# SOP Template
# Criteria for Acceptable Calibration Results and Action for Out-of-Tolerance Equipment

This SOP defines the **criteria for acceptable calibration results** and outlines the necessary actions to take when equipment falls out-of-tolerance. It establishes clear acceptance limits for calibration accuracy to ensure reliable and precise measurements. Procedures include identification of out-of-tolerance conditions, documentation requirements, equipment quarantine protocols, corrective measures, and re-calibration processes. The goal is to maintain optimal equipment performance, compliance with quality standards, and overall operational integrity through proactive monitoring and timely interventions.

## 1. Purpose

To define the acceptance criteria for calibration results and formalize response actions for out-of-tolerance equipment to ensure measurement reliability and quality compliance.

## 2. Scope

This SOP applies to all measurement and test equipment requiring calibration in the facility.

## 3. Definitions

- **Calibration:** Comparison of measurement instrument readings to a known standard to determine accuracy.
- **Acceptance Criteria:** Tolerance limits within which equipment measurement results are considered valid.
- **Out-of-Tolerance (OOT):** Equipment readings that fall outside the specified acceptance criteria.
- **Quarantine:** Temporary removal of equipment from service pending resolution of calibration issues.

## 4. Criteria for Acceptable Calibration Results

Calibration results shall be deemed acceptable if:

- All measured values fall within the manufacturer's or regulatory specified tolerance limits.
- No drift or error greater than the Maximum Permissible Error (MPE) or % of reading as defined in the calibration standard.
- No signs of damage or abnormal instrument behavior are observed during calibration and functional checks.

| Parameter | Acceptance Limit |
|---|---|
| Instrument Reading | Within Â± X% of reference standard |
| Repeatability | < Y units standard deviation |
| Drift | < Z units/year (as specified) |
| Other Criteria | Refer to equipment-specific calibration documentation |

## 5. Actions for Out-of-Tolerance Equipment

> **Note:** All findings and actions must be clearly documented using the designated calibration record forms.

1. **Identification:** Mark equipment as â€˜Out-of-Tolerance' and remove from operational use immediately.
2. **Quarantine:** Transfer equipment to a designated quarantine area to prevent usage.
3. **Notification:** Report OOT results to the responsible supervisor and quality management promptly.
4. **Root Cause Investigation:** Initiate investigation to determine the cause of failure.
5. **Impact Assessment:**
    - Review records to identify processes/products affected by the equipment since last calibration.
    - Notify affected departments and initiate additional checks if required.
6. **Corrective Action:** Repair, adjust, or recalibrate equipment as necessary.
7. **Recalibration:** Perform and document recalibration before returning equipment to service.
8. **Documentation:** Complete all calibration records including OOT findings, actions, and approvals.

## 6. Documentation Requirements

- Calibration certificates for all equipment.
- OOT incident reports and root cause analysis forms.
- Corrective and preventive action (CAPA) documentation.
- Equipment quarantine log.

## 7. Responsibilities

- **Calibration Technician:** Perform calibrations, document results, and initiate OOT actions.
- **Quality Assurance:** Review calibration records, oversee OOT investigations, and approve returned equipment.
- **Equipment Owners:** Ensure all equipment is calibrated as required before use.

## 8. References

- Manufacturer calibration procedures and limits
- ISO/IEC 17025 Calibration Requirements
- Internal Quality Management Procedures

## 9. Revision History

| Version | Date | Description of Change | Approved By |
|---|---|---|---|
| 1.0 | 2024-06-01 | Initial release | QA Manager |