STANDARD OPERATING PROCEDURE TEMPLATE · INFORMATION MANAGEMENT, LIS AND PRIVACY

Laboratory Information System (LIS) Validation

Governing requirement: 42 CFR 493.1291(a)

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 validate LIS functions and interfaces before use and after changes.

2. Scope

LIS, middleware and interfaces.

3. Responsibility

- Laboratory director: approves policies and validations.
- LIS / IT administrator: maintains systems, access and backups and documents changes.
- All staff: protect patient information and report suspected incidents.

4. Definitions

Interface: Electronic connection between systems.

5. Materials, equipment and records

- Validation plan
- Test patients

6. Procedure

1. Write a validation plan.

2. Test result transmission, calculations, units, reference ranges, flags, comments and critical values.

3. Check reports in every destination system.

4. Document and approve before go-live.

5. Re-verify after changes and periodically **[Frequency]**.

Frequency	

7. Quality control

• Review access, audit logs or validation records on the schedule in this SOP and document the review.

8. Interpretation, reporting and documentation

• Record the activity, date, result and initials on the form or log, and have the supervisor review records **[Review frequency]**.

Review frequency	

• Keep records per the record retention SOP (at least 2 years under 42 CFR 493.1105 unless a longer period applies).

9. Limitations and cautions

• 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 Laboratory Requirements (CLIA)
https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493

• 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 493.1291 https://www.ecfr.gov/current/title-42/section-493.1291

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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