SOP title	Temperature mapping and qualification		
SOP No.		Version	
Effective date		Review date	
Department		Site	

1. Purpose

To demonstrate that storage areas and equipment maintain the required temperature throughout, and to identify where monitoring sensors should be placed.

2. Scope

Cold rooms, refrigerators, freezers and controlled storage areas.

3. Responsibilities

Engineering and QA; validation team or approved contractor.

4. Definitions

5. Procedure

1. Prepare a mapping protocol defining the area, logger number and positions (a 3D grid covering corners, centre, top, bottom, doors and near cooling units), logging interval, duration and acceptance criteria.
2. Use calibrated loggers with valid certificates.
3. Map empty and loaded states, and summer and winter conditions where ambient affects performance.
4. Run the study for a duration that captures normal operation, defrost cycles and door openings, typically several days.
5. Include tests such as door opening and power-off recovery where relevant.
6. Analyse results: identify hot and cold spots, check all points stayed within limits, and calculate recovery time after door openings.
7. Write a mapping report with conclusions and approved monitoring sensor locations.
8. Re-map after major changes (equipment, layout, racking) and at a defined frequency, for example every [2–3] years or as risk assessment requires.

6. Records

Mapping protocol; mapping report; logger calibration certificates.

7. References

8. Revision history

Version	Date	What changed and why	Changed by

9. Approval

	Name & designation	Signature	Date
Prepared by			
Reviewed by			
Approved by (QA)			

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