Controlled Temperature Chamber Mapping

April 2012

A Concept Paper by the ISPE Packaging Community of Practice

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Acknowledgements

This concept paper was written by members of the ISPE Packaging Community of Practice (COP) and reviewed by members of the ISPE Commissioning and Qualification (C&Q), HVAC, and Packaging COPs.

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1 Introduction

This document provides guidance on good practices for the mapping of controlled temperature chambers, warehouses, and refrigerated storage areas used to store raw material, work in progress, or finished product. It is intended to be used when specifying commissioning and qualification activities.

The principles described in this document may be considered for controlled temperature chambers such as cold rooms, freezers, and warehouses. The approach is consistent with that described in the ISPE Good Practice Guide: Cold Chain Management [1], with examples provided that are more pertinent to a warehouse.

1.1 Key Terms

Commissioning

A well planned, documented, and managed engineering approach to the start-up and turnover of facilities, systems, and equipment to the end-user, that results in a safe and functional environment that meets established design requirements and stakeholder expectations [2].

Equipment Qualification (EQ)

Action of proving and documenting that equipment or ancillary systems are properly installed, work correctly, and actually lead to the expected results. Qualification is part of validation, but the individual qualification steps alone do not constitute process validation [3].

1.1.1 Risk-based Approach

With the advent of ASTM-E2500 “Standard Guide for Specification, Design, and Verification of Pharmaceutical and Biopharmaceutical Manufacturing Systems and Equipment” [4] may use a risk-based approach, with the equipment being verified; for further information see:

1. The ISPE Good Practice Guide: Cold Chain Management [1]

2. The ISPE Guide: Science and Risk-Based Approach for the Delivery of Facilities, Systems and Equipment [5]

There should be a clear definition of the acceptance criteria; typically this is provided in a User Requirement Specification (URS) or equivalent document.

Temperature mapping is used to confirm that the system is operating to meet specifications, i.e. the temperature range within the unit is acceptable.

It is a standard practice in the pharmaceutical industry to provide monitoring with an independent system; advantages of this practice include:

- Calibration of the monitoring sensors can be carried out without impacting the system operation

- The independent system becomes the “quality system of record”

- The data can be used to provide continuous verification of acceptable system performance

Mapping results may be used to define the number and location of monitoring sensors for a warehouse, cold room, or chamber.

2 When to Perform Temperature Mapping

Temperature mapping a warehouse should start as early as possible during commissioning and qualification. This allows the early detection and resolution of any performance issues. It also allows potential operational constraints to be identified and discussed with users, to determine if the constraints are acceptable or require resolution.

Systems that support the warehouse Heating, Ventilation, and Air Conditioning (HVAC) should be commissioned prior to temperature mapping of the warehouse, to help ensure complete and representative testing. Alternatively, the operating state of support systems should be understood to allow evaluation of sub-system operational issues that may affect test results. Sub-system operational issues should be monitored independently in case investigation is required, e.g.:

*It can be acceptable to temperature map the area served by an HVAC system where a chilled water system which supports HVAC system operation has not been fully balanced, **if**:*

- *the chilled water system is known to provide an adequate supply of chilled water at a constant temperature*

***Note:** the Building Management System (BMS)/Building Automation System (BAS) could be used to provide supporting data that:*

- *the chilled water supply temperature is within the operating limits*
- *the HVAC system cooling control valve does not open completely – indicating that an adequate supply of chilled water has been available for the duration of the test*

2.1 Prior to Temperature Mapping

Before temperature mapping commences, responsibilities should be defined (e.g., in a Commissioning Plan) and the following aspects should be considered:

- Scope of testing required
- Review and approval of test method statements
- Progress reporting
- Reporting and handling of test discrepancies
- Location and marking of mapping points
- Definition of the acceptance criteria/expected results[1]
- Witnessing requirements and notification procedures
- Handling/retention of raw data
- Format and content of the commissioning report (e.g., is a particular documentation practice required?)

[1] Note that acceptance criteria are “non-negotiable” test results, expected results may be acceptable across a range, or are results taken for reference purposes.

- Defined responsibilities for operating and maintaining a facility during commissioning, until it is handed over to the User.

- Who is responsible for maintaining the operating log for the system from start-up to handover?

The level of detail, number of personnel, or number of suppliers involved in temperature mapping can vary depending on the type of project. For example, commissioning of an air conditioned warehouse in a new facility can involve several groups (e.g., construction manager, system installation contractors, commissioning contractors); for a custom built refrigerated storage room purchased through a design/build qualify contract, the requirements and responsibilities may lie with one company.

Temperature mapping equipment should be calibrated.

Documents which should be available from the supplier/construction company (as applicable), include:

- Control System Input/Output (I/O) list

- Control System Drawings (e.g., control panel layout, wiring diagram)

- Equipment and instrument lists

- Materials receiving and inspection reports/material certifications

- Equipment receipt and/or installation verification records

- Cable tests (continuity, insulation)

- Grounding (earth) tests

- Motor “megger” and rotation tests

- Fuse and breaker ratings/overload settings

- Control loop wiring checks

- Piping leak (hydrostatic) tests

- Pipework cleaning/flushing records

- Record of cleaning for ductwork

- Ductwork and Air Handling Unit (AHU) leakage tests

- Operation and Maintenance manuals

- As built drawings/specifications

The test requirements will depend on the type of system, and how critical performance is to the product and/or business. Project specifications should define documentation and test requirements.

2.2 Commissioning Activities

Commissioning of the system should follow Good Engineering Practice (GEP).

Where temperature mapping is of a controlled temperature environment, the local surrounding environment should, where possible or applicable, be kept at the worst case conditions to challenge the unit during commissioning (see summer winter mapping below).

Commissioning activities may be divided into four broad categories:

1. Inspection of the physical installation (e.g., field verification of installation drawings) and documentation (test) verification (e.g., ductwork leakage tests) to ensure compliance with design specifications.

2. Pre-operational safety checks

3. Setting to Work, defined as setting a static system into motion or “shake down” and regulation and adjustment

4. Functional testing

Regulation and adjustment and functional testing may be iterative activities as the system is fine tuned.

Inspection of the Physical Installation

The commissioning engineer’s scope of work should include confirmation that:

- equipment and materials were received, checked, and compliant with documented specifications
- installation has been completed in accordance with the design specifications
- documented evidence of the correct installation is available

The approach to inspection of the physical installation may vary depending on the project.

These activities may also be assigned to the construction manager/supplier, rather than the commission engineer.

Completion of this stage should verify that the installation meets specifications.

Pre-operational Safety Checks

The scope of the pre-start up checks is usually defined by the User. The checks may be simple, e.g., including a review of the safety critical construction field test data (e.g., wiring tests, motor rotational jog test results, pipework leakage test results) and a safety walk down of the area. The checks may also be a more comprehensive documented review of the construction records.

Setting to Work

This is the initial start up and tuning of the system. This may include calibration of the instruments and a complete check of the control system sequence of operation, including alarms and interlocks.

Functional Testing

The system should be tested (mapped) to confirm its load capacity and the temperature distribution in all working modes. This may be achieved using data loggers, radio data loggers, a Kaye Validator™, or equivalent.

Where the area being tested has duty/standby conditioning units (systems), these should be tested to ensure that they will perform similarly to the main system. Alternatively, testing should confirm that the performance of the controlled temperature chamber when operating using the “worst-case” system is acceptable.

3 Selection of Mapping Equipment

Selection of the equipment to be used for mapping should consider the required accuracy and repeatability related to the predefined acceptance criteria, e.g.:

A unit may have acceptance criteria of 2°C to 8°C, with a user requirement specification of 3°C to 7°C (expected results). If the mapping system has an accuracy of ± 0.3°C, then the acceptance criteria would become 2.3°C to 7.7°C, and the expected results would become 3.3°C to 6.7°C.

Some of the low cost (budget) mapping dataloggers have accuracy specifications of ± 2°C. Use of these devices would not be appropriate for this application.

Temperature sensors with a rapid response time are typically used for temperature mapping, to help to provide accurate information on system performance.

If humidity has been defined as a critical quality attribute, and there are no significant sources of humidity in the warehouse, it may be assumed that absolute humidity will equalize within the warehouse. Two mapping sensors mounted at different heights are suggested, again to be in locations selected to detect changes from the most significant influences, e.g., door opening.

Mapping sensor locations should be documented. The proposed load test strategy should be reviewed and approved by the Quality Unit and the warehouse/system owner.

4 Determining the Number and Locations for the Mapping Sensors

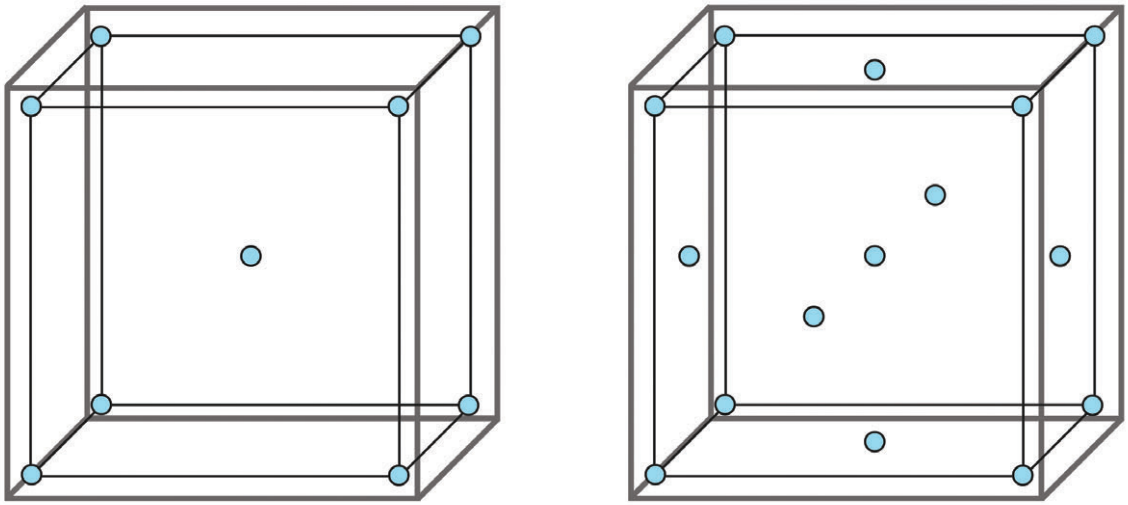
Although there is little guidance on the mapping of controlled temperature chambers, the following may provide useful information:

- The French Standard (NF X15-140 October 2002 Measurement of Air Moisture – Climatic and Thermostatic Chambers – Characterization and Verification) provides some information that is useful to consider when determining the number and location of sensors, see Figure 4.1 [6].
- The German Standard DIN 12880 Electrical Laboratory Devices – Heating Ovens and Incubators [7]
- The Australian Standard AS2853-1986: Enclosures – Temperature Controlled – Performance Testing and Grading [8].
- IEC 60068 Environmental Testing Parts 3-5, 3-6, 3-7, and 3-11 [9]

The diagram on the left of Figure 4.1 shows the suggested minimum number of mapping sensor locations to be used for a system with a chamber volume up to approximately 70 cubic feet, (2 m^3).

The diagram on the right of Figure 4.1 shows the minimum number of mapping sensor locations suggested by the French standard to be used for a system with a chamber volume of up to 700 cubic feet (20 m^3).

Figure 4.1: Example Sensor Locations



Note: the inner box represents the working area (where product is stored), the circles represent the sensor locations.

The sensor locations used for mapping should be defined based on:

- Where product will be stored
- The potential major influences on the internal conditions during use
- The number and location of heating/cooling units

There should be a scientifically based rationale developed for the number and location of the sensors; however, there are some basic requirements:

- For a warehouse, data should be available on the external conditions, this data may come from another source, e.g., the BMS/BAS (not the mapping system).

- For a conditioned room within a facility, e.g., a cold room, there should be data on the conditions at the time of testing outside the store, to ensure that any open door tests are representative of normal operating conditions. The data could be provided by the BMS/BAS system or a sensor included in the mapping system.

Where appropriate there should be a mapping sensor adjacent to the system control sensor (this may not be practical if the control is from a number of sensors that are being used to calculate an average temperature).

When defining the number of sensors and the locations, factors to consider include:

- The mapping sensor locations should be increased as necessary to monitor areas where changes in the conditions are likely to be found during use, e.g., conditions for product located near a conditioned air discharge.

- Where there are multiple air conditioning units or HVAC outlets which operate consistently, the area treated by each unit may be treated as a zone, with the mapping sensor layout developed to suit those zones.

- An area may be laid out so that it can be divided into zones that will perform similarly, e.g., there may be end zones, and internal zones. Temperature mapping a representative zone may provide adequate data.

A rationale that describes the location and number of sensors to be used should be developed. This should be reviewed and approved by the Quality Unit and the area/system owner.

Load Testing

When defining how the unit will be tested, the following should be considered:

- Is the area used to condition the stored material, or does it arrive within the specified conditions?

- What is the worst case condition:

    - An empty store with the maximum specified load arriving at the most extreme conditions permitted?

    - A store with the maximum load – this may be considered in terms of the thermal mass or maximum size load providing maximum restrictions to airflow?

- What will be the worst case conditions in use:

    - Doors held open for the maximum specified time in extreme environmental conditions?

The area/system owner may also want to use this opportunity to test system performance with simulated failures, to provide data that may be useful to defend continued use of the system during operation with an equipment failure.

4.1 Summer/Winter Testing

An organization may use a risk assessment to determine if seasonal testing is required. Risk mitigation factors to consider include:

- A robust software program was used to calculate the HVAC design
- The commissioning practices used for the HVAC system confirm that the components perform to meet the design specification (i.e., fan volumes with clean and simulated dirty filters, heating and cooling coil capacities)
- The number and location of the monitoring sensors are adequate to provide evidence if the environment exceeds the specified conditions

Organizations may perform mapping of warehouses over a full year. The external conditions are compared to the specified design conditions, and a judgment made to determine if the results adequately represent all seasons (likely seasonal extremes). These results are used to help define locations for the permanent monitoring locations and to ensure that locations consider the impact of seasonal variations on the locations likely to experience minimum/maximum temperatures. These uses should be taken into consideration during the comparison of the results.

For controlled temperature rooms, e.g., cold rooms, it may be considered adequate to map the system once, on the basis that the surrounding environment is controlled and the monitoring system provides adequate assurance that the internal conditions are being maintained.

The rationale for the load and seasonal testing should be defined in a document that is reviewed and approved by the Quality Unit and the area/system owner.

A sample document is included in Appendix 1.

It is considered good practice to review the initial monitoring data and compare the results with the defined requirements of the URS, to ensure that the requirements have been met.

Where user requirements have not been met, the designer/supplier should be asked to review the data and make recommendations for corrective action, to ensure that the system complies with the design specification. Depending on the contracts in place these modifications may be at the design authority's or equipment supplier's expense.

The USP provides guidance in General Chapter <1079> "Good Storage and Shipping Practices" [17].

5 Location of the Permanent Monitoring Sensors

Once testing is complete, the test data should be reviewed to determine where the permanent monitoring sensors can be located.

The monitoring sensors should be mounted in the position where stored product will experience the maximum and minimum temperatures (and/or maximum or minimum humidity, where applicable) during normal operation.

The optimum locations can be determined by reviewing the monitoring data considering periods or tests that represent normal use, e.g.:

- Operation in working hours
- Operation outside working hours
- Loading
- Unloading

The mapping results and the data analysis can be interpreted and summarized in a report recommending the optimum locations for approval by the Quality Unit and the area/system owner.

Where testing has demonstrated that equipment failure can have a significant impact on local conditions (e.g., where conditioning is provided by a number of independent HVAC units), the data can be used to recommend actions to be taken in the case of such an event, e.g., putting a defined shelf area out of use.

It is considered normal to experience short term temperature excursions due to door opening, personnel and truck movement. There are two approaches normally used to minimize nuisance alarms from these events:

- Putting time delays into the alarm system so that an alarm is given only if the temperature has been outside the alarm set point for more than a pre-defined time
- Putting the sensor into a container of thermal fluid to slow down the response time

Both of these approaches are intended to provide a simulation of the impact of the packaging acting as an insulator to the product, significantly damping out any short term temperature excursion on the temperature of the stored product. The approach used should be documented, and include a supporting rationale.

Data used to determine the number and location of the monitoring sensors may be interpreted in several ways. Two example interpretations are provided in Appendices two and three.

6 Appendix 1 – Sample Document Defining the Number and Location of Temperature Mapping Sensors to be Used and the Load Test Rationale

6.1 Introduction

This document is intended to provide a record of the rationale used to select the sensor locations for the temperature mapping of John's Warehouse, and the associated load test strategy.

The mapping will be used to determine the number and locations for the permanent monitoring sensors, based on the product storage locations that experience maximum and minimum temperature conditions during simulated normal use.

It should be noted that the product stored has no critical humidity requirements; therefore, humidity will be neither mapped nor monitored.

6.2 Approach

The following points were considered:

- External Heat Gains and Losses
- Internal Heat Gains and Losses

External Heat Gains and Losses

The major heat gains and losses to the warehouse are due to the influences of the external environment, with the most significant being through the North wall and ceiling.

All other influences will be consistent; areas within the warehouse which are adjacent to the temperature controlled storage room, will be air conditioned. During normal use the doors will be opened for loading and unloading, influencing the internal conditions.

Vinyl curtains are placed at each entrance, with inflatable seals to seal onto the truck sides for loading and unloading.

Internal Heat Gains and Losses

- *Lighting* – the lighting is from low energy fluorescent lamps, these are left on during the working day
- *Product* – the product stored in the warehouse is supplied at the storage temperature, so will not put a significant heating or cooling load onto the space
- *Equipment* – the equipment used comprises a stacking forklift truck; this is a relatively small intermittent load
- *Personnel* – on average there are approximately two people working in the area – the heat gains are, therefore, small and transient.

Air conditioning is by a single system with outlets equally spaced in the aisles as shown on the attached drawing.[2]

[2] A drawing could be attached for clarity.

6.3 Sensor Placement

The areas considered during the mapping are those areas where product will be stored.

The sensor locations proposed have been generated using the French Standard “NF X15-140 October 2002 Measurement of air moisture – Climatic and thermostatic chambers – Characterization and verification” [6] for guidance.

The chamber has been divided into zones, with each zone supplied by an air conditioning vent.

The end zones are different to the center zones in that they have the end walls/door influences; however, the symmetrical nature of the design of the central zones has allowed the number of mapping sensors proposed to be reduced.

A temperature sensor will be placed in the location of the lowest and highest storage point at which product could be stored, and at each corner of the room on the racking nearest the perimeter.

One temperature sensor will be located in the center of these locations at mid-level.

6.4 Monitoring System Sensor Placement

The mapping will be used to define the number and location of the permanent locations that will be used for mounting the system monitoring sensors.

Load Testing

The warehouse will be mapped using two “load” scenarios. In both cases there will be a minimum amount of thermal mass so that the impact of the change is seen quickly:

- “Empty”
    - The warehouse will be mapped empty, so that there are no constraints on air flow, with the lowest average airflow velocity in the room.
- “Full” sections
    - The unit is considered as a number of zones that operate independently; the front (i.e., nearest the door) zone and a half will be filled with empty boxes simulating the largest stored product case. This scenario will give minimum thermal mass, but maximum interruption of airflow, allowing the effect on the temperature distribution to be seen in the filled zones.

Note: the area selected was based on the fact that the warehouse is symmetrical.

Summer/Winter Conditions

The mapping sensor layout is uniform – when the data is analyzed the following will be considered:

- The North wall of the warehouse and the roof are exposed to external conditions, potentially influencing the temperatures at high level, and along that wall
- Local weather data from the meteorological office provided weather data showing the 90% and 95% summer/ winter conditions to be:

- Summer x
- Winter y

The design is specified to maintain internal conditions at all conditions up to and including the 95% limits.

The initial mapping is to be in summer, the data obtained from this may be used may be used to recommend a reduced number of sensors to be maintained through to the winter season; the mapping will be considered complete when seasonal variation has been experienced that exceeds the 90% design conditions.

7 Appendix 2 – Use of Measurement Uncertainty to Determine the Monitoring Sensor Locations from the Mapping Data

The maximum temperature(s) and minimum temperature(s) should be found during the mapping activity. This data can be analyzed to determine the locations representing temperature extremes.

- Where monitoring sensors can be located at the maximum and minimum temperature spots, alarm limits can be determined based on Critical Operational Data (COD)/Measurement Uncertainty (MU) of sensor and calibration standards.

- Where monitoring sensors cannot be located at the maximum and minimum temperature spots, an offset should be added to the COD/MU to account for the offset between the maximum and minimum temperature spots and the monitoring sensor(s).

1. For alarm sensor(s) installed at the locations of maximum and minimum temperature as determined in mapping; the COD/MU for each device should be included when establishing upper and lower limits for the alarm range.

2. For alarm sensors permanently mounted at a location other than the maximum and minimum temperature locations as determined in mapping, the offset between the maximum and minimum temperature spots and the monitoring sensor(s) should be determined. When establishing upper and lower limits for the alarm range, any offsets due to the sensor location should be included in addition to the COD/MU for each device.

In addition, the measurement uncertainty of both types of sensors (i.e., the sensors used during temperature mapping and the permanently installed monitoring sensors) should be considered in establishing the alarm limits. Measurement Uncertainty calculation and application:

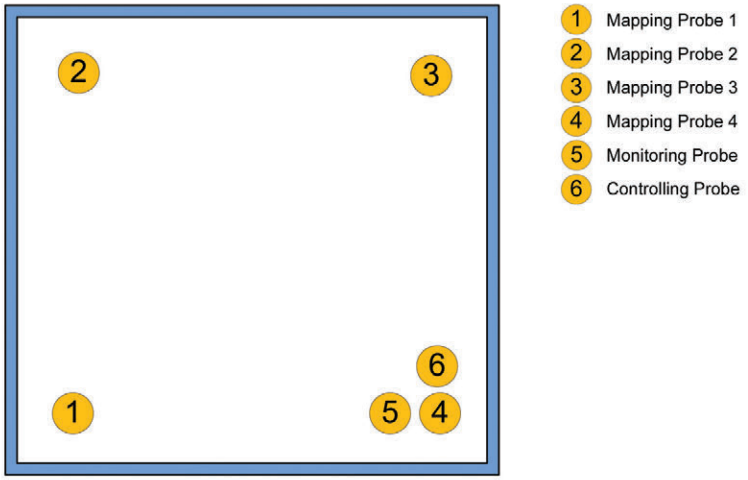
For the low limit: $DL \geq Limit + [GB - U_{sr}]$
For the high limit: $DL \leq Limit - [GB - U_{sr}]$

Where:

DL = Decision Limit
Limit = PAR (Proven Acceptable Range), Action or Safe Operating Limits
GB (Guard Band) = $k * u_{system}$
k = coverage factor which must be ≥ 2.00
u_{system} = calculated measurement uncertainty
U_{sr} = Required Uncertainty of Limits (usually = 0 to indicate no allowable excursion from the alarm value)

Examples

Figure 7.1



Given: $u_{T1} = u_{T2} = u_{T3} = u_{T4} = u_{T5} = u_{T6} = 0.125$ °C

Usr for each sensor = 0°C (no data available to allow for temperatures above or below the Proven Acceptable Range.)
k = 2 (corresponds to confidence > 97.7% for single sided alarm; 2 σ)
Proven Acceptable Range (PAR) = 2°C to 8°C
GB = u_s * k = 0.125 °C * 2 = 0.25°C

A. If all sensors are within GB = 0. 25°C of each other, the differences in temperature can be attributed to the measurement uncertainty of the sensors and the location of the monitoring sensor can be at any one of the locations of the mapping sensors. The Alarm limits are:
$DL_H = 8 – (GB – U_{sr}) = 7.75$°C
$DL_L = 2 + (GB – U_{sr}) = 2.25$°C

B. If sensor 1 shows highest temperature at 7.0°C and Monitoring Sensor 5 shows lowest temperature of 6.5°C at that same time, the following applies:

a. If you leave the monitoring sensor in the existing location, include 0.5 °C offset and measurement uncertainty for sensors 1 and 5 in the calculation (i) for the high alarm limit. The low alarm limit calculation (ii) remains the same as in example A.

i. $DL_H = 8 – (0.5 + 2\sqrt{(u_{T1}^2 + u_{T5}^2)} – U_{sr}) = 8 – (0.5 + 2\ (.177) – 0 = 7.15$°C

ii. $DL_L = 2 + (GB – U_{sr}) = 2.25$°C

b. If you relocate the monitoring sensor to the location of the high temperature, include 0.5°C offset and measurement uncertainty for sensors 2 and 5 in the calculation (ii) for the low alarm limit. The high alarm limit calculation (i) remains the same as in example A.

i. $DL_H = 8 – (GB – U_{sr}) = 7.75$ °C

ii. $DL_L = 2 + (0.5 + 2\sqrt{(u_{T2}^2 + u_{T5}^2)} – U_{sr}) = 2.85$°C

C. If sensor 1 shows highest temperature at 7.0°C and sensor 2 shows lowest temperature of 6.0°C and monitoring sensor shows value of 6.5°C at the same time as the sensor 1's high and sensor 2's low, the following applies:

   a. If you leave the monitoring sensor in the existing location, include 0.5 °C offset and measurement uncertainty for sensors 1 and 5 in the calculation (i) for the high alarm limit and the 0.5°C offset and measurement uncertainty for sensors 2 and 5 in the calculation (ii) for the low alarm limit.

      i. $DL_H = 8 – (0.5 + 2\sqrt{(u_{T1}^2 + uT_5^2)} – U_{sr}) = 7.15°C$

      ii. $DL_L = 2 + (0.5 + 2\sqrt{(u_{T2}^2 + u_{T5}^2)} – U_{sr}) = 2.85°C$

   b. If you relocate the monitoring sensor to the location of the high temperature, include 1.0 °C offset (difference between the high and low locations) and measurement uncertainty for sensors 2 and 5 in the calculation (ii) for the low alarm limit. The high alarm limit calculation (i) remains the same as in example A.

      i. $DL_H = 8 – (GB – U_{sr}) = 7.75°C$

      ii. $DL_L = 2 + (1.0 + 2\sqrt{(u_{T2}^2 + u_{T5}^2)} – U_{sr}) = 3.35°C$

   c. If you relocate the monitoring sensor to the location of the low temperature, include 1.0 °C offset (difference between the high and low locations) and measurement uncertainty for sensors 1 and 5 in the calculation (i) for the high alarm limit. The low alarm limit calculation (ii) remains the same as in example A.

      i. $DL_H = 8 – (1.0 + 2\sqrt{(u_{T2}^2 + u_{T5}^2)} – U_{sr}) = 6.65°C$

      ii. $DL_L = 2 + (GB – U_{sr}) = 2.25 °C$

   d. If you place monitoring sensors at each of the high and low temperature locations, then there is no offset and only the single device measurement uncertainty is included in the calculation. The monitoring sensor in the high temperature location will only alarm for high temperatures excursions (i) and the monitoring sensor in the low temperature location will only alarm for the low temperature excursions (ii).

      i. $DL_H = 8 – (GB – U_{sr}) = 7.75°C$

      ii. $DL_L = 2 + (GB – U_{sr}) = 2.25°C$

Example Protocol

1. Define system

   a. Description: -10°C freezer, 20' × 20' × 10' with redundant compressor/evaporator systems located in CRT Warehouse with single door opening to warehouse and one wall exposed to external temperatures.

   b. Process Parameters (acceptance criteria): -17°C to -3°C. U_{sr} is considered "0" because the product will be considered unacceptable if the temperature goes outside of these parameters as defined in stability studies.

2. Establish rationale for sensor locations. Using the guidance in Section 4 of this paper, identify sensor locations and document them as follows (this example shows an excessive number of sensors for the space only to demonstrate various rationales):

   a. Sensors 1 to 9: Basic layout – high and low at each corner plus one in middle of room.

   b. Sensors 10 to 25: high, middle and low on fixed racks due to restriction of air flow

c. Sensor 26: external door to unconditioned space with potential impact on room condition

d. Sensor 27, 28, 29: external wall due to temperature extremes greater than 10 degrees from room setpoint

e. Sensor 30: potential exposure to heat from defrost cycles of the system.

f. Sensor 31: monitoring external conditions (for information only – not subject to acceptance criteria)

g. Sensor 32: Control and/or monitoring sensor location

3. Define Equipment

a. Model – Validator 2000 Data Logger and Sensor Input Modules with T Type Thermocouples

b. Description

i. Validator 2000 S/N 590030

ii. Sensor Input Modules (SIMS)

1. 940030

2. 940031

3. 940032

c. Calibration information

i. Validator 2000 last cal 11/15/2010; due 11/15/2011

ii. Sims last cal 11/15/2010; due 11/15/2011

iii. Sensor calibration initiated on 12/14/2010 using temperature standard MK 15/65 Kaye 03/14/2010 with temperature reference MKR-80

1. Identify measurement uncertainty of sensors and data collector (from calibration report)

a. Accuracy = +/-0.125°C

iv. Calculate GB for system

1. $GB = k*u_s = 2*0.125 = 0.25°C$

d. Define Acceptance Criteria

i. For the low limit: $DL \geq Limit + [GB – U_{sr}] = (-17) + 0.25 = -16.75°C$

ii. For the high limit: $DL \leq Limit – [GB – U_{sr}] = (-3) – 0.25 = -3.25°C$

e. Set-up parameters

i. Sample rate – Once every 5 minutes

ii. Test time – At least 24 hours (include time to capture defrost cycles and switchover of redundant systems).

4. Place equipment in space.

5. Verify that values are being recorded.

6. Start Time: _____

7. End Time: _____

8. Evaluate data for temperature uniformity for each sensor.

   a. Minimum reading with time and sensor number.

   b. Maximum reading with time and sensor number.

   c. If minimum and maximum readings are within the acceptance criteria for the room, then the uniformity is acceptable for this system.

   d. Compare minimums and maximums to the monitoring device values and determine if relocation of the monitoring sensor is required or an offset in the alarm strategy is required or other action is necessary.

   e. Mean Kinetic Temperature (for CRT (Controlled Room Temperature) Warehouse with areas allowing specified temperature excursions over specified periods of time only)

8 Appendix 3 – Report Recommending the Location for Freezer Temperature Monitoring Sensors

8.1 Introduction

The Freezer was mapped using 36 independent sensors connected to a temperature mapping system during commissioning, with the mapping sensors located as shown in Figure 8.1. A series of tests were performed to ensure that the system met performance specifications during simulated use.

The Freezer performance will be monitored by the BMS, with an independent chart recorder used as a backup system. The mapping data obtained during the commissioning tests was used to determine the BMS and chart recorder sensor locations.

8.2 Product Temperature

The monitored room air temperatures are intended to be kept between -15°C and -25°C. The product is placed in the room at temperatures within this range of refrigerated temperatures; so it is not considered necessary to separately monitor the product temperature.

Temperature monitoring sensors will be located in a small container of glycerin, to simulate the thermal response of the product packaging.

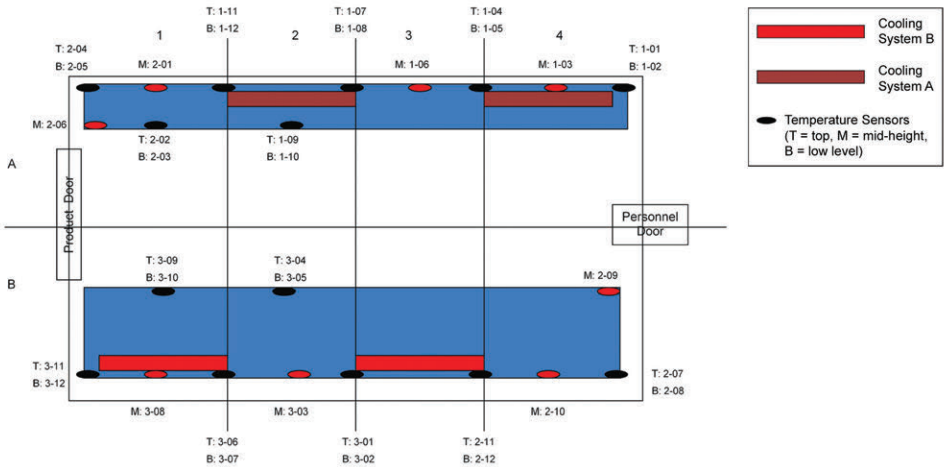
Monitoring System

The BMS and chart recorder sensor elements will be placed in the room and monitor worst case air temperature based on the conclusion contained in this report. There are six (6) temperature sensors for use as Freezer temperature monitors.

Approach

The following test results were used as the basis for determining the BMS and chart recorder sensor locations, so that they represent the worse case conditions (minimum and maximum temperatures) during simulated normal use of the Freezer. The sensors are intended to be placed in a location that will see the most rapid changes in the air temperature, in order to achieve the earliest possible alarm in case of an out of limit operation.

Figure 8.1: Mapping Sensor Locations



Commissioning Test 1 – Baseline Readings

This test was used to confirm the proper operation of the refrigeration systems by monitoring system operational parameters. The freezer operation was monitored for a minimum of 24 hours, in steady state conditions with no door opening.

Commissioning Test 2 – Open Door Test Empty

This test was used to determine the effect on the freezer temperature while the freezer sliding door was left open. The test was conducted with the system furthest from the door (system A) operating, to provide worst case conditions, i.e., minimum forced air mixing adjacent to the door) The door was opened for a one hour period with the internal vinyl curtains closed; the test period was adequate to indicate the conditions that the system would maintain if the door was left open.

Commissioning Test 3 – Open Door Test Loaded

This test was used to demonstrate the system performance loaded, using empty boxes to simulate the load (maximum volume, minimum thermal mass).

The test was conducted with the system furthest from the door (system A operating, to provide worst case conditions, i.e., minimum forced air mixing adjacent to the door). For each load, an open door test was conducted. The door was opened for a one hour period with the internal vinyl curtains closed; the test period was adequate to indicate the conditions the system would maintain if the door was left open.

Table 8.1: Test Results

1 – Baseline Readings, Empty	**Temperature (°C)**	**Location**
Minimum average temperature		
Maximum average temperature		
Minimum temperature		
Maximum temperature		
2 – Open Door Empty	**Temperature (°C)**	**Location**
Minimum average temperature		
Maximum average temperature		
Minimum temperature		
Maximum temperature		
3 – Open Door Loaded	**Temperature (°C)**	**Location**
Minimum average temperature		
Maximum average temperature		
Minimum temperature		
Maximum temperature		

Considerations

The locations recommended for the BMS sensors are those generally representing the minimum and maximum temperatures during the tests, considering the following:

- The sensor should ideally be accessible for ease of calibration
- The sensor should provide a reading reasonably representative of the minimum and maximum temperatures product will be exposed to during normal operation of the freezer
- The highest risks of temperature excursions are during door opening. During operation, normal traffic into the room is performed with the opened door through the curtains of the cold room.
- The sensors should be distributed as much as possible, to try to represent the whole freezer
- The central area of the freezer is considered to be more stable in terms of temperature than the perimeter zones, as there are no doors and the external environmental influences are significantly less
- The accuracy of the mapping sensors used is ± 0.5°C

Minimum Temperature Locations

The location experiencing the minimum average temperature and minimum temperature during test 1 was location x. The minimum value recorded during testing was x, recorded at sensor x during test 1 and at location x during test 2.

Maximum Temperature Locations

The maximum temperature locations are influenced by the defrosting of the unit coolers, and the door opening. This creates a heat gain as the dense cooled air leaves the freezer and warm air enters the room to replace it, continuing to enter after the door is closed through the vents to ensure that the freezer is not under pressure or vacuum.

The locations showing the maximum temperature during test 1 was x; and the maximum average temperature x. During test 2 the maximum average of x was obtained at location x with the maximum of x obtained at location x.

8.3 Discussion

Based on the data the following locations were considered for the BMS sensors ….

Conclusions

The sensor locations proposed are therefore as follows:

- The Locations for the **Minimum** temperature are:
- The Locations for the **Maximum** temperature are:

Attached are two graphs showing the mapping data from each of the three tests:

1. The data obtained from all the mapping sensors
2. The data obtained from the locations selected as the monitoring sensors

The graphs show that the selected locations provide an adequate reading of the temperature extremes within the freezer during the testing.

9 Appendix 4 – References

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17. USP General Chapter <1079> "Good Storage and Shipping Practices"

10 Appendix 5 – Acronyms

AHU	Air Handling Unit
BAS	Building Automation System
BMS	Building Management System
COD	Critical Operational Data
CRT	Controlled Room Temperature
GEP	Good Engineering Practice
HVAC	Heating, Ventilation, and Air Conditioning
I/O	Input/Output
MKT	Mean Kinetic Temperature
MU	Measurement Uncertainty
SIMS	Sensor Input Modules
URS	User Requirement Specification

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