

CHANGE NOTICE

CN No.: 18.0-3-2

Effective Date: 1/10/92

Affected Document: 033-YMP-QP 18.0, "Audits"

R.E. Hamati/R.E. Monks
Prepared by:

N/A
Approved by: (Technical Area Leader) Date

Royce S Monks 12/13/91
Approved by: (YMP QA Manager) Date

W. L. Selame 12/15/91
Approved by: (YMP Leader) Date

Training Required: Yes No

Major Changes Minor Changes

Reason for Change:

- 1) Clarify that audits may be conducted of activities or organizations.
- 2) Clarify that CARs are to be considered when evaluating audit schedules.
- 3) Eliminate unnecessary requirements.
- 4) Add requirement that audit report must be signed by lead auditors.

THIS CHANGE NOTICE SUPERSEDES PREVIOUS CHANGE NOTICE 18.0-3-1 DATED 12/5/91. THE PREVIOUS REPLACEMENT PAGES STAND "AS IS"; THEREFORE, NO REPLACEMENT PAGES ARE BEING ISSUED.

Section 18.0.5.1.2, third line, added words.

Section 18.0.5.1.4, item (b), added words.

Section 18.0.5.4, second line, added words.

Section 18.0.5.4, second paragraph, delete second sentence.

Section 18.0.5.6, second paragraph, first sentence, added words.

NOTE: THIS CHANGE NOTICE IS TO BE FILED AT THE FRONT OF THE AFFECTED DOCUMENT



CHANGE NOTICE

CN No.: 18.0-3-1

Effective Date: 12/5/91

Affected Document: 033-YMP-QP 18.0, "Audits"

R.E. Hamati

Prepared by:

N/A

Approved by: (Technical Area Leader)

Date

Rogers Moulton 12/4/91
Approved by: (YMP QA Manager) Date

W. L. Blaine 12/4/91
Approved by: (YMP Leader) *gab* Date

Training Required: Yes No

Major Changes

Minor Changes

Reason for Change:

Clarify that audits may be conducted of activities or organizations. Clarify that CARs are to be considered when evaluating audit schedules.

1. Replace pages 2, 3, 4 and 5 (See attached)

Section 18.0.5.1.2, third line, added words.

Section 18.0.5.1.4, item (b), added words.

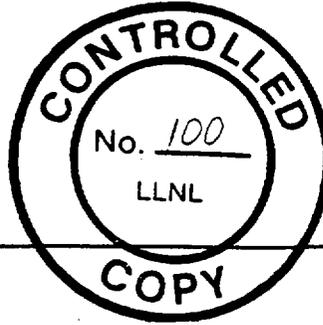
Section 18.0.5.4, second line, added words.

Section 18.0.5.4, second paragraph, delete second sentence.

Section 18.0.5.6, second paragraph, first sentence, added words.

NOTE: THIS CHANGE NOTICE IS TO BE FILED AT THE FRONT OF THE AFFECTED DOCUMENT

YUCCA MOUNTAIN PROJECT



No.: 033-YMP-QP 18.0
Revision: 3
Effective Date: 11/1/91
Page: 1 of 9

Subject:

AUDITS

Training Required: Yes No

Comment: QA Personnel Only

Approved by: [Signature] (for) 10/24/91 Yucca Mountain Project Leader Date
Approved by: [Signature] 10/24/91 YMP Quality Assurance Manager Date

18.0.1 PURPOSE

This procedure establishes the audit program for LLNL-YMP activities.

18.0.2 SCOPE

This procedure applies to LLNL-YMP activities at LLNL or field locations and to LLNL-YMP audit of subcontractors.

18.0.3 RESPONSIBILITIES

The LLNL-YMP Quality Assurance Manager (QAM) is responsible for assuring that this procedure is implemented and remains effective. Actions assigned to the QA Manager may be delegated to the QA Staff.

18.0.4 TERMS AND DEFINITIONS

See Tab C, "Terms and Definitions", for definitions that particularly apply to this procedure.

- Adverse Finding
- Audit
- Audit Finding
- Condition Adverse to Quality
- Observation
- Quality Elements
- Significant Condition Adverse to Quality

The relationship between Adverse Findings, Nonconformance Reports (NCRs) and Corrective Action Reports (CARs) is shown in Exhibit C of Procedure 033-YMP-QP 16.0.

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18.0.5 PROCEDURE

18.0.5.1 Audit Schedules

The frequency with which an activity is audited is a function of its importance to the overall success of the Yucca Mountain Project (YMP). Audits are performed as early in the life of an activity as practical and are continued at intervals consistent with the schedule for accomplishing the activity. The frequency may also depend on the specific quality elements that must be audited to provide continued assurance of compliance and effectiveness. All applicable program elements for project activities, however, are audited at least annually, or at least once during the life of the activity, whichever is shorter. **Subcontractor quality assurance programs must be audited in accordance with paragraph 18.0.5.1.3 below.** The scheduling process shall address all applicable elements of the QA program. Quality elements not applicable shall be documented.

18.0.5.1.1 Audit Numbering

Audits are numbered when the schedule is issued. The number begins with the two digit fiscal year designation, followed by a sequentially assigned number. If an audit is rescheduled, its number remains the same. If an audit is added to the schedule, it is given the next number in the sequence, regardless of when the audit is scheduled. If an audit is deleted, its number is not reassigned.

18.0.5.1.2 Internal Audit Schedule

At the beginning of each fiscal year, the QAM issues a 12-month internal audit schedule to the YMP Leader, Associate Project Leader, Assistant Project Leaders, Technical Area Leaders, Task Leaders, and the Director, QA Division-YMP. The schedule identifies those organizations and/or activities to be audited, the months in which the audits are scheduled to take place, and the quality elements against which the audits will be conducted. The QAM may schedule audits of an organization's subcontractors at the same time as an audit of the organization's internal activities to provide for a more complete and coherent review. If this is done, the scheduled audit of the subcontractor(s) appears on both the internal and external audit schedules.

18.0.5.1.3 External Audit Schedule

Subcontractor audits shall be performed on a triennial basis when supplemented by annual evaluations. Subcontractor quality assurance programs will be evaluated on at least an annual basis to determine if an audit is necessary, and this evaluation shall be documented. If an annual evaluation indicates the need for an audit, one shall be performed prior to the triennial period. The need for audits of a Subcontractor will also be evaluated when major changes to contract scope or work methodology occurs.

Subcontractors not performing quality affecting work may be audited at the discretion of the QAM.

At the beginning of each fiscal year, the QAM issues a 12-month external audit schedule to the YMP Leader, Associate Project Leader, Assistant Project Leaders, Technical Area Leaders, Task Leaders, and the Director, QA Division-YMP. This schedule shows which subcontractors are to be audited, the months in which the audits are scheduled to take place, and the quality elements against which the audits will be conducted.

When feasible, audits of subcontractors are coordinated with other organizations performing work for YMPO. In such cases, copies of audit reports are distributed to **affected Participant organizations**.

Audits of other DOE Integrated Contractors may be conducted with the approval of the cognizant DOE Field Office and are included on the external audit schedule.

18.0.5.1.4 Changes to Audit Schedules

The audit schedules are monitored, evaluated and revised, as necessary, to assure that audit coverage remains current. The evaluation includes an assessment of the effectiveness of the program based upon:

- a. Previous audit results and the effectiveness of corrective actions;
- b. Nonconformance Reports and Corrective Action Reports;
- c. Information from other sources such as: YMPO, the American Society of Mechanical Engineers (ASME), Nuclear Regulatory Commission, etc.

Changes to either the internal or external audit schedule during the year in which they are effective are approved by the QAM. Copies of the audit schedules, and any subsequent changes, are sent to the YMP Leader, Associate Project Leader, Assistant Project Leaders, Technical Area Leaders, Task Leaders, and the Director, QA Division-YMP.

18.0.5.1.5 Scheduling of Additional Audits

The QAM may schedule additional audits when:

- a. Significant changes are made in functional areas of the quality assurance or technical programs (such as significant reorganization or procedure revisions),
- b. It is suspected that the quality of an item or service is in jeopardy because of deficiencies in the quality assurance program,
- c. Assessment of the program effectiveness is considered desirable,
- d. An audit is requested by the YMP Leader or a Technical Area Leader, or
- e. In the opinion of the QAM, an additional audit is appropriate.

18.0.5.2 Audit Team Selection

Audits are performed by personnel qualified in accordance with procedure 033-YMP-QP 18.2, "Qualification of Quality Assurance Audit Personnel." The QAM designates the Lead Auditor. The Lead Auditor designates the other members of the audit team. The audit team may include one or more technical specialists. **These specialists are selected by the Lead Auditor from the list of individuals whose qualifications have been reviewed and accepted by the YMP Leader and QAM.**

Multidisciplinary audit teams are employed when activities to be audited involve more than a single Technical Area.

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Audit team members are independent of any direct technical responsibility for the organization to be audited, and they must not have personally performed any of the work being audited. Personnel who have direct responsibility for performing the activity to be audited are not involved with audit team selection. Audit personnel have sufficient authority and organizational freedom to make the audit process meaningful and effective.

Prior to commencing the audit, the Lead Auditor documents an assessment that assigned personnel have experience or training commensurate with the scope, complexity, or special nature of the activities to be audited. This assessment is documented on the Audit Planning Worksheet, Exhibit A.

18.0.5.3 Lead Auditor

The Lead Auditor is responsible for preparing the audit plan, conducting the opening and closing meetings, and managing the audit. The Lead Auditor ensures that the audit team is prepared before the audit begins. The Lead Auditor is also responsible for the preparation and approval of the audit report.

18.0.5.4 Audit Planning

An audit plan is prepared for each audit. The plan includes the scheduled date(s) of the audit; the audit scope; the organization and/or activity to be audited; the quality elements, QAPP requirements, TIPs, and Quality Procedures to which the organization or activity is to be audited; the organizations to be contacted (if external to LLNL-YMP); and the names of the auditors. The scope of the audit is established by considering the quality elements applicable to the organization or activity, the results of previous audits, the nature and frequency of identified deficiencies, and significant changes in personnel, organization, or in the QA Program. The audit plan is prepared in accordance with the format shown in Exhibit B, Audit Plan Format and is sent to the YMP Leader and the appropriate Technical Area Leader and Task Leaders prior to the audit.

A checklist based on quality assurance requirements pertaining to the organization's activities is prepared.

18.0.5.5 Performance of the Audit

18.0.5.5.1 Opening Meeting

Each audit begins with an opening meeting attended by the audit team members and members of the organization to be audited. The opening meeting is scheduled by the QAM. During this meeting, the audit objectives are reviewed and any questions regarding performance of the audit are answered. A schedule of events is established by mutual agreement.

18.0.5.5.2 Audit Performance

Objective evidence is examined and interviews are conducted, as necessary, to determine whether Quality Assurance requirements are being implemented effectively and are adequate for effective control for the particular activity. Conditions that require prompt corrective action are reported immediately to the appropriate Task Leader and Technical Area Leader. The audit team assures that all checklist questions are addressed and that this is documented on the checklists.

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In external audits, the audit results are documented by the audit personnel and discussed with management having responsibility for the area audited. Conditions that require prompt corrective action are reported immediately to the management of the audited organization and to the cognizant YMP Technical Area Leader.

Audits of Subcontractors are documented and take into account, where applicable:

- (1) review of subcontractor 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 subcontractor; and
- (4) results of audits from other sources, e.g., customer, ASME, or NRC audits.

18.0.5.5.3 Closing Meeting

Each audit ends with a closing meeting. All Adverse Findings are discussed to assure understanding of what was observed. Adverse Findings and observations include all deficiencies, nonconformances, and potential quality problems identified during the audit.

18.0.5.6 Audit Report

The results of audits are documented using an audit report (Exhibit C), which contains the following information: audit number, audit scope, identification of personnel contacted during the audit and members of the audit team, a statement concerning the effectiveness of the implementation of the quality elements that were audited, and a brief statement of each Adverse Finding accompanied by a discussion in sufficient detail to enable corrective action to be taken by the audited organization.

The audit report must be signed by the Lead Auditor and issued no later than 30 calendar days after the closing meeting. Copies are distributed to the appropriate Technical Area Leader(s) and Task Leader(s), the YMP Leader, Associate Project Leader, Assistant Project Leaders, and the LLNL Energy Program Leader.

Each Adverse Finding is further identified and processed using a Corrective Action Report (CAR) or a Nonconformance Report (NCR). Findings pertaining to items are processed as NCRs using 033-YMP-QP 15.0, "Nonconforming Items". Other findings are processed as CARs using 033-YMP-QP 16.0, "Corrective Action".

The audited organization must respond to adverse audit findings, using the NCR or CAR systems, within 30 calendar days of receipt of the audit report, NCR, or CAR, whichever comes first.

The audit report may also contain observations which may be in the form of comments or recommendations and are based on an auditor's experience. These do not require a response.

18.0.6 CLOSURE OF AUDITS

Audits are considered closed upon issuance of the audit report and any Corrective Action Reports or Nonconformance Reports that result from Adverse Findings. When the audit is closed, the QAM forwards a copy of the audit report to the Director, QA Division-YMP.

18.0.7 RETAINED DOCUMENTATION

Quality assurance records resulting from the implementation of this procedure are transmitted to the Local Records Center as QA Records in accordance with procedure 033-YMP-QP 17.0, "Quality Assurance Records".

Audit records include the following:

- **Audit Schedules,**
- **Audit Planning Worksheet,**
- **Audit Plan,**
- **Completed Audit Checklist,**
- **Audit Report.**

<p>UNIVERSITY OF CALIFORNIA Lawrence Livermore National Laboratory</p>	<p>YUCCA MOUNTAIN PROJECT</p> <p>Page ____ of ____</p>	
AUDIT PLANNING WORKSHEET		
AUDIT NO: _____		
SCHEDULED DATES: _____		
ORGANIZATION TO BE AUDITED: _____	WBS: L _____	
LEAD AUDITOR: _____		
AUDIT TEAM: _____		
P		
AUDIT NOTIFICATION AND PLAN ISSUED (Denoted By Date):		
PROJECT LEADER: _____	TASK LEADER: _____	
TECH. AREA LD: _____	AUDIT TEAM: _____	
PLANNING ITEMS		
<p>Team Qualifications Checked:</p> <p>____ Auditors</p> <p>____ Technical Specialists</p> <p>Indoctrination of Technical Specialists in the Audit Process</p> <p>Previous Audit Findings Rev'd: _____</p> <p>Previous Audit Report Rev'd: _____</p> <p>Team Members Briefed:</p> <p>____ Scope of Audit</p> <p>____ Team Assignments</p> <p>____ Checklist Comments</p> <p>____ Previous Findings</p> <p>____ Items of Interest</p>	<p>DATE</p> <p>M</p> <p>_____</p> <p>_____</p> <p>_____</p>	<p>SIGNATURE</p> <p>_____</p> <p>_____</p> <p>_____</p>
DATE(S) CONDUCTED: _____		
AUDIT REPORT DUE: _____		
AUDIT REPORT ISSUED (Denoted by Date):		
PROJECT LEADER: _____	TASK LEADER: _____	
TECH AREA LD: _____	AUDIT TEAM: _____	
DOE YMPQ (2cy): _____		
AUDIT FILE DISTRIBUTION: (Denoted By Date)		
ORIGINAL TO QA RECORDS: _____		
COPY TO SPONSOR (Ext ONLY): _____		

YMP 021 REV 1

EXHIBIT A
AUDIT PLANNING WORKSHEET

(Sections of the Plan should follow those outlined below.)

Audit No.

Dates of the Audit

Organization to be Audited (Title and WBS Number)

Scope and Basis of the Audit

Members of the Audit Team

External Organizations to be Contacted (if appropriate)

DOE Field Office to be contacted (if appropriate)

List of QA Requirements (Quality Elements, QAPP requirements, and implementing TIPS)

Previous audit findings and observations

Procedures or Checklist

Lead Auditor

Date

EXHIBIT B
AUDIT PLAN FORMAT

(Sections of the Report should follow those outlined below.)

Audit No: _____ Dates of the Audit _____

Scope and Basis of the Audit _____

Previous Audit Findings and Observations _____

List of Persons and Organizations Contacted During the Audit _____

List of the Audit Team Members _____

Statement Concerning the Effectiveness of the Implementation of QA _____

A Statement of Each Finding and Any Observations (if appropriate) _____

Reference to Nonconformance Reports and Corrective Action Reports Initiated (if appropriate) _____

Lead Auditor

Date

EXHIBIT C
AUDIT REPORT FORMAT