STANDARD OPERATING PROCEDURE TEMPLATE · PERSONNEL, TRAINING AND COMPETENCY

Delegation of Duties

Governing requirement: 42 CFR 493.1407(b) and 493.1445(b)

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 document delegation of laboratory director and supervisory responsibilities to qualified individuals in writing.

2. Scope

All duties that the laboratory director or technical consultant / supervisor delegates.

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

Delegation: Written assignment of a responsibility to a qualified person; the delegator remains accountable.

5. Materials, equipment and records

- Delegation of duties form

6. Procedure

1. List each duty to be delegated and the regulation it comes from.

2. Confirm the delegate meets the qualifications for the duty.

3. Record delegate name, duty, start date and signatures of delegate and laboratory director.

4. Do not delegate duties that regulation reserves to the director, such as signing procedures and attesting PT where required **[Duties retained by director]**.

Duties retained by director	

5. Review delegations annually and when personnel change.

6. Post the current delegation list where staff can see it.

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

• Keep current and prior delegations at least 2 years.

9. Limitations and cautions

• The laboratory director remains responsible for all delegated duties.

• 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. Delegation of duties

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

Duty delegated	Regulation	Delegate	Delegate signature	Director signature	Start date	End 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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