QAD: Technical Audits

Audit scope

4.14.1

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

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

Technical audits will be performed by a technical audit team assigned by the Quality Manager, Laboratory Director, Lead Auditor, and Assistant Lead Auditor. They should make every effort to choose individuals as technical auditors who are tactful, thorough, objective, self-confident, and technically competent as required.

Technical audit teams will consist of

4.14.1

- two auditors for Biology and one for all other technical disciplines
- 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 section 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.

Continued on next page

QAD: Technical Audits, Continued

Technical audit schedule and due dates

4.14.1

Technical audits will occur as part of the laboratory-wide internal audit which will occur in October of each year. This schedule is subject to change according to laboratory needs.

The draft audit report and the post-audit meeting should be completed on or before the end of the last business day during the audit week.

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

Continued on next page

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 notifies the technical auditing team and provides the appropriate training or training materials. NOTE: Refer to *QAD: Laboratory System Audit* for more information on the audit process.
2	The Lead/Assistant Lead Auditors provide 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 and all information is gathered. See Step 7 of *Quality System audit process* in *QAD: Laboratory System Audit* for the records that are turned in to the Lead Auditor. See Steps 8-14 of *Quality System audit process* in *QAD: Laboratory System Audit* for further information on the audit process.
6	By early afternoon on the last day of the audit, the Lead and Assistant Lead Auditors present a draft report to the audit team to review. By close of business, the final draft of the report will be presented and discussed with the Laboratory Director, Quality Manager, unit supervisors, and technical leads during the post-audit conference. Corrective actions for non-conformances 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 Lead Auditor prepares the final audit report that is reviewed by all team members.

4.14.3

Continued on next page

QAD: Technical Audits, Continued

Audit process (continued)

4.14.4

Stage	Description
8	The Lead Auditor 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.
9	The Lead Auditor 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 Lead Auditor signs the "Corrective Action Completed and Accepted" section of the *Corrective Action Request* form.
11	The Lead Auditor submits the following to the Quality Manager and Laboratory Director: • 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 records are reviewed by the Quality Manager and 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 has reviewed and retained copies.

Continued on next page

QAD: Technical Audits, Continued

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.