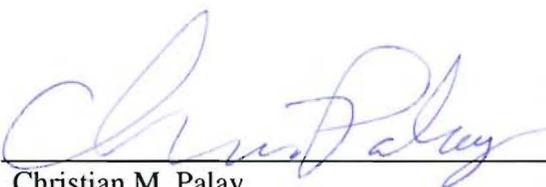


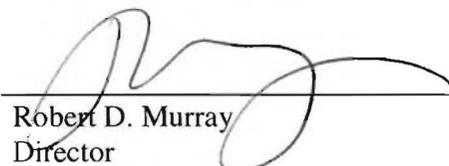


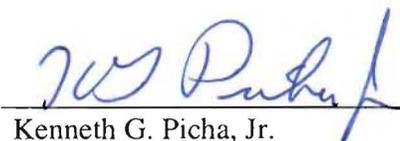
Office of Environmental Management (EM)

Subject: Surveillances

Administrative Procedure

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Approval:  4-27-2011
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Date

Concurrence:  4-27-2011
Kenneth G. Picha, Jr.
Acting Deputy Assistant Secretary
Safety and Security Program
Date

1.0 PURPOSE

- 1.1 This procedure establishes the responsibilities and process for scheduling, planning, performing, and documenting Quality Assurance (QA) oversight of the High-Level Radioactive Waste (HLW) and Used Nuclear Fuel (UNF) programs. These HLW and UNF programs are based on the Quality Assurance Requirements and Description (QARD, DOE/RW-0333P).

2.0 SCOPE

- 2.1 The objectives of this program are to ensure effective, efficient programs and operations through application of comprehensive and integrated assessment activities. The planning and application of this procedure is applied using the graded approach. Items, services, or programs that contribute the greatest risk to quality, safety, and mission are assessed with the greatest rigor and frequency.

3.0 APPLICABILITY

- 3.1 This procedure applies to EM personnel and contractors who are directly or indirectly involved with the QARD oversight functions of programs related to HLW and UNF activities as conducted by the Office of Standards and Quality Assurance at EM Headquarters.

4.0 REQUIREMENTS and REFERENCES

- 4.1 Quality Assurance Requirements and Description (QARD), DOE/RW-0333P, Revision 20
- 4.2 EM-QA-002, Quality Assurance Program Plan (QAPP)
- 4.3 AP-1.1Q, High Level Waste (HLW) and Used Nuclear Fuel (UNF) Independent Oversight Program Description
- 4.4 AP-16.1Q, Corrective Action
- 4.5 AP-17.1Q, Quality Assurance Records
- 4.6 AP-18.1Q, Audits

5.0 DEFINITIONS

- 5.1 Surveillance – The act of monitoring or observing to verify whether an item or activity conforms to specified requirements.

6.0 GENERAL RESPONSIBILITIES

- 6.1 Director, Office of Standards and Quality Assurance
 - 6.1.1 Ensures that a QA program that meets regulatory management requirements is established, maintained, and implemented.
 - 6.1.2 Responsible for providing the necessary resources for the surveillance team the resources necessary to implement the surveillance.
 - 6.1.3 Verifies that activities subject to the QARD have been correctly performed by surveillances, and/or audits.
- 6.2 QA Lead, Office of Standards and Quality Assurance
 - 6.2.1 Responsible for the selection of Surveillance Team Leader (STL), Surveillance Team Members (STM), and Technical Specialist (TS).
 - 6.2.2 Responsible for the development and distribution of the HLW and UNF Audit/Surveillance Schedule.
- 6.3 Environmental Management Consolidated Business Center (EMCBC), Office of Logistics Management
 - 6.3.1 Responsible for maintaining QA Records associated with this procedure.
- 6.4 Each individual is responsible for the quality of his/her work. All individuals are responsible for identifying potential and existing conditions adverse to quality, and reporting them through the appropriate program outlined in AP-16.1Q, Corrective Action.

7.0 GENERAL INFORMATION

Methods used to conduct a Surveillance include, at a minimum, review of documents and direct observation of work activities. Other methods likely to be employed during surveillance include data analysis and personnel interviews. Surveillance is a planned and documented assessment of programs, processes, systems, and/or activities performed to determine compliance to requirements and to identify systemic issues, potential risk, emerging issues, and areas for improvement. The conduct of surveillance is less formal than an audit or evaluation and usually maintains a more singular line of inquiry. Documentation of surveillances usually includes a formal report that may contain findings and/or observations. Findings require corrective action follow-up and tracking.

8.0 PROCEDURE

8.1 Surveillance Team Selection

8.1.1 QA Lead, Office of Standards and Quality Assurance

8.1.1.1 During assessment planning and scheduling activities, select the Surveillance Team Leader (STL), Surveillance Team Members (STM), and Technical Specialist (TS), as applicable, needed to meet the scope and complexity of the surveillance.

8.1.1.2 Ensure that the selected personnel for conducting a surveillance meet the following criteria:

8.1.1.2.1 Have sufficient authority and organizational freedom to make the process meaningful and effective.

8.1.1.2.2 Will be independent of any direct responsibility for performing the work that is to be assessed by the surveillance.

8.1.1.2.3 Will have experience and training commensurate with the scope, complexity, or special nature of the activities under the surveillance.

8.1.1.3 Assign a Surveillance Team Leader to manage and conduct the surveillance as delineated in the Assessment Schedule.

8.1.1.4 Ensure that the STL has been qualified per the AP-2.1Q, Qualification of Audit Personnel.

8.1.2 Surveillance Team Leader

8.1.2.1 Prior to performing the surveillance, verify that Surveillance Team Members and Technical Specialists meet the requirements specified in the AP-2.1Q, Qualification of Audit Personnel.

8.1.3 Director, Office of Standards and Quality Assurance

8.1.3.1 Provide the surveillance team the resources necessary to implement the surveillance.

8.2 Surveillance Notification

8.2.1 Surveillance Team Leader

8.2.1.1 Notify the organization subject to the surveillance via memo from the Deputy Assistance Secretary for the Safety and Security Program of the planned surveillance as soon as practical:

8.2.1.1.1 Prior to issuing the memo, contact the management of the organization to be evaluated by surveillance and discuss the scope of the surveillance.

8.2.1.1.2 Confirm activity schedules and the availability of personnel from the organization scheduled for surveillance.

8.2.1.1.3 Request a point of contact for the surveillance.

8.2.1.1.4 Request access to the areas of activity, related documentation, and personnel.

8.2.1.1.5 Request for logistical support (e.g., Meeting facilities for team caucus as well as separate management debriefings, workspace for the surveillance team, access to computer stations, copy machines, telephone, or fax, etc.)

8.3 Preparing for Surveillance Activities

8.3.1 Surveillance Team Leader

8.3.1.1 Identify and obtain the documents appropriate to the assigned surveillance.

8.3.1.2 Initiate Form 2.2-1, Surveillance Report in accordance with the form instructions, Attachment A.

8.3.1.3 Assign STM activities and criteria from the scope of the surveillance.

8.3.1.4 When deemed necessary, by the STL, direct team members to prepare Form 18.1-1, Quality Assurance Audit Checklist, and use it as guidance during the surveillance.

8.4 Surveillance Performance

8.4.1 Surveillance Team Leader

- 8.4.1.1 Initiate surveillance at the organization with an entrance meeting, if requested by the organization.
 - 8.4.1.1.1 Take attendance of the meeting using Form 18.1-2, Attendance Sheet.
 - 8.4.1.1.2 Give a brief overview of the surveillance scope, the schedule, and how the surveillance will be conducted.
- 8.4.1.2 Conduct the surveillance.
 - 8.4.1.2.1 Manage and supervise the surveillance team, when used.
 - 8.4.1.2.2 Coordinate the preparation and issuance of Corrective Action Requests per AP-16.1Q, Corrective Action.
 - 8.4.1.2.3 If a condition is identified as being a significant condition adverse to quality during the course of the surveillance brief the organization's management as soon as practical.
 - 8.4.1.2.4 Generate the surveillance report and accumulate records.
- 8.4.1.3 Using the surveillance team members and/or technical specialists, conduct the surveillance using the following methods or combination methods, and provide results to STL for inclusion into the surveillance report.
 - 8.4.1.3.1 Examine objective evidence for proper and effective implementation of the QARD;
 - 8.4.1.3.2 Interview Personnel;
 - 8.4.1.3.3 Review process objectives and measurement criteria;
 - 8.4.1.3.4 Review records;
 - 8.4.1.3.5 Observe activities, personnel performance, in-process analysis, and testing; and

- 8.4.1.3.6 Determine the technical adequacy and effectiveness of analytical processes used in engineering, scientific investigation, operations, technical activities, or processes.
- 8.4.1.3.7 Upon discovery of a condition adverse to quality, immediately report conditions posing imminent danger to affected personnel and the responsible manager, and follow-up in writing.
- 8.4.1.3.8 Elevate issues that cannot be resolved by the surveillance team and organization under the surveillance to the Director, Office of Standards and Quality Assurance.
- 8.4.1.3.9 Verify that conditions adverse to quality, which were reported by the responsible organization to be isolated and corrected during the surveillance, were actually corrected, and document them.
- 8.4.1.3.10 As appropriate, conduct meetings with the surveillance team to discuss surveillance progress and any issues identified during the surveillance.
- 8.4.1.3.11 As appropriate, conduct meetings with the management under surveillance progress and identify any issues during the meetings.

8.5 Completing the Surveillance Report

8.5.1 Surveillance Team Leader

- 8.5.1.1 Document the results of the surveillance in the report in accordance with Attachment A – Surveillance Report Instructions. Issue the report within approximately 30 days of completing surveillance field work.
- 8.5.1.2 Attach any condition reports as initiated to the surveillance report for issuance to the responsible organization. After issuance, further processing of the condition report will be governed by the procedure.
- 8.5.1.3 Sign the surveillance report, prepare a transmittal memo and obtain the Director, Office of Standards and Quality Assurance approval.

8.6 Surveillance Report Distribution

8.6.1 Director, Office for Standards and Quality Assurance

8.6.1.1 Approve and sign the surveillance report, and forward the surveillance report and the transmittal memo to the Deputy Assistant Secretary, Safety and Security Program for approval and initials on the transmittal memo.

8.6.1.2 Distribute the surveillance report and transmittal memo to the responsible organization's management and provide copies to the appropriate representatives to the interested organizations.

9.0 RECORDS MAINTENANCE

Records listed shall be collected and submitted to the EMCBC in accordance with AP-17.1Q, Quality Assurance Records, as individual records or included in a records package, as specified. Records listed in 9.2 shall be maintained and dispositioned through the EMCBC Records Management Center procedures.

9.1 QA Records

9.1.1 Lifetime Records

9.1.1.1 Surveillance Report

9.1.1.2 Completed QA Checklists

9.1.1.3 Personnel Contacted List

9.1.2 Nonpermanent Records

9.1.2.1 Attendance Sheets

9.2 Non QA Records

9.2.1 Long Term Records

9.2.1.1 Surveillance Notification Letter

9.2.1.2 Surveillance Report Transmittal Letter

10.0 FORMS USED

Form 18.1-1, Quality Assurance Audit Checklist

Form 18.1-2, Attendance Sheet

Form 2.2-1, Surveillance Report

Form 5.1-1, Record of Revision

11.0 ATTACHMENTS

Attachment A – Surveillance Report Instructions

Attachment A – Surveillance Report Instructions

Format is optional; however, the following elements must be addressed in the surveillance report, as applicable. If using an alternate format, elements must be combined, as necessary.

1. Number assigned for the surveillance obtained from either the assessments schedule or the HLW/UNF Oversight Lead, and title of the surveillance.
2. Include the dates of the surveillance activity.
3. Organization responsible for the product, process, or activity that is being assessed in the surveillance.
4. Manager of the organization identified in block 3 that is being assessed in the surveillance.
5. Describe the scope of the surveillance in detail, including product, process, or activity assessed in the surveillance.
6. Provide discussion of the verification of the effectiveness of previously completed corrective actions, when applicable.
7. Provide a detailed description of the observed activities, objective evidence, and the evaluation of QARD sections or procedures as applicable. Include sufficient detail to allow a reviewer of this document to retrace steps.
8. Identify or reference the criteria considered during the surveillance (QARD sections, procedures, specifications, drawings, etc.).
9. Identify persons contacted during the surveillance by name and organization.
10. State conclusions resulting from the surveillance. When appropriate to the scope of the surveillance, include statements in relation to the adequacy of the requirements, their implementation, and the effectiveness of implementation.
11. Identify each Condition Report initiated during the surveillance by number and provide a summary of each (if none, enter N/A).
12. The name and signature of the Director of Quality Assurance and Standards and date signed.

Form 2.2-1 – Surveillance Report

Surveillance Report		Form Number 2.2-1 Page of
1. Report Number	2. Date(s) of Surveillance	
3. Organization Responsible for Product, Process, or Activity	4. Responsible Manager	
5. Product, Process, Activity Assessed		
6. Existing Condition Report(s) Relevant to Block 5		
7. Description of Activity/Characteristics/Attribute Assessed		
8. Criteria Used in Evaluation (e.g., procedure requirements)		
9. Identify Personnel Contacted		
10. Conclusions		
11. Condition Report(s) Initiated		
12. QA Surveillance Team		
13. QA Surveillance Team Leader		
_____	_____	_____
Printed Name	Signature	Date
14. Director of Quality Assurance and Standards		
_____	_____	_____
Printed Name	Signature	Date

RECORD OF REVISION

DOCUMENT: AP-2.2Q, Surveillances

If there are changes to the controlled document, the revision number increases by one. Indicate changes by one of the following:

- I Placing a vertical black line in the margin adjacent to sentence or paragraph that was revised.
- I Placing the words GENERAL REVISION at the beginning of the text.

Rev. No.	Description of Changes	Revision on Pages	Date
0	Original	All	04/27/2011