QAD: Laboratory System Audit

Audit scope
8.8.1
8.8.2

Audits are performed against all laboratory manuals (technical and non-technical), 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 17025:2017
- ANAB ISO/IEC 17025:2017 Accreditation Requirements (AR 3125)
- ASCLD/LAB Policy on Measurement Traceability
- ASCLD/LAB Policy on Measurement Uncertainty

Note: See ISO 19011 for guidance.

Internal audit

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

Audit team

The Laboratory Director and Quality Manager will select a Lead Auditor and an Assistant Lead Auditor (at least one auditor should be from laboratory management). The Quality Manager will notify the auditors that they were selected. The Quality Manager will function as the subject matter expert for the Quality Assurance Section.

The Laboratory Director and Quality Manager will assist the Lead and Assistant Lead Auditors in picking their audit team.

Audit training

All auditors will receive training from the Quality Manager in the design and implementation of quality audits.

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QAD: Laboratory System Audit, Continued

Audit schedule and due date

8.8.1.1 AR

The laboratory-wide internal audit will occur in April of each year. The final draft report and post-audit meeting are due 60 days after the closing meeting.

Quality System audit process

8.8.1.a.1 AR
8.8.1.b.1 AR

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

Stage	Description
1	The Quality Manager and Laboratory Director appoint the Lead and Assistant Lead auditors and ensures they have the appropriate training.
2	The Lead/Assistant Lead Auditor, Laboratory Director, and Quality Manager select the technical audit team.
3	The Quality Manager notifies the technical auditors of their assignments and the scheduled week for the audit. The laboratory staff will be notified of the scheduled audit week and who the auditors will be for their units.
4	The Quality Manager/Laboratory Director provide 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.

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QAD: Laboratory System Audit, Continued

Quality System audit process (continued)

8.8.1.a.1 AR

Stage	Description
5	The Lead/Assistant Lead Auditors review the *Quality Manual* and ANAB documents to develop a checklist of audit questions covering all program requirements. The two lead auditors are responsible for reviewing the non-technical manuals and identifying any gaps between the laboratory procedures and the accreditation requirements. ISO 19011:2018 may be helpful with this process. These forms can be accessed from the External Documents folder in Qualtrax. The two Lead Auditors will split up responsibilities with auditing the four non-technical manuals: • Quality Manual (QM) • Administrative Manual • Evidence Manual • Safety Manual
6	At least one technical auditor from each technical discipline will be responsible for completing one full audit trail worksheet on a case. This process ensures that each technical area is in compliance to the accreditation requirements. See *QAD: Technical Audits* for more information.
7	The following forms will be completed and turned in: • Checklist – one from every auditor • Questions/Answers (see suggested interview questions) – one from every auditor • List of records checked – one from every auditor • Full Audit Trail Form – one per technical discipline • Modified Audit Trail Worksheet – one from the Lead or Assistant Lead Auditor

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QAD: Laboratory System Audit, Continued

Quality System audit process (continued)

Stage	Description
8	One week prior to the audit, the audit leaders will email the audit team the audit plan, potential gaps, and items they would like the technical auditors to focus on for each discipline.
9	The technical auditors will begin review of technical procedures at least one business day before the audit.
10	On the first day of the audit week, the team will have a meeting where the lead auditor will go over the guidelines and structure of the audit.
11	On the first day of the audit week, the auditors will complete review of the technical procedures and begin to pull case files, technical records, quality records, and administrative records.
12	Throughout the audit week, the auditors will find conformance by comparing records, observations, interview answers, and procedures to the ANAB Accreditation requirements. The Lead/Assistant Lead Auditors are responsible for addressing questions regarding non-conformances and drafting a final report for the laboratory audit.
13	At the end of each day, the audit team has meetings to discuss concerns or non-conformances.
14	By Thursday afternoon, all auditor notes are turned into the Lead /Assistant Lead Auditors. A final discussion on non-conformance will occur before end of business day on Thursday. The Lead/Assistant Lead Auditors continue to work on a draft report.
15	By early afternoon (last day of audit), the Lead and Assistant Lead Auditor 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 and Quality Manager 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.
16	The Lead Auditor prepares and signs the final audit report.
17	The Lead Auditor initiates *Corrective Action Request* forms for each finding (see *DPC: Corrective Action*).

8.8.2.b.1 AR

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QAD: Laboratory System Audit, Continued

Quality System audit process (continued)

Stage	Description
18	The Lead Auditor monitors the progress of the corrective actions and fills out the "Audit" section of each *Corrective Action Request* form.
19	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.
20	The Lead Auditor submits the following to the Quality Manager and 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 • list of cases reviewed for each discipline
21	The audit documents 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 had reviewed and retained copies.