STANDARD OPERATING PROCEDURE TEMPLATE · PERSONNEL, TRAINING AND COMPETENCY

Job Description: General Supervisor

Governing requirement: 42 CFR 493.1461 (qualifications) and 493.1463 (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 General Supervisor position as required by CLIA Subpart M.

2. Scope

The General Supervisor 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

General Supervisor: Must meet 42 CFR 493.1461.

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: General Supervisor. Reports to: **[Reports to]**. Hours / schedule: **[Schedule]**.

Reports to	
Schedule	

2. Is accessible to testing personnel at all times testing is performed.

3. Provides day-to-day supervision and monitors test analyses and specimen examinations.

4. Ensures remedial actions are taken when test systems deviate.

5. Provides orientation to testing personnel.

6. May perform annual competency assessment when delegated.

7. Qualifications: meets 42 CFR 493.1461 and any state requirement. Documentation on file: **[Qualification documents on file]**.

Qualification documents on file	

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

Required training	

9. Competency is assessed per the competency assessment SOP.

10. 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 493.1461 https://www.ecfr.gov/current/title-42/section-493.1461

• eCFR, 42 CFR 493.1463 https://www.ecfr.gov/current/title-42/section-493.1463

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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