STANDARD OPERATING PROCEDURE TEMPLATE · ADMINISTRATION AND QUALITY MANAGEMENT

# Internal Audit

Governing requirement: 42 CFR 493.1239, 493.1249, 493.1289, 493.1299

**Applies to:** ☑ Waived ☑ Moderate complexity ☑ High complexity

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|---|---|---|---|
| **Laboratory name** | | **CLIA number** | |
| **Document number** | | **Version** | |
| **Effective date** | | **Next review due** | |
| **Author** | | **Department / section** | |
| **Approved by (laboratory director)** | | **Director signature** | |
| **Approval date** | | **Supersedes document** | |

**Important:** Template only. Before use, this document must be reviewed, adapted to your laboratory's instruments, test systems and the manufacturer's instructions, and approved, signed and dated by the laboratory director. Check current federal, state and accreditation requirements. Not legal advice. Sound Lab Consultants is not affiliated with or endorsed by CMS, CDC, FDA, OSHA, CAP, COLA, The Joint Commission, CLSI or any manufacturer.

## 1. Purpose

To plan and perform periodic internal audits of laboratory processes and records and track findings to closure.

## 2. Scope

All laboratory sections and quality system essentials.

## 3. Responsibility

- Laboratory director: approves this policy, assigns responsibility for quality activities and reviews results.
- Technical consultant / technical supervisor: reviews technical aspects, investigates issues and signs off corrective actions.
- Quality lead (if assigned): coordinates records, tracking and reporting.
- All laboratory staff: follow this procedure and report problems promptly.

## 4. Definitions

**Tracer:** An audit that follows one specimen from order to report through all records.

## 5. Materials, equipment and records

- Audit schedule
- Audit checklist
- Findings log

## 6. Procedure

**1.** Prepare an annual audit schedule covering every section **[Audit schedule]**.

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| **Audit schedule** | |

**2.** Use a checklist built from CLIA, state and accreditor requirements.

**3.** Perform at least one specimen tracer per section per audit.

**4.** Interview staff, review records and observe testing.

**5.** Record findings with objective evidence.

**6.** Open CAPAs for findings and assign due dates.

**7.** Report results to the laboratory director and staff.

**8.** Verify closure of prior findings at the next audit.

## 7. Quality control

• Auditors should not audit their own work where practical.

## 8. Interpretation, reporting and documentation

• Keep audit reports at least 2 years.

## 9. Limitations and cautions

• An internal audit does not replace required surveys or inspections.

• This is a generic template. Adapt it to your instruments, test systems, manufacturer instructions, state law and accreditation standards before use.

## 10. References


• CMS, State Operations Manual Appendix C: Survey procedures and interpretive guidelines for laboratories https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/som107ap_c_lab.pdf

• eCFR, 42 CFR Part 493 Subpart K: Quality system for nonwaived testing https://www.ecfr.gov/current/title-42/part-493/subpart-K

• eCFR, 42 CFR 493.1239 https://www.ecfr.gov/current/title-42/section-493.1239


## 11. Audit findings log

Fill in electronically or print. Keep completed forms per the record retention policy.

| Date | Area | Finding | Requirement | CAPA # | Due | Closed |
|---|---|---|---|---|---|---|
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## 12. Lab-specific notes

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| **Notes and local requirements** | |

## 13. Revision history

| Version | Date | Description of change | Author | Approved by |
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## 14. Annual review log

Procedures and changes must be approved, signed and dated by the current laboratory director before use (42 CFR 493.1251(d)).

| Review date | Reviewed by | Signature | Changes needed (Y/N) | Comments |
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