STANDARD OPERATING PROCEDURE

Laboratory Data Recording SOP

Document no.	SOP-LAB-010
Revision	1.0
Owner	QA Manager
Effective date	September 15, 2026
Review cycle	Every 12 months

1. Purpose

To ensure laboratory data is recorded at the time it is generated, corrected transparently when needed, reviewed by a second person, and archived so it remains retrievable and trustworthy.

2. Scope

Applies to data recorded in bound notebooks, worksheets or the LIMS during sample testing, calculations and instrument readings, across all laboratory departments.

Definitions

Contemporaneous entry	A data entry made at the time the observation or measurement actually occurs, not from memory afterward.
Audit trail	The electronic or paper record showing who entered, changed or reviewed a piece of data and when.
Out-of-specification (OOS) result	A test result that falls outside the acceptance criteria and requires investigation before release.

3. Responsibilities

Lab Analyst	Records data at the time of observation and performs required calculations and self-checks.
QA Specialist	Performs second-person review of records and investigates flagged out-of-specification results.
Laboratory Manager	Approves record corrections beyond routine single-line strikeouts and resolves recurring documentation issues.
LIMS Administrator	Manages user access, backups and audit trail configuration in the LIMS.

RACI matrix

Activity	Lab Analyst	QA Specialist	Laboratory Manager	LIMS Administrator
Record data at time of observation	R/A	-	-	-
Perform second-person review of records	C	R/A	I	-
Investigate an out-of-	R	A	I	-

Activity	Lab Analyst	QA Specialist	Laboratory Manager	LIMS Administrator
specification result				
Manage LIMS user access and backups	I	C	I	R/A

R = Responsible, A = Accountable, C = Consulted, I = Informed

4. Materials and PPE

Materials, tools and systems

- LIMS or bound, page-numbered laboratory notebook
- Calibrated instruments with current asset IDs
- Approved worksheet and calculation templates
- Data correction and review log
- Records retention schedule

5. Procedure

Step	Task	Owner	Done
5.1	**Record data at the time of observation** Enter each reading, weight or observation into the LIMS or notebook at the moment it is generated, not from memory later in the shift.	Lab Analyst	☐
5.2	**Use the approved recording method** Use only the designated LIMS field, worksheet or bound notebook page for the test being performed, writing in permanent ink if recording on paper.	Lab Analyst	☐
5.3	**Identify the instrument and materials used** Record the asset ID of the instrument, and the lot numbers of reagents or reference standards, alongside the result they produced.	Lab Analyst	☐
5.4	**Sign and date each entry** Sign or initial and date each page or LIMS entry as it is completed, including partial entries left at the end of a shift.	Lab Analyst	☐
5.5	**Correct errors transparently** Draw a single line through an incorrect entry so the original is still legible, write the correction beside it, and initial and date the change. **Warning:** Never use correction fluid, erase, or overwrite an original entry.	Lab Analyst	☐
5.6	**Reference formulas in calculations** Show the formula or reference used for any calculated result, not just the final number, so the calculation can be checked later.	Lab Analyst	☐
5.7	**Flag out-of-specification results** When a result falls outside the acceptance criteria, flag it immediately in the LIMS and notify QA before releasing or repeating the test. **Checkpoint:** An OOS result is flagged and communicated to QA before any retest is started.	Lab Analyst	☐

Step	Task	Owner	Done
5.8	**Perform second-person review** Have a qualified second reviewer check calculations, transcription and completeness of the record before results are released. **Checkpoint:** The second reviewer's signature and date appear on the record before release.	QA Specialist	☐
5.9	**Investigate flagged results** Open an investigation record for any OOS or flagged result, documenting the suspected cause and any corrective action taken.	QA Specialist	☐
5.10	**Back up electronic records** Confirm the LIMS or electronic worksheet backup runs on schedule and verify a recent backup can be restored.	LIMS Administrator	☐
5.11	**Control access to records** Restrict LIMS accounts and shared drive folders to authorized staff, and remove access promptly when someone changes roles or leaves.	LIMS Administrator	☐
5.12	**Archive completed records** Move completed notebooks, worksheets and LIMS batches to archive storage per the records retention schedule once testing is closed out.	QA Specialist	☐

6. Quality checks

- Every entry is signed, dated and made at the time of observation.
- Corrections show the original entry, the change, and who made it.
- Every released result has a documented second-person review.
- OOS results have a linked investigation record before disposition.

7. Records

- Laboratory notebooks and worksheets
- LIMS audit trail
- Data correction and review log
- OOS investigation records

8. KPIs

- Percentage of records with completed second-person review
- Number of documentation errors found per audit
- Average time to close an OOS investigation
- Number of backup restoration tests passed per year

9. Common mistakes

- Writing down results from memory at the end of the shift instead of in real time.
- Using correction fluid to hide an incorrect entry.
- Releasing a result before the second-person review is complete.
- Not flagging an out-of-specification result before repeating the test.

10. Revision history

Revision	Date	Description	Reviewed by

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1.0	September 15, 2026	Initial release	Ilia Pirozhenko

Approval

Prepared by	Approved by	Date

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