Supplement 8

Temperature mapping of storage areas

Technical supplement to WHO Technical Report Series, No. 961, 2011

Annex 9: Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products

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Contents

Abbreviations

3PL	third-party logistics (provider)
CAPA	corrective and preventive action (procedures)
EDLM	electronic data logging monitor
GMP	good manufacturing practice
IQ	installation qualification
NIST	National Institute of Standards and Technology (US)
SLA	service level agreement
SOP	standard operating procedure
TTSPP	time- and temperature-sensitive pharmaceutical product

Acknowledgements

The author of this document is Jean Bédard, President and Chief Executive Officer, Infitrak Inc.

Glossary

Component: Any major piece, part or assembly of the main equipment or sub-equipment that does not have its own power supply and could not operate as a stand-alone unit (valves, or switches).

Controller: A device that interprets a mechanical, digital or analogue signal, generated by a sensor, to control an item of equipment or component.

Deviation: For installation qualification: any discrepancy between the installation specifications and the actual (as found) installation. For operational qualification: any discrepancy between the protocol and the actual performed test, test function methodology, testing equipment, and testing material.

Electronic data logging monitor (EDLM): A small portable device that measures and stores temperature readings at predetermined time intervals by means of an electronic sensor. They have programmable alarm capabilities, integrated displays, and can create reports and graphs which may be permanently stored, shared and analysed via proprietary hardware, software, desktop application or through hosted databases.

Installation qualification (IQ): The process of obtaining and documenting evidence that the premises, equipment and supporting systems have been provided and installed in compliance with their design specifications.

Instrument: A device that interprets a mechanical, digital or analogue signal generated by a sensor, and converts it into engineering units (°C, percentage relative humidity, mA, etc.) through scaling.

Key operating parameters: parameters that must be maintained in order to process or produce products with consistent quality attributes and those that may have an impact on the proper operation of the equipment.

Main equipment: Major equipment to be qualified.

Mapping: Documented measurement of the temperature and/or relative humidity distribution within a storage area, including identification of hot and cold spots.

Operational qualification (OQ): The process of obtaining and documenting evidence, under controlled conditions, that the premises, equipment and supporting systems operate in accordance with their design specifications.

Performance qualification (PQ): The process of obtaining and documenting evidence that the premises, equipment and supporting systems, as connected together, will consistently perform in accordance with the approved process method and specifications.

Pharmaceutical product: Any product intended for human use or veterinary product intended for administration to food producing animals, presented in its finished dosage form, that is subject to control by pharmaceutical legislation in either the exporting or the importing state and includes products for which a prescription is required, products which may be sold to patients without a prescription, biologicals and vaccines. Medical devices are not included.[1]

Refrigeration equipment: The term "refrigeration" or "refrigeration equipment" means any equipment whose purpose is to lower air and product temperatures and/or to control relative humidity.

Sensor: A mechanical device (pressure switch, bimetal temperature switch, etc.), or a digital or analogue transducer (limit switch, pressure sensor, temperature sensor, etc.) that generates a mechanical or electrical signal to an instrument or a controller in order to be interpreted.

Service level agreement (SLA): A service level agreement or contract is a negotiated agreement between the customer and service provider that defines the common understanding about materials or service quality specifications, responsibilities, guarantees and communication mechanisms. It can either be legally binding, or an information agreement. The SLA may also specify the target and minimum level performance, operation or other service attributes.[2]

Standard operating procedure (SOP): A set of instructions having the force of a directive, covering those features of operations that lend themselves to a definite or standardized procedure without loss of effectiveness. Standard operating policies and procedures can be effective catalysts to drive performance improvement and improve organizational results.

Storage temperature: The temperature range listed on the TTSPP label, and within the regulatory filings, for long-term storage.

Temperature-controlled: Includes any environment in which the temperature is actively or passively controlled at a level different from that of the surrounding environment within precise predefined limits.

Time and temperature-sensitive pharmaceutical product (TTSPP): Any pharmaceutical good or product which, when not stored or transported within predefined environmental conditions and/or within predefined time limits, is degraded to the extent that it no longer performs as originally intended.

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[1] Definition from WHO/QAS/08.252 Rev 1 Sept 2009. *Proposal for revision of WHO good distribution practices for pharmaceutical products – Draft for comments*.

[2] Definition from International Air Transport Association (IATA). 2013/2014 Perishable cargo regulations (ePCR) & temperature control regulations (eTCR). Geneva: IATA.

Validation: Documented testing performed under highly controlled conditions, demonstrating that processes, methods, and systems consistently produce results meeting predetermined acceptance criteria.[3]

[3] Parenteral Drug Association. PDA Technical Report No. 39: Guidance for temperature controlled medicinal products: maintaining the quality of temperature-sensitive medicinal products through the transportation environment. Berlin: PDA; 2007.

1. Introduction

This technical supplement has been written to amplify the recommendations given in section 4.7 of WHO Technical Report Series No. 961, 2011, Annex 9: *Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products*.[4] The purpose of a temperature mapping study is to document and control the temperature distribution within a storage area.

This document describes how to carry out a systematic mapping procedure in any cold room, freezer room or other temperature-controlled store. It does not cover mapping of small-scale cold chain equipment such as refrigerators or freezers. Generally speaking, these products are independently tested and prequalified for the storage of TTSPPs, although it is still important that the equipment is correctly installed and operated.[5]

The following Technical Supplements are also relevant:

- *Checking the accuracy of temperature control and monitoring devices*
- *Qualification of temperature-controlled road vehicles*
- *Qualification of temperature-controlled storage areas*
- *Temperature and humidity monitoring systems for transport operations.*

1.1 Requirements

All new temperature-controlled storage areas must be temperature-mapped as part of a fully documented verification process, before the installation is commissioned and handed over by the installer. Until this has been done, it is not safe to store TTSPPs in such areas. The temperature mapping procedures should:

- demonstrate the air temperature profile throughout the storage area, when empty and in a normal loaded condition;
- define zones which should not be used for storage of TTSPPs (for example areas in close proximity to cooling coils, cold air streams or heat sources); and
- if required, demonstrate the time taken for temperatures to exceed the designated limits in the event of a power failure.

Depending upon the routine monitoring strategy, subsequent mapping exercises may also be required periodically – for example, every three years – in order to demonstrate continuing compliance. In situations where multiple

[4] http://apps.who.int/medicinedocs/documents/s18683en/s18683en.pdf

[5] See for example: http://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/

fixed monitors provide continuous data, a periodic re-evaluation which assesses all aspects of system performance since the initial mapping may be more appropriate. In addition mapping should be carried out whenever significant modifications are made to the store. Examples include changes in the pattern of use that may increase loading or affect air circulation, or changes to the refrigeration equipment, such as an alteration to the set point. Finally re-mapping may be justified whenever an analysis of temperature and/or humidity monitoring records shows unexplained variability outside normal operating limits.

All mapping exercises should be fully documented in order to demonstrate compliance to management, clients and the regulatory authorities.

1.2 Objectives

The objective of this Technical Supplement is to provide clear guidance on how to conduct a temperature-mapping study in a temperature-controlled storage area. This guidance applies to any space designed for long-term or short-term storage of TTSPPs or other temperature-sensitive products.

1.3 Target readership

This document is relevant to wholesalers, warehouse operators, distributors, dispatchers and third-party logistics providers (3PLs) who store and distribute TTSPPs. The specific target audience within these organizations includes those who have direct responsibility for quality management, for example, quality assurance (QA) managers and operations managers.

2. Guidance

A temperature-mapping exercise is required for any space allocated for the storage and handling of products with a specified labelled storage temperature. This includes freezer rooms, cold rooms, temperature-controlled storage areas, quarantine areas and receiving and loading bays. It may also include laboratories. The permitted temperature ranges in these areas will vary – for example: −25.0 °C to −10.0 °C, 2.0 °C to 8.0 °C, or 15.0 °C to 25.0 °C. Temperature-mapping may also need to be carried out in spaces without active temperature control.

A mapping study establishes the temperature distribution within the zone being mapped and locates hot and cold spots. The data collected provide an essential source of information to ensure that all TTSPPs are correctly stored within their labelled temperature range(s). Mapping may also be used to identify zones where remedial action is needed; for example by altering existing air distribution to eliminate hot and cold spots, or by retro-fitting new air distribution equipment to reduce temperature stratification in high-bay warehouses.[6]

The temperature-mapping process has four stages:

a. Prepare a mapping protocol.
b. Carry out the mapping exercise.
c. Prepare a mapping report.
d. Implement the recommendations by carrying out the remedial and other actions identified in the mapping report. A follow-up mapping exercise may then be needed to verify the effectiveness of the remedial actions.

2.1 Associated materials and equipment

A mapping operation requires a sufficient number of electronic data logging monitors (EDLMs) to ensure that the temperature distribution in the space to be mapped is adequately characterized. In addition, suitable computer equipment and software is needed to store and analyse the data. The selected EDLMs must:

- be technically suitable for the specific mapping task and for the intended operating environment;
- provide a reliable and continuous record of time-temperature data;
- have an appropriate temperature range so that all anticipated temperature extremes can be recorded (e.g. from −30 °C to +60 °C);

[6] High bay pallet racking stores are particularly susceptible to temperature stratification. It is essential that such stores are comprehensively mapped over their full working height.

- have a user-programmable data sampling period, allowing time intervals to be set in the range from 1 minute to 15 minutes (maximum) and sufficient memory for the intended length of the study and the chosen recording interval;
- have a US National Institute of Standards and Technology (NIST)-traceable 3-point calibration certificate with a guaranteed error of no more than ± 0.5 °C at each calibration point;
- enable the recorded time-temperature data to be downloaded to a computer system for subsequent analysis;
- have data storage and analytical software that complies with applicable regulatory requirements (for example: 21 CFR part 11).[7,8,9]

2.2 The mapping protocol

A detailed and comprehensive protocol should be prepared, reviewed and approved before the mapping exercise begins. A well-designed protocol will help ensure that the mapping study is correctly carried out. With suitable adjustments or options to cover the full range of temperature regimes, a standard protocol can be used to map any storage area in the facility.

The mapping protocol should contain the following sections:

a. Approval page and change control history
b. Acronyms and glossary
c. Description and rationale
d. Scope
e. Objectives
f. Methodology
g. Mapping report template
h. Annexes as needed, including templates for the mapping report.

The content of each of these sections is detailed below.

2.2.1 Approval page and change control history

Include a standard template for recording approvals and changes to the document. Table 1 provides an example.

[7] United States Pharmacopeia: Chapter 1079: Good storage & shipping practices.
[8] United States Pharmacopeia: Chapter 1118: Monitoring devices – time, temperature and humidity.
[9] US Food & Drug Administration (FDA): 21 CFR part 11.

Table 1
Example of standard template for approvals and changes to the document

Approvals	Name	Date	Signature
Authorized by:			
Reviewed by:			
Revised by:			
Original author:			

Version history

No.	Date	Description of change	Reason for change
1		Original	
2			
3			
4			
5			

If the protocol has been prepared by a qualified third party, it should be authorized by the responsible person within the commissioning organization.

2.2.2 Acronyms and glossary

Define the acronyms and technical terms used in the protocol.

2.2.3 Description and rationale

Describe the installation to be mapped and outline the reasons for carrying out the exercise.

2.2.4 Scope

Clearly define the scope and purpose of the mapping study. The fundamental purpose is to identify temperature deviations affecting the chosen storage area(s) at the time the study is conducted, so that remedial action can be taken.

Depending upon the circumstances, a temperature-mapping study may be carried out in an empty storage area – for example during operational qualification of a new cold room – or in a storage area where TTSPPs are already being kept – for example after alterations have been made to an existing cold room. See Technical Supplement: *Qualification of temperature-controlled storage areas*.

If storage areas are affected by seasonal temperature variations, at least two temperature-mapping studies may be needed in each area to observe the effect of seasonal variation. Typically, one should be carried out during the warmest season and one during the coldest season. This will represent the worst-case scenarios and will establish whether the mapped area is able to maintain stable temperatures throughout the year. Typically, two-season mapping is not necessary for cold rooms and freezer rooms.

The results of the two studies can be compared so that systematic issues related to the season can be identified. These seasonal effects need to be separated from any other site-specific issues arising at the times when the comparative studies are done.

2.2.5 Objectives

The detailed objectives of the study should be clearly defined, and should include:

- Mapping of temperature variations within the selected storage areas. Typically these areas include freezer rooms, cold rooms and warehouses. Packing areas, loading bays and other areas in which temperature-sensitive products are stored, or are temporarily held when in transit may also be mapped and monitored, although temperatures in these areas are likely to fluctuate when doors are opened.
- Measuring temperature variations at each location within the chosen area, by day of the week and time of day.
- Documenting high and low temperature fluctuations caused by the environmental control systems operating at the time of the study – for example, heating, cooling and ventilation.
- Identifying potential airflow issues that may be the cause of temperature variations.
- Recommending where TTSPPs can safely be stored in the mapped area and where they must *not* be stored. These recommendations should take account of any temperature deviations identified during the study as well as the approved temperature range(s) for the products being stored in the area.
- Identifying the best places to locate temperature sensors for routine monitoring in circumstances in which a monitoring system is to be installed. If a monitoring system is already installed, identify the best places to relocate temperature sensors (if necessary).
- Making recommendations for any remedial actions needed to overcome the problems identified in the study.

2.2.6 Methodology

The methodology for conducting a temperature mapping study involves the following steps. It is important to note that steps 1 to 5 must be completed *before* the mapping protocol can finally be approved.

Step 1 – select EDLMs: Select the type of EDLM to be used. Choose a device that has sufficient memory for the intended duration of the study and the selected recording interval. As noted in section 2.1, all loggers must have a NIST-traceable 3-point calibration completed and valid (within the current year), and have an error of no more than ± 0.5 °C at each calibration point. Valid calibration certificates for each of the data loggers used in the study must be included in the mapping report. Some EDLMs with built-in batteries and a limited life are not designed to be recalibrated; otherwise calibration should be done annually.

Calibration temperature points used for the calibration of EDLMs should cover the required temperature range for each of the areas being studied. In general there should be one calibration point below the low end of the range, one calibration point in the middle of the range, and one calibration point above the high end of the range.

To ensure consistency, use only one type of device per mapping study. Provide a link to the manufacturer's user instructions so that those responsible for programming and reading the devices understand how to perform these actions correctly.

It may be appropriate to include an EDLM device that is able to monitor door openings, programmed so that the readings on the temperature monitoring devices can be aligned with door opening times.

Step 2 – designate the mapping team: Identify and list the team members. Record their signatures and initials so that signed records can be traced back to the person who prepared the document. Ensure that all team members receive the training needed to perform their assigned tasks.

Step 3 – survey the site: Conduct a site survey of the area(s) to be mapped. The following information is required for each thermally separate area being mapped:

- length, width and height;
- drawing of each area, showing elements, such as shelving or pallet racking, that may have an effect on the even heating or cooling of the space and which may affect its temperature stability. The shelving or pallet racking will be used to place the EDLMs, so it is important to record these components accurately;
- the location of heating and cooling components, including air distribution outlets and/or ceiling fans;
- the location of existing temperature recording sensors and temperature controlling sensors.

Step 4 – establish acceptance criteria: The protocol should define the required acceptance criteria, based on the type of TTSPPs being stored, clearly stating the temperature limits that are allowable within the area to be mapped – for example: +2.0 °C to +8.0 °C or +15.0 °C to +25.0 °C. However, some mapping studies may be performed without predefining any acceptance criteria. This type of study can be used to establish the types of product that can safely be stored in a specific space, and what remedial actions might have to be taken to improve the thermal performance of the space in order to optimize its use.

If the temperature-mapping study is designed to include door opening(s), this should be stated in the study methodology and acceptance criteria. Also the door opening parameters (frequency and duration) should be defined. The temperature should be maintained within the defined temperature limits except for a maximum of 30 minutes following the door opening.

Step 5 – determine EDLM locations: Use the site survey to mark the required locations of the EDLMs. A risk-based approach can be applied to define these locations. However, the following guidelines will help determine the number and location of the EDLMs required.

Length and width: EDLMs should be arranged in a grid fashion along the width and length of the area so that the area is reasonably covered, with EDLMs located every 5–10 metres.[10] The chosen sensor grid should take account of:

- the layout of the area (e.g. whether it is square or includes alcoves);
- the degree to which shelving and products may affect airflow;
- where products are placed. The positions of EDLMs should coincide with locations where TTSPPs are actually stored or planned to be stored. For example, it may be unnecessary to fit EDLMs in areas such as the upper part of high loading bays;
- other considerations that may warrant more or fewer EDLMs.

Height: At each point on the grid, arrange EDLMs vertically as follows:

- If the ceiling height is 3.6 metres or less, position EDLMs directly above one another at high, medium and low level (e.g. one EDLM at floor level, one at 1.2 metres and one EDLM at 3.0 metres.
- If the ceiling height is greater than 3.6 metres, EDLMs can be arranged in vertical arrays at the bottom, middle (multiple) and top of the space. For instance, for a storage area 6 metres in height, EDLMs can be positioned in each grid location at heights of 0.3 metres, 1.8 metres, 3.6 metres and 5.4 metres.

[10] In very large facilities, this can be up to 20 or 30 metres.

Give each logger location a unique ID. It may be helpful to use a generic floor plan or diagram to decide where each logger should be positioned – see Figures 1 and 2. Figure 1 shows part of a pallet racking cold room with an adjoining temperature-controlled packing area. Figure 2 shows a small walk-in cold room with products stored on shelves – the shelves (on which the EDLMs should be placed) have been omitted for clarity. If products are also stored on pallets in the centre of the room, additional EDLMs should be placed in this location.

Figure 1
Typical location of data loggers in a pallet racking storage area

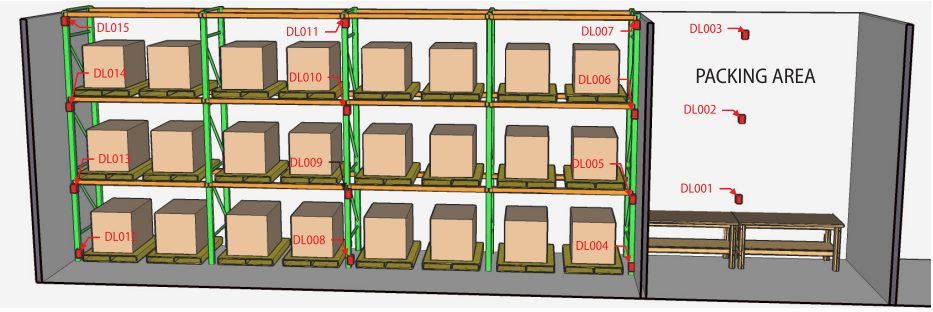
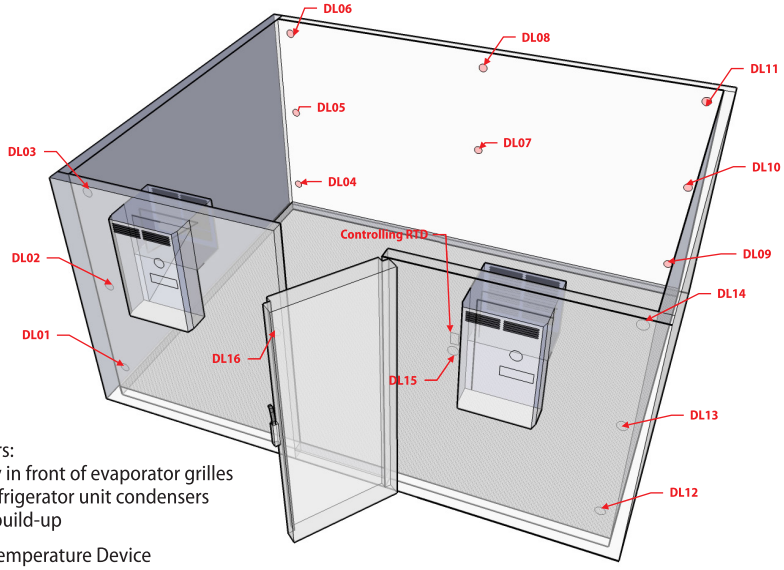


Figure 2
Typical location of data loggers in a walk-in cold room



Additional sensors:
DL17, 18: Directly in front of evaporator grilles
DL19, 20: Near refrigerator unit condensers
to monitor heat build-up

RTD: Recording Temperature Device

Step 6 – record EDLM, monitoring sensors and thermostat locations: Record the EDLM locations on a temperature data logger location table – see example in **Annex 1.1**. Also record the location identification and set point for each thermostat in the storage area – see example in **Annex 1.2**.

Step 7 – label and program the EDLMs: Label each EDLM with a unique ID, taken from the temperature data logger location table. Enter the manufacturer's serial number on the temperature data logger location table (**Annex 1.1**). Recording the serial number ensures that the device can be traced to its calibration certificate. Program each device, ensuring that the recording interval is the same – typically this should be set between 1 and 15 minutes. Set the same start time for all units. This is *essential*; otherwise the readings downloaded from the individual devices cannot be time-correlated. Make sure that the start time setting allows enough time for all the units to be fixed in position before recording begins.

Step 8 – fix EDLMs in position: Fix the EDLMs in position making sure that each one is placed exactly as shown on the temperature data logger location table and drawing. Position and fasten the devices so that they cannot be damaged or displaced during the course of routine store operations. Ensure that sufficient time is allowed for the EDLMs to be conditioned to the ambient temperature before the mapping exercise begins.

Step 9 – conduct the mapping exercise: There is no formal time limit for a mapping study. Typically, for warehouses and other ambient storage areas, it should be run for a minimum of seven consecutive days – including five working days and two weekend days. For temperature-controlled equipment which is not critically affected by diurnal or seasonal variations in ambient temperature (e.g. freezer rooms and cold rooms), the mapping study should be run for between 24 and 72 hours, or longer if justified. If the room is fitted with duplicate refrigeration units – with or without automatic changeover – it is essential to map temperatures over a period that includes the operation of both units running separately; preferably for a similar time period. The temperature distribution in the room may vary depending upon which system is running.[11]

At the end of the study, collect the EDLMs and double-check their serial numbers and locations against the installation notes.

Step 10 – download and consolidate the data: Download the EDLM readings and consolidate the data for the analysis described in section 2.4.

[11] Duplicate units are sometimes set up so that one system runs most of the time and the other only cuts in at a higher temperature. This ensures that the second unit runs infrequently and therefore reduces the chances of a simultaneous breakdown.

2.2.7 Mapping report template

The mapping report should include the following sections:

a. *Introduction:* a description of the objectives of the mapping study.
b. *Summary:* a summary and discussion of the results organized in the sequence set out in the mapping protocol, including a summary of deviations (if any).
c. *Conclusions and recommendations:* a general conclusion for all verifications and observations indicating the acceptability of the equipment for operation. Recommendations and remarks can be incorporated in this section.
d. *Report annexes:* The annexes to the report should contain the following:
   - the site survey, showing EDLM locations;
   - the raw data, presented using the appropriate test data sheet format – see **Annex 1**.
   - spreadsheet data and related temperature graphs for every EDLM used in the mapping exercise;
   - raw results of the data analysis, including hot and cold spots;
   - key documents and notes prepared during the mapping exercise, together with any other supporting material;
   - deviation reports, including corrective and preventive actions (CAPA) forms, if required: this may include a recommendation for partial or total re-mapping;
   - calibration certificates for all EDLMs used.

2.3 Conducting the mapping exercise

Conduct the mapping exercise in accordance with the protocol. Ensure that all relevant personnel in the store are fully briefed so as to avoid inadvertent disruption or deactivation of the EDLMs. At the end of the study period, collect all the devices, deactivate them, and download the data for analysis.

If the mapping exercise does not include automatic logging of door openings, an access log should be kept during the study so that any temperature excursions caused by personnel movement can easily be identified. Power outages should similarly be recorded.

2.4 Analysing the data and preparing the mapping report

The mapping report should follow the general template outlined in section 2.2.7. The following subsections outline the data analysis process that precedes the writing of the report.

2.4.1 Preliminary analysis

Analyse the overall temperature stability of the study area and identify the variations that occur. Compare the measured temperatures against the acceptance criteria. The analysis of the overall temperature stability should consider factors such as:

- the ability of the environmental control systems to maintain temperatures within the acceptance criteria limits (if any);
- the overall temperature stability of the area being monitored, and the range in fluctuations it experiences over the study period;

The analysis of temperature variations should consider factors such as:

- variations experienced by individual EDLMs;
- temperature variations along vertical and horizontal planes, depending on the size of the area, and distribution of EDLMs;
- temperature variations in locations close to heating and cooling components, as compared to those farthest away from these units.

2.4.2 Minimum and maximum temperatures and hot and cold spots

A mapping study measures temperature fluctuations. From these data, the analyst can identify the minimum and maximum temperatures that occur in the mapped area during the study period.

Minimum temperature refers to the lowest temperature recorded in the mapped space over the study period; maximum temperature refers to the highest value recorded during the same period. Either or both of these temperatures may be outside the specified acceptance criteria for the store. **Annex 1.3** shows a standard form that can be used to record these data, together with the mean values discussed in section 2.4.4.

A cold spot refers to the lowest temperature(s) recorded in the space over the study period, but these lowest temperature(s) remain within the specified temperature range (e.g. cold spots identified between +15.0 °C and +17.5 °C in a room with a specified temperature range of +15.0 °C to +25.0 °C).

A hot spot refers to the highest temperature(s) recorded in the area studied over the study period, but these highest temperature(s) remain within the specified temperature range (e.g. hot spots identified between +23.0 °C and +25.0 °C in a room with a specified temperature range of +15.0 °C to +25.0 °C).

The purpose of determining hot and cold spots is to identify the locations where the monitoring system sensors should preferentially be located. Hot and cold spots need to be determined seasonally as they may be significantly different in summer and in winter. *Note:* It is also important to look at the overall high and low trends rather than just the highest and lowest temperatures. Average values can be useful to help confirm true hot and cold spots.

2.4.3 Mean temperatures

Arithmetic mean temperatures can be applied to each of the separate areas being monitored over the study period. These mean temperature measurements can be useful in storage areas where the temperature fluctuates with time in a repetitive pattern (e.g. sinusoidal fluctuation or periodic peak occurrence) and where the temperature also varies depending upon the location of the data logger.

The use of mean temperatures enables the analyst to determine a mean temperature for a given EDLM location over the study period. These figures can then be compared between all the EDLM locations within the space. This enables the analyst to identify the locations where the mean temperatures are consistently lower or higher, an outcome that cannot be achieved simply by comparing individual data points.

In Figure 3, the minimum and maximum temperatures have been calculated from the data points for two locations (EDLM-1 and EDLM-2). The plot shows that the EDLM-2 location is clearly cooler on average, although there are also times when the two locations experience similar low and high temperatures.

Despite the usefulness of mean figures, it is essential not to disregard the actual temperature data because these figures reveal the occurrence of temperatures that are outside the specified storage temperature range.

2.4.4 Interpreting the results and making recommendations

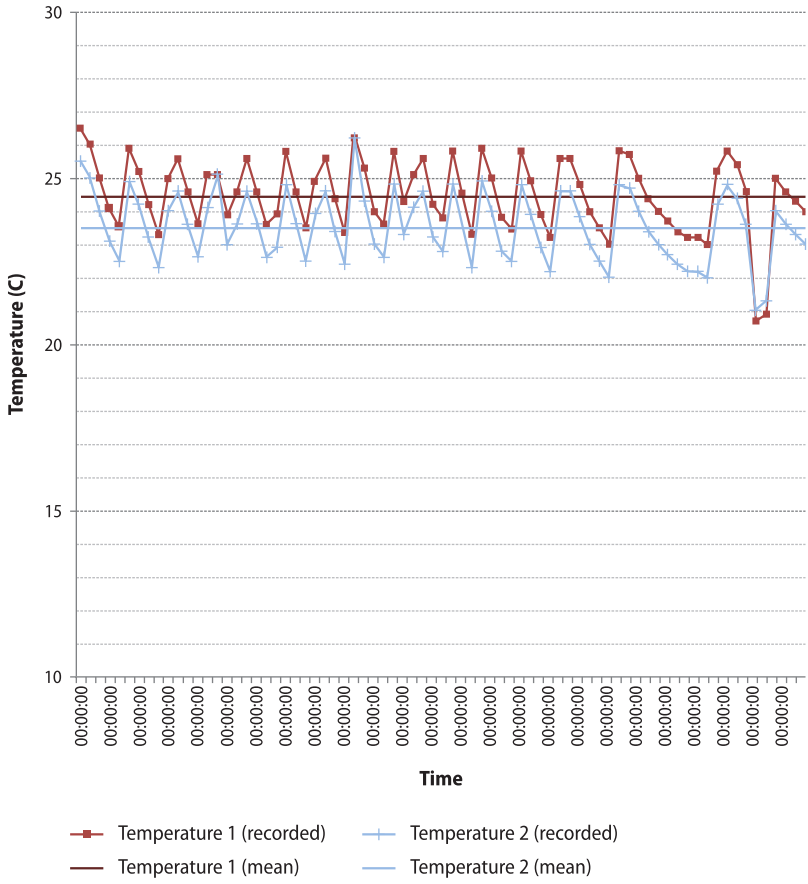
This section outlines how to interpret the results, and how to use these results to support the report's recommendations:

- Document the internal temperature variations observed within the space, taking account of the EDLM reading errors specified by the device manufacturer.
- Use the data analysis to assess the overall temperature stability of the mapped space in relation to the stated acceptance criteria (if any).
- Assess the overall thermal stability of the space during the study period with specific reference to the high and low temperatures experienced.
- List the factors that explain the observed temperature variations. For example, the location of the heating and cooling components and doors.[12]

[12] Thermal stability will be affected by three main factors: the external ambient temperature; the type of building construction and the performance of the heating or cooling system. The first two factors are less significant for freezer rooms and cold rooms built inside an existing structure.

- Assess consistent and inconsistent temperature variations and fluctuations within the space in terms of their potential impact on product storage.
- Based on the observed temperature fluctuations at the mapped locations within the space, make recommendations about the optimum storage locations for highly sensitive products, and those that are less sensitive.
- Based on the observed temperature fluctuations at the mapped locations within the space, make recommendations on the optimum location of the temperature sensor(s) used for routine temperature monitoring and the control sensors used to activate the heating and cooling systems.

Figure 3
Use of mean temperatures



2.4.5 Report auditing

The report's content, including data sheets, results, spreadsheets and graphs should be audited and peer-reviewed by a competent independent person. The reviewer should confirm, approve and sign the major reported test and verification results and the recommendations arising from these results. If the report has been prepared by a qualified third party, it should be approved by the person who commissioned the study.

2.5 Implementing the mapping report recommendations

The final outcome and purpose of a mapping exercise is the implementation of the report recommendations. A detailed discussion of implementation is outside the scope of this document, but it could include any of the following outcomes:

- A drawing or diagram showing where TTSPPs can safely be stored in the space that has been mapped: It is possible that there may be some zoning involved. For example, products that are not affected by freezing could be allocated to parts of a cold room where the mapping study has shown some freezing risk.
- Allocation of pallet bays to specific categories of TTSPP on the warehouse management system in order to control where stocks are positioned.
- Repositioning of temperature monitoring sensors and/or environmental control sensors.
- Adjustment of air outlets to reduce temperature stratification and/or minimize cold and hot spots.
- Upgrading of mechanical systems to improve temperature control and performance.
- A decision to use the space for other purposes because it is unsuitable for storage of TTSPPs.

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Annex 1

Test data sheets

The following sections show examples of the type of data collection forms used in a mapping exercise.

A1.1 Test data sheet: temperature data logger locations

Data logger ID number	Data logger serial number	ID number on schema	Mounting height (metres)	Description/comments
DL-001		1	0.3	
DL-002		2	2.8	
DL-003		3	5.4	
DL-004		4	0.3	
DL-005		5	2.8	
DL-006		6	5.4	
DL-007		7	0.3	
DL-008		8	2.8	
DL-009		9	5.4	
DL-010		10	0.3	
DL-011		11	2.8	
DL-012		12	5.4	
DL-013		13	0.3	
DL-014		14	2.8	
DL-015		15	5.4	
DL-016		16	0.3	
DL-017		17	2.8	
DL-018		18	5.4	
DL-019		19	0.3	

Table *continued*

Data logger ID number	Data logger serial number	ID number on schema	Mounting height (metres)	Description/comments
DL-020		20	2.8	
DL-021		21	5.4	
DL-022		22	0.3	
DL-023		23	2.8	
DL-024		24	5.4	

A1.2 Test data sheet: temperature distribution

Thermostat information		
Location	**Set point**	**Comment**
Near entrance door #1	20 °C	Locked
Near loading dock #4	20 °C	Locked

A1.3 Test data sheet: temperature distribution

Data logger ID number	Minimum temp. recorded (°C)	Maximum temp. recorded (°C)	Mean temp. (°C)	Within range?		Inspected by	Date
				Yes	No		
DL-001	18.6	22.4	20.5	☒	☐	JB	
DL-002				☐	☐		
DL-003				☐	☐		
DL-004				☐	☐		
DL-005				☐	☐		
DL-006				☐	☐		
DL-007				☐	☐		
DL-008				☐	☐		
DL-009				☐	☐		
DL-010				☐	☐		
DL-011				☐	☐		
DL-012				☐	☐		
DL-013				☐	☐		
DL-014				☐	☐		
DL-015				☐	☐		
DL-016				☐	☐		
DL-017				☐	☐		
DL-018				☐	☐		
DL-019				☐	☐		
DL-020				☐	☐		
DL-021				☐	☐		
DL-022				☐	☐		
DL-023				☐	☐		
DL-024				☐	☐		

Table *continued*

Mapping period starts at (date/hour):	
Mapping period ends at (date/hour):	
Checked by:	Date:

Revision history

Date	Change summary	Reason for change	Approved