



PRINCE EDWARD ISLAND  
**PHARMACY BOARD**

*Member Organization of the National Association of Pharmacy Regulatory Authorities (NAPRA)*

**Cold Chain Policy**

June, 2013, Reviewed July 2013

Review date: June 2016



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## **Introduction**

Pharmacists have a responsibility to ensure that medications are stored in accordance with manufacturers' recommendations. Certain medications, such as vaccines and biologics, have specific temperature requirements that, when not complied with, they may become less effective. Maintaining the potency of a vaccine is important for several reasons including:

- Administration of compromised vaccines may cause the re-emergence of preventable diseases resulting in increased costs to the health care system; as well as
- A decreased confidence in health care professionals when a patient must be re-vaccinated after receiving a vaccine that was ineffective.

“Cold chain” refers to an uninterrupted series of storage and distribution activities which maintain the product within a specific temperature range. Staff should be properly trained to maintain the cold chain, recognize when there is a break in the chain and how to handle a break in the cold chain. Staff should also be familiar with the stabilities of temperature sensitive medications available in their pharmacy. Pharmacies should designate one staff member to act as vaccine coordinator whose responsibility is to oversee the vaccine supply.

## **Purpose**

The purpose of this policy is to provide pharmacists and pharmacies a document that outlines the requirements for storage of temperature sensitive medications, including vaccines and biologics.



## Policy

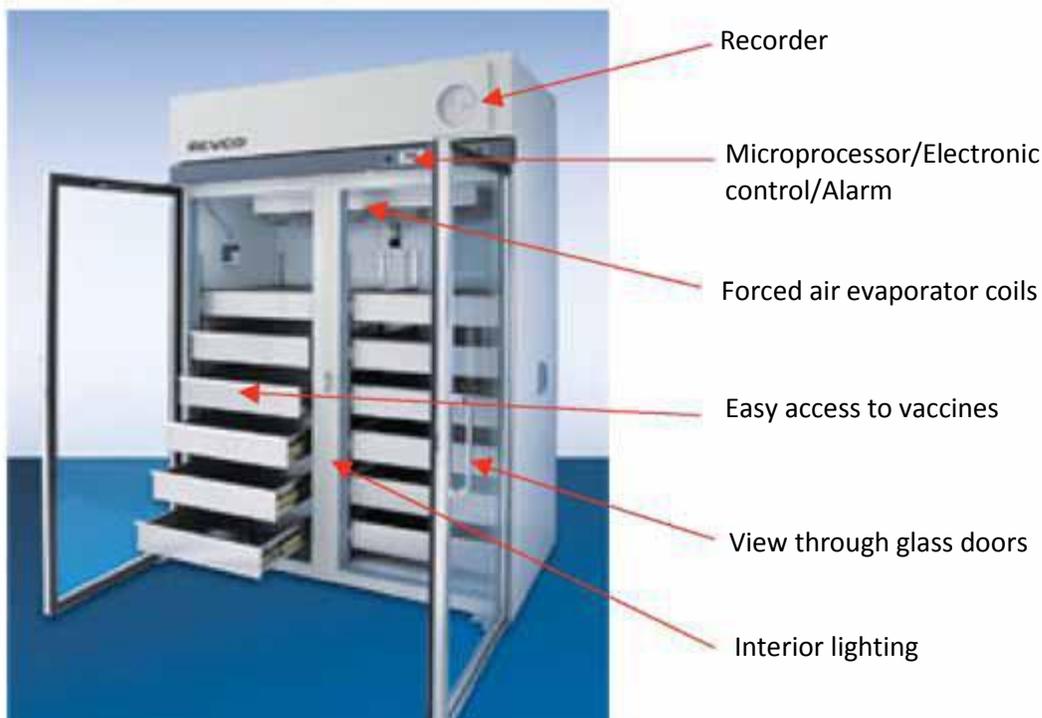
Pharmacy manager will ensure that the pharmacy adheres to the Cold Chain Policy when storing temperature sensitive medications such as vaccines and biologics.

### 1 Choosing a Refrigerator

#### 1.1 Purpose Built Refrigerators (pharmacy or lab-style)

- Purpose built refrigerators are temperature sensitive which respond well to fluctuations either when the ambient or room air fluctuates or when the unit is defrosted. This type of unit is recommended.
- As a result of the glass doors on Purpose Built Refrigerators, extra effort must be taken to protect vaccines from light.

**Figure 1. Purpose Built Refrigerator**



#### 1.2 Domestic Refrigerator

- Domestic refrigerators are designed for food storage.
- The refrigerator and freezer must have separate external doors.
- There are two types of domestic refrigerators: Frost-Free and Manual/cyclic defrost.

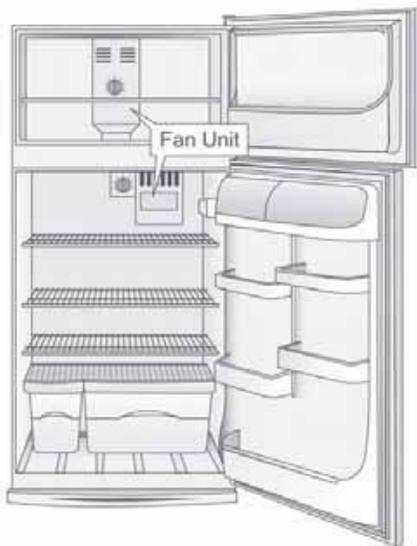


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- The Manual/cyclic defrost refrigerators are not recommended for drug storage due to the variation in temperatures within the unit, especially near the evaporator (usually located in the back of the unit).
- The Frost-Free type is recommended with precautions and modifications including:
  1. Removing the crisper from the bottom of the unit.
  2. Place large water bottles in the crisper area, the door and against the walls of the unit.
  3. Keep freezer packs or ice cube trays in the freezer.
  4. Know the various temperature zones located in the unit.
  5. Know the location of the vent in the unit which varies between manufacturers. Drugs should be kept away from the air vent to avoid freezing.

**Figure 2. Domestic Frost-Free Refrigerator**



## 1.3 Bar Refrigerators

- Any style of small, single door unit with freezer and refrigerator combined in one compartment.
- The temperature fluctuations are unpredictable with this type of unit. **This type is not acceptable. Pharmacies must switch to a purpose built or modified domestic refrigerator by June 1, 2013.**



#### 1.4 Using Pharmaceutical Storage Refrigerator

- At no time should the refrigerator be used to store anything other than medications. Do not store staff lunches or beverages in the refrigerator (with the exception of water bottles in a domestic refrigerator for temperature maintenance).
- No vaccines or any other medications should be stored on the doors, in the crisper area, or close to the walls of the refrigerator where the temperature fluctuations are the greatest.
- Ensure the refrigerator is properly installed with appropriate clearance around the unit.
- Connect the unit to a dedicated circuit that is not required for other appliances.
- Label the refrigerator electrical outlet and the power breaker switch to alert others that it belongs to the refrigerator.
- A new refrigerator may take 2-7 days after turning on to reach the required temperature range of +2°C to +8°C. Ensure the temperature is within range before stocking the unit.
- Do not overstock the refrigerator. Filling the unit too full prevents proper air circulation around the product thus affecting the product temperature.

## 2 Temperature Monitoring

### 2.1 Temperature Range

- Refrigerator's central temperature must be kept between +2°C to +8°C. Thermometers set to +5°C provide the best safety margins for temperature fluctuations between +2°C and +8°C.
- Freezer compartments must be kept at -15°C or colder.

### 2.2 Thermometers

- All refrigerators must have a thermometer that has a continuous monitoring ie. Data logger or a digital minimum/maximum thermometer.
- The min/max thermometer shows the current temperature as well as the minimum and maximum temperatures that were reached since the thermometer was reset.
- There should be separate thermometers to monitor both the refrigerator and freezer compartments.
- Ideally, select a thermometer that can be mounted on the outside of the refrigerator with a probe on a cord that is placed inside a vaccine or diluent box in the refrigerator. This allows the temperature to be monitored without opening the door.



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- The probe should be placed in the center of the unit away from the walls, coils or vent.
- If the unit has batteries they should be changed every 6 months to ensure proper functioning of the thermometer.
  - Thermometers should be calibrated within  $\pm 1^{\circ}\text{C}$  or better. Check with the thermometer supplier to ensure calibration.

**Figure 4. Digital Min/Max thermometer**



## 2.3 Recording Temperatures

- The minimum and maximum temperatures should be recorded on a temperature log (see appendix 1), placed on the door of the unit, at the time of pharmacy opens as well as closing time.
- It is important to reset the minimum/maximum temperatures to the current temperature after recording to obtain meaningful records.

## 3 Vaccine Storage

### 3.1 How to store

- Vaccines should be stored in a separate refrigerator from other medications. Frequent opening of the unit door results in temperature fluctuations. If they must be stored with other medications, store on separate shelves or trays to avoid medication errors.
- Open the door as little as possible and only when necessary.
- Rotate vaccine stock; use vaccines that will expire first.



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- Document the date of opening for a multi-use vial. Also document the date of reconstitution. Store any opened vial within the original box to protect from light.
- Vaccines should be stored in their original boxes with caps on. Light exposure may cause loss of potency of the vaccine.
- Vaccines should be stored with space between each large box or tray of vaccines to allow proper air circulation between the products to maintain consistent temperatures. No more than %50 of the internal volume of the refrigerator should be filled with vaccines.

Figure 3. How to Store Vaccines



## 4 Cold Chain Break

### 4.1 What is a "Cold-Chain Break"?

- A "cold-chain break" occurs when the temperature drops below +2°C or rises above +8°C.



#### 4.2 What to do when there is a break in the cold-chain.

- All pharmacies should have written Policies and Procedures outlining what to do in the event of a Cold Chain Break.
- Check that the thermometer is working correctly. Does the battery need to be changed?
- Check that the plug is still connected.
- Quarantine all product that is has been exposed in another properly functioning unit until it can be determined if the products are safe to use.
- Check the product monographs and/or manufacturer for information on stability of medications involved.
- For government supplied vaccines, contact the regional distribution center for further instructions.

#### 4.3 Power failure

- Pharmacies should have a policy and procedure in place for power outages.
- When the power outage is time-limited and the time the power will be restored is known, do not open the doors of the refrigerator or freezer. Continue to monitor the temperature during the outage.
- If the temperature in the refrigerator rises above 8°C or above -15°C in the freezer the pharmacy should follow their policy and procedure for cold chain break.

### 5 Transporting Vaccines

#### 5.1 Insulated Containers

- Insulated containers (coolers) are used to transport quantities of vaccine off site during one working day, or to store quantities of vaccine needed for immunization on site during a working day, thus avoiding frequent opening of the refrigerator. Also used for transportation of patient supply of vaccine.
- The cooler must be able to maintain vaccine temperature between +2°C to +8°C during transport and throughout clinics. Thin walled, recreational Styrofoam coolers are not acceptable. Coolers or lunch bags brought in by patients should not be used.
- The temperature inside the cooler is maintained with ice/gel packs, and insulating materials.
- The cooler should meet the following criteria: large enough to store vaccines, ice/gel packs, and insulating material during transport; external surface material is strong and durable; lid is tight fitting.



## 5.2 Ice packs/gel packs

- Keep enough frozen ice packs and /or refrigerated gel packs (at +2°C to +8°C) ready to meet the vaccine transport needs of your clinic or health unit.
- Set ice packs on their edge and allow space between them for air circulation in the freezer. Stacking icepacks on top of each other in the freezer may result in uneven or partial freezing, and decrease the efficacy of the icepacks.
- Ensure that ice packs are completely frozen before use.

## 5.3 Insulating Materials

- Insulating materials are used as a barrier to prevent direct contact between vaccines and frozen packs.
- Insulating materials include flexible insulating blankets and gel packs at refrigerator temperature, bubble wrap, crumpled packing paper or Styrofoam peanuts.
- A layer of paper towelling is not sufficient as a barrier to protect vaccines from contact with frozen material.

## 5.4 Basic principles for packing vaccines

- Vaccines should be packed in layers using the following materials: Refrigerated and/or frozen pack, insulating barrier (e.g. bubble wrap, crumpled brown packing paper, Styrofoam peanuts), vaccine, a temperature monitor, and filler materials (may be the same as those used as insulating barriers) to prevent shifting of the contents during transport. The number and placement of refrigerated or frozen packs inside the container will depend on container size, outside temperature, and jurisdictional variations in storage and handling materials.
- Be sure to place an insulating barrier (e.g., bubble wrap, crumpled brown packing paper, Styrofoam peanuts) between the refrigerated or frozen packs and the vaccines to prevent accidental freezing.
- Pack vaccines in their original packaging on top of the barrier. Do not remove vaccine vials from boxes. Be sure to fill any spaces between vaccine boxes with crumpled paper or other filler to prevent shifting of contents in the insulated container.
- Use a properly placed min/max thermometer, data logger, or cold chain monitor near the vaccine. The temperature-monitoring device should be placed in the middle of the vaccines and should not come in contact with the refrigerated or frozen packs.
- Record vaccine type(s), lot numbers, brand names, quantity, date, time, and originating facility on a packing slip on the inside of the container.



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- Attach labels to the outside of the container to clearly identify the contents as being valuable, fragile, and temperature sensitive vaccines that require refrigeration immediately upon shipment arrival.
- Encourage patients transporting vaccines to pick up on the date of their appointment for administration and discourage storage at home in an unmonitored refrigerator. If this is unavoidable, provide patients with appropriate packing materials and educate the patient on safe transport and storage.



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## Appendix 1- Daily Temperature Log

Minimum and Maximum temperature should be recorded daily upon store opening and closing. Place an X in the box that corresponds with the temperature. If the temperature falls in the shaded areas, this represents an unacceptable temperature and appropriate “cold chain break” procedures should be followed.

Month \_\_\_\_\_ Year \_\_\_\_\_

Day of the month																												
Staff initials																												
°C Temp	am	pm																										
+11 °C																												
+10 °C																												
+9 °C																												
+8 °C																												
+7 °C																												
+6 °C																												
+5 °C																												
+4 °C																												
+3 °C																												
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0 °C																												
-1 °C																												
-2 °C																												

Take immediate action if the temperature falls in the shaded area

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