

Standard Operating Procedure (SOP): Storage Temperature Monitoring and Recording

This SOP details **storage temperature monitoring and recording** procedures to ensure the integrity and safety of stored products. It covers the correct methods for measuring temperature, the frequency of monitoring, the use of calibrated instruments, documentation protocols, and corrective actions for deviations. The goal is to maintain optimal storage conditions, prevent spoilage, comply with regulatory standards, and guarantee product quality and safety throughout the storage period.

1. Purpose

To provide standardized procedures for monitoring and recording the temperature of storage environments to safeguard product quality, safety, and regulatory compliance.

2. Scope

This SOP applies to all personnel responsible for storing temperature-sensitive products in designated storage areas (e.g., refrigerators, freezers, warehouses).

3. Responsibilities

- Authorized personnel must perform and record temperature monitoring as outlined.
- Supervisors must ensure that temperature monitoring is conducted, documented, and reviewed regularly.
- Maintenance teams are responsible for calibration and upkeep of monitoring equipment.

4. Materials and Equipment

- Calibrated thermometers/data loggers (digital or analog).
- Temperature monitoring/recording logs or electronic recording system.
- Corrective action forms (if deviations occur).
- Protective gloves (where applicable).

5. Procedures

5.1 Storage Temperature Ranges

Storage Area	Required Temperature Range
Refrigerator	2Â°C to 8Â°C
Freezer	-25Â°C to -15Â°C
Ambient Storage	15Â°C to 25Â°C

5.2 Monitoring Method

1. Use a calibrated thermometer or data logger placed in the warmest location of the storage area.
2. Read and record the temperature at the scheduled intervals.
3. Check the calibration status of the instrument before use. Do not use instruments that are past due calibration.

5.3 Frequency of Monitoring

- Manual monitoring: At least twice daily (opening and closing times).
- If using data loggers: Review recorded data at least once daily.

5.4 Documentation

1. Record each reading in the temperature log with date, time, measured value, and initials.
2. Document calibration status and any maintenance performed on instruments.

- 3. Retain records for a minimum of three years or as per regulatory requirements.

5.5 Handling Deviations

- 1. If a temperature outside the acceptable range is detected:
 - Notify the supervisor immediately.
 - Document the deviation in the log and on a corrective action form.
 - Assess affected products for safety and quality as per company protocol.
 - Implement corrective measures (e.g., adjust equipment, relocate products).
- 2. Record actions taken and the outcome in the corrective action log.

6. References

- Company Quality Manual
- Regulatory guidelines for storage of temperature-sensitive products (e.g., USP, WHO, FDA)
- Equipment calibration certificates

7. Revision History

Version	Date	Description	Author
1.0	2024-06-07	Initial version	[Your Name]