

# Standard Operating Procedure (SOP)

## Environmental Control Requirements for Storage Areas

**Purpose:** This SOP defines the **environmental control requirements for storage areas**, including temperature and humidity regulation, ventilation standards, pest control measures, contamination prevention, and monitoring protocols. The goal is to maintain optimal conditions for stored materials, ensuring their quality, safety, and compliance with regulatory standards.

### 1. Scope

This SOP applies to all storage areas used for the preservation of raw materials, finished goods, components, and any other items requiring controlled environmental conditions.

### 2. Responsibilities

- Facilities Department: Maintain environmental control systems and equipment.
- Quality Assurance (QA): Monitor compliance and review environmental data.
- Warehouse/Storage Staff: Report deviations and maintain cleanliness.

### 3. Environmental Control Requirements

Parameter	Requirement	Control/Monitoring Method
Temperature	Maintain within <b>specified range</b> for the material (e.g., 15-25°C or as per product label/specific SOP).	Continuous monitoring via calibrated temperature data loggers. Records reviewed daily.
Humidity	Maintain relative humidity within <b>specified range</b> (e.g., 35-65% or as per product requirements).	Continuous monitoring with calibrated hygrometers. Data reviewed daily.
Ventilation	Provide adequate air exchange and prevent stale air accumulation; install HEPA filters if required by product sensitivity.	Routine HVAC system inspections and maintenance as per schedule.
Pest Control	Implement pest prevention and control measures. No signs of pest activity permitted.	Routine inspections and records; use of physical and chemical controls as necessary.
Contamination Prevention	Store materials off the floor and away from walls; separate incompatible items; maintain cleanliness.	Regular cleaning schedules and documented visual inspections.

### 4. Monitoring & Documentation

- All environmental parameters (temperature, humidity, etc.) must be recorded and reviewed daily.
- Any deviations must be immediately reported to QA and investigated.
- Maintain calibration records for all monitoring equipment.

### 5. Deviation Handling

In the event of any deviation from established environmental parameters, storage staff must notify QA and initiate corrective actions as per the deviation management SOP.

### 6. Training

All personnel involved in storage area activities must be trained on this SOP and retrained as required.

## 7. Review

This SOP shall be reviewed annually or upon significant change in regulatory or operational requirements.

## 8. References

- Relevant local and international regulations (e.g., GMP, GDP, ISO standards)
- Manufacturer's storage recommendations
- Company Deviation Management SOP
- Equipment Calibration SOP

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