

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

REVISION RECORD

TITLE: Quality Assurance Program Trend Evaluation and Reporting	PROCEDURE NO. QAAP 2.9	REV. NO. (current) 2
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DESCRIPTION OF PROPOSED REVISION AND RATIONALE:

Editorial changes have been incorporated as identified in Draft 3A to clarify the requirements of the procedure. These clarifications are incorporated to eliminate confusing items identified in Revision 2 and do not affect the overall process delineated in the procedure.

PREPARER OF PROPOSED REVISION Michael J. Donovan DATE 08/29/91

TYPE OF REVISION (Check One): MAJOR MINOR

SIGNATURE TO AUTHORIZE REVISION R. W. Clap DATE 8/30/91
Responsible Associate or Office Director

TYPE OF REVISION (Check One): MAJOR MINOR

CONCURRENCE SIGNATURE R. W. Clap DATE 8/30/91
for Director, OQA

RECOMMENDED TRAINING: READ CLASSROOM OTHER

Reading or classroom training as identified in individual I&T Matrixes.

R. W. Clap for DATE 8/30/91
RESPONSIBLE ASSOCIATE OR OFFICE DIRECTOR OR QA TRAINING OFFICER

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QUALITY ASSURANCE ADMINISTRATIVE PROCEDURE

2.9, REV. 3

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OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
QUALITY ASSURANCE ADMINISTRATIVE PROCEDURE

Title:

QUALITY ASSURANCE PROGRAM TREND EVALUATION AND REPORTING

Procedure No.:

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09/02/91

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Concurrence

R.W. Coe

Date:

8/30/91

Approval

R.W. Coe

Date:

8/30/91

1.0 PURPOSE

This procedure establishes responsibilities, identifies requirements and prescribes methods for implementing a quality assurance program trend evaluation and reporting system.

2.0 SCOPE

This procedure applies to significant conditions adverse to quality identified by or for 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

3.2.1 The definition of standard terms may be found in the Glossary contained in Reference 3.1.1.

3.2.2 Adverse trend - Repetitive occurrences of the same problem or closely related problems within a twelve month period.

3.2.3 Generic adverse trend - An adverse trend whose nature and cause(s) are common to two or more organizations in the PROGRAM.



4.0 RESPONSIBILITIES

4.1 DIRECTOR, OFFICE OF QUALITY ASSURANCE (OQA)

The Director, OQA is responsible for:

- 4.1.1 Evaluating Division-level input to the "Quality Assurance Program Trends Report" and identifying any generic adverse trends.
- 4.1.2 Preparing and issuing the "Quality Assurance Program Trends Report" on a quarterly basis.
- 4.1.3 Monitoring corrective action progress for adverse and generic adverse trends.
- 4.1.4 Issuing and maintaining this procedure.

4.2 QUALITY ASSURANCE DIVISION DIRECTORS (QADDs)

The OCRWM Headquarters and Yucca Mountain QADDs are responsible for:

- 4.2.1 Evaluating, at quarterly intervals, Corrective Action Requests (CARs) that identify significant conditions adverse to quality.
- 4.2.2 Initiating and following up on corrective action for any adverse or generic adverse trends.
- 4.2.3 Preparing and submitting their sections of the "Quality Assurance Program Trends Report" to the Director, OQA.

4.3 ASSOCIATE AND OFFICE DIRECTORS, OCRWM

Associate and Office Directors, OCRWM are responsible for taking action to correct adverse trends in their areas of responsibility.

5.0 GENERAL

- 5.1 The Director, OQA shall provide a quarterly report to OCRWM management and participant organizations on results of trend evaluation and investigations and corrective actions for adverse trends.
- 5.2 Each QADD provides sections of the quarterly "Quality Assurance Program Trends Report" to the Director, OQA. As appropriate, the QADDs' sections of the report shall address:
 - a) status of previously reported trends including evidence (when applicable) that trends have been satisfactorily corrected;



- b) description of identified current adverse and generic adverse trends based on trend evaluation results;
- c) identification of the problems constituting each current adverse or generic adverse trend; and
- d) summaries of identified causes and actions required to correct current adverse or generic adverse trends.

5.3 The consolidated quarterly "Quality Assurance Program Trends Report" prepared by the Director, OQA shall include:

- a) report sections prepared by each QADD; and
- b) description of any generic adverse trends identified during the Director, OQA's review of the divisional report sections.

6.0 PROCEDURE

6.1 TREND EVALUATION

- 6.1.1 QADDs shall, on a quarterly schedule, evaluate CARs reporting significant conditions adverse to quality issued during the preceding twelve month period for evidence of adverse or generic adverse trends. The need for, and type of statistical aids for trend data evaluation shall be established on a case by case basis by management decision.
- 6.1.2 In the event an adverse or generic adverse trend is identified, the QADD shall initiate a CAR in accordance with QAAP 16.1, *Corrective Action* and request appropriate corrective actions by affected organizations.
- 6.1.3 In the event the need for corrective action by a participant organization is identified, the QADD shall request, in writing, that the participant initiate appropriate corrective actions in accordance with their internal procedures. Alternatively, if the trend affects a single participant organization, the QADD may issue a CAR directly to that organization.

6.2 TREND REPORT

- 6.2.1 The QADDs shall prepare their sections of the quarterly report as defined in Subsection 5.2 and provide them to the Director, OQA.
- 6.2.2 The Director, OQA shall evaluate the QADDs' input for evidence of generic adverse trends. In the event a generic adverse trend is identified, the Director, OQA

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shall direct the QADDs to initiate appropriate corrective action.

6.2.3 The Director, OQA shall combine the QADDs' input and his evaluation into the "Quality Assurance Program Trends Report" as defined in Subsection 5.3.

6.2.4 OCRWM managers shall take action to correct adverse trends in accordance with QAAP 16.1, *Corrective Action*.

6.2.5 The Director, OQA shall distribute the quarterly "Quality Assurance Program Trends Report" to OCRWM management and participating organizations.

7.0 QUALITY ASSURANCE RECORDS

Records generated as a result of this procedure shall be processed and maintained in accordance with the requirements specified in QAAP 17.1, *QA Records Management*. As a minimum, the quarterly "Quality Assurance Program Trends Report" is considered a QA Record.

8.0 ATTACHMENTS

8.1 ATTACHMENT I - Flowchart



ATTACHMENT I FLOWCHART

