STANDARD OPERATING PROCEDURE TEMPLATE · PERSONNEL, TRAINING AND COMPETENCY

Personnel Qualifications and Records Policy

Governing requirement: 42 CFR 493 Subpart M (493.1403-493.1495)

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 ensure every person performing or supervising nonwaived testing meets CLIA Subpart M and state qualification requirements before starting work, and that evidence is on file.

2. Scope

All laboratory personnel: laboratory director, technical consultant, technical supervisor, clinical consultant, general supervisor, cytotechnologists and testing personnel.

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

Primary source verification: Confirming a credential directly with the issuing school, board or agency.

Personnel file: The record of qualifications, training, competency and job description for one employee.

5. Materials, equipment and records

- Personnel file checklist
- Foreign education evaluation, if applicable
- State license verification

6. Procedure

1. Identify the CLIA role(s) the employee will hold and the complexity of testing.

2. Collect evidence of education (diploma, transcript or primary source verification), certification and state license as applicable **[State license requirements]**.

State license requirements	

3. For foreign education, obtain an equivalency evaluation from an acceptable credential evaluation service.
4. Confirm the qualification pathway in the applicable section: moderate complexity (493.1405, 1411, 1417, 1423); high complexity (493.1443, 1449, 1455, 1461, 1483, 1489).
5. Document required experience and training for the pathway used.
6. Have the laboratory director (or designee) sign that qualifications were verified before work begins.
7. List each employee and role on the personnel roster and, for CMS surveys, on Form CMS-209 when requested.
8. Re-verify licenses at renewal **[Renewal tracking method]**.

Renewal tracking method	

9. Keep files for active staff and for **[Retention period after separation]** after separation.

Retention period after separation	

7. Quality control

- Audit **[Number]** personnel files per year against the checklist.

Number	

8. Interpretation, reporting and documentation

- A missing credential means the person may not test until it is obtained.

9. Limitations and cautions

- State licensure (for example CA, NY, FL and others) can be stricter than CLIA.
- 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
- CMS, Clinical Laboratory Improvement Amendments (CLIA)
https://www.cms.gov/medicare/quality/clinical-laboratory-improvement-amendments

11. Personnel file checklist

Fill in electronically or print. Keep completed forms per the record retention policy.

Employee	CLIA role	Education verified	License / cert	Job description signed	Training done	Competency current

12. Lab-specific notes

Notes and local requirements	

13. Revision history

Version	Date	Description of change	Author	Approved by

14. 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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