STANDARD OPERATING PROCEDURE TEMPLATE · PERSONNEL, TRAINING AND COMPETENCY

Job Description: Laboratory Director

Governing requirement: 42 CFR 493.1443 (qualifications) and 493.1445 (responsibilities)

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 define the duties, qualifications and reporting lines of the Laboratory Director position as required by CLIA Subpart M.

2. Scope

The Laboratory Director position at **[Laboratory name]** for **[Complexity of testing covered]** testing.

Laboratory name	
Complexity of testing covered	

3. Responsibility

- Laboratory director: ensures staff are qualified, trained and competent before testing and signs delegations.
- Technical consultant / technical supervisor: performs or delegates training and competency assessment.
- Supervisor / manager: maintains personnel records and schedules training and assessments.
- Employee: completes training, keeps credentials current and reports changes.

4. Definitions

Laboratory Director: Must meet 42 CFR 493.1405 (moderate) or 493.1443 (high complexity) and state requirements.

5. Materials, equipment and records

- Copies of diploma, transcript or primary source verification
- State license, if required **[State license type]**

State license type	

- Signed job description

6. Procedure

1. Position title: Laboratory Director. Reports to: **[Reports to]**. Hours / schedule: **[Schedule]**.

Reports to	
Schedule	

2. Ensures quality testing in all phases and an appropriate, safe environment.

3. Ensures performance specifications are verified or established before patient testing.

4. Ensures PT enrollment, QC, quality assessment and corrective action programs.

5. Ensures personnel are qualified, trained and competent and that duties are delegated in writing.

6. Is onsite at least once every 6 months with at least 4 months between visits, documents visits, and is accessible for consultation.

7. Approves, signs and dates all procedures.

8. Qualifications: meets 42 CFR 493.1443 and any state requirement. Documentation on file: **[Qualification documents on file]**.

Qualification documents on file	

9. Required training before independent work: **[Required training]**.

Required training	

10. Competency is assessed per the competency assessment SOP.

11. Employee and laboratory director sign and date this job description; update it when duties change.

7. Quality control

• Verify qualifications before the employee starts work; keep evidence in the personnel file.

8. Interpretation, reporting and documentation

• Keep the signed job description in the personnel file.

9. Limitations and cautions

• Qualification requirements were revised by CMS effective December 28, 2024; confirm the current eCFR text and state rules before hiring.

• 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 493.1443 https://www.ecfr.gov/current/title-42/section-493.1443

• 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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