STANDARD OPERATING PROCEDURE TEMPLATE · ADMINISTRATION AND QUALITY MANAGEMENT

Laboratory Director Responsibilities Policy

Governing requirement: 42 CFR 493.1407 and 493.1445

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**	

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1. Purpose

To document how the laboratory director carries out responsibilities required under 42 CFR 493.1407 (moderate complexity) and 493.1445 (high complexity).

2. Scope

The laboratory director of record on the CLIA certificate.

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

Laboratory director: The individual responsible for the overall operation and administration of the laboratory, named on the CLIA certificate.

5. Materials, equipment and records

- Delegation of duties record
- Onsite visit log

6. Procedure

1. The director ensures testing systems provide quality results in all phases of testing.

2. The director ensures the physical plant and environment are appropriate and safe.

3. The director ensures verification of performance specifications before patient testing and enrollment in approved PT.

4. The director ensures QC and quality assessment programs are established and maintained.

5. The director ensures employees are qualified, trained and competent and that responsibilities are specified in writing.

6. The director approves and signs all procedures and is accessible to provide consultation **[How the director can be reached]**.

How the director can be reached	

7. The director is onsite at least once every 6 months, with at least 4 months between the two minimum visits, and documents each visit with evidence of director activities (42 CFR 493.1407(c), 493.1445(c)). Planned visit months: **[Planned onsite visit months]**.

Planned onsite visit months	

8. Delegated duties are documented in writing; the director remains responsible for them (493.1407(b), 493.1445(b)).

9. The director directs no more than five laboratories (493.1407(d), 493.1445(d)). Laboratories currently directed: **[Number of labs directed]**.

Number of labs directed	

7. Quality control

• Review director activity records at management review.

8. Interpretation, reporting and documentation

• Keep onsite visit and delegation records.

9. Limitations and cautions

• State law may add director requirements; check your state licensure rules.

• 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 Subpart M: Personnel for nonwaived testing
https://www.ecfr.gov/current/title-42/part-493/subpart-M

• 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 493.1407 https://www.ecfr.gov/current/title-42/section-493.1407

• eCFR, 42 CFR 493.1445 https://www.ecfr.gov/current/title-42/section-493.1445

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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