Temperature Mapping Template

Temperature Mapping Protocol would guide the Temperature Mapping Template to capture the readings of the actual study. Wherein, Temperature Mapping Protocol would cover "*what you plan to do*" and Temperature Mapping Template would capture "*what you actually did and found".* Moreover there can not be a single template for this topic as the need may differ based on location, objective, methodology, but it can definitely be summarized within below points.

1.0 Objective and Scope:

1.1 Objective of Temperature Mapping study

____
____
____

1.2 Stage of Qualification

- ☐ Initial Qualification
- ☐ Requalification
- ☐ After Changes

1.3 Area to be Mapped

- ☐ Warehouse
- ☐ Coldroom
- ☐ Incubator
- ☐ Transport Vehicle
- ☐ Other

1.4 Temperature Range

From ☐ Temperature in ______ units
To ☐ Temperature in ______ units

2.0 Regulatory References

Guiding Regulatory Body ________
Guidelines as provided

1. ______________________________
2. ______________________________
3. ______________________________

3.0 Responsibility Matrix:

RACI model will help in designating Responsibility, Accountable, Consulting, Informing.

Task/ Activities	Quality Assurance	Engineering	Validation	External Service Providers
Task 01	R	A	C	I
Task 02	C	A	I	R
Task 03	I	C	A	R
Task 04	A	R	C	I

3.1 Pointers to elaborate:

1. Pointer 01
2. Pointer 02
3. Pointer 03

4.0 Equipment and Instruments

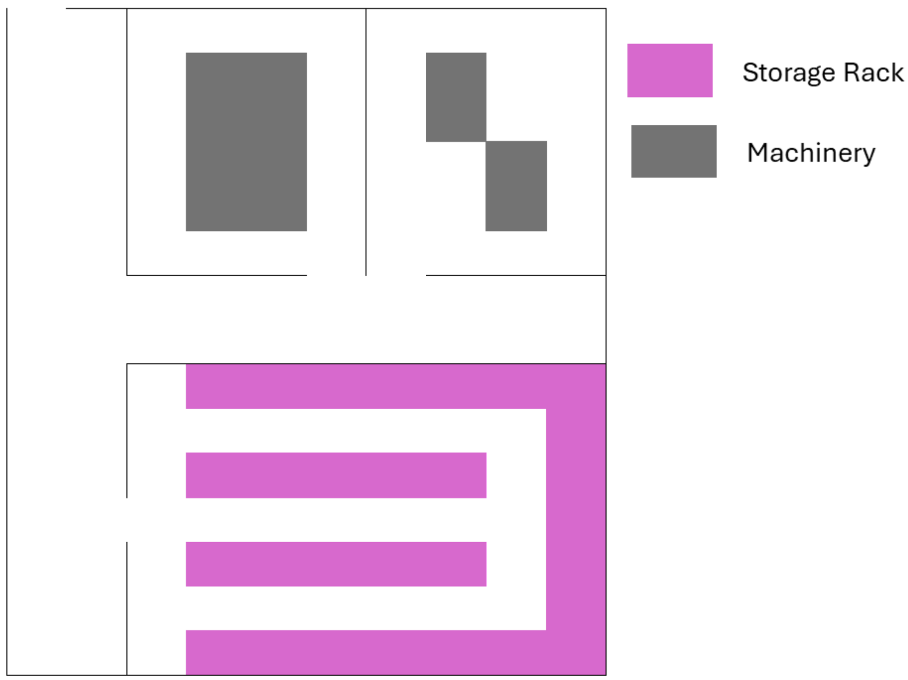
Details of equipment and instruments can be elaborated here.

Equipment/ Instruments	Calibration Status	Accuracy	Resolution
Data Loggers	CS01	Ac01	Re01
Temp Probes	CS02	Ac02	Re02
Thermometer	CS03	Ac03	Re03
Humidity Loggers	CS04	Ac04	Re04

5.0 Design of the Study

5.1 Preparation Stage

5.1.1 Layout



Mock layout

5.1.2 Size

Size of the room selected for the study: ____________ (in meters)

Area of the room selected for the study: ____________ (in m^2)

5.1.3 Observations about the layout

1. Observation 01
2. Observation 02
3. Observation 03

5.1.4 Previous known facts

1. Fact 01
2. Fact 02
3. Fact 03

5.1.5 Empty and Loaded Conditions

1. Conditions 01
2. Conditions 02
3. Conditions 03

5.1.6 Normal and worst-case operational conditions

1. Conditions 01
2. Conditions 02
3. Conditions 03

5.2 Implementation Stage

5.2.1 Sensors

Planned number of Sensors: ____________________

5.2.2 Sensor Height distribution

Sensor distribution at various heights, with % distribution and reason for the chosen height

Height	Number of Sensors	(height) Reason	% Distribution
Low			
Medium			
High			
Other			

5.2.3 Sensor Placement

Sensor placement at various location with reason

Sensor ID	Duration (in days)	(location) Reason
Sensor 01		
Sensor 02		
Sensor 03		
…		
Sensor 15		

(support this with a layout map, marking the locations of the sensors placed, along with their height map and hot/ cold classification) - attach annexure for multiple paged sensor placement

5.3 Observation Stage

5.3.1 Collecting observations

Date	Date01	Date02	Date03	Date04	Date05	Date06	Remarks
Sensor ID							
Sensor 01							
Sensor 02							
Sensor 03							
…							
Sensor 15							

- attach annexure for multiple paged sensor observation collection

5.3.2 Double Checks

1. Check 01
2. Check 02
3. Check 03

6.0 Acceptance Criteria

Study shall be allowed to be accepted if:

1. Criteria 01
2. Criteria 02
3. Criteria 03

(this would contain, allowed temperature range, max excursion limits in range and time duration, which data would be considered as complete, how would sensor failures be handled)

7.0 Execution Methodology

1. Step 01
2. Step 01
3. Step 01

(checklist shall be created, placing of sensors, starting of the study, recording both interior - exterior environmental conditions, handling deviations at run time, how the data would be retrieved, secure data and maintaining its integrity)

8.0 Deviation Handling

1. Handling 01
2. Handling 02
3. Handling 03

(how deviations would be handled, how excursions would be identified, who and how would be the investigate, who and how would be determine the RCA, how CAPA requirements be mapped, what would be the re-mapping criteria)

9.0 Data Interpretation

1. Point 01
2. Point 02
3. Point 03

(explain how data will be downloaded by creating a RACI for downloading, analyzing, plotting graphs, interpretation and summarization of the data)

10.0 Recommend Changes

1. Change 01
2. Change 02
3. Change 03

(how and who would recommend changes based on the finding of the deviation investigation, which changes will lead to layout modifications, capacity changes, equipment replacement, training requirements of handling personnel and how to handle seasonal variations)

11.0 Requalification

1. Plan 01
2. Plan 02
3. Plan 03

(summarize the finding and recommend duration for requalification, basis on which requalification and timelines for requalification)