

## QAD: Quality Audits

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**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.

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**Audit target**

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

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**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.

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## QAD: Quality Audits, Continued

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**Audit completion**

The audit inspections must be completed and a draft report provided by the end of the calendar year. The production of the report fulfills the ASCLD/LAB annual audit requirement.

**4.14.1.2**

The internal audit final report and audit records will be retained for at least one accreditation cycle or four years (whichever is greater).

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

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**Reviewing other aspects of laboratory management and operation**

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

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**Annual report to ASCLD/LAB 4.14.5**

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

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