CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES QUALITY ASSURANCE PROCEDURE	Proc. QAP-011 Revision 0 Page 1 of 8

Title

QAP-011 AUDITS

EFFECTIVITY AND APPROVAL

Revision 0 of this procedure became effective on 10/04/90. This procedure consists of the pages and changes listed below.

Page No.	Change	Date Effective
ALL	0	

SUPERSEDED

Supersedes Procedure No. NONE

Approvals

Written By	Date	Technical Review	Date
Robert Brient	9/25/90	R Engelhardt	10/1/90
Quality Assurance	**Date**	**Cognizant Director**	**Date**
Dennis Mahoney	10/2/90		10/4/90

CNWRA Form QAP-1

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 RESPONSIBILITY

(1) The Director of Quality Assurance is responsible for the implementation of this procedure.

(2) Audit personnel are responsible for performing their tasks in accordance with this procedure.

3. PROCEDURE

3.1 Audit Schedules

(1) Audit schedules shall be developed for each calendar year based on audit frequency requirements, the timing of important events, and in coordination with the quality assurance activities being conducted.

(2) Internal audits shall be scheduled so that each element of the CQAM is evaluated annually.

(3) As necessary, the audit schedule shall be revised to ensure that the objective of complete coverage of all quality elements and activities is met.

(4) Supplemental audits of specific subjects shall be conducted as necessary to (1) verify corrective actions taken for a previous audit finding and (2) to provide coverage of activities which could not be evaluated because of the timing of the previous audit. Supplemental audits shall be incorporated into the audit schedule revisions.

(5) Supplier audits shall be scheduled as required by CQAM Section 7 for initial qualification and to

maintain qualification, usually every three years. Supplier audits to maintain qualification shall be included in the audit schedule.

3.2 Audit Preparation

(1) An audit plan shall be prepared for each audit, including the following, as a minimum:

(a) The audit scope; the activities and quality elements to be audited

(b) Organizations to be audited

(c) The audit team and the team leader

(d) Applicable documents providing the source of requirements to be audited

(e) Tentative schedule of audit activities

(f) The audit checklist or reference to this audit procedure

(2) Audit personnel shall not have direct responsibility for the activities being audited.

(3) Lead auditors and auditors shall be qualified in accordance with CQAM Section 2.

(4) 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.

(5) Prior to the start of the audit, the audit team shall be identified. The audit team leader, certified as a lead auditor, shall be appointed, and shall have the following duties:

(a) Issuance of an audit notification letter or memorandum

(b) Coordination of the audit plan and checklist preparation

(c) Preparation of the audit team prior to the start of the audit

(d) Organization and direction of the audit

(e) Conduct of pre- and post-audit conferences

(f) Coordination of the preparation and issuance of the audit report

(g) Evaluation of responses to audit-generated Corrective Action Requests

(6) Audit team members shall be selected based on their knowledge of the quality elements and/or technical issues relevant to the activity being audited.

(7) An audit notification memorandum or letter shall be prepared and distributed, preferably two weeks prior to the start of the audit. The notification shall include a copy of the audit plan and schedule for the pre-audit conference. Copies of the notification shall be distributed to the Center President, affected Directors and Element Managers, QAC Chairman, and as applicable, supplier management.

3.3. Performance

(1) An audit shall be performed using a checklist prepared prior to the start of the audit.

(2) Audit checklist questions shall be based on the requirements of the quality assurance documents applicable to the activity being audited. The basic requirements from 10CFR50, Appendix B, NQA-1, or other code or standard, may also be referenced in the audit checklist.

(3) The checklist may be revised as necessary, deleting items not applicable, and adding items based on the

results of observations or other findings.

(4) Using sufficient and appropriate evaluation of records, discussion with audited personnel, and direct observation of quality-related activities, the auditor shall evaluate the implementation of the quality elements.

(5) During the audit, the auditor shall note the findings of each audit checklist item, the conclusions of the evaluation, and include or refer to the extent and type of observations and records reviewed. The auditor shall provide each checklist item with a status, as follows:

S - Satisfactory: the objective evidence examined indicates effective implementation,

U - Unsatisfactory: The objective evidence examined indicates that implementation is ineffective,

N/A - Not Applicable: The requirement is not applicable to the activity being audited.

(6) Unsatisfactory conditions shall be reported in accordance with CQAM Section 16, "Corrective Action."

3.4 Audit Conferences

(1) Pre-audit conferences shall be conducted with the audited activity 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 preliminary findings and to identify the individuals responsible for corrective action of the findings.

3.5 Audit Reports

(1) Within 30 days of completion of the audit, the audit team leader shall complete the audit report based on the checklist results. The audit report shall be approved and issued by the Director of QA, and distributed to the Center President, management of the Center, the Chairman of the QAC, and the management of the audited organization (for supplier audits). Distribution shall include each individual responsible for corrective action.

(2) The audit report shall consist of the following.

(a) Introduction, identifying:

- o Audit number
- o Audit dates
- o Scope of the audit
- o Applicable requirements documents
- o Audit team leader and team members
- o Persons contacted during the audit
- o Audit conferences held

(b) Summary of findings, describing:

- o The evidence reviewed and results of the quality elements examined
- o Unsatisfactory conditions, with reference to associated Corrective Action Requests
- o Observations; conditions which are not unsatisfactory, but if not corrected could result in unsatisfactory conditions

(c) A statement of effectiveness of the quality elements audited and effectiveness or the

overall implementation for the activities audited.

(d) Approval of the report by the audit team leader and Director of Quality Assurance.

(3) A description of the objective evidence reviewed and the results of the examination of each quality element on the checklist shall be placed in the audit report file. This file shall also contain copies of the completed Corrective Action Requests associated with the audit.

3.6 Corrective Action

(1) Corrective Action Requests (CAR) shall be initiated by the audit team leader in accordance with CQAM Section 16 for each unsatisfactory finding. CARs shall be issued on a timely basis, at the latest, concurrent with the audit report issuance.

(2) In accordance with CQAM Section 16, the CAR shall identify the individual responsible for the corrective action response. This individual shall be responsible for investigating the unsatisfactory finding, for scheduling corrective action, including action to prevent recurrence, and for providing a written response within the specified period.

(3) The audit team leader shall be responsible for reviewing the adequacy of the corrective action responses.

3.7 Follow-up

In accordance with CQAM Section 16, the implementation and effectiveness of corrective action shall be evaluated through follow-up activities.

4. RECORDS

(1) Audit reports shall be maintained as QA records in accordance with CQAM Section 17 and retained in quality

assurance files for a minimum of six years.

(2) Completed audit checklists and attachments and other audit field notes shall be retained in quality assurance files for a minimum of six years.

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Title

QAP-011 AUDITS

EFFECTIVITY AND APPROVAL

Revision 1 of this procedure became effective on 8/30/2002. This procedure consists of the pages and changes listed below.

Page No.	Change	Date Effective
ALL	0	8/30/2002

Supersedes Procedure No. QAP-010, Revision 0, Change 0

Approvals

Written By Mark R. Ehnstrom MARK R. EHNSTROM	Date 8/28/02	Concurrence Review Thomas A. Mayes THOMAS A. MAYCES	Date 8/28/02
Quality Assurance Bruce Mabrito BRUCE MABRITO	Date 8/28/2002	CNWRA President Wesley C. Patrick WESLEY C. PATRICK	Date 8/29/02

CNWRA Form QAP 1 (12/92)

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 CNWRA Scheduled Audits

(1) Internal audits 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) Internal audits shall be scheduled so that each element of the CNWRA Quality Assurance Manual is evaluated annually.

(3) Internal 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 as required by CNWRA Quality Assurance Manual Section 7 and performed in accordance with this procedure.

(5) Audits and observation audits of others (such as the U.S. Department of Energy, etc.) are directed by the CNWRA client and other procedures are followed.

3.2 Audit Preparation

(1) An audit plan shall be prepared for each audit, including the following, as a minimum:

(a) The audit scope (e.g., activities, products, projects, and quality elements to be audited)

(b) Organization to be audited

(c) The audit team and the team leader

(d) Applicable documents providing the source of requirements to be audited

(e) Tentative schedule of audit activities

(f) The audit checklist or reference to this audit procedure

(2) Audit personnel shall not have direct responsibility for the activities being audited.

(3) Lead auditors and auditors shall be qualified in accordance with the Southwest Research Institute quality system, which meets the requirements of American National Standard Institute/American Society of Mechanical Engineers NQA-1.

(4) 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.

(5) Prior to the audit, the audit team shall be appointed by the lead auditor in consultation with 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

(c) 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 and issuance of the audit report

(g) Evaluating responses to audit-generated Corrective Action Requests

(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 and schedule for the pre-audit conference. Copies of the notification shall be distributed to the CNWRA President, affected Directors and Element Managers, and as applicable, suppliers.

3.3 Performance

(1) An audit shall be performed using a checklist prepared before the audit.

(2) Audit checklist questions shall be based on the requirements of the quality assurance documents applicable to the activity being audited. The basic requirements from 10 CFR Part 50, Appendix B; 10 CFR Part 63; 10 CFR Part 72; NQA-1; or other code or standard, may also be referenced in the audit checklist.

(3) The checklist may be revised as necessary, deleting items not applicable, and adding items based on the results of observation or other findings.

(4) Using sufficient and appropriate evaluation of records, discussion with audited personnel, and direct observation of quality-related activities, the auditor shall evaluate the implementation of the quality elements.

(5) During the audit, the auditor shall note the findings of each audit checklist item, the conclusions of the evaluation, and include or refer to the extent and type of observations and records reviewed. The auditor shall provide for each checklist item a status, 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 or materially nonconforming products

Minor - Nonconformances: the objective evidence examined identified a minor noncompliance to requirements, which does not indicate a significant breakdown in the quality system or not likely to lead to delivery of nonconforming product.

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

(6) Major - Nonconformances shall be reported in accordance with CNWRA Quality Assurance Manual Section 16, "Corrective Actions."

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 preliminary findings and to identify the individuals responsible for corrective action of the findings.

3.5 Audit Reports

(1) Within 30 days of the completion of the audit, the audit team leader shall complete the audit report based on the checklist results. 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:

- The evidence reviewed and results of the quality elements examined
- Unsatisfactory conditions, with reference to associated Nonconformance Reports and Corrective Action Requests
- Observations and recommendations of conditions that (1) are not unsatisfactory, but if not corrected could result in unsatisfactory conditions, or (2) should be considered as possible improvements to the overall program.

(c) A statement of effectiveness of the quality elements audited and effectiveness of the overall implementation for the projects, activities, products, and quality elements audited.

(d) Copies of Corrective Actions Requests or Nonconformance Reports initiated as a result of the audit.

(e) Approval of the report by the audit team leader and Director of Quality Assurance.

3.6 Corrective Action

(1) A Corrective Action Request shall be initiated by the audit team leader in accordance with QAP-010 for each Major Nonconformance identified during the audit. All Corrective Action Requests should be issued concurrent with the audit report.

(2) Minor nonconformances identified during the audit shall be documented on Nonconformance Reports in accordance with QAP-009.

(3) The audit team leader shall be responsible for reviewing the adequacy of the corrective action responses.

3.7 Follow-up

In accordance with the CNWRA Quality Assurance Manual, Section 16, the implementation and effectiveness of corrective actions shall be evaluated through follow-up activities by CNWRA quality staff.

4. RECORDS

Audit reports shall be maintained as Quality Assurance records in accordance with the CNWRA Quality Assurance Manual, Section 17 and retained in quality assurance files.