OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT QUALITY ASSURANCE ADMINISTRATIVE PROCEDURE

Title: MANAGEMENT ASSESSMENT			
Procedure No.: QAAP 2.7	Revision: 1	Date: 11/12/91	Page 1 of 7
Concurrence: [signature]	Date: 9/30/91	Approval: [signature]	Date: 9/30/91

1.0 PURPOSE

This procedure establishes responsibilities and methods for planning, conducting, documenting, reporting, and administering a system whereby the scope, adequacy, status, and effectiveness of the quality assurance (QA) program is regularly assessed by management.

2.0 SCOPE

This procedure applies to assessments conducted by management of the Office of Civilian Radioactive Waste Management (OCRWM).

3.0 REFERENCES AND DEFINITIONS

3.1 REFERENCES

3.1.1 *Quality Assurance Requirements Document* (QARD), DOE/RW-0214

3.1.2 *Quality Assurance Program Description Document* (QAPD), DOE/RW-0215

3.2 DEFINITIONS

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

4.0 RESPONSIBILITIES

4.1 DIRECTOR, OCRWM

The Director, OCRWM has overall responsibility for:

4.1.1 Conducting annual independent assessments of the OCRWM QA program to verify adequacy and effectiveness of implementation;

4.1.2 Appointing and instructing the assessment team leader and members for the performance of scheduled assessments;

9110160152 910930
PDR WASTE
WM-11 PDR

ADD: Ken Hooks
LH. Encl.
102.7
WM-11
NH03

4.1.3 Meeting with Associate and Office Directors, OCRWM to discuss the status of the QA program and its implementation and any QA problem areas or concerns;

4.1.4 Approving and issuing the management assessment plan and report; and

4.1.5 Ensuring that appropriate action is taken concerning recommendations included in the management assessment report.

4.2 ASSOCIATE AND OFFICE DIRECTORS, OCRWM

The Associate and Office Directors, OCRWM have responsibility for reviewing assessment results and responding to recommendations affecting their areas of responsibility.

4.3 ASSESSMENT TEAM LEADER

The assessment team leader has overall responsibility for:

4.3.1 Planning and coordinating performance of the assessment activity;

4.3.2 Documenting and reporting assessment information to the Director, OCRWM; and

4.3.3 Assembling and processing the records package for the completed assessment.

4.4 ASSESSMENT TEAM MEMBERS

Assessment team members are responsible for:

4.4.1 Conducting assigned portions of the assessment;

4.4.2 Documenting identified adverse conditions on Corrective Action Requests for processing in accordance with QAAP 16.1, *Corrective Action;* and

4.4.3 Reviewing and concurring with the assessment report.

4.5 DIRECTOR, OFFICE OF QUALITY ASSURANCE (OQA)

The Director, OQA is responsible for preparing and maintaining this procedure.

5.0 GENERAL

5.1 Management shall annually assess the adequacy of the OCRWM quality assurance program to ensure effective implementation.

5.2 The following options are available when selecting an organization/team to conduct the assessment:

a) External to the Department of Energy (DOE) - Assessment by a commercial QA organization or consultant;

b) Internal to DOE - Assessment by a team comprised of personnel from DOE Headquarters, Field Offices, or Project Offices; or

c) Internal to OCRWM - Assessment by the Director, Associate, Office, or Division Directors, or other line managers.

5.3 Assessment team members shall be:

a) independent of the OQA and shall not assess activities in their areas of responsibility; and

b) trained in the content and implementation of the QARD, QAPD, and this procedure.

5.4 The following methods, as appropriate, shall be used in performance of management assessments:

a) Interviews with PROGRAM management and staff to assess the effectiveness of implementation of the QA program;

b) Surveillance or inspections of ongoing activities affecting quality;

c) Discussions with PROGRAM management and staff regarding problems in activities affecting quality;

d) Review of audit, surveillance, corrective action, trend, and PROGRAM review reports and supporting documentation; and

e) Attendance at postaudit conferences.

6.0 PROCEDURE

6.1 INDEPENDENT MANAGEMENT ASSESSMENT

The Director, OCRWM shall determine the assessment option to be used (Subsection 5.2) and appoint an assessment team leader. Additional assessment team members and technical specialists shall be assigned, as necessary, by the Director, OCRWM.

6.2 PLANNING

6.2.1 The assessment team leader shall develop a plan to describe the scope, approach, methods, and information sources, and consider the following:

a) Methods for performing the assessment;

b) Instructions from the Director, OCRWM and specific requirements for performing the assessment;

c) Establishing performance indicators to be used as a basis for determining effectiveness;

d) OCRWM QARD and QAPD;

e) Applicable OCRWM procedures;

f) Technical requirements;

g) Audit, surveillance, inspection, and previous assessment reports;

h) Evaluating the OCRWM QA organization's activities and records;

i) Evaluating PROGRAM activities and records;

j) Evaluating adequacy of resources, including personnel and facilities;

k) Evaluating adequacy and effectiveness of personnel training; and

l) Assessment options to be used as described in Subsection 5.2, including any additional or special training required for assessment team members.

6.2.2 The Director, OCRWM shall approve the assessment plan for use.

6.3 PERFORMANCE

The assessment team shall perform the management assessment in accordance with the assessment plan developed in Subsection 6.2.

6.4 DOCUMENTATION

6.4.1 Upon completion of the assessment, the assessment team leader shall document results of the assessment activity in an assessment report. The report shall include the following information:

a) An executive summary describing the results of the assessment;

b) A description of the scope of the assessment activity;

c) Identification of assessment team members;

d) Identification of personnel contacted during the assessment activity;

e) A description of the results that addresses specific findings, scope, status, adequacy, compliance, and effectiveness of implementation of the OCRWM QA program requirements;

f) An evaluation of the status, adequacy and effectiveness of organizational structure, personnel training, and QA reporting and communications;

g) Identification of conditions adverse to quality; and

h) Assessment team recommendations.

6.4.2 The assessment team members shall review and concur with the report.

6.4.3 The assessment team leader then signs the report and submits it to the Director, OCRWM for approval and issue.

6.4.4 Conditions adverse to quality reported during management assessments shall be documented on Corrective Action Requests and processed in accordance with QAAP 16.1.

6.5 FOLLOW-UP ACTIVITIES

6.5.1 The Director, OCRWM shall ensure that affected Associate and Office Directors review assessment reports and respond to recommendations affecting their areas of responsibility.

6.5.2 The Director, OCRWM shall evaluate responses from affected Associate and Office Directors for adequacy.

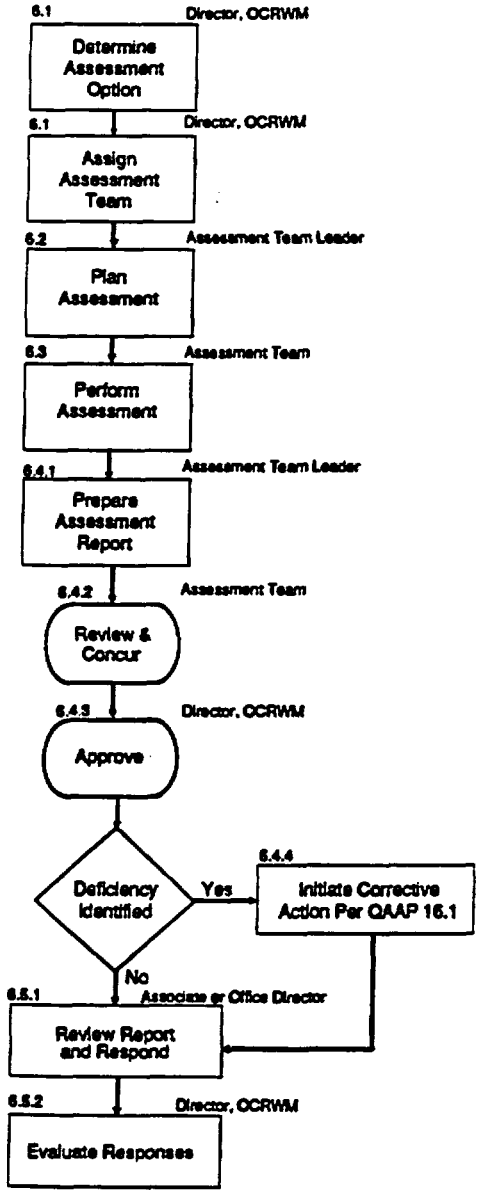
7.0 RECORDS

Management assessment plans and reports are QA records and shall be collected and maintained in accordance with QAAP 17.1, *QA Records Management*.

8.0 ATTACHMENTS

Attachment I - QAAP 2.7 Flowchart

ATTACHMENT I

QAAP 2.7 FLOWCHART

MANAGEMENT ASSESSMENT