

SOP Template: Review and Approval of Calibration Records

This SOP details the process for the **review and approval of calibration records**, ensuring accuracy, compliance, and traceability in measurement instruments. It covers the responsibilities for record verification, criteria for acceptance, documentation standards, and approval workflows. The objective is to maintain the integrity of calibration data, support quality assurance, and comply with regulatory requirements by implementing systematic review and formal approval procedures.

1. Purpose

To define the standardized process for reviewing and approving calibration records to ensure reliability, traceability, and compliance with applicable quality and regulatory standards.

2. Scope

This procedure applies to all personnel responsible for calibration activities, review, and approval of records for measurement instruments within the organization.

3. Responsibilities

Role	Responsibility
Calibration Technician	Perform calibration; complete all required fields in calibration records accurately; submit records for review.
Reviewer	Verify the accuracy, completeness, and compliance of the calibration record; check traceability and measurement results.
Approver (e.g., QA or Supervisor)	Formally approve or reject the record; ensure all acceptance criteria are met and documented.

4. Procedure

- Calibration Execution:** Perform instrument calibration following approved procedures and record all data legibly and accurately.
- Record Completion:** Ensure calibration records include instrument ID, calibration date, reference standards, environmental conditions, results, and technician signature.
- Submission for Review:** Submit completed records to the designated reviewer promptly after calibration.
- Review Process:**
 - Check that all fields are completed and legible.
 - Verify that calibration results are within acceptance criteria.
 - Confirm appropriate reference standards and documentation of traceability.
 - Identify discrepancies or incomplete data and request corrections as needed.
- Approval Workflow:**
 - Once reviewed and found satisfactory, forward records to the authorized approver.
 - Approver reviews and documents final approval with date and signature.
- Record Storage:** Store approved calibration records in a secure, retrievable system per company policy and regulatory retention times.

5. Criteria for Acceptance

- All fields on calibration record completed and legible.
- Calibration results within specified tolerances or acceptance limits.
- Use of certified and traceable reference standards.
- No unauthorized corrections or data alterations.
- Documentation of reviewer and approver with signatures and dates.

6. Documentation Standards

- Use ink for manual records; initial and date any corrections (do not use correction fluid).
- Ensure electronic records are protected against unauthorized alteration and have an audit trail.
- Maintain all calibration records in accordance with record retention policies.

7. References

- Company Quality Manual
- Regulatory requirements (e.g., ISO/IEC 17025, GMP, or applicable local regulations)
- Instrument-specific calibration procedures

8. Revision History

Version	Date	Description of Change	Approved By
1.0	2024-06-15	Initial SOP release	QA Manager

End of SOP Template.