SOP: Temperature and Humidity Control Monitoring

This SOP establishes guidelines for **temperature and humidity control monitoring**, detailing the procedures for accurately measuring and regulating environmental conditions to ensure optimal storage and operational efficiency. It covers the use of monitoring equipment, data recording, maintenance of control systems, and corrective actions to maintain specified temperature and humidity levels, thereby preserving product quality and ensuring compliance with regulatory standards.

1. Purpose

To define procedures for monitoring, documenting, and controlling temperature and humidity in designated areas to ensure environmental conditions remain within specified limits.

2. Scope

This SOP applies to all storage and operational areas where temperature and humidity control is required.

3. Responsibilities

- Personnel: Responsible for daily monitoring and initial response to deviations.
- Supervisors/Managers: Oversee monitoring, ensure compliance, and coordinate corrective actions.
- Maintenance Team: Responsible for servicing and calibrating monitoring equipment.

4. Definitions

- **Temperature**: The degree of heat present, measured in Celsius (°C) or Fahrenheit (°F).
- Humidity: The amount of water vapor in the air, measured as relative humidity (%RH).
- Control Range: The specified temperature and humidity limits for an area.

5. Procedure

5.1. Monitoring Equipment Use

- Use calibrated temperature and humidity data loggers or sensors.
- Place monitoring devices at representative locations within the area.
- Verification of equipment calibration is to occur at least annually.

5.2. Measurement and Recording

- Record readings at the designated frequency (e.g., hourly, daily) in the Temperature and Humidity Log Sheet or via digital system.
- Ensure the following data is recorded:
 - Date and time of reading
 - Temperatures and humidity values
 - Initials of personnel

5.3. Data Review

Supervisors/Managers review records daily/weekly for deviations.

5.4. Corrective Actions

- If readings fall outside the control range, implement immediate corrective actions as per deviation protocol.
- Document all deviations and actions taken.

5.5. Maintenance of Control Systems

- · Check HVAC or climate control systems regularly.
- Report and address malfunctions promptly.

6. Documentation and Records

- Maintain all temperature/humidity records for a minimum of 3 years or as required by regulations.
- Secure all records to prevent loss or alteration.

7. Training

- All relevant personnel must be trained in temperature and humidity monitoring procedures.
- Maintain training records.

8. References

- · Manufacturer manuals for monitoring equipment
- Relevant regulatory guidelines

9. Revision History

Version	Date	Changes	Approved By
1.0	2024-06-01	Initial release	Quality Manager