

**CENTER FOR NUCLEAR WASTE
REGULATORY ANALYSES**

Proc. QAP-011

Revision 2 Change 0

QUALITY ASSURANCE PROCEDURE

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Title

QAP-011 AUDITS

EFFECTIVITY AND APPROVAL

Revision 2 of this procedure became effective on 10/11/04. This procedure consists of the pages and changes listed below.

<u>Page No.</u>	<u>Change</u>	<u>Date Effective</u>
All	0	10/11/04

Supersedes Procedure No. QAP-011, Revision 1, Change 1, dated 7/21/2004

Approvals

Written By	Date	Concurrence Review	Date
/s/Robert Brient	10/8/2004	/s/Patrick Mackin	10/11/2004
Quality Assurance	Date	Cognizant Director	Date
/s/Mark R. Ehnstrom	10/8/2004	/s/Budhi Sagar	10/11/2004

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QAP-011 AUDITS

1. PURPOSE

The purpose of this procedure is to describe the methods of scheduling, preparing for, performing, reporting, and following up audits.

2. RESPONSIBILITIES

- (1) The Center for Nuclear Waste Regulatory Analyses (CNWRA) Director of Quality Assurance is responsible for implementing this procedure.
- (2) Audit personnel are responsible for performing their tasks in accordance with this procedure.

3. PROCEDURE

3.1 Scheduled Audits

- (1) An internal audit shall be scheduled, at a minimum, for each calendar year by the Director of CNWRA Quality Assurance. The timing of this audit will take into consideration program status, as well as quality assurance and technical activities being conducted.
- (2) Technical areas to be audited shall be selected based on level and importance of ongoing and time since last audit.
- (3) Supplemental audits shall be conducted as necessary to (1) verify corrective actions taken for a previous audit finding and (2) provide coverage of activities that could not be evaluated because of the timing of the previous audit.
- (4) Supplier audits shall be scheduled when required by QAP-016 and performed in accordance with this procedure.

3.2 Audit Preparation

- (1) The audit team leader shall be appointed by the Director of Quality Assurance. The audit team leader must be certified as a lead auditor, and shall have the following duties:
 - (a) Issuing an audit notification letter or memorandum
 - (b) Coordinating the audit plan and checklist preparation

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- (c) Selecting the audit team and preparing the audit team prior to the start of the audit
- (d) Organizing and directing the audit
- (e) Conducting pre- and post-audit conferences
- (f) Coordinating the preparation of the audit report
- (g) Evaluating responses to audit-generated Corrective Action Requests
- (2) An audit plan shall be prepared for each audit, including the following, as a minimum:
 - (a) Audit scope (e.g., activities, products, projects, and quality elements to be audited)
 - (b) Organization to be audited
 - (c) Audit team and the team leader
 - (d) Applicable documents providing the source of requirements to be audited
 - (e) Tentative schedule of audit activities
 - (f) Audit checklist or reference to this audit procedure
- (3) Audit personnel shall not have direct responsibility for the activities being audited.
- (4) Lead auditors and auditors shall be qualified in accordance with the Southwest Research Institute® Quality System Procedures, which meet the requirements of American National Standard Institute/American Society of Mechanical Engineers NQA-1.
- (5) Technical specialists not certified as auditors or lead auditors may be utilized as audit team members. Their qualifications as technical specialists shall be determined by the Director of Quality Assurance and documented.
- (6) Audit team members shall be selected based on their knowledge of the quality elements and/or technical areas relevant to the activity being audited.
- (7) An audit notification memorandum or letter shall be prepared and distributed approximately two weeks prior to the start of the audit. The notification shall include a copy of the audit plan. Copies of the notification shall be distributed to the CNWRA President, affected directors and managers, and as applicable, suppliers.

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3.3 Performance

- (1) Audits shall be performed using a checklists prepared before the audit.
- (2) Audit checklist questions shall be based on the requirements of the quality assurance documents or technical documents applicable to the activity being audited.
- (3) Checklists may be revised during the audit as necessary, deleting items not applicable, and adding items based on the audit observations or other findings.
- (4) Auditors shall evaluate the implementation of the quality elements and performance of technical activities using sufficient and appropriate evaluation of records, discussion with audited personnel, and direct observation of activities.
- (5) During the audit, the auditor shall document the findings and include or refer to the extent and type of observations and records reviewed. The auditor shall provide a status for each checklist item, as follows:

S - Satisfactory: the objective evidence examined indicates effective implementation

Major - Nonconformances: the objective evidence examined indicates that implementation is ineffective, there is a significant breakdown in the quality system, or the condition is likely to lead to delivery of materially nonconforming products. Major nonconformances shall be addressed in accordance with QAP-010, Corrective Action.

Minor - Nonconformances: the objective evidence examined identified a minor noncompliance to requirements, which does not indicate a significant breakdown in the quality system or is not likely to lead to delivery of materially nonconforming products. Minor nonconformances shall be addressed in accordance with QAP-009, Nonconformance Control.

N/A - Not Applicable: the requirement is not applicable to the activity being audited, or the timing was such that the requirement has not yet been implemented.

3.4 Audit Conferences

- (1) Pre-audit conferences shall be conducted with management of the audited organization to review the scope and purpose of the audit, introduce the audit team, and coordinate audit activities.
- (2) Post-audit conferences shall be conducted with management of the audited organization to identify findings and to identify the individuals responsible for corrective action of the findings.

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3.5 Audit Reports

- (1) Within 30 days of the completion of the audit, the audit team leader shall complete the audit report. The audit report shall be approved and issued by the Director of Quality Assurance, and distributed to the CNWRA President, management of the CNWRA, and management of the audited organization (for supplier audits). Distribution should also include each individual responsible for corrective action.
- (2) The audit report shall consist of the following.
 - (a) Introduction, identifying:
 - Audit number
 - Audit dates
 - Scope of the audit
 - Applicable requirements documents
 - Audit team leader and team members
 - Persons contacted during the audit
 - Audit conferences held
 - (b) Summary of findings, describing:
 - Evidence reviewed and results of the quality elements and activities examined
 - Unsatisfactory conditions, with reference to associated Nonconformance Reports and Corrective Action Requests
 - Observations and opportunities for improvement of the quality system.
 - (c) A statement of adequacy and effectiveness of the quality system and its implementation.
 - (d) Copies of Corrective Action Requests or Nonconformance Reports initiated as a result of the audit.
 - (e) Approval signatures of the audit team and Director of Quality Assurance.

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3.6 Follow-up

In accordance with the CQAM, Section 16, the implementation and effectiveness of corrective actions shall be evaluated through follow-up activities by CNWRA quality staff. If necessary to determine the effectiveness of corrective actions, followup audits shall be conducted as described in 3.1(3).

4. RECORDS

The following audit-related documents shall be maintained and retained as Quality Assurance records in accordance with QAP-012:

- Audit plans
- Auditor and technical specialist qualifications
- Completed checklists
- Meeting attendance rosters
- Audit reports