

QAD: Quality Audits

Quality audits

4.14.1

The quality audit is a primary tool for evaluating the quality of the laboratory work product and quality functions of the laboratory. Its purpose is to assess compliance with the requirements of the Quality System of the laboratory, ISO/IEC 17025:2005, and policy requirements by ASCLD/LAB.

Audits will be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited.

Audit target

It must be stressed that the target of the quality audit is not the individual but the Quality System itself.

Gathering information

Assessment of compliance to quality standards is accomplished first through the gathering of information. Basic techniques for information gathering include:

- *reviewing* of procedures and program requirements
 - *examination* of reports, records, and facilities
 - *observation* of laboratory activities
 - *questioning* of staff
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Addressing deficiencies

The information gathered in the audit is used to determine if quality deficiencies exist. Deficiencies can be addressed through:

- *findings* of non-conformance with mandatory standards or procedures
 - *suggestions* for improvement
 - *observations* of opportunities for improvement (changes that should be initiated)
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Audit frequency

4.14.1.1

Quality audits are performed annually for the technical and quality operations of the laboratory.

Continued on next page

QAD: Quality Audits, Continued

Audit completion

All audit inspections must be completed and draft reports provided by the end of the calendar year (see *QAD: Technical Audits, Technical audit schedule and due dates* in the *Quality Manual*). The production of the report fulfills the ASCLD/LAB annual audit requirement.

4.14.1.2

Internal audit final reports and audit records will be retained for at least one accreditation cycle or five years (whichever is greater).

Audits are closed when all corrective actions are completed (see *QAD: Quality System Audit, Quality system audit process* or *QAD: Technical Audits, Audit process* for additional information).

Reviewing other aspects of laboratory management and operation

The laboratory will conduct an annual review of the *Administrative, Evidence, and Safety Manuals*.

Annual report to ASCLD/LAB 4.14.5

An ASCLD/LAB-International Annual Audit Report will be sent to ASCLD/LAB within thirty (30) calendar days following the laboratory's accreditation anniversary date.
