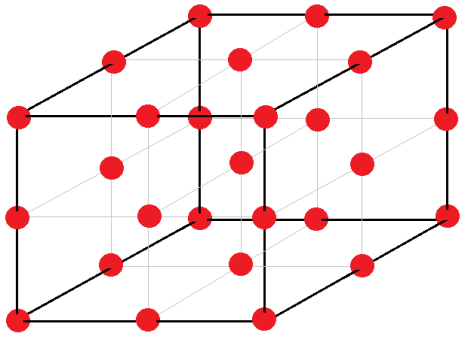


溫度測繪評估

Temperature Mapping

張富文

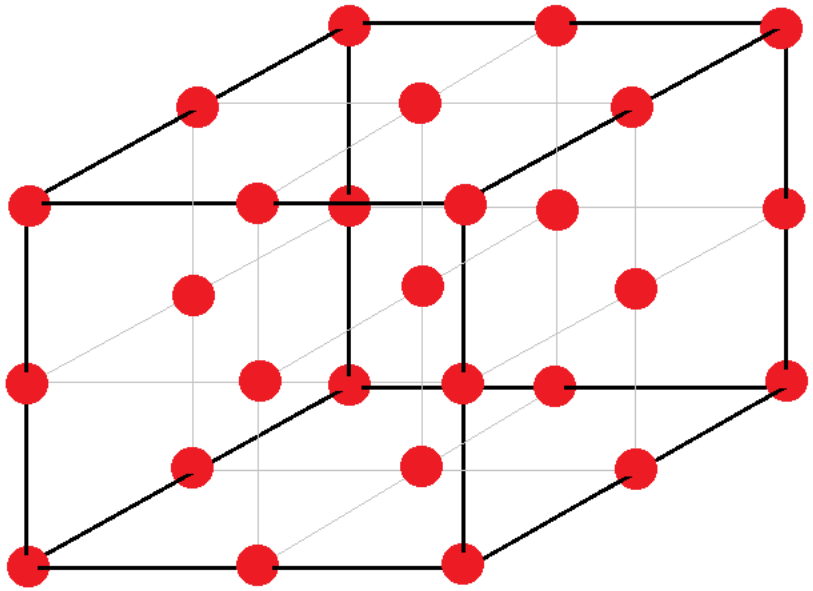
2015-Sep-17

CONTENTS

Temperature Mapping

Temperature Mapping is the processes of recording and mapping the temperature in a 3 dimensional space.

Mapping grid



我國藥品GMP 規範
PIC/S Guide to GMP for Medical Products, Part 1,

3.19. Storage areas should be designed or adapted to ensure good storage conditions. In particular, they should be clean and dry and maintained within acceptable temperature limits. Where special storage conditions are required (e.g. temperature, humidity) these should be provided, checked and monitored.

3.19 儲存區應經設計或調適，以確保良好的儲存條件。特別是儲存區應保持潔淨與乾燥，並維持在可接受的溫度範圍內。有特別儲存條件要求時(例如溫度及濕度)，應提供這些儲存場所，並加以檢查/核對與監測。

USP/General Chapters: <1079> GOOD STORAGE AND SHIPPING PRACTICES

ESTABLISHING TEMPERATURE PROFILES

Temperature profiles can be compiled by using a suitable number of thermometers or other temperature recording instruments. They should be placed throughout the warehouse in divided sections and should record the maximum and minimum temperatures during a 24-hour period for a total of three consecutive 24-hour periods.

Guidelines and Requirements

WHO Technical Report Series, No.961, 2011
Annex 9
Model guidance for the storage and transport of time- and temperature – sensitive pharmaceutical products

4.5 **Temperature and humidity control and monitoring in storage**

4.5.1 ***Temperature control***

➢control sensors positioned at the hot and cold spots determined by temperature mapping, even if affected by door opening, unless recommendations are being made not to store products in such areas;

Guidelines and Requirements

WHO Technical Report Series, No.961, 2011
Annex 9
Model guidance for the storage and transport of time- and temperature – sensitive pharmaceutical products

WORLD TRADE ORGANIZATION

11. **Quality Management**

11.4.1 ***Standard operating procedures***

- qualification and validation procedures, including temperature mapping;

PHARMACEUTICAL INSPECTION CONVENTION

PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME

PE 011-1
1 June 2014

PIC/S GUIDE TO GOOD DISTRIBUTION PRACTICE FOR MEDICINAL PRODUCTS

Guidelines and Requirements

CHAPTER 3 PREMISES AND EQUIPMENT

3.3 TEMPERATURE AND ENVIRONMENT CONTROL

3.3.1 Suitable equipment and procedures should be in place to check the environment where medicinal products are stored. Environmental factors to be considered include temperature, light, humidity and cleanliness of the premises.
3.3.2 An initial temperature mapping exercise should be carried out on the storage area before use, under representative conditions. Temperature monitoring equipment should be located according to the results of the mapping exercise, ensuring that monitoring devices are positioned in the areas that experience the extremes of fluctuations. The mapping exercise should be repeated for significant changes according to the results of a risk assessment exercise. For small premises of a few square meters which are at room temperature, an assessment of potential risks (e.g. heater / air-conditioner) should be conducted and temperature monitors placed
accordingly.

Guidelines and Requirements

CHAPTER 9 TRANSPORTATION

9.3 CONTAINERS, PACKAGING AND LABELLING

9.3.2 Selection of a container and packaging should be based on the storage and transportation requirements of the medicinal products; the space required for the amount of medicines; the anticipated external temperature extremes; the estimated maximum time for transportation including transit storage at customs; the qualification status of the packaging and the validation status of the shipping containers.

9.4 PRODUCTS REQUIRING CONTROLLED CONDITIONS

9.4.4 If temperature-controlled vehicles are used, the temperature monitoring equipment used during transport should be maintained and calibrated at regular intervals. Temperature mapping under representative conditions should be carried out and should take into account seasonal variations, if applicable.

我國藥品GDP 規範

公告「西藥藥品優良運銷規範(第三部：運銷)」，自即日起生效。
風險管理組衛生福利部 公告
發文日期：中華民國104年7月16日
發文字號：部授食字字第1041102778號
附件：「西藥藥品優良運銷規範(第三部：運銷)」中英文對照條文1份
主旨：公告「西藥藥品優良運銷規範(第三部：運銷)」，自即日起生效。
依據：藥物優良製造準則第三條。

我國藥品GDP 規範

第 3 章作業場所及設備(Chapter 3 Premises and Equipment)

3.3.溫度及環境管制(Temperature and Environment Control)

3.3.1應具備適當的設備及程序以確認藥品的儲存環境。需考量的環境因素包括作業場所的溫度、濕度、光線及清潔。

3.3.2儲存區應在代表性的條件下於開始使用前進行初步的溫度測繪評估。溫度監測設備應依照測繪評估結果設置，以確保監測設備是位於歷經極端溫度波動的位置。溫度測繪評估應依風險評估於有重大改變時重複執行。若為數平方公尺之小型常溫作業場所，應執行潛在之風險評估(如冷或暖氣機)，並依照其評估結果放置溫度監測器。

我國藥品GDP 規範

第 9 章運輸 (Chapter 9 Transportation)

9.3 裝存箱櫃、包裝及標示(Containers, packaging and labelling)

9.3.2 選擇裝存箱櫃及包裝時，應考量藥品儲存與運送的要求、藥品數量所需的空間、預期外部極端溫度、儲存在海關過境之最長時間、包裝的驗證狀態及運輸容器的確效狀態。

9.4 需要管制條件的產品(Products requiring controlled Conditions)

9.4.4 溫控車在運送時所使用的溫度監測設備應定期進行維護及校正，並於代表性條件下執行溫度測繪，且應考量季節變化(必要時)。

其他

ASTM D3103 - 07e1 Standard Test Method for Thermal Insulation Performance of Distribution Packages

Mapping Processes

1. Establish a validation plan
2. Consider areas at risk
3. Develop a validation protocol
4. Set up data loggers distribution
5. Select suitable devices
6. Conduct test
7. Retrieve data and analysis
8. Remediation
9. Documentation

Mapping Processes

1. Establish a validation plan
- Regulatory compliance
- Quality commitment
- Risk-based approach

Mapping Processes

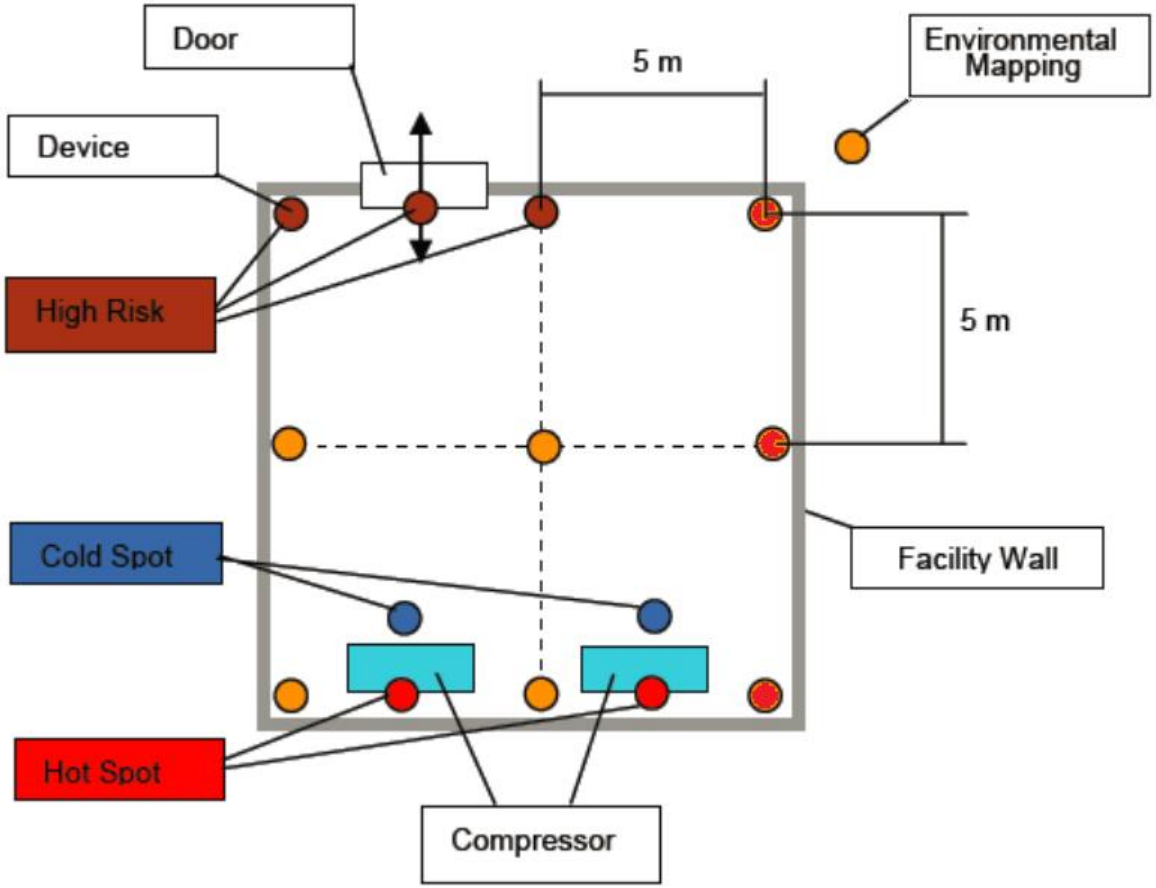
1. Establish a validation plan(cont’ d)

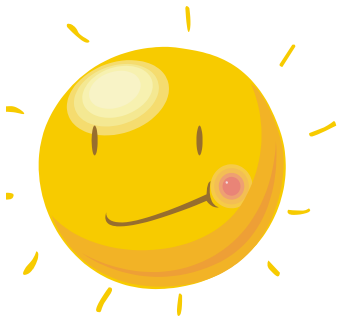
Validation Master Plan:

- Objective
- Roles/Responsibilities
- Activities
- Schedule
- Resources
- Procedures

Mapping Processes

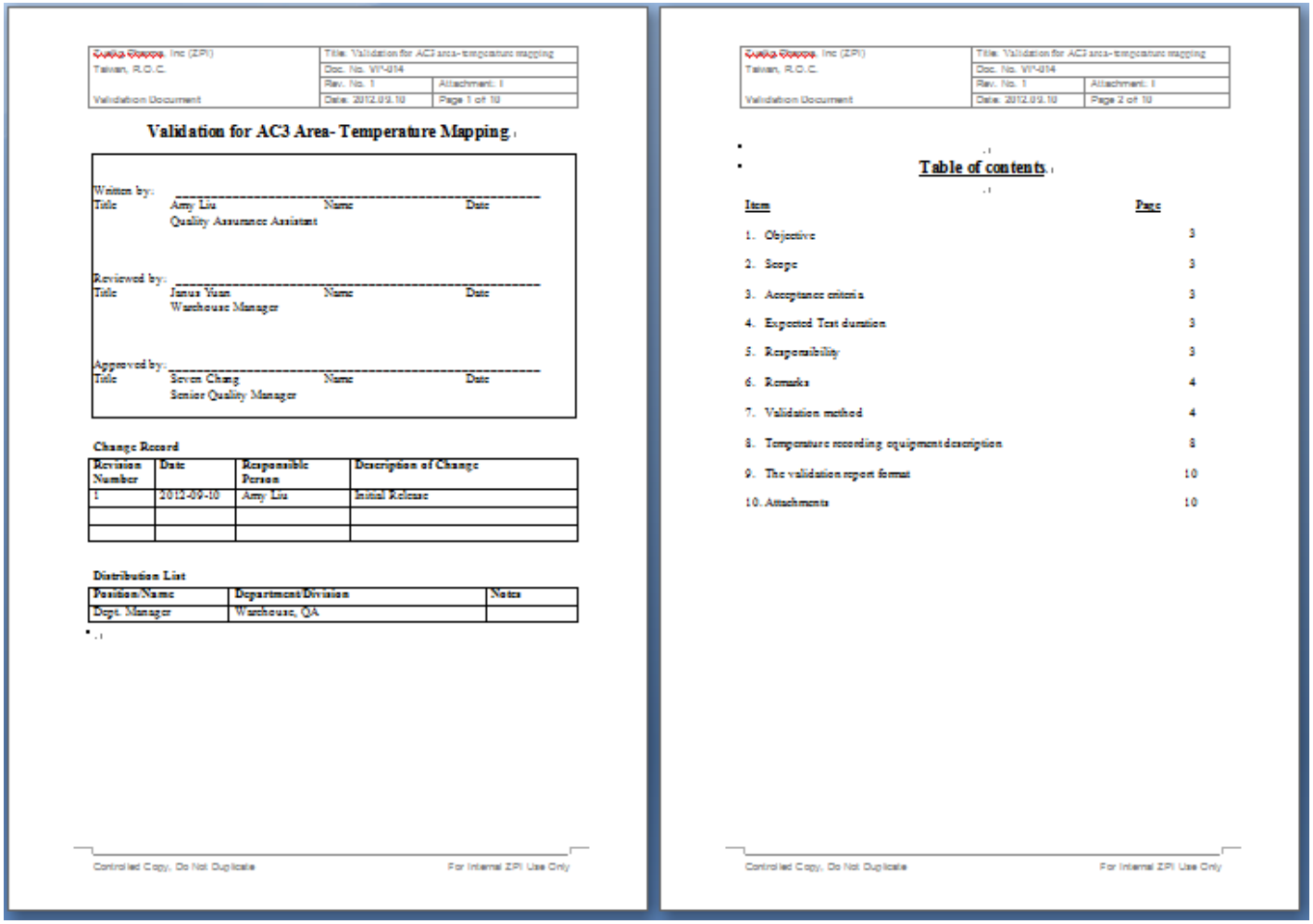
2. Consider areas at risk





Mapping Processes

3. Develop a validation protocol



[redacted] Inc (ZPI) Taiwan, R.O.C.	Title: Validation for AC3 area- temperature mapping	
	Doc. No. WI-014	
	Rev. No. 1	Attachment: I
Validation Document	Date: 2012.09.10	Page 1 of 10

Validation for AC3 Area- Temperature Mapping

Written by:
Title: Quality Assurance Assistant — Name: Amy Liu — Date: _____

Reviewed by:
Title: Warehouse Manager — Name: Janus Yuan — Date: _____

Approved by:
Title: Senior Quality Manager — Name: Seven Chang — Date: _____

Change Record

Revision Number	Date	Responsible Person	Description of Change
1	2012-09-10	Amy Liu	Initial Release

Distribution List

Position/Name	Department/Division	Notes
Dept. Manager	Warehouse, QA	

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[redacted] Inc (ZPI) Taiwan, R.O.C.	Title: Validation for AC3 area- temperature mapping	
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	Rev. No. 1	Attachment: I
Validation Document	Date: 2012.09.10	Page 2 of 10

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Mapping Processes

4. Set up data loggers distribution

TL – Top level
ILn – Intermediate levels
LL - Lowest level

A mapping grid has always at least 2 levels.

Mapping Processes

5. Select suitable devices

TempTale®4 Dry Ice

TempTale®4 Humidity

- Brand
- Data Capacity
- Sampling Rate
- Monitoring range and Accuracy
- Size
- Battery Life
- Calibrations
- Software

Mapping Processes

6. Conduct test

- Interventions

Mapping Processes

7. Retrieve data and analysis

2012-11-1 3:24 AM	19	2012-11-1 3:25 AM	18.7	2012-11-1 3:26 AM	17.7	2012/11/1 03:30	17.2	2012/11/1 03:30	17.6	2012/11/1 03:30	19.1	2012-11-1 3:23 AM	18.6	2012-11-1 3:23 AM	18.7	2012-11-1 3:23 AM
2012-11-1 3:39 AM	18.9	2012-11-1 3:40 AM	18.7	2012-11-1 3:41 AM	17.7	2012/11/1 03:45	17.1	2012/11/1 03:45	17.7	2012/11/1 03:45	19.1	2012-11-1 3:38 AM	18.6	2012-11-1 3:38 AM	18.7	2012-11-1 3:38 AM
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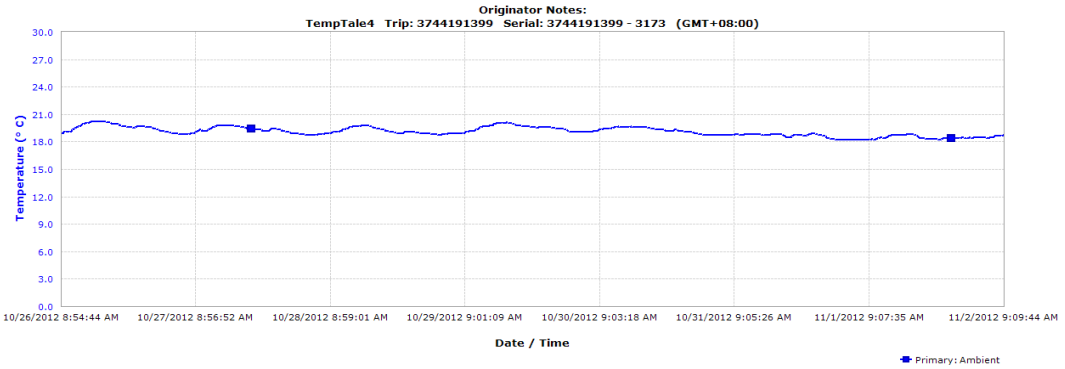


Mapping Processes

8. Remediation

- Removing product from problem areas (such as hot spots near ceilings).
- Changing work practices (such as keeping doors open or closed).
- Changing racking or shelving configurations.

Repositioning racks or shelving to improve air circulation.

- Changing the location of heating devices.

Mapping Processes

8. Remediation(Cont’ d)

- Adding air conditioning.
- Improving ventilation.
- Installing more or larger-capacity fans.
- Adding humidification or dehumidification.
- Installing an HVAC control system.

Mapping Processes

9. Documentation

Mapping and Monitoring

From mapping study we may collect the following information:

- *The impact of interventions*
- *Identification of hot and cold spots,*
- *Variation of temperature at a single point,*
- *Temperature variation across the area,*
- *Length of time of any temperature excursions.*

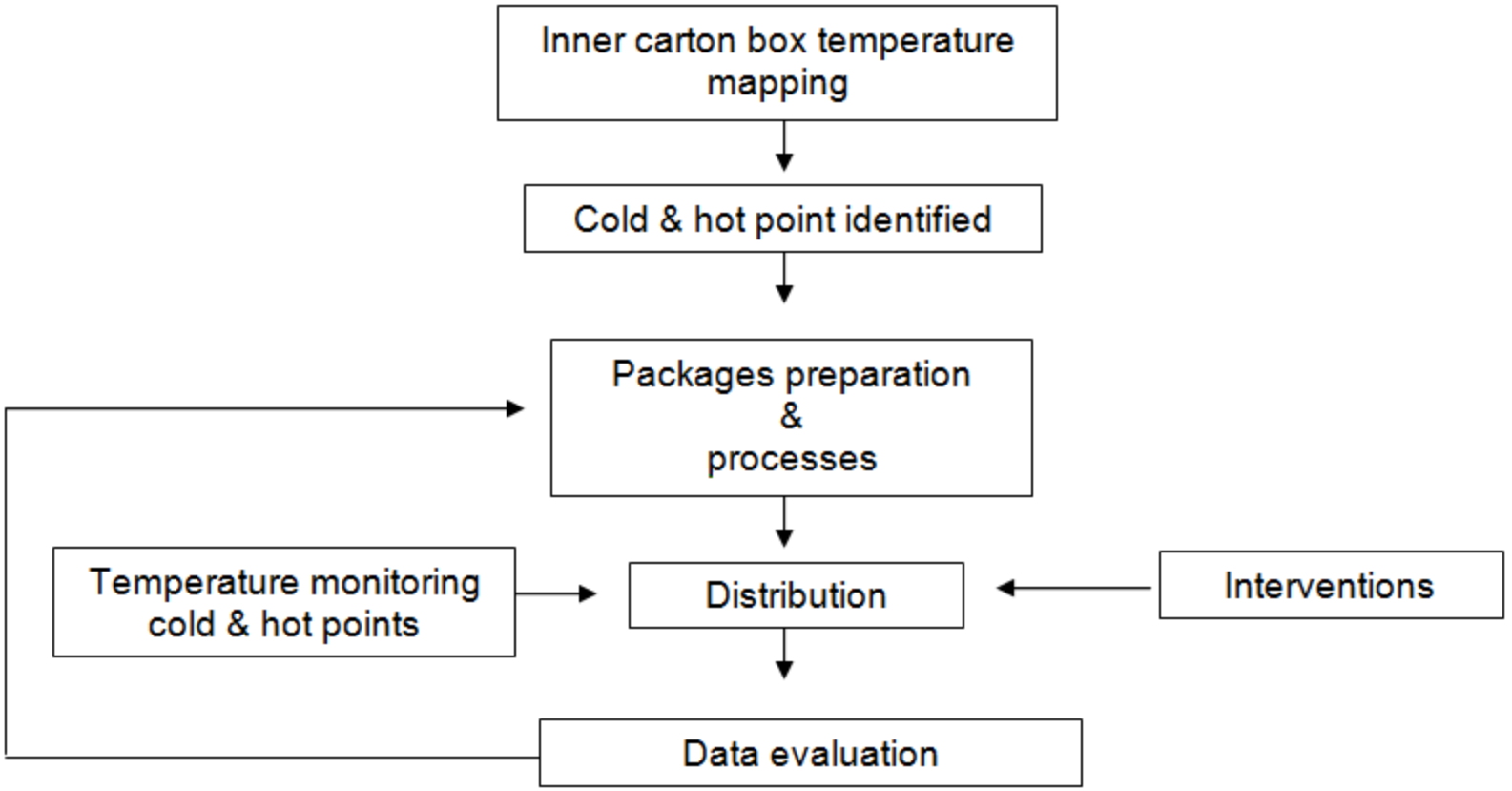
Mapping and Monitoring

- Monitoring is the continuous long term recording process on the identified *hot and cold spots.* Additional points may be considered.

- Temperature mapping is very different from routine monitoring. One of the key differences is the number of points the temperature is measured at in the temperature controlled area.

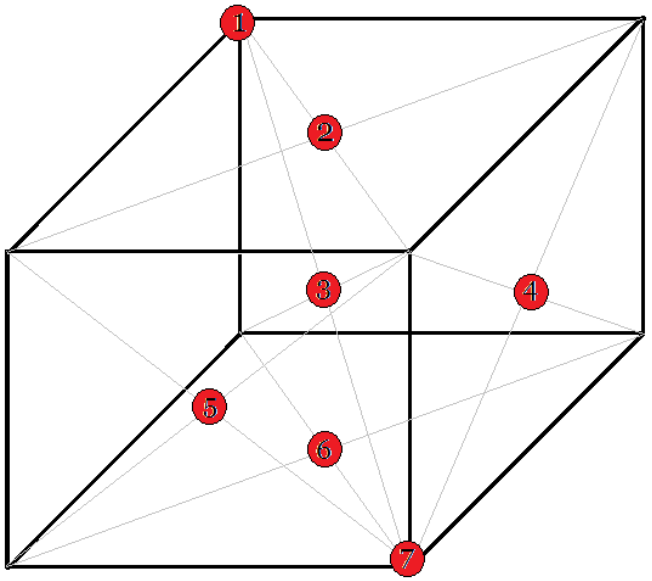
Cold Chain Packages

Validation method



Cold Chain Packages

1. Temperature Mapping



- Annual re-validation in representative seasons in alternate.
- Each package has to pass the validation at least 3 consecutive times.
- Worst case

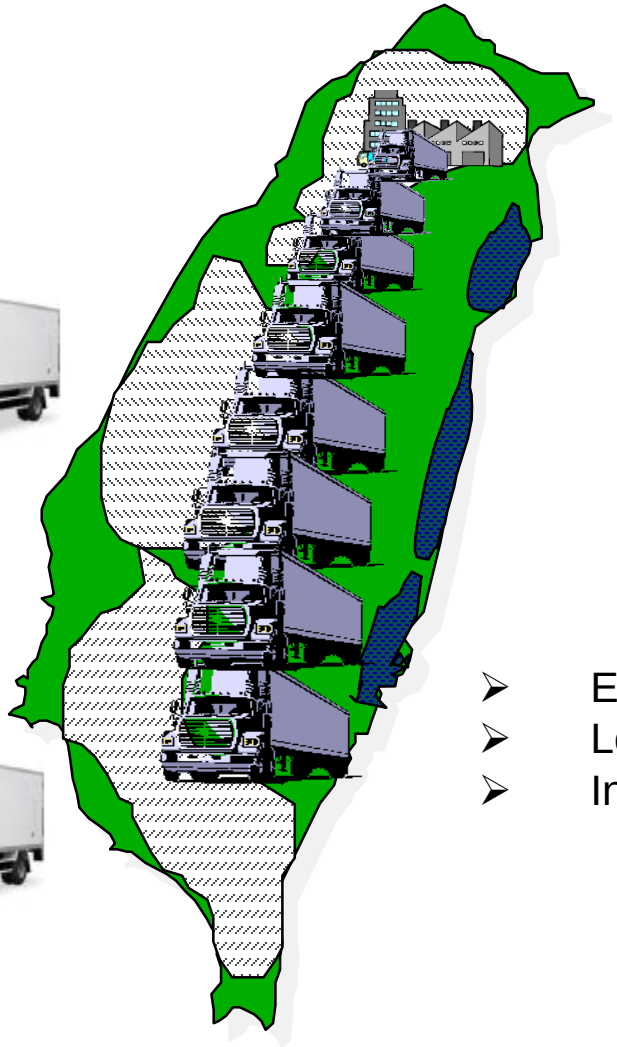
Reference: ASTM D3103 - 07e1

Cold Chain Packages

2. Distribution Runs

Vans

Vans



- E2E processes covered
- Loading patterns run
- Intervention

Temperature-controlled Vehicles

1. Temperature Mapping

- New vehicle: IOPQ / Calibration
- Empty Loading
- At least 7 monitoring points covered risk areas: air blower/doors

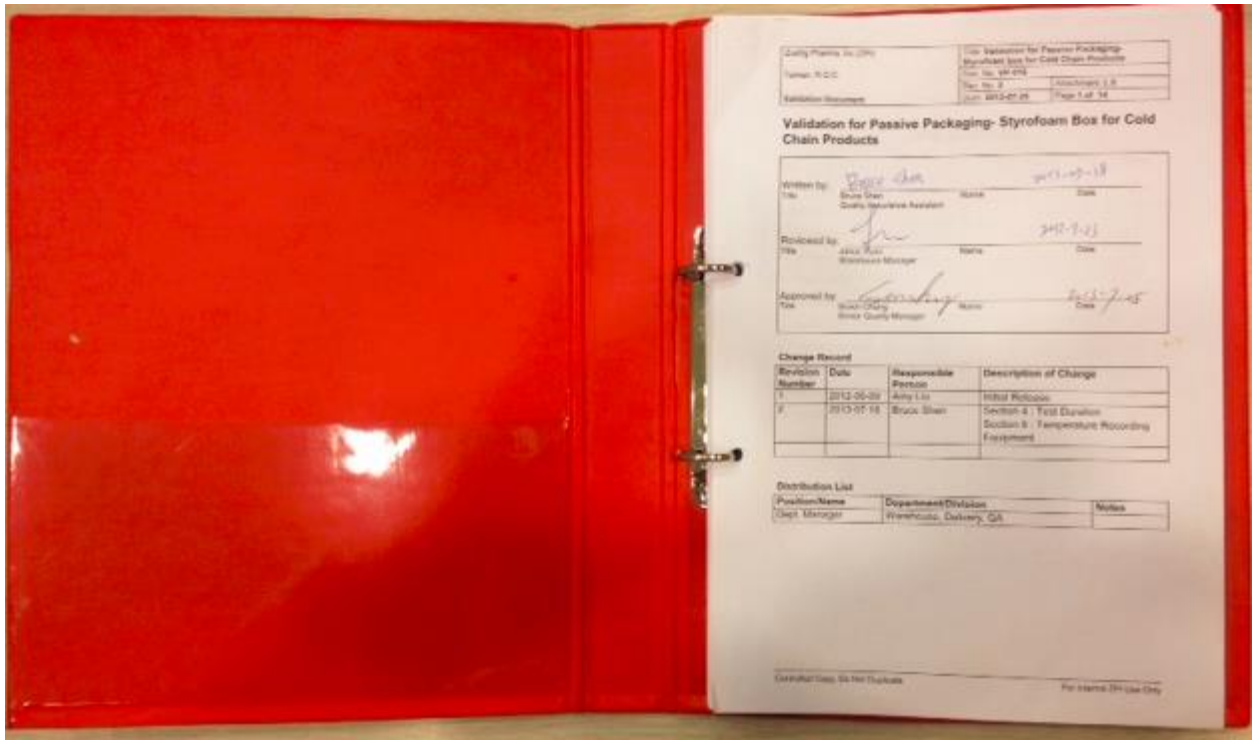
Temperature-controlled Vehicles

2. Distribution Runs

- Loading patterns run
- Duration at least 4 hours should cover and be done at known times of external temperature extremes, e.g., noon.
- Profiling should be conducted in both summer and winter.

Cold Chain Packages

3. Protocol & Report



- The End -

實作練習

1. 試描繪出倉庫溫度測繪點
- 在一白紙上畫出自己倉庫平面圖
- 約略說明倉庫長、寬、高
- 約略標示貨架區、出入口、設施設備安裝位置等
- 約略標明空調系統配置
- 在繪製好的圖上標出溫度測繪點
- 與學員分享與說明自己的測繪點圖

實作練習

2. 試擬定年度確效或驗證計畫
- 可參照投影片(Mapping Processes)內容撰寫
- 與學員分享與說明確效或驗證計畫