

E355 : Cold Chain Management

P06

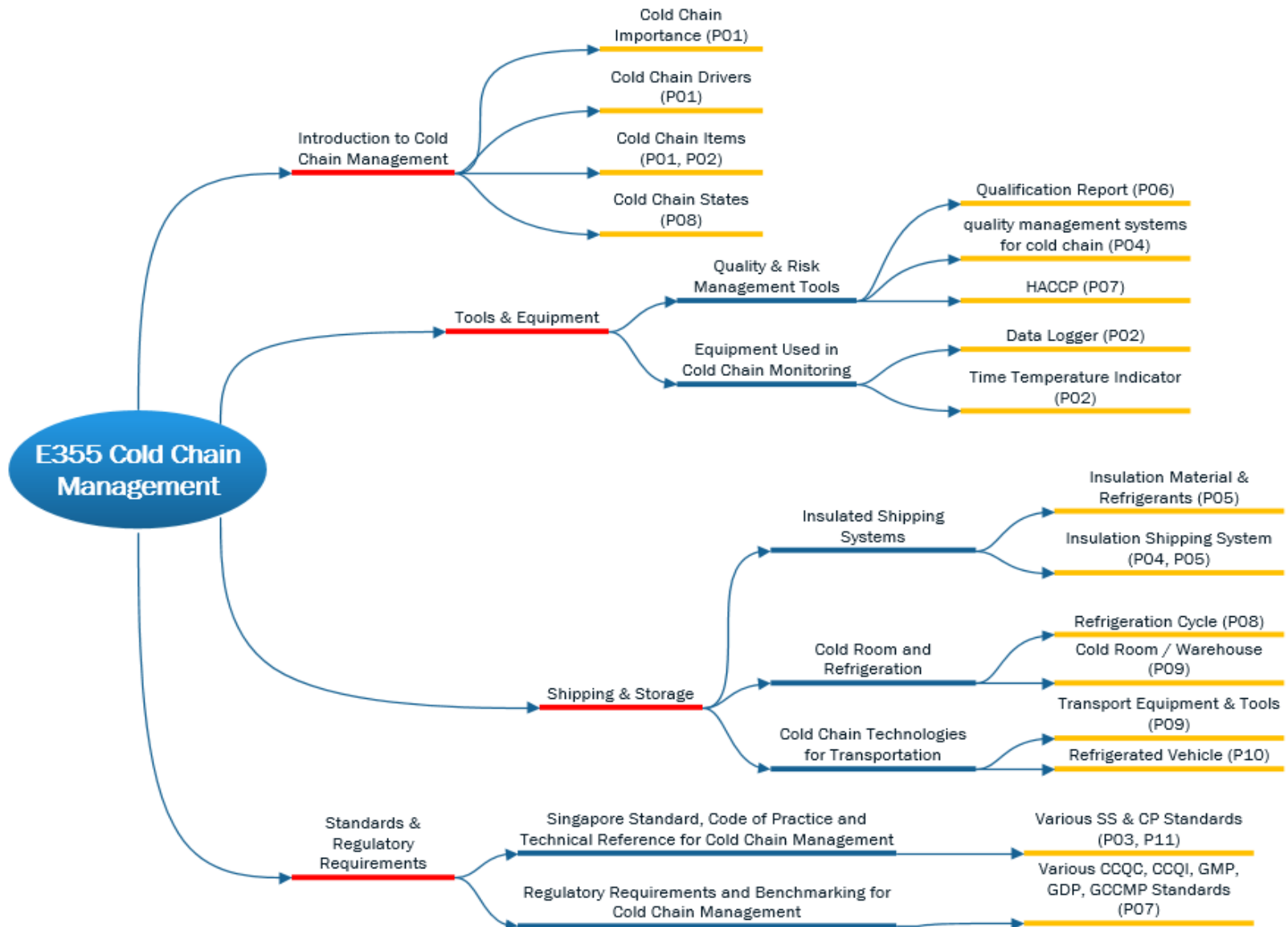
Ship the Correct Box



- Freight Management of Cold Products
- Criteria for Selection of Insulated Shipping System
- Ambient Temperature and its Impact on Cold Box Performance

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E355 Cold Chain Management - Topic Tree



Good Practices in Cold Chain Distribution Management (Cold box shipping system)



1. Know the Product (packaging)
 - ▶ Understand its tolerance (temperature range), sensitivity & size
 - ▶ Qualification & validation of packaging system
2. Know the Market
 - ▶ Understand all the regulations
3. Plan the Logistics Chain
 - ▶ Factors affecting the transit time and temperature
4. Know your Partners
 - ▶ Choose the correct service provider
5. Get the basics right
 - ▶ Establish Standard Operating Procedures (SOP)
 - ▶ Pre-shipment monitoring
 - ▶ Communication is vital to all parties

Know the Product – Need for Qualified Packaging



- ▶ A system that has documented evidence on how the packaging system and processes perform when operated within established parameters
- ▶ Based on the requirements of the product and the temperature that it will be subjected to throughout the duration of the transit, a package can be qualified through tests
- ▶ Factors to consider when selecting packaging:
 - ▶ Transit time
 - ▶ Transit temperature
 - ▶ Refrigerant Volume
 - ▶ Product Size





- ▶ Transit time is the amount of time that the shipment is expected to take from the time of packing until the time of delivery
 - ▶ For instance, a shipment from Sydney to Singapore may be delivered in a shorter transit than from Singapore to Bangkok; although the flight is shorter to Bangkok, the clearance process may take longer
- ▶ Transit temperature refers to the ambient temperatures that the shipment may endure, especially to various destinations with different climates and seasons
 - ▶ For instance, summer temperature in Sydney may be 36°C but in Singapore is 31°C

Temperature Profile Study



- ▶ Knowledge of the ambient temperature in the distribution system is essential for selection of the correct insulated system

- ▶ The information of the ambient temperature can be found by:
 - ▶ Using data loggers to measure the actual temperature throughout the distribution system
 - ▶ Using extreme temperatures of the region (e.g. <http://www.ista.org/forms/climatesoftheworld.pdf>)
 - ▶ Using international standards, such as ISTA 5B and ISTA 7D

Sample of Ambient Temperature Profile



A sample summer and winter ambient profile may look like this:

Description	Duration (hours)	Summer Temperature (°C)	Winter Temperature (°C)
Package is assembled and stored for pickup	9.0	22	22
Package is loaded onto local carrier	1.0	35	-10
Transportation to airport	2.0	35	-10
Held at airport	4.0	22	22
Air transport to destination hub	5.0	35	-15
Held at destination hub for sorting	5.0	22	22
Loaded at airport for ground transportation	1.0	35	-10
Ground transportation for local delivery	2.0	35	-10
Unloaded and held at location	1.0	35	-10

- *For extreme temperatures, the temperature in Cardiff can be as low as 2°F, or -17°C*

Qualified Packaging

Refrigerant Volume & Product Size



- ▶ The volume of refrigerant used has a critical impact on the temperature control of the shipment
 - Packaging used should be appropriately proportioned to the product
 - The prescribed packaging guide should be followed for a validated package

- ▶ Product Size has an impact on the package performance as well
 - A same package with a smaller volume of product may drop below required temperature
 - The key is to select the correct packaging for the volume of product



Qualification of Insulated Shipping System (Cold Box)



- ▶ Perform thermal testing to qualify the insulated shipping system
- ▶ Certified 3rd party test labs use environmental chambers to simulate ambient temperature profiles that a package may encounter in the distribution cycle
- ▶ Thermocouple probes and temperature data loggers measure temperatures within the product load to determine the response of the package to the test conditions
- ▶ Replicated testing based on a qualification protocol is used to create a final qualification report that can be used to defend the configuration when audited by regulators

Qualification of Insulated Shipping System (Cold Box)



Laboratory Test of Packaging

- ▶ Thermal testing is the process of determining if a custom packaging configuration will be successful in holding the temperature of a temperature-sensitive product within its acceptable temperature criteria when it is exposed to ambient conditions
- ▶ The pre-specified ambient conditions are the temperature profiles programmed into environmental chambers that will simulate the temperature conditions that the package may be exposed to



Qualification of Insulated Shipping System (Cold Box)



Steps for Qualification Testing

1. Determine the ambient profile to subject the box to
2. Condition the refrigerants as per given by the manufacturer
3. Condition the data loggers and the products based on the temperature that the product needs to be maintained at for at least 24 hours
4. Configure data logger **(3 for internal and 2 for ambient)**, prepare shipping system based on packing instructions from manufacturer, including payload and data logger.
5. Set up environmental chamber to simulate ambient profile and place packed shipping system in with data loggers.
6. At the end of test, download temperature profile from data logger to analyze results, document results in qualification report

Qualification of Insulated Shipping System (Cold Box)



What is in a Qualification Report

(refer to resources for sample of qualification report)

- Master front page
 - Gives reference to the qualified product, test range and the date of creation
 - The signature sign-off section is also featured here
- Executive Summary
 - Outlines what was tested, and specifications it was tested to according to the protocol criteria
- Result Summary
 - Outline of the system's performance during each test
 - Thumbnail graphs and configuration illustrations are also added to this page
- Methodology
 - Detailed descriptions of the test procedure
- Ambient Temperature profiles
 - Full details of the ambient temperature profiles used to qualify the cold box

Qualification of Insulated Shipping System (Cold Box)



What is in a Qualification Report

- System diagram
 - Each part is labelled and clear instructions are given regarding part name, location and any pre-packaging temperature condition requirements
- System specification
 - Quick reference for all parts contained within the cold box system, as well as data related to final packed solution
- Test result
 - Shows a time/temperature graph of the system's performance during the test
- Results review, conclusion and deviations
 - Results related to the qualification, and any deviations in performance
- Appendixes
 - Test criteria, equipment calibration documents and tables of reading

Interpreting the Performance Summary



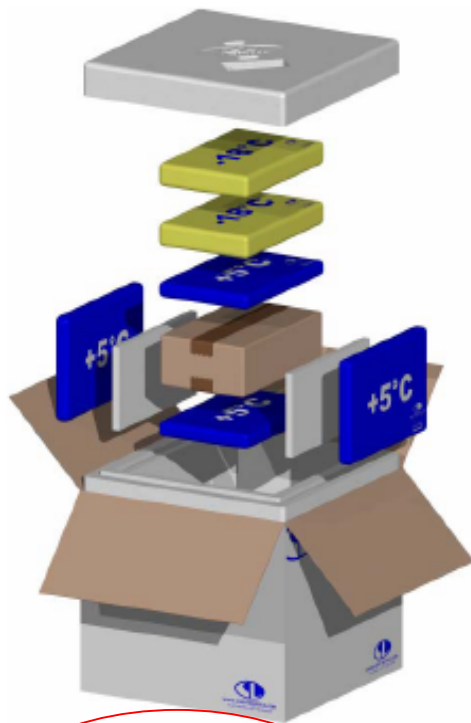
www.sca-cool-logistics.com

T1677-6 PERFORMANCE SUMMARY

72 HOUR WINTER (SE ASIA) SYSTEM – 4.5L PRODUCT LOAD

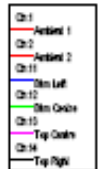
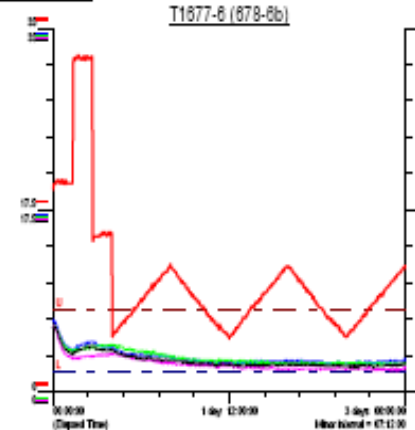
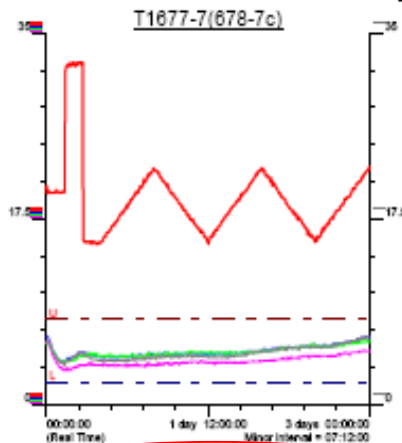
Heading with
payload limit

SYSTEM DIAGRAM



TEMPERATURE CONTROLLED SHIPPING SYSTEM +2°C TO +8°C

PERFORMANCE SUMMARY



WINTER UPPER

Ambient Temperature Profile
20°C for 4 hours, 32°C for 4 hours,
15°C for 4 hours,
15°C to 22°C ramped over 12 hours,
22°C to 15°C ramped over 12 hours,
Repeat 22°C to 15°C ramped profile

Results
Product temperature:
2°C to 8°C for 72 hours, 00 minutes +
Maximum product temperature was 6.4°C @ 00:00
Minimum product temperature was 3.2°C @ 03:40

WINTER LOWER

Ambient Temperature Profile
20°C for 4 hours, 32°C for 4 hours,
15°C for 4 hours,
15°C to 12°C ramped over 12 hours,
12°C to 5°C ramped over 12 hours,
Repeat 12°C to 5°C ramped profile

Results
Product temperature:
2°C to 8°C for 72 hours, 00 minutes +
Maximum product temperature was 6.9°C @ 00:10
Minimum product temperature was 2.1°C @ 54:40

Ambient Temperature Profile and
product Temperature

Product Space: 300 x 180 x 85mm (4.5 litres)

Conditioning time of frozen

CoolPacs prior to assembly: 20 minutes

BILL OF MATERIALS

- 1x CL7725 EPS Moulding (base and lid)
- 1x Printed Cardboard Outer Carton
- 4x WS3020 Cool-Pacs @ +5°C
- 2x WS3020 Cool-Pacs @ -18°C
- 2x EPS Spacer (300x160x15mm)
- 1x Inner Carton (300x180x85mm)

BOM

SYSTEM SPECIFICATION

CL7725 Dimensions
External Dimensions: 456 x 456 x 386mm
Internal Dimensions: 320 x 320 x 245mm

System Weight: 11.2kg
Volumetric Weight: 13.4kg

System Specification

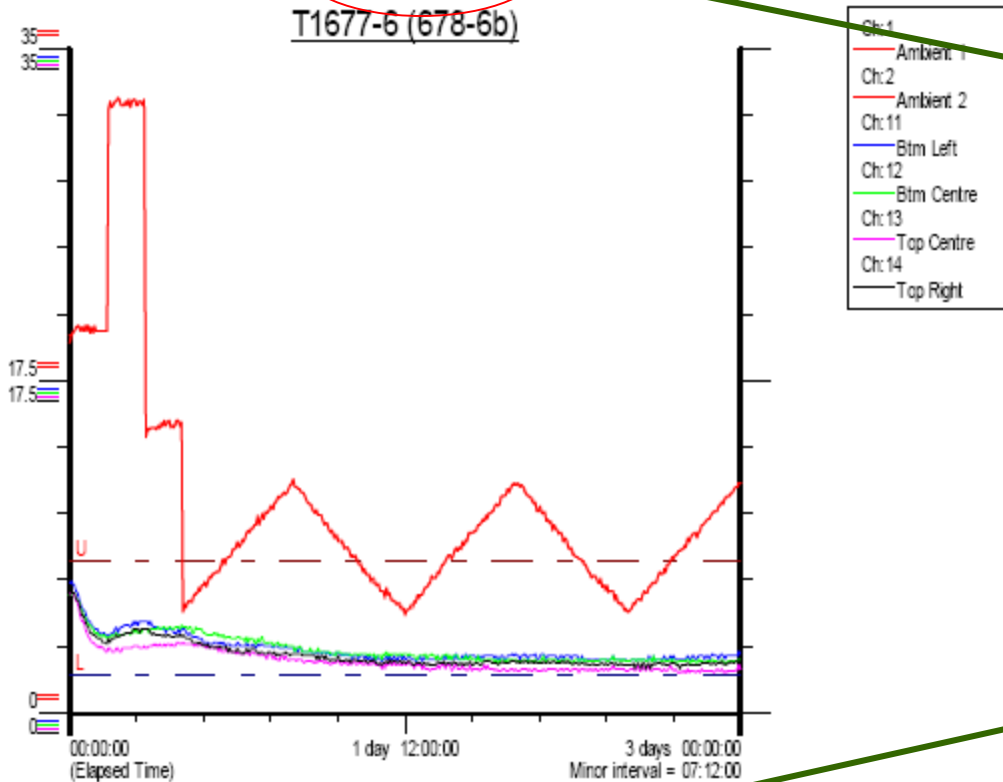
Performance Summary-Winter profile



T1677-6 PERFORMANCE SUMMARY

72 HOUR WINTER (SE ASIA) SYSTEM – 4.5L PRODUCT LOAD

T1677-6 (678-6b)



Ensure that the profile is for the right continent i.e. SE Asia

From the ambient temperature profile, check lowest temperature range of the destination location falls within these profiles

WINTER LOWER

Ambient Temperature Profile
20°C for 4 hours, 32°C for 4 hours,
15°C for 4 hours,
5°C to 12°C ramped over 12 hours,
12°C to 5°C ramped over 12 hours,
Repeat 12°C to 5°C ramped profile

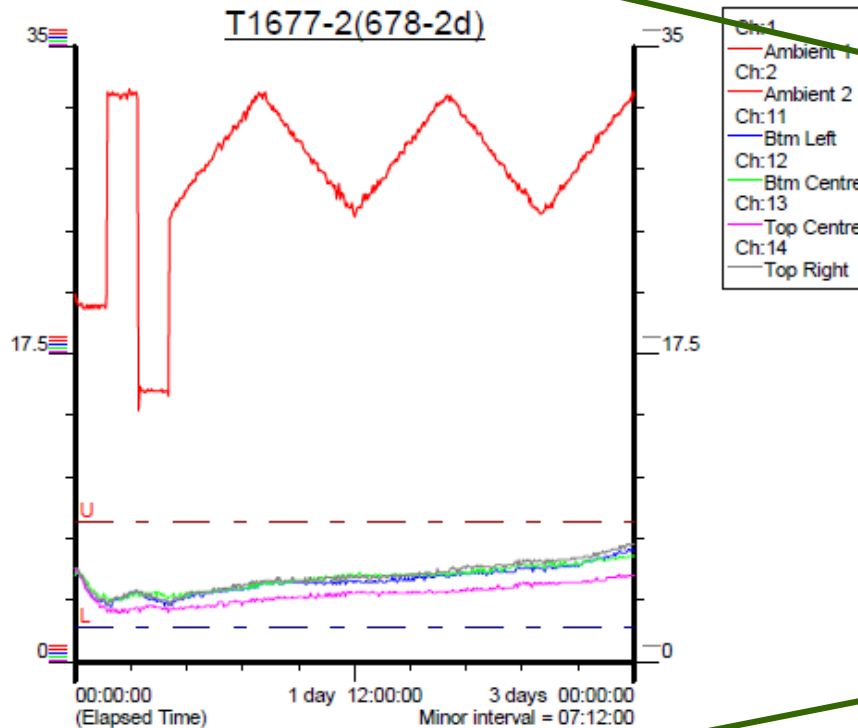
Results
Product temperature:
2°C to 8°C for 72 hours, 00 minutes +
Maximum product temperature was 6.9°C @ 00:10
Minimum product temperature was 2.1°C @ 54:40

Performance Summary-Summer profile



T1677-2 PERFORMANCE SUMMARY

72 HOUR SUMMER (SE ASIA) SYSTEM – 4.5L PRODUCT LOAD



Ensure that the profile is for the right continent i.e. SE Asia

From the ambient temperature profile, check the temperature range of the destination location falls within these profile

SUMMER UPPER

Ambient Temperature Profile

20°C for 4 hours, 32°C for 4 hours,
15°C for 4 hours,
25°C to 32°C ramped over 12 hours,
32°C to 25°C ramped over 12 hours,
Repeat 32°C to 25°C ramped profile

Results

Product temperature:
2°C to 8°C for 72 hours, 00 minutes
Maximum product temperature was 6.7°C @ 71:10
Minimum product temperature was 2.8°C @ 04:10

Cold Chain Shipping Systems



Multiple-Use V.S. Single-Use Systems

Multiple Use	Single Use
Often used in closed loop logistics where the start and end point of distribution is the same.	Used in opened loop logistics where packaging is distributed and not returned to the origin.
More environmental friendly	Environmentally unfriendly
Per trip cost is cheaper	Per trip cost is more expensive
Need to check for damages to ensure quality after every use	No need to check for damages

Types of Active Cold Chain Shipping System



Reefer Container



Envirotainer



Types of Passive Cold Chain Shipping System



Carton / Box (Reusable)

Carton / Box (Single Use)

Envelop / Pouch



Know the Market –

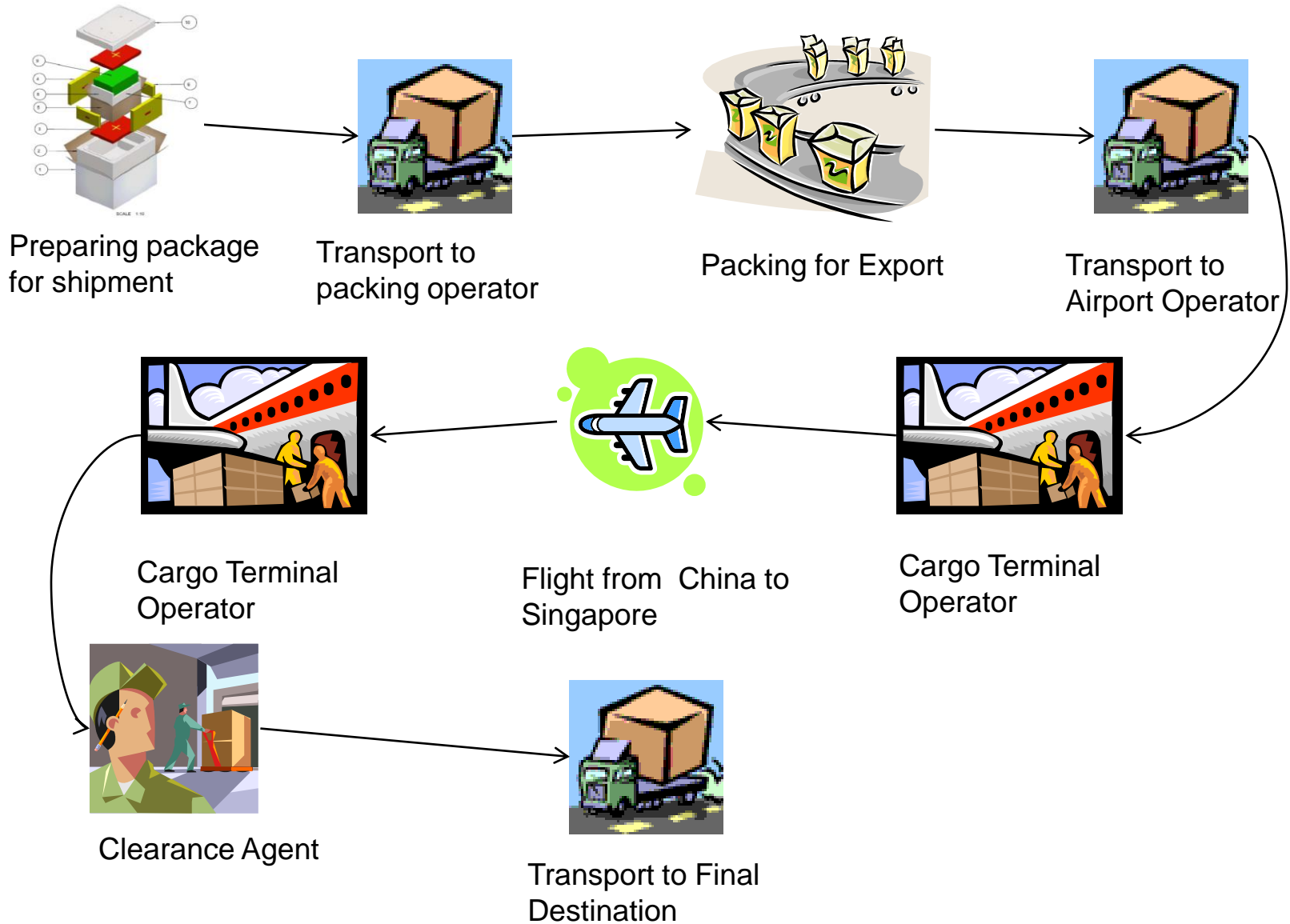
Relevant Industrial Guidelines in Cold Chain



Recommended industry guidelines

- ▶ IATA Perishable Cargo Regulations (PCR) – an essential reference guide for all parties involved in the packaging and perishables for air transportation
- ▶ Good Manufacturing Practices (GMP) – a guideline for manufacturers to ensure quality of product
- ▶ Good Distribution Practices (GDP) – a guideline to ensure products are stored, transported and handled in suitable conditions
- ▶ Good Cold Chain Management Practices (GCCMP) – a set of good storage and shipping practices for temperature-controlled products

Plan the Logistics Chain - Cold Chain Logistics



Possible Cold Chain Breaks



- ▶ During Transport to Packing
- ▶ When packing
- ▶ Waiting for and loading to Transport
- ▶ During transport (if unrefrigerated)
- ▶ Unloading from Transport to Airport store
- ▶ When moving the dolly on tarmac
- ▶ Awaiting and when loading to Aircraft
- ▶ In flight/ On Board
- ▶ When unloading the Aircraft
- ▶ At break bulk point in airport terminal
- ▶ When loading, unloading truck and during road transport



Selection of Service Provider



- ▶ Criteria to look for in a good service provider include:
 - Equipment is in good working condition/ regularly calibrated and suitable for your product
 - Expertise in the destination market
 - Expertise in checking and recording the condition of your product
 - Capability to store/ pack your product appropriately before/during/after transport
 - Effective system to ensure all documentation is completed and stored
 - Effective system of communication established
 - Contingency plan in place, and the capability to recover your product

Get the Basics Right



Establish Standard Operating Procedures (SOP)

- ▶ Every step along the chain needs to be managed and controlled, and this is best done through the development of SOPs
- ▶ All the control points and nodes must be considered and communication must be made clearly to all parties
- ▶ For instance, in the case of Customs inspection where they need to open up the package,
 - Shipper will usually be advised
 - Handlers will have instructions on what temperature the product needs to be maintained, and how to repack the package

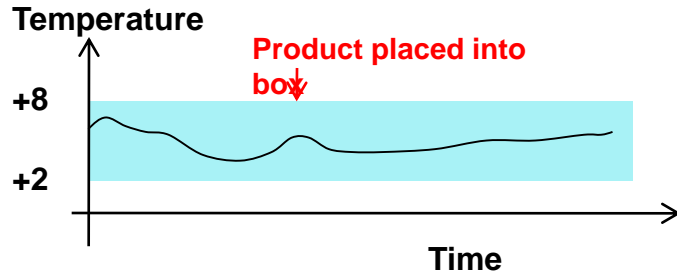
Get the Basics Right



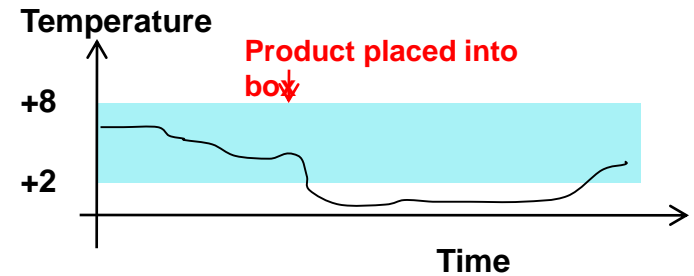
Pre-Shipment Monitoring

- ▶ A beneficial technique for ensuring that a box has been set up correctly is to do pre-shipment monitoring, e.g:
 - Prepare and final condition gel packs 2.5hrs prior to the expected packing time of the shipment
 - Pack the boxes and start monitoring the temperature 2hrs before product is placed in the box
 - After 2hrs & before placing the product in the box, check the temperature
 - If the box is at the correct temperature, place the product in
 - If the box is not at the correct temperature, delay the packing until the temperature is correct, or abort the process
- ▶ As soon as the product has been placed into the box, note down the time and from the graph that has been downloaded, check if the box or product has been conditioned correctly

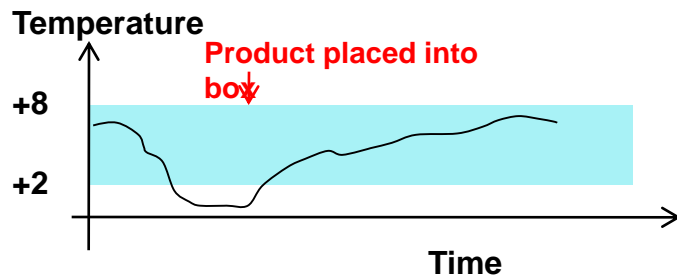
Examples of Pre-Shipment Monitoring Graph



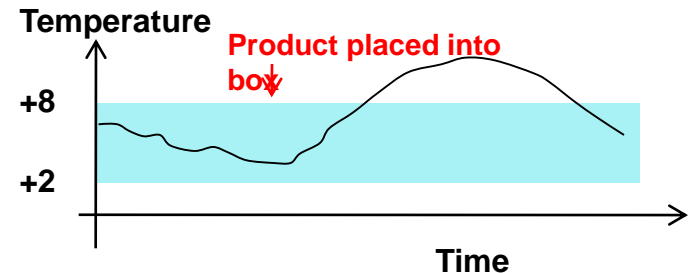
- The refrigerants were set up correctly, and the product was of the correct temperature



- The product was too cold, and caused the temperature in the box to fall below **+2°C**



- The refrigerants were not prepared correctly, and dropped below **+2°C** before product was placed in



- The product was too hot, and caused the temperature in the box to rise above **+8°C**

Get the Basics Right



Communication & Airline handling

- Handling errors by the airlines can jeopardize the integrity of the product inside the package
- Airline and transport handlers at origin and destination must be informed about the importance of the temperature-controlled package through labels and consignment notes
- Examples of basic instructions:
 - ▶ **DO NOT STORE IN DIRECT SUNLIGHT**
 - ▶ **SHIPPER LOADED UNIT – DO NOT OPEN**
 - ▶ **DO NOT FREEZE**
- The label requirements has to be in compliance to the IATA Regulations (will be covered in detail under E356-Pharmaceutical and Bio-chem Supply Chain)



Effective Communication - Example of Labels



- ▶ When dealing with markings & labels, think about who will read it and what it will mean to them
- Example of a misleading label, as handlers might misinterpret and store the package in cold store

Temperature Sensitive
Maintain at +2°C to +8°C

- Example of clear labels

Temperature Sensitive Product Enclosed
Store between +20°C to +25°C

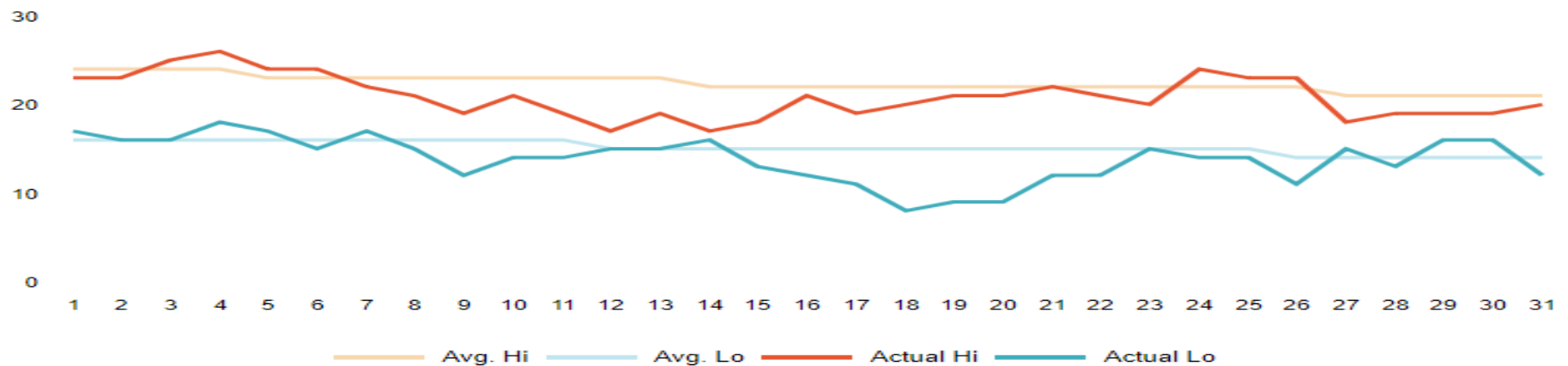
Remove Product from packaging
and store at +2°C to +8°C

Today's Problem

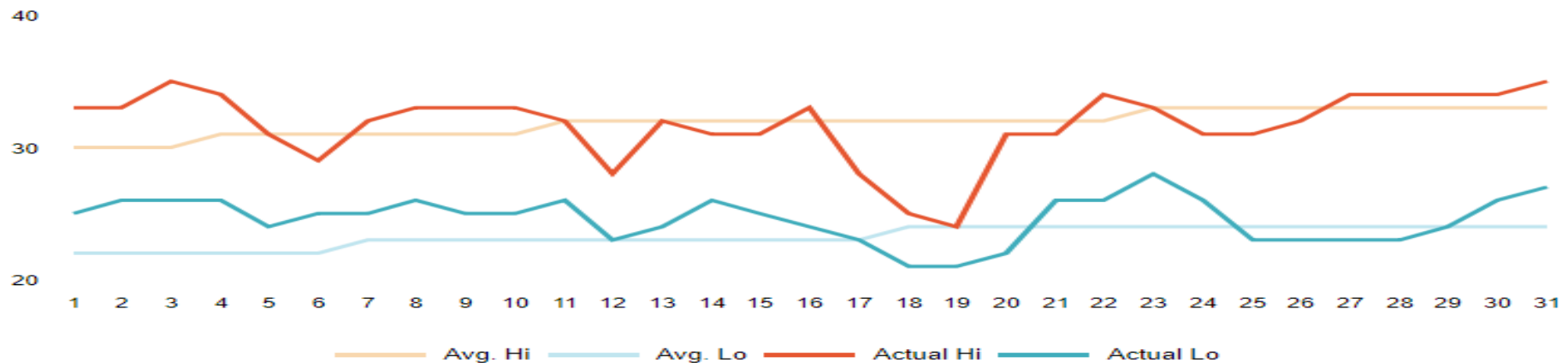


- You need to find out the distribution conditions of the vaccines for the 2 different batches (In the month of May and December) – below data from www.accuweather.com

Temperature Graph December 2017



Temperature Graph May 2017



Today's Problem



- The selected boxes have to be validated by 3rd Party Laboratory Testing company, i.e. you should use qualified systems that are able to sustain the product temperature at the required temperature range of +2°C to +8°C throughout the shipping duration (72 hours) till the final destination noting the quarterly ambient temperature profile.
- Therefore, you should use:
 - 2 units of T1677-6: 72 HOUR WINTER (SE ASIA) SYSTEM – 4.5L PRODUCT LOAD in December (required volume of 5 liters)
 - 2 units T1677-2: 72 HOUR SUMMER (SE ASIA) SYSTEM – 4.5L PRODUCT Load in May (required volume of 7 liters)

Today's Problem



In addition, other considerations you need to take note of are:

- ▶ The refrigerants of the cold box must be properly conditioned, and the product must also be maintained within the temperature range when it is packed
- ▶ Temperature loggers have to be placed inside the box and used for pre-shipment and post-shipment monitoring
- ▶ You should choose a reliable service provider who is familiar with handling of his products and familiar with both the domestic and foreign market
- ▶ Communication should be made clear to all parties
- ▶ As you are using a box meant for a larger volume of products, you will need to fill up the additional space with other filler materials such as bubble packs

Learning Objectives



- Describe how freight management of cold products can be achieved
- Recognize the criteria for selecting a suitable insulated shipping system for the given requirement
- Recognize the importance of preparing the cold box based specifications
- Discuss how ambient temperature can affect the performance of the cold box
- Evaluate the suitability an insulated box for a given set of requirements