USP Efforts on the Storage and Distribution of Drug Products: Historical Background, General Chapters and What Next?

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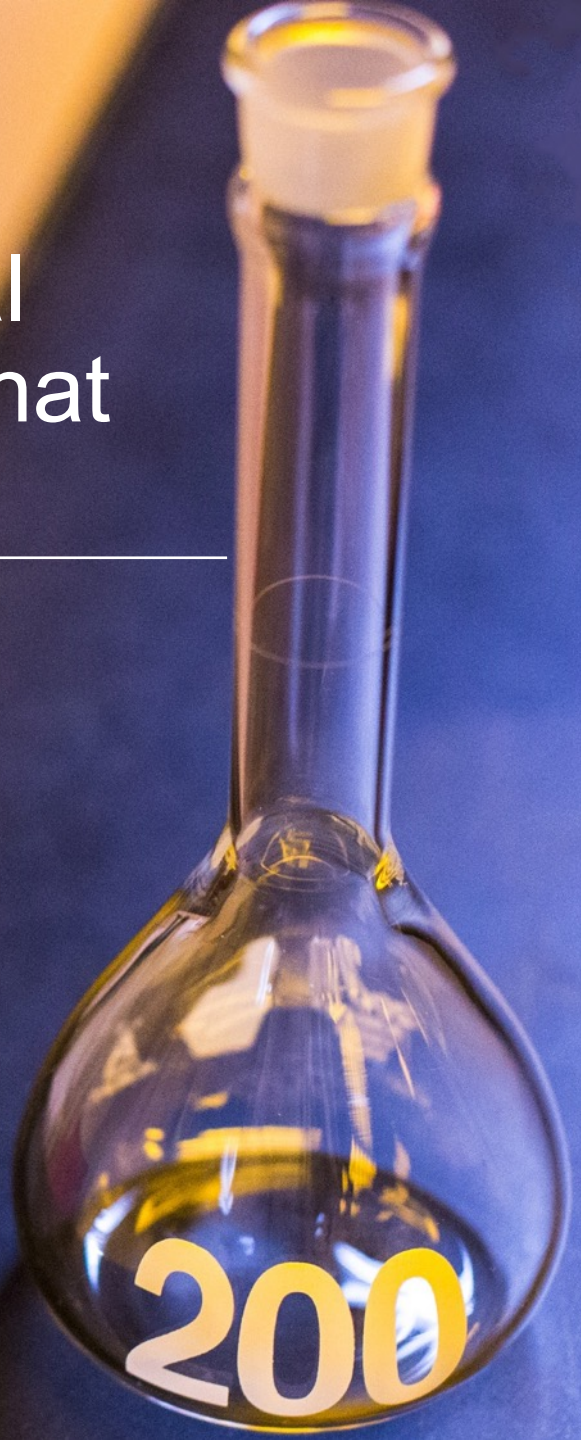

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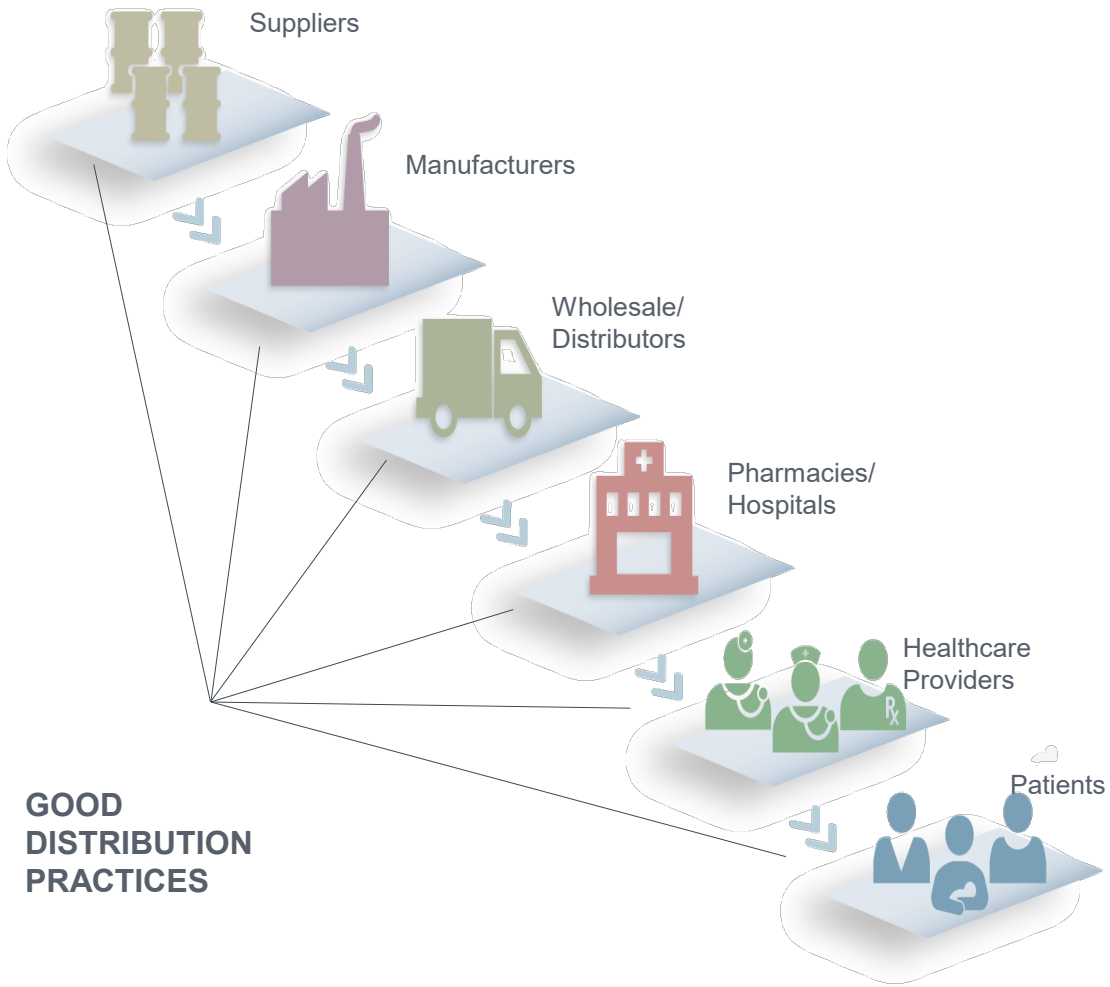
Resolution No. 10 – Drug Storage Standards

At the 1995 Quinquennial meeting, USP adopted Resolution 10, which encouraged USP to identify compendial items for which storage and shipment in the distribution system are of special concern, so that proper storage and shipment instructions can be included with the compendial item, such that the integrity of the item is maintained until received by the patient.

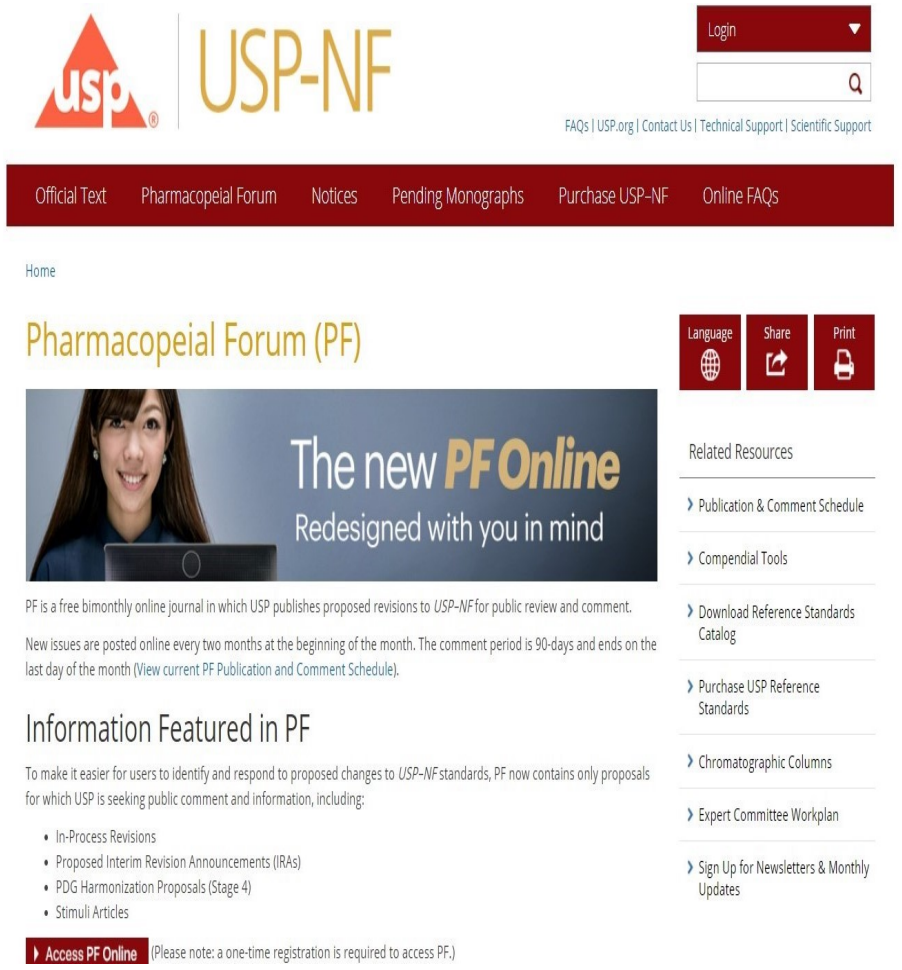


Topic Development

- Initial step in addressing this resolution was to conduct a survey.
  - Goal of the survey
    - Determine if there were temperature-sensitive products in the market and if so, how many.
  - Based on the poor response from the survey, shipping studies were conducted to determine what is the temperature and humidity to which drugs are exposed to during shipping.
  - Shipping studies were conducted
    - Temperature Fluctuations During Mail Order Shipment of Pharmaceutical Articles Using Mean Kinetic Temperature Approach, PF 23 (3), 1997
    - Temperature and Humidity Conditions During Shipment in International Commerce PF 25 (2), 1999
    - A Study of the Temperature and Humidity Variations in the Shipment and Distribution of Anthrax Vaccines PF 26 (3), 2000

<1141> Packaging, Storage, and Distribution of Pharmacopeial Articles

- Initial chapter developed on the topic in 2000:
  - Objective: outline concerns around the proper packaging, storage and distribution of temperature-sensitive drug products.
    - Packaging
    - Storage
    - Distribution
    - Special Packaging Considerations
    - Environmental Issues
    - Labeling
  - Based on industry feedback it was decided to expand the topic to include to all drug products, not just temperature-sensitive preparation.



<1079> Good Storage and Shipping Practices

- Chapter development/official 2000-2005:
  - Storage in Warehouses, Pharmacies, Trucks, Shipping Docks and Other Locations
  - Distribution and Shipment of Pharmacopeial Articles
  - Shipment from Manufacturer to Wholesaler
  - Shipment from Manufacturer or Wholesaler to Pharmacy
  - Shipment from Pharmacy to Patient or Customer
  - Returns of Pharmaceutical Articles from Patient or Customers
  - Storage of Physician Samples Handled by Sale Representatives in Automobiles
  - Stability, Storage, and Labeling
  - Statement/Labeling of Immediate Containers or Package Insert

<1079> Good Storage and Shipping Practices

Chapter update in 2007:

- Responsibilities of Supply Chain Partners
- Labeling Information
- Quality Management System
  - Good Documentation Practices
  - Storage Management System
  - Distribution Management System
  - Environmental Management System
  - Risk Management System

USP Supply Chain Workshop 2012

What did we learn?

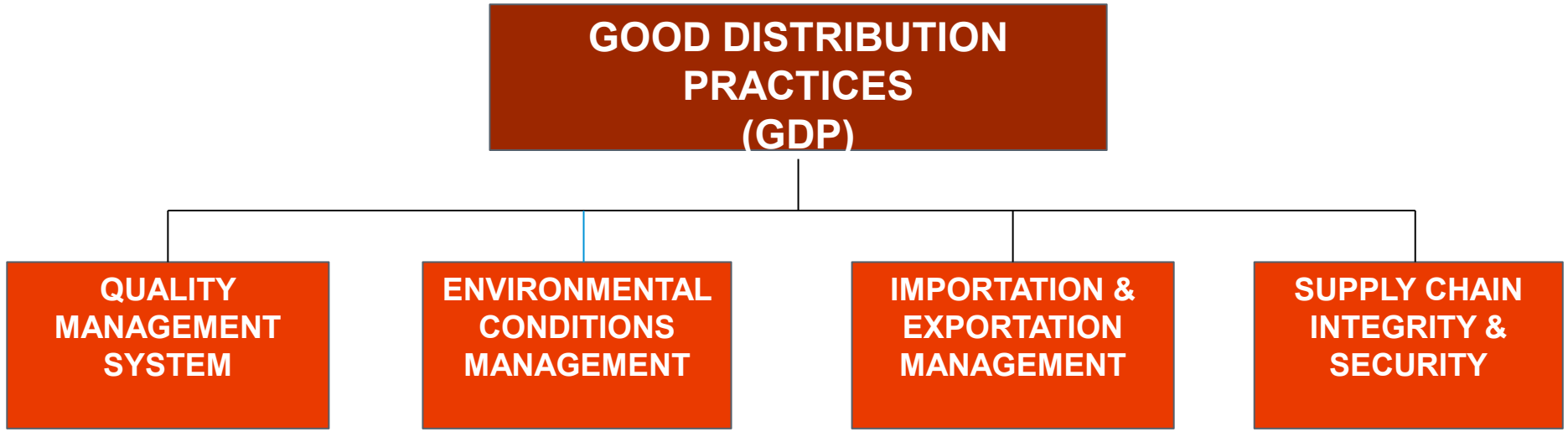
- USP's current approach to GDP has been piecemeal:
  - Individual components, (e.g. Excipients; Drug Products)
  - Individual topics (e.g. Storage & Shipping; Supply Chain Integrity, Importation and Exportation)
- A holistic approach to Good Distribution Practices (GDP) is preferred:
  - Acquisition of ingredients (API's, excipients)
  - Authentication and drug pedigree steps
  - Delivery of medicines to the end-users
  - Adherence to labeled storage conditions

<1083> Good Distribution Practices

- Four GDP topics covering quality management system, environmental conditions management, importation and exportation management and supply chain integrity and security will serve as the foundation for the GDP chapters.
- Generally, they apply to all materials and products, regardless of their regulatory category.
- These topics include the basic principles that provide guidance on how to establish and maintain:
  - a quality management system that ensures the quality, integrity, safety and efficacy of materials and products during sourcing and distribution (e.g. personnel, storage buildings, transportation vehicles, etc.).
  - temperature and humidity control during product holding and transportation.
  - supply chain integrity from importation and exportation procedures to minimizing counterfeiting, cargo thefts, diversion
  - traceability of individual products and shipments throughout the supply chain.

<1083> Good Distribution Practices

- **Pharmacopeial Forum: 38 (2) March 2012**



- The Drug Quality and Security Act (DQSA), was enacted by US Congress on November 27, 2013.
- Reevaluation of the <1083> suite of chapters, in light of the new legislation, led to postponement
  - Renewed focus on the topic of storage and shipping of finished drug products

Recent Development and Revision

Storage and Transportation

- <1079> Risks and Mitigation Strategies for the Storage and Transportation of Finished Drug Products (2020)

- <1079.1>Storage and Transportation of Investigational Drug Products (2018)

Temperature Control

- <659> Packaging and Storage Requirements (2020)

- <1079.2 > Mean Kinetic Temperature in the Evaluation of Temperature Excursions During Storage and Transportation of Drug Products (2020)

<1079> Risks and Mitigation Strategies for the Storage and Transportation of Finish Drug Products – Game-Changer Rationale

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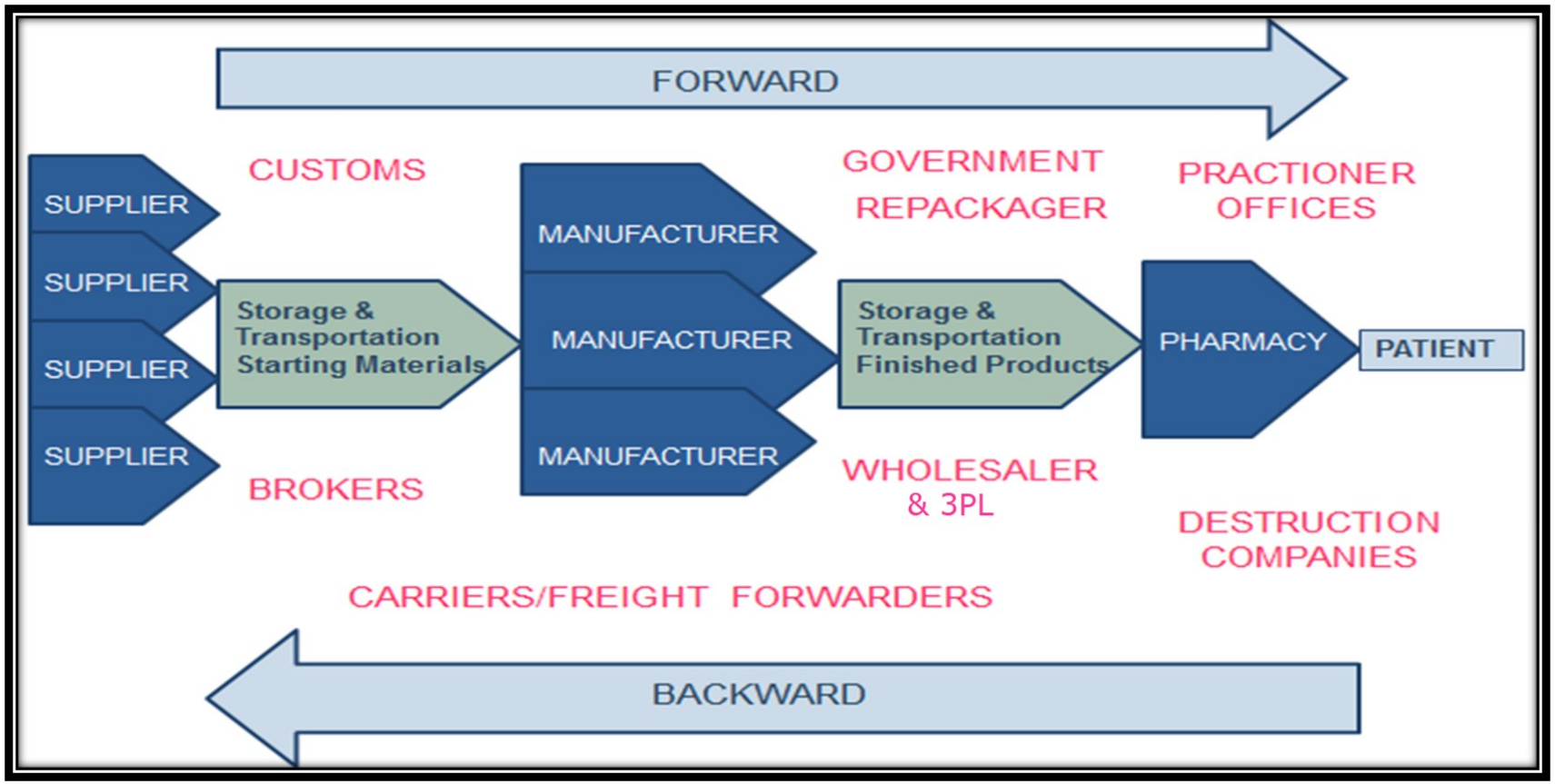
Pharmaceutical Supply Chain Overview



- Complexity of the supply chain
- Key activities: Storage and transportation
- Different modes of transport and climate zones
- Shared responsibility

Goal within the Pharmaceutical Supply Chain

- To maintain the integrity of drug products throughout the supply chain
- To ensure drug products reach the end user with their safety, identity, strength, quality, and purity intact
- Provide evidence that drug products are stored and shipped according to labeled storage conditions

USP General Chapter Rationale

Previous: <1079> *Good Storage and Distribution Practices for Drug Products*

- Good practices approach
- Potentially overlaps regulatory perspective

Current: <1079> *Risks and Mitigation Strategies for Storage and Transportation of Finished Drug Products*

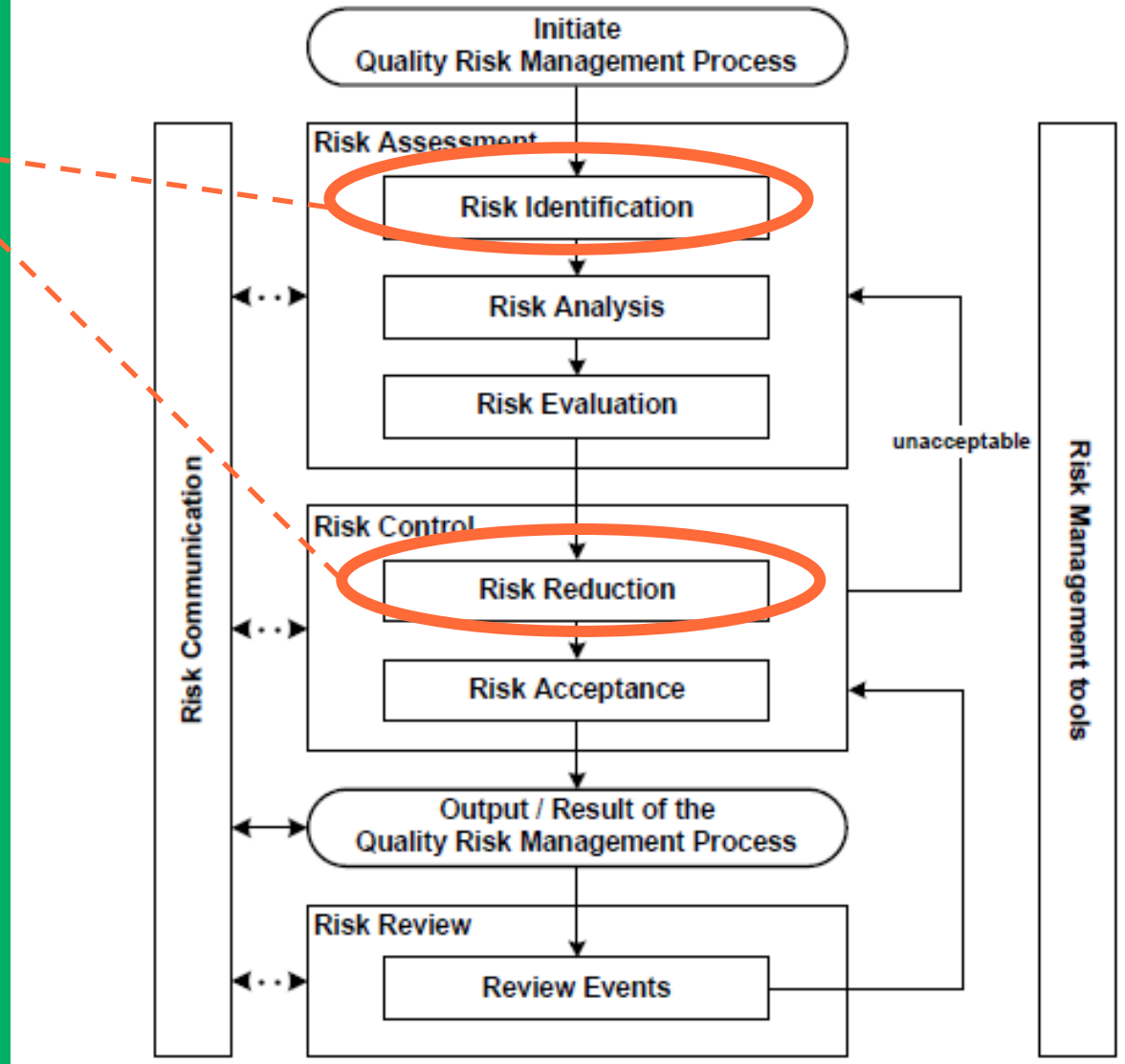
- Risk-based approach
- Provides education and builds knowledge

Harmonized Reference in Quality Risk Management – ICH Q9

Key points for <1079>

FAQ in Quality Risk Management

1. What might go wrong?
2. What is the likelihood? (Probability)
3. Which are the consequences? (Severity)
4. Can we detect? (Detectability)
5. How can we mitigate?



New <1079> and Risk-Based Approach

Risk identification is the systematic use of information to identify potential sources of harm (hazards). Information can include historical data, theoretical analysis, informed opinions, product and process knowledge, and the concerns of stakeholders. Risk identification addresses the question:

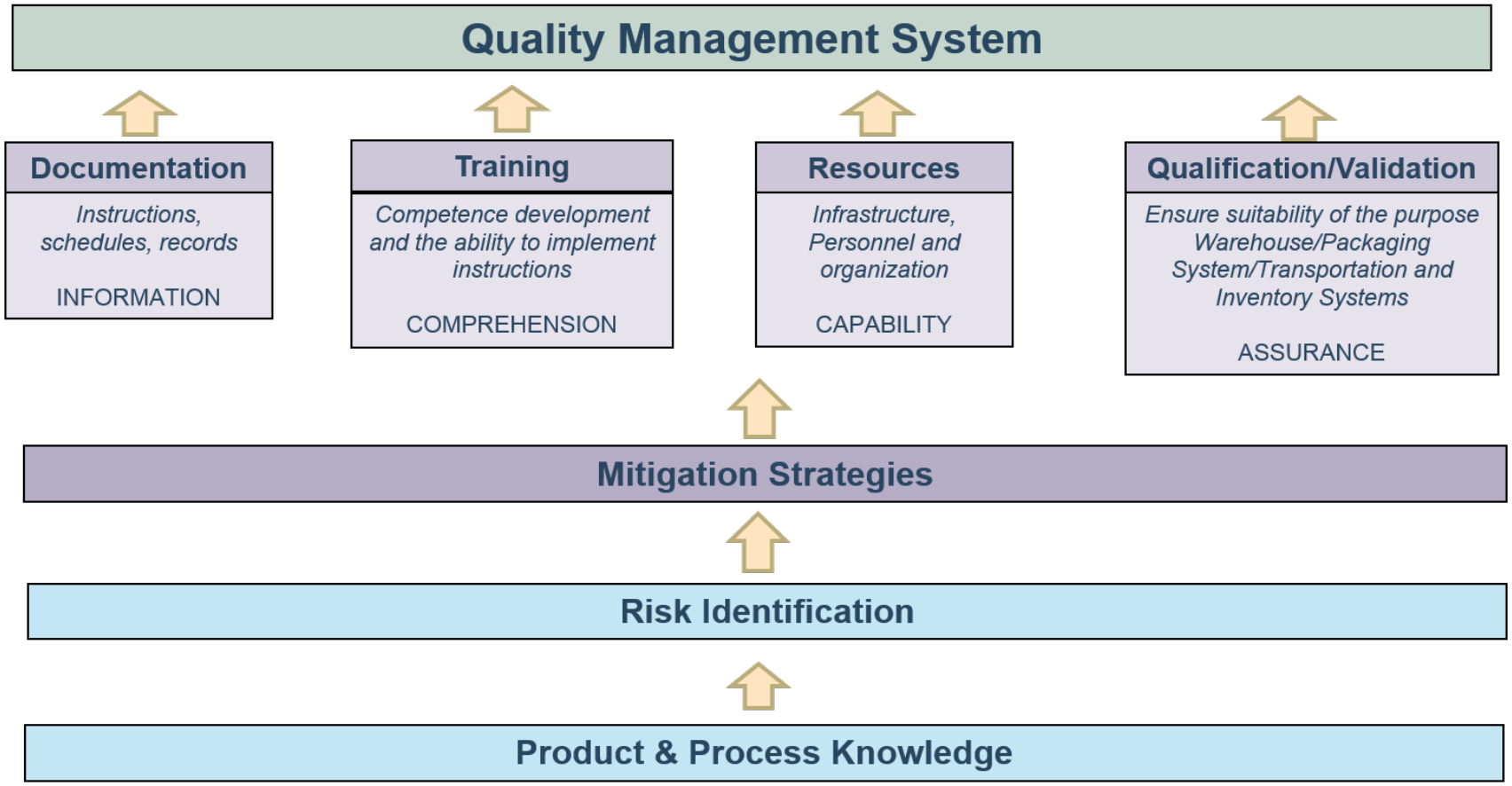
What might go wrong?

Mitigation strategies are a part of the risk control process, specifically risk reduction. Risk reduction addresses the question:

What can be done to reduce or eliminate risks?

In this way, risk reduction can include actions taken to mitigate the severity or probability of harm or loss. Processes that improve the detectability of hazards and quality risks can also be used as part of a risk control strategy.

Risk-based approach for a QMS



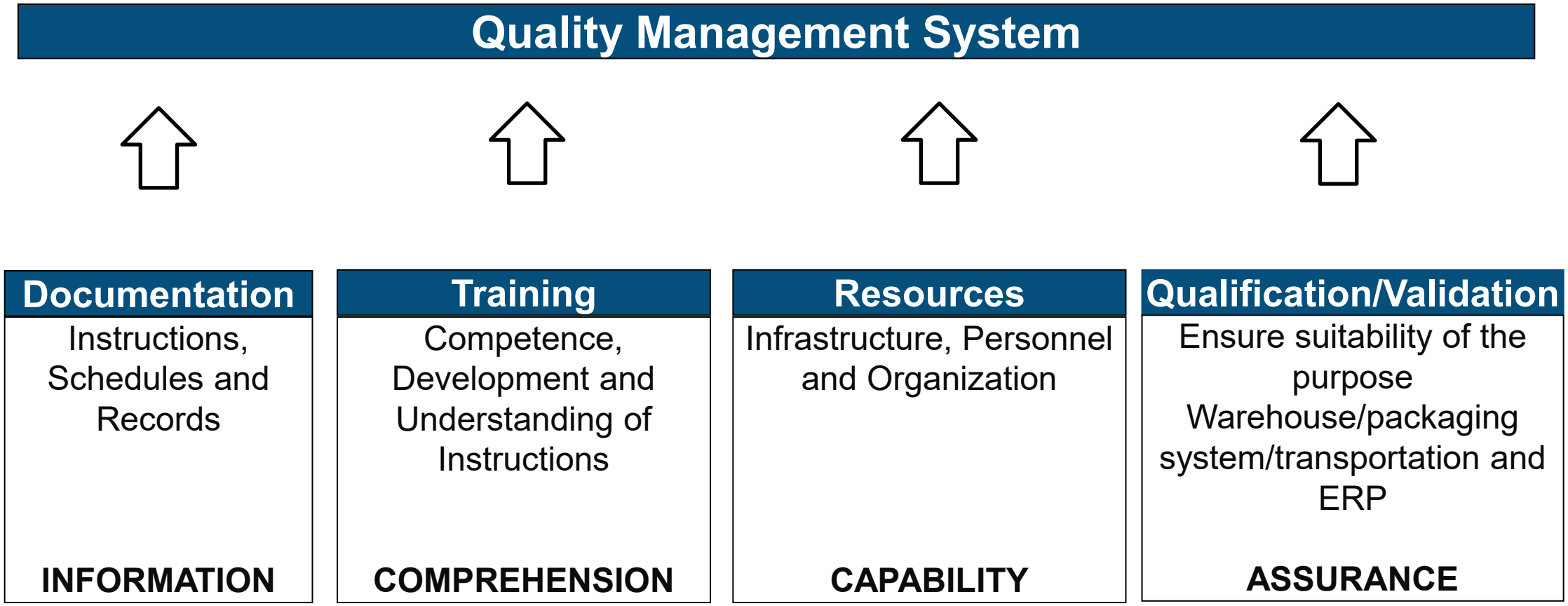
Product knowledge includes but is not limited to the following:

- Intended use
- Storage conditions
- Potential hazards to environment and personnel (e.g., hormones, cytotoxic drug products, radiopharmaceuticals)
- Inherent vulnerability (e.g., high potential for abuse, high-value drugs attractiveness cargo theft, counterfeiting, and diversion)

Process knowledge includes, but is not limited to, the following:

- Knowledge of supply chain partners
- Physical modes of transportation (air, sea, rail, or road)
- Transportation routes
- National and international regulation

Risk-based approach for a QMS



Storage and Transport Main Risks and Mitigation Strategies

HAZARD	EFFECT	MITIGATION STRATEGY	MITIGATION CATEGORY
General Risk			
Human error due to excessive duties, lack of training, competence	Mishandling along the supply chain Affects product quality, integrity and patient safety	Evaluate training effectiveness (are trainees competent on key aspect of the SOP?) Appropriate number of personnel to avoid excessive duties placed on one individual Address the right person to the right place based on the right education, experience and competency to perform a job	Training and Resources
Procurement/Sales			
Buy from/Sell to unlicensed trading partners	Legal sanctions	Supplier Qualification Customer Qualification Checks to ensure license is current and appropriate Quality agreements between supplier and trading partners.	Documentation and Resources
Receiving/Shipping			
Receive adulterated, falsified, recalled product	Patient safety Introduction into legitimate supply chain a product that is potentially substandard, illegal	Quarantine Quality Control test Packaging identification fingerprints Recall awareness	Documentation and Training

	or counterfeited	Notify regulatory authorities or trading partners	
Receive product that was not ordered	Unmatched transaction (e.g. wrong paper work/transaction data sent) Introduction into legitimate supply chain a product that is potentially substandard, illegal or counterfeited	Receiving SOP and training	Documentation and Training
Mix products with different status (Rejected/Recalled/Returned)	Patient safety Shipping/selling of inappropriate product	Product segregation Warehouse layout (logical flow and holding areas in order to avoid mix ups) Receiving SOP	Documentation and Resources
Shipping/Receiving delays due to inclement weather, natural disasters, traffic disruption	Patient safety Arrival delays Temperature out of specification (Temperature excursions, e.g. accidentally freezing when is snowing)	Reschedule the delivery Temporary parking (waiting for availability to unload). This could mean offloading to temperature controlled facility or vehicle Recondition materials to ensure temperature maintenance during delay Rescue Services	Documentation, Training and Resources
Storage			
Improper entry into a materials management system: wrong batch number, wrong expiration date, wrong status (e.g. approved product that should be quarantined); wrong amount	Inaccurate stock pick or ship product that was quarantined with improper status marked as approved	Stocking SOP Software validation	Documentation and Validation
Product stored in wrong physical location	Patient safety Picking error (software show location however can pick the wrong product if no check of physical location)	Stocking SOP Automated checking system	Documentation, Training and Validation
	Product exposed to temperature excursions	SOP that shows a list of products and their Temperature Specification	Documentation

	Legal sanctions for Controlled Substance Risk of diversion for Controlled Substance	SOP that shows a list of products and their license category (controlled, radiopharmaceuticals, etc.)	Documentation
Environmental conditions out of specification	Affects product quality, integrity and patient safety (e.g. freezing of vaccine or biologic) Product loss (e.g. money)	Warehouse, packaging and transportation qualification (temperature mapping) Product storage identification	Qualification/Validation, Training and Documentation
	Out-of-range cold or hot areas; product storage temperature excursion; product loss; financial loss; patient product availability	Qualification: temperature mapping; Storage temperature monitoring program; Homogenous airflow; Monitoring, alarms; Excursion handling SOP	Documentation, Resources and Qualification
Temperature Monitoring Device Failure	Out-of-range cold or hot areas; Product storage temperature excursion; Product loss	Back-up monitoring devices with independent power source Excursion handling SOP	Documentation and Resources
Storage /Temperature System Failure due to: • loss of electrical power • failure of temperature control or air circulation systems • unusual weather event	Out-of-range cold, warm or hot areas; Product storage temperature excursion; Product loss	Temperature and power alarms, Back-up power and coolant systems (redundant) and/or contingency storage; Excursion handling SOP	Documentation and Resources
Fear of Reporting Non-conformance/Exception conditions	Affects product integrity and patient safety due to serious conditions not communicated	Independent quality reporting structure; Education on product integrity and impact to patients and the supply chain	Training and Resources

Applicable Mitigation Strategies	Role of the Organization within the Supply Chain					
	Manufacturer	Wholesaler distributor	Pharmacy/ Compounding Pharmacy	Hospital/Health care providers	Brokers	Freight Forwarders
Documentation (Manuals, Procedures, Protocols, Records)						
Quality Manual	Yes	Yes	Yes	Yes	Yes	Yes
Labeling	Yes	Yes	Yes	Yes	No	No
Procurement	Yes	Yes	Yes	Yes	Yes	Yes
Receiving	Yes	Yes	Yes	Yes	No	Yes
Picking	Yes	Yes	Yes	Yes	No	Yes
Packing	Yes	Yes	Yes	No	No	No
Sales	Yes	Yes	Yes	No	Yes	No
Storage	Yes	Yes	Yes	Yes	No	Yes
Transportation	Yes	Yes	Yes	No[1]	No	Yes
Supplier Qualification	Yes	Yes	Yes	Yes	Yes	Yes
Customer Qualification	Yes	Yes	No	No	Yes	Yes
Quality Agreements	Yes	Yes	Yes	Yes	Yes	Yes
Licenses and Authorizations	Yes	Yes	Yes	Yes	Yes	Yes
Recall	Yes	Yes	Yes	Yes	Yes	Yes
Return	Yes	Yes	Yes	Yes	No	No
Temporary parking	No	No	No	No	No	Yes
Excursion handling	Yes	Yes	Yes	Yes	No	Yes
Disposal of expired and rejected drug product	Yes	Yes	Yes	Yes	No	Yes
Pest Control and Pallet Conservation	Yes	Yes	Yes	Yes	No	Yes
Training	Yes	Yes	Yes	Yes	Yes	Yes
Resources						
Product segregation	Yes	Yes	Yes	Yes	No	Yes
Storage area (layout/logical flow)	Yes	Yes	Yes	Yes	No	Yes[2]
Maintenance	Yes	Yes	Yes	Yes	No	Yes
Calibration	Yes	Yes	Yes	Yes	No	Yes
Monitoring Systems and Alarms	Yes	Yes	Yes	Yes	No	Yes
Appropriate number of personnel	Yes	Yes	Yes	Yes	Yes	Yes
Organizational chart/job descriptions	Yes	Yes	Yes	Yes	Yes	Yes
Qualification/Validation						
Temperature Mapping	Yes	Yes	Yes	Yes	No	Yes
Shipping Packaging qualification	Yes	Yes	Yes	No[1]	No	No
Software validation (automated checking systems, ERPs, ERP-like systems)	Yes	Yes	Yes	Yes	Yes	Yes

<1079> Summary

- The principles can be used globally and are useful for API, dietary supplements,
- Is not meant to prescribe specific approaches or discuss regulatory frameworks
- Was written to provide helpful information to stakeholders of the Pharmaceutical Supply Chain

The New <1079.2> Mean Kinetic Temperature in the Evaluation of Temperature Excursions During Storage and Transportation of Drug Products

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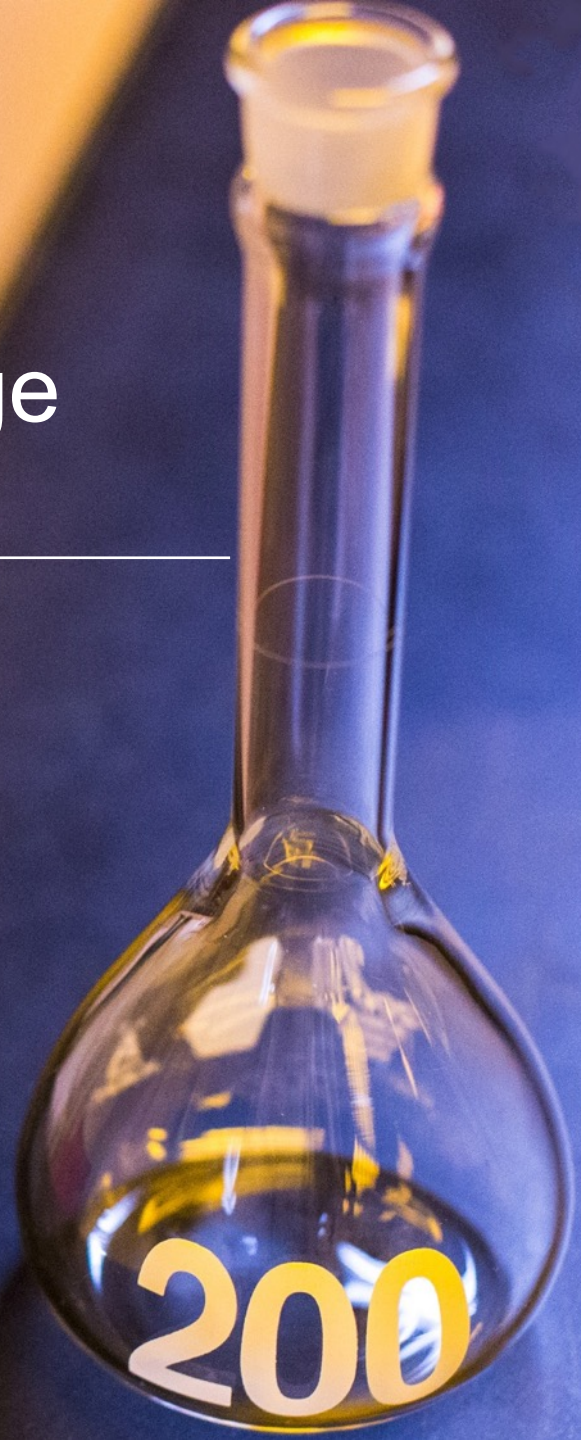
January 27, 2021



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<1079> Risk Mitigation Strategies for the Storage of Finished Drug Products

- Primary chapter used for the storage, handling, and distribution of drugs – references <659>, <1079.2> and to articles on MKT
- <1079> 4.1.5 EXCURSION HANDLING
  - Short-term temperature excursions can occur during distribution, storage, and transportation….
  - See <659> for excursion allowances and MKT limits and Mean Kinetic Temperature in the Evaluation of Temperature Excursions During Storage and Transportation of Drug Products <1079.2> for MKT. MKT should be calculated for the period of time that a drug is in residence at a warehouse and/or in transit on a truck to avoid the problem of diluting the impact of excursions by calculating annual MKT values. [1,2] (<1079> December 1, 2020, p.12)

[1] Seevers RH, Hofer J, Harber P, Ulrich DA, Bishara R. The use of mean kinetic temperature (MKT) in the handling, storage and distribution of temperature sensitive pharmaceuticals. Pharmaceutical Outsourcing. May/June 2009;12–17.

[2] Anderson C, Seevers R, Hunt D. The use of mean kinetic temperature to aid evaluation of temperature excursions: proper and improper application. Pharm Forum. 2018;44(4)

<659> Controlled Cold Temperature (CCT)

- Maintained thermostatically between 2º and 8ºC
- Excursion not to exceed 24 hours
- Excursions between 2º to15ºC (storage and transportation) are permitted as long as the MKT does not exceed 8ºC)
- Excursions cannot occur more than one time during possession of the product within the supply chain, unless directed by the manufacturer or supported by stability data
- Calculation and documentation of MKT:
  - References <1079.2> Mean Kinetic Temperature in the Evaluation of Temperature Excursion During Storage and Transportation of Drug Products
  - References Anderson C, Seevers R, Hunt D The Use of Mean Kinetic Temperature to Aid Evaluation of Temperature Excursions: Proper and Improper Application. Pharm Forum. 2018; 44(4) http://www.usppf.com/pf/pub/index.html

<659> Controlled Room Temperature (CRT)

- Maintained thermostatically between 20º and 25ºC
- Excursions cannot exceed 24 hours
- Excursions between 15-30ºC (…pharmacies, hospitals, and warehouses, and during shipping allowed as long as the MKT does not exceed 25ºC)
- Transient spikes up to 40ºC are permitted as long as:
  - They do not exceed 24 hours
  - MKT cannot exceed 25ºC
- CRT alternatively can be stored and shipped Cool or CCT unless otherwise specified on the monograph or on the label
- Storage time in controlled cold or cool place cannot be used to calculate excursion temperature outside of controlled room temperature ranges
- Spikes above 40ºC may be permitted only if the manufacturer so instructs
- Calculation and documentation of MKT:
  - References <1079.2> Mean Kinetic Temperature in the Evaluation of Temperature Excursion During Storage and Transportation of Drug Products
  - References Anderson C, Seevers R, Hunt D The Use of Mean Kinetic Temperature to Aid Evaluation of Temperature Excursions: Proper and Improper Application. Pharm Forum. 2018; 44(4) http://www.usppf.com/pf/pub/index.html

<1079.2> Mean Kinetic Temperature in the Evaluation of Temperature Excursions during Storage and Transportation of Drug Products

- Math Calculations*
  - Controlled Room Temperature (CRT) – Use 30 days (or average time product is in your possession) of temperature data
  - Controlled Cold Temperature (CCT) – Use 24 hours of temperature data
  - Temperature data for calculations should go back from the end of the excursion (e.g., if a CCT excursion began on June 5th, 2020 at 7:30 AM and ended at 10:30 AM on the same day you would calculate the MKT using temperature data from June 4th, 2020 at 10:30 AM through June 5th, 2020 at 10:30 AM)
  - Temperature data points for CRT, USP recommends to use the high and the low temperature for each day
  - Temperature data points for CCT, USP recommends to use all the data points recorded during the time period (e.g., every 15 minutes)

*This in the process of being changed to move MKT calculation to <1160> Pharmaceutical Calculations

Mean Kinetic Temperature Stimuli Articles

- *The Use of Mean Kinetic Temperature to Aid Evaluation of Temperature Excursions: Proper and Improper Applications*, published in the PF 44(4), July 2018:
  - Stimuli Article to the revision of <659> and <1079>
    - **Authors**: Chris Anderson, Desmond Hunt, and Robert Seevers published July of 2018
  - Covered the use of MKT for excursions for CRT and CCT products
- *The Use of Mean Kinetic Temperature to Aid Evaluation of Temperature Excursions for Controlled Cold Temperature Drugs: Proper and Improper Application* PF 45(5), September 3, 2019
  - New Stimuli Article to the revision of <659> and <1079.2>, the new MKT excursion management chapter
    - **Authors**: Chris Anderson, Desmond Hunt, and Robert Seevers published September of 2019
  - Greater focus on CCT (2-8ºC) excursions

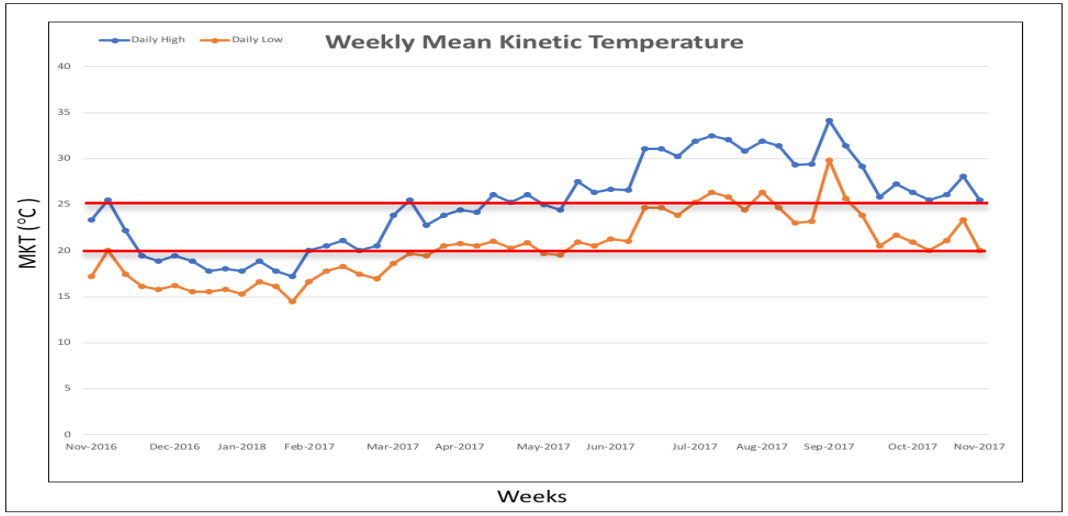
The MKT Equation

$$\text{MKT or } T_k = \frac{-\Delta H / R}{ln\left(\frac{\Sigma e^{-\Delta H / RT_1} + \cdots + e^{-\Delta H / RT_n}}{n}\right)}$$

ΔH =	**83.144 kJ/mol**
R =	8.3144 × 10^{-3} kJ/mol · K (universal gas constant)
T_1 =	Value for the temperature recorded during the first time period; the time periods can be minutes, hours, days, or weeks
T_n =	Value for the temperature recorded during the nth time period
n =	Total number of storage temperatures recorded during the observation period

CRT 52-Week MKT Versus 30-Day Example

52-Week MKT = 23.98°C

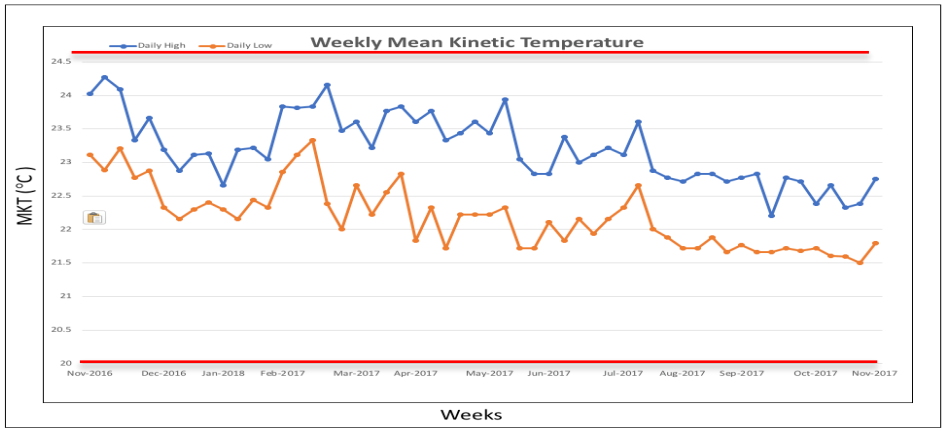


	Temperature (°C)			Temperature (°C)			Temperature (°C)	
Day[b]	High	Low	Day	High	Low	Day	High	Low
158	24.37	19.58	168	24.19	19.79	178	30.91	23.65
159	22.28	19.56	169	23.69	19.67	179	29.71	22.98
160	23	19.85	170	32.4	25.44	180	29.44	22.84
161	23.5	19.58	171	32.72	26.01	181	28.49	22.84
162	23.43	18.93	172	31.04	24.61	182	28.64	21.83
163	22	19.34	173	30.52	23.58	183	30.17	22.06
164	22.43	19.54	174	29.6	23.92	185	29.99	23.58
165	22.92	19.56	175	30.98	24.19	186	31.44	24.21
166	23.94	19.34	176	32.27	25.91	187	32	24.83
167	24.92	19.83	177	32.2	27.23	**188**	**33.58**	**26.6**

[a]**MKT calculated for 30 days is 28.98°C** (84.16°F), which is over 25°C (77°F), and is unacceptable.
[b]Day within the 365-day study period.

CRT 52-Week MKT Versus 30-Day Example

52-Week MKT = 22.75 °C

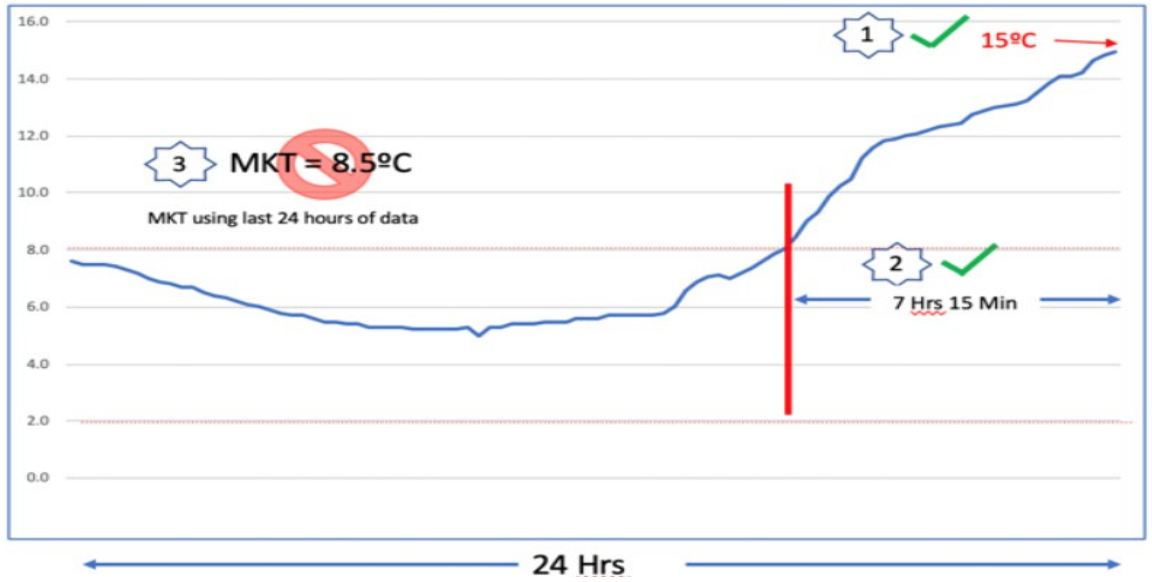


	Temperature (°C)			Temperature (°C)			Temperature (°C)	
Day[b]	High	Low	Day	High	Low	Day	High	Low
64	23.33	21.67	74	22.78	22.22	84	23.33	22.78
65	23.89	21.67	75	22.77	22.22	85	23.33	22.78
66	23.33	22.78	76	23.33	22.22	86	23.33	22.78
67	24.44	23.33	77	23.33	22.22	87	23.89	22.78
68	23.89	23.33	78	23.33	22.22	88	23.89	23.33
69	23.33	22.78	79	23.89	22.78	89	25	22.78
70	22.78	22.22	80	24.44	22.78	90	23.33	22.78
71	23.33	22.22	81	23.89	22.22	91	22.78	22.78
72	23.89	22.22	82	23.89	22.22	92	24.44	22.78
73	22.78	22.22	83	23.33	22.22	93	25.56	23.33

[a]**MKT calculated for 30 days was 23.14°C** (73.65°F), which was under 25°C (77°F) and therefore acceptable.
[b]Day within the 365-day study period.

CCT MKT Example

Passive Shipper Example

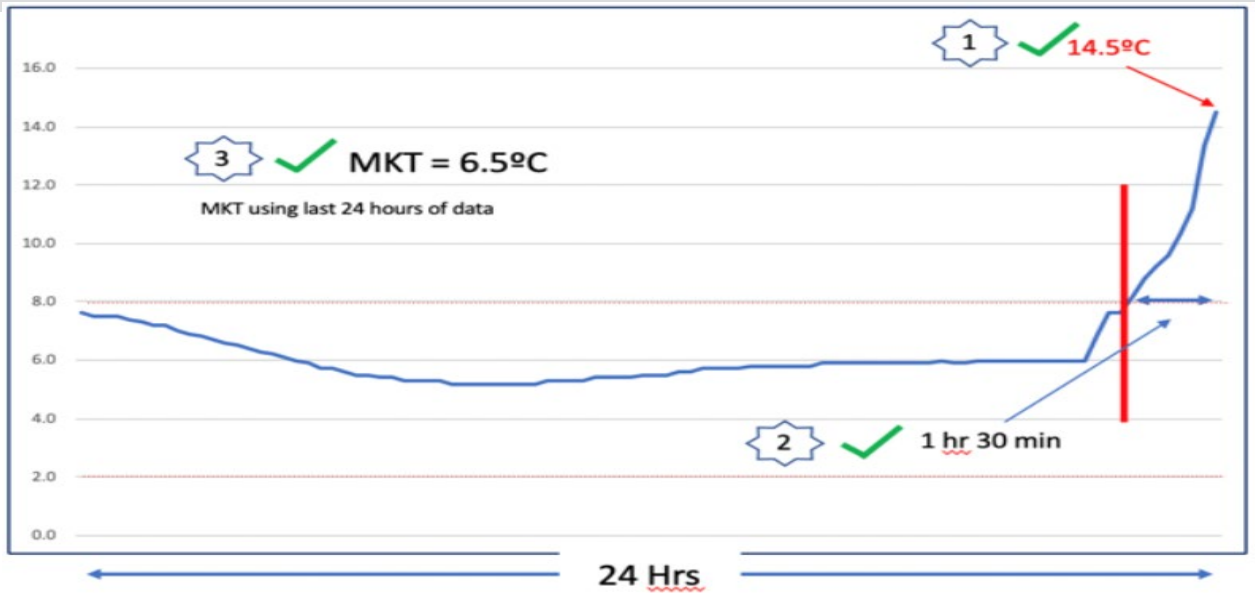


In this example, a passive shipper went out of CCT at 16 hours and 45 minutes

1. The high temperature was 15°C ✓
2. The excursion was less than 24 hours ✓
3. The MKT was 10.5°C for the last 24 hours (outside the excursion MKT limit) ⊘
4. In this case, the product should be quarantined and the manufacturer(s) should be contacted for disposition ⊘

CCT MKT Example

Passive Shipper Example

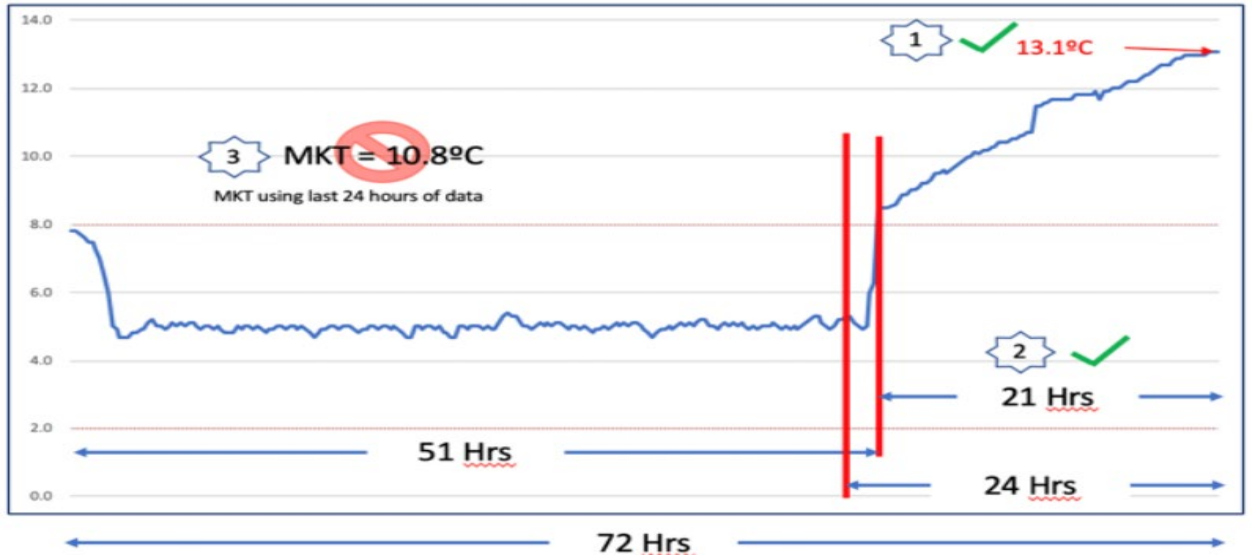


In this example, a passive shipper went out of CCT at 23 hours and 30 minutes

1. The high temperature was 14.5°C
2. The excursion was less than 24 hours
3. The MKT was 6.5°C for the last 24 hours (outside the excursion MKT limit)
4. In this case, the product would be considered acceptable for release to salable inventory

CCT MKT Example

Refrigerated Trailer Example

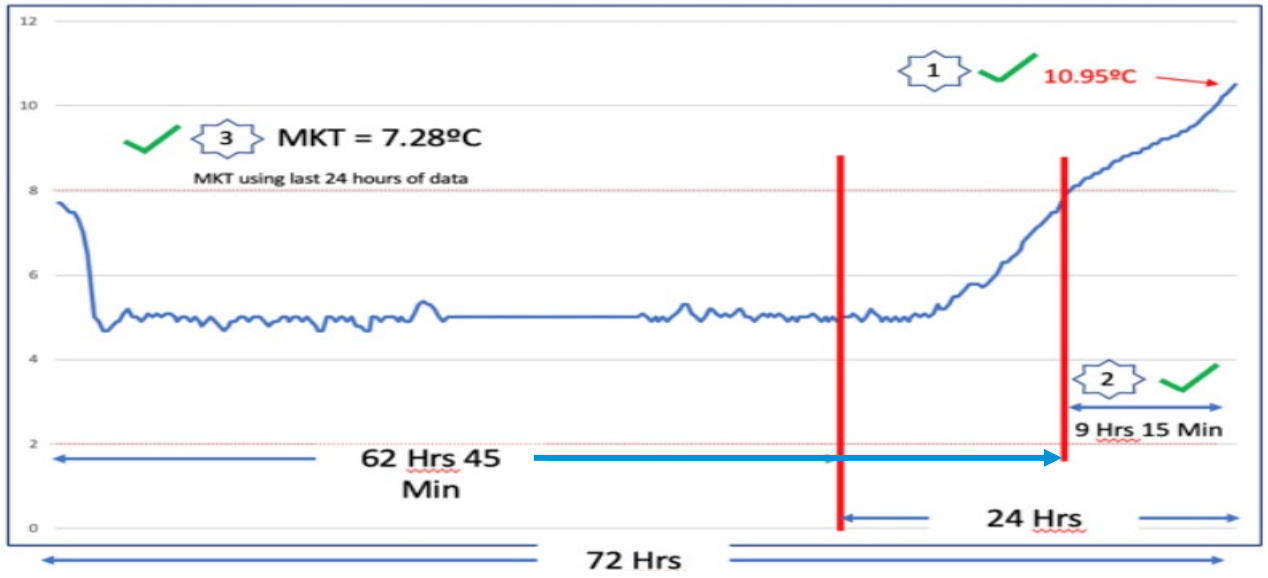


In this example, a refrigerated trailer making a delivery went out of CCT at 51 hours

1. The high temperature was 13.1°C ✓
2. The excursion was less than 24 hours ✓
3. The MKT was 10.88°C for the last 24 hours (outside the excursion MKT limit)
4. In this case, the product should be quarantined and the manufacturer(s) should be contacted for disposition

CCT MKT Example

Refrigerated Trailer Example



In this example, a refrigerated trailer making a delivery went out of CCT range at 62 hours and 45 minutes

1. The high temperature was 10.95°C
2. The excursion was less than 24 hours
3. The MKT was 7.28°C for the last 24 hours (within the excursion MKT limit)
4. In this case, the product would be considered acceptable to release to salable inventory

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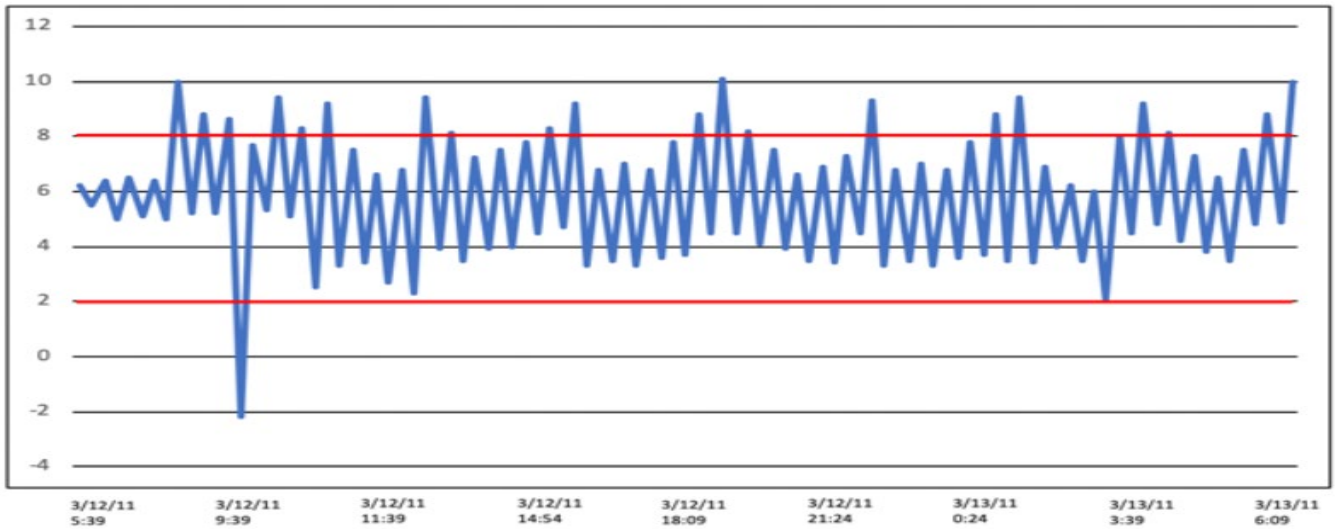


In this example, a refrigerated trailer making a delivery went out of CCT range multiple times due to a cycle-type of active system that turns the unit off until a target temperature is reached triggering the unit to come back on until a set point towards the lower end of the range is reached

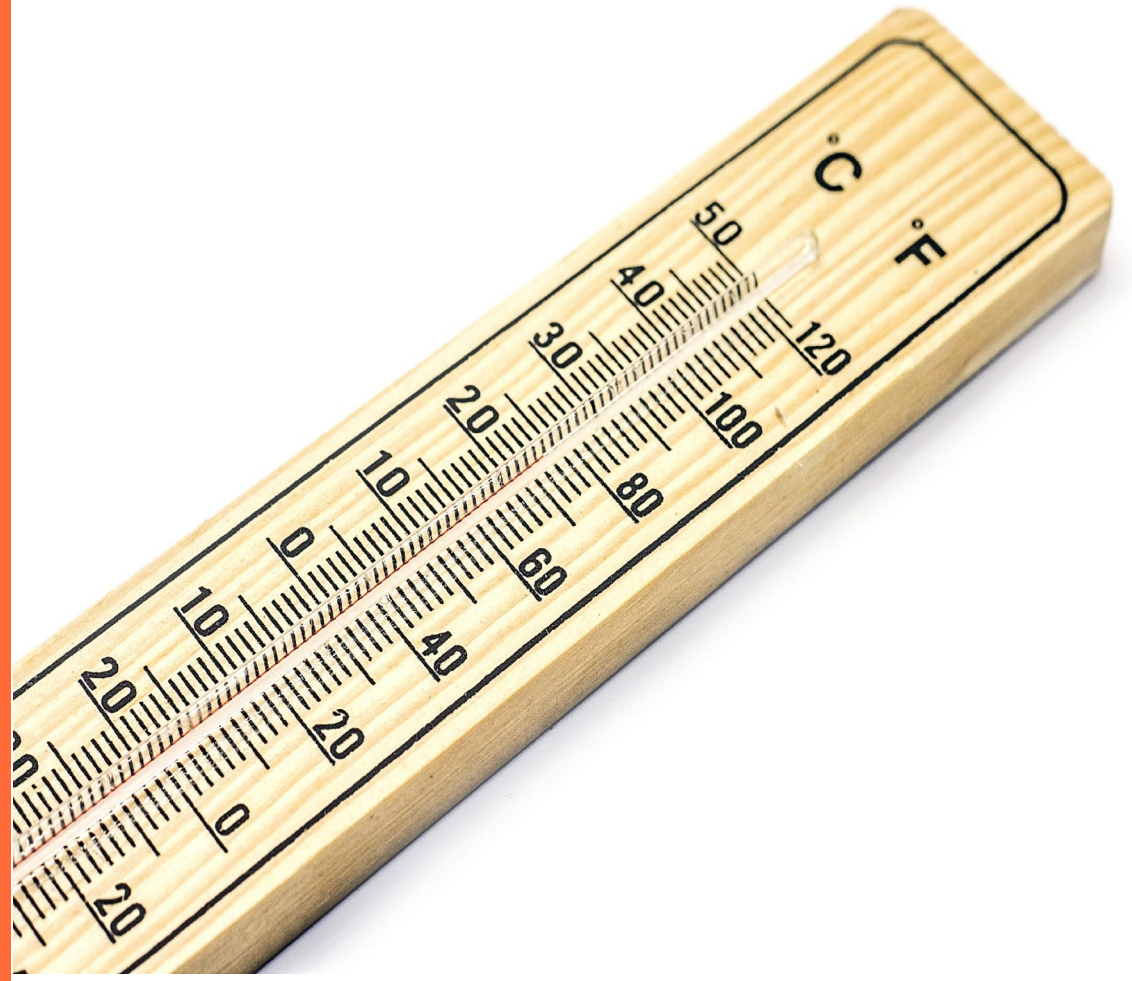
1. The high temperature was 10.1°C ✓ but the low temperature was -2.2°C ⊘
2. The excursions were each less than 24 hours, 21 hours and 45 minutes between the first and last excursion ✓
3. The MKT was 6°C for 24 hours (within the excursion MKT limit) ✓
4. In this case, however, the system is out of control and the USP would recommend evaluation by the product manufacturers ⊘

COVID-19 Vaccine “Frozen”

- For the upcoming COVID-19 Frozen vaccinations (-20° and -70°C), USP does not currently recommend an excursion range outside of what has been published by the manufacturers. Additionally, USP does not currently recommend using MKT to evaluate any excursions of frozen COVID-19 Vaccines.
- USP will be posting operational guidance for healthcare professionals aimed at handling and administration.

What is Next?

1. <1079.3> Monitoring Devices—Time, Temperature, and Humidity (Current ⟨1118⟩)
2. < 1079.4> Qualification of Storage Areas
3. <1079.5> Qualification of Shipping Systems
4. <1079.6> Transport Route Profiling Qualification
5. <1079.7> Information Systems for Distribution Validation/Verification Studies



Thank You

Questions?