Standard Operating Procedure (SOP): Temperature Monitoring Equipment Calibration and Validation

Purpose:

This SOP details the procedures for **temperature monitoring equipment calibration and validation**, ensuring accuracy and reliability of temperature measurements. It covers the selection of calibration standards, calibration frequency, validation techniques, documentation requirements, and corrective actions for equipment found out of tolerance. The goal is to maintain equipment performance within specified limits to support quality control and regulatory compliance.

Scope:

This SOP applies to all temperature monitoring equipment (e.g., thermometers, data loggers, temperature sensors) used in regulated environments within [Company Name].

Responsibilities:

- **Quality Assurance (QA):** Oversight of calibration/validation program, review of records, and approval of deviations/corrections.
- **Equipment Users:** Identify due calibration, report anomalies, and ensure equipment is handled properly.
- **Calibration Technicians:** Perform calibration, validation, and maintain records.

Procedure:

1. **Selection of Calibration Standards:**
    - Use reference standards traceable to national/international standards (e.g., NIST, ISO).
    - Verify standards are within current calibration validity date.
2. **Calibration Frequency:**
    - Perform calibration at intervals specified by manufacturer or internal risk assessment (typically annually or semi-annually).
    - Immediate recalibration after repair, relocation, or suspected drift.
3. **Calibration Procedure:**
    - Clean equipment prior to calibration.
    - Compare equipment readings at designated points (e.g. 0Â°C, 25Â°C, 50Â°C) against the standard.
    - Record results and calculate deviations.
    - Adjust or recalibrate if outside acceptable limits.
4. **Validation:**
    - Conduct validation after calibration, installation, or relocation to confirm correct operation in situ.
    - Document comparison with baseline/reference data.
5. **Documentation:**
    - Maintain calibration and validation records, including dates, reference standards, results, deviations, corrective actions, and responsible personnel signatures.
    - Label equipment with calibration status and next due date.
6. **Corrective Actions for Out-of-Tolerance Equipment:**
    - Immediately quarantine and tag the equipment "OUT OF SERVICE".
    - Investigate root cause and impact on products/processes.
    - Perform necessary adjustments and recalibration.
    - Document all actions and inform QA for impact assessment.

References:

- ISO/IEC 17025: Testing and Calibration Laboratories
- Manufacturer Equipment Manuals
- Internal Quality Manual [Document Number]

Attachments/Forms:

- Calibration Record Form
- Validation Checklist
- Corrective Action Report Form

Revision History:

Revision	Date	Description	Approved by

1.0	[YYYY-MM-DD]	Initial Release	[Name/Signature]