QAD: Quality System Audit

Audit scope
4.14.1

Audits are performed against the *Quality Manual*, assessing each of its documented components for compliance with Quality System requirements and its effectiveness as a quality tool.

Audit format

The program audit may be internal, external, or a combination of both.

This audit should be vertical in format, covering every program requirement.

The *Quality Manual* will be checked against the following:

- ISO/IEC 17025:2005
- 2011 ASCLD/LAB-*International* Supplemental Requirements
- ASCLD/LAB Policy on Measurement Traceability
- ASCLD/LAB Policy on Measurement Uncertainty

Note: Each auditor who performs an audit of the Quality Manual will fill out the *ASCLD/LAB-International Field Assessment Guide for Testing Laboratories* form to check that the Laboratory's Management System is in compliance with the ASCLD/LAB-International Program requirements.

Internal audit
4.14.1

The internal audit program shall address all elements of the management system, including testing and/or calibration activities.

Audit team

The Laboratory Director will select an auditor from laboratory management. The Quality Manager will notify the auditor that they were selected. The Quality Manager will function as the subject matter expert.

NOTE: Additional technical staff may be selected to assist in the audit.

Audit training

The auditor should receive training from the Quality Manager in the design and implementation of quality audits.

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QAD: Quality System Audit, Continued

Audit schedule and due date

The Quality System audit should begin by November 1st of each year. The draft report and post-audit meeting are due by the last working day of December.

Quality System audit process

The following table gives the general process for performing the Quality System audit.

Stage	Description
1	The Laboratory Director appoints the auditor and ensures he or she has the appropriate training.
2	The Quality Manager notifies the auditor of their assignment.
3	The Quality Manager/Laboratory Director provides a suggested Audit Plan. The Audit Plan includes the scope, audit criteria, time frame, and roles/responsibilities of the auditors. The auditor may change the plan as needed.
4	The auditor reviews the *Quality Manual* and ASCLD/LAB-*International* documents to develop a checklist of audit questions covering all program requirements. NOTE: Each auditor assigned to audit the Quality System will use an audit trail worksheet for at least one case file.
5	The auditor develops interview questions for the Quality Manager and other personnel who may have been involved in the administration of system components.
6	Appropriate quality records are requested and the audit is performed. A draft report is prepared by the auditor.
7	The auditor conducts a post-audit conference with the Laboratory Director and the Quality Manager. The draft report is presented and discussed. Corrective actions for findings are established. NOTE: Any observations or suggestions resulting from the audit will be included in the report along with the follow-up prior to the audit closure.
8	The auditor prepares and signs the final audit report.
9	The auditor initiates *Corrective Action Request* forms for each finding (see *DPC: Corrective Action*).
10	The auditor monitors the progress of the corrective actions and fills out the "Audit" section of each *Corrective Action Request* form.

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QAD: Quality System Audit, Continued

Quality System audit process (continued)

Stage	Description
11	When satisfied that a corrective action has been implemented and that the corrective action effectively corrects the finding, the auditor signs the "Corrective Action Completed and Accepted" section of the *Corrective Action Request* form.
12	The auditor submits the following to the Laboratory Director: • the final report • *Corrective Action Request* forms • the audit checklist • the audit trail worksheets • interview questions used during the audit along with the responses
13	The audit documents are reviewed by the Laboratory Director. If all is in order, the audit is closed. NOTE: All audit records are stored with the Quality Manager once the Laboratory Director had reviewed and retained copies.