WHITE PAPER

The Compliance Clock You Didn't Know Was Ticking:

How USP ⟨1079.2⟩ MKT Should Be Shaping Your Temperature Excursion Policy

Prepared by MaxQ | Cold Chain Compliance Series | 2026

Executive Summary

Most specialty pharmacy operations teams have heard the term *Mean Kinetic Temperature (MKT)*. Yet many excursion assessment practices remain misaligned with the intent and application of MKT as defined in USP ⟨1079.2⟩. As a result, pharmacies may spend significant time investigating temperature events, quarantining products, or making disposition decisions based on incomplete or incorrect interpretations of temperature data.

This white paper translates the requirements of USP ⟨1079.2⟩ (including the August 2025 revisions) into clear, actionable guidance for specialty pharmacy directors and operations managers. It explains what MKT is, what it is not, the three most common misapplications seen in the field, and how validated packaging reduces the frequency and severity of the excursions that trigger MKT calculations in the first place.

> *Key insight: An excursion is a nonconforming event. MKT is a tool for evaluating its impact — not a mechanism for making product risk disappear.*

1. What Is Mean Kinetic Temperature — and What Isn't It?

MKT is a single calculated temperature that represents the cumulative thermal stress a product has experienced over a defined period. Unlike a simple average temperature, MKT uses the Arrhenius equation to weight higher temperatures more heavily — because elevated temperatures accelerate chemical degradation at a non-linear rate.

Think of it this way: two products can experience the same average temperature over a week but have very different degradation outcomes if one spent a concentrated period at 38°C. MKT captures that difference. A simple mean does not.

What MKT Is NOT

- MKT is not a method for "fixing" a temperature excursion retroactively
- MKT is not appropriate for all product types (biologics, phase-change products like suppositories, emulsions, and suspensions may require alternative assessment)
- MKT is not a substitute for understanding actual excursion temperatures and duration
- MKT is not a license to operate a system with repeated excursions

> *"MKT alone is not enough to assess the impact of a temperature excursion." — USP ⟨1079.2⟩, Section 4*

2. The USP ⟨1079.2⟩ Requirements Most Pharmacies Are Missing

The August 2025 revision to USP ⟨1079.2⟩ reinforces and clarifies requirements that many operations teams are not yet implementing. Below are the critical compliance parameters every specialty pharmacy should have in their SOPs.

Table 1: USP ⟨1079.2⟩ Allowable Excursion Limits by Storage Type

Storage Type	MKT (NMT)	MKT Calculation Window	Acceptable Excursion Range	Max Temperature	Max Excursion Time
CCT (2°–8°C)	8°C	24 hours from excursion	8°–15°C	NMT 15°C	24 hours
CRT (20°–25°C)	25°C	Days in possession, or 30 days if unknown	15°–20°C and 25°–30°C	NMT 40°C (transient)	24 hours
Room Temp / Climatic Zone IVb (15°–30°C)	30°C	Days in possession, or 30 days if unknown	30°–40°C	NMT 40°C	24 hours

Source: USP ⟨1079.2⟩, Table 1, including August 2025 revisions.

The 30-Day Rule for CRT — and Why It Matters

For controlled room temperature (CRT) and climatic zone IVb products, USP ⟨1079.2⟩ specifies that MKT should be calculated using the actual number of days a product remains in the holder's possession, or 30 days if that duration is unknown. This is grounded in data showing that products spend an average of 30 days in U.S. warehouse storage.

This means the 30-day window is a default for when you don't know — not a blanket rule for every situation. If your pharmacy can track actual product dwell time, that is the number you should use.

The 24-Hour Rule for CCT

Cold chain temperature (CCT) products — those stored at 2°–8°C — are held to a much stricter standard. MKT for CCT excursions must be calculated using only the preceding 24 hours of temperature data. This reflects the greater sensitivity of refrigerated products to thermal stress.

Each CCT excursion must be treated as a separate, independent event. The chapter is explicit: a storage or transportation system with repeated CCT excursions is a system out of control.

3. The Three Most Common MKT Misapplications

Misapplication #1: Using 52 Weeks of Data

The most widely cited misuse in the chapter is using a full year (52 weeks) of temperature data to calculate MKT during an excursion event. USP ⟨1079.2⟩ calls this out by name.

The logic seems intuitive but is flawed: spreading an excursion across 52 weeks of "good" temperature data dilutes the impact of the excursion and can lead an organization to incorrectly conclude the product is unaffected. In reality, the product may not have even been in that location for 52 weeks, making the data entirely irrelevant.

> *The MKT calculation window must reflect actual product exposure time — not the full history of a storage location.*

Misapplication #2: "Cooling Down" After an Excursion

A common mistake in excursion assessment is including temperature data collected after a shipment has been delivered and returned to controlled storage conditions when calculating Mean Kinetic Temperature (MKT). For example, a shipment may experience a significant temperature excursion during transit, but once it is placed in a temperature-controlled warehouse, the lower storage temperature can reduce the overall calculated MKT and create the appearance of compliance.

USP ⟨1079.2⟩ explicitly cautions against this approach. The purpose of MKT is to evaluate the cumulative thermal stress experienced by a product during a defined storage or transportation period. Once a product has been exposed to elevated temperatures, any resulting chemical degradation, potency loss, or reduction in stability cannot be reversed by subsequent exposure to lower temperatures.

In other words, cooling a product after an excursion does not "erase" the thermal damage that may have already occurred. Including post-excursion storage data in an MKT calculation can artificially dilute the impact of the excursion and may lead to inappropriate product disposition decisions.

When evaluating a temperature excursion, the assessment period should focus on the relevant storage or transportation interval during which the excursion occurred. The goal is to understand the thermal stress experienced by the product, not to average that stress away through later exposure to favorable conditions.

Misapplication #3: Using MKT as the Sole Assessment Tool

MKT is one input into an excursion evaluation — not the entire evaluation. USP ⟨1079.2⟩ specifies that MKT must be accompanied by answers to the following questions:

- How long was the temperature excursion?
- What were the specific excursion temperatures?
- Did temperatures exceed USP allowable limits (per Table 1)?
- What time frame was used for the MKT calculation?

Pharmacies that run MKT and stop there are leaving themselves exposed. A complete excursion record must document all four of the above, with scientifically sound justification for any disposition decision.

4. When MKT Cannot Be Used

USP ⟨1079.2⟩ is clear that MKT is not appropriate for all products or situations. Pharmacies dispensing the following should have alternative assessment protocols in place:

- Products subject to phase change: suppositories, liquids, suspensions, emulsions, creams
- Biological products (biologics): MKT is specifically identified as potentially unsuitable
- Products where clinical data indicate that excursions impact quality or safety regardless of MKT results

When MKT cannot be used, USP recommends stability and stress studies, as well as freeze-thaw and high-temperature cycling studies, to assess risk. Critically, when MKT is not appropriate, that fact must be communicated to supply chain partners.

> *Specialty pharmacies dispensing biologics should review whether their current excursion SOP appropriately excludes MKT as the assessment method for those products.*

5. Compliance Checklist: Is Your Pharmacy MKT-Ready?

Use the checklist below to evaluate whether your current temperature excursion SOP aligns with USP ⟨1079.2⟩ requirements.

Compliance Item	In Place?
SOP specifies correct MKT window: 24h for CCT, 30 days (or days in possession) for CRT	☐
MKT calculation does not use 52 weeks of historical data	☐
Excursion evaluation documents duration, specific temperatures, and whether USP limits were exceeded	☐
Post-excursion temperature reduction is NOT used as a compliance fix	☐
Biologics and phase-change products have alternative excursion assessment protocols	☐
Each CCT excursion is treated as an independent event	☐
Repeated excursions trigger system review, not additional MKT calculations	☐
Packaging qualification data is on file and aligned to actual shipping lanes/conditions	☐
Supply chain partners have been notified when MKT is not applicable to a product	☐
August 2025 USP ⟨1079.2⟩ revisions have been reviewed and SOPs updated accordingly	☐

Conclusion

USP ⟨1079.2⟩ provides a well-defined framework for evaluating temperature excursions. The challenge is not the regulation itself — it is that many specialty pharmacy operations teams are working from incomplete interpretations of what MKT requires.

The August 2025 revisions reinforce several key points: the correct time windows for different storage classes, the prohibition on using MKT to “unfix” a degradation event, and the requirement to communicate when MKT is not the appropriate tool for a given product.

At MaxQ, we work alongside specialty pharmacy operations teams to ensure that packaging performance and documentation align with USP requirements — so that when an excursion does occur, the evaluation is straightforward, defensible, and audit-ready.

Ready to review your cold chain packaging against USP ⟨1079.2⟩ compliance requirements?

Contact MaxQ at www.packmaxq.com to schedule a complimentary packaging review with our cold chain compliance experts.

References

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