# Standard Operating Procedure: Temperature and Humidity Control Monitoring

This SOP details the procedures for **temperature and humidity control monitoring** to ensure optimal environmental conditions. It includes guidelines for calibrating and maintaining monitoring equipment, regular data recording and analysis, threshold setting for alerts, and corrective actions to maintain product quality and safety. Proper monitoring helps prevent equipment failure, reduce energy costs, and maintain compliance with regulatory standards.

## 1. Purpose

To outline the procedures and responsibilities for monitoring, controlling, and maintaining temperature and humidity conditions in designated areas to ensure product quality, safety, and regulatory compliance.

## 2. Scope

This SOP applies to all personnel involved in monitoring and maintaining temperature and humidity-controlled environments within the facility.

## 3. Responsibilities

- **Facility Manager:** Ensure the overall implementation and periodic review of this SOP.
- **Designated Staff:** Perform daily monitoring, data recording, and equipment maintenance.
- **Quality Assurance:** Review records, investigate deviations, and ensure regulatory compliance.

## 4. Procedure

### 4.1 Equipment Calibration and Maintenance

- Ensure all temperature and humidity monitoring devices are calibrated at intervals recommended by the manufacturer or as required by regulations.
- Log all calibration and maintenance activities in the Equipment Maintenance Log.
- Replace or repair faulty equipment promptly and document corrective actions.

### 4.2 Monitoring and Data Recording

- Record temperature and humidity readings at least **twice daily** or as specified for the area.
- Use electronic data loggers where possible for automated, continuous monitoring.
- Document all readings in the Temperature and Humidity Log Sheet (see example below).

| Date | Time | Location | Temperature (Â°C) | Humidity (%) | Initials | Comments |
|------|------|----------|-------------------|--------------|----------|----------|
| 2024-06-01 | 08:00 | Storage Room A | 21.5 | 45 | JS | - |

### 4.3 Setting Alert Thresholds

- Define acceptable temperature and humidity ranges for each area or process, based on regulatory requirements and product specifications.
- Configure equipment to raise visual/audible alarms or send notifications if readings fall outside set thresholds.

### 4.4 Corrective Actions

- Upon alert or deviation, investigate the cause immediately.
- Document the deviation, impact on products, and corrective/preventive actions taken.
- Notify Quality Assurance if product quality or safety may be compromised.

# 5. Records & Documentation

- Temperature and Humidity Log Sheets
- Calibration and Maintenance Records
- Deviation and Investigation Reports

# 6. Training

- All personnel responsible for monitoring must be trained on this SOP and the operation of the monitoring equipment.

# 7. References

- Manufacturer's instructions for equipment use and calibration
- Relevant regulatory guidelines (e.g. FDA, WHO GMP, ISO standards)

# 8. Revision History

| Revision No. | Date | Description | Approved By |
|---|---|---|---|
| 01 | 2024-06-02 | Initial SOP creation | QA Manager |