STANDARD OPERATING PROCEDURE TEMPLATE · ADMINISTRATION AND QUALITY MANAGEMENT

Quality Assessment Program

Governing requirement: 42 CFR 493.1239, 493.1249, 493.1289, 493.1299

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 establish ongoing monitoring that identifies and corrects problems in each testing phase and verifies corrective actions work.

2. Scope

General laboratory systems, pre-analytic, analytic and post-analytic systems for all nonwaived testing.

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 indicator: A measurable item used to monitor performance, with a target and review frequency.

5. Materials, equipment and records

- Quality indicator log
- QA meeting minutes
- CAPA log

6. Procedure

1. Select quality indicators for each phase: **[Pre-analytic indicators]**, **[Analytic indicators]**, **[Post-analytic indicators]**.

Pre-analytic indicators	

Analytic indicators	
Post-analytic indicators	

2. Set a target, data source and owner for each indicator.

3. Collect data **[Data collection frequency]** and summarize monthly.

Data collection frequency	

4. Review QC, PT, calibration verification, maintenance and comparison records as part of analytic assessment (493.1289).

5. Review complaints, communications problems and personnel competency issues as part of general systems assessment (493.1239).

6. Review test requisitions, specimen rejections and pre-analytic errors (493.1249).

7. Review report accuracy, corrected reports, critical value notification and turnaround times (493.1299).

8. Open a CAPA when an indicator misses its target or a trend appears.

9. Evaluate effectiveness of corrective actions and record the outcome.

10. Discuss the assessment results with staff and record attendance.

11. Present a summary to the laboratory director for review and signature **[Review frequency]**.

Review frequency	

7. Quality control

• Each indicator has defined acceptable performance; exceptions trigger investigation.

8. Interpretation, reporting and documentation

• Keep quality assessment records at least 2 years (493.1105(a)(5)).

9. Limitations and cautions

• Indicators should change over time as problems are fixed and new risks appear.

• 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 493.1239 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

• eCFR, 42 CFR 493.1105 https://www.ecfr.gov/current/title-42/section-493.1105

11. Quality indicator monitoring log

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

Month	Indicator	Target	Result	Met (Y/N)	Action / CAPA #	Reviewed by

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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