STANDARD OPERATING PROCEDURE TEMPLATE · ADMINISTRATION AND QUALITY MANAGEMENT

Laboratory Risk Assessment

Governing requirement: 42 CFR 493.1256(d) (IQCP) and 493.1239

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 identify potential failures in the testing process, estimate their risk, and put controls in place to reduce risk to an acceptable level.

2. Scope

New tests, new instruments, process changes, IQCP development and annual quality reviews.

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

Risk: The combination of how often a failure may occur and how severe the harm would be.

Control measure: An action or check that prevents or detects a failure.

5. Materials, equipment and records

- Process map
- Risk scoring table **[Scoring scale]**

Scoring scale	

- Manufacturer information, QC and PT history

6. Procedure

1. Map the testing process from order to report.

2. For each step, list potential failures in the specimen, test system, reagents, environment and testing personnel.
3. Score each failure for likelihood **[Likelihood scale]** and severity **[Severity scale]**.

Likelihood scale	
Severity scale	

4. Identify existing controls and add new ones where risk is unacceptable.
5. Document the residual risk and the director's acceptance.
6. Reassess when the process changes, after significant errors, or at least **[Reassessment frequency]**.

Reassessment frequency	

7. Quality control

• Monitor failures and complaints after implementation to confirm controls work.

8. Interpretation, reporting and documentation

• Keep the risk assessment with the related IQCP or procedure.

9. Limitations and cautions

• A risk assessment cannot reduce QC below the manufacturer's minimum requirements.

• This is a generic template. Adapt it to your instruments, test systems, manufacturer instructions, state law and accreditation standards before use.

10. References

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

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

11. Risk assessment worksheet

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

Process step	Potential failure	Likelihood	Severity	Control measure	Acceptable (Y/N)

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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