



### WHO DOES THIS APPLY TO:

- Fabricators
- Packager/Labellers
- Distributors
- Importers
- Wholesalers
- Third-party warehouse facilities
- Transportation providers
- Anyone who stores, handles, and/or transports drug products

### KEY POINTS:

- Health Canada Guidance document (Guide-0069) revised January 28, 2011. Key changes:
  - Excursions to labelled storage conditions are permitted if supporting stability data is available.
  - Refrigerators/freezers must be commercial grade and a plan must be in place in the event of a power failure (i.e. backup power or alternate storage available).
  - Shipping containers should be qualified to meet extremes of ambient temperature within the distribution environment and procedures should account for unforeseen shipping delays.
- Everyone must ensure appropriate storage and transportation conditions are met through their GMP activities from the point of manufacture to the final distribution point.
- These requirements are designed to maintain the quality, safety and effectiveness of drug products.

View the guidance document at:  
<http://www.hc-sc.gc.ca/dhp-mps/compli-conform/gmp-bpf/docs/gui-0069-eng.php>

# Quick NOTES

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GUIDE-0069



- They apply to:
  - Drugs for human and veterinary use.
  - Clinical trial drugs for human use.
  - Samples distributed to professionals.
- Store, handle, and transport drug products:
  - According to conditions outlined on product labels and in procedures.
  - In containers that prevent damage and maintain the integrity and quality of the products.
  - Under predetermined conditions as supported by stability data.
  - Such that they're not exposed to temperatures/humidity levels outside recommended environmental storage conditions.
  - Storage areas are clean, dry, have adequate circulation and maintained within acceptable temperature limits.
- Refrigerators and Freezers:
  - Equipped with a backup power source or have an alternate storage available in the event of a power failure.
  - Be of commercial grade.
- Environmental controls (e.g., temperature, humidity) play a key role in maintaining drug quality. Temperature is one of the most important parameters to control.
  - Control and monitor temperatures using calibrated monitoring devices.
  - Monitor at locations representing the extremes of the temperature range.
  - Maintain records and evaluate based on product requirements.

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- Maintain adequate documentation:
  - Have written procedures for the storage and shipping of drug products that:
    - Take into account the nature of the drug products and expected local conditions.
    - Describe any special handling precautions.
    - Identify what to do if deviations occur (e.g., temperature excursions).
  - When commercial carriers are used, specify all pertinent conditions in a written contract between the distributor, importer or wholesaler, and the third-party carrier.

## FAQs:

### 1. What are the key changes in the 2011 revision?

- Excursions permitted with supporting stability data.
- Commercial grade refrigerators/freezers
- Power failure plan required
- Shipping containers should be qualified to meet extremes of ambient temperature within the distribution environment and procedures should account for unforeseen shipping delays.

### 2. Do all refrigerated transportation containers need a monitoring system?

- Refrigerated vehicles/transportation containers should be mapped and monitored if they provide the primary means for environmental control. A monitoring system is not necessary if a qualified insulated container is used.

### 3. What happens if temperature excursions outside the labeled storage conditions occur?

- Product quality must be evaluated and documented, and corrective actions taken where necessary. Clear directions should be provided to the recipient for the evaluation and/or disposal of products and monitoring devices.

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#### 4. What are some requirements for refrigerators and freezers used to store drugs?

- They must be well maintained and free from frost build-up. They should allow for adequate air distribution, have orderly storage within the chamber, and be equipped with sensors for continuous monitoring and alarms at the locations representing the temperature extremes. They should be of commercial grade.

#### 5. What is temperature mapping?

- Temperature mapping involves a series of studies that create temperature profiles for a storage area. These studies allow the range of temperature to be established, including hot spots and cold spots, during a typical workday, overnight, through weekends and seasonally. These studies help ensure that storage areas are able to provide conditions that remain within the extremes of the temperature range established for a particular product.

#### 6. What is the difference between temperature mapping and qualification?

- Qualification of equipment or systems (e.g., a refrigerator) is the proof that a process (e.g., refrigeration) can meet a given quality standard (e.g., maintain a temperature of 2° to 8°C). Temperature mapping is one of the possible tests to qualify the process.

#### 7. What is shipping validation?

- Shipping validation provides documented evidence that methods of packaging, preserving, and monitoring of drug products during transport meet regulatory requirements for temperature-sensitive products throughout the distribution and shipping process.

#### 8. How do I set up a temperature monitoring program?

- Contact us! We can help you ensure your drug products are transported, handled, and stored in a compliant manner. Contact us with any questions related to Health Canada's Good Manufacturing Practices.

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