STANDARD OPERATING PROCEDURE TEMPLATE · REGULATORY, CERTIFICATES AND SURVEYS

Survey and Inspection Preparation

Governing requirement: 42 CFR 493.1777 and SOM Appendix C

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 be prepared for surveys at any time.

2. Scope

CMS, state and accreditation surveys.

3. Responsibility

- Laboratory director: signs regulatory submissions and plans of correction and is accountable for compliance.
- Laboratory manager / compliance lead: tracks certificates, deadlines and notifications.
- Technical consultant / technical supervisor: provides technical evidence for submissions.

4. Definitions

Survey: Onsite inspection of compliance.

5. Materials, equipment and records

- Self-audit checklist
- Document index

6. Procedure

1. Keep records organized by requirement.

2. Perform self-audits **[Frequency]**.

Frequency	

3. On survey day, greet surveyors and assign escorts.

4. Provide requested records promptly.

5. Take notes of findings.

6. Plan corrections.

7. Quality control

• Review this process at least annually and after any survey or regulatory change.

8. Interpretation, reporting and documentation

• Record the activity, date, result and initials on the form or log, and have the supervisor review records **[Review frequency]**.

Review frequency	

• Keep records per the record retention SOP (at least 2 years under 42 CFR 493.1105 unless a longer period applies).

9. Limitations and cautions

• 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

• CMS, CLIA-approved accreditation organizations and exempt states (PDF) https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/AOList.pdf

• eCFR, 42 CFR 493.1777 https://www.ecfr.gov/current/title-42/section-493.1777

11. Lab-specific notes

Notes and local requirements	

12. Revision history

Version	Date	Description of change	Author	Approved by

13. 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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