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A Practical Approach to the Use of Mean Kinetic Temperature (MKT) in Trailer Validation

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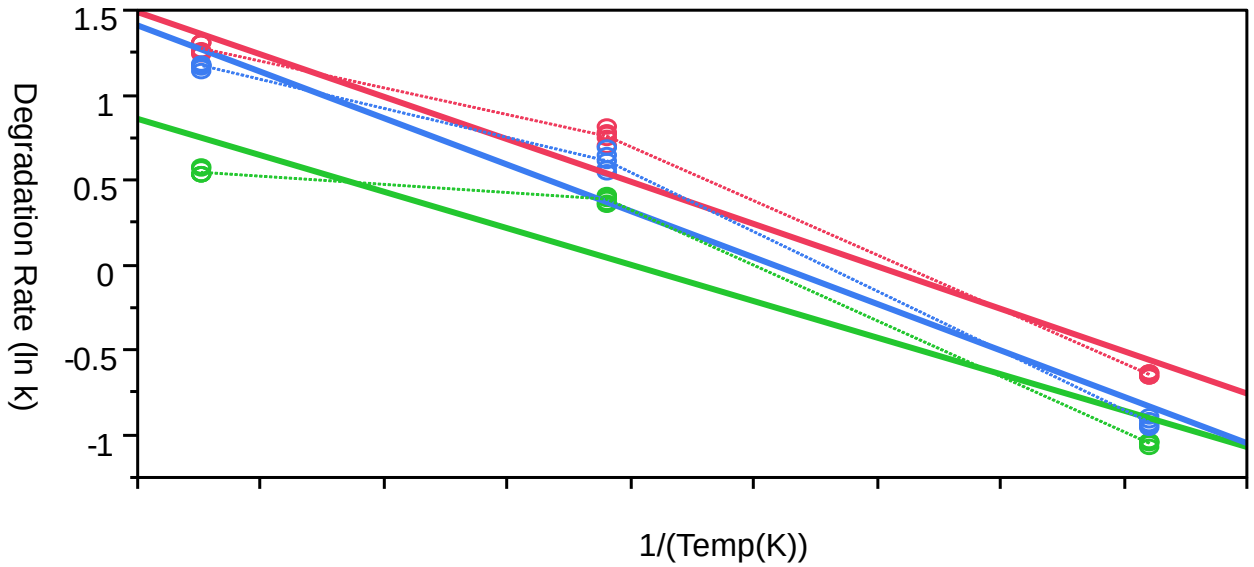
Is Mean Kinetic Temperature (MKT) applicable in 'Last Mile' Logistics?

- Review stability and transport validation data
- Determine rate of product degradation within temperature ranges
- Products which degrade quickest are the worst case

The key is to show a relationship exists between degradation and temperature

A range of temperatures and durations were studied to determine the relationship.

- **Multiple products and temperature tests**
  - **Various temperature used**
  - **Duration ranged from 20 hours to 200+ hours**



Linear relationship seen between temperature and degradation rate

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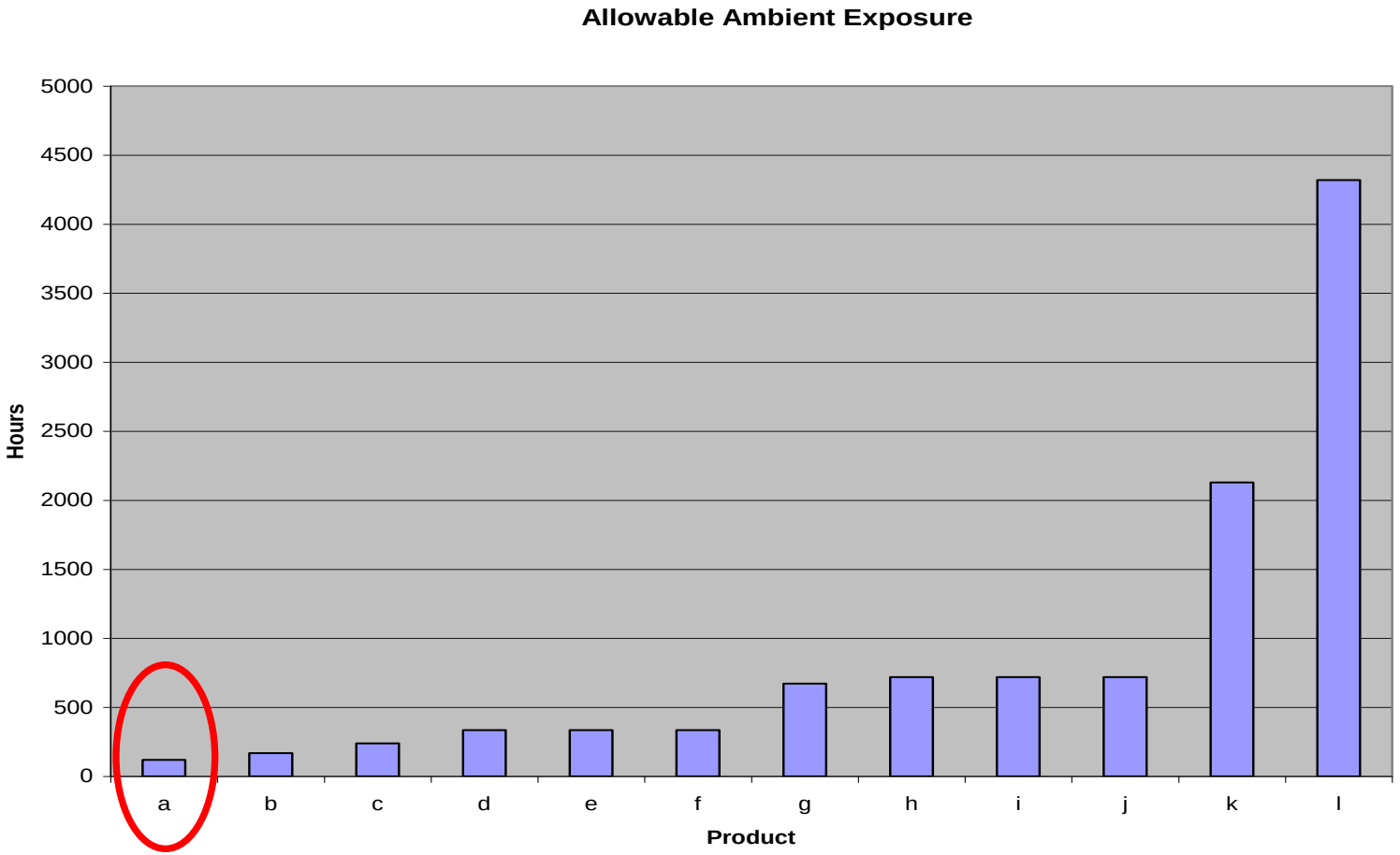
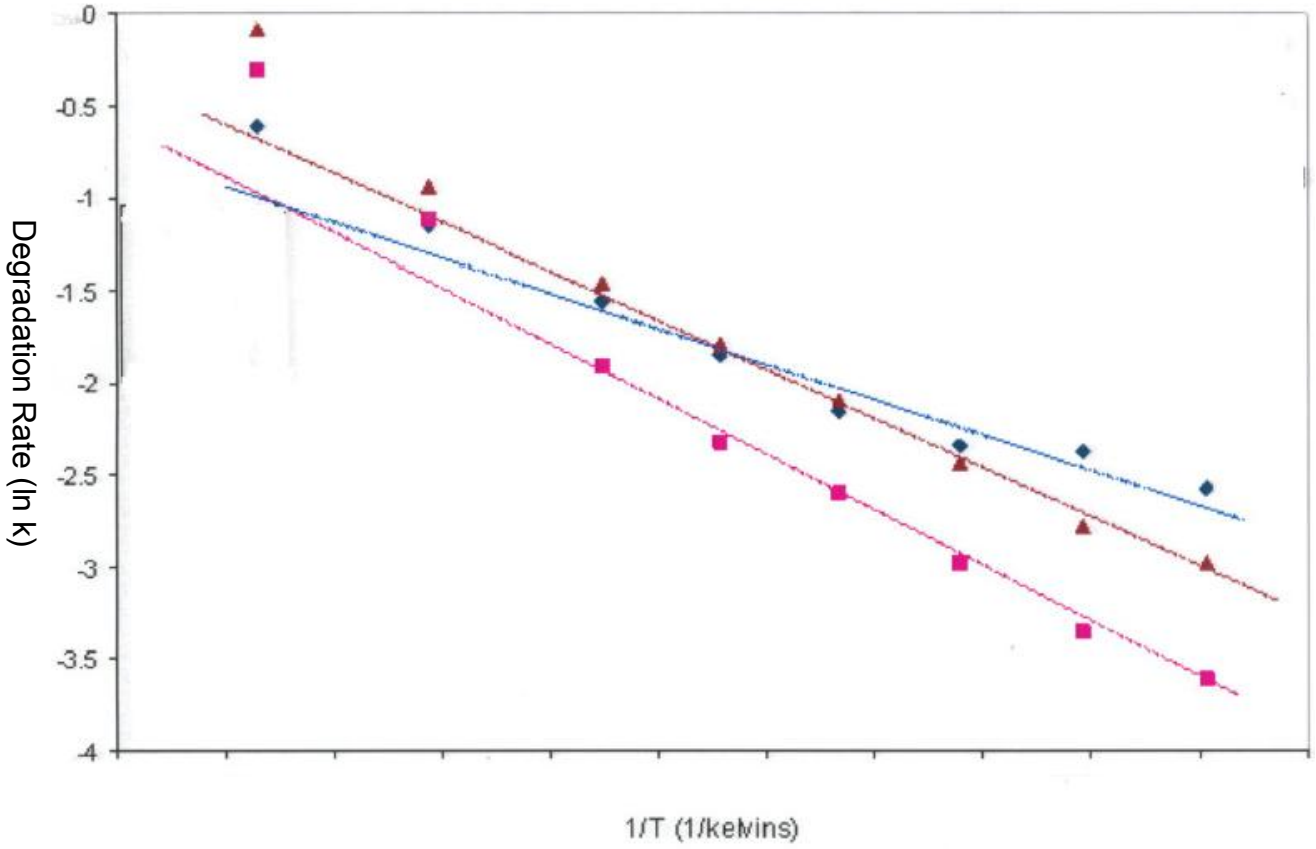
Stability studies defined the molecule most susceptible to degradation.



Molecule with minimal allowable ambient exposure was used as the worst case

We studied this molecule to understand the degradation pathway.

- **Relationship must be confirmed for product and temperature ranges**



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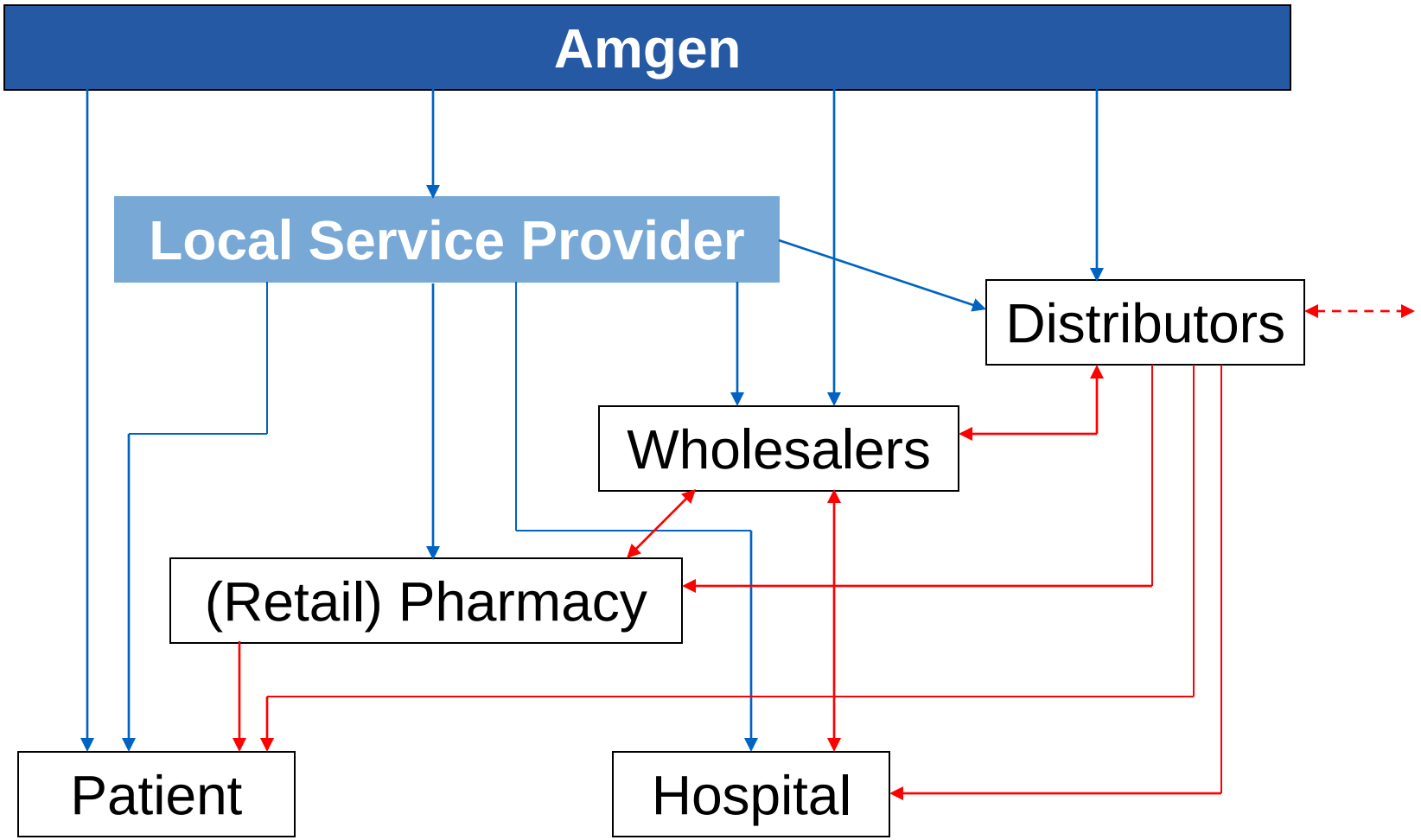
Our data showed a linear degradation pathway.

- Use least stable molecule as worst case approach
- Stability tested across a large range of temperatures
- Identification of which temperature ranges have an linear relationship

Our data confirmed MKT could be used for temperature ranges from 0 to 29ºC

We needed to focus on ‘Last Mile’ Logistics in very complex channels of distribution.

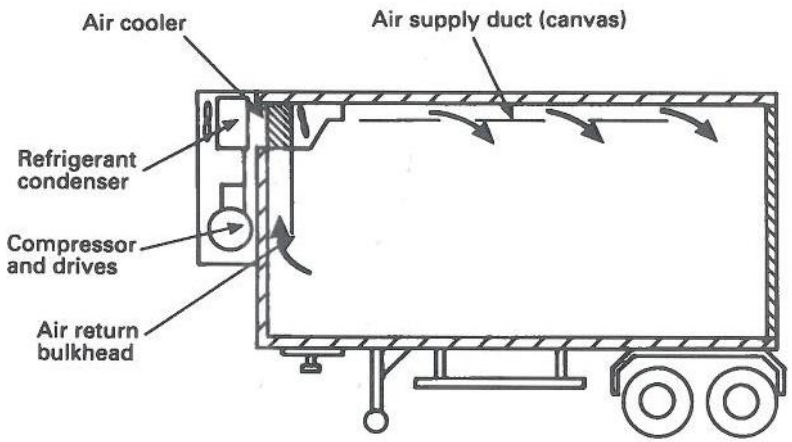


Trailers can be validated based on FDA general principles of process validation.

- **Installation Qualification (IQ)**
  - Insures that the system/equipment and its components are installed correctly and to the original manufacturer's specifications.
- **Operational Qualification (OQ)**
  - The OQ, tests are performed on the critical parameters of the system/process. These are usually the independent and/or manipulated variables associated with the system/equipment
- **Performance Qualification (PQ)**
  - This phase tests the ability of the process to perform over long periods of time within tolerance deemed acceptable.

Two major ‘critical to quality’ systems need to validated on a refrigerated trailer.

- **Insulated Trailer**
  - **Insulating capacity**
- **Refrigeration unit**
  - **Cooling / Heating efficiently**
  - **Air flow efficiency**



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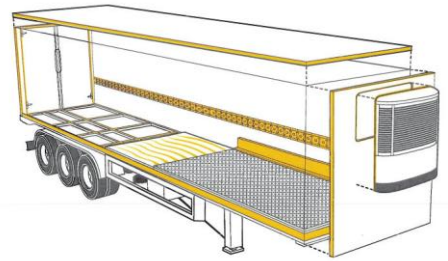
Specifications insure that the system/equipment and its components are installed correctly.

- **The trailer's insulating specification or data sheet**



- **The trailer refrigeration / heating system specification or data sheet**

Confirming correct installation to manufacturing specifications is the IQ

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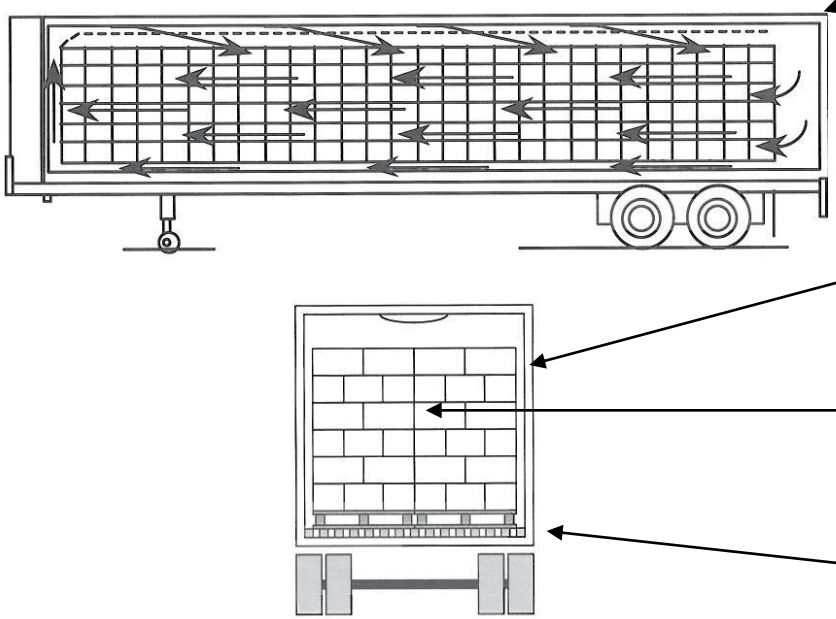
Three tests are performed per ATP Standards to meet OQ requirements.

- Insulating capacity of the trailer
- Trailer refrigeration / heating system capacity to remove and add heat generated by:
  - Residual heat from the air inside the trailer
  - Exterior heat conducted through the floor, walls and ceiling
  - Infiltration heat from outside air through small holes, cracks and seals
- A trailer air circulation system air flow to carry the heat of the trailer to the refrigeration unit where it can be removed

The IQ and OQ showed that optimized air flow is key.



Air Circulation 1 to 2 meters per second. Air exchange 60 per hour

4” Clearance from Walls

Centerline Loading

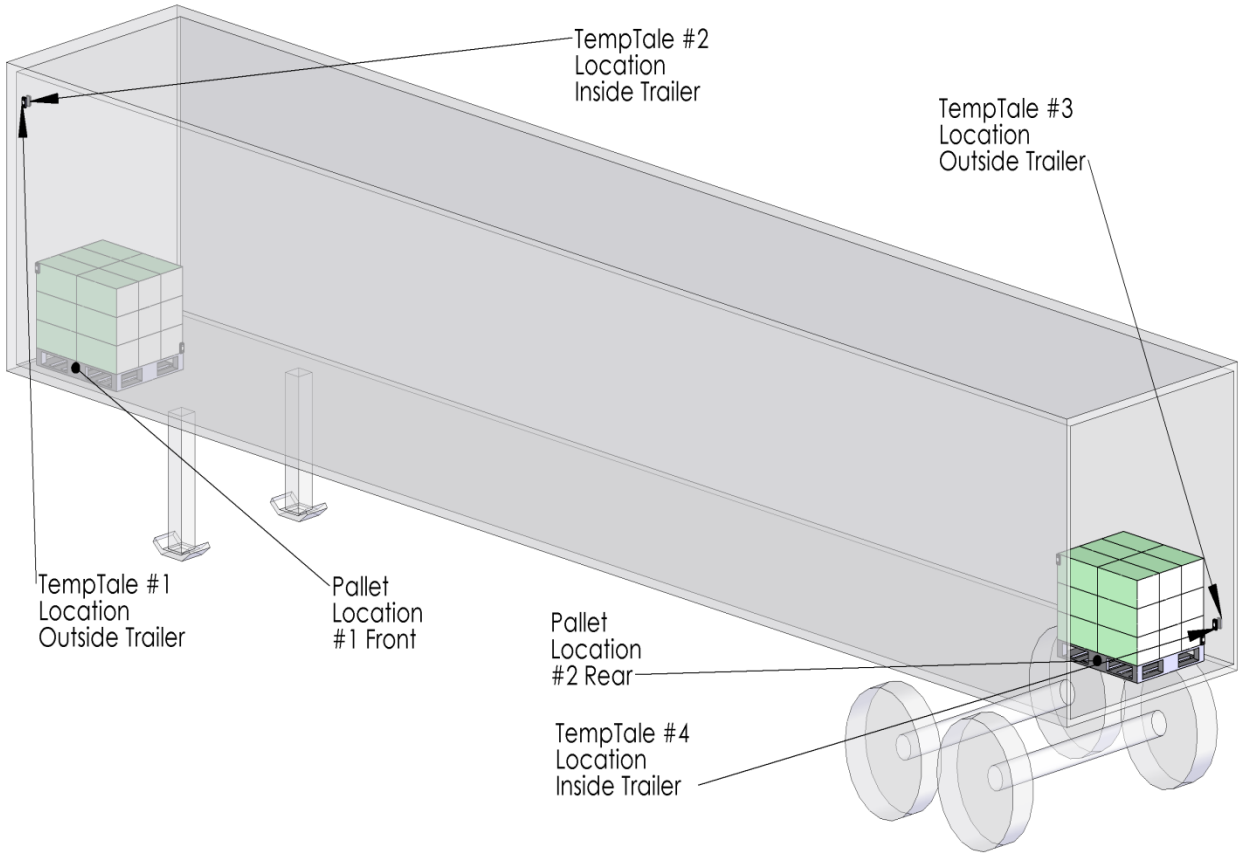
Slotted Flooring

PQ shows performance over time within acceptable tolerances.

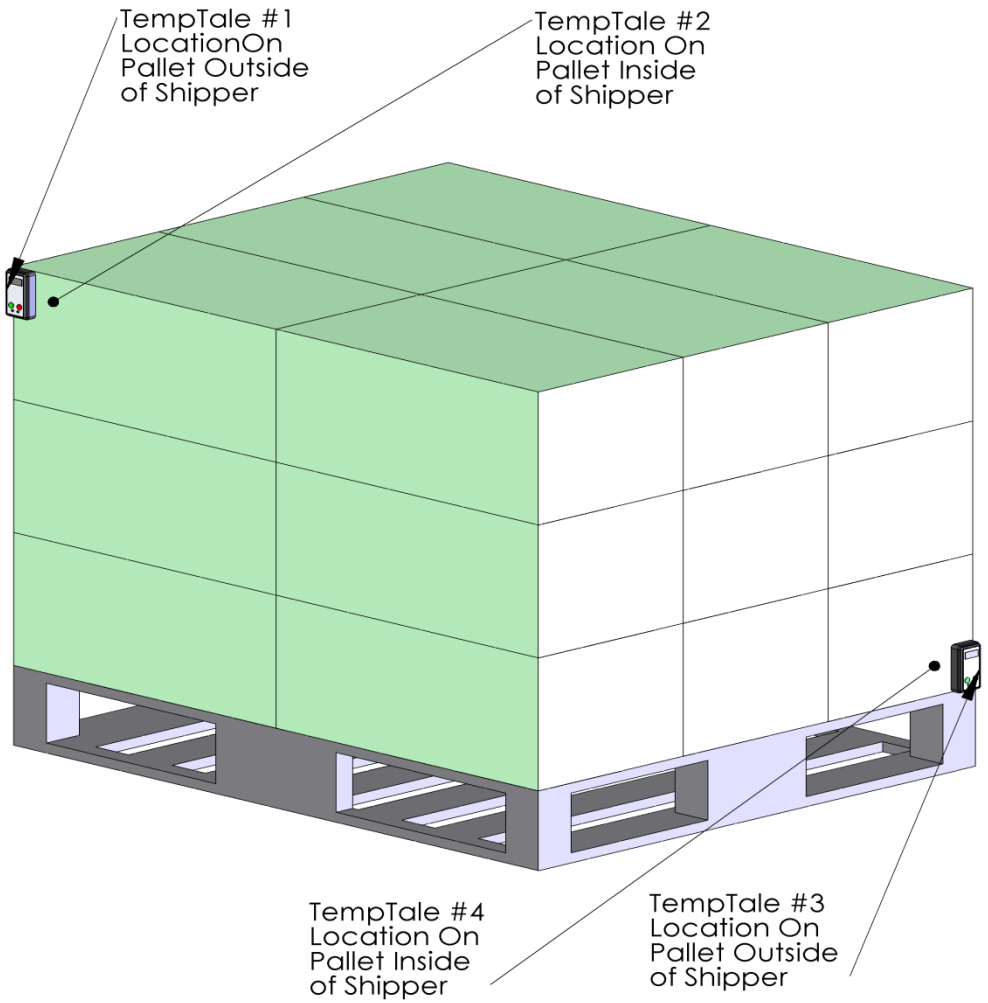
- Maintaining product temperature is dependent on the configuration and orientation of the pallets placed within the trailer.
- Airflow is critical to maintaining temperature and NOT the size of the trailer.
- The thermal dynamics of a trailer is governed by the mechanics of its cooling system.

Criteria of a successful test are that the temperature of the trailer maintains 2°C to 8°C MKT during transport

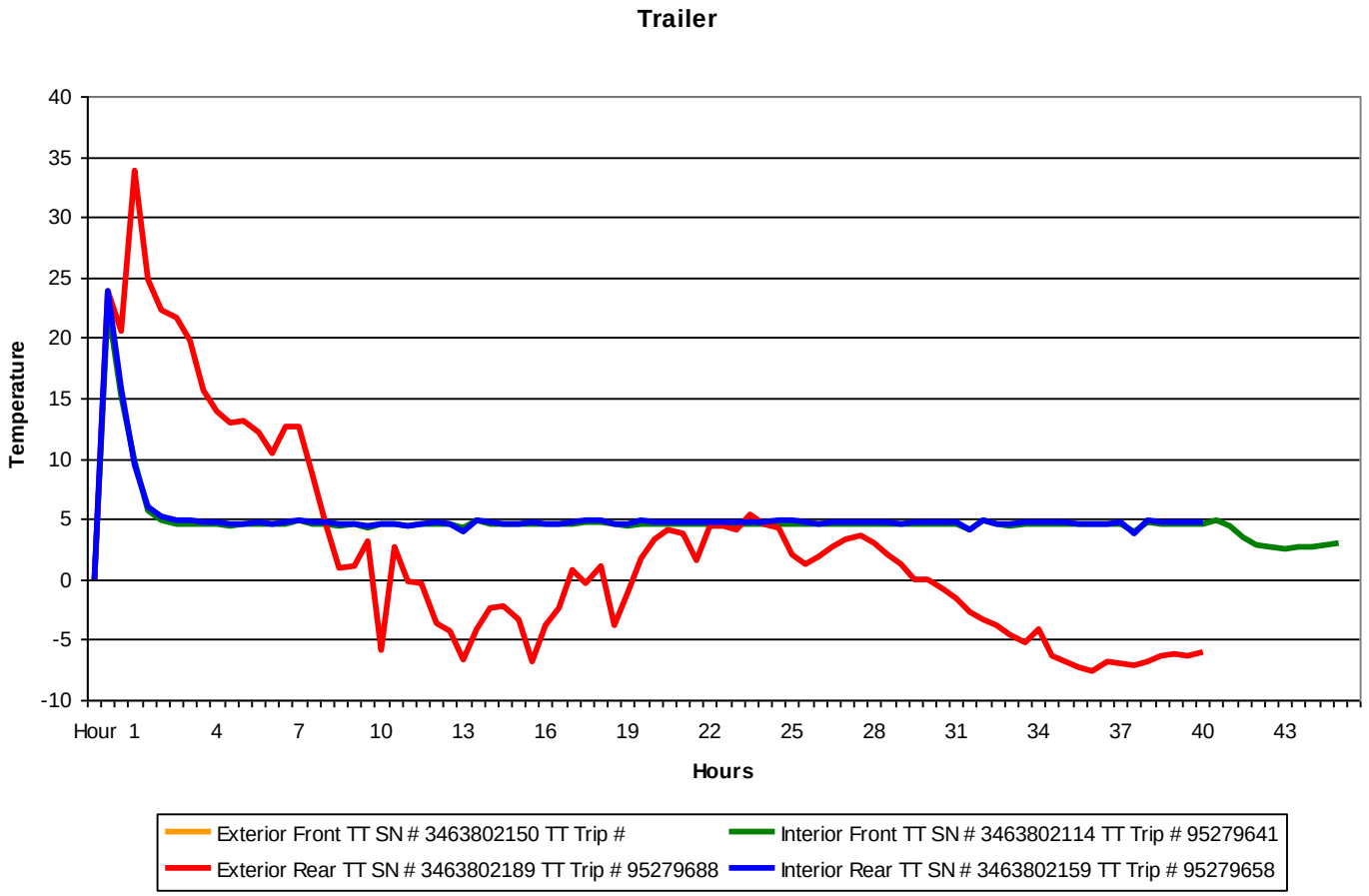
Temperature recording devices were placed in the front and back of trailer.



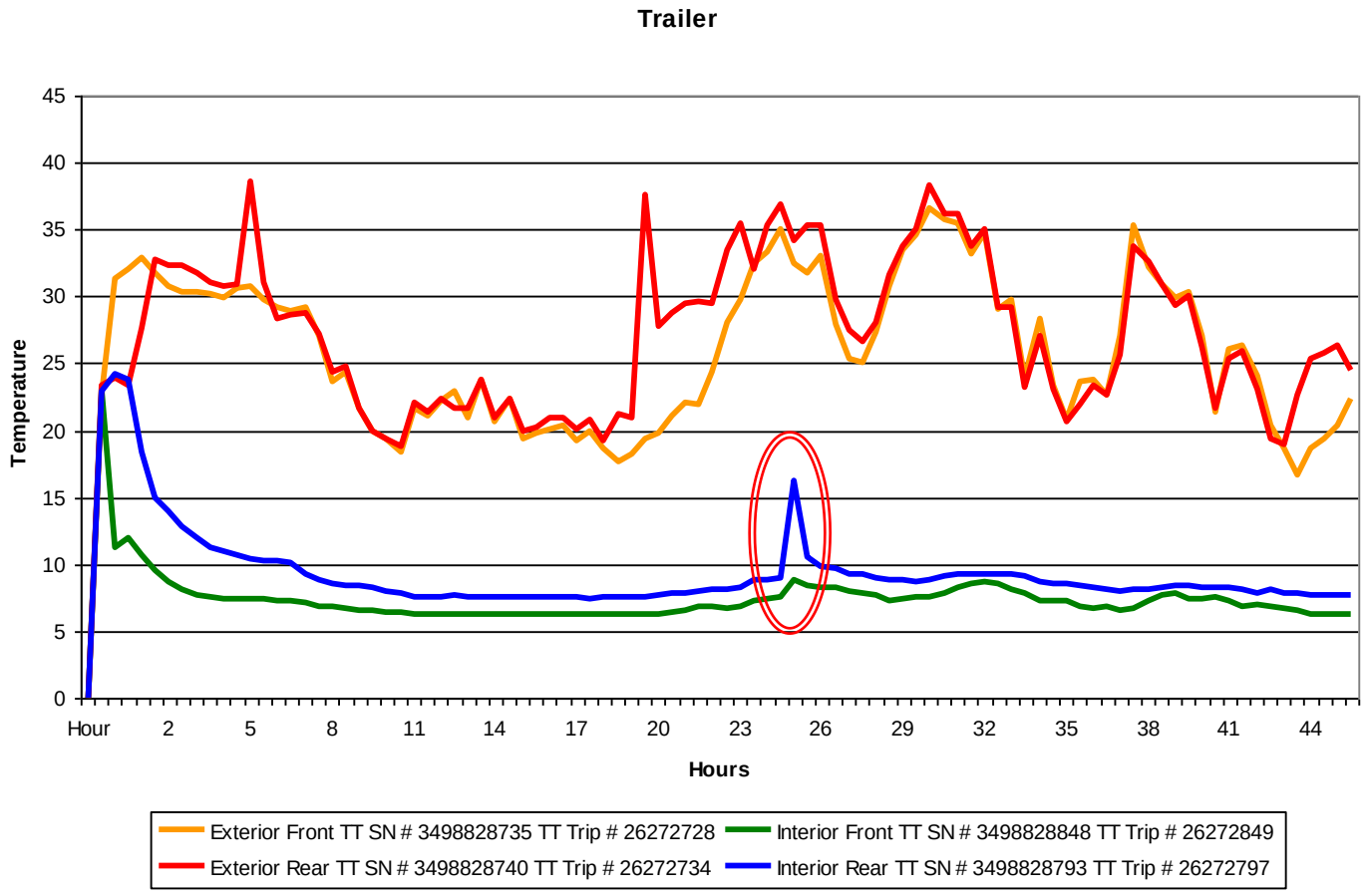
Recording devices were placed on pallet to measure air and product temperature.



Winter test results met acceptance criteria.



Summer test results showed transitory spike, but met acceptance criteria.



Combining good science and a practical operational approach yield benefits.

- Confirmed no impact to product quality throughout the process
- MKT can be used a tool to link stability studies and operational requirements
- Ensure compliance and reduce costs