

# Training Module: Data Integrity and Information Governance

**Focus Area:** QM Section 5.10 (ISO 15189:2022 Clause 7.6)

## 1. Scope

This module applies to all personnel who generate, enter, or verify laboratory data. It covers manual record-keeping, standalone computer usage, and LIMS operations.

## 2. Introduction and Objectives

In a microbiology lab, a result is only as good as the data trailing it. This module ensures that every observation—from a colony count on a plate to a final validated report—is traceable, secure, and accurate.

- **Objective 1:** Master the "Permanent Record" standard for manual entries.
- **Objective 2:** Understand personal accountability in LIMS (Identity & Audit Trails).
- **Objective 3:** Execute "Downtime Protocols" to ensure service continuity during system failures.

## 3. Structural Content

- **Data Lifecycle:** Collection  $\rightarrow$  Transcription  $\rightarrow$  Verification  $\rightarrow$  Storage.
- **Physical Security:** Protecting the lab's "Paper Memory."
- **Digital Hygiene:** Password integrity, cybersecurity, and screen-lock protocols.
- **Verification Science:** How to spot transcription and calculation errors.

## 4. Actionable Procedures

1. **The "Single-Line" Rule:** Demonstrating the only acceptable way to correct a manual error (No white-out, no scrubbing).
2. **LIMS Login Protocol:** The strict prohibition of "Proxy Logins" (never perform work under another person's ID).
3. **Data Transcription Check:** The "Second-Eye" principle for manual results.
4. **Emergency Switch:** How to pivot to manual reporting when the LIMS or Network is down.

## 5. Visual Aids

- **Correct vs. Incorrect Entry Examples:** Visual "Do's and Don'ts" for manual bench logs.
- **The LIMS Hierarchy Map:** Visualizing access levels (Who can View vs. Who can Authorize).

## 6. Methodologies for Teaching & Training

- **The "Audit Trail" Scavenger Hunt (Group Work):** Trainees are given a final report and must find the original bench log, the autoclave printout for that day, and the person who verified the result.
- **Live Demo:** A walk-through of the LIMS audit trail function showing how the system "remembers" every change.
- **The "Crashed System" Drill:** A timed exercise where the trainer "shuts down" the computers, and staff must process 3 mock samples using only paper forms.

## 7. Competencies to Develop and Achieve

- **Traceability:** Can link a final electronic result back to the original manual observation.
- **Integrity:** Correctly identifies and documents an error using the signed-and-dated strike-through method.
- **Security Awareness:** Demonstrates a "Clean Desk" policy and automatic locking of workstations.

## 8. Assessment Tools

- **Data Entry Practical:** Trainees enter 10 complex results (e.g., AST patterns) into the system; the trainer checks for 100% accuracy.
- **Calculations Test:** Trainees must manually calculate a result (e.g., a dilution factor) and compare it to a spreadsheet's automated output.

## 9. Guidelines for the Trainer

- **Focus on the "Why":** Explain that data integrity is a legal requirement and a patient safety necessity.
- **The "No-Sharing" Policy:** Be firm about password sharing. Use real-world examples of how shared accounts make it impossible to defend staff in a legal dispute.

## 10. Pre-Test and Post-Test

### 1. How should an error on a manual worksheet be corrected?

- a) Covered with correction fluid.
- b) Erased and rewritten.
- c) Crossed out with a single line, signed, and dated.

### 2. When is it acceptable to share your LIMS password with a colleague?

- a) When they are too busy to log in.
- b) When they have forgotten their own password.
- c) Never.

### 3. What is an "Audit Trail"?

- a) A list of patients waiting for tests.
- b) A chronological record of who changed what data and when.
- c) A path to the archive room.

### 4. If the LIMS fails, what is the primary objective of the "Downtime Protocol"?

- a) To wait until the IT team fixes the issue.
- b) To ensure patient samples are still tracked and results are safely delivered manually.
- c) To send all staff home early.

**5. True/False:** Any spreadsheet used for antibiotic zone diameter conversions must be validated before use.

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### Practical Training Scenario:

*"A technician is entering a sensitive antibiotic sensitivity result and accidentally clicks the wrong button, then realizes they are logged in under a senior's ID who left the terminal open."*

- **Training Discussion:** Why is this a breach of **5.10.4.2**? How does this destroy the **Audit Trail (5.10.4.3)**? What should be done immediately (Log out and log back in under the correct ID)?