STANDARD OPERATING PROCEDURE TEMPLATE · ADMINISTRATION AND QUALITY MANAGEMENT

Occurrence and Nonconforming Event Management

Governing requirement: 42 CFR 493.1282 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 capture, classify, investigate and correct laboratory occurrences (errors, near misses, deviations and accidents).

2. Scope

All laboratory staff and all phases of 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

Occurrence: Any event that deviates from procedure or expected results, whether or not harm occurred.

Near miss: An error caught before it reached the patient or the report.

5. Materials, equipment and records

- Occurrence report form **[Electronic or paper]**

Electronic or paper	

- Occurrence log

6. Procedure

1. Any employee who discovers an occurrence takes immediate safe action and reports it within **[Reporting time frame]**.

Reporting time frame

2. Complete an occurrence report: what happened, when, specimen/patient identifiers, immediate action.
3. The supervisor classifies severity **[Severity scale]** and phase (pre-analytic, analytic, post-analytic).

Severity scale

4. Notify the laboratory director immediately when patient harm is possible or a result was reported in error.
5. Investigate; open a CAPA when needed.
6. Correct affected reports per the corrected reports SOP.
7. Trend occurrences monthly and report at quality review.
8. Use a non-punitive approach that encourages reporting.

7. Quality control

• Review the occurrence log at least **[Review frequency]**.

Review frequency

8. Interpretation, reporting and documentation

• Keep occurrence records at least 2 years.

9. Limitations and cautions

• Occurrence reports contain patient information; protect them as confidential.

• 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 493.1282 https://www.ecfr.gov/current/title-42/section-493.1282

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

11. Occurrence log

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

Date	Event description	Phase	Severity	Immediate 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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