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Supplement 8

Temperature mapping of storage areas

存贮区域温度分布研究

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

WHO 第961号技术报告附录9：时间温度敏感药品贮运指南

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Abbreviations 缩写

3PL	Third Party Logistics (provider)	第三方物流（服务商）
CAPA	Corrective and Preventive Action (procedures)	纠正预防措施（程序）
EDLM	Electronic Data Logging Monitor	电子数据记录监测仪
GMP	Good Manufacturing Practice	优良生产规范
IQ	Installation Qualification	安装确认
NIST	National Institute of Standards and Technology (US)	国家标准技术研究所（美国）
SLA	Service Level Agreement	服务水平协议
SOP	Standard Operating Procedure	标准操作规程
TTSPP	Time and Temperature-Sensitive Pharmaceutical Product	时间和温度敏感药品

Glossary 术语（略）

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 standalone unit (valves, switches, etc.).

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

Deviation: For IQ: Any discrepancy between the installation specifications and the actual (as found) installation. For OQ: Any discrepancy between the protocol and the actual performed test, test function methodology, testing equipment, testing material etc.

Electronic Data Logging Monitor (EDLM): A small portable device that measures and stores temperature at pre-determined 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, % RH, 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.

[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*.

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 pre-defined limits.

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

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

[2] Definition from IATA. *2013/2014 Perishable Cargo Regulations (ePCR) & Temperature Control Regulations (eTCR)*
[3] PDA Technical Report No. 39: *Guidance for Temperature Controlled Medicinal Products: Maintaining the Quality of Temperature-Sensitive Medicinal Products through the Transportation Environment*, 2007.

1. Introduction 概述

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.

本技术补充文件是为了细化WHO第961号技术报告附录9：时间温度敏感药品贮运指南第4.7部分中给出的建议。进行温度分布研究的目的是记录和控制一个存贮区域内的温度分布。

This document describes how to carry out a systematic mapping procedure in any cold room, freezer rooms or other temperature-controlled store. It does not cover mapping of small scale cold chain equipment such as refrigerators of 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].

本文描述了在低温房、冷冻房或其它温控存贮区域如何系统地实施温度分布研究。它不包括小型冷链设备，如冰箱和冰柜的温度分布研究。一般来说，这些产品应在存贮TTSPP之前进行独立测试和预确认，设备的正确安装和运行也是很重要的。

The following Technical Supplements are also relevant:

以下技术补充文件与本文相关：

- *Checking the accuracy of temperature control and monitoring devices.*
- *温度监控装置的准确度检查*
- *Qualification of temperature-controlled road vehicles.*
- 温度控制运输卡车的确认
- *Qualification of temperature-controlled storage areas.*
- *温度控制存贮区域的确认*
- *Temperature and humidity monitoring systems for transport operations.*
- *运输中的温湿度监测系统*

1.1 Requirements 要求

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:

在安装对象调试完成并移交之前，所有新的温控存贮区域必须进行温度分布研究，将其作为全面记录的确认过程的一部分。在温度分布研究完成之前，在该区域存贮TTSPP被认为是不安全的。温度分布研究过程应：

- Demonstrate the air temperature profile throughout the storage area, when empty and in a normal loaded condition;

[4] http://apps.who.int/medicinedocs/documents/s18683en/s18683en.pdf
[5] See for example: http://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/

- 描绘出整个存贮区域的空气温度概况，包括空置时和正常装载情况下
- 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
- 确定不能用于TTSPP存贮的区域（例如，接近冷却盘管、冷气或热源的地方），以及
- If required, demonstrate the time taken for temperatures to exceed the designated limits in the event of power failure.
- 必要时，找出断电时温度超出设定限度的时间长度

Depending upon the routine monitoring strategy, subsequent mapping exercises may also be required on a periodic basis – for example, every three years – in order to demonstrate continuing compliance. In situations where multiple fixed monitors provide continuous data, a periodic re-evaluation which assesses all aspects of system performance since initial mapping may instead be 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 a re-mapping exercise may be justified whenever an analysis of temperature and/or humidity monitoring records show unexplained variability outside normal operating limits.

根据常规监测策略的不同，可能还需要定期进行后续温度分布研究---例如，每3年---以证明其持续符合性。如果有多个固定的监测器可以提供连续的数据，则可以进行对初始的温度分布研究后系统的各方面性能进行定期评估来替代定期后续温度分布研究。另外，如果对存贮区域有重大的改造，则需要进行温度分布研究。例子包括改变使用方式可能会增加装载量或影响空气循环，改变冰冻设备，例如改变设定温度。最后，如果温度和/或温度监测记录分析显示有超出正常运行限度的未知原因的变化，则要论证是否需要重新进行温度分布研究。

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

所有温度分布研究均应全面记录，以证明其符合管理、客户和法规机构的要求。

1.2 Objectives 目的

The objective of the 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.

本技术补充文件的目的是清楚地指导如何在一个温度受控存贮区域内实施温度分布研究。本指南适用于任何设计用于长期或短期存贮TTSPP或其它温度敏感药品的空间。

1.3 Target readership 目标读者

This document is relevant to wholesalers, warehouse operators, distributors, dispatchers and 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.

本文件相关方为存贮和销售 TTSPP 的批发商、仓库营运方、销售方、发货方和 3PL。这些组织内特定的读者包括对质量管理有直接责任的人员，例如 QA 经理和营运经理。

2. Guidance 指南

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, 15.0°C to 25.0°C, etc. Temperature mapping may also need to be carried out in spaces without active temperature control.

所有用于存贮和处理有特定存贮温度要求的药品的空间均需要进行温度分布研究。其中包括冷冻间、低温间、温度受控存贮区域、待检区和收卸货区，还可能包括化验室。在这些区域内允许的温度范围可能会有差别—例如，-25.0°C至-10.0°C、2.0°C至8.0°C、15.0°C至25.0°C等。没有主动温度控制的区域可能也需要实施温度分布研究。

A mapping study establishes the temperature distribution within the zone being mapped and it locates hot and cold spots. The collected data provides 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 needs to be taken; 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] .

温度分布研究可以建立起所研究区域内的温度分布模型，找出最冷点和最热点。所收集的数据可能提供基本的信息来源，以保证所有TTSPP都能正确的存贮在其标示的温度范围内。温度分布研究还被用于辨别需要采取补救措施的区域，例如，通过改变现有的气流分布来消除最冷和最热点，或通过改装新的空气分配设备来减少高架仓库里的温度分层。

A temperature mapping exercise involves a four stage process, as follows:

进行温度分布研究包括以下四个步骤：

a. Prepare a mapping protocol. 起草一个温度分布研究方案

b. Carry out the mapping exercise. 实施温度分布研究

c. Prepare a mapping report. 起草温度分布研究报告

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. 实施补救措施来弥补温度分布研究报告中识别出的问题。可能之后还需要进行温度分布研究来确认补救措施的有效性。

2.1 Associated materials and equipment 辅助物料和设备

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:

进行温度分布研究操作需要有足够数据的电子数据记录仪（EDLM）来保证所研究的空间里的温度分布的特征得到充分的分析。另外，还需要有适当的计算机设备和软件来存贮和分析数据。所选择的

[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. 高位货架的温度情况尤其要引起关注，很有必要对这种存贮区进行全面温度分布研究，覆盖所有工作高度。

EDLM必须：

- Be technically suitable for the specific mapping task and for the intended operating environment;
- 技术角度适用于特定的温度分布研究任务，可用于所需的操作环境
- Provide a reliable and continuous reliable record of time-temperature data;
- 可以持续可靠地记录时间温度数据
- Have an appropriate temperature range so that all anticipated temperature extremes can be recorded (e.g. from -30°C to +60°C)
- 具有适当的温度范围，可以记录所有涉及的极端温度（例如，从-30°C到+60°C）
- Have a user-programmable data sampling period, allowing time intervals to be set in the range from one minute to 15 minutes (maximum) and with sufficient memory for the intended length of the study and the chosen recording interval;
- 数据采样间隔可以由用户编程，读数时间间隔可以设定在1-15分钟（最大），具有足够的内存，可以存贮所需研究的时间长度及所选择的记录间隔的数据
- Have a NIST- traceable 3-point calibration certificate with a guaranteed error of no more than ± 0.5°C at each calibration point.
- 有一个NIST可追溯3点校正证书，其中保证其各校正点的误差不超过0.5°C
- Allow the recorded time-temperature data to be downloaded to a computer system for subsequent analysis;
- 记录的时间和温度数据可以下载至计算机系统用于随后的分析
- Have data storage and analytical software that complies with applicable regulatory requirements (for example: 21 CFR part 11)[7],[8],[9].
- 具有数据存贮和分析软件，符合可适用的法规要求（例如21CFR第11部分）

2.2 The mapping protocol 温度分布研究方案

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.

应起草一份详细完整的方案，在开始实施前审核和批准。一个设计完善的方案有助于保证温度分布研究正确的实施。可以制订一个标准的方案用于对场所内所有的存贮区域进行温度分布研究，在使用时对其进行适当的调整或选择以覆盖全部的温度范围即可。

The mapping protocol should contain the following sections: 温度分布研究方案应包括以下部分

a. Approval page and change control history. 批准页和变更历史

b. Acronyms and glossary. 术语

c. Description and rationale. 描述和科学依据

d. Scope 范围

[7] United States Pharmacopoeia: Chapter 1079: *Good Storage & Shipping Practices*.
[8] United States Pharmacopoeia: Chapter 1118: *Monitoring Devices – Time, Temperature and Humidity*.
[9] US Food & Drug Administration (FDA): *21 CFR part 11*.

e. Objectives. 目的

f. Methodology 方法

g. Mapping report template. 温度分布研究的报告模板

h. Annexes as needed, including templates for the mapping report 需要时加入附录，包括分布研究报告的模板

The content of each of these sections is detailed below.

每个部分的内容详述如下：

2.2.1 Approval page and change control history: 批准页和变更历史

Include a standard template for recording approvals and changes to the document. The following is an example:

包括一个记录对文件的批准和变更的标准模板。以下是一个例子：

Approvals 批准	**Name 姓名**	**Date 日期**	**Signature 签名**
Authorized by: 起草			
Reviewed by: 审核			
Revised by: 修订			
Original author: 原始作者			

Version history 版本历史

No 序号	Date 日期	Description of change 变更描述	Reason for change 变更理由
1		Original 新编	
2			
3			
4			

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

如果已经由有资质的第三方起草了方案，则应由调试组织里的责任人批准。

2.2.2 Acronyms and glossary: 术语

Define the acronyms and technical terms used in the protocol.

定义方案中所使用的技术术语。

2.2.3 Description and rationale 描述和理论依据

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

描述要进行温度分布研究的对象，简要说明实施该研究的理由。

2.2.4 Scope: 范围

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 being conducted, so that remedial action can be taken.

清楚界定温度分布研究的范围和目的。基本目的是找出影响所选择的存贮区域在实施研究期间的温度偏差，从而可能采取弥补措施。

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 carried out in an existing cold room. See Technical Supplement: *Qualification of temperature-controlled storage areas*.

根据环境不同，温度分布研究可以在空载存贮区域进行----例如，在新的低温间运行确认中---也可以在已存贮有TTSPP的存贮区域进行-----例如在对已有低温间进行改变后。参见技术补充文件：温控存贮区域的确认。

If storage areas are affected by seasonal temperature variations, at least two temperature mapping studies may need to be carried out in each area in order to observe the effect of seasonal variation. Typically, one should be carried out during the warmest season and one during the coldest season because this will represent the worst-case scenario. This 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.

如果存贮区域受到季节温度波动的影响，则需要在各区域至少进行2次温度分布研究，以观察季节性波动产生的影响。一般来说，一个在最冷季节另一个在最热季节，因为这样可以代表最差情形。这样可以知道进行温度分布研究的区域是否可以在全年维持稳定的温度。一般来说，对于低温间和冷冻间不需要做两季研究。

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

两季研究要进行比较，找出与季节有关的问题。这些季节性影响要与其它在比较性研究实施时发现的与场所相关的问题进行区别。

2.2.5 Objectives: 目的

Clearly define the detailed objectives of the study, as follows:

清楚界定研究的详细目的，如下：

- Mapping 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.
- 对所选择的存贮区域内的温度变化分布情况进行研究。一般来说这些区域包括冷冻房、低温房和仓库。包装区、装货区和其它温度敏感产品存贮的区域，或在转运期间临时放置的区域可能也需要进行温度分布研究和监测，这些区域的温度可能会因为开门而有波动。
- Measuring temperature variations at each location within the chose area, by day of the week, and time of day.
- 在所选择的区域内，测量每个点的温度波动，一周中的指定的天，以及每天指定的时间点。
- 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.

- 记录研究期间由于环境控制系统运行所引起的高低温波动，例如，加热、冷却和通风。
- Identifying potential airflow issues that may be the cause of temperature variations.
- 找出可能引起温度差异的潜在的气流问题。
- Recommending where TTSPS 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.
- 建议TTSPP可以安全存贮在进行研究的区域内的位置，以及不能存贮的位置。这些建议应考虑在研究中发现的所有温度偏差，以及要存贮在区域内的所批准的产品温度范围。
- Identifying the best places to locate temperature sensors, for routine monitoring, in circumstances in which a monitoring system is installed. If a monitoring is already installed, identify the best places to re-locate temperature sensors (if necessary).
- 如果要安装监测系统的话，找出放置常规监测温度探头的最佳位置。如果已经安装了监测系统，找出最佳位置重新定位安装温度探头（必要时）。
- Making recommendations for any remedial actions needed to overcome the problems identified in the study.
- 对于在研究中发现的问题，给出弥补措施建议。

2.2.6 Methodology 方法学

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

以下步骤列出了实施温度分布研究的方法学。要注意第1-5步必须在温度分布研究方案最终批准之前就完成。

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 1.4, 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 re-calibrated; otherwise calibration should be done annually.

第1步---选择EDLM。选择要使用的EDLM类型。选择有足够内存的装置来存贮研究时长和记录间隔所产生的数据。如1.4部分所提到，所有数据记录仪必须完成可追溯到NIST的3点校正并在有效期内（在当前年），其误差在每个校正点不应超过± 0.5°C。研究中所用的每个数据记录仪的有效的校正证书均应包括在分布研究报告中。有些EDLM具有内置电池，其设计为有限使用时间长度，不需要进行再次校正的，否则就要每年校正。

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.

用于EDLM校正的校正温度点应覆盖研究区域所需的温度范围。一般来说，应有一个校正点低于范围

的下限，一个校正点在范围中间，一个校正点高于范围的上限。

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.

为了保证一致性，在一个温度分布研究中只能使用一种类型的装置。要提供生产商的使用手册，这样负责实施和读取装置的人能知道如何正确实施这些活动。

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.

最好能有一个EDLM装置能够监测开门情况，其编程方式最好能让开门时间点可以读到温度监测数据。

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.

第 2 步---组成研究小组：找到并列出小组成员。记录其签名和首字母，这样签名记录可以追踪到准备文件的人。确保所有小组成员均受到实施其所接受任务的培训。

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:

步3步：现场调查：对于要进行研究的区域进行现场调查。每个要进行研究的区域均应提供以下信息：

- Length, width and height dimensions.
- 长度、宽度和高度尺寸。
- 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 have an effect on its temperature stability. The shelving or pallet racking will be used to place the EDLMs, so it is important to record these components accurately.
- 每个区域的平面图，显示出要件，例如货架或托盘架，这可能对空间的致冷和加热产生影响，从而对其温度稳定性产生影响。货架或托盘架将用来放置EDLM，因此对这些部件进行准确记录非常重要。
- The location of heating and cooling components, including air distribution outlets and/or ceiling fans.
- 加热和致冷组件，包括空气送风出口和/或天花板风机位置。
- The location of existing temperature recording sensors and temperature controlling sensors.
- 已有温度记录感应器和温度控制感应器的位置。

STEP 4 – establish acceptance criteria: Generally speaking the protocol should define the required acceptance criteria, based on the type of TTSPs 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 pre-defining 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 carried out to improve the thermal performance of the space in order to optimize its use.

第4步---设定可接受标准：一般来说，方案应界定所需要的可接受标准，依据是要存贮的TTSPP。在

其中要清楚说明进行温度分布研究的区域所允许的温度限度---例如：+2.0°C 到 +8.0°C 或+15.0°C到+25.0°C。但是有些温度分布研究在实施时可能并没有预定的可接受标准。这类研究可以用于确定在特定的空间内能安全存贮的产品类型，以及必须采取什么弥补措施来改善空间的热学性能，以优化其使用情况。

If the temperature mapping study is designed to include door opening(s), this should be described in the study methodology and acceptance criteria. Also the door opening parameters (frequency, 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.

如果温度分布研究的设计包括了开门测试，则应在研究方法学和可接受标准中进行描述。还要界定开门参数（频率、开门时长）。在开门之后最长30分钟内，区域内温度应维持在界定的温度限度内。

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 the location of EDLMs. However, the following guidelines will help determine the number and location of the EDLMs required:

第5步---选择EDLM安放位置：在平面图上标记需要放置EDLM的位置。可以使用基于风险的方法来确定EDLM的位置。以下指南有助于决定需要放置的EDLM的数量和位置：

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 EDML locations every 5-10 metres[10]. The chosen sensor grid should take account of:

长度和宽度：EDLM应沿着区域的平面分格线每5-10米进行放置，这样可以合理覆盖整个区域。在选择放置感应器的位置时要考虑：

- The layout of the area (e.g., whether it is square or includes alcoves).
- 区域的平面布置情况（例如，是否是方形，是否有凹进去的房间
- The degree to which shelving and products may affect airflow.
- 货架和药品对气流影响的程度
- Where products are placed. The positions of EDLMs should coincide with locations where TTSPs 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.
- 药品要放置的位置。EDLM的位置应与TTSPP实际存贮或计划要存放的位置相同。例如，不需要将EDLM放置在高位装货区的上部分区域。
- Other considerations that may warrant more or fewer EDLMs.
- 可能需要更多或更小EDLM的理由

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

高度：在垂直线上，如下放置 EDLM：

- 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, 1.2 metres and one EDLM at 3.0 metres.
- 如果顶高为3.6米或更低，可以直接将EDLM放置在高、中、低位置（例如，在地板面，1.2米、3.0米高处各放置一个EDLM）

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- 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 six metres in height, EDMLs can be positioned in each grid location heights of 0.3 metres, 1.8 metres, 3.6 metres and 5.4 metres.
- 如果顶高大于3.6米，则EDLM可以按序放置在垂直方向的上中（可以多个）下部。例如，对于高6米的存贮区域，EDLM可以在0.3米、1.8米、3.6米和5.4米位置各放置一个。

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 and 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. The（译者注：这里原文如此，疑似打字错误）. If products are also stored on pallets in the centre of the room, additional EDLMs should be placed in this location.

给每个位置一个唯一的编号。这样有助于使用一个通用的平面图来决定每个记录仪要放置的位置---参见图1和2.图1展示了邻近温控包装区域的一部分托盘货架低温房。图2展示的是一个小型的走入式低温间，产品存贮在货架上---货架（在这里要放置EDLM）没有画出来。如果产品还存贮在房间中央的托盘上，则在此位置还要放置另外的EDLM。

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

图 1—托盘式货架存贮区域内典型的数据记录仪定位

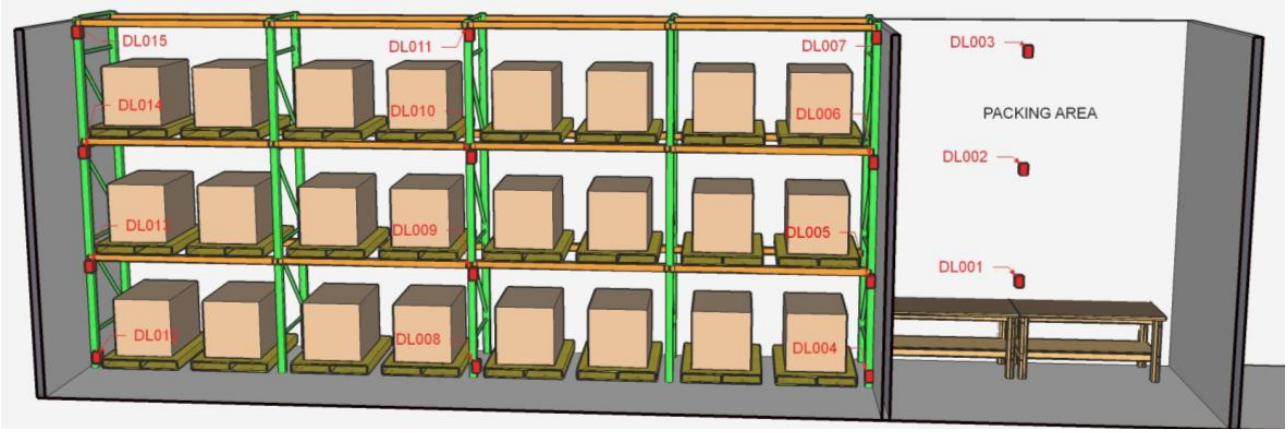
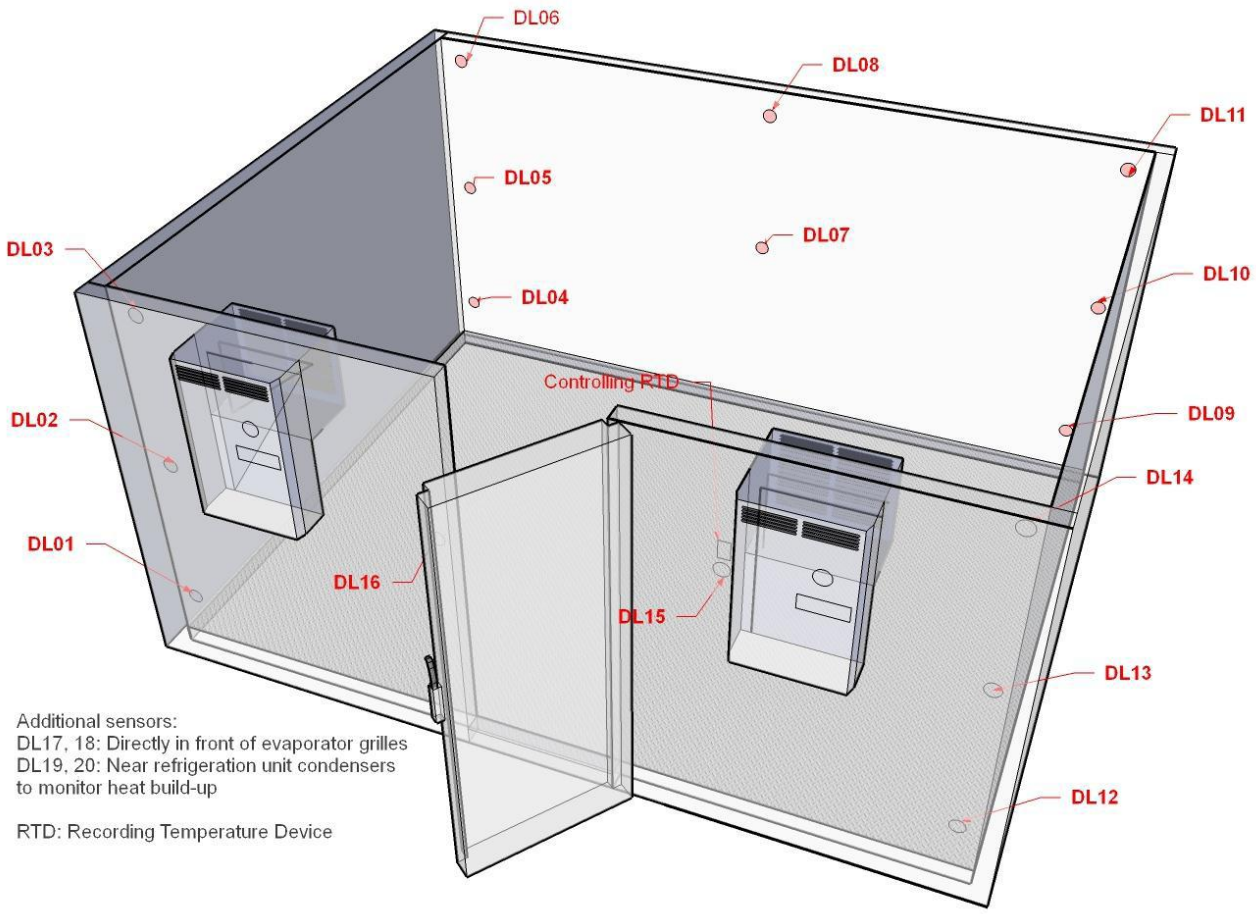


Figure 2 – Typical location of data loggers in a walk-in cold room

图 2---走入式低温间里典型的数据记录仪定位



另加感应器：DL17、18：在蒸发器格栅的正前方；DL19、20：接近冷冻单元冷凝器用于监测热累积情况

RTD：记录温度装置

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**.

第6步——记录EDLM、监测感应器和温控器的位置：在温度数据记录仪位置表上记录EDLM位置---参见附录1.1中例子。还要记录存贮区域的各温控仪位置编号和设定点---参见附录1.2例子。

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 one and 15 minutes. Set the same start time for all units. This is *essential;* otherwise the downloaded readings from the individual devices cannot be time-correlated. Make sure that the start time setting gives you enough time to fix all the units in position before recording begins.

第7步---标识和设定EDLM：对每个EDLM标识上一个唯一的ID号，该ID号是温度数据记录仪位置表中已给定的编号。将生产商的序列号录入温度数据记录仪位置表格中（附录1.1）。记录序列民，确保装置可以追溯到其校正证书。对每个装置编程，确保记录时间间隔是相同的---一般来说应该是1到15分钟之间。给所有单元设定相同的开始时间。这个是很重要的，否则从单个装置中下载的读数就时间点就不能相互对应。要确保所设定的开始记录时间之前你能有足够的时间来将所有装置固定在指定位置。

STEP 8 – fix EDLMs in position: Fix the EDLMs in position. Make 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.

第8步---将EDLM固定在指定位置：固定EDLM在指定位置。要确保每个EDLM均根据温度数据记录仪位置表和图纸所示放置在正确的位置。放好，固定装置，这样保证在常规存贮操作过程中不会被损坏或被放到别的地方去。要确保在温度分布研究开始之前，有足够的时间来让EDLM达到环境温度。

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 more 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].

第9步---实施温度分布研究：温度分布研究并没有一个正式的时间限度。一般来说，对于仓库和其它的室温存贮区域，应至少运行连续7天---包括7个工作日和2天周末。对于不会受到一天24小时或季节性气温波动的温控设定，（例如，冷冻间和低温间），温度分布研究应持续24-72小时，或如果有相关论证时，持续更长时间。如果房间里装有两个冷冻单元----不管有没有自动切换---则需要对2个单元分别运行一段时间来实施温度分布实验，2次时间长度最好相似。房间内的温度分布可能会因为所运行的系统不同而不同。

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

在研究结束后，收集EDLM，根据安装清单再次检查其序列号和位置。

STEP 10 – download and consolidate the data: Download the EDLM readings and consolidate the data for the study analysis described in Section 2.4.

第10步---下载和整合数据：下载EDLM读数，整合数据，按2.4所述进行研究分析。

2.2.7 Mapping report template 温度分布研究报告模板

The mapping report should include the following sections:

温度分布研究报告应包括以下部分：

a. *Introduction:* a description of the objectives of the mapping study.
介绍：温度分布研究目的描述

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).
摘要：按温度分布研究方案中设定的顺序，对结果进行汇总和讨论，其中包括对偏差汇总（如有）。

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 as well.

[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.

结论和建议：所有确认和缺陷总体结论，说明运行设备的可接受程度。也可以写下建议和备注。

d. *Report annexes:* The report annexes should contain the following: 报告附录。报告附录应包括以下内容：

- The site survey, showing EDLM locations.
- 现场实况，显示EDLM实际位置
- The raw data, presented using the appropriate test data sheet format - see **Annex 1.**
- 原始数据，使用适当的测试数据表格式，参见附录1.
- Spreadsheet data and related temperature graphs for every EDLM used in the mapping exercise.
- 用于分布研究的每个EDLM的表格数据和相关温度图表。
- Raw results of the data analysis, including hot and cold spots.
- 原始数据结果的分析，包括最热点和最冷点。
- Key documents and notes prepared during the mapping exercise, together with any other supporting material.
- 温度分布研究过程中制订的关键文件和备房，以及其它支持性文件。
- Deviation reports, including Corrective and Preventive Actions (CAPA) forms, if required. This may include a recommendation for partial or total re-mapping.
- 偏差报告，包括纠正和预防措施（CAPA）表格（必要时）。可以包括部分或全部再研究的建议。
- Calibration certificates for all EDLMs used.
- 所有使用的EDLM的校正证书。

2.3 Conducting the mapping exercise 实施温度分布研究

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.

根据方案实施温度分布研究。确保存贮所涉及的所有相关的人员都被告知了相关信息，以避免对EDLM的不良干扰或关闭。在研究结束时，收集所有装置，关闭，下载数据进行分析。

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.

如果分布研究不包括对开门的自动记录，则在研究过程中需要保持一份进出登记本，这样可以很容易地识别出由于人员进出所引起的所有温度波动。断电情况也要进行记录。

2.4 Analyzing the data and preparing the mapping report 分析数据制作温度分布报告

The mapping report should follow the general framework outlined in Section 2.2.7. The following sub-sections outline the data analysis process that precedes the writing of the report.

温度分布报告应按照第2.2.7部分给出的通用大纲制作。以下子部分列出了编写报告之前的数据分析过程。

2.4.1 Preliminary analysis 初步分析

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:

对研究区域的整体温度稳定性进行分析，找出所发生的差异。将所测得的温度与可接受标准进行细弱。总体温度稳定性分析应考虑一些因素如：

- The ability of the environmental control systems to maintain temperatures within the acceptance criteria limits (if any).
- 环境控制系统将温度维持在可接受限度内的能力（如有）。
- The overall temperature stability of the area being monitored, and the range in fluctuations it experiences over the study period.
- 被监测的区域的全面温度稳定性，以及在研究期间所经历的波动范围。

The analysis of temperature variations should consider factors such as:

对温度变化的分析应考虑一些因素如：

- Variations experienced by individual EDLMs.
- 单个EDLM所经历的变化
- Temperature variations along vertical and horizontal planes, depending on the size of the area, and distribution of EDLMs.
- 横向和纵向平面的温度差异，这取决于区域的大小以及EDLM的布置
- Temperature variations in locations close to heating and cooling components, as compared to those farthest away from these units
- 接近加热和冷却部件的位置的温度变化，与远离这些单元的温度相比

2.4.2 Minimum and maximum temperatures and hot and cold spots 最低最高温度和冷点热点

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.

温度分布研究测量的是温度的波动情况。从这些数据中，分析员可以找出研究期间在被研究的区域中所发生的最高和最低温度。

Minimum temperature refers to the lowest temperature value 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.

最低温度指在研究期间所记录的分布研究空间中的最低温度值；最高温度指在同一研究期间所记录的最高温度值。这两个温度或其中一个温度可能会超出存贮区域指定的可接受标准。附录1.3显示了一个标准表格，可以用来记录这些数据，以及2.4.4部分中所讨论的平均值。

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

冷点指研究期间所记录的空间内的最低温度值，但这些最低温度值仍在指定的温度范围内（例如，房间要求温度范围为+15.0°C 到 +25.0°C，所找到的冷点为+15.0°C 到 +17.5°C。

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

热点指研究期间所记录的空间内的最高温度值，但这些温度值仍在要求的温度范围内（例如，房间要求温度范围为+15.0°C 到 +25.0°C，所找到的热点为+23.0°C 到 +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.

确定冷点和热点的目的是找出监测系统探头安装的最佳位置。热点和冷点需要根据季节来确定，因为在冬天和夏天可能会有显著差异。

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.

注：要查看总体的高低温趋势，而不要只是查看最高和最低温度。在确认真实热点和冷点时可能平均值会有很有用。

2.4.3 Mean temperatures 平均温度

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, periodic peak occurrence…) and where the temperature also varies depending upon the data logger location.

算术平均温度可以用于计算研究期间所监测的各区域。在温度周期性波动的存贮区内，这些平均温度测量值可能会很有用（例如，正弦波动，周期峰值……），以及根据数据记录仪位置不同的温度差异。

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 exercise which cannot be achieved simply by comparing individual data points.

使用平均温度可以让分析人员确定一个指定EDLM位置在研究期间的平均温度。将空间内不同位置的EDLM所得到的平均温度值进行比较，分析人员就可以找出平均值一直较低或较高的位置，这是通过简单比较单个数据点无法获得的。

In Figure 1, 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 clearly times when the two locations experience similar low and high temperatures.

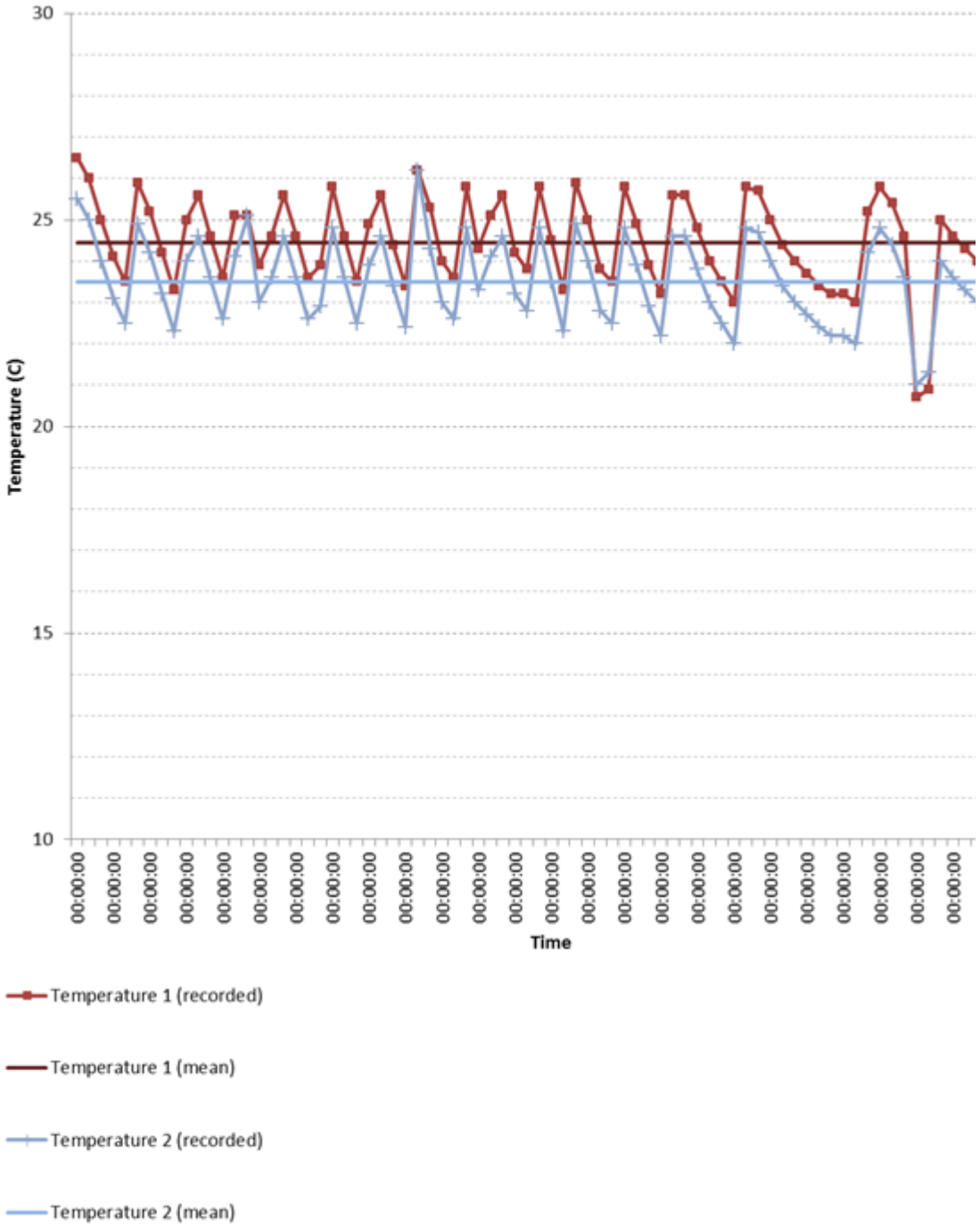
在图1中，显示了两个位置点（EDLM-1和EDLM-2）的数据点所计算得到的最大温度值和最小温度值。从图可知，虽然两个位置有几次有相似的高低温，但EDLM-2位置平均来讲明显要更冷。

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

虽然说平均值很有用，但也不要忽略了实际的温度数据，这些原始的温度数值显示了超出要求存贮温度范围的温度发生情况。

Figure 3 – Use of mean temperatures

图 3----使用平均温度



2.4.4 Interpreting the results and making recommendations 诠释结果给出建议

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

本部分概括说明如何对结果进行诠释，如何利用这些结果来支持报告的建议：

- Document the internal temperature variations observed within the space, taking account of the EDLM reading errors specified by the device manufacturer.
- 记录在空间内观察到的内部温度波动，考虑仪器生产商给出的EDLM读数误差
- Use the data analysis to assess the overall temperature stability of the mapped space in relation to the stated acceptance criteria (if any).
- 利用数据分析来评估温度分布所研究的空间总体的温度稳定性，与所要求的可接受标准进行对比（如有的话）
- Assess the overall thermal stability of the space during the study period with specific reference to the high and low temperatures experienced[12].
- 评估研究期间空间内整体热学稳定性，可以参考所经历的最高和最低温度
- List the factors that explain the observed temperature variations. For example, the location of the heating and cooling components and doors.
- 列出所观察到的温度差异的理由。例如，加热或致冷部件的位置，门的位置。
- Assess consistent and inconsistent temperature variations, and fluctuations, within the space in terms of their potential impact on product storage.
- 评估空间内持续的和间断的温度差异和波动，其对产品存贮潜在的影响
- Based on the observed temperature fluctuations of mapped locations within the space, make recommendations about the optimum storage locations for highly sensitive products, and those that are less sensitive.
- 根据所观察到的空间内分布位置的温度波动，做出关于优化高敏感性药品及次敏感性药品存贮位置的建议
- Based on the observed temperature fluctuations of 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.
- 根据所观察到的空间内温度分布位置的温度波动，做出关于优化常规温度监测用温度感应器，以及用于控制加热和冷却系统的感应器位置的建议。

2.4.5 Report auditing 报告审计

The report 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.

报告的内容，包括数据表、结果、表彰和图表均应由一个有资质的独立人员进行审计和专家评估。审核人员应确认、批准并签署报告的主要测试和确认结果，并给出从这些结果中得到的建议。如果报告是由一个有资质的第三方起草的，则应由委托该研究的人员进行批准。

2.5 Implementing the mapping report recommendations 实施温湿度分布研究报告中的建议

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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:

一个温湿度分布研究的最终结果和目的是实施报告的建议。本文的范围不包括对实施的详细讨论，但该讨论可以包括以下结果：

- 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 which are not affected by freezing could be allocated to parts of a cold room where the mapping study has shown some freezing risk.
- 一张显示在空间中可以安全存放TTSPP的位置的图或表。可能会涉及到一些区域。例如，不受冷冻影响的药品可以放在低温室部分，而这部分区域在温湿度分布研究中可能显示具有冷冻风险。
- Allocation of pallet bays to specific categories of TTSPP on the warehouse management system in order to control where stocks are positioned.
- 仓库管理系统中特定类别TTSPP托盘区定位
- Re-positioning of temperature monitoring sensors and/or environmental control sensors.
- 重新定位温度监测感应器和/或环境控制感应器
- Adjustment of air outlets to reduce temperature stratification and/or minimize cold and hot spots.
- 调整空气出口，以减少温度分层和/或将冷热点减至最少
- Upgrading of mechanical systems to improve temperature control and performance.
- 升级机械系统以提升温度控制和表现
- A decision to use the space for other purposes because it is unsuitable for storage of TTSPPs.
- 决定使用该空间作为其它用途，因为它不适用于TTSPP的存贮

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- 美国FDA，21CFR第11部分，电子记录、电子签名
- WHO Technical Report Series No. 961, 2011, Annex 9: *Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical* http://apps.who.int/medicinedocs/documents/s18683en/s18683en.pdf
- WHO第961号技术报告附录9：时间温度敏感药品的贮运指南

Annex 1 – Test data sheets

附录1：测试数据表

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

以下部分展示的是在温度分布研究中使用的数据收集表的类型样例

A1.1 Test data sheet: temperature data logger locations 测试数据表：温度数据记录仪位置

Data logger ID number 数据记录仪编号	Data logger serial number 数据记录仪序号	ID number on schema 计划中的编号	Mounting ht (metres) 安装高度	Description / Comments 备注
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	
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 测试数据表：温度分布

Thermostat Information 温控仪信息		
Location	Set point 设定点	Comment 备注
Near entrance door #1	20C	Locked

Near loading dock #4	20C	Locked

A1.3 Test data sheet: temperature distribution 测试数据表：温度分布

Data logger ID number 数据记录仪编号	Min. temp. Recorded (°C) 最低温度	Max temp. Recorded (°C) 最高温度	Mean temp. (°C) 平均温度	Within range? 是否在范围内
Yes	No	Inspected by	Date	
DL-001	18.6	22.4	20.5	JB