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OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT QUALITY ASSURANCE ADMINISTRATIVE PROCEDURE

Title:
SURVEILLANCE PROGRAM

Procedure No.:
QAAP 18.3

Revision:
3

Date:
01/03/92

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Concurrence
R.W. Chap
Date: 12/17/91
For DH

Approval
R.W. Chap
Date: 12/17/91
For DH

1.0 PURPOSE

This procedure establishes the responsibilities and methods for planning, conducting, and documenting quality assurance (QA) surveillances.

2.0 SCOPE

This procedure applies to all internal and external QA surveillances conducted 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 Deficiency: A characteristic that renders the quality of an item or activity unacceptable or indeterminate.

3.2.2 Surveillance: The act of monitoring or observing to verify whether an item or activity conforms to specified requirements.

3.2.3 The definitions of other quality assurance related terms are found in the Glossary contained in Reference 3.1.1.



4.0 RESPONSIBILITIES

4.1 ASSOCIATE AND OFFICE DIRECTORS, OCRWM

The Associate and Office Directors, OCRWM are responsible for providing qualified technical personnel to participate in surveillances.

4.2 DIRECTOR, OFFICE OF QUALITY ASSURANCE, (OQA)

The Director, OQA is responsible for:

- 4.2.1 Preparing and maintaining this procedure;
- 4.2.2 Scheduling surveillances;
- 4.2.3 Appointing Surveillance Team Leaders; and
- 4.2.4 Approving and distributing surveillance reports.

4.3 SURVEILLANCE TEAM LEADER (STL)

The STL is responsible for:

- 4.3.1 Identifying the surveillance team;
- 4.3.2 Notifying organizations of scheduled surveillances;
- 4.3.3 Ensuring that the surveillance team is properly oriented, trained and qualified;
- 4.3.4 Coordinating preparation of surveillance checklists or marked-up procedures, as appropriate;
- 4.3.5 Conducting pre and postsurveillance meetings, as required;
- 4.3.6 Directing the conduct of the surveillance;
- 4.3.7 Coordinating preparation of the surveillance report and Corrective Action Requests; and
- 4.3.8 Ensuring that surveillance record packages are prepared and submitted to the appropriate records center.

4.4 SURVEILLANCE TEAM PERSONNEL

Surveillance team personnel are responsible for:

- 4.4.1 Preparing surveillance checklists or marked-up procedures, as appropriate;



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4.4.2 Performing surveillances; and

4.4.3 Preparing surveillance reports and Corrective Action Requests.

5.0 GENERAL

5.1 QA SURVEILLANCES

QA surveillances are to be used to:

5.1.1 Monitor work in progress;

5.1.2 Document compliance or noncompliance with requirements and procedures;

5.1.3 Identify actual and potential deficiencies and concerns;

5.1.4 Provide management information on activities under surveillance;

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

5.1.6 Verify timely implementation of corrective action.

5.2 SURVEILLANCE PERSONNEL

5.2.1 Surveillance teams may consist of one or more persons. When only one person performs the surveillance, that individual shall assume the responsibilities of the STL.

5.2.2 Surveillances shall be performed by personnel who are knowledgeable in, but not directly responsible for, the activities under surveillance.

5.2.3 Surveillance personnel shall have appropriate training prior to participation in any surveillance activity.

6.0 PROCEDURE

6.1 SCHEDULING

6.1.1 The Director, OQA shall develop a schedule specifying surveillance coverage.

6.1.2 The surveillance schedule shall contain, as a minimum, the following information:

a) Organization to be surveilled;

b) Location and date; and



c) Activities to be surveilled.

6.1.3 The Director, OQA shall review the surveillance schedule at least quarterly and revise as necessary to assure adequate coverage. The transmittal of updated schedules shall identify major changes in the previously scheduled surveillances with appropriate justification.

6.1.4 Copies of the surveillance schedule and updates shall be distributed to the Associate and Office Directors.

6.1.5 Scheduled surveillances may be supplemented by unannounced, unscheduled surveillances as deemed necessary.

6.2 **PREPARATION**

6.2.1 The Director, OQA shall appoint an STL for each surveillance.

6.2.2 The STL shall identify the surveillance team and verify compliance with the requirements of Subsection 5.2.

6.2.3 Surveillance team personnel shall prepare for an assigned surveillance by familiarizing themselves with the following:

- a) Organization to be surveilled;
- b) Requirements/criteria governing the activity to be surveilled; and
- c) Appropriate documentation from previous deficiencies, surveillances, or audits.

6.2.4 The STL shall brief the team on:

- a) Scope of the surveillance;
- b) Surveillance team responsibilities; and
- c) Logistics and surveillance team protocol and conduct.

6.2.5 The surveillance team may choose to develop a specific checklist using Attachment I, "Quality Assurance Checklist" or to utilize the procedures that govern the activity to be surveilled.

6.2.6 The STL 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 STL may conduct a brief presurveillance meeting with management of the surveilled organization to:

- a) Identify the scope of the surveillance;
- b) Introduce team members and identify contacts;
- c) Become familiar with the facility; and
- d) Determine the status of activities to be surveilled.

If a meeting is held, attendance shall be documented using Attachment II, "Attendance Record."

6.3.2 The surveillance team shall use the surveillance checklist or the applicable marked-up procedures to guide its activities. All activities shall be documented.

6.3.3 The STL shall notify the management of the surveilled organization of potential deficiencies to provide the opportunity for additional information, documentation, or remedial action required to resolve potential deficiencies during the course of the surveillance.

6.3.4 The STL should arrange a postsurveillance meeting with management of the surveilled organization. If a meeting is held, attendance shall be recorded on Attachment II. The following should be discussed, as appropriate:

- a) Corrective Action Requests (CARs);
- b) Problems noted during the surveillance;
- c) Any corrective actions taken during the conduct of the surveillance; and
- d) Positive aspects and/or comments or recommendations for improvements.

6.4 REPORTING

6.4.1 The STL shall coordinate the preparation of a surveillance report using the format shown in Attachment III, "Surveillance Report Format and Content."



- 6.4.2 The surveillance report shall describe results of the witnessing or monitoring of activities in brief, concise statements, and shall indicate if the requirements associated with the activities being surveilled were complied with. The STL shall ensure that all relevant information from the checklist or marked-up procedures has been addressed in the surveillance report.
- 6.4.3 If CARs result from the surveillance, the STL shall coordinate with team members the preparation of the CARs in accordance with QAAP 16.1, *Corrective Action*. CARs shall be referenced within the surveillance report.
- 6.4.4 The surveillance report shall be signed by the STL as the preparer and forwarded to the Director, OQA for review and approval.
- 6.4.5 As a minimum, the Director, OQA will distribute copies of the approved surveillance report as follows:
- a) Organization surveilled; and
 - b) Affected Associate and Office Directors.
- The surveillance is considered closed upon issuance of the surveillance report.
- 6.4.6 The completed surveillance record package shall be submitted by the STL to the appropriate records center in accordance with Section 7.0.

7.0 RECORDS

Surveillance reports and surveillance schedules generated as a result of this procedure are considered QA Records and shall be collected and maintained in accordance with requirements specified in QAAP 17.1, *QA Records Management* or OMP-17-01, *Records Management: Record Source Implementation*.

Note: CAR record packages shall be maintained as QA records separately from the surveillance record package.

8.0 ATTACHMENTS

- 8.1 Attachment I - Quality Assurance Checklist
- 8.2 Attachment II - Attendance Record
- 8.3 Attachment III - Surveillance Report Format and Content
- 8.4 Attachment IV - QAAP 18.3 Flowchart



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ATTACHMENT I (Example)
QUALITY ASSURANCE CHECKLIST

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WASHINGTON, D.C.

PAGE _____ OF _____
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QUALITY ASSURANCE CHECKLIST

ORGANIZATION EVALUATED		<input type="checkbox"/> EXTERNAL	<input type="checkbox"/> AUDIT	PREPARED BY _____ DATE _____
DATES OF EVALUATION		<input type="checkbox"/> INTERNAL	<input type="checkbox"/> SURVEILLANCE	
CONTROLLING DOCUMENT (Title, Number, Revision)			ACTIVITY EVALUATED	
ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS	

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

III-V 09/91



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**ATTACHMENT I (Continued)
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RADIOACTIVE WASTE MANAGEMENT
U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.**

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QUALITY ASSURANCE CHECKLIST (continuation sheet)

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

REV. 09/91



**ATTACHMENT III (Example)
SURVEILLANCE REPORT FORMAT AND CONTENT**

COVER SHEET

Identify surveillance number, primary activity evaluated, organization evaluated, and locations and dates of the surveillance. The cover sheet should also bear the dated preparer and approval signatures of the STL and the Director, OQA.

MAIN BODY

SECTION 1.0 EXECUTIVE SUMMARY

Describe the results of the surveillance in brief, concise statements addressing any corrective action required.

SECTION 2.0 SCOPE

Describe the full range of activities evaluated. List the documents that govern the activities.

SECTION 3.0 SURVEILLANCE TEAM

List the name and assigned area of responsibility of each surveillance team member.

SECTION 4.0 PERSONNEL CONTACTED

Identify personnel attending the pre and postsurveillance meetings and contacted during the surveillance. Refer to attached Attendance Records, as applicable.

SECTION 5.0 SURVEILLANCE RESULTS

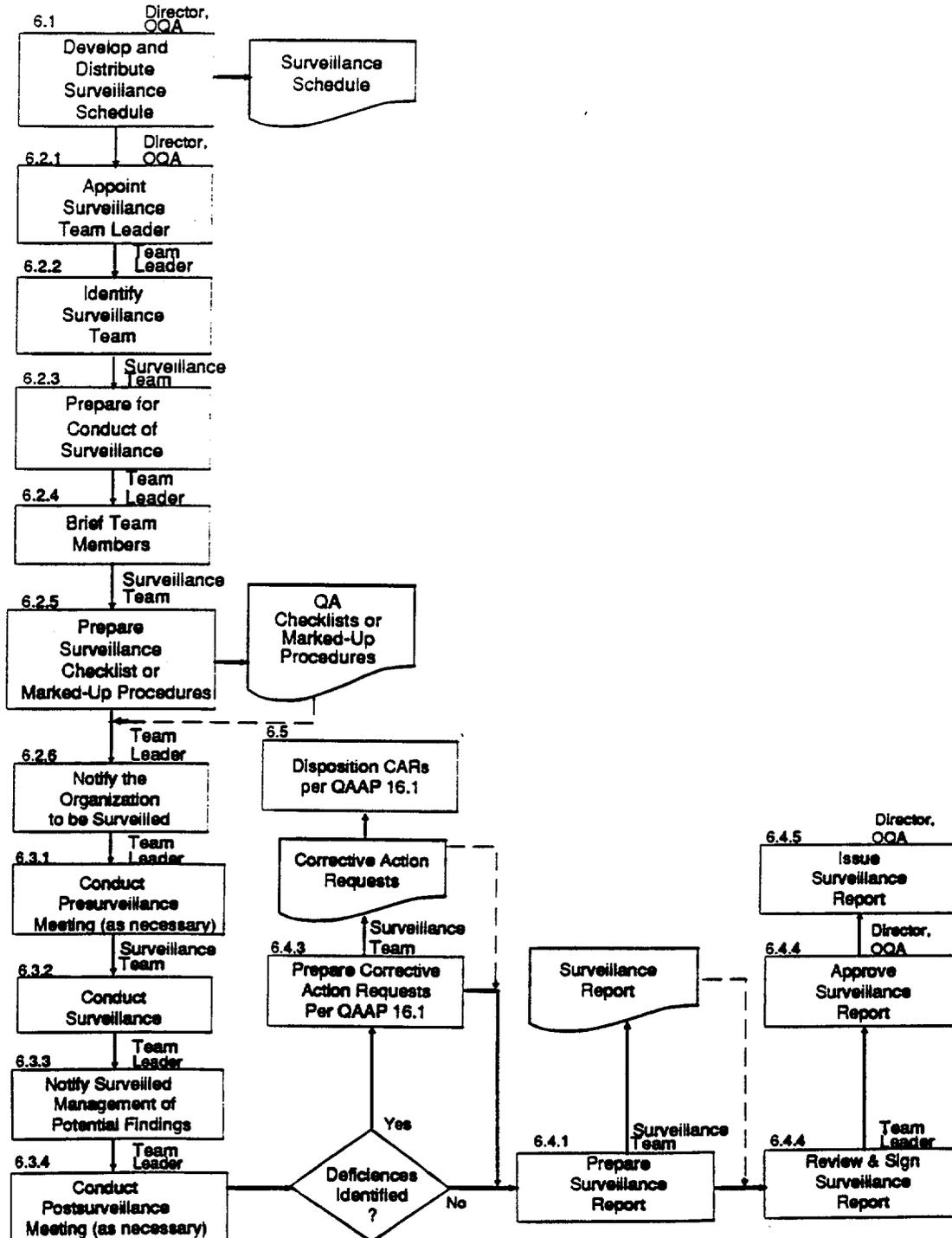
Briefly discuss and reference any Corrective Action Requests and summarize any immediate corrective actions taken. Describe any measuring and test equipment used during the surveillance. Provide the detailed description of the items and activities examined during the surveillance, including relevant information from the checklist or marked-up procedures. Include a statement as to the adequacy and effectiveness of the quality assurance program controls surveilled.

SECTION 6.0 RECOMMENDATIONS

Identify any recommendations the surveillance team considers appropriate to the surveillance.



ATTACHMENT IV
QAAP 18.3 FLOWCHART



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WASHINGTON, D.C.

REVISION RECORD

TITLE: Surveillance Program	PROCEDURE NO. QAAP 18.3	REV. NO. (current) 2
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DESCRIPTION OF PROPOSED REVISION AND RATIONALE:

Revise QAAP 18.3, Revision 2 per attached Approval copy, Revision 3. The content and distribution of Surveillance Schedules have been revised for correctness.

PREPARER OF PROPOSED REVISION <u>Thomas E. Rodgers</u> Thomas E. Rodgers	DATE <u>12/13/91</u>
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TYPE OF REVISION (Check One):	MAJOR <input type="checkbox"/>	MINOR <input checked="" type="checkbox"/>
SIGNATURE TO AUTHORIZE REVISION <u>R.W. Cliff</u> Responsible Associate or Office Director	DATE <u>12/17/91</u>	

TYPE OF REVISION (Check One):	MAJOR <input type="checkbox"/>	MINOR <input checked="" type="checkbox"/>
CONCURRENCE SIGNATURE <u>R.W. Cliff</u> for Director, OQA	DATE <u>12/17/91</u>	

RECOMMENDED TRAINING:	READ <input checked="" type="checkbox"/>	CLASSROOM <input type="checkbox"/>	OTHER <input type="checkbox"/>
Self-study recommended for all OCRWM personnel who will be performing internal or external QA surveillances.			
<u>R.W. Cliff</u>	DATE <u>12/17/91</u>		
RESPONSIBLE ASSOCIATE OR OFFICE DIRECTOR OR QA TRAINING OFFICER			