University of California
Lawrence Livermore National Laboratory

NUCLEAR WASTE MANAGEMENT PROGRAM

CONTROLLED COPY NO. 0089

No.: 033-YMP-R 18
Revision: 0
Date: December 15, 1988
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Subject: AUDITS

Approved: FEB 10 1989

Approved by: 12/19/88 Date
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Approved by: 12/15/88 Date
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1.0 GENERAL REQUIREMENTS

All LLNL-YMP activities are subject to planned and scheduled internal and external audits to assure that procedures and activities comply with the overall Quality Assurance (QA) program and to determine their effectiveness. A system of planned, periodic audits to provide an objective evaluation of the quality-related practices, procedures, instructions, activities, and items including the review of documents and records is established to assure that the QA program is effective and properly implemented. The audits are performed in accordance with written procedures using checklists by appropriately trained personnel who do not have direct responsibility for performing the activities being audited. Audit results are documented, reported to, and reviewed by responsible management. Tracking systems are instituted for audit findings to assure that all findings are appropriately addressed and to identify quality trends. All deficiencies, nonconformances, and potential quality problems identified during the audit are documented and monitored until verification of effective corrective action is made. The audited organization describes in a formal report the corrective action taken to address findings, and submits the report to the auditing organization and responsible management.

Follow-up action, including verification of corrective action or reaudit of specific areas, are performed.

1.1 PROJECT AUDITS

Internal audits of the LLNL-YMP are conducted by the LLNL-YMP QA Manager. External audits of LLNL-YMP subcontractors are conducted by the LLNL-YMP QA Manager. Audits of the LLNL-YMP may also by conducted by the DOE Project Office.

1.1.1 DOE PROJECT OFFICE AUDITS

The DOE Project Office QA Department develops a schedule defining the DOE Project Office audits planned for each fiscal year. This schedule is approved and issued by the DOE Project Office as an annual planning document. As a minimum the DOE Project Office audits the LLNL-YMP annually. The audits cover the entire scope of the LLNL-YMP QAPP. Additional audits are conducted when a unique need arises or when an audit is requested by the LLNL-YMP. The LLNL-YMP is audited to verify the effectiveness and adequacy of implementation of all elements of the LLNL-YMP QAPP and the DOE Project Office QA Plan.

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These audits eliminate the need for LLNL-YMP to conduct audits of other High-level Nuclear Waste Program participating organizations. Representatives of the LLNL-YMP may be invited to participate in a DOE Project Office audit when the audited activities are of mutual interest. Copies of audit documents for the DOE Project Office audits are sent to the audited organization.

1.1.2 LLNL-YMP AUDITS

The LLNL-YMP conducts internal audits (covering the entire LLNL-YMP QAPP) on an annual basis. Subcontractor **quality assurance programs are evaluated on an annual basis to determine if an audit is necessary (see 1.2.2 below).** Audits are scheduled, planned, conducted and reported as described in the LLNL-YMP QAPP. External and internal audit schedules, dates, and changes thereto, are sent to the DOE Project Office Quality Assurance Manager. Audit schedules identify the date of the audit, the activities to be audited, and the requirements to which the activities will be audited.

1.2 SCHEDULING

Internal and external QA audits, are scheduled in a manner that provides coverage and coordination with ongoing QA program activities. Audits are scheduled at a frequency commensurate with the status and importance of the activity and are initiated early enough to assure effective QA. The LLNL-YMP performs or arranges for annual evaluations of suppliers. This evaluation is documented and takes into account, where applicable, (1) review of supplier furnished documents and records such as certificates of conformance, nonconformance notices, and corrective actions; (2) results of previous source verifications, audits, and receiving inspections; (3) operating experience of identical or similar products furnished by the same supplier; and (4) results of audits from other sources, e.g., customer, ASME, or NRC audits.

1.2.1 INTERNAL AUDITS

Applicable elements of the LLNL-YMP QAPP are audited at least annually or at least once during the life of the activity, whichever is shorter. The scope of the audit is established by: considering the results of any previous audits, the nature and frequency of identified deficiencies, and any significant changes in personnel, organization, or in the QA program.

1.2.2 EXTERNAL AUDITS

Subcontractor audits are performed at least on a triennial basis and are supplemented by annual evaluations. Subcontractor quality assurance programs are evaluated on an annual basis to determine if an audit is necessary, and this evaluation is documented. If annual evaluations indicate the need for an audit, one will be performed prior to the triennial period. The need for audits of a supplier will also be evaluated when major changes to contract scope or work methodology occurs. Preaward surveys may serve as the first audit if the scope and conduct of the survey is similar to the scope of other supplier audits where the scope of work is comparable.

When audits are performed triennially, each affected organization shall perform or arrange for annual evaluations of the subcontractor. This evaluation shall be documented and shall take into account, where applicable, the following:

- **Review of supplier-furnished documents and records such as certificates of conformance, nonconformance notices, and corrective actions.**
- **Results of previous source verifications, surveillances, audits, management assessments, and receiving inspections.**
- **Operating experience of identical or similar products furnished by the same supplier.**
- **Results of audits from other sources.**

1.2.3 JOINT AUDITS

If more than one purchaser buys from a single supplier, a purchaser may either perform or arrange for an audit of the supplier on behalf of itself and other purchasers to reduce the number of external audits of the supplier. The scope of this audit satisfies the needs of all of the purchasers, and the audit

report is distributed to all the purchasers for whom the audit was conducted. Nevertheless, each of the purchasers relying on the results of an audit performed on behalf of several purchasers remains individually responsible for the adequacy of the audit.

1.3 PREPARATION

Preparation for an audit includes the items listed below.

1.3.1 AUDIT PLAN

The LLNL-YMP develops and documents an audit plan for each audit. This plan identifies the audit scope, requirements, audit personnel, activities to be audited, organizations to be notified, applicable documents, schedule, and written procedures or checklist.

1.3.2 PERSONNEL

The LLNL-YMP selects and assigns auditors who are independent of any direct responsibility for the performance of the activities that they are to audit. If the audit is to be an internal one, then the personnel who have direct responsibility for performing the activities to be audited are not involved in the selection of the audit team. Audit personnel have sufficient authority and organizational freedom to make the audit process meaningful and effective. Appendix F defines the requirements for the qualification of QA audit personnel.

1.3.3 SELECTION OF AUDIT TEAM

An audit team is identified before the beginning of each audit. This team contains one or more auditors and has an individual qualified as a lead auditor who organizes and directs the audit, coordinates the preparation and issuance of the audit report, and evaluates the responses. The audit team leader identifies the technical specialists, if any, to participate in the audit and includes this information in the audit plan. Audit team members selected to participate in audits for technical purposes have appropriate technical expertise or experience in the work being audited. Multidisciplinary audit teams are employed when activities to be audited involve more than a single technical area. The audit team leader assures that the audit team is prepared before the audit begins.

1.4 PERFORMANCE

Audits are performed in accordance with written procedures using checklists as early in the life of the activity as practical and are continued at intervals consistent with the schedule for accomplishing the activity. Elements selected for audit are evaluated against specified requirements including a review of corrective actions taken on deficiencies in the area being audited that were identified during previous audits. Objective evidence is examined to the depth necessary to determine if these elements are adequate for effective control and to determine whether or not they are being implemented effectively. The audit results are documented by audit personnel and are reviewed by management having responsibility for the area audited. Conditions that require prompt corrective action are reported immediately to the management of the audited organization. Audit findings are reviewed with the audited organizations at a closing meeting.

1.5 REPORTING

The audit report is signed by the audit team leader and issued within 30 calendar days. This report includes the following information, as appropriate:

- o Description of the audit scope.
- o Identification of the auditors.
- o Identification of persons contacted during audit activities.
- o Summary of audit results, including a statement of the effectiveness of the QA program elements that were audited.
- o Description of each reported adverse audit finding in sufficient detail to enable corrective action to be taken by the audited organization.

1.6 RESPONSE

Management of the audited organization or activity investigate adverse audit findings; determine root cause; schedule corrective action, including measures to prevent recurrence; and, within thirty calendar days of receipt of the audit report, notify the appropriate organizations in writing of action taken or planned. The adequacy of audit responses are evaluated by or for the auditing organization.

1.7 FOLLOW-UP ACTION

Follow-up action is taken to determine whether or not corrective action has been accomplished as scheduled and is verified by the auditing organization. An analysis of audit results is performed by the QA organization to identify quality trends. The results of the analysis are reported to responsible management for review, assessment, and appropriate action.

1.8 RECORDS

1.8.1 AUDITS

As a minimum, audit records include the following:

- o Identification of the organization(s), activities, or items audited and the individual(s) contacted during the audit(s).
- o Description of any deficiencies, nonconformances, and potential quality problems identified.
- o Audit plans, audit reports, written replies, and the record of completion of corrective action, and close-out of the audit.

1.8.2 PERSONNEL RECORDS

Records of personnel qualifications for Auditors and Lead Auditors performing audits are established and maintained by the LLNL-YMP. Records for each Lead Auditor are maintained and updated annually.

2.0 SURVEILLANCES

The LLNL-YMP audit program is supplemented by independent surveillance activities. The purpose of a surveillance is to monitor or observe items or activities to verify conformance to specified requirements. These surveillances are conducted by the LLNL-YMP and are scheduled or implemented on a random basis.

Measures for the surveillance of site investigation activities are established and executed in accordance with procedures prepared by the LLNL-YMP. Surveillances are scheduled and conducted based on the activity's relative impact or importance, or both, to the LLNL-YMP. All deficiencies, nonconformances, and potential quality problems identified during surveillances are documented and monitored until verification of effective corrective action is made. Specific requirements applicable to surveillance activities are as follows:

2.1 PLANNING

Surveillances are performed to written checklists or surveillance plans whenever practical. The documentation identifies characteristics, methods, and acceptance criteria, provides for recording objective evidence of results, and accuracy of the equipment necessary to perform surveillance. The specification of acceptance criteria related to surveillances may be as simple as "to verify proper implementation of procedures" or "to verify conformance to requirements."

2.2 REPORTING INDEPENDENCE

Surveillance personnel do not report directly to the immediate supervisors who are responsible for the work being surveilled.

2.3 RECORDS

As a minimum, surveillance records identify the following:

- Item or activity.
- Date of surveillance.
- Name of individual performing the surveillance.
- Identification of the organization(s), activities, or items surveilled, including the name or names of personnel contacted.
- Description of any deficiencies, nonconformances, and potential quality problems identified during the surveillance. Nonconformances are handled in accordance with the requirements of 033-YMP-R 15 or R 16, as applicable.
- Surveillance criteria.
- Equipment used during the surveillance.
- Results.
- Acceptance statement.