

# Principles of Qualification for Transport

## Technical Report 39

### Qualification Testing Process

- Define
  - Identification of Requirements
- Design & Test
  - Design Qualification (DQ)
  - Component/System Specification (CS)
  - Operational Qualification (OQ)
  - Performance Qualification (PQ)
- Implementation
- Continuous Monitoring

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Guidance for Temperature-  
Controlled Medicinal  
Products: Maintaining the  
Quality of Temperature-  
Sensitive Medicinal Products  
through the Transportation  
Environment

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# Define – Identification of Requirements

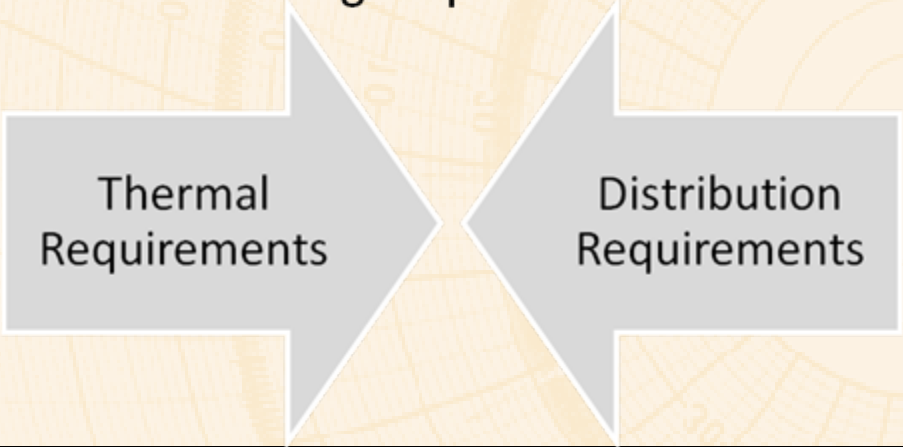
- Assess Current Operations
- Identify Tier 1 Requirements – bare minimum to run test
  - Duration, profile, temp criteria, product
- Identify Tier 2 Requirements – produces most efficient solution

## Thermal

- Allowable temp excursions
- Monitoring requirements

## Distribution

- Size/weight Restrictions
- Reusable Solution
- Environmental Impact
- Multi-product Packaging
- Physical Testing Requirements
- Seasonal or Universal Packout
- Storage Requirements
- Cost Constraints

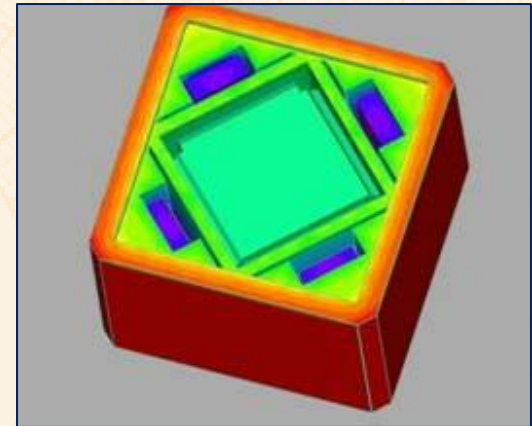


Thermal  
Requirements

Distribution  
Requirements

# Design & Test – Design Qualification

- Integrate requirements from define phase
- Design Considerations
  - Materials – cost of components vs. total cost including freight
  - Ease of pack-out
  - Shipping Durations and Lanes
  - Number of SKUs
  - Temperature Monitors
  - Conduction or Convection Driven
- Design Development
  - Historical Testing Results
  - Advanced Predictive Thermal Modeling

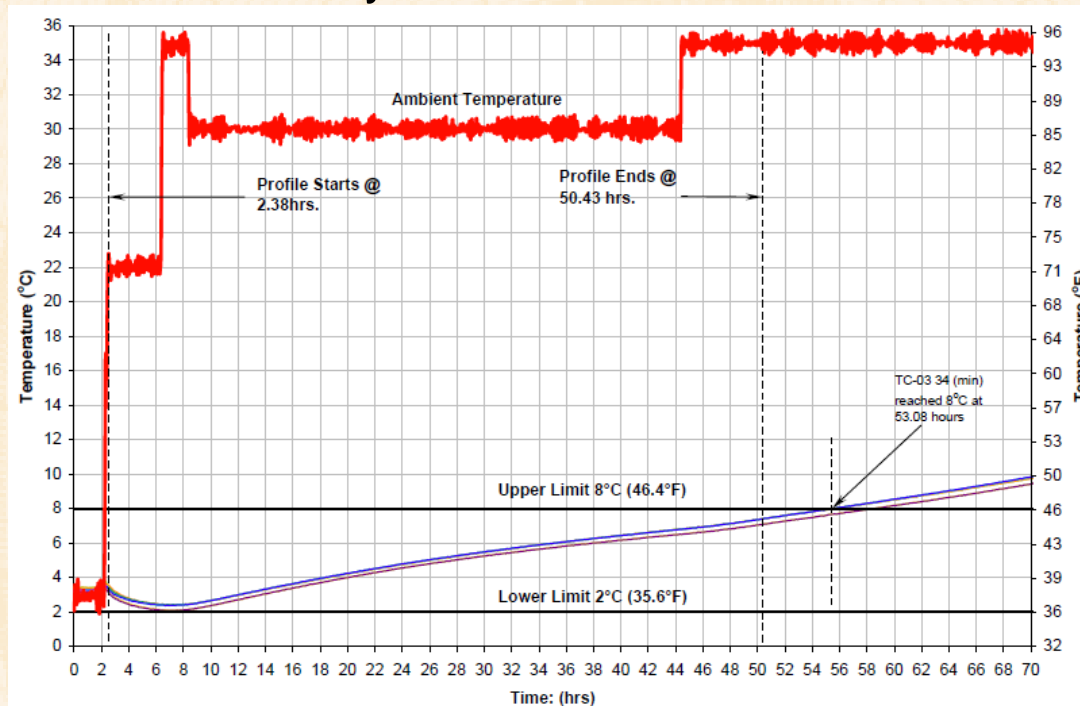


# Design & Test – Design Qualification

## Ambient Temperature Profile Development

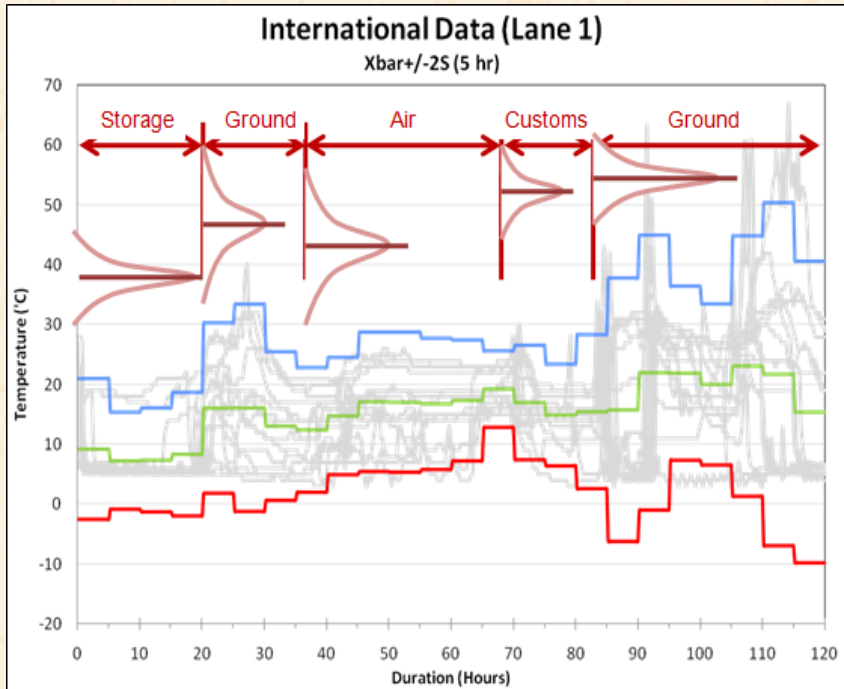
- One of the most important factors in design and qualification
- Three Standard Methods

### 1. Industry Guidelines – ISTA 7D

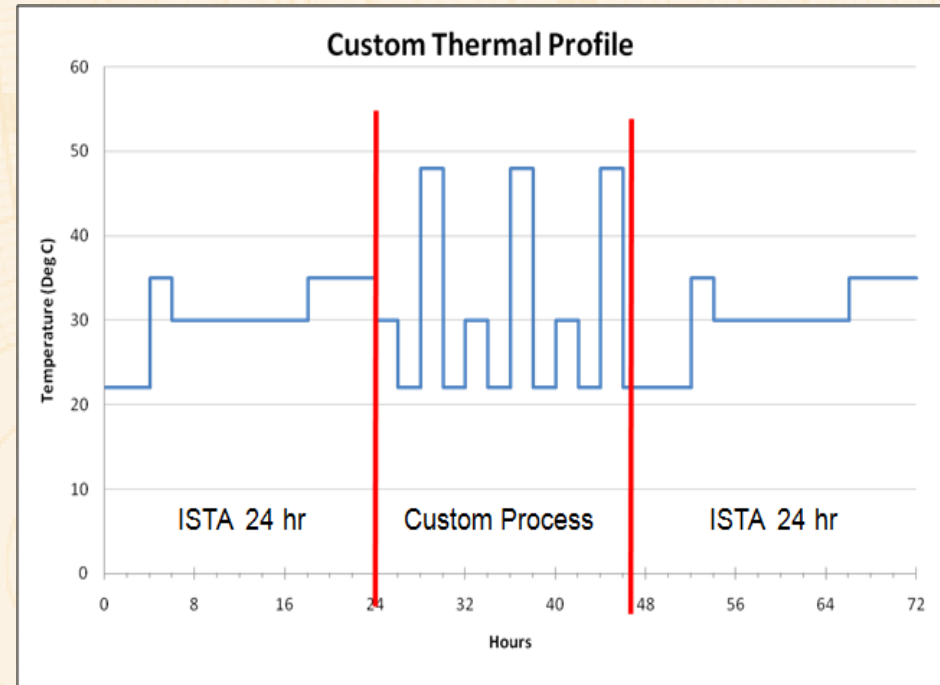


# Design & Test – Design Qualification

## 2. Shipping Lane Mapping



## 3. Custom



# Design & Test – Design Qualification

## Design Qualification (DQ) – Proof of Concept

- N=1, multiple designs

## Process

- Equipment Used
- Protocol
  - Acceptance Criteria
  - Ambient Temperature Profile & Duration
  - Minimum & Maximum Product Loads
  - Thermocouple Locations – example to be included later
  - Materials, Pack-out and Pre-conditioning
- Run Actual Test
- Review Results
  - Approve or re-design



# Design & Test – Operational Qualification

## Operational Qualification (OQ) – Design Verification

- N=3, one design

## Process

- Same as DQ
- If custom product is utilized, may require lead-time for production tooling
- More in depth Protocol
- Complete Report with Calibration Records



# Design & Test - Performance Qualification

What is it?

- Verifying that the package works in the real world

What do you need?

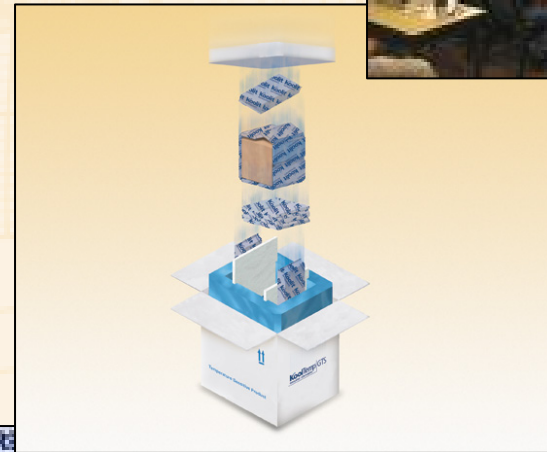
- The number of shipments to monitor
- The location of the monitors
  - Inside and Outside the box
  - Proper Thermocouple Placement during Qualifications will allow for:
    - Understanding the product temperature variance from edge to center
    - Understanding the correlation between air and product temperature to define a monitoring location

How do you do it?

- Performed on site in the real process

# Implementation

- Delivery of solution components
  - Storage
  - Freezer & Refrigerator Validation
- Pre-conditioning of refrigerants
  - On or off-site?
- Training
  - Visual Aids
  - Seminars/Presentations
  - SOPs



# Continuous Monitoring

Best practices suggest that ongoing, periodic performance testing should be completed to ensure previously qualified systems are still within specifications.