STANDARD OPERATING PROCEDURE TEMPLATE · ADMINISTRATION AND QUALITY MANAGEMENT

Management Review

Governing requirement: 42 CFR 493.1407 / 493.1445 (director responsibility) and Subpart K

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 have the laboratory director and management periodically review the quality system and make documented decisions for improvement.

2. Scope

Quality management system of the entire laboratory.

3. Responsibility

- Laboratory director: approves this policy, assigns responsibility for quality activities and reviews results.
- Technical consultant / technical supervisor: reviews technical aspects, investigates issues and signs off corrective actions.
- Quality lead (if assigned): coordinates records, tracking and reporting.
- All laboratory staff: follow this procedure and report problems promptly.

4. Definitions

Management review: A documented periodic review of quality performance by laboratory leadership.

5. Materials, equipment and records

- Quality indicator summaries
- PT results
- Audit and survey results
- CAPA status

6. Procedure

1. Hold management review **[Frequency]** with the laboratory director and section leads.

Frequency	

2. Review quality indicators, PT results, QC trends, complaints, occurrences, audit findings, CAPA status, staffing, training and competency status.

3. Review changes in test menu, regulations, volume and resources.

4. Record decisions, assigned actions and due dates.

5. Track actions to completion at the next review.

6. Laboratory director signs the minutes.

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 minutes at least 2 years.

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 Subpart K: Quality system for nonwaived testing
https://www.ecfr.gov/current/title-42/part-493/subpart-K

• 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. 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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