NYE COUNTY NUCLEAR WASTE REPOSITORY PROJECT OFFICE

QUALITY ADMINISTRATIVE PROCEDURE

TITLE: **Audits and Surveillances**	REVISION: **2** DATE: **9-17-08** PAGE: **1 of 11**
PROCEDURE NUMBER: **QAP-18.1**	SUPERSEDES: **Revision 1, 3-31-04**
APPROVAL Director 9/18/08 Date	CONCURRENCE Geoscience Manager 9/17/08 Date Quality Assurance Officer 9/17/08 Date

1.0 PURPOSE

This quality administrative procedure (QAP) describes Nye County Nuclear Waste Repository Project Office (NWRPO) requirements and responsibilities for internal surveillances and audits of quality-affecting activities conducted by NWRPO personnel and external surveillances and audits of contractors and commercial vendors, such as analytical laboratories, not operating under the NWRPO Quality Assurance Program Plan (QAPP).

2.0 APPLICABILITY

This QAP applies to the performance of surveillances and audits for activities subject to the requirements of the NWRPO QAPP.

3.0 DEFINITIONS

3.1 ***Audit***—planned and documented investigation, examination, or evaluation of objective evidence to determine compliance of the NWRPO technical program with established procedures, instructions, drawings, and other applicable documents.

3.2 ***Nonconformance***—a deficiency in characteristic, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate.

3.3 ***Quality administrative procedure***—a procedure developed to implement the quality assurance (QA) requirements described in the QAPP.

3.4 ***Quality Assurance Program Plan***—the controlled plan that outlines the NWRPO QA requirements, which are based principally on the applicable portions of the requirements set forth by the U.S. Nuclear Regulatory Commission and the American National Standards Institute for nuclear power plants, as adapted for a nuclear waste repository.

3.5 ***Surveillance***—monitoring a quality-affecting item or activity to verify that it conforms to specific requirements of NWRPO QA plans and procedures.

4.0 RESPONSIBILITIES

4.1 Director

The Director or designee is responsible for ensuring that the QA Officer (QAO) establishes an audit and surveillance program for NWRPO technical programs and that QA and technical personnel have the appropriate support and authority to meet audit and surveillance objectives in a timely manner.

4.2 Quality Assurance Officer

The QAO is responsible for developing, scheduling, and implementing the NWRPO audit and surveillance program. The QAO is also responsible for providing the scope and schedule for planned audits or surveillances to the Director or designee, Geoscience Manager (GSM), and Principal Investigator (PI). The QAO is also responsible for developing an audit plan, performing the audit as planned, performing pre- and post audit briefings, and preparing the audit report

4.3 Geoscience Manager

The GSM is responsible for participating in audit conferences and ensuring that the PI responds to audit and surveillance reports in an appropriate and timely manner.

4.4 Technical Personnel

NWRPO technical personnel are responsible for fully supporting audits or surveillances as needed and requested by NWRPO QA personnel.

5.0 PROCESS

The QAO may perform several surveillances each fiscal year. A full audit of the NWRPO QA program shall be performed at least once in a three-year period.

5.1 Audit or Surveillance Initiation

Early in each fiscal year, the QAO shall prepare a schedule of audits and surveillances at a frequency commensurate with the status and importance of the activity, which shall be maintained in the NWRPO QA records center (QARC). Additional audits or surveillances shall be conducted when deemed necessary by the QAO.

The QAO may plan and conduct surveillances with the assistance of one or more NWRPO QA management contractor(s), if approved by the Director or designee.

5.2 Auditor and Surveillance Personnel Qualifications

Auditors shall have experience or training commensurate with the scope, complexity, or special nature of the activities to be audited. Specifically, the auditors shall be trained in NWRPO audit implementation and reporting as presented in this QAP, and be familiar with methods of examining, questioning, evaluating, and documenting specific audit items and closing out audit findings.

A list of auditors and their qualifications shall be maintained in the QARC, as well as the qualifications of the QAO and NWRPO QA management contractors.

5.3 Audits

The QAO shall identify areas or activities to be audited and a tentative schedule for the audit. If applicable, the QAO shall also identify the lead auditor and audit team members.

5.3.1 Preparation of the Audit Plan

The QAO shall develop an audit plan for each audit containing the following information:

- Preparation date of audit plan
- Unique audit number
- Audit schedule
- Names of lead auditor and audit team members, if applicable
- Audit scope, including specific areas or activities to be audited
- Checklist of items to be audited.
- Applicable documents (e.g., procedures, regulations, or standards) that govern the audited activities

- Responsible person(s) to be notified for audit

Attachments 1 and 2 present a sample audit plan and checklist.

5.3.2 Audit Notification

The QAO shall notify the responsible PI of the area to be audited. Notification shall include the following:

- Audit scope
- Scheduled audit date
- Name of lead auditor, if other than the QAO

Notification shall generally be provided at least 5 working days prior to the initiation of an internal audit; however, unscheduled audits may occur when deemed necessary by the QAO. Formal written notification shall always be provided for external audits of contractors or commercial vendors.

5.3.3 Pre-Audit Conference

A pre-audit conference shall be held to discuss questions regarding the audit and its scope. The conference shall be attended by the GSM and one or more representatives (including the PI or designee where possible) responsible for an area of work or activity to be audited. At the conference, the following shall be done:

- Introduce the conference attendees
- Establish communication
- Present the basic elements of the audit plan (i.e., scope, items to be examined, and proposed schedule)
- Schedule and discuss the format of the post-audit conference
- Discuss possible assistance needed by conference attendees to achieve audit goals

5.3.4 Audit Activities

Audit interviews and the examination of activities shall be documented in detail by the QAO. The auditor shall request specific items of evidence for examination. If an item cannot be produced immediately, the QAO shall allow a reasonable amount of time for it to be produced; if it cannot be produced in a reasonable amount of time, it shall be noted on the audit checklist as “not available for audit,” and evaluated for a possible negative finding. Upon completion of the audit, the audit team shall ensure that the audit checklist is complete and prepare a draft audit report, detailing both favorable and unfavorable findings and/or observations.

5.3.5 Post-Audit Conference

A post-audit conference shall be held immediately following the audit and attended by the individuals who attended the pre-audit conference. The audit team shall discuss its findings and observations with the GSM and responsible PI. Suggestions shall be made regarding corrective action on any findings. If deemed necessary, a tentative follow-up audit date shall be established.

5.3.6 Audit Report

A final audit report shall be prepared by the QAO and issued to the responsible PI, GSM, and Director or designee for review within 15 days of the audit. A sample audit report is presented as Attachment 3. Nonconforming conditions described in QAP-15.1, *Control of Nonconforming Items or Activities,* requiring prompt corrective action shall be reported to the responsible PI, GSM, and Director or designee immediately. The audit report shall contain, at a minimum, the following:

- Audit date, subject, purpose, and scope
- Names of audit team members, if applicable
- Responsible individual(s) contacted
- Audit activities
- Determination of the effectiveness of the QA program elements for providing the required control on the activity audited
- Findings and observations, with a detailed description of the root cause, where possible
- Proposed corrective action, with measures suggested to prevent recurrences
- Recommendations for improvements to the QA program and or implementation
- Planned follow-up audit or surveillance, if required

Copies of audit reports shall be submitted to the QARC.

5.3.7 Response to Audit Report

The responsible PI or designee shall respond in writing to the final audit report within 30 days of receipt. The PI shall investigate all findings, observations, and proposed corrective action. The PI shall notify the QAO in writing of planned corrective action activities before the response date. Nonconformances and respective corrective actions identified during the audit shall be resolved according to QAP-15.1 and QAP-16.1, *Corrective Action*.

Follow-up action described in the audit report, including another audit or surveillance of the deficient areas, shall be taken no later than 60 days after the audit.

If it is discovered during a follow-up audit or surveillance that the nonconformance has not been satisfactorily corrected, this fact shall be documented in a follow-up audit report, and additional audits shall be conducted until the nonconformance is corrected.

5.4 Surveillances

5.4.1 Surveillance Plan

A surveillance plan shall be prepared by the QAO addressing, as appropriate, the same elements as the audit plan described in Section 5.3.1.

5.4.2 Surveillance Notification

The QAO shall notify the responsible PI or designee of the surveillance scope and schedule at least 5 working days prior to the surveillance; however, an unscheduled surveillance may be made when deemed necessary by the QAO. Formal written notification shall always be provided for external surveillances of contractors or commercial vendors.

5.4.4 Surveillance Activities

Surveillance personnel shall verify specific items in the surveillance checklist by examining the appropriate data, equipment, and records and, when necessary, interviewing the responsible PI and staff members. Interviews and examinations shall be documented in detail by surveillance personnel. At the completion of the surveillance, the QAO shall write a draft surveillance report detailing both favorable and unfavorable findings and observations.

5.4.5 Post-Surveillance Conference

The QAO shall conduct a conference immediately following the surveillance and discuss any findings and observations with the responsible PI and/or staff member, as appropriate. The QAO shall clarify findings with the attendees and resolve them during the conference, if possible. The QAO shall also establish a closure plan and schedule for any remaining findings.

5.4.6 Surveillance Report

The QAO shall prepare the final surveillance report and submit it within 15 days to the responsible PI, GSM, and Director or designee for review. Findings identified as nonconformances, as defined in QAP-15.1, that require prompt corrective action shall be reported to the responsible PI, GSM, and Director or designee immediately. The surveillance report, similar in format to the audit report, shall contain the following:

- Surveillance date, subject, purpose, and scope
- Name of the QAO and participating team members
- Responsible individual(s) contacted

- Surveillance activities
- Findings and observations, with a detailed description of the root cause, where possible
- Proposed corrective action, with measures described to prevent recurrence
- Planned follow-up surveillance, if required

A copy of the surveillance report shall be submitted to the QARC.

5.4.7 Response to Surveillance Report

The responsible PI or designee shall respond in writing to any remaining findings and observations in the final surveillance report as soon as practicable but no later than 30 days of receipt of the report. The response shall include the corrective action plan as described in QAP-16.1, and its implementation schedule for all outstanding findings and observations. The findings identified as nonconformances and the respective corrective actions shall be resolved according to QAP-15.1 and QAP-16.1.

Follow-up action described in the surveillance report, including another surveillance of the deficient areas, shall be taken no later than 30 days after the PI response.

If it is discovered during a follow-up surveillance that the nonconformance has not been satisfactorily corrected, this fact shall be documented in a follow-up surveillance report, and additional surveillance(s) shall be conducted until the nonconformance is corrected.

6.0 RECORDS

Documents generated by this QAP are QA records and shall be submitted to the QARC by the QAO. Prior to submittal, the QAO shall ensure that each document is complete, legible, and adequately identifiable, as specified in QAP-17.1, *Records Management*.

The QA records generated by this QAP shall include the following:

- Auditor and surveillance personnel qualifications
- List of qualified auditors and lead auditors
- Audit and surveillance schedules, plans, checklists, and reports

7.0 REFERENCES

QAP-15.1, *Control of Nonconforming Items or Activities*. Quality Administrative Procedure. Nye County Nuclear Waste Repository Project Office (NWRPO). Pahrump, Nevada.

_QAP-16.1, *Corrective Action*.

_QAP-17.1, *Records Management*.

QAPP, *Nye County Nuclear Waste Repository Project Office Quality Assurance Program Plan*. Quality Assurance Program Plan. NWRPO. Pahrump, Nevada.

8.0 ATTACHMENTS

Attachment 1 Sample Audit Plan

Attachment 2 Sample Audit Checklist

Attachment 3 Sample Audit Report

Attachment 1
Sample Audit Plan

Audit Plan Prepared: January 20, 2004
J. Jones, Lead Auditor

Quality Assurance Audit Plan
Nye County Nuclear Waste Repository Project Office
Audit Number NWRPO-29

1.0 SCOPE

This audit includes all quality-affecting activities associated with the field activities within the Borehole Monitoring Work Activity.

2.0 SPECIFIC AREAS (ACTIVITIES TO BE AUDITED)

Borehole monitoring team

Equipment calibration, verification of procedures for tagging and logging maintenance checks on equipment.

3.0 RESPONSIBLE PERSON(S) TO BE NOTIFIED

J. Gonzales

B. Richardson

C. Windsor

4.0 APPLICABLE REFERENCE DOCUMENTS

NWRPO QA Program Plan, Rev 04, Section 12, Pg. 30-31

QAP-12.1, *Control of Measuring and Test Equipment*

TP-9.2, *Procedures for Operating Westbay MOSDAX Groundwater Monitoring Equipment in Nye County Wells*

5.0 PLANNED DATES OF AUDIT

June 21 – 22, 2004.

6.0 CHECKLIST

See attached.

Attachment 2
Sample Audit Checklist

Nye County Nuclear Waste Repository Project Office **QUALITY ASSURANCE AUDIT CHECKLIST**	Form QAP-18.1 Rev.0 03-31-04 Page ____ of ___
Date of Evaluation:	
Type of Activity:	☐ Audit
	☐ Surveillance
Auditors/Surveillance Personnel:	
Controlling Document:	
QA Program Plan:	
Activity Evaluated	

Criterion/Requirement	**Comments/Recommendations**

Attachment 3
Sample Audit Report

QUALITY ASSURANCE AUDIT REPORT

Nye County
Nuclear Waste Repository Project Office
Audit Number NWRPO-29

Date: March 3, 2004

To: J. Gonzales, Responsible Supervisor/PI

From: NWRPO Audit Team

Subject: Audit of calibration system, tagging, logging of maintenance checks on NWRPO borehole monitoring equipment.

PURPOSE: To verify that the controls established by the NWRPO Quality Assurance Program are effective in assuring that all measuring and test equipment is adequately controlled, calibrated at specified intervals, and adjusted when necessary. The aim of this audit as well as the entire QA program is to provide adequate confidence that the NWRPO oversight activities will result in valid data.

SCOPE: The audit covered the procedures delineated for the Borehole Monitoring team and related QA procedures dealing with the control of measuring and test equipment.

SUMMARY: The measuring and test equipment utilized at NWRPO monitoring boreholes appears to be in control and to be gathering valid data.

Lead Auditor: D. Jones

Dates of Audit: June 21 - 23, 2004

Person Contacted: J. Gonzalez

AUDIT CONDUCT: All NWRPO borehole-monitoring instruments were evaluated. Equipment calibration procedures were audited against the NWRPO QA Program Plan, Revision 4, 6/15/03, section 12.0, entitled Control of Measuring and Test Equipment; as well as Procedures for Borehole Monitoring Instrumentation (NWRPO Technical Procedure TP-9.2).

The audit conducted was focused on the items on the audit checklist (Attachment 2).

Recommendations: Implementation of the governing procedure QAP-12.1 could be improved by requiring in QAP-12.1 that calibration records be submitted to the QARC semi-annually.