

SANDIA NATIONAL LABORATORIES
WASTE ISOLATION PILOT PLANT
QUALITY ASSURANCE PROCEDURE (QAP)
QAP 18-1

QA AUDIT REQUIREMENTS

Revision E

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1.0 PURPOSE

This Quality Assurance Procedure defines the necessary actions and responsibilities with respect to the Sandia WIPP QA Auditing Program.

2.0 SCOPE

This QAP applies to all activities conducted by Sandia National Laboratories in support of the Waste Isolation Pilot Plant (WIPP).

3.0 REFERENCES

- ASME NQA-1, latest revision and applicable addenda, Supplement 2S-3 and Supplement 18S-1
- DOE Order 5700.6C
- Sandia National Laboratories, WIPP Quality Assurance Program Description

4.0 DEFINITIONS

Auditor - An individual qualified by experience and/or training to participate in a QA Audit.

External Audit - Audits of Sandia Contractors.

Internal Audit - Audits of Sandia and Sandia Contractors working directly under the WIPP QAPD.

Lead Auditor - An individual who through training, testing and experience has been certified in writing by the SNL WIPP Project Manager, as a lead auditor.

QA Audit - A documented activity performed in accordance with written procedures or checklists to verify by examination and evaluation of objective evidence, that applicable elements of the quality assurance program have been developed, documented, and effectively implemented in accordance with specified requirements.

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5.0 RESPONSIBILITIES

5.1 WIPP QA Chief. The WIPP QA Chief will:

- Maintain QA audit schedule;
- Issue advance notification of audit;
- Select the audit team leader for each audit;
- Approve the audit plan and report.

5.2 Audit Team Leader. The audit team leader will:

- Coordinate the audit with the organization to be audited;
- Select the audit team members in accordance with Section 10;
- Prepare audit plan and checklist;
- Brief audit team members;
- Organize and direct audit;
- Prepare audit report;
- Evaluate audited organization's response to the audit report;
- Decide whether to re-audit corrective action;
- Close out audit.

5.3 Audit Team. The audit team members will:

- Assist in planning details of audit;
- Conduct audit under direction of the audit team leader;
- Assist in preparing audit report;
- Assist in follow-up and close-out of audit.

5.4 Audited Organization (auditee). The responsibilities of the auditee include:

- Assist in planning and scheduling audit to minimize disruption of normal routines;
- Participate in opening meeting with audit team;
- Provide access for audit team to activities and materials under audit;
- Provide information and documentation needed by audit team;
- Participate in close-out meeting with audit team;
- Take corrective action on findings;
- Respond to audit report, when required;
- Respond to audit team follow-up activities.

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6.0 PREPARATION

6.1 Scheduling. An audit schedule will be developed and maintained by the WIPP QA Chief for all audits performed by SNL in support of the WIPP. Due to the unpredictability of timing experimental activities, the schedule will be used as a guide. Frequent changes may be made to coincide with changing work priorities. The initial audit of an activity or contractor should be scheduled concurrent with, or as close as practical to, initial performance of the activity to assure timely implementation of quality requirements. Subsequent audits should be scheduled commensurate with the importance of the activity, normally not more often than once per year. As changes to the audit schedule occur, the WIPP QA Chief shall indicate those changes on the master audit schedule and periodically issue updates. Copies of the audit schedule will be sent to the DOE QA Managers and SNL Managers.

6.2 Development of Schedule. At the beginning of each fiscal year, the QA Chief will review the Annual Program Plan and suggest to management areas to be audited. Management will review these and give input, written or verbal, to the Chief. If the publication of the Annual Plan is delayed, the most recent plan will be used. The audit schedule will be revised, if necessary to reflect any changes when the new Program Plan is issued. Selection criteria for audit areas and program elements include:

- importance of activity in terms of project priorities;
- status of the activity;
- risk and complexity of the activity; and
- previous work, such as earlier audits, NCR's, etc.

Once the areas have been determined by management and QA, the QA Chief evaluates all applicable QA program elements and determines which ones are to be included in the audit schedule.

6.3 Selection of Audit Team Leader. The WIPP QA Chief may be the audit team leader or an individual may be selected by the SNL WIPP Program Manager or the WIPP QA Chief. The individual must be a qualified lead auditor in accordance with the requirements of Section 9, or equivalent requirements. The audit team leader will be independent of any direct responsibility for performance of the activities which are audited. In the case of internal audits, the Project Manager will select an audit team leader to replace the QA Chief for those areas which the Chief is directly responsible.

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9.0 QUALIFICATION OF LEAD AUDITORS

- 9.1 Introduction.** This section provides requirements for the qualification of a lead auditor.
- 9.2 Communication.** A lead auditor shall have the ability to communicate effectively, both orally and in writing. This determination is attested to in writing by the lead auditor's employer.
- 9.3 Training.** A lead auditor will be trained to the extent necessary to assure competence in auditing skills. Training in the following areas shall be given based upon management evaluation of the particular needs of each prospective lead auditor:
- Knowledge and understanding of the WIPP QA Programs, NQA-1 and other nuclear-related codes, standards, regulations, and regulatory guides, as applicable;
 - General structure of QA programs as a whole;
 - Auditing techniques of examining, questioning, evaluating, and reporting; methods of identifying and following up on corrective action items; and closing out audit findings;
 - Audit planning;
 - On-the-job training to include applicable elements of the audit program.
- 9.4 Audit Participation.** A lead auditor will have participated in a minimum of five (5) quality assurance audits within a period of time not to exceed 3 years prior to the date of qualification, one audit shall be a nuclear quality assurance audit within the year prior to qualification. Note: WIPP is a nuclear facility, therefore all WIPP audits are nuclear quality assurance audits.
- 9.5 Examination.** The prospective lead auditor will pass an examination which will evaluate the comprehension of and ability to apply the body of knowledge identified in paragraph 9.3, above. The test may be oral, written, practical, or any combination of the three types. The examination may be administered by the 6000 QA Chief, SNL Division 7152 or the WIPP QA Chief, or an examining agency (e.g. DOE, Sandia, Westinghouse, Marvin Johnson and Assoc., American Society of Quality Control). Objective evidence of completion of the exam will be maintained by the Sandia WIPP QA Office.
- 9.6 Certification of Qualification.** Each lead auditor will be certified as being qualified to lead audits via a memorandum from the individual's supervisor. This certification will, as a minimum, document the following:

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- employer's name;
- lead auditor's name;
- date of certification or recertification;
- basis of qualification (i.e., education, experience, communication skills, training, examination, etc.);
- signature of employee's supervisor.

9.7 Proficiency Maintenance. A lead auditor maintains proficiency by continued participation in audits, review and study of current QA program documents, and participation in additional training programs. An annual assessment of proficiency is made by the manager of the individual concurrent with merit review. If recertification is required, the manager will document the need and state what must be completed to meet recertification requirements.

9.8 Requalification. Lead auditors who fail to maintain their proficiency for a period of 2 years or more require requalification. Candidates for requalification are required to retrain in accordance with Section 9.3, under go reexamination in accordance with Section 9.5 and participate as an Auditor in at least one nuclear quality assurance audit.

10.0 QUALIFICATION OF AUDIT TEAM MEMBERS

10.1 Requirements. The lead auditor shall document the qualification of each audit team member as part of the audit plan. Selected team members shall have expertise or training commensurate with the scope, complexity or special nature of the area to be audited. Auditors must be independent of any direct responsibility for the performance of the activities to be audited. They shall have sufficient authority and organizational freedom to ensure an objective audit.

10.2 Methods. Competence may be developed by one or more of the following:

- orientation to provide a working knowledge and understanding of applicable portions of NQA-1, the Quality Assurance Program and this procedure;
- programs to provide general and specialized training in audit performance;
- on the job training under direct supervision of a lead auditor.