STANDARD OPERATING PROCEDURE TEMPLATE · ANALYTIC: QC, CALIBRATION, VERIFICATION AND EQUIPMENT

Individualized Quality Control Plan (IQCP)

Governing requirement: CMS IQCP (42 CFR 493.1256(d) alternative QC)

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 a risk-based QC plan for a test system as allowed by CMS.

2. Scope

Nonwaived tests where the lab elects IQCP (not available for waived tests or pathology specialties excluded by CMS).

3. Responsibility

- Testing personnel: perform the procedure, record results and stop patient testing when criteria are not met.
- Technical consultant / technical supervisor: sets acceptance criteria, reviews records and approves corrective action.
- Supervisor: ensures schedules are met and records are reviewed on time.
- Laboratory director: approves the procedure and any change to criteria.

4. Definitions

IQCP: Risk assessment + quality control plan + quality assessment, approved by the laboratory director.

5. Materials, equipment and records

- Manufacturer information
- QC and PT history
- Risk assessment template

6. Procedure

1. Define the test system, specimen, environment, reagents and testing personnel components.

2. Perform a risk assessment of all five components across all phases.

3. Write the quality control plan: control types, frequency **[QC frequency in IQCP]**, and other measures (built-in controls, training).

QC frequency in IQCP	

4. Ensure QC is never less than the manufacturer requires.

5. Laboratory director signs and dates the IQCP before implementation.

6. Quality assessment: monitor errors, complaints and QC trends; review the IQCP at least **[Review frequency]** and after failures.

Review frequency	

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

• 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

• CMS excludes some specialties and situations; check current CMS guidance.

• 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

• CMS, Individualized Quality Control Plan (IQCP) frequently asked questions (PDF)
https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/faqs-iqcp.pdf

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

• eCFR, 42 CFR 493.1256 https://www.ecfr.gov/current/title-42/section-493.1256

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

Free template from Sound Lab Consultants, soundlabconsult.com. Download more free templates at soundlabconsult.com/laboratory-sop-library.