STANDARD OPERATING PROCEDURE TEMPLATE · PERSONNEL, TRAINING AND COMPETENCY

New Employee Orientation and Training

Governing requirement: 42 CFR 493.1413(b)(7) and 493.1451(b)(7)

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 each new employee is oriented, trained and found competent before independently performing patient testing.

2. Scope

All new laboratory employees and employees moving to a new section or test.

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

Training checklist: A list of tasks and procedures the trainee must complete with trainer sign-off.

5. Materials, equipment and records

- Training checklist per section **[Section checklists]**

Section checklists	

- Procedure manual
- Safety training records

6. Procedure

1. Complete general orientation: facility, safety, bloodborne pathogens, chemical hygiene, fire and emergency procedures, HIPAA.

2. Review job description and sign it.

3. Assign a qualified trainer **[Trainer]**.

Trainer	

4. For each test: read the procedure, observe the trainer, perform under supervision, then perform independently with review.

5. Test **[Number of samples]** known specimens or PT samples with acceptable agreement before release.

Number of samples	

6. Trainer and supervisor sign each checklist item.

7. Technical consultant / supervisor signs release to independent testing.

8. Perform first competency assessment within 6 months of starting patient testing.

7. Quality control

• Follow the laboratory's QC policy and the manufacturer's instructions; record QC before reporting patient results.

• Stop patient testing and take corrective action when QC or acceptance criteria are not met.

8. Interpretation, reporting and documentation

• File completed checklists in the personnel file.

9. Limitations and cautions

• Do not release a trainee to report results before sign-off.

• 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 493.1413 https://www.ecfr.gov/current/title-42/section-493.1413

• eCFR, 42 CFR 493.1451 https://www.ecfr.gov/current/title-42/section-493.1451

11. Training checklist

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

Task / procedure	Read SOP	Observed	Performed with supervision	Released	Trainer initials	Date

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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