional requirements, as appropriate, on Attachment I.

6.2 READING ASSIGNMENTS

6.2.1 Each employee shall read the standard and specific job-related documents identified on Attachment I and II.

6.2.2 The supervisor shall sign and the employee shall initial the Reading Assignment Sheet (Attachment II), after assigned materials have been read.

6.3 PREPARATION FOR CLASSROOM INSTRUCTION

6.3.1 The OCRWM Training Officer shall prepare, on at least a quarterly basis, a tentative schedule of indoctrination and training courses.



6.3.2 The OCRWM Training Officer shall request from cognizant supervisors the appointment of classroom instructors. Following their appointment, the OCRWM Training Officer shall finalize the quarterly indoctrination and training schedule.

6.3.3 Instructors, with assistance from the OCRWM Training Officer, shall prepare a Lesson Plan (Attachment IV) and all presentation materials necessary to support the classroom indoctrination and training courses.

6.3.4 The OCRWM Training Officer shall distribute, prior to each indoctrination and training course, written notification of the course, class location, class schedule and required attendees.

6.4 CLASSROOM INSTRUCTION

6.4.1 Employees shall attend indoctrination and training classes, identified on their Training Matrices, at the times they are scheduled.

6.4.2 Classroom instruction shall proceed as identified in the approved Lesson Plan (Attachment IV).

6.4.3 Employees shall sign an Attendance Record (Attachment III) upon completion of each indoctrination and training class which they attend. The instructor shall forward the Attendance Record to the OCRWM Training Officer who shall process it as a record, along with the Lesson Plan, in accordance with Section 7.0.

6.5 POST-INSTRUCTION EVALUATION

6.5.1 Whenever personnel certification is required, an examination shall be developed to evaluate the prospective candidate's comprehension of and ability to apply the body of knowledge presented during training.

6.5.2 Examinations required for certification of audit personnel shall be prepared and conducted in accordance with QAAP 18.1, "Certification of Audit Personnel". Other certification examinations shall be prepared and conducted in accordance with the specific QAAP requiring certification.



6.5.3 At the discretion of the OCRWM Training Officer, personnel not requiring certification may be either subject to examination or requested to participate in other forms of evaluation. The evaluations shall be designed to either assess the adequacy of indoctrination and training course material, the effectiveness of instructors, the attentiveness of the class, or a combination thereof. Such evaluations, when required, shall be documented and used to improve classroom instruction materials and techniques. The evaluation report shall reference the applicable class Attendance Record and related indoctrination and training documentation and shall be processed as a record in accordance with Section 7.0.

6.6 ADDITIONAL INDOCTRINATION AND TRAINING

6.6.1 At the discretion of the OCRWM Training Officer, job and task analysis techniques may be used to assess job positions and upgrade Training Matrices associated with the positions or improve instruction materials associated with courses required for the positions. The results of such analyses shall be documented.

6.6.2 Employees shall receive additional indoctrination whenever there is a significant change to either the QAR or QAPD documents.

6.6.3 Employees shall receive additional indoctrination or training, comparable to that required initially, whenever there is a significant change to a document identified in their Training Matrix. Regardless of significance, employees shall be required to read all changes to documents identified in their Training Matrix.

6.6.4 The need for either additional indoctrination or training shall be evaluated whenever an employee is assigned to a new position or the employee's position description is revised. The results of the evaluation shall be documented on the employee's Training Matrix.

6.6.5 Individual employee's training matrices shall be reviewed annually by the cognizant supervisor.



7.0 RECORDS

7.1 DOCUMENTATION

Documentation generated as a result of this procedure shall be collected and maintained in accordance with requirements specified in QAAP 17.1, "Records Management." The OCRWM Training Officer is responsible for collecting all documentation required by this procedure and entering it into the records management system described in QAAP 17.1. At a minimum, attachments I, II, III and IV are considered QA Records.

8.0 ATTACHMENTS

- 8.1 ATTACHMENT I - Training Matrix
- 8.2 ATTACHMENT II - Reading Assignment Sheet
- 8.3 ATTACHMENT III - Attendance Record
- 8.4 ATTACHMENT IV - Lesson Plan
- 8.5 ATTACHMENT V - QAAP Flowchart



ATTACHMENT IV (SAMPLE)

LESSON PLAN
COVER SHEET

A. GENERAL INFORMATION

- 1. LESSON PLAN TITLE _____
- 2. REVISION NUMBER _____ DATE _____
- 3. Author: _____ Date: _____
(Printed Name)
- 4. Reviewed: _____ Date: _____
(Printed Name) (Signature)
COGNIZANT SUPERVISOR
- 5. Approved: _____ Date: _____
(Printed Name) (Signature)
OCRWM TRAINING OFFICER

B. COURSE DETAILS

- 1. Course Objectives _____

- 2. Summary of Course _____

- 3. Terms to be Defined _____

- 4. Documentation to be discussed _____

- 5. Prerequisites for attending course (if any) _____

- 6. Instruction methods and materials _____

- 7. Instructional materials _____



ATTACHMENT IV (Cont'd)
LESSON PLAN INSTRUCTIONS

A. GENERAL INFORMATION

1. State title of course
2. Begin with Revision 0
3. Identify author of Lesson Plan, normally the instructor
4. Obtain approval of the cognizant technical supervisor
5. Obtain approval of the OCRWM Training Officer

B. COURSE DETAILS

1. Describe objective in behavioral terms, e.g., "At the conclusion of the class, attendees should be able to accurately and completely fill out an XYZ Form."
2. Briefly state material to be covered in the course.
3. Identify terms that the instructor will be defining.
4. Identify documents that the class will be receiving instruction on preparing.
5. Identify other courses attendees must complete prior to attending this course.
6. Identify classroom instruction methods (e.g., lectures, workshops, structured question and answer sessions).
7. Identify instructional materials and equipment (e.g., viewgraphs, handouts, films, slides, etc.).

C. COURSE OUTLINE

Instructor Prompt - Identify the time allotted for each new item (viewgraph, slide, activity, etc.)

Course Outline - Identify material to be presented. Refer handouts, etc. and how they will be used and what will be said. Do not prepare a detailed text that contains every spoken word but do include enough information that another instructor could readily give the same course. If viewgraphs, handouts or other materials are used, copies should be attached to the Lesson Plan.



ATTACHMENT IV (cont'd)
LESSON PLAN
CONTINUATION SHEET

Lesson Plan _____ Page ____ of ____

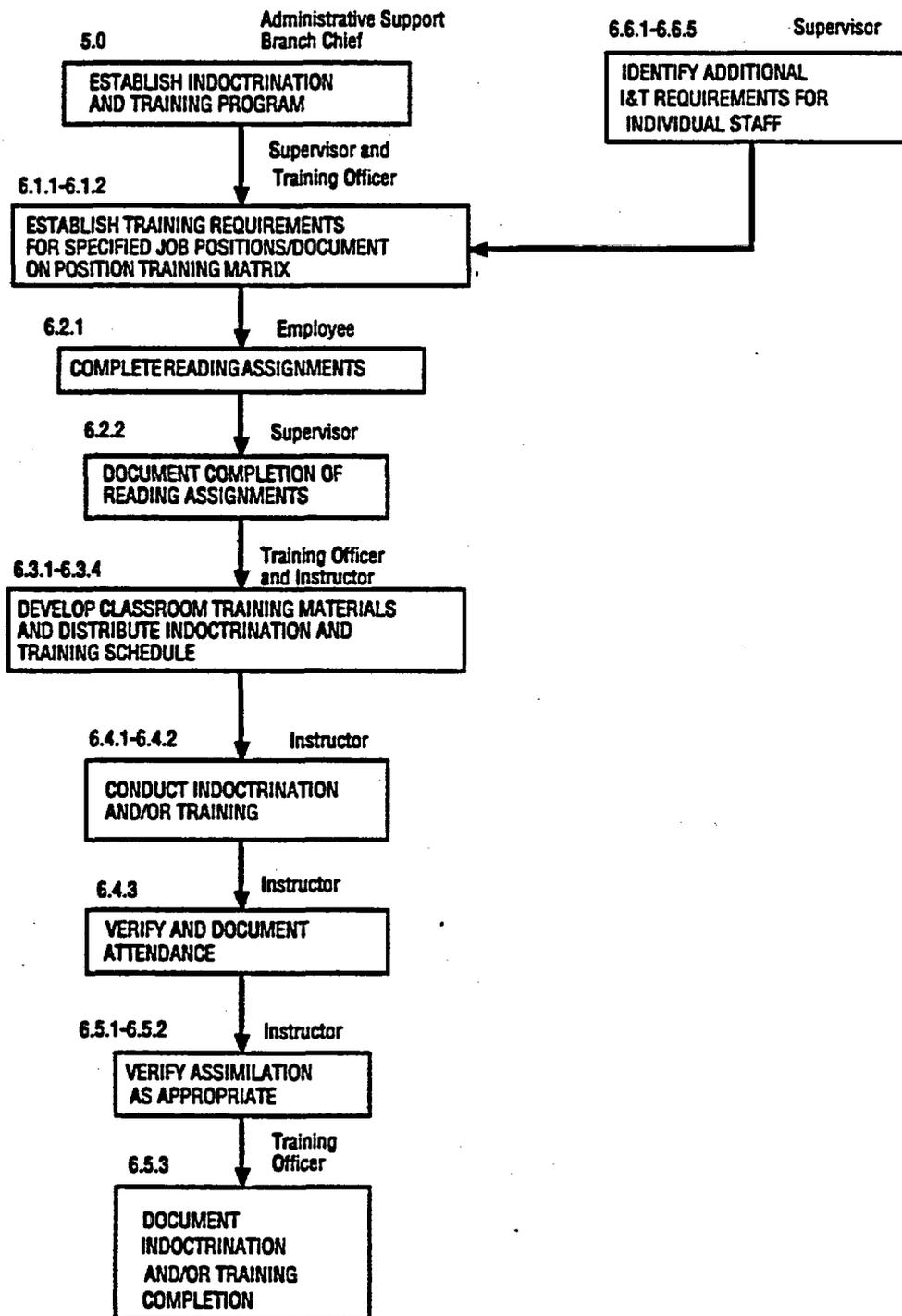
COURSE OUTLINE

Instructor Prompt	Course Outline



ATTACHMENT V

INDOCTRINATION AND TRAINING





OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
QUALITY ASSURANCE ADMINISTRATIVE PROCEDURE

TITLE: QUALITY ASSURANCE PROGRAM DOCUMENT REVIEW

Procedure No.: QAAP 2.5	Revision: 0	Date: 3/27/89	Page: 1 of 9
Director, OCRWM <i>[Signature]</i>	Date: 12/1/88	Director, OQA <i>[Signature]</i>	Date: 12/1/88

1.0 PURPOSE

The purpose of this procedure is to establish the responsibilities and methods for review, acceptance, approval or concurrence of Quality Assurance (QA) documents internally generated by the Office of Civilian Radioactive Waste Management (OCRWM) or their support contractors and externally generated (Project Office, PROGRAM participant and contractors) QA documents submitted to OCRWM for review, acceptance, approval or concurrence.

2.0 SCOPE

This procedure applies to QA documents generated externally (Project Office, PROGRAM participant and contractors) and submitted to OCRWM for review, acceptance, approval or concurrence. This procedure additionally applies to the review, acceptance, approval or concurrence of QA documents generated by OCRWM or their support contractors, with the exception of OCRWM Quality Assurance Administrative Procedures (QAAPs), which are governed by QAAP 5.1.

3.0 REFERENCES AND DEFINITIONS

3.1 REFERENCES

3.1.1 "Quality Assurance Requirements for the Civilian Radioactive Waste Management Program", (QAR) DOE/RW-0214, 1988.

3.1.2 "Quality Assurance Program Description for the Civilian Radioactive Waste Management Program", (QAPD) DOE/RW-0215, 1988.

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 Acceptance - The act of reviewing a document and acknowledging that it may be used for the purpose intended at that time.



- 3.2.3 Approval - A documented act of endorsing an acceptance.
- 3.2.4 Concurrence - This term is used to indicate agreement that a document is suitable for use and that review of a document has been satisfactorily completed.
- 3.2.5 Mandatory Comment - Comment requiring resolution that identifies and describes a significant conflict with, or deviation from, existing OCRWM policy; quality assurance requirement; programmatic or management requirement; technical position; or responsibilities for implementation of established requirements.
- 3.2.6 Quality Assurance Review - An examination of a document to determine compliance with DOE Orders relating to QA and the QAR document.

4.0 RESPONSIBILITIES

4.1 DIRECTOR, OCRWM

The Director, OCRWM, or his designee has overall responsibility for:

- 4.1.1 Acceptance, approval or concurrence of OCRWM, OCRWM-reviewed Project Office, PROGRAM-participant and contractor QA program documents.

4.2 ASSOCIATE DIRECTORS, OCRWM

The Cognizant Associate Director(s), OCRWM, or designees are responsible for:

- 4.2.1 Concurring with OCRWM, OCRWM-reviewed Project Office, PROGRAM-participant and contractor QA program documents within their area of responsibility.

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 Reviewing and commenting on QA program-documents to assure proper quality requirements are adequately addressed;
- 4.3.3 Maintaining and tracking QA program document review status;
- 4.3.4 Assigning responsibility for coordinating the review of QA program documents; and



4.3.5 Establishing specific review and acceptance criteria.

5.0 GENERAL

- 5.1 QA program documents received by OCRWM for review, acceptance, approval or concurrence may be generated internally by OCRWM or their support contractors, or externally by Project Offices, Program participants and contractors.
- 5.2 The OCRWM review and acceptance, approval or concurrence of QA program documents shall be accomplished in accordance with this QAAP.
- 5.3 Comments shall be documented on the Document Review Record (DRR), Attachments I and II. QA program-document reviewer(s) shall document comments or annotate "No Comments" on a Document Review Record (DRR), Attachments I and II.
- 5.5 Resolution of comments on internally generated QA program documents shall be accomplished between the organization that prepared the QA program document and the reviewing organization. In the event that the original reviewer(s) is unavailable for resolution, the Director, OQA, shall designate a qualified replacement to resolve the comments. The resolution of mandatory comments shall be documented by the organization that prepared the QA program document, adjacent to the reviewers comments on the DRR. The reviewer(s) shall indicate agreement or disagreement with resolution of these comments in the column on the DRR provided for this purpose.
- 5.6 Comments that cannot be resolved by the reviewing organization and the originating organization shall be brought to the attention of the appropriate management level and, if not resolved, are elevated progressively to the Director, OQA, and if necessary, to the Director, OCRWM.
- 5.7 Resolution of comments on externally generated QA program documents is accomplished in accordance with the originating organizations procedures.

6.0 PROCEDURE

6.1 INITIATING QA DOCUMENT REVIEW

- 6.1.1 Upon receipt of a QA document for review, the Director, OQA, assigns the OQA staff individual(s) required to conduct the review. The reviewer(s) shall also include representatives of all sections of OCRWM that are cognizant of activities covered by the QA document.



6.1.2 The Director, OQA, forwards the QA document to the reviewer(s). A DRR is attached, with the review and acceptance criteria specified. (The DRR may, for example, specify the review to be accomplished in accordance with QAAP 2.5 and the acceptance criteria as 10CFR50, Appendix B.)

6.2 QA DOCUMENT REVIEW

6.2.1 The reviewer(s) perform(s) the review, following the specified review and acceptance criteria annotated on the DRR.

6.2.2 The reviewer(s) document(s) comments on the DRR. If the reviewer(s) delegate(s) additional personnel to perform the review, the reviewer(s) consolidate(s) all comments onto a single set of DRRs, resolving any conflicting comments.

6.2.3 When the review produces comments, the reviewer(s) identify(s) the mandatory comments, as appropriate.

6.2.4 Upon completion of the review, the reviewer(s) forward(s) the signed DRR to the Director, OQA, for further action.

6.3 ACTION SUBSEQUENT TO REVIEW

6.3.1 The Director, OQA, reviews the DRR to determine the extent of the comments.

6.3.2 If no comments exist, the Director, OQA, prepares an acceptance, approval or concurrence letter or memorandum for the Director, OCRWM, signature and forwards the letter or memorandum, the DRR, and the document to the Director, OCRWM, for his action.

6.3.3 If comments exist and are annotated as mandatory, the Director, OQA, prepares a letter or memorandum to transmit the DRR to the document preparer organization for comment response/resolution.

6.4 COMMENT RESOLUTION

6.4.1 Resolution of comments is accomplished by the document preparer organization.

6.4.2 The resolution of comments is documented by the document preparer organization on the same DRR(s) in which the comments appear.

6.4.3 The document preparer organization resubmits the document and the DRR to the Director, OQA.



- 6.4.4 Following re-submittal of the document and the DRR by the document preparer organization, the Director, OQA, forwards the document and DRR to the cognizant reviewer(s) for verification of comment resolution.
- 6.4.5 The cognizant reviewer(s) indicate(s) agreement or disagreement with the resolution of these comments by indicating acceptance or rejection in the space provided on the DRR and initialing the DRR adjacent to the comment response.
- 6.4.6 If any comment resolution is rejected by the reviewer(s), the DRR is returned to the document preparer organization, accompanied with the rationale for rejection.
- 6.4.7 The steps identified in 6.4.2 through 6.4.6 may be accomplished in concert via a comment resolution meeting or a comparable format that produces an acceptable end result and documents the results.
- 6.4.8 Following the completion of the resolution of comments on the DRR, the document preparer organization revises the document, as necessary, and resubmits the document along with the completed DRR package to the Director, OQA.
- 6.4.9 If all comments have been resolved, the Director, OQA, prepares an acceptance, approval or concurrence letter or memorandum for the signature of the Director, OCRWM, and forwards the letter or memorandum, the DRR, and the document to the Director, OCRWM, for action.
- 6.4.10 If comments cannot be resolved to the satisfaction of the reviewer(s) and the document preparer organization, they shall be brought to the attention of the appropriate management level and, if not resolved, are elevated progressively to the Director, OQA, and if necessary, to the Director, OCRWM.
- 6.4.11 Review of revisions to previously accepted, approved or concurred with QA documents shall be accomplished in accordance with provisions of Sections 6.1, 6.2; 6.3 and 6.4 of this QAAP.



6.5 ACTION SUBSEQUENT TO ACCEPTANCE/APPROVAL/CONCURRENCE

6.5.1 Subsequent to document acceptance, approval or concurrence by the Director, OCRWM, the document shall be issued for use by one of the following methods:

- a) Distribution and control in accordance with the requirements established in QAAP 6.1, "Controlled Documents".
- b) Release Project Office, PROGRAM participant or contractor documents to the preparer organization for issuance in accordance with respective procedures.

6.5.2 Issuance of revisions to previously accepted, approved or concurred with QA documents shall be accomplished in accordance with section 6.5.1, a or b, respectively.

6.5.3 When an OCRWM QA Program document is revised and reissued, the portion or portions of the document that have been revised shall be identified by a change bar (a vertical line in the margin adjacent to the line or lines that were revised). A total rewrite shall so be stated on the new "Table of Contents" and change bars are not necessary.

7.0 RECORDS

7.1 Documentation generated as a result of this procedure is collected and maintained in accordance with requirements specified in QAAP 17.1 "Records Management". At a minimum, attachments I and II are 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 Flowchart



ATTACHMENT II (TYPICAL)

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

SHEET ____ OF ____
WBS NO. _____

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

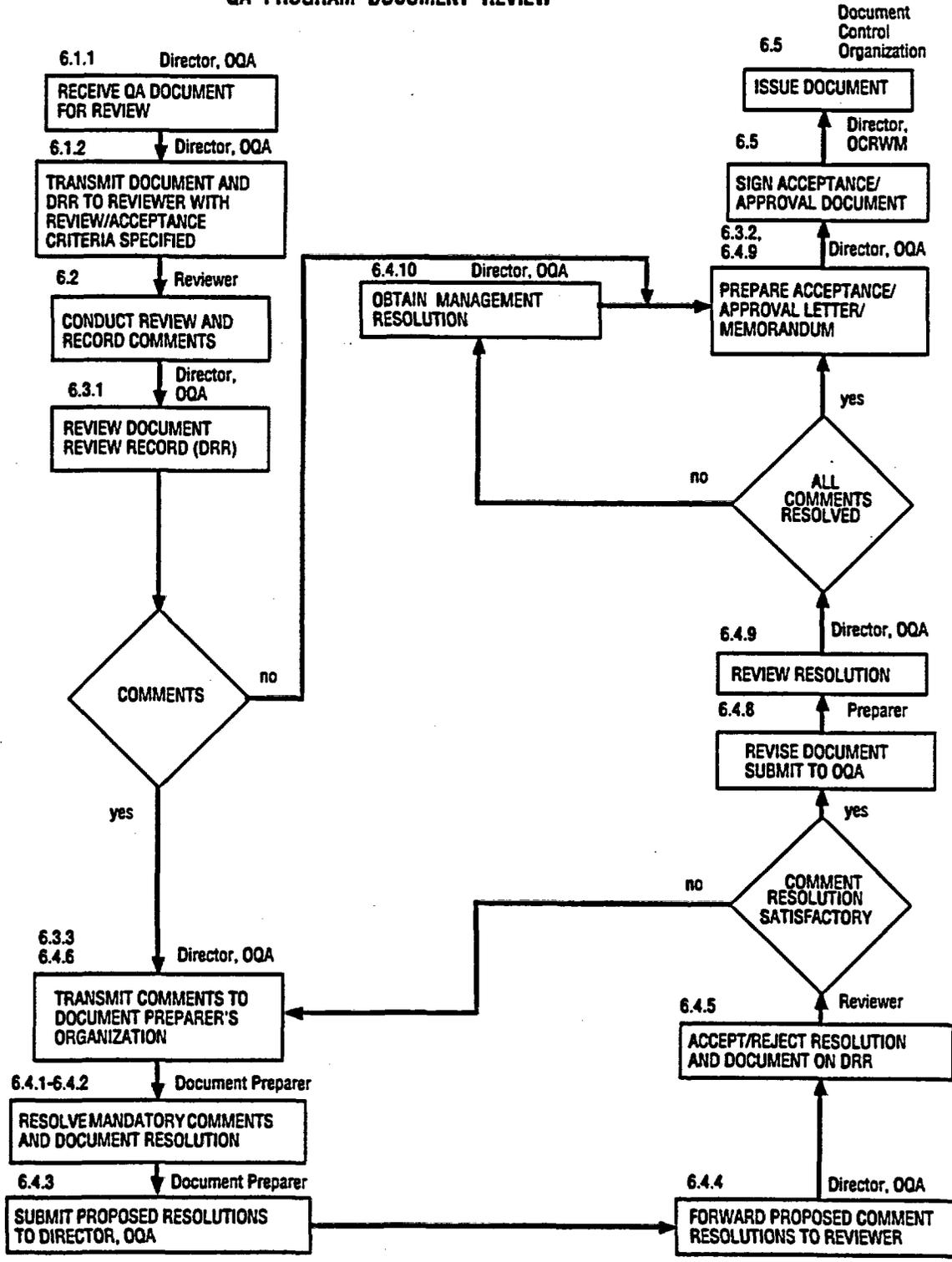
RESPONSE BY

Signature Date



ATTACHMENT III

QA PROGRAM DOCUMENT REVIEW





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

TITLE: READINESS REVIEW

Procedure No.: QAAP 2.6	Revision: 0	Date: 3/27/89	Page: 1 of 18
Director, OCRWM <i>[Signature]</i>	Date: 2/10/89	Director, OQA <i>[Signature]</i>	Date: 2/7/89

1.0 PURPOSE

This procedure establishes the Office of Civilian Radioactive Waste Management (OCRWM) responsibilities and methods for conducting OCRWM-initiated Readiness Reviews.

2.0 SCOPE

This procedure shall apply to OCRWM review of readiness to start or continue a design phase, process, or other activity when it is determined that a formal review is necessary. This procedure shall also be used in verifying that specified prerequisites and programmatic requirements have been completed prior to the start or continuation of a design phase, process, or other activity.

3.0 REFERENCES AND DEFINITIONS

3.1 REFERENCES

- 3.1.1 "Quality Assurance Requirements for the Civilian Radioactive Waste Management Program," (QAR)-DOE/RW-0214, 1988.
- 3.1.2 "Quality Assurance Program Description for the Civilian Radioactive Waste Management Program," (QAPD)-DOE/RW-0215, 1988.

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 Action Items List - A list that identifies items requiring disposition at designated times prior to the start or continuation of the design phase, process, or other activity undergoing review. The list is used during Readiness Review to verify whether the items are "Open" or "Closed."



- 3.2.3 Cognizant Associate Director, OCRWM - The Associate Director, OCRWM, responsible for a specific Readiness Review. Generally, this will be the Associate Director, OCRWM, responsible for the functional area that is the subject of the Readiness Review.
- 3.2.4 Open Items List - A list that identifies items needing additional work before the items can be "Closed". The individual(s) or group(s) responsible for action(s) and expected time(s) for closure are identified.
- 3.2.5 Readiness Review Board - A group appointed by the Cognizant Associate Director, OCRWM, to review and approve recommendations developed by the Start-up Team regarding start or continuation of a design phase, process, or other activity undergoing Readiness Review.
- 3.2.6 Readiness Review Plan - A documented plan that defines the actions necessary for implementing a Readiness Review.
- 3.2.7 Readiness Review Tree - A systematic analysis of major items to be reviewed using graphical displays of information designed to aid the user in recalling details that must be considered and the relationship of these details to one another.
- 3.2.8 Start-up Team - A group appointed by the Cognizant Associate Director, OCRWM, to perform activities associated with a Readiness Review.
- 3.2.9 Technical Holds List - A list that identifies items discovered during Readiness Review that could impact the schedule or have other significant consequences regarding the design phase, process, or other activity undergoing review. The kinds of items that would be listed include, but are not limited to; funding restraints, permitting delays, or budget considerations.
- 3.2.10 Technical Holds Sheet - A document that identifies a specific item discovered during Readiness Review that could impact the schedule or have other significant consequences regarding the design phase, process, or other activity undergoing review. Selected information from the Technical Holds Sheet is compiled on the Technical Holds List.



4.0 RESPONSIBILITIES

4.1 DIRECTOR, OCRWM

The Director, OCRWM, or designee has the overall responsibility for:

4.1.1 Reviewing recommendation(s) of the Readiness Review Board and authorizing the start or continuation of the design phase, process, or other activity undergoing review.

4.2 ASSOCIATE DIRECTORS, OCRWM

The Associate Directors, OCRWM, or designee are responsible for:

4.2.1 Determining if and when a Readiness Review should be performed;

4.2.2 Determining and approving the scope of the Readiness Review;

4.2.3 Establishing reviewer qualifications;

4.2.4 Appointing the chairperson(s) and members of the Readiness Review Board and Start-up Team, as appropriate.

4.3 ASSOCIATE DIRECTOR, OFFICE OF FACILITIES SITING AND DEVELOPMENT (OFS)

In addition to responsibilities identified in 4.2 above, the Associate Director, OFSD, or designee is also responsible for:

4.3.1 Preparing and maintaining this QAAP.

4.4 COGNIZANT ASSOCIATE DIRECTOR, OCRWM

In addition to responsibilities identified in 4.2 above, the Cognizant Associate Director, OCRWM, or designee is also responsible for:

4.4.1 Acting as the OCRWM liaison with the organization(s) preparing reports and documents to be evaluated during the Readiness Review;

4.4.2 Determining the mechanism for tracking and closure of items incorporated on the Open Items List and Technical Holds List, as appropriate, developed during the Readiness Review;

4.4.3 Approving Readiness Review plans, Readiness Review Trees, and Action Items Lists; and

4.4.4 Approving Readiness Review recommendations and reports.



4.5 BRANCH CHIEFS, OCRWM

The Branch Chiefs, OCRWM, or designee are responsible for:

- 4.5.1 Recommending through the proper management chain, initiation of a Readiness Review to the Cognizant Associate Director, OCRWM.

4.6 READINESS REVIEW BOARD

The Readiness Review Board (RRB) is responsible for:

- 4.6.1 Reviewing the Readiness Review Plan, Readiness Review Tree, and Action Items List prepared by the Start-up Team prior to commencing a Readiness Review;
- 4.6.2 Reviewing, as appropriate, the Open Items List, Technical Holds List, and recommendations developed by the Start-up Team during the Readiness Review; and
- 4.6.3 Notifying the Cognizant Associate Director, OCRWM, regarding recommendations developed by the Start-up Team after the Readiness Review.

4.7 START-UP TEAM

The Start-up Team (ST) is responsible for:

- 4.7.1 Developing the Readiness Review Plan, Readiness Review Tree, and Action Items List prior to initiating the Readiness Review;
- 4.7.2 Developing the Open Items List and Technical Holds List, as appropriate, during a Readiness Review; and
- 4.7.3. Reporting progress and recommendations regarding a Readiness Review to the Readiness Review Board.

4.8 DIRECTOR, OFFICE OF QUALITY ASSURANCE (OQA)

The Director, OQA, or designee is responsible for:

- 4.8.1 Performing surveillance of Readiness Review, as required, to assure that the review conforms to the guidance in this QAAP; and
- 4.8.2 Providing resources and assistance in the Readiness Review, as requested.



5.0 GENERAL

- 5.1 Determination of the need for a Readiness Review shall be made by the Associate Director, OCRWM, who has functional responsibility for the design phase, process, or other activity to which the review is related.
- 5.2 In determining the scope of a Readiness Review, it must be decided if both a RRB and a separate ST are needed. On Readiness Review of smaller-segmented aspects of the design phase, process, or other activity, the RRB can also be the ST, thereby eliminating the need for a separate group. If only a RRB is appointed, the RRB shall perform both the ST and RRB functions defined in this procedure. (Attachment I provides administrative guidelines for conducting a Readiness Review.)
- 5.3 The Cognizant Associate Director, OCRWM, shall appoint members to the RRB and the ST, as applicable. The RRB and ST members may be OCRWM or support-contractor personnel, as deemed appropriate. Normally, the RRB and ST chairperson will be an OCRWM representative. The RRB and ST membership appointment(s) shall be documented.
- 5.4 The Cognizant Associate Director, OCRWM, shall develop, maintain, and provide specific qualification requirements for designated RRB and ST members. RRB and ST members shall be qualified by education and experience in the discipline subject(s) undergoing Readiness Review.
- 5.5 The Cognizant Associate Director, OCRWM, shall provide to designated RRB and ST members, written guidelines regarding reports and documents to be evaluated during the Readiness Review. Examples of reports and documents to be evaluated include, but are not limited to: results of applicable Management Assessments; Peer Reviews; Design Reviews; Technical Document Reviews; and related Readiness Reviews.
- 5.6 The Cognizant Associate Director, OCRWM, shall develop, maintain and provide to designated RRB and ST members, written instructions that establish or reference appropriate review and acceptance criteria that shall be used by RRB and ST members to perform the Readiness Review. Example references containing such review and acceptance criteria include, but are not limited to: applicable industry codes; standards; NUREGS; Federal Regulations; study plans; and Site Characterization Plan.
- 5.7 The mechanism for resolving and closing "Open" Items and Technical Holds, as appropriate, generated by the Readiness Review must be determined prior to dissolution of the RRB and ST. This mechanism shall be documented to assure tracking and proper closure of the "Open" Items and Technical Holds.



6.0 PROCEDURE

6.1 INITIATING READINESS REVIEW

- 6.1.1 The Branch Chiefs, OCRWM, shall recommend (through the proper management chain) initiation of a Readiness Review to the Cognizant Associate Director, OCRWM, when a design phase, process or other activity within the Associate Director's area of responsibility has progressed to the point where a Readiness Review may be appropriate.
- 6.1.2 Upon determination that a Readiness Review is required, the Cognizant Associate Director, OCRWM, shall define the scope of the review and appoint a RRB and ST. The ST shall prepare the Readiness Review Plan (Attachment II), Readiness Review Tree (Attachment III), and Action Items List (Attachment IV).
- 6.1.3 The Readiness Review Board shall review the Readiness Review Plan, Readiness Review Tree, and Action Items List developed by the ST. Any change(s) in the Readiness Review Plan, Readiness Review Tree, or Action Items List shall be documented by the RRB. The RRB shall advise the ST chairperson of any change(s) made.
- 6.1.4 The Cognizant Associate Director, OCRWM, shall approve, as appropriate, the Readiness Review Plan, Readiness Review Tree, and Action Items List prior to start of Readiness Review.

6.2 READINESS REVIEW

- 6.2.1 Subsequent to completion of 6.1.4 above, the ST shall use the approved Readiness Review Plan, Readiness Review Tree, and Action Items List, to assure that all identified items to be evaluated during the Readiness Review have been addressed and "Closed", as appropriate.
- 6.2.2 Subsequent to completion of 6.2.1 above, any action item remaining "Open" on the Action Items List shall be incorporated on an Open Items List (Attachment V) for tracking and closure.
- 6.2.3 Subsequent to completion of 6.2.2 above, items discovered during Readiness Review that could impact the schedule or have other significant consequences regarding the design phase, process, or other activity undergoing review shall be documented, as appropriate, on Technical Holds Sheets (Attachment VI) and incorporated on a Technical Holds List (Attachment VII) for tracking and closure.



6.2.4 Subsequent to completion of 6.2.3 above, the ST shall prepare a final report with recommendations regarding readiness to start or continue the design phase, process, or other activity undergoing Readiness Review and forward the report, Open-Items List, and Technical-Holds List to the RRB Chairperson.

6.3 ACTION SUBSEQUENT TO REVIEW

6.3.1 Subsequent to completion of 6.2.4 above, the RRB shall review and evaluate the final report of the ST to assure all identified items on the Action-Items List have been "Closed" or have been incorporated on an Open-Items List, as appropriate. In addition, the RRB shall assure that items discovered during Readiness Review that could impact the schedule or have other significant consequences regarding the design phase, process, or other activity undergoing review have been documented on Technical-Hold Sheets and incorporated on a Technical-Holds List, as appropriate.

6.3.2 The RRB chairperson shall issue a letter or memorandum to the Cognizant Associate Director, OCRWM, providing the ST's recommendation regarding readiness to start or continue the design phase, process, or other activity undergoing Readiness Review.

6.3.3 Subsequent to completion of 6.3.2 above, the Cognizant Associate Director, OCRWM, shall approve the recommendation to start or continue the design phase, process, or other activity undergoing Readiness Review and notify the Director, OCRWM, requesting authorization.

6.3.4 Subsequent to notification by the Cognizant Associate Director, OCRWM, the Director, OCRWM, shall authorize the start or continuation of the design phase, process, or other activity undergoing Readiness Review based on recommendations in the final report.

7.0 RECORDS

7.1 Documentation generated as a result of this procedure is maintained in accordance with requirements specified in QAAP 17.1, "Records Management". At a minimum, attachments II through VII are QA records.



8.0 ATTACHMENTS

- 8.1 Attachment I - OCRWM Administrative Guide for Readiness Review**
- 8.2 Attachment II - OCRWM Readiness Review Plan**
- 8.3 Attachment III - OCRWM Readiness Review Tree**
- 8.4 Attachment IV - OCRWM Readiness Review Action Items List**
- 8.5 Attachment V - OCRWM Readiness Review Open Items List**
- 8.6 Attachment VI - OCRWM Readiness Review Technical Holds Sheet**
- 8.7 Attachment VII - OCRWM Readiness Review Technical Holds List**
- 8.8 Attachment VIII - QAAP Flowchart**



**ATTACHMENT I
OCRWM ADMINISTRATIVE GUIDE FOR READINESS REVIEWS**

I INTRODUCTION

This guide is written to assure compliance with the current requirements of the OCRWM QAR and QAPD that relate to PROGRAM Readiness Reviews. These requirements apply to the planning and accomplishment of the design phase, process, or other activity under suitably controlled conditions, including assurance that prerequisites for accomplishing the given design phase, process, or other activity have been satisfied.

The purpose of this document is to provide sufficient information to chairpersons of Readiness Review Boards and Start-up Teams to allow them to effectively advise Board and Team members, and make optimum contributions to Readiness Reviews.

II. READINESS REVIEW PLAN

The Readiness Review Plan shall be prepared by the Start-up Team prior to starting the Readiness Review Tree. The Plan shall contain an independent, logical, and systematic approach to achieve the specific goal outlined by the Cognizant Associate Director, OCRWM. The Plan shall contain a list of all items (see Attachment II for examples) to be addressed during the Readiness Review.

The Plan should include the following points, as appropriate.

- Introduction and overview
- Scope and area(s) to be covered
- Objectives to be determined
- Reference procedures to be used
- Actual readiness-review actions and description of how the Readiness Review will be conducted
- Readiness-Review guidelines
- Readiness-Review assumptions
- Readiness-Review schedule, indicating significant milestones, including due dates of draft(s) and final report(s).

III. READINESS REVIEW TREE

The Readiness Review Tree (See Attachment III for example) shall be developed by the Start-up Team and approved by the Readiness Review Board prior to starting a Readiness Review. Where possible, the Tree should be developed using previously approved Trees as guides to assure comprehension by others and to aid coordination of the Readiness Review.



ATTACHMENT I cont'd
OCRWM ADMINISTRATIVE GUIDE FOR READINESS REVIEWS

The Tree should be a logical and systematic analysis of factors that are necessary and sufficient for the Readiness Review. The lowest elements on the Tree are starting points for further downward expansion resulting in a level of detail determined by the characteristics and complexity of the design phase, process, or other activity undergoing review.

IV. ACTION ITEMS LIST

Subsequent to Readiness Review Board review of the Readiness Review Plan and Readiness Review Tree, the Start-up Team shall develop a comprehensive Action Items List (See Attachment IV). The Action Items list shall also be submitted for Readiness Review Board review. Items shown on the Action Items List shall be used to track progress and prevent oversights during the Readiness Review.

V. OPEN ITEMS LIST

During Readiness Review, action items not yet completed or otherwise deficient shall be incorporated on an Open Items list (See Attachment V) by the Start-up Team. The Open Items list shall:

- Reference "Open" or deficient items by Action Items List number.
- Define action(s) required to close "Open" or deficient items
- Assign action responsibility to close "Open" or deficient items
- Estimate completion date(s) for "Open" or deficient items.

VI. TECHNICAL HOLDS SHEET

Any item discovered during Readiness Review that could impact the schedule or have other significant consequences regarding the design phase, process, or other activity undergoing Readiness Review shall be documented on a Technical Holds Sheet (See Attachment VI). These items are considered so vital to the activity undergoing review that they must be "Closed" prior to the start or continuation of the design phase, process, or other activity undergoing review or must be completed at a specified juncture during performance of the design phase, process, or other activity.

Conditional approval to start or continue the design phase, process, or other activity undergoing Readiness Review may be granted when an acceptable "work-around" method is approved for an item on a Technical Holds Sheet. This method shall be documented on the Technical Holds Sheet as a temporary corrective action.

VII. TECHNICAL HOLDS LIST

This list compiles information contained on Technical Holds Sheets relative to Review that could impact the schedule or have other significant consequences regarding the design phase, process, or other activity undergoing review (See Attachment VII).



ATTACHMENT II
OCRWM READINESS REVIEW PLAN

EXAMPLES OF POSSIBLE READINESS REVIEW ACTION ITEMS

1. Do organizational plans exist?
2. Do site management plans exist?
3. Do site activity plans (mobilization, characterization, investigations, etc) exist?
4. Are there plans that address staffing/personnel?
5. Are there plans to address questions from the public?
6. Has OCRWM approved the plans?
7. Has training been provided?
8. Has policy been established by OCRWM?
9. Are contracts in place?
10. Are scopes of work for subcontractors clear, concise, and up-to-date?
11. Have technical specifications been developed and approved?
12. Have Quality Assurance specifications been developed and approved?
13. Have the quality assurance programmatic requirements, e.g., 10 CFR 60, 10 CFR 50, and NQA-1, been defined?
14. Have the quality assurance programmatic requirements, e.g., 10 CFR 60, 10 CFR 50, and NQA-1, been defined for prime contractors?
15. Have quality levels, inspection points, hold points and QA reviews been established, reviewed and approved?
16. Have the quality assurance/quality control interfaces been defined and documented?
17. Are documents in place to assure that all applicable regulatory requirements have been addressed including local, state, or federal permits?
18. Has the proper level of authority been delegated to the field?



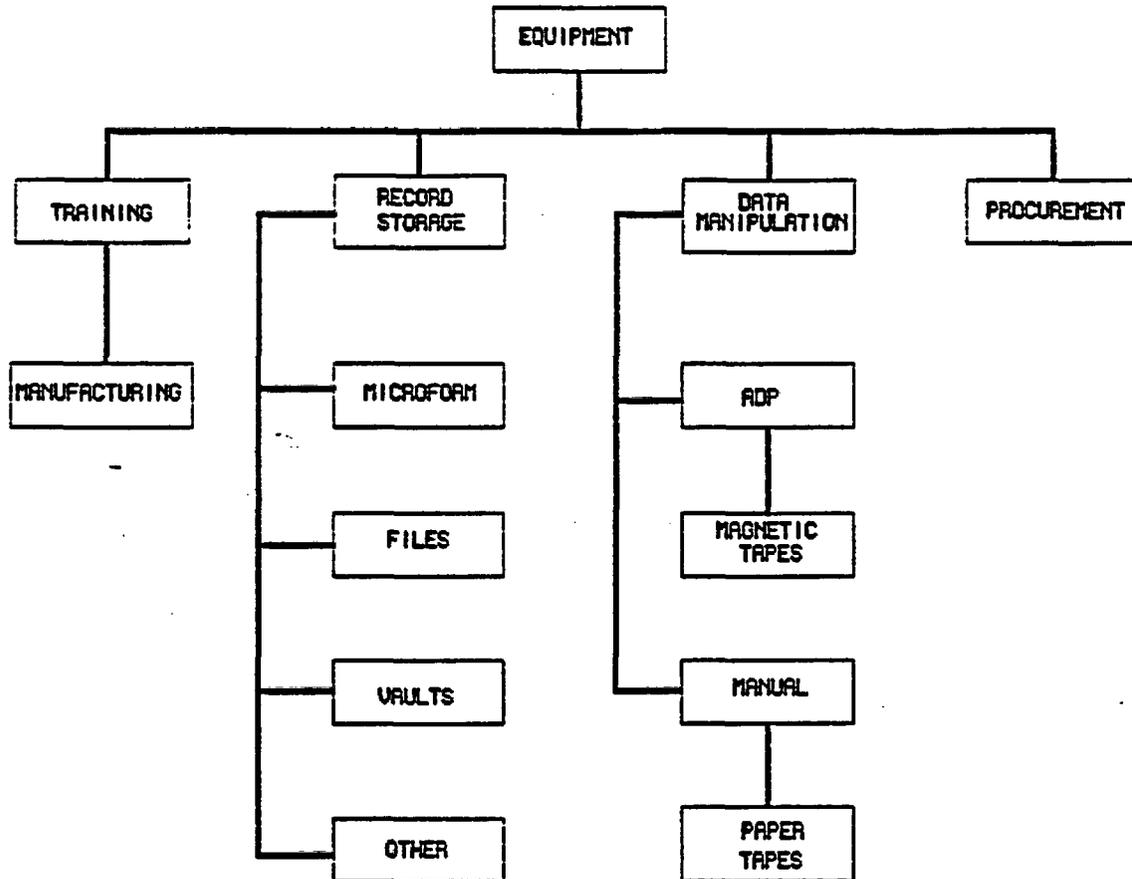
**ATTACHMENT II cont'd
OCRWM READINESS REVIEW PLAN**

19. Have all physical interfaces been established?
20. Are logical interfaces between network activities established?
21. Do implementing procedures exist?
22. Do change control procedures exist for plans and procedures?
23. Have procedures been approved by OCRWM?
24. Has equipment been procured?
25. Have the facilities been acquired?
26. Are the facilities operational?
27. Are funds available to do the work?
28. Has handling of data from field activities been addressed?
29. Has handling of information/records been addressed?
30. Have safety and health measures been identified?
31. Have security requirements been addressed?
32. Have security measures related to computer access been addressed?



ATTACHMENT III
(Example)

OCRWM READINESS REVIEW TREE





ATTACHMENT V (Typical)

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

SHEET ____ OF ____
WBS NO. _____

READINESS REVIEW OPEN-ITEMS LIST

OPEN ITEM NO.	PREREQUISITE I.D.	PREREQUISITE ASSIGNEE	ITEM/DEFICIENCY	ACTIVITY REQUIRED	ESTIMATED COMPLETION DATE	ACTIVITY ASSIGNED

REV. 1/89



ATTACHMENT VI (Typical)

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

SHEET ____ OF ____
WBS NO. _____

READINESS REVIEW TECHNICAL-HOLD SHEET

READINESS REVIEW

ACTION ITEM

TECHNICAL HOLD NO.

PREREQUISITE DESCRIPTION

DESCRIPTION OF TECHNICAL HOLD

DESCRIPTION OF CORRECTIVE ACTION (Explain corrective action, potential impact, responsible organization.)

PREREQUISITE ASSIGNEE

NETWORK NO.

Name

Date

APPROVALS

STARTUP TEAM

REVIEW BOARD

NAME AND FUNCTION

DATE

NAME AND FUNCTION

DATE

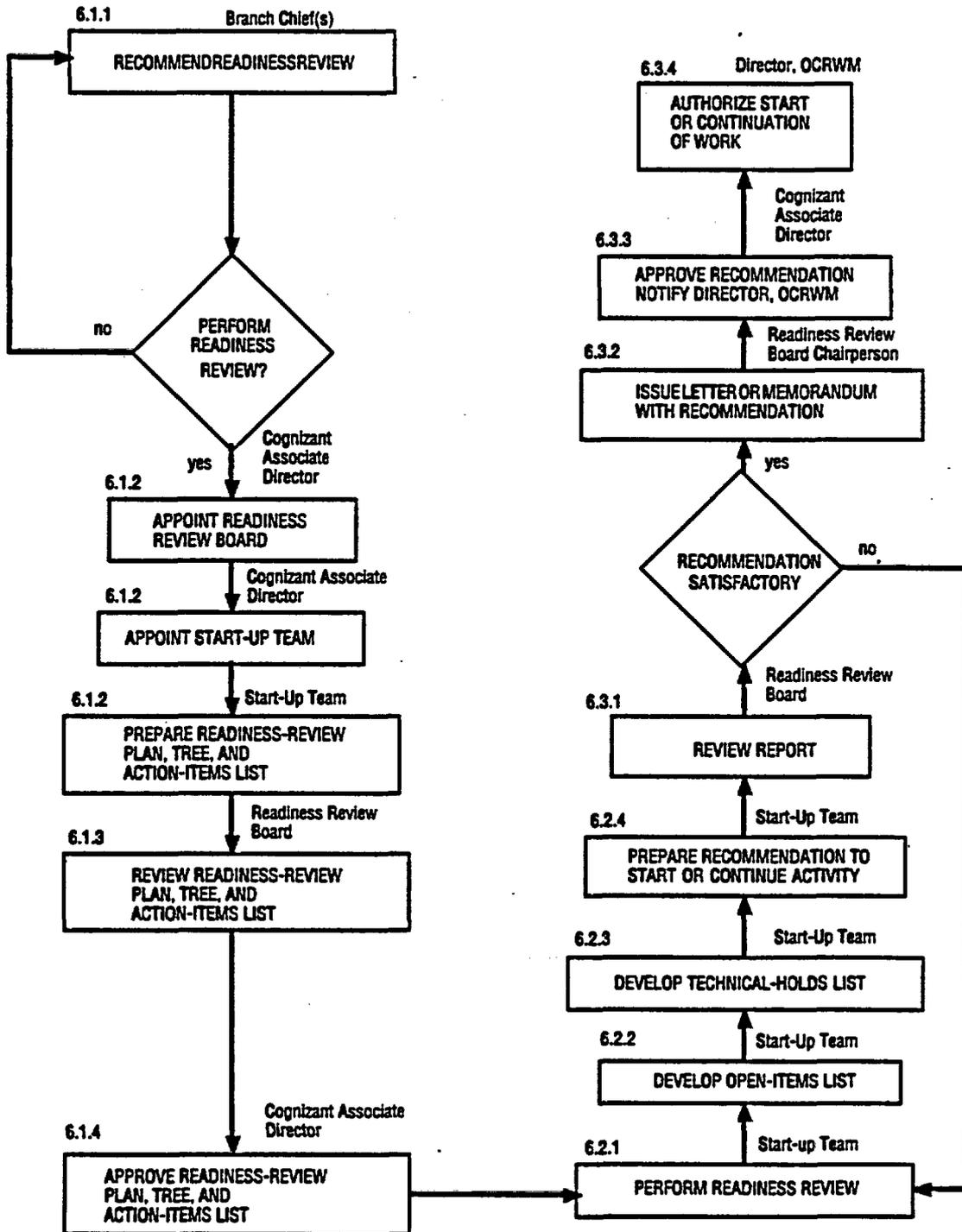
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REV. 1/89



ATTACHMENT VIII

READINESS REVIEW





OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
QUALITY ASSURANCE ADMINISTRATIVE PROCEDURE

TITLE: TECHNICAL DOCUMENT REVIEW

Procedure No.: QAAP 3.1	Revision: 0	Date: 3/27/89	Page: 1 of 10
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Director, OCRWM <i>Paul Con</i>	Date: 2/10/89	Director, OQA <i>John B. Corbett</i>	Date: 2/7/89
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1.0 PURPOSE

This procedure establishes the Office of Civilian Radioactive Waste Management (OCRWM) responsibilities and methods for the review, acceptance or approval, and release of technical documents.

2.0 SCOPE

This procedure addresses technical documents prepared by OCRWM, PROGRAM Participants, and OCRWM managed contractors that are submitted for review, acceptance, and release by OCRWM.

3.0 REFERENCES AND DEFINITIONS

3.1 REFERENCES

3.1.1 "Quality Assurance Requirements for the Civilian Radioactive Waste Management Program", (QAR)-DOE/RW-0214, 1988.

3.1.2 "Quality Assurance Program Description for the Civilian Radioactive Waste Management Program", (QAPD)-DOE/RW-0215, 1988.

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 Acceptance - This term is used to indicate that a technical document is suitable for its intended use.

3.2.3 Cognizant Associate Director, OCRWM - The Associate Director, OCRWM, responsible for review, acceptance, and release of a specific technical document. Generally, this will be the Associate Director, OCRWM, responsible for the functional area that is the subject of the technical document.

3.2.4 Major Revision - Changes to a document that affect a process described in the document, the basic content, or a change in concept.



- 3.2.5 Mandatory Comment - Comment that the reviewer has determined requires resolution prior to document acceptance. These comments may include identified deviations from existing approved OCRWM policy, quality assurance requirements, programmatic or management requirements, technical positions, or any other criteria applicable to the document.
- 3.2.6 Technical Document - A document that specifies scientific or engineering requirements, presents scientific or engineering information or data; or describes scientific or engineering processes.
- 3.2.7 Technical Review - A documented review by individuals with sufficient technical knowledge of the material being reviewed to be able to render a decision on its adequacy. Technical reviews are reserved for documents that contain material that is within the current state-of-the-art and is based on accepted standards, criteria, principals and practices.

4.0 RESPONSIBILITIES

4.1 DIRECTOR, OCRWM

The Director, OCRWM, or designee has the overall responsibility for:

- 4.1.1 Assuring that OCRWM implements the Technical Document Review process as described in this procedure.

4.2 ASSOCIATE DIRECTORS, OCRWM

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

- 4.2.1 Reviewing PROGRAM schedules and plans in each of their areas of technical cognizance to determine what technical documents will be reviewed by OCRWM.

4.3 COGNIZANT ASSOCIATE DIRECTOR, OCRWM

The Cognizant Associate Director, OCRWM, or designee is responsible for:

- 4.3.1 Identifying specific documents requiring technical document review and accepting these documents for subsequent release;
- 4.3.2 Designating individual(s) or organization(s) within his own functional area(s) of responsibility as reviewer(s) and arranging for such support;



4.3.3 Identifying the need for review by other organizations and arranging through other Associate Directors for such outside support as may be needed; and

4.3.4 Coordinating, controlling, distributing, and obtaining resolution of all comments.

4.4 ASSOCIATE DIRECTOR, OFFICE OF FACILITIES SITING AND DEVELOPMENT (OFS)

In addition to the responsibilities outlined in 4.2 above, the Associate Director, OFSD, or designee is also responsible for:

4.4.1 Preparing and maintaining this QAAP.

4.5 DIRECTOR, OFFICE OF QUALITY ASSURANCE (OQA)

The Director, OQA, or designee is responsible for:

4.5.1 Reviewing and commenting on technical documents submitted for review to assure that quality requirements specified were satisfied.

4.5.2 Verifying that OCRWM organizations review and accept technical documents, within their areas of responsibility and assuring that the reviews are conducted in accordance with this procedure.

5.0 GENERAL

5.1 Technical documents subject to review by OCRWM may be generated by OCRWM, PROGRAM Participants, and OCRWM-managed contractors. Review, acceptance, and release of technical documents shall be conducted in accordance with this procedure.

5.2 Types of technical documents subject to review by OCRWM may include, but are not limited to, system requirements documents, design basis documents, performance assessments, study plans, technical specifications, technical reports, test reports, test plans, design reports, and results of analyses.

5.3 Technical documents subject to review by OCRWM may also require Design Review or Peer Review.

5.4 Technical document review status shall be maintained by the Cognizant Associate Director, OCRWM, who shall also designate the document(s) for either Design Review or Peer Review, as appropriate.



- 5.5 The aggregate expertise of the designated reviewer(s) should encompass the subject area of the technical document. The Cognizant Associate Director, OCRWM, shall select the reviewer(s) from OCRWM, PROGRAM Participants, and OCRWM-managed contractors, as needed, to cover the subject matter of the document. The reviewer(s) shall not have directly participated in the development of the technical document.
- 5.6 The Cognizant Associate Director, OCRWM, shall document the rationale for selection of the specified reviewer(s). This rationale shall address the qualifications of the reviewer(s) relative to the review subject.
- 5.7 The Cognizant Associate Director, OCRWM, shall develop, maintain and provide to the designated reviewer(s) written instructions that establish or reference appropriate review and acceptance criteria which the reviewer(s) shall use to evaluate a document during a technical review. Documents containing such review and acceptance criteria include, but are not limited to, PROGRAM and site specific requirements documents, industry codes, standards, NUREGS, Federal Regulations, and interfacing technical documents.
- 5.8 Once the review and acceptance criteria have been established, the designated reviewer(s) shall provide comments.
- 5.9 Technical document reviewer(s) shall document comments or "No Comments" on a Document Review Record (DRR). The DRR is comprised of a Document Review Record (Attachment I) and as many Document Review Record Continuation Sheets (Attachment II) as necessary.
- 5.10 Resolution of comments shall be accomplished between the organization that prepared the technical document and the reviewer(s). In the event that the reviewer(s) is unavailable for resolution, the Cognizant Associate Director, OCRWM, shall designate a qualified replacement to resolve the comments.
- 5.11 The resolution of comments shall be documented by the organization that prepared the technical document, adjacent to the reviewer(s) comments on the same DRR on which the comments appear.

6.0 PROCEDURE

6.1 PLANNING TECHNICAL DOCUMENT REVIEWS

- 6.1.1 The Associate Directors, OCRWM, shall review PROGRAM schedules and plans in each of their areas of technical cognizance at least semi-annually to determine what technical documents will be reviewed by OCRWM.



6.1.2 If technical documents are received by OCRWM, other than those identified by 6.1.1, the Associate Director(s) shall determine whether or not a technical document review is required, on a case-by-case basis.

6.1.3 Subsequent to receipt of technical documents for review by OCRWM in accordance with Sections 6.1.1 and 6.1.2 above, the Associate Director(s), OCRWM shall determine if a technical document shall also undergo Design Review and/or Peer Review, on a case-by-case basis.

6.2 INITIATING TECHNICAL DOCUMENT REVIEW

6.2.1 Subsequent to 6.1.1 and 6.1.2 above, the Cognizant Associate Director, OCRWM, shall identify the applicable review and acceptance criteria in written instructions and designate the individual(s) or organization(s) required for review.

6.2.2 The technical document shall be forwarded to the reviewer(s), along with a memorandum requesting technical document review, written instructions containing the review and acceptance criteria, and a DRR.

6.3 TECHNICAL DOCUMENT REVIEW

6.3.1 Using guidance provided in the memorandum requesting technical document review and the instructions containing the review and acceptance criteria, the designated reviewer(s) shall conduct the review. Mandatory comments regarding the technical documents shall be documented on a DRR.

6.3.2 If the designated reviewer(s) delegates additional staff within the reviewer's organization to perform the review, it shall be the responsibility of the designated reviewer(s) to consolidate comments onto a single DRR. This consolidation shall include resolving any conflicting comments generated by the reviewer's staff.

6.3.3 Upon completion of the review, the designated reviewer(s) shall sign and date the DRR, and return the DRR and technical document to the Cognizant Associate Director, OCRWM.

6.4 ACTION SUBSEQUENT TO REVIEW

6.4.1 Following receipt of the technical document and DRR from the reviewer(s), the Cognizant Associate Director, OCRWM, shall review the DRR to determine the extent of the comments.



- 6.4.2 If no comments exist, the Cognizant Associate Director, OCRWM, shall prepare an acceptance letter, sign the technical document, if appropriate, and take action to release the document per Section 6.6.
- 6.4.3 If mandatory comments exist, the Cognizant Associate Director, OCRWM, shall transmit the technical document and DRR to the organization that prepared the technical document, for comment resolution.

6.5 COMMENT RESOLUTION

- 6.5.1 The comment response/resolution is documented on the same DRR(s) on which the comments appear.
- 6.5.2 Comment resolution may be accomplished via a comment resolution meeting or a comparable format that produces an acceptable end result that is documented.
- 6.5.3 Once an acceptable resolution is reached, the commentor or designated representative and the document preparer indicate acceptable resolution by initialing and dating the space provided on the DRR adjacent to the comment response.
- 6.5.4 Following the completion of the resolution of comments on the DRR, the document preparer revises the document, as necessary, forwards the completed document along with the completed DRR package, to the Cognizant Associate Director, OCRWM, for his action in accordance with section 6.4.
- 6.5.5 If comments cannot be resolved to the satisfaction of the reviewing organization and the document preparer organization, they shall be brought to the attention of the appropriate management level until resolution is reached.

6.6 DOCUMENT ISSUANCE

- 6.6.1 Subsequent to document acceptance the Cognizant Associate Director, OCRWM, shall provide for release of the document, which may consist of any of the following actions:
- (a) Transmitting a PROGRAM Participant prepared document to the PROGRAM Participant for release in accordance with their procedures;
 - (b) Releasing an OCRWM prepared document to the OCRWM document control organization for controlled distribution in accordance with QAAP 6.1, "Controlled Documents"; or
 - (c) Releasing an OCRWM prepared document for publication.



6.6.2 Baseline documents are approved for release in accordance with QAAP 3.4, "Configuration Management".

7.0 RECORDS

7.1 Documentation generated as a result of this procedure is collected and maintained in accordance with the requirements specified in QAAP 17.1, "Records Management". At a minimum, attachments I and II of this procedure are 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 Flowchart



ATTACHMENT I (Typical)

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

SHEET 1 OF _____
WBS NO. _____

DOCUMENT REVIEW RECORD

DOCUMENT NAME
REVISION
DATE

REVIEW INSTRUCTIONS/ACCEPTANCE CRITERIA

REVIEW INSTRUCTIONS/CRITERIA PREPARED BY

Signature

Date

REVIEW INSTRUCTIONS/CRITERIA APPROVED BY

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

Signature

Date

RESPONSE BY

Signature

Date

REV. 1/89



**OCRWM QA
ADMINISTRATIVE
PROCEDURE**

Procedure No.:

QAAP 3.1

Revision:

0

Page:

9 of 10

ATTACHMENT II (Typical)

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

SHEET ____ OF ____
WBS NO. _____

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

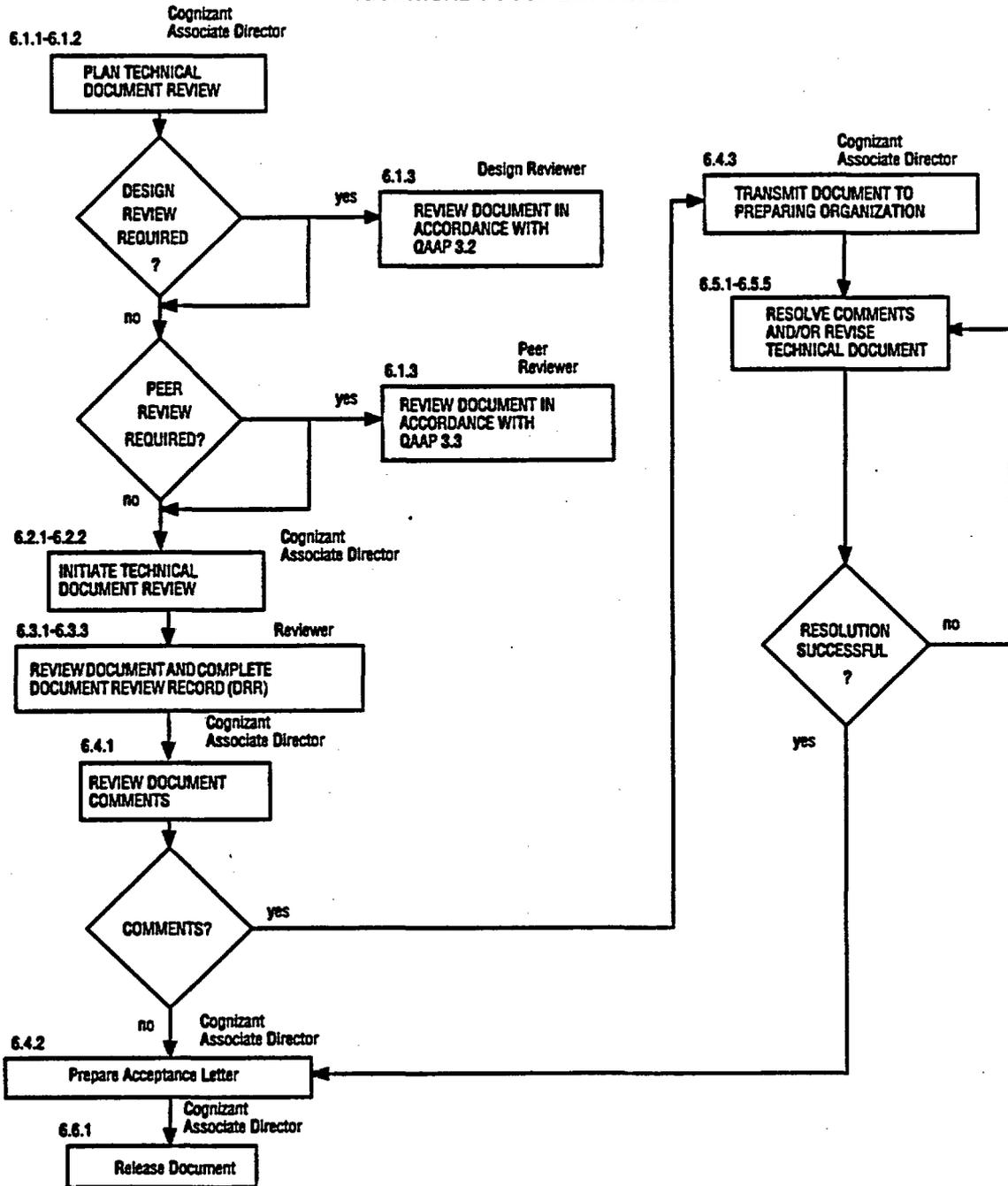
Date

REV. 1/89



ATTACHMENT III

TECHNICAL DOCUMENT REVIEW





OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
QUALITY ASSURANCE ADMINISTRATIVE PROCEDURE

TITLE: DESIGN REVIEW

Procedure No.: QAAP 3.2	Revision: 0	Date: 3/27/89	Page: 1 of 11
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Director, OCRWM <i>[Signature]</i>	Date: 2/10/89	Director, OQA <i>[Signature]</i>	Date: 2/7/89
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1.0 PURPOSE

This procedure establishes responsibilities and prescribes methods for conducting design reviews by the Office of Civilian Radioactive Waste Management (OCRWM) for designs that have been developed by OCRWM PROGRAM participants. Design reviews are conducted to verify technical adequacy of completed designs and to gauge the effectiveness of PROGRAM participant design-control measures. The procedure also provides for in-process design reviews and OCRWM participation in design reviews sponsored by PROGRAM participants.

2.0 SCOPE

This procedure applies to OCRWM management, staff, and support personnel involved in planning, performing, documenting, and reporting results of design reviews. Acceptance by the design-review team does not constitute OCRWM approval of a design.

3.0 REFERENCES AND DEFINITIONS

3.1 REFERENCES

3.1.1 "Quality Assurance Requirements for the Civilian Radioactive Waste Management Program", (QAR)-DOE/RW-0214, 1988.

3.1.2 "Quality Assurance Program Description for the Civilian Radioactive Waste Management Program", (QAPD)-DOE/RW-0215, 1988.

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 Critical Design Review - An in-depth technical review of a completed design phase to ensure that all technical requirements are met. A critical design review satisfies the requirements of reference 3.1.1 for design verification.



- 3.2.3 Design Review - Refers to either a Critical Design Review or a Milestone Design Review, as defined herein. OCRWM design reviews are referred to as "Second-level Design Reviews" in reference 3.1.2.
- 3.2.4 Design Verification - The act of determining and documenting that the design is correct and conforms to all specified requirements. The Critical Design Review is an accepted means of accomplishing design verification.
- 3.2.5 Milestone Design Review - Review conducted periodically during the design process to ascertain the status of technical progress, cost, schedule, and attainment of project objectives. A Milestone Design Review does not meet reference 3.1.1 requirements for design verification unless the requirements for a Critical Design Review are met.
- 3.2.6 Participant Design Review - Review sponsored by a PROGRAM participant in which OCRWM representatives participate.

4.0 RESPONSIBILITIES

4.1 ASSOCIATE DIRECTORS, OCRWM

The Associate Directors, OCRWM, or designee(s) are responsible for:

- 4.1.1 Determining what designs are subject to the design review process;
- 4.1.2 Scheduling and monitoring design reviews for designs developed within their areas of responsibility;
- 4.1.3 Assigning design-review leaders; and
- 4.1.4 Providing resources for implementing OCRWM design reviews.

4.2 ASSOCIATE DIRECTOR, OFFICE OF FACILITIES SITING AND DEVELOPMENT (OFSD)

In addition to responsibilities outlined in 4.1 above, the Associate Director, OFSD, or designee is also responsible for:

- 4.2.1 Preparing and maintaining this QAAP; and
- 4.2.2 Ensuring effective implementation of the OCRWM design-review program.



4.3 DIRECTOR, OFFICE OF QUALITY ASSURANCE (OQA)

The Director, OQA, or designee is responsible for:

- 4.3.1 Providing resources and assistance in the design-review process, as requested.

5.0 GENERAL

OCRWM conducts design reviews to assess the status and progress of design activities (Milestone Design Reviews), to provide an additional level of independent design verification to particular designs (Critical Design Review), or both.

5.1 CRITICAL DESIGN REVIEW

5.1.1 Critical design reviews are performed by the OCRWM to provide additional assurance that designs meet all technical requirements, and that the responsible design organization's design-control program is performing satisfactorily. These detailed technical reviews cover all aspects of the design, including interfaces with other structures, systems, and components, and meet reference 3.1.1 requirements for design verification.

5.1.2 Designs subject to OCRWM critical design reviews will have been previously design verified in accordance with reference 3.1.1, by the assigned design organization. Primary responsibility for design verification remains with the assigned design organization.

5.2 MILESTONE DESIGN REVIEW

5.2.1 Milestone design reviews are performed by the OCRWM at milestones in the design process primarily to assess the status of the design effort relative to technical progress, cost, and schedule, and to provide assurance that specified requirements are being fulfilled. Milestone design reviews are typically conducted at established percent-completions and at the end of each design phase.

5.2.2 Unless conducted in accordance with the requirements for a critical design review for a 100-percent complete-design phase, the milestone design review does not fulfill the needs of reference 3.1.1 for design verification.

5.3 PARTICIPANT DESIGN REVIEWS

5.3.1 The OCRWM may elect to participate in a design review sponsored by a PROGRAM participant. In such cases, the OCRWM representative(s) will perform in accordance with the applicable participant's procedures.



5.4 DESIGN REVIEW TEAM MEMBERS

The following requirements apply to Critical Design Reviews:

5.4.1 The team members for Critical Design Reviews shall have demonstrated competence in their respective disciplines at least equivalent to that required to perform the design. Documentation of competence should reference degrees, professional certifications and affiliations, and summarize relevant experience. A statement or record of resume verification should be included.

5.4.2 The team members for Critical Design Reviews shall not have performed the design, specified a singular design approach, nor ruled out certain design considerations.

5.5 ALTERNATE CALCULATIONS

5.5.1 Alternate calculations, wherein analyses are conducted by alternate methods to verify correctness of the original analyses, may be used to support the design review.

5.6 QUALIFICATION TESTS

5.6.1 Where the original design verification was based partially upon qualification tests in accordance with reference 3.1.1, review of qualification test documentation may be used in support of the OCRWM design review.

5.7 EXTENT OF DESIGN REVIEW

5.7.1 The rigor and detail required of the design review is a function of the importance to radiological safety or waste isolation, the complexity, degree of standardization, the state-of-the-art, the degree of departure from accepted and proven engineering practices, and the similarity with previously proven designs of the engineered system, structure, or component.

6.0 PROCEDURE

6.1 SCHEDULING

6.1.1 Each OCRWM Associate Director with responsibilities for design shall review program schedules at least semi-annually and determine what designs will be reviewed by the OCRWM in their area of responsibility.



6.1.2 For each design review scheduled, the cognizant OCRWM Associate Director shall determine what type of design review will be conducted, i.e., Milestone Design Review, OCRWM participation in PROGRAM participant-sponsored design review, or Critical Design Review. Considerations for this determination should include those concepts identified in 5.7.1, above.

6.1.3 The cognizant OCRWM Associate Director shall assign a design-review leader for each design review and provide other resources, as needed.

Note: The following instructions for planning, preparation, implementation and reporting are mandatory for Critical Design Reviews, but may be selectively applied for other design reviews.

6.2 PLANNING

6.2.1 The design review leader shall develop a design review plan. The plan shall document the following aspects of the design review:

- a) The exact scope of the design review. Record the specific system(s), structure(s), or component(s) that will be the subject of the review;
- b) Identify all functionally and physically interfacing systems, structures, and components;
- c) Identify all design output documents subject to review;
- d) Determine all disciplines that might affect or be affected by the system(s), structure(s), or component(s) subject to review. Consider operations, maintenance, and construction experts; as well as the design, radiological-safety, and materials-engineering disciplines;
- (e) Establish reviewer qualification requirements, considering the complexity and state-of-the-art of the design; (see section 5.4) and,
- (f) Identify all information, data, and analytical tools that provided input to or support to the design. Consider design requirements documents, safety analyses documents, calculations, computer code and hardware documentation, background information supporting advanced or state-of-the-art engineering techniques, codes, standards, and interface control documents.



- 6.2.2 The design review leader shall contact the responsible design organization and establish a schedule and location for the design review. This information shall be included in the design review plan.
- 6.2.3 The cognizant Associate Director shall approve the design review plan.
- 6.2.4 The design review leader shall assemble the review team from OCRWM, participant, and/or external resources. Documentation of all team members' qualifications shall be obtained, and verified as necessary, in accordance with QAAP 2.2, "Personnel Qualification". The reviewers' independence, per Section 5.4, shall be documented.

6.3 PREPARATION

- 6.3.1 The design review leader shall assemble the review team to prepare for the review. Preparation shall include the following:
- a) Familiarization with the scope, schedule and plan for the design review, and the technical requirements of the particular design. Copies of applicable requirements documents shall be provided to the design-review team members;
 - b) Assurance that the reviewers have been trained to this QAAP;
 - c) Familiarization with the subject system(s), structure(s) or component(s) designs. Design output, such as drawings and specifications, should be provided if available; and
 - d) Assignment of responsibility to team members for areas of the design and preparation of checklists or instructions to be used in the review, as appropriate. The checklists or instructions should address specific design inputs contained in the requirements documents. Attachment I provides subjects to be considered in the review.
- 6.3.2 The design review leader shall review and approve checklists and/or instructions developed by team members.
- 6.3.3 The design review leader should arrange for the responsible design organization to present an overview of the design and design processes, and to make available the cognizant engineers and all information supporting the design.



6.3.4 The accomplishment of the preparation phase shall be documented prior to execution of the design review.

6.4 EXECUTION

6.4.1 The design review team should receive an overview of the design and design processes from the cognizant design organization.

6.4.2 The design review team shall conduct an in-depth review in the assigned areas according to the design review plan and the checklists or instructions that have been developed. Subject items 1 through 6 of Attachment I must be addressed.

6.4.3 If any part of the design uses unproven or beyond state-of-the-art approaches, the design-review leader shall recommend to the cognizant Associate Director that a peer review be performed for that aspect, in accordance with QAAP 3.3, "Peer Review". The recommendation and resulting actions shall be documented in the design review report.

6.4.4 The design review team members shall document review comments and comment resolutions in accordance with QAAP 3.1, "Technical Document Review" and resolve all comments with the responsible design organization. The review team member and responsible design engineer shall sign the comment sheets upon resolution of the comments.

6.4.5 Where a significant difference of opinion prevents consensus within the design review team or resolution between the design review team and responsible design organization, the design review leader shall ensure that the difference is elevated for decision to the appropriate management level until resolution is reached.

6.4.6 If a significant deficiency in a previously verified design is discovered, the adequacy of the design-control/design-verification program is in doubt. In such cases, the design review leader shall initiate corrective action in accordance with QAAP 16.1, "Corrective Action".

6.4.7 Any issues that remain open subsequent to completion of the design review shall be monitored and tracked by the design review leader to ensure resolution. The design review leader shall report the status of open issues to the cognizant Associate Director monthly. The cognizant Associate Director shall monitor the status of all design reviews through closure.



6.5 REPORTING

6.5.1 The design review leader, with input from team members, shall prepare a report of the design review results. The report shall describe the following:

- (a) Scope of the design review, including specific systems, structures, and components;
- (b) Identify the review team members and design organization personnel contacted during the review;
- (c) Summarize results of the review;
- (d) Any significant problems encountered or deficiencies identified and the resolutions, including corrective actions initiated;
- (e) Identify any open issues and actions to be taken; and,
- (f) Present any review team recommendation, such as the need for a peer review on some unique aspect of a design.

6.5.2 The report shall be signed by the design review team leader and forwarded to the cognizant Associate Director, Division Director, and the responsible Branch Chief.

6.5.3 The cognizant Associate Director shall forward a copy of the report to the design organization.

6.5.4 A package consisting of the design review plan, checklists or procedures, comment and resolution records, reviewer qualification and verification records, alternate calculations or other records of design verification, and the design review report shall be submitted to the OCRWM records management system by the review team leader. Documentation regarding open issues and closure thereof shall be added to the package as it is developed.

7.0 RECORDS

Documentation generated as a result of this procedure is collected and maintained in accordance with the requirements specified in QAAP 17.1 "Records Management".

8.0 ATTACHMENTS

8.1 Attachment I - Design Review Subjects

8.2 Attachment II - QAAP Flowchart



**ATTACHMENT I (Example)
DESIGN REVIEW SUBJECTS**

This is a list of subject areas that should be considered in the design review. This is not intended to be a comprehensive list applicable to all designs. Critical Design Reviews must address items 1 through 6.

- 1) Were the design inputs correctly selected?
- 2) Are assumptions necessary to perform the design activity adequately described and reasonable? Where necessary, are the assumptions identified for subsequent reverifications when the detailed design activities are completed?
- 3) Was an appropriate design method used?
- 4) Were the design inputs correctly incorporated into the design?
- 5) Is the design output reasonable compared to design inputs?
- 6) Are the necessary design input and verification requirements for interfacing organizations specified in the design documents or in supporting procedures or instructions?
- 7) Have all computer codes used in the design analysis been validated, and verified on the computer systems used in design?
- 8) Were design, design verification, and peer review (as applicable) procedures correctly implemented?
- 9) Have qualified and certified materials and parts been specified where appropriate?
- 10) Is the design specified producible by conventional means?
- 11) Does the design adequately consider maintainability, operability, reliability and radiological safety?
- 12) Are the appropriate quality and quality assurance requirements specified?
- 13) Are the applicable codes, standards, and regulatory requirements including issue and addenda properly identified and are their requirements for design met?
- 14) Have applicable construction and operating experience been considered?
- 15) Have the design interface requirements been satisfied?



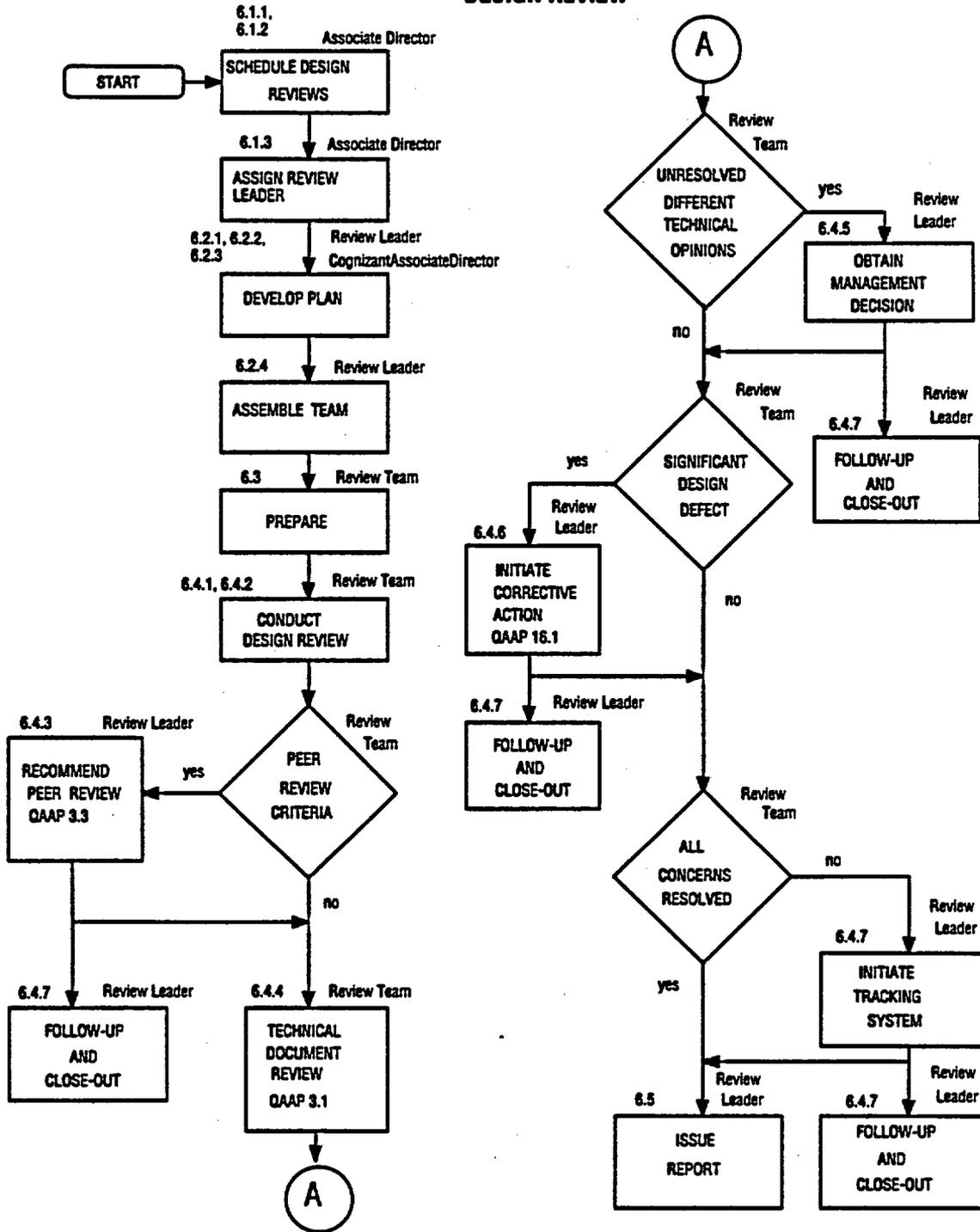
ATTACHMENT I cont'd

- 16) Are the specified parts, equipment, and processes suitable for the required application?
- 17) Are the specified materials compatible with each other and the design environmental conditions to which the material will be exposed?
- 18) Have adequate maintenance features and requirements been specified?
- 19) Are accessibility and other design provisions adequate for performance of needed maintenance, in-service inspection, and repair?
- 20) Has the design properly considered radiation exposure to the public and plant personnel?
- 21) Are the acceptance criteria incorporated in the design documents sufficiently detailed and specific to allow verification that design requirements have been satisfactorily accomplished?
- 22) Have adequate pre-operational and subsequent periodic test requirements been appropriately specified?
- 23) Are adequate handling, storage, cleaning and shipping requirements specified?
- 24) Are adequate identification requirements for control of items and materials specified?
- 25) Is the design cost effective (considering DOE and regulatory restraints)?
- 26) Are requirements for record preparation, submitted review, and approval, retention, adequately specified?



ATTACHMENT II

DESIGN REVIEW





OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
QUALITY ASSURANCE ADMINISTRATIVE PROCEDURE

TITLE: PEER REVIEW

Procedure No.: QAAP 3.37	Revision: 0	Date: 3/27/89	Page: 1 of 10
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Director, OCRWM <i>[Signature]</i>	Date: 2/10/89	Director, OQA <i>[Signature]</i>	Date: 2/7/89
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1.0 PURPOSE

This procedure establishes the responsibilities and methods for planning, conducting, documenting, and administering peer reviews performed by or on behalf of the Office of Civilian Radioactive Waste Management (OCRWM).

2.0 SCOPE

This procedure shall apply to review of work, when adequacy of information or suitability of procedures and methods cannot otherwise be established through testing, alternate calculations, or reference using previously established standards and practices.

3.0 REFERENCES AND DEFINITIONS

3.1 REFERENCES

3.1.1 "Quality Assurance Requirements for the Civilian Radioactive Waste Management Program," (QAR)-DOE/RW-0214, 1988.

3.1.2 "Quality Assurance Program Description for the Civilian Radioactive Waste Management Program," (QAPD)-DOE/RW-0215, 1988.

3.2 DEFINITIONS

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

3.2.2 Cognizant Associate Director, OCRWM - The Associate Director, OCRWM, for whom a peer review is conducted. Generally, this will be the Associate Director, OCRWM, responsible for the functional area that is the subject of the review.

3.2.3 Peer - A person having technical expertise in the subject matter to be reviewed (or a critical subset of the subject matter) to a degree at least equivalent to that needed for the original work.



- 3.2.4 Peer Review - A documented, critical review performed by peers who are independent of the work being reviewed (See Section 5.5).
- 3.2.5 Peer Review Group - An assembly of independent peers representing an appropriate spectrum of knowledge and experience in the subject matter to be reviewed (See Section 5.3).
- 3.2.6 Peer Review Report - A documented, detailed report of proceedings and findings of a peer review (See Section 5.8).

4.0 RESPONSIBILITIES

4.1 DIRECTOR, OCRWM

The Director, OCRWM, or designee has overall responsibility for:

- 4.1.1 Reviewing findings of the peer reviewer(s) and authorizing release of the peer review report; and
- 4.1.2 Appointing members of peer review groups following nominations by the Cognizant Associate Director.

4.2 ASSOCIATE DIRECTORS, OCRWM

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

- 4.2.1 Determining if and when a peer review should be performed;
- 4.2.2 Determining the scope of the peer review; and
- 4.2.3 Nominating a peer reviewer or peer review group, on a case-by-case basis, as appropriate. A peer review chairman shall be appointed by the peer review group when peer review is conducted by more than one peer reviewer.

4.3 ASSOCIATE DIRECTOR, OFFICE OF FACILITIES SITING AND DEVELOPMENT (OFSD)

In addition to responsibilities identified in 4.2 above, the Associate Director, OFSD, or designee is also responsible for:

- 4.3.1 Preparing and maintaining this QAAP.



4.4 COGNIZANT ASSOCIATE DIRECTOR, OCRWM

In addition to responsibilities identified in 4.2 above, the Cognizant Associate Director, OCRWM, or designee is also responsible for:

- 4.4.1 Establishing peer review qualifications;
- 4.4.2 Acting as the OCRWM liaison with the organization(s) doing work to be evaluated during the peer review;
- 4.4.3 Providing acceptance of the peer review plan, checklist, and report, as appropriate; and
- 4.4.4 Assuring that a peer review plan is prepared.

4.5 BRANCH CHIEFS, OCRWM

The Branch Chiefs, OCRWM, or designees are responsible for:

- 4.5.1 Recommending through the appropriate management chain, initiation of peer review to the Cognizant Associate Director, OCRWM, when work within the Associate Director's area of responsibility has progressed to the point where peer review is appropriate.

4.6 PEER REVIEWERS

The peer reviewer(s) are responsible for:

- 4.6.1 Performing peer review(s) in accordance with this QAAP; and
- 4.6.2 Organizing and reporting peer review results.

4.7 DIRECTOR, OFFICE OF QUALITY ASSURANCE (OQA)

The Director, OQA, or designee is responsible for:

- 4.7.1 Performing audits and/or surveillances of the peer review process to assure that the review conforms to the guidance of this QAAP; and
- 4.7.2 Providing resources and assistance in the peer review, as requested.



5.0 GENERAL

- 5.1 Peer review shall be used when the adequacy of a critical body of information can only be established by alternate means, but there is no agreement within the cognizant technical community regarding applicability or appropriateness of the alternate means. Peer reviews should be used in a confirmatory sense and not as a substitute for readily collectable data.
- 5.2 Peer review shall be considered when one or more of the following conditions exist:
- 5.2.1 Critical decisions or interpretations are or will have to be made in the face of significant uncertainty;
 - 5.2.2 Decisions or interpretations having significant impact on performance-assessment conclusions are or will have to be made;
 - 5.2.3 Novel or beyond state-of-the-art testing, plans and procedures, or analyses are or will be used;
 - 5.2.4 Accepted detailed technical criteria or standard industry procedures do not exist or are in the development stage;
 - 5.2.5 Results of tests are not reproducible or repeatable;
 - 5.2.6 Data or interpretations are ambiguous; or
 - 5.2.7 Data is questionable, since it may not have been collected in conformance with an established QA program.
- 5.3 The collective technical expertise and qualifications of a peer reviewer or group shall span the technical issues and areas involved in the work to be reviewed, including differing bodies of scientific thought. Technical areas more central to the work to be reviewed shall receive proportionally more representation in a peer review group.
- 5.4 The number of peers comprising a peer review group shall vary with the following:
- 5.4.1 Complexity of the work to be reviewed;
 - 5.4.2 Importance of assuring that safety or waste isolation performance goals are met;
 - 5.4.3 Number of technical disciplines involved;
 - 5.4.4 Degree to which uncertainties in the data or technical approach exist; and



5.4.5 Extent to which differing viewpoints are strongly held within the applicable technical and scientific community concerning the issues under review.

5.5 Members of a peer review group shall be independent of the original work to be reviewed. Independence in this case means that the peer was not involved as a participant, supervisor, technical reviewer, or advisor in the work being reviewed, and to the extent practical, has sufficient freedom from funding considerations to assure that the work is impartially reviewed. In those cases where total independence cannot be met, a documented rationale as to why someone of equivalent technical qualifications and greater independence was not selected shall be included in the peer review report.

5.6 Since the peer review process may vary from case to case, a peer review plan shall be prepared by the Cognizant Associate Director or the peer review group prior to initiating a peer review. The peer review plan shall describe the work to be reviewed, the spectrum of expertise of the peer review group, and the suggested method and schedule necessary to produce a timely peer review report. Written minutes of meetings, deliberations, and peer review activities shall also be prepared.

5.7 A peer reviewer or group shall consider the following, as appropriate, when evaluating work during peer review:

5.7.1 Validity of basic assumptions and acceptance requirements employed;

5.7.2 Uncertainty of results and consequences, if incorrect;

5.7.3 Appropriateness and limitations of methodology and procedures;

5.7.4 Adequacy of application;

5.7.5 Accuracy of calculations and extrapolations;

5.7.6 Verification of computer software;

5.7.7 Validity of conclusions; and

5.7.8 Alternative interpretations.

5.8 Any questions or other clarifications needed regarding the work undergoing peer review shall be directed back to the preparing organization by the Cognizant Associate Director. Responses provided by the preparing organization shall be distributed to all peer reviewers to assure consistent evaluation during peer review.



- 5.9 A report, documenting the results of peer review, shall be prepared and issued that will include, but not be limited to, the following:
- 5.9.1 A clear description of the work reviewed;
 - 5.9.2 Conclusions reached by the peer review process, including alternative interpretations;
 - 5.9.3 The methodology, reasoning, and judgment used in reaching the conclusions;
 - 5.9.4 Individual statements by peer review group members, as applicable, reflecting dissenting views or additional comments, as appropriate;
 - 5.9.5 A listing of the peers, their individual technical qualifications, and evidence of independence, including potential technical and/or organizational partiality; and
 - 5.9.6 All peer reviewer(s) shall sign the peer review report.

6.0 PROCEDURE

6.1 INITIATING PEER REVIEW

- 6.1.1 Upon determination that a peer review is required, the Cognizant Associate Director, OCRWM, shall initiate the review by identifying the work to be reviewed, the scope and timing of the review, and the peer reviewer(s).
- 6.1.2 The Cognizant Associate Director or the peer reviewer(s) shall prepare a peer review plan that describes the work to be reviewed and the suggested method and schedule necessary to produce a report. The plan shall be reviewed by all peer reviewers. This shall also be true of changes made to the plan by the Cognizant Associate Director when submitted for approval.

6.2 PEER REVIEW

- 6.2.1 Using guidance provided in the approved peer review plan, the peer review group shall begin peer review. The peer review shall be conducted as a joint meeting or as a separate review, where each member independently reviews the work. Each member of a peer review group shall prepare comments and/or provide a dissenting opinion, as appropriate.



- 6.2.2 Peer reviewers shall document their results, which shall address, at a minimum, the suitability of the work being reviewed for its intended purpose, and whether or not the work conforms to specified requirements.
- 6.2.3 The peer reviewer(s) shall review the comments and any dissenting opinions for clarity and appropriateness.
- 6.2.4 Subsequent to completion of 6.2.3 above, the peer reviewer(s) shall prepare a written peer review report.
- 6.2.5 Subsequent to completion of 6.2.4, the peer reviewer(s) shall prepare an acceptance letter for the Cognizant Associate Director, OCRWM, signature and forward the acceptance letter and peer review report to the Cognizant Associate Director, OCRWM.
- 6.2.6 Subsequent to peer review report acceptance by the Cognizant Associate Director, OCRWM, the Cognizant Associate Director, OCRWM, shall request release of the peer review report by the Director, OCRWM.

6.3 ACTION SUBSEQUENT TO ACCEPTANCE

- 6.3.1 Subsequent to release of the peer review report by the Director, OCRWM, the Cognizant Associate Director, OCRWM, shall provide for release of the peer reviewed document, which may consist of any of the following actions:
- a) Transmitting a PROGRAM Participant prepared document to the PROGRAM Participant for release in accordance with their procedures;
 - b) Releasing an OCRWM prepared document to the OCRWM organization responsible for controlled distribution; or
 - c) Releasing an OCRWM prepared document for publication.
- 6.3.2 Any action taken by OCRWM to resolve the views of the peer reviewer(s) after publication of the final report shall be traceable to the report and documented.

7.0 RECORDS

- 7.1 Documentation generated as a result of this procedure is collected and maintained in accordance with requirements specified in QAAP 17.1, "Records Management". At a minimum, attachment I is a QA record.



8.0 ATTACHMENTS

- 8.1 Attachment I - Peer-Review Checklist**
- 8.2 Attachment II - QAAP Flowchart**



ATTACHMENT I (Typical)

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

SHEET ____ OF ____
WBS NO. _____

PEER REVIEW CHECKLIST

PEER REVIEW NUMBER

REVIEW DATE

PEER REVIEWER SHALL SIGN AND DATE THE FOLLOWING WHEN COMPLETED

- _____
Signature _____
Date The scope of the review identified.
- _____
Signature _____
Date Review personnel identified, qualifications documented and indoctrination provided, as appropriate.
- _____
Signature _____
Date All reference material and data are available for review.
- _____
Signature _____
Date All written reviewer comments have been received and reviewed.
- _____
Signature _____
Date Revised documents peer reviewed, as appropriate.
- _____
Signature _____
Date Peer review report prepared and submitted to the cognizant Associate Director, OCRWM.
- _____
Signature _____
Date Peer review report and other applicable documents transmitted to originator with Director, OCRWM, acceptance or concurrence.
- _____
Signature _____
Date Peer review documents entered into records system.

The above peer review steps have been carried out in compliance with QAAP 3.3.

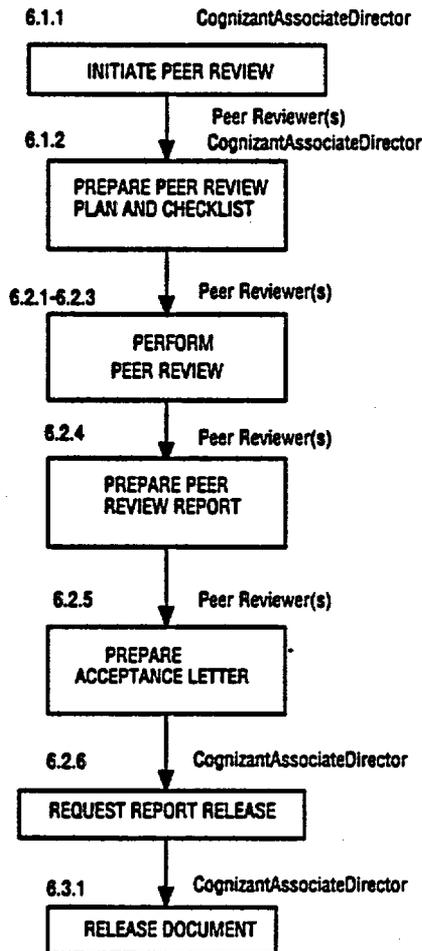
PEER REVIEWER CHAIRMAN _____
Date

COGNIZANT ASSOCIATE DIRECTOR _____
Date



ATTACHMENT II

PEER REVIEW





OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
QUALITY ASSURANCE ADMINISTRATIVE PROCEDURE

TITLE: PREPARATION OF QUALITY ASSURANCE ADMINISTRATIVE PROCEDURES

Procedure No.: QAAP 5.1	Revision: 0	Date: 3/27/89	Page: 1 of 14
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Director, OCRWM <i>[Signature]</i>	Date: 12/1/88	Director, OQA <i>[Signature]</i>	Date: 12/1/88
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1.0 PURPOSE

The purpose of this procedure is to establish responsibilities, requirements and 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 of all OCRWM QAAPs that address the implementation of requirements established in the OCRWM Quality Assurance Requirements for the Civilian Radioactive Waste Management Program document.

3.0 REFERENCES AND DEFINITIONS

3.1 REFERENCES

- 3.1.1 "Quality Assurance Requirements for the Civilian Radioactive Waste Management Program", (QAR) DOE/RW-0214, 1988.
- 3.1.2 "Quality Assurance Program Description for the Civilian Radioactive Waste Management Program", (QAPD) DOE/RW-0215, 1988.

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 - Changes to a procedure that affect a process within the procedure, the basic content, or a major change in concept.



- 3.2.3 Mandatory Comment - Comment requiring resolution that identifies and describes a significant conflict with, or deviation from, existing OCRWM policy; quality assurance requirement; programmatic or management requirement; technical position; or responsibilities for implementation of established requirements.
- 3.2.4 Minor Revision - Changes such as typographical errors; wording changes for clarity; and editorial changes, where the basic meaning and content of the procedure does not change.
- 3.2.5 QAAP - Quality Assurance Administrative Procedures which implement the OCRWM QAR and QAPD documents by prescribing specific measures, methods or systems to be utilized to assure QA Program compliance and define the specific individual(s) or organization(s) responsible for implementation.

4.0 RESPONSIBILITIES

4.1 DIRECTOR, OCRWM

The Director, OCRWM, or his designee has responsibility for:

- 4.1.1 Approval of all QAAPs and QAAP revisions.

4.2 ASSOCIATE DIRECTORS, OCRWM

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

- 4.2.1 Identifying the need for development and preparation of QAAPs within their functional areas of responsibility;
- 4.2.2 Providing signatory concurrence of QAAPs through the review process;
- 4.2.3 Assuring that personnel under their supervision are identified for appropriate training, and have received the appropriate training; and
- 4.2.4 Assuring implementation of actions 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, to the Director, OQA; and

4.3.2 Developing, reviewing, and resolving comments on assigned QAAPs in accordance with requirements of this procedure.

4.4 DIRECTOR, MANAGEMENT SYSTEMS AND SUPPORT DIVISION (MSSD)

The Director, MSSD, or designee is responsible for:

4.4.1 Distribution of all approved QAAPs and/or revisions, in accordance with QAAP 6.1 "Controlled Documents".

4.5 DIRECTOR, OFFICE OF QUALITY ASSURANCE (OQA)

The Director, OQA, or designee is responsible for:

4.5.1 Preparing and maintaining this QAAP;

4.5.2 Coordinating the development and maintenance of all QAAPs;

4.5.3 Providing signatory concurrence on all QAAPs and QAAP revisions, prior to approval by the Director, OCRWM;

4.5.4 Determining the need for establishing new and/or revising existing QAAPs;

4.5.5 Interpreting quality assurance requirements for subsequent inclusion into the appropriate QAAPs;

4.5.6 Performing and/or coordinating the review of QAAPs to assure adequate qualitative and quantitative instructions for compliance; and

4.5.7 Informing the OCRWM QA Training Officer of any newly planned, developed and/or revised QAAPs, so that appropriate training may be implemented.

5.0 GENERAL

5.1 OCRWM QAAPs shall be prepared in accordance with this procedure and shall be contained and controlled within the OCRWM QAAP Manual (a controlled document containing OCRWM QAAPs).

5.2 QAAPs are procedures which implement the OCRWM QAR and QAPD documents.



**OCRWM QA
ADMINISTRATIVE
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- 5.3 QAAPs shall be reviewed by each appropriate Associate Director affected by and/or with defined responsibility. Procedure review comments and resolutions shall be documented.
- 5.4 All OCRWM QAAP's shall utilize Attachment I "Procedure Title Page" and Attachment II "Procedure Continuation Page". The required information is as follows:
- 5.4.1 QAAP Subject - The title or subject of the procedure;
 - 5.4.2 QAAP Number - The appropriate alpha numeric identification as assigned by the Director, OQA;
 - 5.4.3 QAAP Revision - The appropriate sequential revision number, with 0 being the first issue;
 - 5.4.4 Date Block - Shall exhibit the effective date of the procedure;
 - 5.4.5 Page Block - Shall exhibit "Page 1 of ____";
 - 5.4.6 Director, OCRWM - Shall exhibit the authorized approval signature and the date signed; and
 - 5.4.7 Director, OQA - Shall exhibit the authorized concurrence signature and the date signed.
- 5.5 All review comments and/or resolution concurrence for all OCRWM QAAPs shall be documented on Attachment III "Document Review Record" and Attachment IV "Document Review Record (Continuation Sheet)".
- 5.6 All OCRWM QAAPs shall be developed in the format described in Attachment V and Attachment VI.
- 5.7 All OCRWM QAAPs shall be uniquely identified (numbered) as determined by the Director, OQA.

6.0 PROCEDURE

6.1 QAAP PREPARATION

- 6.1.1 When a valid need for a QAAP has been identified, the Director, OQA, assigns a QAAP preparer. To maintain uniformity, each QAAP shall be prepared in the format described in Attachment V and Attachment VI.



- 6.1.2 The preparer develops the QAAP Purpose and Scope sections and should develop a flow chart to depict the various steps or sequence of activities associated with the procedure. Flow charts may be incorporated into the procedure when appropriate.
- 6.1.3 Each page of the procedure shall be identified as "page ___ of ___", including all attachments.
- 6.1.4 All attachments shall be contained within the border confines of Attachment II, and identified as "SAMPLE", "EXAMPLE" or "TYPICAL", whichever is appropriate.
- 6.1.5 The preparer should be aware of the following word usage during QAAP development:
- a) shall or will expresses a mandatory requirement directed towards an action/activity in the procedure;
 - b) should denotes expectation relative to desired results; and
 - c) may denotes permission.

6.2 QAAP REVIEW

- 6.2.1 Upon completion of the initial draft QAAP, the preparer shall submit the draft to the Director, OQA.
- 6.2.2 The Director, OQA, shall establish a realistic comment-due date and solicit comments from each Associate Director, at a minimum. The review and acceptance criteria shall be contained in or referenced on Attachment III.
- 6.2.3 The reviewer(s) perform(s) the review, following the specified review and acceptance criteria annotated or referenced on the DRR.
- 6.2.4 Review comments are documented on the DRR. Each organization requested to perform a review shall provide a consolidated set of comments for subsequent resolution, on a single set of DRRs.
- 6.2.5 When the review produces comments, the reviewer shall identify the mandatory comments, as appropriate.
- 6.2.6 Upon completion of the review, the reviewer forwards the completed DRR to the Director, OQA, for further action.



6.3 ACTION SUBSEQUENT TO REVIEW

- 6.3.1 The Director, OQA, reviews the DRR to determine the extent of the comments.
- 6.3.2 If no comments exist, the Director, OQA, signs the appropriate block on the QAAP title page, forwards the QAAP (by memorandum) to the Director, OCRWM, soliciting his approval signature.
- 6.3.3 Upon obtaining procedure approval, the Director, OQA, informs the OCRWM QA Training Officer, so that training may be implemented. The Director, OQA, then forwards the procedure to the Director, MSSD, for control and distribution in accordance with QAAP 6.1, "Controlled Documents".
- 6.3.4 If comments exist, and are annotated as mandatory, the Director, OQA, forwards the DRR(s) to the procedure preparer for comment response/resolution.

6.4 COMMENT RESPONSE/RESOLUTION

- 6.4.1 The comment response/resolution is documented on the same DRR(s) on which the comments appear.
- 6.4.2 Comment resolution may be accomplished via a comment resolution meeting or a comparable format that produces an acceptable end result that is documented.
- 6.4.3 Once an acceptable resolution is reached, the commentator and the document preparer indicate acceptable resolution by initialing and dating the space provided on the DRR adjacent to the comment response.
- 6.4.4 Following the completion of the resolution of comments on the DRR, the document preparer revises the document, as necessary, forwards the completed document along with the completed DRR package, to the Director, OQA, for his action in accordance with Section 6.3.
- 6.4.5 Comments that cannot be resolved by the reviewing organization and the originating organization shall be brought to the attention of the appropriate management and, if not resolved, are elevated progressively to the Director, OQA, and if necessary, to the Director, OCRWM.



6.5 REVISIONS

- 6.5.1 Revisions to approved QAAPs are accomplished in accordance with provisions of Section 6.2, 6.3 and 6.4 above. When an OCRWM QAAP is revised, the entire document is reissued.
- 6.5.2 Major revisions to approved QAAPs are accomplished on an "as needed" basis. Minor revisions are accomplished when the subject QAAP is next revised.
- 6.5.3 When an approved OCRWM QAAP is revised, it shall be issued as the next sequential revision number. The section(s) of the document that has been revised shall be identified by a change bar (a vertical line in the margin adjacent to the line or section that was revised).

6.6 CONTROL AND DISTRIBUTION

- 6.6.1 Only approved QAAPs are included in the OCRWM QAAP Manual and become effective on the date indicated on the title page.
- 6.6.2 The Director, OQA, transmits all approved QAAPs and/or approved revisions to the Director, MSSD, for action per section 6.3.3.

7.0 RECORDS

- 7.1 Documentation generated as a result of this procedure is collected and maintained in accordance with requirements specified in QAAP 17.1, "Records Management". At a minimum, attachments III and IV are 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 - QAAP Flowchart



**OCRWM QA
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ATTACHMENT I (Example)



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

TITLE:

Procedure No.:

Revision:

Date:

Page:

of

Director, OCRWM

Date:

Director, OQA

Date:

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

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



**OCRWM QA
ADMINISTRATIVE
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ATTACHMENT II (Example)



**OCRWM QA
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Procedure No.:

Revision:

Page:

of

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WASHINGTON, D.C.**



**OCRWM QA
ADMINISTRATIVE
PROCEDURE**

Procedure No.:
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ATTACHMENT III (Typical)

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

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



ATTACHMENT IV (Typical)

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

SHEET ____ OF ____
WBS NO. _____ (1)
DR NO. _____ (2)
REVISION NO. _____ (3)

DEFICIENCY REPORT

AUDIT/SURVEILLANCE (4)		RESPONSIBLE ORGANIZATION (5)		REFERENCE DOCUMENTS (6)	
REQUIREMENTS (7)					
DESCRIPTION OF CONDITION (8)					
RECOMMENDED ACTIONS TO CORRECT CONDITION (9)					
ORIGINATOR (10) _____ Signature Date				BRANCH/DIVISION/OFFICE (11)	
YES NO [] [] SIGNIFICANT (12) [] [] REPETITIVE (13)				CAR NO. (14)	
(15) RESPONSE DUE	(16) OOA	_____ Signature Date		(17) DIRECTOR, OOA	_____ Signature Date
REMEDIAL ACTIONS (18)					
EXTENT (19)					
PLANNED COMPLETION (20)		RESPONSIBLE MANAGER (21) _____ Signature Date		PROJECT MANAGER/ASSOCIATE DIR. (22) _____ Signature Date	
RESPONSE (23) [] ACCEPT * [] REJECT		OOA SIGNATURE (24) _____ Signature Date		DIRECTOR, OOA (25) _____ Signature Date	
COMPLETION DATE (26)		RESPONSIBLE MANAGER (27) _____ Signature Date		PROJECT MANAGER/ASSOCIATE DIR. (28) _____ Signature Date	
OOA VERIFICATION (29) [] SATISFACTORY * [] UNSATISFACTORY		OOA (30) _____ Signature Date		DIRECTOR, OOA (31) _____ Signature Date	

*DOCUMENT JUSTIFICATION FOR REJECTION ON CONTINUATION SHEET

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 which will interface with the procedure being written.

3.2 DEFINITIONS

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

4.0 RESPONSIBILITIES

Identify the individual(s) or organization(s) who have the major responsibility for the implementation of the procedure. Restrict this to the OCRWM personnel who have direct involvement in the subject activity.

5.0 GENERAL

Delineates requirements and/or provides 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 Should always 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, "Records Management". At a minimum, attachments (list the attachments by number, i.e., I, II) are considered QA Records.

8.0 ATTACHMENTS

A listing of all exhibits, illustrations, forms, appendices, etc., referred to 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.)

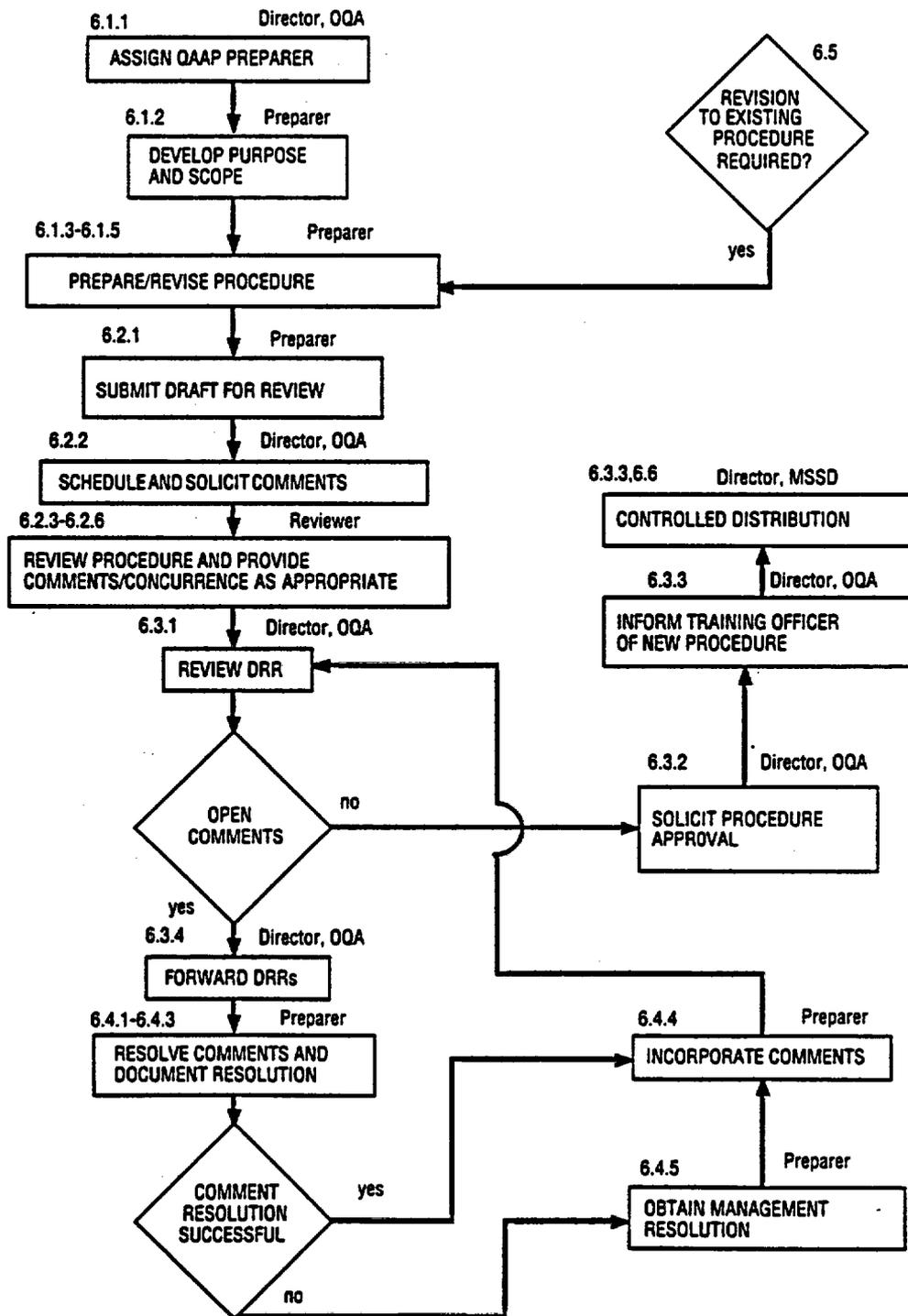
1.1.1 (Third level indentures shall be written in sentence and/or paragraph format in lower case letters and shall not bear titles.)

- 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 utilized, shall always be on a separate line.
- c) With the exception of the following, there shall always be a double space between indentures: fourth level indentures, e.g. a), b) shall be single spaced between indentures when the text does not exceed one line.



ATTACHMENT VII

PREPARATION OF QUALITY ASSURANCE ADMINISTRATIVE PROCEDURES





OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
QUALITY ASSURANCE ADMINISTRATIVE PROCEDURE

TITLE: CORRECTIVE ACTION

Procedure No.: QAAP 16.1	Revision: 0	Date: 3/27/89	Page: 1 of 16
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Director, OCRWM <i>[Signature]</i>	Date: 3/10/89	Director, OQA <i>[Signature]</i>	Date: 3/17/89
---------------------------------------	------------------	-------------------------------------	------------------

1.0 PURPOSE

This procedure prescribes the responsibilities and methods for identifying, correcting, preventing recurrence, and closure of deficiencies.

2.0 SCOPE

This procedure applies to any deficiency, or apparent deficiency, in OCRWM PROGRAM activities or products that is identified by or on behalf of OCRWM personnel. This procedure shall be used by OCRWM personnel and OCRWM contractor support personnel for evaluating and correcting deficiencies identified within the OCRWM organization.

3.0 REFERENCES AND DEFINITIONS

3.1 REFERENCES

- 3.1.1 "Quality Assurance Requirements for the Civilian Radioactive Waste Management Program", (QAR) DOE/RW-0214, 1988.
- 3.1.2 "Quality Assurance Program Description for the Civilian Radioactive Waste Management Program," (QAPD) DOE/RW-0215, 1988.

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 Corrective Action - measures taken to rectify conditions adverse to quality and, where necessary, to prevent recurrence. Corrective action includes remedial action and investigative action as defined below.



- 3.2.3 Corrective Action Report (CAR) - a document used by the Director, OQA, to report and/or elevate deficiencies that are determined to be significant or of importance sufficient to warrant the attention of the Director, OCRWM.
- 3.2.4 Deficiency - a condition of an item or activity, attribute, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate.
- 3.2.5 Deficiency Report (DR) - a document used to report deficiencies in activities or products discovered by OCRWM personnel or OCRWM support contractor personnel, and to record the corrective actions.
- 3.2.6 Investigative Action - actions taken to determine the overall extent, depth, and root cause of a deficiency, including identification of similar deficiencies related to those specifically identified.
- 3.2.7 Product - includes items, as defined in reference 3.1.1; documents that result from PROGRAM activities and software.
- 3.2.8 Remedial Action - actions taken to correct specifically identified deficiencies.
- 3.2.9 Root Cause - the most fundamental circumstances that are manifest by an observed deficiency, i.e., where the deficiency is but a symptom of a more basic problem.
- 3.2.10 Significant Deficiency - a significant condition adverse to quality that, were it to remain uncorrected, could seriously affect safety or waste isolation.

4.0 RESPONSIBILITIES

4.1 DIRECTOR, OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT (OCRWM)

The Director, OCRWM, or designee is responsible for:

- 4.1.1 Approving the issuance, resolution, and closeout of Corrective Action Reports.

4.2 OCRWM MANAGERS

OCRWM Managers (i.e., the Cognizant Branch Chief, Division Director, Associate Director, or Director) or their designees, are responsible for:



- 4.2.1 Controlling activities and/or the use of products identified as deficient until resolution is reached;
- 4.2.2 Taking immediate action to correct deficiencies where threat of degradation or irretrievable loss to the OCRWM PROGRAM exists;
- 4.2.3 Taking remedial action to correct identified deficiencies;
- 4.2.4 Investigating deficiencies to determine the overall extent of the problem and root cause; and
- 4.2.5 Implementing measures to prevent recurrence of deficiencies.

4.3 OCRWM PERSONNEL

OCRWM and OCRWM support contractor personnel are responsible for:

- 4.3.1 Identifying and reporting deficiencies observed in the conduct of PROGRAM activities or in the characteristics of PROGRAM products;
- 4.3.2 Initiating a Deficiency Report (DR), as necessary; and
- 4.3.3 Providing support in resolving deficiencies.

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 Assuring that activities and/or products identified as deficient are controlled until resolution is reached;
- 4.4.3 Determining the significance of deficiencies and initiating a Corrective Action Report (CAR), as required;
- 4.4.4 Tracking the status of all OCRWM DRs and CARs;
- 4.4.5 Investigating and validating reported deficiencies;
- 4.4.6 Evaluating proposed corrective actions;
- 4.4.7 Verifying implementation of corrective actions; and
- 4.4.8 Closing out the DR or CAR upon verification of corrective actions.



5.0 GENERAL

- 5.1 All OCRWM and support personnel are required to report deficiencies in execution of QL1 or QL2 activities or in characteristics of QL1 or QL2 products, upon discovery. The OQA shall be contacted as soon as practical upon discovery of a deficiency. This procedure may also be used to address deficiencies in QL3 activities or QL3 products that are considered important to PROGRAM objectives. Deficiencies may be discovered through audits, surveillances, reviews, observation of work in-process, trend analysis, or examination and testing of products or software.
- 5.2 If an apparent deficiency in the OCRWM PROGRAM is identified by an outside organization (for example the NRC), and reported to the OCRWM, the Director, OQA, shall initiate the required actions in accordance with this procedure.
- 5.3 A Deficiency Report (DR) (Attachment I) shall be prepared in accordance with Section 6.0 of this procedure upon detection of programmatic or implementation deficiencies (e.g., procedure violations or inadequacies), for OCRWM product deficiencies, and for Participant-product deficiencies identified by OCRWM personnel.
- 5.4 The Director, OQA, shall evaluate reported deficiencies to determine whether or not a CAR is warranted, and initiate a CAR as appropriate. A DR is not necessarily required to initiate a CAR. The CAR is needed for significant deficiencies, as described below, and for other deficiencies that are repetitive and for which previous corrective action has been ineffective.
- 5.5 The Director, OQA, shall determine whether or not the deficiency is significant, based on the criteria given below. This determination may be changed by the Director, OQA, as determined through investigation of a deficiency. Examples of significant deficiencies are:
- 5.5.1 Serious errors in design, construction, or fabrication which were detected subsequent to formal quality verification and acceptance (e.g., a significant design error discovered during an OCRWM design review of a previously verified design that impacts a Q-List item);
- 5.5.2 Serious errors in the execution or results of scientific investigations, performance assessments, or performance confirmation, that were detected subsequent to acceptance of the resulting data (e.g., deficiencies in the conduct of activities which are included on the Quality Activities List that have a potential for impact on waste isolation);



5.5.3 A breakdown in a QA program (i.e., failure of an organization to establish and implement prescribed QA and technical requirements, plans, and procedures); and/or

5.5.4 Deficiencies that may require a stop work order (SWO) in accordance with QAAP 16.2, "Stop Work".

5.6 The status of each DR and CAR shall be tracked by the OQA from submittal to closure.

5.7 DRs and CARs shall be analyzed for trends by the OQA, in accordance with QAAP 2.9, "QA Program Status Reporting".

6.0 PROCEDURE

6.1 DEFICIENCY REPORTING

6.1.1 OCRWM or OCRWM support contractor personnel, upon discovering an apparent deficiency, shall determine the appropriate course of action based upon the criteria of Section 5.0. If a DR is warranted, the OCRWM or OCRWM support contractor personnel shall notify the Director, OQA, of the condition within one work day and initiate a DR. The DR shall be signed and submitted to the OQA.

6.1.2 If a deficiency is a result of an audit or surveillance, the Lead Auditor or surveillance leader shall monitor the DR/CAR status and ensure that adequate corrective actions are implemented.

6.1.3 The Director, OQA, and responsible management shall determine whether immediate corrective measures are needed to prevent degradation or loss to the PROGRAM. These measures shall be recorded on the DR.

6.1.4 Where products are suspect as being deficient, the Director, OQA, and the management responsible for the product shall take action to mark, segregate, or otherwise control use of these products to preclude their inadvertent use until disposition is final and approved.

6.1.5 Where an activity is conducted in a deficient or improper manner, the Director, OQA, and the management responsible for the activity shall take action to control the activity and its effects until permanent corrective measures are implemented.



6.2 INITIAL EVALUATION

6.2.1 The OQA shall enter the DR into a status tracking system.

6.2.2 The OQA shall initially investigate the reported deficiency to determine whether a deficiency exists. Other OCRWM organization(s) shall support the OQA in the investigation, as necessary. If no deficiency exists, the OQA shall take steps to cancel the DR in accordance with Section 6.7 of this QAAP.

6.2.3 The Director, OQA, shall determine whether a CAR is required based upon the criteria of Sections 5.4 and 5.5.

6.3 CORRECTIVE ACTION REPORT

6.3.1 For deficiencies requiring a CAR as prescribed in Sections 5.4 and 5.5, the Director, OQA, shall initiate a CAR.

6.3.2 The basis of the CAR may be one or more DRs or major concerns otherwise brought to the attention of the Director, OQA. Where applicable, the DRs shall be included and processed with the CAR.

6.3.3 The Director, OQA, shall evaluate the need to suspend affected work activities in accordance with QAAP 16.2, "Stop Work", and take appropriate actions. Reference to the SWO shall be recorded on the CAR.

6.3.4 The Director, OCRWM, shall sign the CAR as concurrence with the CAR and as direction to pursue corrective actions.

6.4 INVESTIGATION

6.4.1 The Director, OQA, shall transmit the DR and/or CAR to the responsible organization within the OCRWM, or reporting directly to OCRWM, who has responsibility for implementing corrective actions. Where more than one organization may be considered responsible, a lead shall be designated by the Director, OQA.

6.4.2 The responsible management shall investigate to determine extent, magnitude, and overall effects of the reported deficiency, and the remedial actions that will be taken to resolve the deficiency. For a CAR, the responsible management shall determine the root cause of the deficiency and what actions will be taken to prevent recurrence of the problem. As applicable, the remedial actions, root cause, extent and effects of the problem, and actions taken to prevent recurrence shall be recorded on the DR and/or CAR.



- 6.4.3 Where deficiency resolution is to accept the results of a technical activity or products, wherein the activities or products do not conform to the original requirements, technical justification for acceptance of the results or products shall be documented on the DR/CAR.
- 6.4.4 If the deficiency disposition requires rejection of a product or other results of activity, planned actions for recovery, in addition to the specific disposition for the product or result, shall be documented on the DR/CAR.
- 6.4.5 If a deficiency involves a breach of the OCRWM technical baseline, and remedial action does not fully restore the activity or product to specified requirements, the baseline shall be modified to reflect the deviation in accordance with QAAP 3.4, "Configuration Management". This action shall be initiated by the management of the organization responsible for corrective action and shall be documented on the DR/CAR.
- 6.4.6 The DR and/or CAR shall be signed by the responsible manager(s), the Project Manager for non-OCRWM organizations, the cognizant Associate Director for internal OCRWM deficiencies, and returned to the OQA for evaluation.

6.5 RESOLUTION

- 6.5.1 The Director, OQA, shall evaluate the DR and/or CAR response received from the responsible organization. He shall ensure that the remedial action is adequate, that the problem was investigated to sufficiently determine its extent, effects, and root cause, and that adequate measures will be taken to prevent recurrence, as applicable. The extent of the evaluation may range from a review of the documented response to an independent field investigation by the OQA, depending on the significance and complexity of the problem.
- 6.5.2 The Director, OQA, shall record the results of the evaluation of the DR/CAR response, sign, and return the DR/CAR to the responsible organization(s).
- 6.5.3 If the planned corrective action is determined to be inadequate, further instructions shall be provided to the responsible organization. The DR/CAR may be reissued as the next sequential revision at this time. The responsible organization shall conduct further investigations, modify the response as necessary, and resubmit the DR/CAR to the OQA.



- 6.5.4 If the corrective action is determined to be adequate, the responsible organization shall continue with implementation of the corrective action.
- 6.5.5 If agreement between the Director, OQA, and the responsible management cannot be reached, the issue shall be elevated in the management hierarchy until resolved. Resolution of the DR/CAR shall then proceed per management directives.
- 6.5.6 The responsible management shall notify the Director, OQA, upon completion of the corrective action by submitting the DR/CAR with the actual completion date and corresponding management signatures. The actual corrective action taken, and any deviations from the planned corrective actions, shall be recorded on the DR/CAR.

6.6 VERIFICATION

- 6.6.1 The Director, OQA, shall evaluate the completed corrective action, as stated on the DR/CAR, to assure that the specific deficiencies were corrected, as well as any underlying root causes of CAR-type deficiencies.
- 6.6.2 The Director, OQA, shall ensure adequate implementation of the corrective action for identified deficiencies by conducting independent verification, such as surveillance or audits at the responsible organization's facility. Verification should be performed within thirty (30) days of notification of corrective action completion although additional follow-up audits may be scheduled. Results of the verification shall be documented and included with the DR/CAR. If the Director, OQA, determines that OQA verification is not necessary, justification for this decision shall be recorded on the DR/CAR.
- 6.6.3 If the corrective action is adequately completed, the DR/CAR shall be signed and closed by the Director, OQA. The CAR shall be signed by the Director, OCRWM, prior to closure. A copy of the closed DR/CAR shall be transmitted to the originator.
- 6.6.4 If the corrective action is inadequate, the responsible management shall be notified by the Director, OQA, to take further actions and the corrective action process shall be reiterated in accordance with this procedure. The DR/CAR shall be reissued as the next sequential revision.



6.7 CANCELLATION

6.7.1 If it is determined through OQA investigation that no deficiency exists, the following steps shall be taken:

- a) The Director, OQA, shall record the justification for cancellation on the DR and return the DR to the originator for concurrence;
- b) The originator shall sign the DR to indicate concurrence with the cancellation. The DR shall be returned to the OQA, closed; or
- c) If the originator does not concur, the Director, OQA, shall elevate the matter to the appropriate management level, until resolution is reached.

6.7.2 If the decision to cancel the DR stands, the Director, OQA, shall record the justification and close the DR.

6.7.3 If it is determined that corrective action is required, the corrective action process shall proceed in accordance with this procedure.

7.0 RECORDS

7.1 Documentation generated as a result of this procedure is collected and maintained in accordance with requirements specified in QAAP 17.1, "Records Management". At a minimum, attachments I and II are considered QA Records.

8.0 ATTACHMENTS

- 8.1 Attachment I - OCRWM Deficiency Report.
- 8.2 Attachment II - OCRWM Corrective Action Report.
- 8.3 Attachment III - QAAP Flowchart



**OCRWM QA
ADMINISTRATIVE
PROCEDURE**

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ATTACHMENT I (Typical)

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

SHEET ____ OF ____
WBS NO _____

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

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ATTACHMENT I cont'd

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

SHEET ____ OF ____
WBS NO. _____

DEFICIENCY REPORT (continuation sheet)

DR. NO. _____

REVISION NO. _____

DATE _____

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WASHINGTON, D.C.**



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ATTACHMENT II (Typical)

- SIGNIFICANT (1)
- REPETITIVE (2)

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

SHEET ____ OF ____
(3) WBS NO. _____
(4) CAR NO. _____
(5) REVISION NO. _____

CORRECTIVE ACTION REPORT

DR. NO. (6)		RESPONSIBLE ORGANIZATION (7)		STOP WORK ORDER NO. (8)	
DESCRIPTION OF CONDITION (9)					
RECOMMENDED ACTION (10)					
(11) RESPONSE DUE		(12) OOA _____ Signature Date		(13) DIRECTOR, OCRWM _____ Signature Date	
REMEDIAL ACTION (14)					
ROOT CAUSE/EXTENT (15)					
MEASURES TO PREVENT RECURRENCE (16)					
PLANNED COMPLETION DATE (17)		RESPONSIBLE MANAGER (18) _____ Signature Date		PROJECT MANAGER/ASSOCIATE DIR. (19) _____ Signature Date	
RESPONSE (20) <input type="checkbox"/> ACCEPT <input type="checkbox"/> REJECT		DIRECTOR, OOA (21) _____ Signature Date		DIRECTOR, OCRWM (22) _____ Signature Date	
COMPLETION DATE (23)		RESPONSIBLE MANAGER (24) _____ Signature Date		PROJECT MANAGER/ASSOCIATE DIR. (25) _____ Signature Date	
OOA VERIFICATION (26) <input type="checkbox"/> SATISFACTORY <input type="checkbox"/> UNSATISFACTORY		DIRECTOR, OOA (27) _____ Signature Date		DIRECTOR, OCRWM (28) _____ Signature Date	

*DOCUMENT JUSTIFICATION FOR REJECTION ON CONTINUATION SHEET

REV. 1/89

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ATTACHMENT II cont'd

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WASHINGTON, D.C.

SHEET ____ OF ____
WBS NO. _____

CORRECTIVE ACTION REPORT (continuation sheet)

CAR NO. _____

REVISION NO. _____

DATE _____

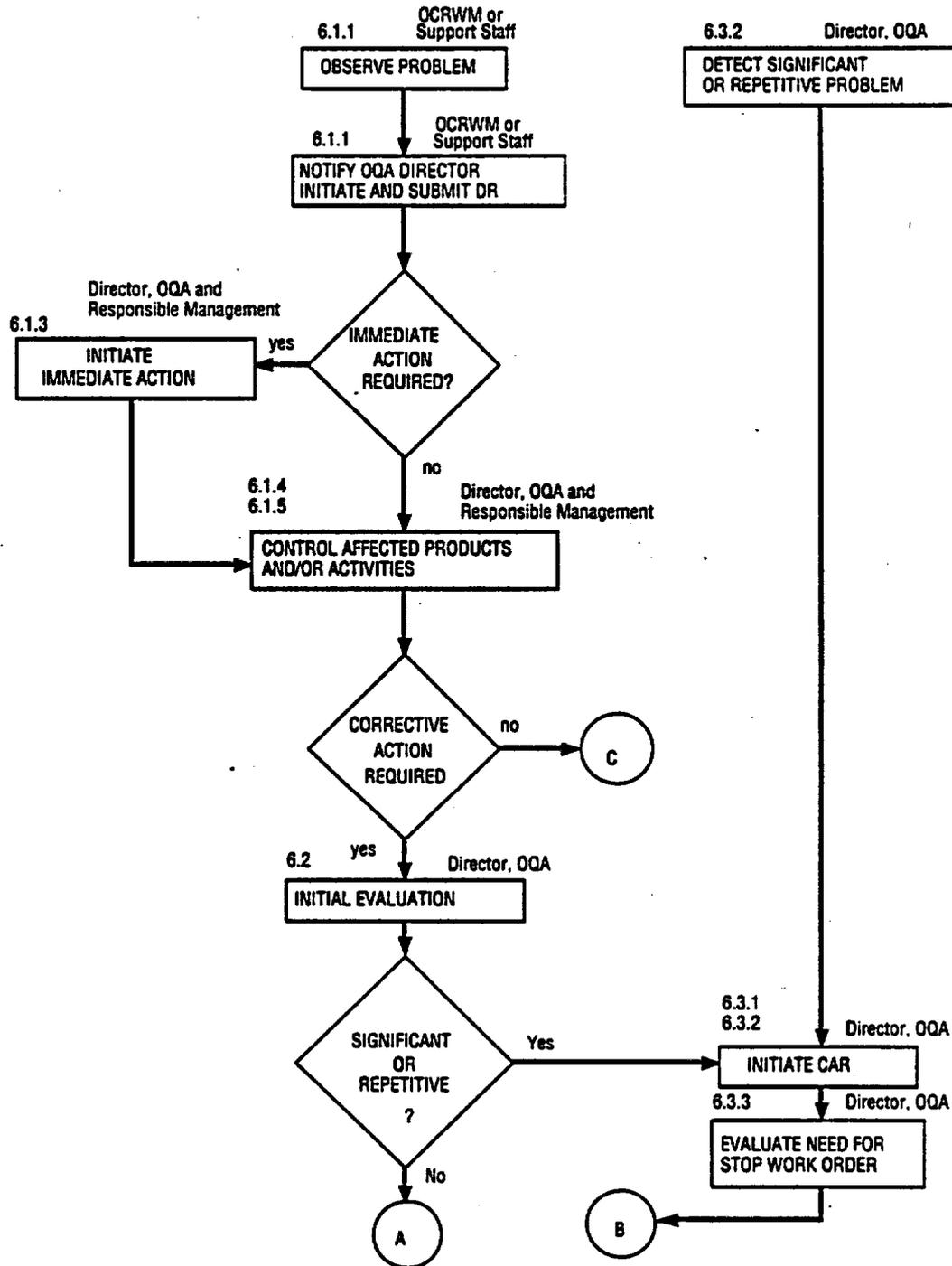
REV. 1/89

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WASHINGTON, D.C.



ATTACHMENT III

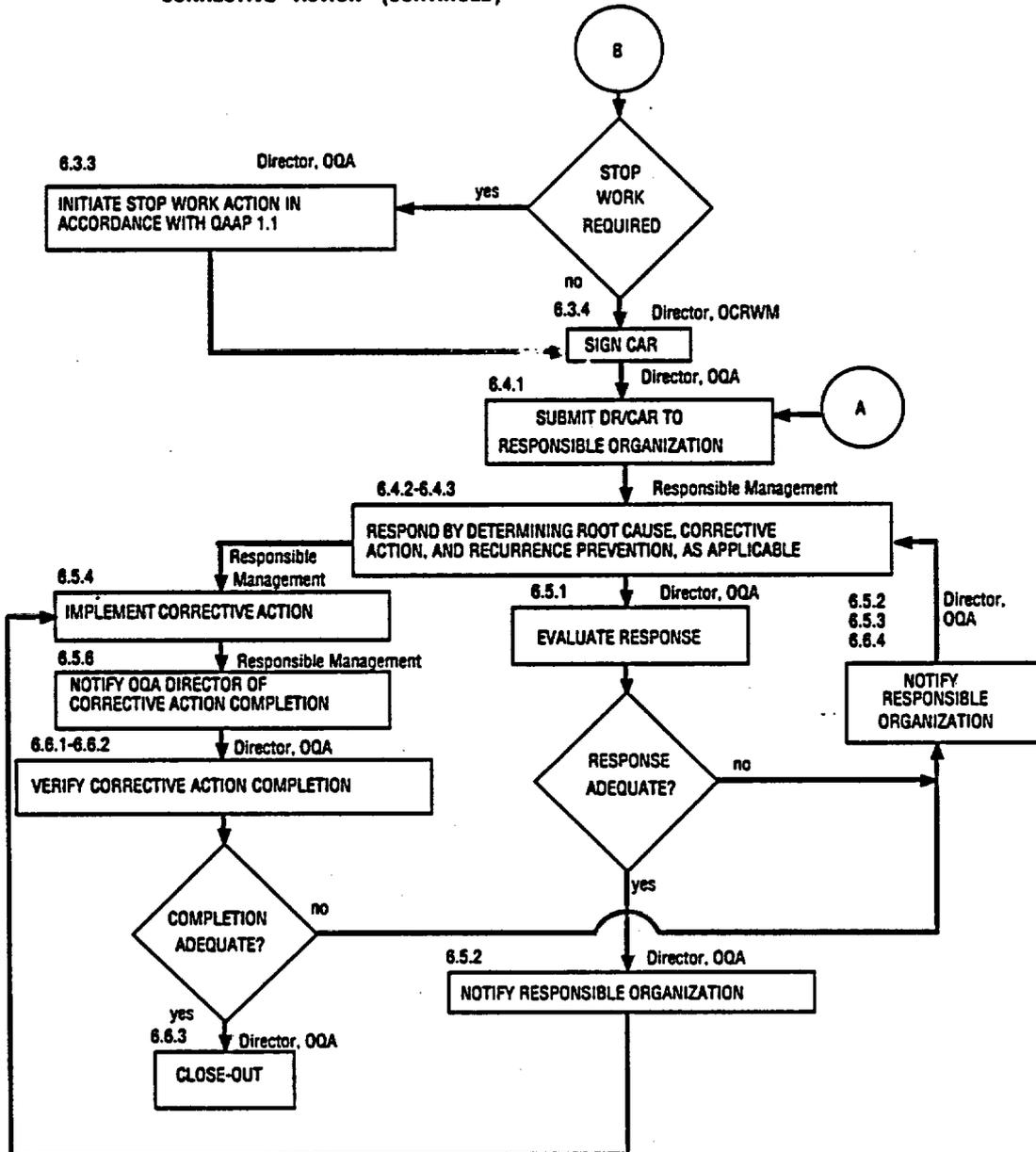
CORRECTIVE ACTION





ATTACHMENT III cont'd

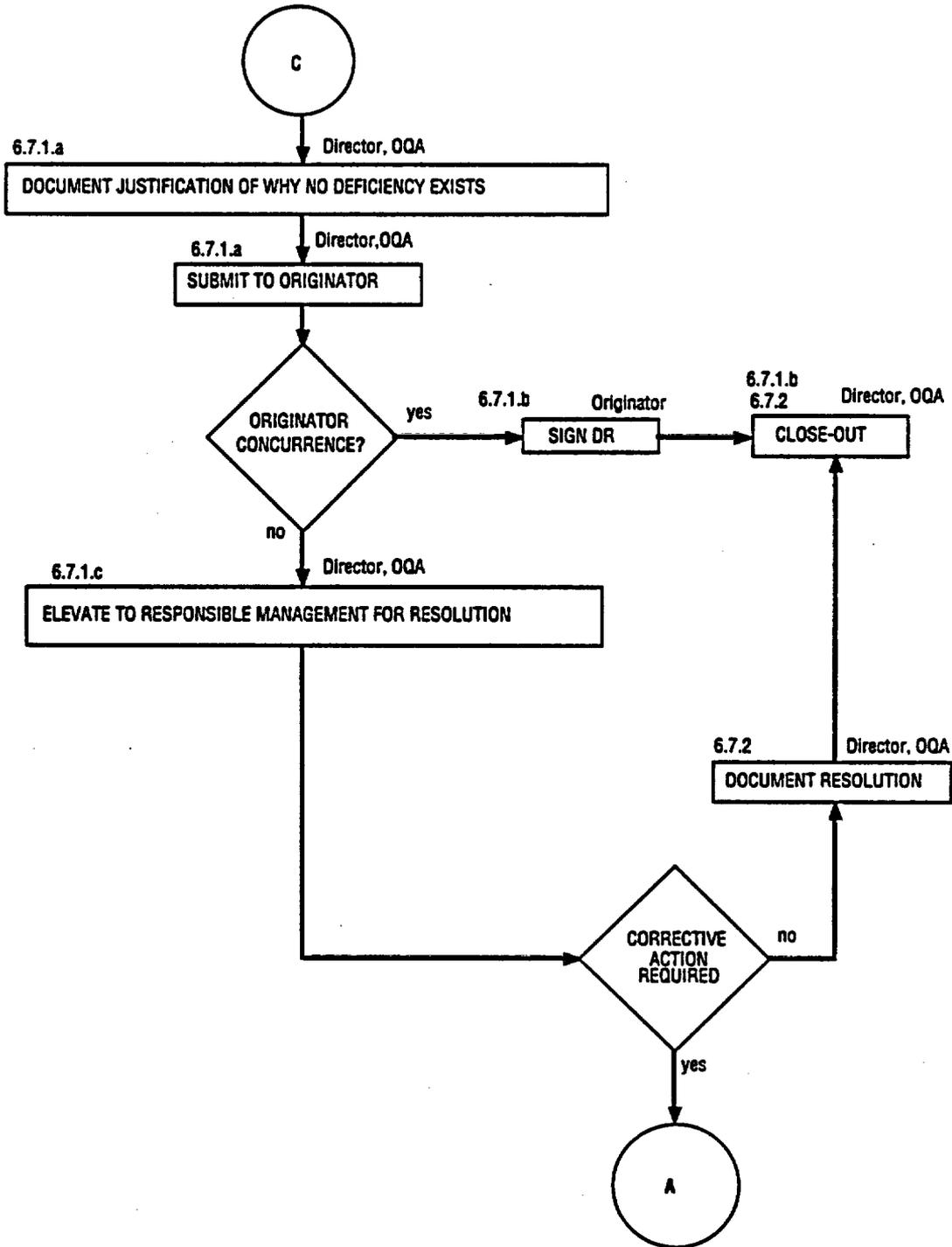
CORRECTIVE ACTION (CONTINUED)





ATTACHMENT III cont'd

CORRECTIVE ACTION (CONTINUED)





OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
QUALITY ASSURANCE ADMINISTRATIVE PROCEDURE

TITLE: CERTIFICATION OF AUDIT PERSONNEL

Procedure No.: QAAP 18.1	Revision: 0	Date: 3/27/89	Page: 1 of 21
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Director, OCRWM <i>[Signature]</i>	Date: <i>12/1/88</i>	Director, QQA <i>[Signature]</i>	Date: <i>2/1/89</i>
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1.0 PURPOSE

This procedure establishes the responsibilities and requirements for training, qualification, and certification of audit personnel for performance of quality audits by the Office of Civilian Radioactive Waste Management (OCRWM).

2.0 SCOPE

This procedure applies to all personnel who perform quality audits for OCRWM.

3.0 REFERENCES AND DEFINITIONS

3.1 REFERENCES

- 3.1.1 "Quality Assurance Requirements for the Civilian Radioactive Waste Management Program," (QAR) DOE/RW-0214, 1988.
- 3.1.2 "Quality Assurance Program Description for the Civilian Radioactive Waste Management Program," (QAPD) DOE/RW-0215, 1988.

3.2 DEFINITIONS

- 3.2.1 The definition of standard terms may be found in the Glossary contained in reference 3.1.1.
- 3.2.2 Auditor - An individual who is qualified and certified to participate in any portion of a QA audit.
- 3.2.3 Auditor-in-Training - An individual who is learning auditing techniques and practices in order to become a qualified auditor.
- 3.2.4 Lead Auditor - An individual who is certified to organize, perform, and direct a QA audit; report audit findings; and evaluate related corrective actions. The Lead Auditor may be referred to as the Audit Team Leader (ATL).



3.2.5 Observer - An individual who is not an active participant in the audit. An observer may be involved with the audit to observe how the audit is conducted, or to become familiar with the auditee's organization and activities. An observer must accompany a qualified auditor during the performance of an audit.

3.2.6 Technical Specialist - An individual assigned to provide advice to the audit team in preparing for and/or performing a QA audit when the scope, complexity, and/or special nature of the activities to be audited warrant a technical specialist to assure an adequate audit.

4.0 RESPONSIBILITIES

4.1 ASSOCIATE DIRECTORS, OCRWM

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

- 4.1.1 Supporting the audit process;
- 4.1.2 Providing technical specialists to participate in audits; and
- 4.1.3 Nominating staff as auditor candidates, as required.

4.2 DIRECTOR, OFFICE OF QUALITY ASSURANCE, (OQA)

The Director, OQA, or designee is responsible for:

- 4.2.1 Preparing and maintaining this QAAP;
- 4.2.2 Implementing the requirements of this procedure;
- 4.2.3 Training of prospective auditors and Lead Auditors;
- 4.2.4 Examining, qualifying and certifying auditors and Lead Auditors; and
- 4.2.5 Ensuring that QA records generated as a result of the implementation of this procedure are maintained.

4.3 LEAD AUDITOR

The Lead Auditor is responsible for:

- 4.3.1 Supervising and evaluating auditors-in-training;



4.3.2 Assuring that audit team members are competent to perform their assigned portion of the audit; and

4.3.3 Documenting audit records stating that auditors were competent, received specific orientation, and were independent of activities which they audited.

4.4 AUDITOR/LEAD AUDITOR CANDIDATES

Auditor and Lead Auditor candidates are responsible for acquiring the requisite orientation and training to assure their competence in auditing skills.

5.0 GENERAL

5.1 Personnel selected for QA audit assignments shall have sufficient experience and training commensurate with the scope, complexity, or special nature of the activities to be audited.

5.2 Competence of personnel to perform required audit functions shall be established by the following:

5.2.1 Orientation that provides a working knowledge of the OCRWM QA program;

5.2.2 Formal training in general and specialized aspects of audit performance; and

5.2.3 On-the-job training, guidance, and counseling under the direct supervision of a Lead Auditor.

5.3 The Director, OQA, when designated by the Director, OCRWM, as Auditor Examiner, is exempt from satisfying the requirements for Lead Auditor qualification and maintenance of proficiency as outlined in this procedure.

6.0 PROCEDURE

6.1 AUDITOR QUALIFICATION

6.1.1 Prospective auditor candidates will be provided training and orientation to develop their competence for performing QA audits.

6.1.2 Auditor training includes orientation in auditing techniques and the understanding of applicable codes, standards, directives, regulations, DOE Orders, and appropriate procedures.



- 6.1.3 After successful completion of the training, auditor candidates shall participate in at least one audit as an auditor-in-training before becoming a certified auditor.
- 6.1.4 A certified Lead Auditor supervises auditors-in-training during an audit, observes the trainee's ability in auditing skills, and submits a written evaluation of the trainee's performance to the Director, OQA.
- 6.1.5 The Director, OQA, based on the prospective auditor's previous experience, possession of adequate audit skills, training, the Lead Auditor's evaluation of the auditor-in-training, and a review of the related documentation, certifies the individual as an auditor. This certification of an auditor's qualification is documented on Attachment I, "Qualification Record Auditor/Lead Auditor".

6.2 LEAD AUDITOR QUALIFICATION

In addition to the requirements of Section 6.1, a Lead Auditor candidate will also meet the requirements of Sections 6.2.1 through 6.2.5 before being certified as a Lead Auditor.

- 6.2.1 The prospective Lead Auditor will demonstrate skills for effective communication, both oral and written. These skills are evaluated and documented by the Director, OQA.
- 6.2.2 The prospective Lead Auditor will have training sufficient to assure competence in auditing skills. This training may include, but is not limited to, on-the-job training. The following areas are considered in determining training needs:
- a) Knowledge and understanding of the OCRWM QA program, ANSI/AMSE NQA-1 and other related codes, standards, regulations and regulatory guides, as applicable;
 - b) Knowledge and understanding of the general structure of quality assurance programs as a whole;
 - c) Knowledge and understanding of auditing techniques, planning, examining, questioning, evaluating, reporting, follow-up and close-out;



- d) Knowledge and understanding of audit planning in the quality-affecting functions for activities such as design, purchasing, fabrication, handling, shipping, storage, cleaning, erection, installation, inspection, testing, statistics, nondestructive examination, maintenance, repair, operation, modification of nuclear facilities or associated components, safety aspects of the work and records management; and
- e) Knowledge and understanding of quality assurance administrative procedures applicable to audits.

6.2.3 The prospective Lead Auditor shall have participated in a minimum of five (5) quality assurance audits within the three (3) years prior to qualification. Audits performed prior to certification by OCRWM may be used to meet this requirement. At least one of the audits shall have been a nuclear QA audit within one year prior to qualification.

6.2.4 The prospective Lead Auditor will successfully complete an examination which evaluates comprehension of, and ability to apply, the body of knowledge identified in 6.2.2. This examination may be oral, written, practical, or any combination of the three types.

6.2.5 The prospective Lead Auditor will provide verifiable evidence that a minimum of ten (10) credits have been accumulated when credits are awarded per subparagraphs (a) through (d) below:

a) Education (4 credits maximum)

Associate degree from an accredited institution, score one (1) credit, or if the degree is in engineering, physical sciences, mathematics or quality assurance, score two (2) credits; or

A Bachelor degree from an accredited institution score two (2) credits, or if the degree is in engineering, physical sciences, mathematics or quality assurance, score three (3) credits. In addition, score one (1) credit for a Master's degree in engineering, physical sciences, engineering management, or quality assurance from an accredited institution.

b) Experience (9 credits maximum)

Technical experience in engineering, manufacturing, construction, operation, or maintenance, score one (1) credit for each full year with a maximum of five (5) credits for this aspect of experience.



If two (2) years of this experience have been in the nuclear industry, score one (1) additional credit; or

If two (2) years of this experience have been in quality assurance, score two (2) additional credits; or

If two (2) years of this experience have been in auditing score three (3) additional credits; or

If two (2) years of this experience have been in nuclear quality assurance, score three (3) additional credits; or

If two (2) years of this experience have been in nuclear quality assurance auditing, score four (4) additional credits.

- c) Other Credentials of Professional Competence (2 credits maximum)

For certification of competency in engineering, science, or quality assurance specialties issued and approved by a state agency or national professional or technical society, score two (2) credits.

- d) Rights of Management (2 credits maximum)

The Director, OQA, may grant up to two (2) credits for other performance factors applicable to auditing which may not be explicitly called out in this instruction. Examples of these factors are leadership, sound judgment, maturity, analytical ability, tenacity, past performance and quality assurance training courses.

- 6.2.6 When the prospective lead auditor meets the requirements of Sections 6.1 and 6.1.1 through 6.2.5, the Director, OQA, will certify on Attachment I, that the individual is qualified as a Lead Auditor.

6.3 MAINTENANCE OF PROFICIENCY

- 6.3.1 Lead Auditors and auditors shall maintain their proficiency through one or more of the following activities:

- a) Participation in at least one QA audit per year (Lead Auditors will participate in at least one QA audit a year, either as a Lead Auditor or auditor); or
- b) Review and study of the codes, standards, procedures instructions, books and other documents related to quality assurance program and program auditing; or



c) Documented participation in training programs.

6.3.2 The activities performed by Lead Auditors and auditors to maintain their proficiency will be listed on Attachment II, "Auditor/Lead Auditor Qualification Maintenance", by the Director, OQA, for each auditor and Lead Auditor.

6.3.3 Based on annual evaluations, the Director, OQA, may extend the certification, require retraining or require requalification. Attachment II identifies the activities performed, the date the activity was performed, and the type of proficiency maintenance activity (i.e., audits performed, reviews/studies conducted, or participation in training programs) for each activity performed. The Director, OQA, dated signature on Attachment I, indicates results of the evaluation are satisfactory and the certification is extended for a period of one year from the date of the evaluation.

6.3.4 Lead Auditors who fail to maintain their proficiency for a period of two (2) years or more shall require requalification. Requalification includes retraining and reexamination in accordance with the requirements of Paragraphs 6.2.2 and 6.2.4 and participation as an auditor in at least one (1) quality assurance audit. The recertification of an individual is documented by the Director, OQA, on Attachment I.

6.3.5 Auditors who fail to maintain their proficiency for a period of two (2) years or more shall require recertification in accordance with the requirements of Section 6.1. The recertification of an individual is documented by the Director, OQA, on Attachment I.

6.4 TECHNICAL SPECIALISTS

6.4.1 Technical specialists are assigned by the Director, OQA, for use in QA audits as advisors in technical matters when the scope, complexity, and/or special nature of the activities to be audited warrant the need of a technical specialist to assure an adequate audit.

6.4.2 Technical specialists may be auditors qualified in accordance with Section 6.1, who participate in the preparation and conduct of the QA audit. Technical specialists who are not qualified auditors will receive training identified in QAAP 2.1, "Indoctrination and Training" and will read Attachment III, "Audit Guide For Technical Specialists", prior to the QA audit. This guide addresses the basics of the QA audit process, the conduct of personnel during the QA audit, and identifies applicable QA auditing documents.



6.5 RECORD OF AUDIT PARTICIPATION

- 6.5.1 When a QA audit is complete, the assigned Lead Auditor prepares a letter to the Director, OQA, that identifies the QA audit number, date(s) of the QA audit, the title or name of the audited organization, and the name of each audit team member that participated in the QA audit.
- 6.5.2 A listing of each QA audit (Attachment IV, "Audit Participation Record") in which a Lead Auditor or auditor participates is maintained by the Director, OQA, and is updated upon receipt of the letter(s) (see Section 6.5.1) documenting participation in a QA audit.
- 6.5.3 A file for each Lead Auditor, auditor, and technical specialist is established and maintained by the Director, OQA, and contains copies of the individual's resume, documentation relating to or supporting the individual's qualifications, educational degree(s), training course certificates, training attendance records, audit participation records and applicable examination results.
- 6.5.4 The Director, OQA, monitors the performance of Lead Auditors and auditors and reviews their qualifications annually. He/she may extend the qualification, require retraining or requalification. These evaluations shall be documented on Attachment I.

6.6 ADMINISTRATIVE REQUIREMENTS

- 6.6.1 The Director, OQA, develops and administers the examination for a Lead Auditor.
- 6.6.2 An independent organization may be delegated this responsibility, however the Director, OQA, retains overall responsibility to see that the examination and its administration conform to this procedure.
- 6.6.3 Integrity of the examination is maintained by the Director, OQA, or other responsible organization through appropriate confidentiality of files and, where applicable, proctoring of examination.
- 6.6.4 The Director, OQA, retains a record of the objective evidence of the examination contents.
- 6.6.5 The Director, OQA, maintains a list of personnel qualified as Lead Auditors.



7.0 RECORDS

7.1 Documentation generated as a result of this procedure is collected and maintained in accordance with requirements specified in QAAP 17.1, "Records Management". At a minimum, attachments I, II, III and IV are considered QA Records.

8.0 ATTACHMENTS

- 8.1 Attachment I - Qualification Record Auditor/Lead Auditor
- 8.2 Attachment II - Auditor/Lead Auditor Qualification Maintenance
- 8.3 Attachment III - Audit Guide for Technical Specialists
- 8.4 Attachment IV - Audit Participation Record
- 8.5 Attachment V - QAAP Flowchart



ATTACHMENT I (TYPICAL)

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

SHEET ____ OF ____
WBS NO. _____

QUALIFICATION RECORD AUDITOR/LEAD AUDITOR

NAME _____		DATE: _____
EMPLOYER _____		
QUALIFICATION CREDIT REQUIREMENTS		CREDITS
EDUCATION - University/Degree/Date <ul style="list-style-type: none"> • Undergraduate Level • Graduate level <p style="text-align: right;">4 Credits Max.</p>		
EXPERIENCE - Company/Dates <ul style="list-style-type: none"> • Technical (0-5 credits) and • Nuclear Industry (0-1 credits) or • Quality Assurance (0-2 credits) or • Auditing (0-4 credits) <p style="text-align: right;">9 Credits Max.</p>		
PROFESSIONAL ACCOMPLISHMENTS - Certificate/Date <ul style="list-style-type: none"> • Professional Engineer • Society <p style="text-align: right;">2 Credits Max.</p>		
MANAGEMENT - Justification Justification _____ _____ _____		
Evaluated by _____ <div style="display: flex; justify-content: space-between;"> Name and Title Date </div> <p style="text-align: right;">2 Credits Max.</p>		
TOTAL CREDITS AWARDED		
AUDIT COMMUNICATION SKILLS Evaluated by _____ <div style="display: flex; justify-content: space-between;"> Name and Title Date </div>		

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ATTACHMENT I (cont'd)

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

SHEET 2 OF _____
WBS NO _____

QUALIFICATION RECORD AUDITOR/LEAD AUDITOR (continuation sheet)

AUDITOR TRAINING COURSES
(Course Title or Topic)

_____	_____	Date
_____	_____	Date

ON-THE-JOB TRAINING AND/OR ORIENTATION
Description

_____	_____	Evaluated by	_____	Date
_____	_____	Evaluated by	_____	Date
_____	_____	Evaluated by	_____	Date

AUDIT PARTICIPATION
ORGANIZATION

LOCATION

AUDIT NO.

DATES

EXAMINATION WRITTEN ORAL PASSED YES NO DATE _____

ADMINISTERED BY _____ DATE _____
Signature and Title

QUALIFICATION

AUDITOR
CERTIFIED BY _____ Director, OQA _____ Date

LEAD AUDITOR
CERTIFIED BY _____ Director, OQA _____ Date

ANNUAL EVALUATION: Certification is valid for a period of one year from latest date.

Signature	_____	_____	_____
Date	_____	_____	_____



**OCRWM QA
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ATTACHMENT II (TYPICAL)

**OFFICE OF CIVILIAN
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WASHINGTON, D.C.**

SHEET ____ OF ____
WBS NO. _____

AUDITOR/LEAD AUDITOR QUALIFICATION MAINTENANCE

NAME	PERIOD COVERED BY THIS RECORD
	FROM _____ TO _____

TRAINING (Courses, Self study, Program documents read, etc.)

SUBJECT COVERED	DATE
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

AUDIT PARTICIPATION

LOCATION	AUDITOR OR LEAD AUDITOR	AUDIT NO.	DATE

CONCURRENCE _____ DATE _____
Supervisor's Signature

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"EXAMPLE"

ATTACHMENT III

AUDIT GUIDE FOR TECHNICAL SPECIALISTS

Technical Specialist

Date

Director, OQA

Date



AUDIT GUIDE FOR TECHNICAL SPECIALIST (cont'd)

I. INTRODUCTION

This document is written on the basis of the current requirements of OCRWM QAR and QAPD, that relate to QA audits, and QAAP 18.2, "Audit Program". These requirements apply to the preparation, performance, reporting, and follow-up of QA audits.

The purpose of this document is to provide sufficient information to technical specialists so that they can effectively advise audit team members and make optimum contributions to the QA audit. The established methods and requirements for QA audits are delineated in QAAP 18.2.

QA audits are unique opportunities to gain further understanding of activities which are normally related to the technical specialist's work or area of expertise. The management systems, procedures, work controls, and other mechanisms which are included in the audit scope are frequently unfamiliar because of the pressures of day-to-day problems in one's own discipline. The QA audit experience provides an opportunity to participate in an orderly analysis of such systems. Therefore, time spent in preparation for, and participation in a QA audit can be worthwhile and can significantly improve the overall value of the QA audit.

You are urged to take sufficient time prior to the first meeting of the audit team to become as familiar as possible with the information provided herein. If you have questions about the audit process, talk to the audit team leader before the QA audit.

II. THE AUDIT PROCESS

As an advisor to the audit team, you will be primarily concerned with the preparation and performance of the audit. You may also participate in writing the report as directed by the audit team leader. The audit follow-up is the responsibility of the audit team leader.

The first audit function in which you may participate is the development of the audit plan. This plan will identify the audit scope, which activities are to be audited, the applicable documents to be audited against, the audit schedule, and the written checklists to be utilized by the auditors.

One of the major activities in planning the audit will be a review of deficiencies or problems reported during previous audits and surveillances or past experience with the audited organization. The past audit records and other related reports provide information pertaining to both past problems for which corrective action has been implemented and for open items which have not yet been closed out.



AUDIT GUIDE FOR TECHNICAL SPECIALIST (cont'd)

The audit team leader will conduct a pre-audit team meeting to discuss details of the audit plan and establish individual responsibilities. A pre-audit meeting will be conducted with the audit team and representatives of the audited organization to outline the audit scope, the audit plan, and other details of the audit. The pre-audit meeting will also introduce the auditors and other participants to personnel of the audited organization with whom the auditors will work. The proposed sequence of events for the audit will be reviewed, and tentative plans for the post-audit meeting will be made.

During the conduct of the audit, it may be advantageous to split the audit team into several groups. The technical specialist of the audit team will be in a group which includes the audit team leader or another auditor. This will assist the technical specialist in concentrating on his/her specialized areas.

The principal audit method is to verify compliance with the Quality Assurance Program and other stated requirements. Objective evidence may take the form of records such as, drawings, specifications, logs, data sheets, test results, or other documents which will assist the auditor in drawing meaningful conclusions in regard to effective implementation of applicable requirements. The audit team leader should be kept fully aware of any needs for special information and should be advised if it is necessary to talk to people or examine records outside the scope of the audit as originally planned. Whenever deficiencies are identified during an audit they should be pointed out to the responsible members of the organization being audited.

The purpose of the post-audit meeting is to review the audit findings with responsible management of the audited organization. This is essential so that if there are any misunderstandings based on insufficient or incorrect information, they can be clarified. In addition, the exit interview gives the audited organization a good understanding of the overall findings so that appropriate corrective action can be initiated as expeditiously as possible - often even before the audit report is returned to the audited organization for formal acknowledgement.

After the QA audit has been completed, the audit team usually meets one or more times to develop the audit report. This report will be prepared in accordance with QAAP 18.2 and be signed by the audit team leader. It will include a summary of the findings and a statement of effectiveness of the QA Program audited. Deficiency Reports which identify deficiencies noted during the audit, will be issued prior to the audit report in accordance with QAAP 18.2 and are attached to the audit report for information purposes. The audit report is to be issued by the audit team within 30 days of completion of the audit.



AUDIT GUIDE FOR TECHNICAL SPECIALIST (cont'd)

III. PERSONAL CONDUCT

One subject of prime importance is the matter of personal conduct of the audit team members. Audits will have various degrees of personal involvement on the part of the audit team and members of the organization being audited.

Conflicts of opinion are frequently unavoidable; however, conflicts of personalities can almost always be avoided by a skillful team member. The point to remember is that an audit evaluates the performance of others. To varying degrees, differences of opinion are almost always factors in the auditor-auditee relationship. Consequently, it is imperative that an auditor be fully aware of the sensitivity of his/her position. The following guidelines are provided to minimize the impact of personal involvements in the audit process.

1. The audit plan and checklist should be used as a guide; however it should not restrict the audit investigation. Departure from the audit checklist should be discussed with the audit team leader.
2. Be objective and listen carefully to responses. Remember that the audited organization will normally understand its system better than you.
3. Avoid personal accusations in audit related conversations with the audited organization.
4. Arguments with individuals from the audited organization should be avoided. If you feel you are correct, accurately document the finding. Next, summarize the audited organization's opinion and acquire concurrence on their position.
5. Tentatively classify each finding at the time it is found. The reason(s) which prompted the classification should be carefully noted for future reference.
6. Record names, titles, places, etc. of individuals you contact during the audit. Material which will be required to support findings should be reproduced, if possible, or its' identity carefully recorded.
7. A finding which is deemed severe enough to warrant immediate action should be brought to the attention of the audit team leader.



AUDIT GUIDE FOR TECHNICAL SPECIALIST (cont'd)

IV. REFERENCES*

These references provide more detailed information relative to QA audits and should be consulted for answers to specific questions. The audit team leader can direct you to the reference which addresses your question.

1. 10 CFR 50 - Appendix B - Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants
2. 10 CFR 60 - Subpart G - Quality Assurance
3. 10 CFR 71 - Subpart H - Quality Assurance
4. 10 CFR 72 - Subpart G - Quality Assurance
5. ANSI/ASME NQA-1 - 1986, Quality Assurance Program Requirements for Nuclear Facilities
6. DOE 5700.6 - Quality Assurance
7. DOE/RW-0005 - Mission Plan
8. DOE/RW-0215 - Quality Assurance Program Description for the Civilian Radioactive Waste Management Program
9. DOE/RW-0214 - Quality Assurance Requirements for the Civilian Radioactive Waste Management Program
10. QAAP 18.1, Certification of Audit Personnel
11. QAAP 16.1, Corrective Action
12. QAAP 18.2, Audit Program

*Latest applicable revision



ATTACHMENT IV (TYPICAL)

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

SHEET ____ OF ____
WBS NO _____

AUDIT PARTICIPATION RECORD

NAME

DATE

EMPLOYER

AUDIT NO.	DATE(S) OF AUDIT	AUDITED ORGANIZATION	*ALA

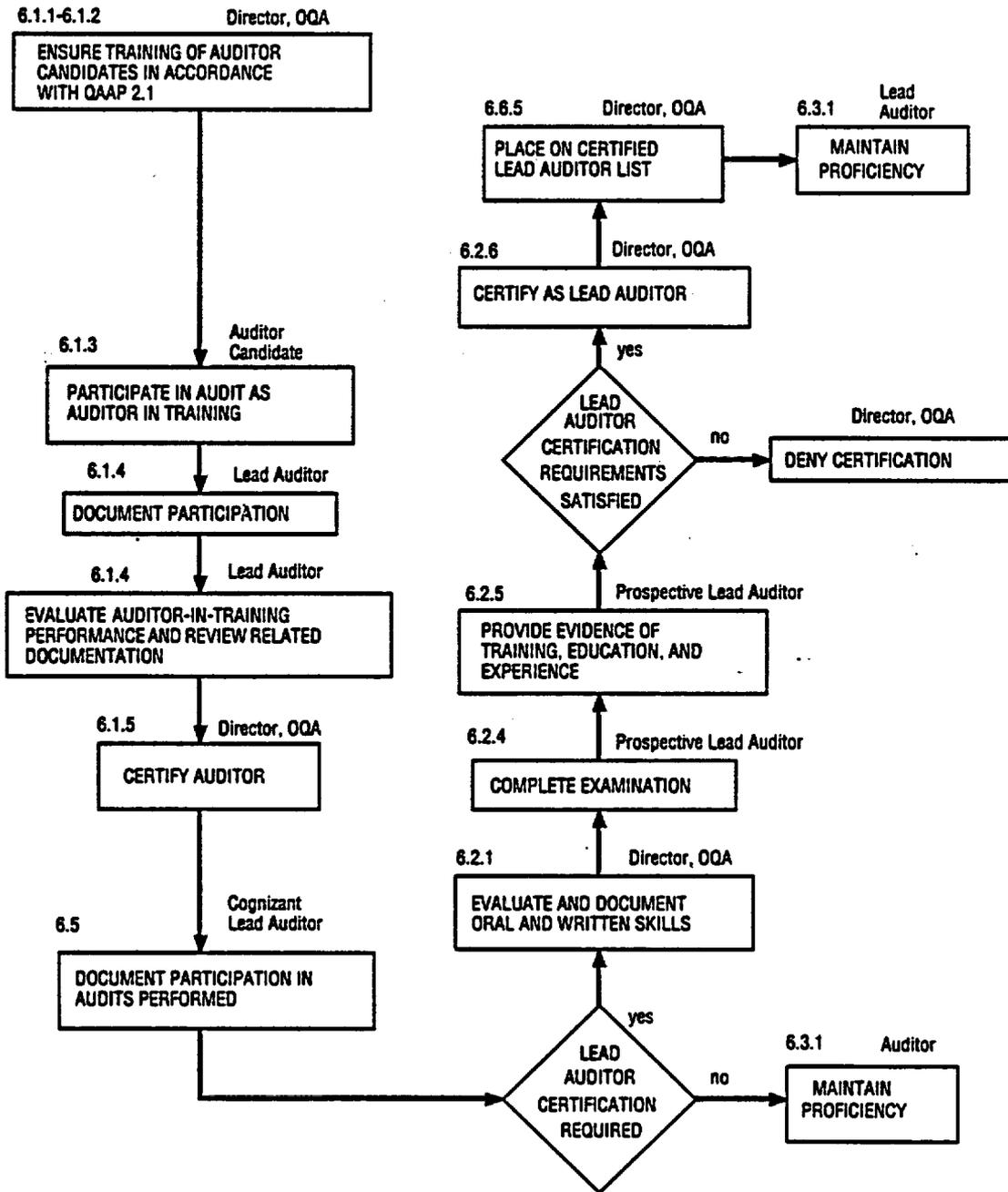
* LIST FUNCTION PERFORMED DURING AUDIT: A AUDITOR, LA LEAD AUDITOR

REV. 1/89



ATTACHMENT V

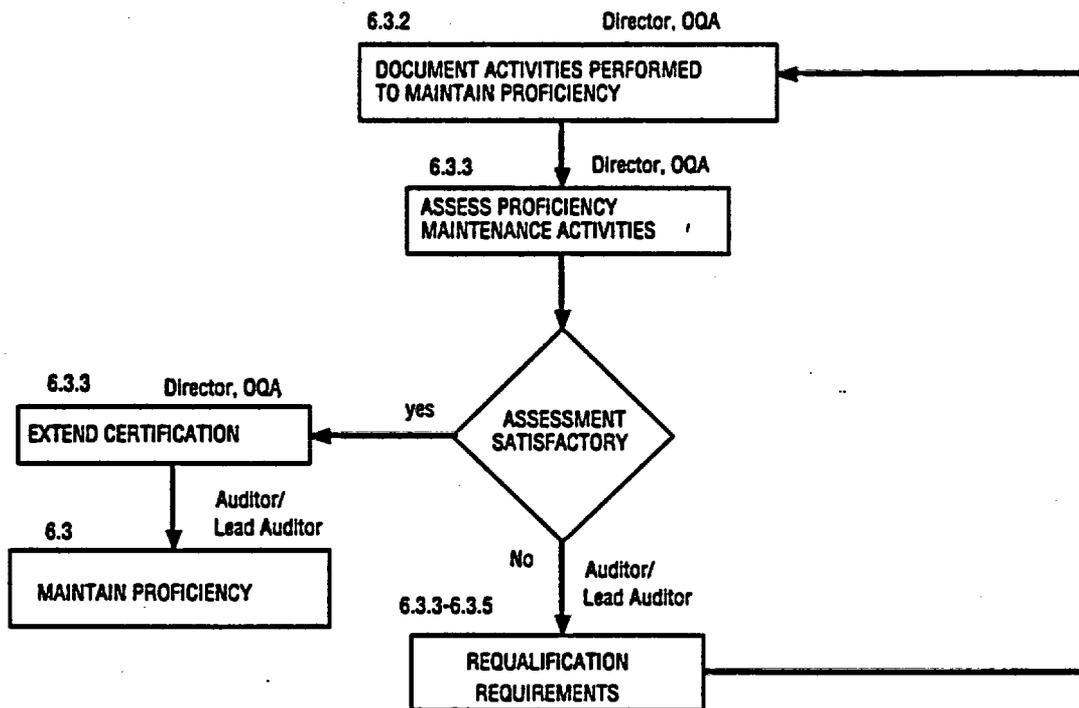
CERTIFICATION OF AUDIT PERSONNEL





ATTACHMENT V (cont'd)

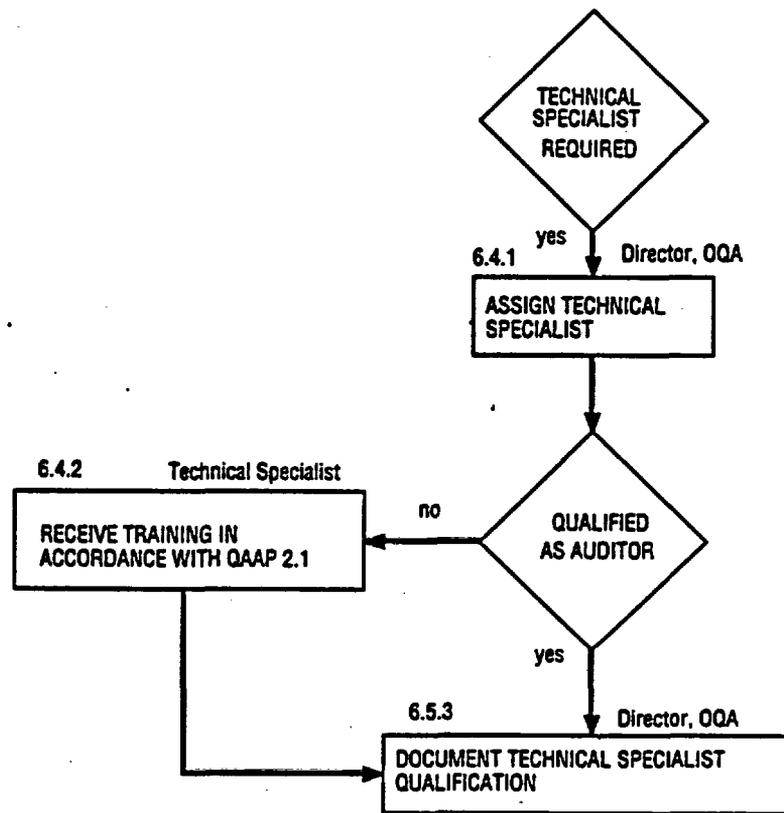
AUDITOR/LEAD AUDITOR PROFICIENCY MAINTENANCE





ATTACHMENT V (cont'd)

QUALIFICATION OF TECHNICAL SPECIALISTS





OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
QUALITY ASSURANCE ADMINISTRATIVE PROCEDURE

TITLE: AUDIT PROGRAM

Procedure No.: QAAP 18.2	Revision: 0	Date: 3/27/89	Page: 1 of 26
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Director, OCRWM <i>[Signature]</i>	Date: 12/1/88	Director, OQA <i>[Signature]</i>	Date: 12/1/88
---------------------------------------	------------------	-------------------------------------	------------------

1.0 PURPOSE

The purpose of this procedure is to establish the responsibilities and methods for planning, conducting, and documenting a formal, comprehensive quality assurance audit program conducted by the Office of Civilian Radioactive Waste Management (OCRWM), Office of Quality Assurance (OQA).

2.0 SCOPE

This procedure applies to all OCRWM internal and external quality assurance audits conducted by OCRWM or in its behalf.

3.0 REFERENCES AND DEFINITIONS

3.1 REFERENCES

3.1.1 "Quality Assurance Requirements for the Civilian Radioactive Waste Management Program", (QAR) DOE/RW-0214, 1988.

3.1.2 "Quality Assurance Program Description, for the Civilian Radioactive Waste Management Program", (QAPD) DOE/RW-0215, 1988.

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 Auditor - An individual who is qualified and certified to participate in any portion of a QA audit.

3.2.3 Finding - An audit finding is any deficiency in an item or activity, attribute, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate. Audit findings are documented on Deficiency Reports (DRs).



- 3.2.4 Lead Auditor - An individual who is certified to organize, perform, and direct a QA audit; report audit findings; and evaluate related corrective actions. The Lead Auditor may be referred to as the Audit Team Leader (ATL).
- 3.2.5 Observation - The recognition by the audit team of a weakness in a quality assurance program that, if left uncorrected, could result in a condition adverse to quality.
- 3.2.6 Observer - An individual who is not an active participant in the audit process. An observer may be involved with the audit to observe how the audit is conducted, or to become familiar with the auditee's organization and activities. An observer must accompany a qualified auditor during the performance of an audit.
- 3.2.7 Technical Specialist - An individual assigned to provide advice to the audit team in preparing for and/or performing a QA audit when the scope, complexity, and/or special nature of the activities to be audited warrant a technical specialist to assure an adequate audit.

4.0 RESPONSIBILITIES

4.1 ASSOCIATE DIRECTORS, OCRWM

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

- 4.1.1 Reviewing and concurring with audit schedules;
- 4.1.2 Providing technical staff as technical specialists to participate in selected quality assurance audits, as requested; and
- 4.1.3 Reviewing audit reports for information or responses.

4.2 DIRECTOR, OFFICE OF QUALITY ASSURANCE (OQA)

The Director, OQA, or designee is responsible for all aspects of the QA audit program including:

- 4.2.1 Preparing and maintaining this QAAP;
- 4.2.2 Scheduling of all audits;
- 4.2.3 Contacting States, Tribes and the NRC, as necessary;
- 4.2.4 Developing audit plans and checklists;
- 4.2.5 Approving audit plans and checklists;



- 4.2.6 Assuring that auditors and Lead Auditors are properly trained, qualified, and certified;
- 4.2.7 Issuing audit reports;
- 4.2.8 Approving audit response evaluations and proposed corrective action;
- 4.2.9 Verifying implementation of corrective action; and
- 4.2.10 Closing audit files.

4.3 LEAD AUDITOR (AUDIT TEAM LEADER)

The Lead Auditor (Audit Team Leader) is responsible for:

- 4.3.1 Audit planning and preparation activities;
- 4.3.2 Orienting other team members and observers;
- 4.3.3 Developing audit plans, checklists, and audit notification documents;
- 4.3.4 Assuring that audit team members are independent of direct responsibility with the activity being audited;
- 4.3.5 Coordinating audit planning sessions, itineraries, and logistics;
- 4.3.6 Conducting daily team briefings with the audited organization;
- 4.3.7 Conducting pre-audit and post-audit meetings;
- 4.3.8 Preparing the audit report;
- 4.3.9 Evaluating audit responses and closing out the audit;
- 4.3.10 Verifying corrective action implementation; and
- 4.3.11 Closing the audit file.

4.4 AUDIT TEAM MEMBERS

The audit team members are responsible for:

- 4.4.1 Preparing for their participation in the audit;
- 4.4.2 Attending all meetings as requested by the audit team leader;



- 4.4.3 Conducting portions of the audit as assigned;
- 4.4.4 Completing assigned portions of the audit checklist; and
- 4.4.5 Writing portions of the audit report.

4.5 TECHNICAL SPECIALIST

The Technical Specialist is responsible for:

- 4.5.1 Providing technical guidance to the audit team members when auditing specific areas which require technical expertise.

5.0 GENERAL

- 5.1 Audits are performed on a regular basis to verify that requirements of the PROGRAM are being met.
- 5.2 Audit schedules are prepared on a fiscal year basis and updated on a quarterly basis.
- 5.3 The attachments to this procedure contain additional information including schedule forms, sample notification letters, and guidance to assist the auditors in performing meaningful audits.

6.0 PROCEDURE

6.1 SCHEDULING

- 6.1.1 The Director, OQA, develops an audit schedule on a fiscal year basis (Attachment I, "OCRWM QA Audit Schedule"). The audit schedule identifies the following:
 - a) Organizations to be audited;
 - b) Location;
 - c) Date;
 - d) Scope;
 - e) Audit team leader;
 - f) Audit team members; and
 - g) State, Indian Tribe, or NRC contacts, as applicable.



- 6.1.2 The audit schedule is updated quarterly as a minimum, concurred with by the Associate Directors and approved by the Director, OQA.
- 6.1.3 After approval, the audit schedule is transmitted to the Director, OCRWM, and each organization and contractor on the audit schedule.
- 6.1.4 Written requests, with justifications for changes to the audit schedule, are sent to the Director, OQA, by the organization or contractor requesting the change. The request and justification is reviewed by the Director, OQA, with changes made to the audit schedule as appropriate. The request and the Director, OQA, acceptance/rejection are filed as QA records.

6.2 AUDIT TEAM SELECTION

- 6.2.1 The Director, OQA, selects the Lead Auditor and audit team members.
- 6.2.2 The Lead Auditor assembles the audit team, comprised of team members who collectively have the appropriate technical expertise commensurate with the scope and complexity of the activities to be audited. Members of the audit team shall be independent of all direct responsibility for the activity to be audited.

6.3 PREPARATION

- 6.3.1 The Lead Auditor assures that the audit team is prepared prior to initiating the audit by conducting one or more team orientation sessions to brief the team members on:
- a) the scope of the audit;
 - b) logistics;
 - c) audit team responsibilities;
 - d) checklist preparation and completion; and
 - e) audit team etiquette and conduct.
- 6.3.2 A visit to the site of the planned audit and meetings with the organization to be audited may be considered to further define the scope and conduct of the audit.



6.4 NOTIFICATION

6.4.1 The Lead Auditor prepares the audit notification memorandum (internal, Attachment II) or letter (external, Attachment III) a minimum 30 calendar days prior to the scheduled audit date.

6.4.2 The audit notification memorandum or letter for internal audits is approved by the Director, OQA, and for external audits by the appropriate Division Directors. Copies of the audit notification are sent to the Director, OCRWM, each affected Associate Director, Division Director, the State, NRC and Indian Tribes, as appropriate.

6.5 AUDIT PLAN

6.5.1 An audit plan, (Attachment IV) developed by the lead Auditor, identifies the following:

- a) Audit scope;
- b) Audit team leader and members;
- c) Documents covered by the audit;
- d) Requirements to be audited;
- e) Activities to be audited; and
- f) Preliminary audit schedule.

6.5.2 The audit plan may be attached to the audit notification memorandum or letter.

6.6 AUDIT CHECKLIST

The Lead Auditor ensures that audit checklists (Attachment V) are developed. The technical portions of the audit checklist should be developed based on input by the technical specialist(s). The composite audit checklist is accepted by the Lead Auditor and approved for use by the Director, OQA. The approved audit checklist should be distributed to the audit team members at least seven days prior to the audit.

6.7 PERFORMANCE

6.7.1 The Lead Auditor arranges for the pre-audit meeting with key personnel within the organization to be audited. Meeting attendance is documented using Attachment VI, "Attendance Record". The purpose of the meeting is to:



- a) Meet the participants, including observers;
- b) Obtain information on the organization and status of work being done;
- c) Discuss the audit's purpose, scope, and requirements and provide information on how the audit will be conducted, observer protocol, which activities and areas are to be audited, and who will cover each area;
- d) Arrange for contacts and escorts when needed;
- e) Arrange for times to meet with key people;
- f) Establish the agenda for the audit;
- g) Answer any questions about the audit; and
- h) Schedule the post-audit meeting.

6.7.2 During the audit, team members will:

- a) Examine and evaluate objective evidence to determine if requirements are being met;
- b) Maintain a list of personnel contacted;
- c) Immediately report any conditions requiring prompt corrective action to the Lead Auditor, who notifies the management of the audited organization and provides written documentation, as necessary;
- d) Obtain permission and/or escort before viewing records in a file or before entering a limited access work area;
- e) Record results on a working copy of the checklist;
- f) Avoid duplicating effort by combining checks on different requirements whenever possible (e.g., when checking a purchase order file for approvals, also check the certifications);
- g) Adequately identify samples so that the audit could be re-traced and the same samples obtained, and record the details of any noncompliance;
- h) Make a copy of noncomplying documents for audit backup material;



- i) When checking a document for more than one attribute or requirement, record the results so that it is clear which requirement or attribute is not in compliance;
- j) Increase the sample size if results are inconclusive;
and
- k) Examine objective evidence to the extent necessary, not to be limited by the checklist if a problem or discrepancy is discovered during the audit (add it to the checklist notes and include it in the audit report).

6.7.3 When a problem is identified outside of the responsibility of the organization being audited, the audit team member notifies the Lead Auditor for further action.

6.7.4 Audit team members shall complete all of their assigned portions of the checklist. Results of the examination are noted on the checklist as satisfactory, unsatisfactory, or not applicable. Documentation that supports the notation is recorded in the comment section of the checklist. The reasons for noting the "not applicable" block will also be recorded (such as, not enough time to complete activity, no activity in the area). For each unsatisfactory notation, a corresponding Deficiency Report (Attachment VII) shall be referenced, or an explanation of the unsatisfactory condition identified.

6.7.5 At the end of each audit day the audit team meets with personnel of the audited organization to discuss progress, problems, and findings. Deficiency Reports should be written daily to prepare for the post-audit meeting.

6.7.6 Prior to the post-audit meeting, the audit team shall meet in private to review and document all audit results, Deficiency Reports and review the audit checklist(s) for completeness and comprehension.

6.8 POST-AUDIT MEETING

6.8.1 The Lead Auditor conducts a post-audit meeting with the management of the audited organization to present the results of the audit, solicit feedback, and discuss response requirements. All audit team participants normally attend the meeting. Meeting attendance is documented using Attachment VI, "Attendance Record".



6.9 AUDIT REPORT

6.9.1 An audit report (Attachment VIII) will be prepared and dispatched within 30 calendar days after the post-audit meeting, under the guidance of the Lead Auditor. The audit report will include:

a) Introduction, covering:

The purpose and scope of the audit;

The basis for the audit (e.g., references);

The identification of the audit team members, observers and personnel contacted during audit activities (usually an attachment);

The period covered by the audit; and

A statement documenting the examination of nonconformance reports, surveillance reports, deficiency reports, corrective action reports and previous audit reports.

b) Summary of Results, covering:

A statement of the effectiveness and adequacy of the QA program as defined in the audit scope;

A summary of applicable technical and/or management assessments;

A summary of the applicable highlights of the audit findings and observations — referencing any Audit Finding/Observation Sheets which provide more detail on each deficiency; and

The areas of concern which may be documented in the summary.

c) Need for a Response, covering:

The corrective action steps to be taken; and

The initial response due date.

d) Closure, providing statements that:

The audit is considered closed upon issuance of the audit report;



Tracking is performed independently for each deficiency;
and

Establishes an initial response date.

6.9.2 The Lead Auditor prepares an Executive Summary and addresses it to management of the audited organization. The executive summary includes:

- a) A brief summary of the audit scope;
- b) Conclusions, areas of concern, and general comments;
- c) Statements from the management/technical representatives, as applicable, and
- d) A brief description of the identified deficiencies, as applicable.

6.9.3 As a minimum, the following will receive a copy of the audit report:

- a) Director, OCRWM;
- b) Cognizant Associate Director, OCRWM;
- c) Director, OQA;
- d) Affected Division Directors;
- e) Audit Team Members;
- f) External interest groups, as appropriate (e.g., State and local governments).

6.10 ADDITIONAL RESPONSE AND EVALUATION

6.10.1 The audited organization is required to respond to the audit report and audit Deficiency Reports within thirty (30) calendar days after receipt of the audit report.

6.10.2 Deficiency Reports shall be processed in accordance with QAAP 16.1, "Corrective Action".

6.10.3 If a response is not received within the required time, progressively stronger action shall be taken as follows:



- a) A phone call from the Lead Auditor to the audited organization will be initiated and documented if the response is not received within thirty-seven (37) calendar days of the audit report transmittal date;
- b) A letter is written if the telephone effort is unsuccessful and the response is not received within forty-seven (47) calendar days of the audit report transmittal date;
- c) If the response to the letter is not received within the allotted time frame, the situation will be elevated to the Director, OQA, for action;
- d) If all actions are unsuccessful, consideration will be given to initiate stop work action in accordance with QAAP 16.2, "Stop Work".

6.10.4 Once the response is received, the Lead Auditor and team members evaluate the response for acceptability in accordance with QAAP 16.1 "Corrective Action". The response evaluations may be dispositioned as: accepted, accepted with modifications, or rejected.

6.10.5 If the response to a specific Deficiency Report includes satisfactory documentation to provide verification of corrective action implementation, then the finding may be closed.

6.10.6 When the response to a Deficiency Report is acceptable, but requires verification prior to closeout, the finding remains open, subject to verification.

6.10.7 The Lead Auditor prepares a response letter from the Director, OQA, to the audited organization within thirty (30) calendar days of receipt of the audit response. The letter advises them of the results of the evaluation and discusses any additional information that may be required.

6.11 FOLLOW-UP AND CLOSEOUT

6.11.1 Deficiency Reports resulting from audits shall be processed in accordance with QAAP 16.1, "Corrective Action", and the Lead Auditor shall monitor status until closure. As each Deficiency Report is verified, the Lead Auditor prepares a memorandum or letter to close the Deficiency Report. The Director, OQA, signs the closeout memorandum or letter and assures that the closeout blocks on the Deficiency Reports are properly completed.



7.0 RECORDS

Documentation generated as a result of this procedure is collected and maintained in accordance with requirements specified in QAAP 17.1, "Records Management." At a minimum, attachments I, II, III, IV, V, VI, VII and VIII are considered QA records.

8.0 ATTACHMENT

- 8.1 Attachment I - OCRWM QA Audit Schedule
- 8.2 Attachment II - Internal Audit Notification Memorandum
- 8.3 Attachment III - External Audit Notification Letter
- 8.4 Attachment IV - Audit Plan Format
- 8.5 Attachment V - Quality Assurance Checklist
- 8.6 Attachment VI - Attendance Record
- 8.7 Attachment VII - Deficiency Report
- 8.8 Attachment VIII - Quality Assurance Audit Report
- 8.9 Attachment IX - QAAP Flowchart



OCRWM QA
ADMINISTRATIVE
PROCEDURE

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(12-84)

ATTACHMENT II (EXAMPLE)
INTERNAL AUDIT NOTIFICATION MEMORANDUM

United States Government

Department of Energy

memorandum

DATE:

REPLY TO
ATTN OF:

RW-3
Notice of Internal QA Audit No. 8__-I-__

SUBJECT:

(Subject office, division or branch to be audited)

TO:

Appropriate Associate Director/Division Director/Branch Chief

Ref:

(Previously issued audit schedule and date of issue)

An internal audit of HQ OCRWM and _____
(Office, division or branch to be audited)
activities associated with _____
(Element to be audited, e.g., document control)
will be conducted _____
(Date of audit)

The purpose of this audit is to _____
_____ The
scope of this audit will cover _____

The primary reference documents for requirements that pertain to this area are:

- ANSI/ASME NQA-1, "Quality Assurance Program Requirements for Nuclear Facilities"
- DOE/RW-0214, "Quality Assurance Requirements for the Civilian Radioactive Waste Management Program"
- Quality Assurance Administrative Procedure, QAAP __, " _____"
(Title)
- _____
(Other procedures or documents as appropriate)

The audit will be performed by _____ of _____
(Personnel names) (Consultant name or OCRWM)
_____ and other OCRWM personnel as required.

Please inform the appropriate members of your staff of this scheduled audit. A specific interview schedule will be established with the persons involved about a week before the audit. Questions regarding this audit should be directed to _____ of the Office of Quality Assurance. The preaudit (Team leader/member or other) and postaudit conferences are scheduled for _____ (Dates, times and places) (as appropriate). Also please notify cognizant management and other appropriate personnel so they are available to attend the preaudit and postaudit meetings as necessary.



ATTACHMENT III (EXAMPLE)

EXTERNAL AUDIT NOTIFICATION LETTER

Department of Energy
Washington, DC 20585

(addressee)

(title)

(contractor name)

(address)

(city, state, zip code)

Dear _____:

Representatives of the OCRWM, Office of Quality Assurance (OQA) will conduct an audit (No. QAS___-E-__) of your quality assurance program activities on _____ as agreed during a telephone conversation between _____ of your organization and _____ of OQA on _____.

The attached audit plan describes the audit scope, the activities to be audited, the requirements, applicable documents, personnel conducting the audit, other audit participants, and the proposed schedule.

Please ensure that adequate facilities are available for conducting preaudit and postaudit meetings, and facilities for the audit team and other participants to caucus and review documents.

Additionally, please ensure that copies of the documents identified below are available for the auditor's use during the audit.

(QA manual, plan, procedures, technical documents, etc.)

Please notify cognizant management and other appropriate personnel of the proposed audit schedules so that they are available to participate in the audit, and to attend the preaudit and postaudit meetings as necessary.

If you require any additional information, please contact _____.

(audit team leader)

at _____ or _____ at _____.

(audit team member)

Sincerely,

_____, Director
Office of Quality Assurance
Office of Civilian Radioactive
Waste Management



ATTACHMENT IV

Example of
Audit Plan Format

Audit Number: _____

Organization: _____

Location of Audit: _____

Dates of Audit: _____

Audit Team Members: _____

AUDIT SCOPE

Activities/Contracts/Tasks to be Audited: _____

Requirements/Criteria to be Audited: _____

Governing Documents: _____

PRELIMINARY AUDIT SCHEDULE:

Pre-audit Meeting: _____

Conduct of Audit: _____

Daily Team Debriefing Time and Location: _____

Post-audit Meeting Date, Time and Location: _____



OCRWM QA
ADMINISTRATIVE
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ATTACHMENT V (TYPICAL)

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

SHEET _____ OF _____
AUDIT/SURVEILLANCE/INSPECTION
NO. _____

QUALITY ASSURANCE CHECKLIST

ORGANIZATION EVALUATED	<input type="checkbox"/> EXTERNAL	<input type="checkbox"/> AUDIT	PREPARED BY _____	DATE _____
DATE(S) OF EVALUATION	<input type="checkbox"/> INTERNAL	<input type="checkbox"/> SURVEILLANCE	CONCURRED BY _____	DATE _____
		<input type="checkbox"/> INSPECTION	APPROVED BY _____	DATE _____

CONTROLLING DOCUMENT (Title, Number, Revision)	ACTIVITY EVALUATED
--	--------------------

ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS

* INDICATE RESULTS: SATISFACTORY (SAT), UNSATISFACTORY (UNSAT), NOT APPLICABLE (N/A)

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WASHINGTON, D.C.



OCRWM QA
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ATTACHMENT V (cont'd)

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

SHEET _____ OF _____
AUDIT/SURVEILLANCE/INSPECTION
NO. _____

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS

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WASHINGTON, D.C.



**OCRWM QA
ADMINISTRATIVE
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ATTACHMENT VII (cont'd)

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

SHEET ____ OF ____
WBS NO. _____

DEFICIENCY REPORT (continuation sheet)

DR. NO. _____

REVISION NO. _____

DATE _____

REV. 1/89

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



ATTACHMENT VIII (EXAMPLE)

QUALITY ASSURANCE AUDIT REPORT
(Suggested Format)

Audit No.

Organization Audited:

Dates of Audit:

Audit Team Members:

_____- _____
_____- _____
_____- _____

1.0 Scope of Audit
Describe the scope (including such things as "verified by review of objective evidence that _____ has an effectively documented and implemented Quality Assurance Program ...").

2.0 Personnel Contacted
W. Doe 1,2,3 Project Manager 1=attended preaudit meeting
J. Smith 2 Engineer 2=contact during audit
G. Jones 3 Technician 3=attended postaudit meeting
A. Wade 1,2,3 QA Manager

3.0 Executive Summary of Audit Results
As a result of the audit, _____ Deficiency Reports were issued for the criteria audited.

3.1 Describe positive points as well as problematic areas. The summary should be brief, and should identify major and minor concerns or problems.

3.2 Summarize and discuss audit findings here. Reference Deficiency Report numbers.

3.3 Describe any comments or recommendations here.

4.0 Definitions
Include any definitions that would enhance and facilitate understanding of the audit report.

5.0 Effectiveness
Include a statement on the effectiveness of the quality assurance program elements audited. The statement should reflect whether the QA program is meaningful as applicable to the scope of work and whether it is effectively implemented.

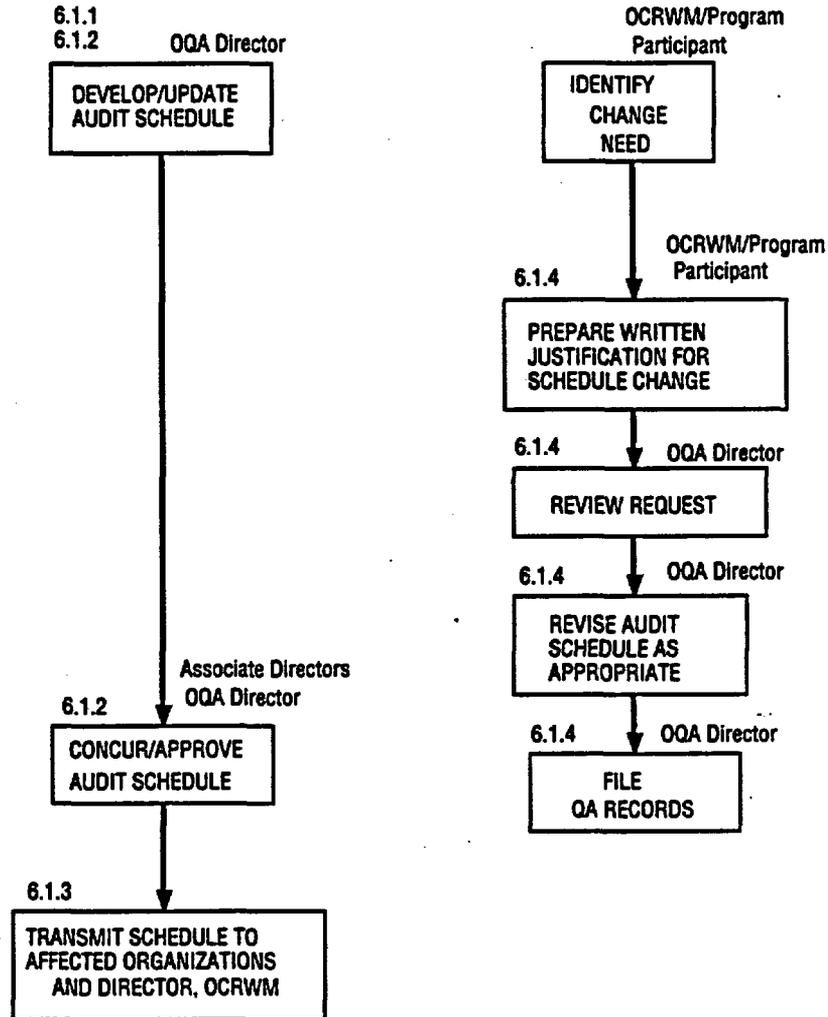
Issued: _____ Date: _____
(Audit Team Leader)

Approved: _____ Date: _____



ATTACHMENT IX

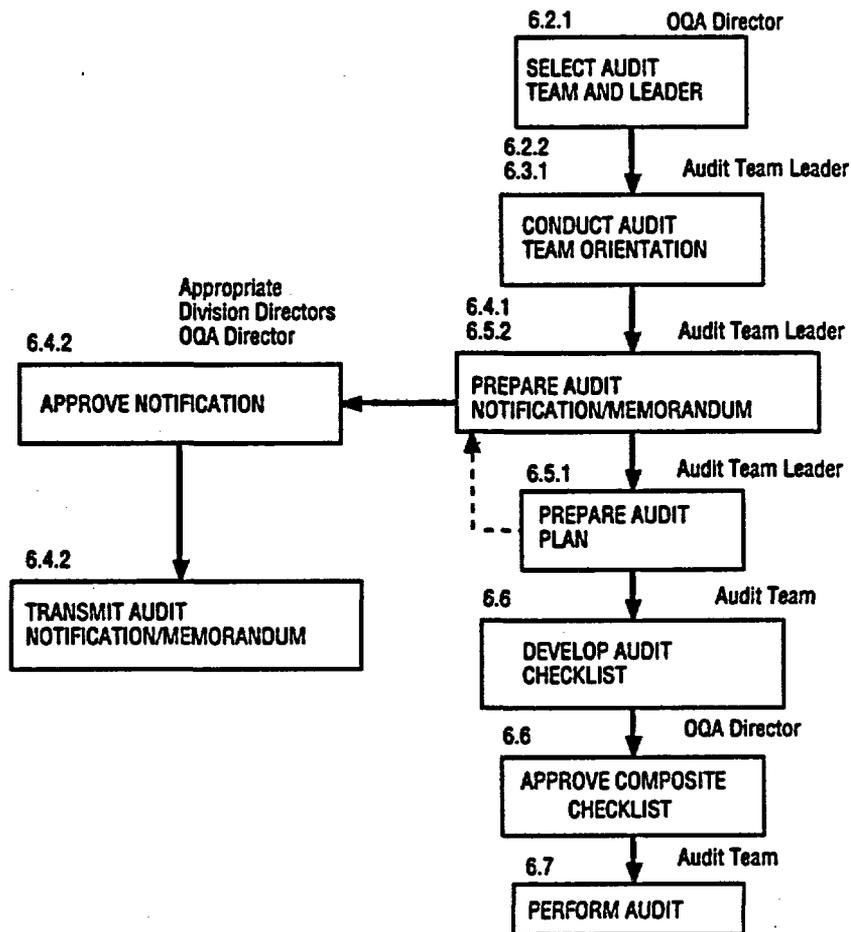
AUDIT SCHEDULING





ATTACHMENT IX (cont'd)

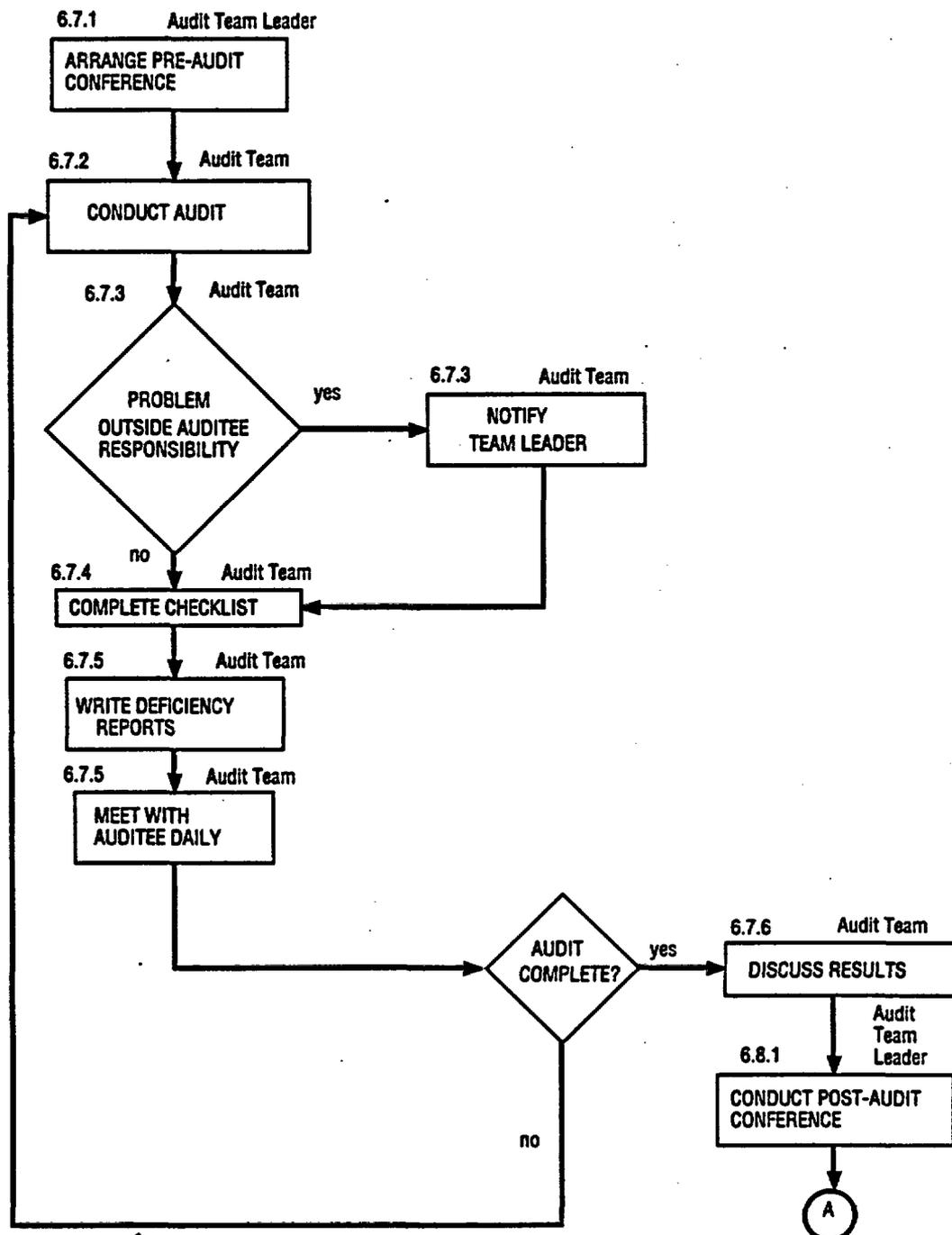
AUDIT PREPARATION





ATTACHMENT IX (cont'd)

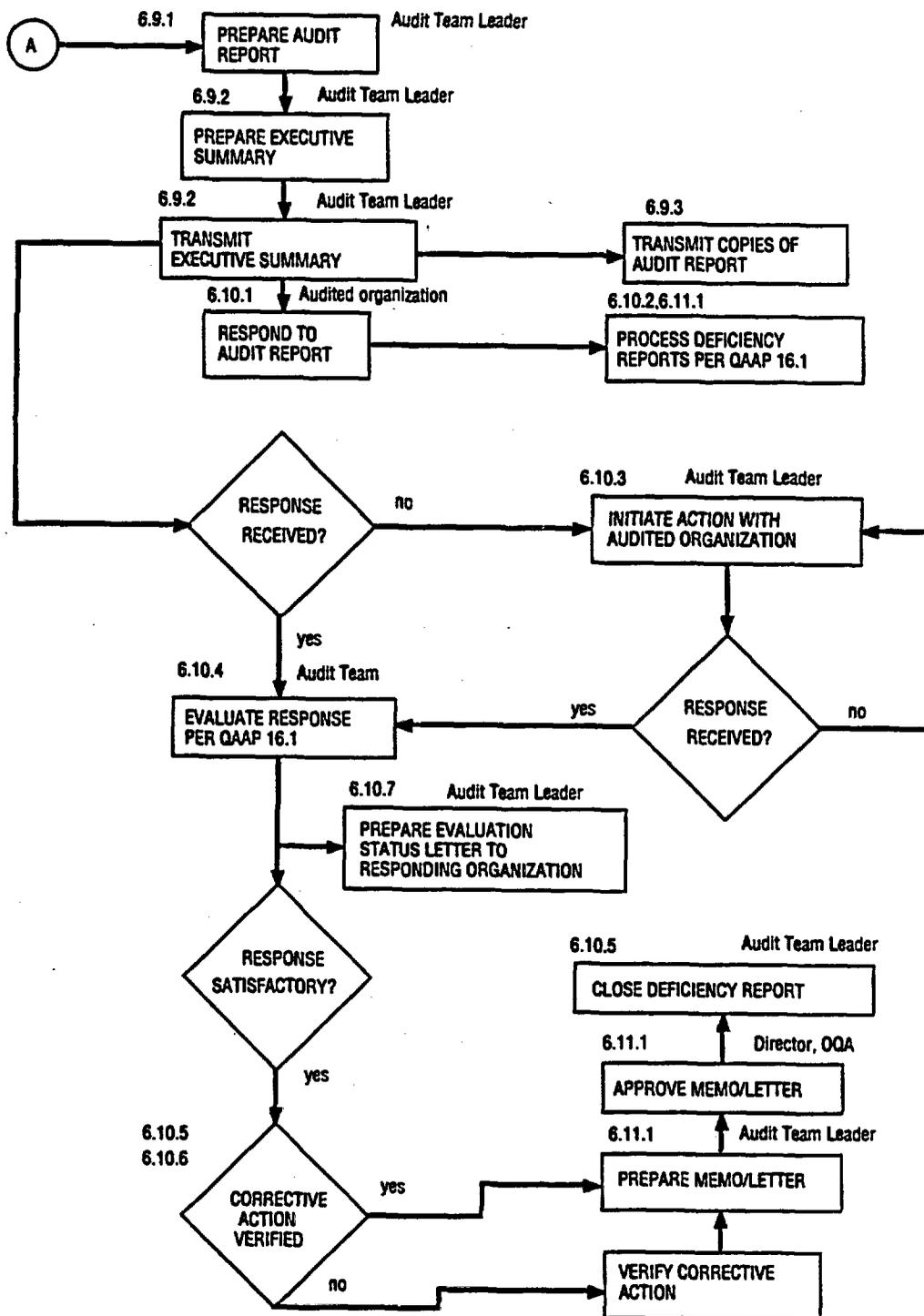
AUDIT PERFORMANCE





ATTACHMENT IX (cont'd)

AUDIT REPORTING, RESPONSE, AND FOLLOW-UP





OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
QUALITY ASSURANCE ADMINISTRATIVE PROCEDURE

TITLE: SURVEILLANCE PROGRAM

Procedure No.: QAAP 18.3	Revision: 0	Date: 3/27/89	Page: 1 of 16
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Director, OCRWM <i>[Signature]</i>	Date: 11/17/89	Director, OQA <i>[Signature]</i>	Date: 11/13/89
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1.0 PURPOSE

This procedure prescribes the Office of Civilian Radioactive Waste Management (OCRWM) responsibilities and methods for scheduling, planning, conducting, documenting and closing out surveillances.

2.0 SCOPE

This procedure applies to all internal and external surveillances conducted by OCRWM or in its behalf.

3.0 REFERENCES AND DEFINITIONS

3.1 REFERENCES

3.1.1 "Quality Assurance Requirements for the Civilian Radioactive Waste Management Program", (QAR) DOE/RW-0214, 1988.

3.1.2 "Quality Assurance Program Description for the Civilian Radioactive Waste Management Program", (QAPD) DOE/RW-0215, 1988.

3.2 DEFINITIONS

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

3.2.2 Deficiency Report: A document used to report deficiencies in activities or items discovered by OCRWM personnel or support personnel, and to record corrective actions.

3.2.3 Surveillance: The act of monitoring or observing to verify whether an item or activity conforms to specified requirements. Surveillance will include witness, verification, observation or evaluation of a test, laboratory activity, drilling activity, construction activity or special procedure and review of associated documentation, as appropriate. Surveillance may be limited to review of documentation.



3.2.4 Surveillance Deficiency: A deficiency identified during a surveillance that shows a lack of compliance with specified requirements or a failure to effectively develop, document or implement one or more applicable elements of the quality assurance program being surveilled.

4.0 RESPONSIBILITIES

4.1 ASSOCIATE DIRECTORS, OCRWM

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

- 4.1.1 Providing technical personnel to participate in surveillances, as requested; and
- 4.1.2 Reviewing surveillance reports for adequate responses and/or information.

4.2 SURVEILLANCE TEAM LEADER

The Surveillance Team Leader is responsible for:

- 4.2.1 Conducting pre-surveillance and post-surveillance meetings, as necessary;
- 4.2.2 Concurring with and approving surveillance checklists, when utilized;
- 4.2.3 Preparing surveillance reports, evaluating surveillance responses, and closing out surveillance reports;
- 4.2.4 Notifying the organization to be surveilled either verbally or in writing;
- 4.2.5 Monitoring and tracking the status of open surveillance/deficiency reports; and
- 4.2.6 Verifying corrective-action implementation.

4.3 SURVEILLANCE TEAM PERSONNEL

Surveillance Team personnel are responsible for:

- 4.3.1 Surveillance-preparation activities;
- 4.3.2 Being adequately prepared for participation in the surveillance;
- 4.3.3 Preparing surveillance checklists, as appropriate; and



4.3.4 Conducting the surveillance.

4.4 DIRECTOR, OFFICE OF QUALITY ASSURANCE (OQA)

The Director, OQA, or designee is responsible for the overall quality assurance (QA) surveillance program including:

4.4.1 Preparing and maintaining this QAAP;

4.4.2 Developing overall surveillance scheduling;

4.4.3 Notifying all affected organizations of postponed and/or rescheduled surveillances;

4.4.4 Appointing members to individual surveillance teams;

4.4.5 Designating a team leader, when more than one person is performing the surveillance;

4.4.6 Assuring that surveillance personnel have experience or training commensurate with the surveillance assignment;

4.4.7 Approving surveillance reports;

4.4.8 Verifying implementation of corrective action; and

4.4.9 Closing surveillance files.

5.0 GENERAL

5.1 QA surveillances are to be used to:

5.1.1 Monitor work in process;

5.1.2 Document compliance or noncompliance with requirements and procedures;

5.1.3 Identify actual and potential deficiencies and deviations promptly;

5.1.4 Promote prompt corrective action by cognizant management responsible for performing the work;

5.1.5 Provide management information on activities under surveillance; and

5.1.6 Verify timely implementation of corrective action.



- 5.2 A surveillance team may consist of one or more persons, as deemed necessary. Where only one person performs the surveillance, that individual shall assume the responsibilities of the surveillance-team leader.
- 5.3 Surveillances shall be performed by personnel who are knowledgeable in and not directly responsible for the activities under surveillance.
- 5.4 Scheduled surveillances may be supplemented by unannounced, unscheduled surveillances, as deemed necessary.
- 5.5 Annual, overall, surveillance scheduling shall be accomplished on a fiscal-year basis and updated quarterly, as a minimum.
- 5.6 Assigned surveillance personnel are responsible for all aspects of surveillance, including the preparation of surveillance attributes or checklists, conduct of the surveillance, reporting, surveillance response and evaluation, follow-up and close out.
- 5.7 Surveillance personnel shall have appropriate training prior to participation in any surveillance activities.

6.0 PROCEDURE

6.1 Scheduling

- 6.1.1 The Director, OQA, shall develop an overall surveillance schedule specifying surveillance coverage of known activities. The schedule shall identify the proposed surveillance personnel, the organization to be surveilled, the location, the date and the activity(ies) to be surveilled. The Director, OQA, should solicit input from cognizant personnel when developing the surveillance schedule.
- 6.1.2 Surveillances may be based on one or more of the following conditions:
- a) The importance of the quality activity to safety or waste isolation, as well as the extent of on-going quality activities;
 - b) The identification of adverse trends as identified in accordance with QAAP 2.9, "QA Program Status Reporting";
 - c) A request or notification from the Director, OCRWM, or Associate Directors, OCRWM, that a test, laboratory activity, drilling activity, construction activity, special procedure, or inspection, is ready for witness, verification, observation, evaluation; or



- d) A process or activity is in jeopardy, due to deficiencies or nonconformance in any or all quality assurance program-elements.

6.1.3 Subsequent to development, copies of the overall surveillance schedule are sent to the following, for information:

- a) Director, OCRWM;
- b) Associate Directors, OCRWM; and
- c) Assigned surveillance personnel.

6.2 Preparation

6.2.1 The surveillance team personnel shall prepare for the conduct of assigned surveillances by familiarizing themselves with the following:

- a) the organization to be surveilled;
- b) location of the surveillance;
- c) date(s) of the surveillance;
- d) activities/items to be surveilled;
- e) requirements/criteria governing the item/activity to be surveilled;
- f) the need for a pre or post surveillance meeting;
- g) appropriate documentation from previous deficiencies, surveillances or audits; and
- h) any special circumstances that require specific consideration (i.e. clearances, contacts for working space, facility lay-out).

6.2.2 The surveillance team may choose to develop a specific checklist or utilize the procedure that governs the item/activity to be surveilled. When a checklist is developed (Attachment I) it must be concurred with and approved by the surveillance team leader.

6.2.3 Prior to performing the surveillance, the surveillance team shall be briefed by the surveillance team leader on:

- a) Scope of the surveillance;



- b) Surveillance team responsibilities; and
- c) Logistics and surveillance team protocol and conduct.

6.2.4 The surveillance team leader shall notify the organization to be surveilled either verbally or in writing.

6.3 PERFORMANCE

6.3.1 Upon arrival at the surveillance location, the surveillance team leader may conduct a brief pre-surveillance meeting to introduce team members, identify the scope of the surveillance, meet counterparts, tour the facility as appropriate, and determine the status of the activity(ies) to be surveilled. As appropriate, meeting attendance shall be documented using Attachment II, "Attendance Record".

6.3.2 The surveillance team shall use the surveillance checklist (or a copy of the applicable procedure) to guide the surveillance and document results of witnessing or monitoring tests, laboratory activities, design review, drilling activities, construction activities, or to document objective evidence of records of the activities reviewed. If a problem or deficiency is discovered outside the scope of the surveillance, objective evidence should be examined to the extent necessary, adding it to the checklist and including it in the surveillance report. In conducting the surveillance, the following techniques should be used, as appropriate:

- a) Review, on a step-by-step basis, applicable requirements with personnel being interviewed;
- b) Observe a sequence of events to determine if the activity is being performed as required; and
- c) Evaluate documentation to determine if the activity was, or is being, performed in accordance with procedures.

6.3.3 Evaluation of each characteristic/attribute shall be documented. When a procedure is utilized in lieu of a checklist, a marked-up copy shall become a record.

6.3.4 Surveillance team personnel should meet briefly with appropriate management staff of the surveilled organization at the conclusion of the surveillance to discuss, as appropriate:

- a) Deficiency Reports (DR);
- b) Problems noted during the surveillance;



- c) Any corrective actions taken during the conduct of the surveillance;
- d) Positive aspects and/or comments or recommendations for improvements; and
- e) Time limitations for responding to Deficiency Reports.

6.4 REPORTING

- 6.4.1 The surveillance team leader shall prepare a Quality Assurance Surveillance Report using the suggested format described in Attachment III. Any deficiency reports shall be cited in the surveillance report and shall be attached.
- 6.4.2 The surveillance report shall describe results of the witnessing or monitoring of activities in brief, concise statements, as to whether the requirements associated with the activities being surveilled were complied with.
- 6.4.3 The surveillance report shall be signed by the surveillance team leader and forwarded to the Director, OQA, for review and approval.
- 6.4.4 As a minimum, the Director, OQA, will distribute copies of the approved surveillance report as follows:
 - a) Organization surveilled;
 - b) Director, OCRWM;
 - c) Affected Associate Directors;
 - d) Project Manager, Yucca Mountain Project Office; and
 - e) Surveillance-team members.

6.5 CORRECTIVE ACTION RESPONSE

- 6.5.1 The organization surveilled shall be requested to respond to the surveillance report within 15 working days of receipt, to document their responses and the anticipated corrective action completion dates on the Deficiency Reports, as applicable.

6.6 SURVEILLANCE CLOSEOUT

- 6.6.1 Deficiency Reports resulting from surveillances shall be processed in accordance with QAAP 16.1, "Corrective Action", for disposition and tracking purposes and surveillance team personnel shall monitor their status until closure.



- 6.6.2 Upon receipt of responses from the surveilled organization, the surveillance team leader shall evaluate acceptability of the responses in accordance with QAAP 16.1, "Corrective Action".
- 6.6.3 The surveillance team leader shall notify the surveilled organization, in writing, when responses are not received within 20 working days of their receipt of the initial report. This notification shall include a request for justification for the delay.
- 6.6.4 If responses are not received within 45 calendar days of the original date, the surveillance team leader shall notify the Director, OQA, for action.
- 6.6.5 The surveillance report shall remain active until all Deficiency Reports are closed out. After all corrective actions have been satisfactorily completed for all Deficiency Reports, the surveillance team leader shall prepare a memorandum closing the surveillance. A copy of the memorandum shall be provided to the surveilled organization.

7.0 RECORDS

Documentation generated as a result of this procedure is collected and maintained in accordance with requirements specified in QAAP 17.1, "QA Records Management". The attachments in Section 8.0 reflect the minimum records required, as appropriate.

8.0 ATTACHMENTS

- 8.1 Attachment I - Quality Assurance Checklist
- 8.2 Attachment II - Attendance Record
- 8.3 Attachment III - Surveillance Report
- 8.4 Attachment IV - QAAP Flowchart



OCRWM QA
ADMINISTRATIVE
PROCEDURE

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ATTACHMENT I (Typical)

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

SHEET _____ OF _____
AUDIT/SURVEILLANCE/INSPECTION
NO. _____

QUALITY ASSURANCE CHECKLIST

ORGANIZATION EVALUATED	<input type="checkbox"/> EXTERNAL <input type="checkbox"/> INTERNAL	<input type="checkbox"/> AUDIT <input type="checkbox"/> SURVEILLANCE <input type="checkbox"/> INSPECTION	PREPARED BY _____	DATE _____
DATE(S) OF EVALUATION			CONCURRED BY _____	DATE _____
			APPROVED BY _____	DATE _____

CONTROLLING DOCUMENT (Title, Number, Revision)	ACTIVITY EVALUATED
--	--------------------

ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS

* INDICATE RESULTS: SATISFACTORY (SAT), UNSATISFACTORY (UNSAT), NOT APPLICABLE (N/A)

REV. 1/89

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



OCRWM QA
ADMINISTRATIVE
PROCEDURE

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ATTACHMENT I (cont'd)

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

SHEET _____ OF _____
AUDIT/SURVEILLANCE/INSPECTION
NO. _____

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS

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

REV. 1/89



ATTACHMENT III (Sample)

DEPARTMENT OF ENERGY
OCRWM
OFFICE OF QUALITY ASSURANCE
QUALITY ASSURANCE SURVEILLANCE REPORT

1.0 Surveillance Number _____

2.0 Date(s) of Surveillance _____

3.0 Organization & Location _____

4.0 Surveillance Team Members:

5.0 Personnel Contacted:

6.0 Scope: Describe document(s) evaluated, test(s) witnessed, and activities monitored.

7.0 Requirements: Describe or list the requirements governing the activity or item surveilled.

8.0 Results: Describe results of testing witnessing and monitoring activities. A brief summary may be given here, including any immediate corrective actions taken.

9.0 Attach Deficiency Reports (if applicable)

Prepared by: _____
Surveillance Team Leader Date

Approved by: _____
Director, OQA Date



ATTACHMENT IV

SURVEILLANCE SCHEDULING

6.1.1 Director, OQA

**DEVELOP
SURVEILLANCE
SCHEDULE**

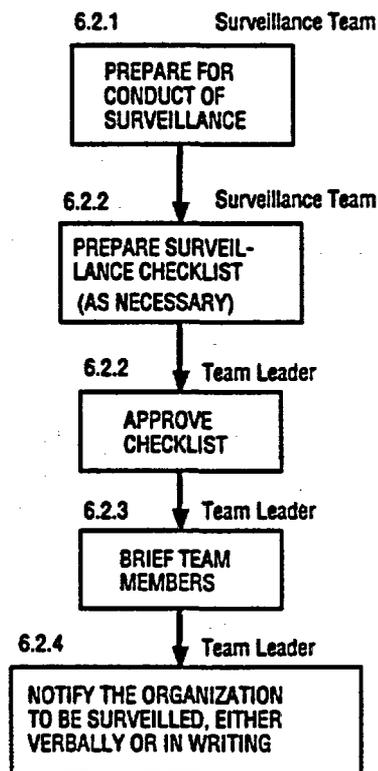
6.1.3

**DISTRIBUTE
SCHEDULE**



ATTACHMENT IV (cont'd)

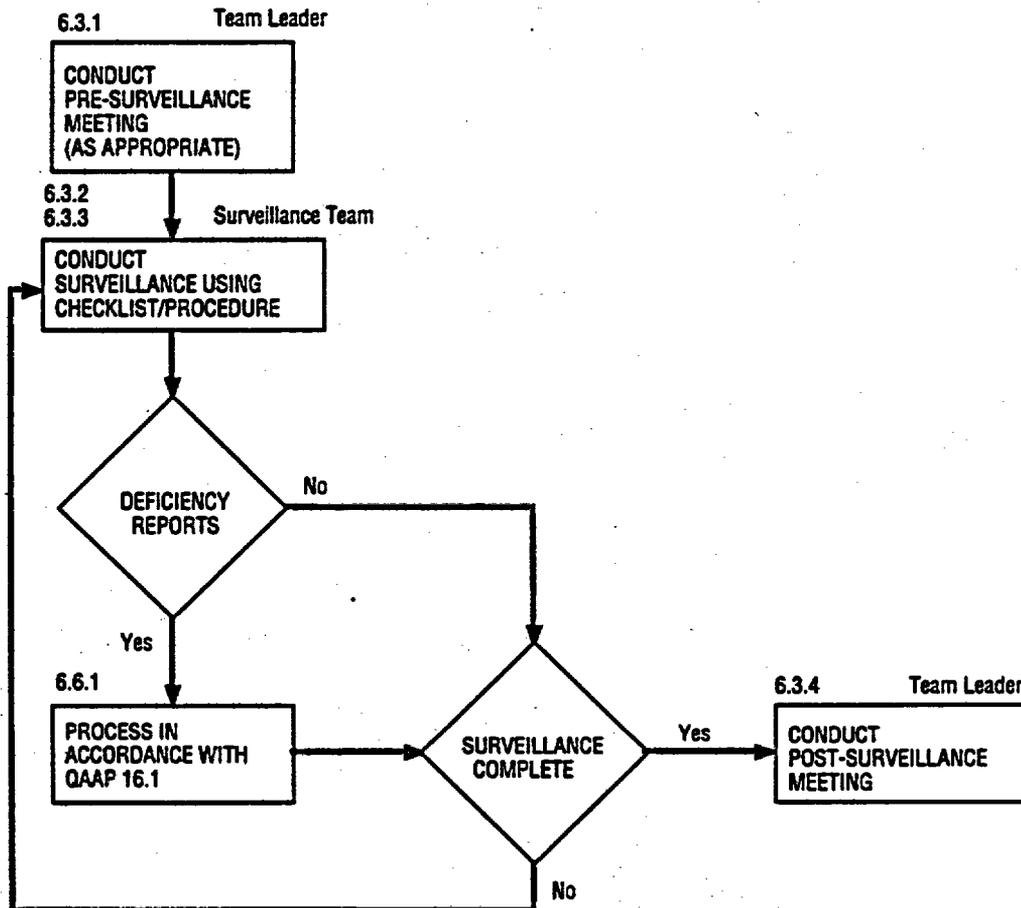
SURVEILLANCE PREPARATION AND NOTIFICATION





ATTACHMENT IV (cont'd)

SURVEILLANCE PERFORMANCE





ATTACHMENT IV (cont'd)

SURVEILLANCE REPORTING AND CLOSE-OUT

