STANDARD OPERATING PROCEDURE TEMPLATE · REGULATORY, CERTIFICATES AND SURVEYS

CLIA Certificate and CMS-116 Management

Governing requirement: 42 CFR 493.51 and 493.39

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 keep the CLIA certificate current and report required changes.

2. Scope

The laboratory's CLIA certificate(s).

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

CMS-116: CLIA application and change form.

5. Materials, equipment and records

- Certificate copy
- Change log

6. Procedure

1. Post or keep the certificate available.

2. Track expiration and fees **[Expiration date]**.

Expiration date	

3. Report changes in ownership, name, location or director (and technical supervisor for high complexity labs) within 30 days (493.51(a); 493.39 for waiver labs).

4. Certificate of Waiver labs notify before performing any nonwaived test (493.39(a)); Certificate of Compliance labs notify within 6 months of adding a specialty or subspecialty or changing methodology (493.51(b)-(c)) **[Notification log location]**.

Notification log location	

5. Keep copies of all filings.

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, Form CMS-116 CLIA application
https://www.cms.gov/medicare/cms-forms/cms-forms/downloads/cms116.pdf

• CMS, Clinical Laboratory Improvement Amendments (CLIA)
https://www.cms.gov/medicare/quality/clinical-laboratory-improvement-amendments

• eCFR, 42 CFR 493.51 https://www.ecfr.gov/current/title-42/section-493.51

• eCFR, 42 CFR 493.39 https://www.ecfr.gov/current/title-42/section-493.39

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

Free template from Sound Lab Consultants, soundlabconsult.com. Download more free templates at soundlabconsult.com/laboratory-sop-library.