

SOP: Cold Storage and Temperature Monitoring Processes

This SOP describes **cold storage and temperature monitoring processes**, focusing on maintaining optimal temperature conditions to ensure product quality and safety. It includes guidelines for proper storage practices, temperature control equipment operation, routine temperature monitoring and recording, calibration of sensors and devices, handling temperature deviations, and documentation protocols. The goal is to prevent spoilage, contamination, and ensure regulatory compliance by consistently maintaining the cold chain throughout storage and handling.

1. Purpose

This SOP provides step-by-step procedures to maintain proper cold storage and ensure accurate temperature monitoring, minimizing risks of spoilage or contamination.

2. Scope

Applies to all personnel responsible for storage and handling of temperature-sensitive products within cold storage areas.

3. Responsibilities

- **Storage personnel:** Follow storage and monitoring procedures, complete documentation.
- **Supervisors:** Verify compliance, review records, and ensure calibration and maintenance.
- **Quality Assurance:** Conduct audits and ensure adherence to regulatory standards.

4. Definitions

- **Cold Storage:** Storage maintained at 2â€"8°C (refrigerated) or -20°C (freezer) unless otherwise specified.
- **Temperature Monitoring Device:** Thermometer, data logger, or other electronic sensor used to track and record temperature.

5. Procedure

5.1. Cold Storage Preparation and Operation

- Ensure storage areas are clean, organized, and free from obstruction.
- Confirm all temperature control devices are plugged in, functional, and set to required setpoints.
- Do not overload shelves or block air circulation.

5.2. Product Storage Practices

- Store products off the floor and away from cooling vents/fans.
- Segregate incompatible or hazardous materials.
- Label shelves and products clearly, with date and batch information.

5.3. Temperature Monitoring & Recording

- Check and log storage area temperatures at specified intervals (e.g., twice daily or as required).
- Use only calibrated and certified thermometers or data loggers.
- Record readings in the temperature log sheet (see template in section 7).
- Investigate and report any value outside the specified range immediately.

5.4. Equipment Calibration

- Calibrate all temperature monitoring devices at least annually, or as required by manufacturer's guidelines.
- Keep calibration certificates and records on file.

5.5. Deviation Handling

- When temperature exceeds allowed limits, notify supervisor and QA immediately.
- Isolate affected products until a quality impact assessment is completed.
- Document all corrective actions and outcomes.

6. Documentation & Records

- Complete temperature log sheets promptly and store for a minimum period per regulatory guidelines.
- Document equipment maintenance, calibration, and deviation investigations.

7. Temperature Log Sheet Template

Date	Time	Storage Area	Temperature (°C)	Initials	Comments/Deviations

8. References

- Manufacturer manuals for cold storage equipment
- Applicable local and international regulatory requirements
- Internal quality management policies

9. Revision History

Version	Date	Description of Change	Approved By
1.0	2024-06-15	Initial Release	