STANDARD OPERATING PROCEDURE TEMPLATE · ADMINISTRATION AND QUALITY MANAGEMENT

Quality Management System Plan (12 Quality System Essentials)

Governing requirement: 42 CFR 493.1200-493.1299 (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 describe the laboratory's quality management system, assign ownership of each quality system essential, and show how the lab monitors, assesses and improves the quality of its testing.

2. Scope

All testing phases (pre-analytic, analytic, post-analytic) and all general laboratory systems.

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

Quality system essentials (QSEs): The 12 building blocks of a laboratory QMS: organization; customer focus; facilities and safety; personnel; purchasing and inventory; equipment; process management; documents and records; information management; nonconforming event management; assessments; continual improvement.

Quality assessment: Ongoing monitoring of each phase of testing to identify and correct problems (Subpart K assessment standards).

5. Materials, equipment and records

- Organization chart **[Org chart location]**

Org chart location	

- Quality indicator list

• Quality meeting minutes

6. Procedure

1. Organization: document the lab's mission, organization chart and who holds each CLIA role **[Laboratory director name/title]**.

Laboratory director name/title	

2. Customer focus: define how client needs and satisfaction are measured **[Customer feedback method]**.

Customer feedback method	

3. Facilities and safety: maintain space, utilities and safety programs (see safety SOPs).

4. Personnel: confirm qualifications, training and competency (Subpart M; competency SOP).

5. Purchasing and inventory: qualify suppliers and control critical supplies.

6. Equipment: install, verify, maintain and calibrate instruments (42 CFR 493.1252, 1254, 1255).

7. Process management: verify methods, run QC, enroll in PT (493.1253, 1256, Subpart H).

8. Documents and records: control documents and retain records (493.1251, 1105).

9. Information management: protect confidentiality and ensure accurate result transmission (493.1231, 1291).

10. Nonconforming event management: capture, investigate and correct occurrences (493.1282).

11. Assessments: audit each phase and review quality indicators **[Assessment schedule]** (493.1239, 1249, 1289, 1299).

Assessment schedule	

12. Continual improvement: use CAPA and management review to drive improvements; report quality status to the director **[Reporting frequency]**.

Reporting frequency	

7. Quality control

• Track quality indicators such as specimen rejection rate, turnaround time, corrected report rate, PT performance and QC failures.

• Targets for each indicator: **[Indicator targets]**

Indicator targets	

8. Interpretation, reporting and documentation

• Summarize quality data at management review; record decisions and assigned actions.

9. Limitations and cautions

• The QMS plan must match how the lab actually operates; update it when services or structure change.

• 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

• CLSI guidelines relevant to this procedure (referenced by name only; obtain current editions from CLSI)

• eCFR, 42 CFR 493.1200 https://www.ecfr.gov/current/title-42/section-493.1200

- eCFR, 42 CFR 493.1239 https://www.ecfr.gov/current/title-42/section-493.1239
- eCFR, 42 CFR 493.1249 https://www.ecfr.gov/current/title-42/section-493.1249
- eCFR, 42 CFR 493.1289 https://www.ecfr.gov/current/title-42/section-493.1289
- eCFR, 42 CFR 493.1299 https://www.ecfr.gov/current/title-42/section-493.1299

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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