STANDARD OPERATING PROCEDURE TEMPLATE · ADMINISTRATION AND QUALITY MANAGEMENT

# Document Control

Governing requirement: 42 CFR 493.1251(d)-(e) and 493.1105(a)(2)

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

| | | | |
|---|---|---|---|
| **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 make sure every procedure, policy, form and job aid used in the laboratory is current, approved by the laboratory director before use, available at the point of use, and retained after it is retired.

## 2. Scope

All controlled documents in the laboratory: procedures, policies, forms, logs, job aids, package inserts used as procedures, and electronic documents in the document management system **[Document management system name or 'paper binder']**.

| | |
|---|---|
| **Document management system name or 'paper binder'** | |

## 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

**Controlled document:** A document whose content, version and distribution are managed under this SOP.

**Master copy:** The single approved original kept by the document control owner **[Document control owner]**.

**Retired (discontinued) document:** A document no longer in use, retained with its dates of initial use and discontinuance.

## 5. Materials, equipment and records

- Document master list / index **[Location of master list]**

| Location of master list | |
|---|---|

- Document numbering scheme **[Numbering format, e.g. DEPT-TYPE-###]**

| Numbering format, e.g. DEPT-TYPE-### | |
|---|---|

- Approval signature page or electronic signature workflow
- Archive for retired documents **[Archive location]**

| Archive location | |
|---|---|

## 6. Procedure

**1.** Draft new or revised documents using the laboratory SOP format (see the Writing and Formatting SOPs template). Assign the next number from the master list.

**2.** Route the draft for technical review by the technical consultant or technical supervisor and record reviewer comments.

**3.** Obtain laboratory director approval: signature and date before the document is used. Changes to a procedure also require director signature and date before use (42 CFR 493.1251(d)).

**4.** Record the effective date and version on the document and update the master list the same day.

**5.** Train affected staff and document that they read the new or revised document before they use it **[Read-and-sign method]**.

| Read-and-sign method | |
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**6.** Distribute controlled copies to **[Point-of-use locations]** and remove all superseded copies from work areas at the same time.

| Point-of-use locations | |
|---|---|

**7.** Mark retired documents with the discontinuance date, move them to the archive and keep them at least 2 years after discontinuance (42 CFR 493.1105(a)(2)).

**8.** Review every controlled document at least every **[Review frequency, e.g. annually]** and whenever the test system, manufacturer instructions, regulation or laboratory director changes.

| Review frequency, e.g. annually | |
|---|---|

**9.** When a new laboratory director is appointed, have the new director review and sign all procedures before or upon assuming responsibility **[Days allowed]**.

| Days allowed | |
|---|---|

**10.** Control external documents (package inserts, operator manuals, regulations) by recording the version or date in use and checking for updates at each review.

**11.** Do not allow handwritten changes on controlled copies unless initialed, dated and approved by **[Who may approve interim changes]**.

| Who may approve interim changes | |
|---|---|

## 7. Quality control

- Audit the master list against point-of-use copies **[Audit frequency]** and record discrepancies.

| Audit frequency | |
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- Any use of an unapproved or outdated document is handled as an occurrence (nonconforming event).

## 8. Interpretation, reporting and documentation

- The master list must show document number, title, version, effective date, last review date and status.

• Keep approval records and read-and-sign records with the document history.

## 9. Limitations and cautions

• Electronic systems must prevent edits to approved versions without a new approval cycle.

• Printed copies are uncontrolled unless stamped or signed as controlled copies.

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

## 10. References


• eCFR, 42 CFR Part 493 Laboratory Requirements (CLIA)
https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493

• 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 493.1251 https://www.ecfr.gov/current/title-42/section-493.1251

• eCFR, 42 CFR 493.1105 https://www.ecfr.gov/current/title-42/section-493.1105


## 11. Document master list

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

| Doc # | Title | Version | Effective date | Last review | Status | Location |
|---|---|---|---|---|---|---|
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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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