QAD: Technical Audits

Audit scope

Technical audits are performed against the laboratory's technical manuals.

4.14.1

Technical audits of disciplines should include, where appropriate, an assessment of each of the following quality issues:

- staff's awareness of quality, administrative, and safety requirements
- document control
- analytical procedure selection and validation
- control of reagents and standards
- equipment calibration and maintenance records
- adequacy of case reports and notes
- evidence handling procedures
- proficiency testing records
- training records
- handling of deficiencies and remedial corrective actions taken
- laboratory orderliness and health and safety measures
- quality components specific to the laboratory discipline or function under audit
- measurement traceability (if applicable)
- measurement uncertainty (if applicable)

Audit format

Audits may be internal, external, or a combination of both.

Audits may be vertical or horizontal.

- *Vertical audits* cover all quality issues within one laboratory discipline or function.
- *Horizontal audits* cover one quality issue at a time in all affected disciplines.

The audit of the DNA program should be a vertical audit and must be external every other year.

In all other cases, the choice of audit format is at the discretion of the Quality Manager.

Continued on next page

QAD: Technical Audits, Continued

Audit teams

Audits will be performed by an audit team assigned by the Quality Manager. The Quality Manager should make every effort to choose individuals for auditors who are tactful, thorough, objective, self-confident, and technically competent as required.

Audit teams will consist of

4.14.1

- a team leader whose expertise is generally outside of the discipline or function being audited and
- a subject matter expert whose expertise is within that discipline or function

An additional member, generally from outside of the discipline or function, may be assigned to an audit team in order to facilitate the audit process.

Exceptions for DNA audits:

- The internal audit of the DNA section will be conducted by a qualified auditor designated as 'team leader' and assisted by a team member designated a 'subject matter expert' from the DNA section.
  – FBI defines "qualified auditor" as someone who is a current or previously qualified DNA analyst who has successfully completed the *FBI DNA Auditor's* training course.
- The external audit will be performed by a team from outside of the laboratory.
- Audits will be conducted using the *FBI Quality Assurance Standards for Forensic DNA Testing Laboratories* document.

Audit training

4.14.1

The Quality Manager is responsible for instructing audit team members in the components and methods of quality auditing prior to their first audit experience. A *Quality Audit Training Manual* is available for this purpose.

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QAD: Technical Audits, Continued

Technical audit schedule and due dates

4.14.1

The following is the general annual audit schedule. This schedule is subject to change according to laboratory needs.

Discipline	Start date, first working day of…	Due date, last working day of…
Comparative Evidence	January	February
Trace Evidence	February	March
Toxicology	April	May
Biology	June	July
Chemistry	July	August
Crime Scene	September	October
Quality System	October	November

The draft audit report and the post-audit meeting should be completed on or before the audit due date.

Corrective actions resulting from audits have a maximum 90-day due date from their initiation after the post-audit meeting (see *Audit process*).

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QAD: Technical Audits, Continued

Audit process

The following table gives the general process for performing an internal quality audit.

Stage	Description
1	The Quality Manager appoints the auditing team and provides the appropriate training or training materials.
2	The Quality Manager provides a suggested Audit Plan. The Audit Plan includes the scope, audit criteria, time frame, and roles/responsibilities of the auditors.
3	The audit team reviews the manual under audit and develops a checklist of audit questions based upon the general requirements of the laboratory's Quality System and those specific to the discipline or function being audited (see *Audit scope* and the *Quality Audit Training Manual*).
4	The audit team develops a list of interview questions for soliciting the information necessary for completing the audit checklist.
5	The audit is performed, all information is gathered, and a draft report containing a summary of the audit results and all findings is prepared by the team leader (see *Quality Audit Training Manual, QAT: The Audit Process, Reporting*).
6	The audit team conducts a post-audit conference with the Laboratory Director, the Quality Manager, and the section or function supervisor and staff. The draft report is presented and discussed. Corrective actions for all 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.
7	The audit team leader prepares the final audit report that is then signed by all team members.
8	The audit team leader initiates *Corrective Action Request* (CAR) forms for each finding (see *DPC: Corrective Action*). The implementation of the correction is assigned to the peer group, appropriate analyst, DNA Technical Lead, or unit supervisor and given a maximum 90-day due date. Extensions must be approved by the Laboratory Director.

4.14.3

4.14.4

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QAD: Technical Audits, Continued

Audit process (continued)

Stage	Description
9	The audit team leader monitors the progress of the corrective actions and fills out the "Audit" section of each *Corrective Action Request* form.
10	When satisfied that a corrective action has been implemented and that the corrective action effectively corrects the finding, the audit team leader signs the "Corrective Action Completed and Accepted" section of the *Corrective Action Request* form.
11	The audit team submits the following to the Quality Manager: • the final report • *Corrective Action Request* forms • a list of the cases reviewed for the audit • the audit checklist • interview questions used during the audit along with the responses
12	The audit documents are reviewed by the Quality Manager. If all is in order, the audit is closed.

If a serious problem is found

4.14.2

If an auditor uncovers a potential problem during the audit process that may affect the quality of the discipline's analytical work or general laboratory operations, the auditor must immediately inform the audit team leader and/or the Quality Manager of the potential problem.

The Quality Manager must begin a problem investigation, meeting with the appropriate unit supervisor, analyst, or peer group, to determine if the problem casts doubt on the effectiveness of laboratory operations or on the correctness or validity of the laboratory's analytical result. If the Quality Manager determines that the problem casts doubt, the Quality Manager must inform the Laboratory Director and begin the corrective action process (see *DPC: Corrective Action* in the *Quality Manual*).

If the problem investigation shows that laboratory results have been affected, the laboratory must inform the submitting agency in writing.