



Refrigerator and Temperature Monitoring Equipment Requirements

Publicly-Funded Vaccines (Roles of SCPP, Ministry of Health and PAS)

The *Pharmacy and Pharmacy Disciplines Act* and the SCPP Regulatory Bylaws define the authorized practices of pharmacists. This document outlines SCPP's terms, conditions, and standards that **all pharmacists must follow when administering drugs, including vaccines, regardless of whether they are publicly or privately-funded.**

In recognition of the key role that Saskatchewan pharmacists play in delivering publicly-funded immunization programs (e.g. Seasonal Influenza Immunization Program, COVID-19 Immunization Delivery Plan), this document highlights areas where the [Saskatchewan Ministry of Health/Drug Plan and Extended Benefits Branch](#) may have set additional requirements. Common questions about the differences between Ministry and SCPP standards can be found in the SCPP's [Administration of Drugs by Injection and Other Routes FAQs](#). However, it is important that pharmacies delivering publicly-funded programs monitor the Ministry website to stay current on the comprehensive list of requirements.

When participating in a publicly funded immunization program, pharmacists and pharmacies agree to the Ministry's terms and conditions for the program (e.g., patient eligibility, informed consent, alternate locations, storage and handling, authorized immunizers, training, documentation, and reporting). **However, if a term or condition is not specifically included in the Ministry's communications, then the SCPP requirements apply.**

DEFINITIONS

“**Purpose-built refrigerator**” is also referred to as a pharmacy, lab-style, or laboratory grade refrigerator.

1. PURPOSE

The SCPP Regulatory bylaws Part J Section 11(3) require the dispensary to be equipped with a refrigerator in good working order. As part of pharmacy operations inspections of equipment as per Section 50 of *The Pharmacy and Pharmacy Disciplines Act*, SCPP requires that the dispensary refrigerators are for medication storage only (i.e. no food/drink storage) and meet guidelines for vaccine storage. See SCPP [Vaccine Storage and Handling Guidelines](#) for policies and procedures that must be in place to ensure the cold chain is maintained and vaccine effectiveness is preserved.

This document will outline SCPP equipment requirements for community pharmacies to assist with equipment selection. However, it is not intended to provide a comprehensive review of all technical functions of refrigerator and temperature monitoring equipment. For more comprehensive information on each section see the Related Resources section for credible resources that provide best practice recommendations.

Practice Tip: Consider Anticipated Services When Selecting Equipment

Careful consideration should be given to anticipated services (e.g., vaccine preventable diseases/travel health, publicly funded vaccines) to ensure equipment selected is appropriate. The following is a best practice recommendation from the Public Health Agency of Canada:

Whenever possible, drugs and/or other biologic products should not be stored with vaccines. Storing non-vaccine items in the vaccine storage unit results in frequent opening of the storage unit door. This allows for a greater chance of temperature instability and excessive exposure to light.

The College requires that all pharmacies adhere to the SCPP Vaccine Storage, Handling and Transport Guidelines to ensure that the cold chain is maintained for all products (e.g., biologics, drugs, vaccines).

Note: For pharmacies participating in the Ministry's publicly-funded immunization program, additional recommendations for storing and monitoring vaccines can be found in the most current version of the SIM, [Chapter 9](#) (e.g. vaccines are not to be stored in the same refrigerator as other drugs, use of data loggers).

Source: Public Health Agency of Canada - [National Vaccine Storage and Handling Guidelines 2015](#), SCPP - [Administration by Injection FAQs](#)

2. POLICY

- 2.1. The pharmacy manager is responsible for understanding the functions and components of the refrigerator to determine if the unit meets the requirements for vaccine storage. Vaccine storage units must be selected carefully and used properly.
- 2.2. Manufacturer's equipment instructions on use and maintenance must be followed to ensure the equipment is functioning properly to maintain the efficacy of the product.
- 2.3. A purpose-built refrigerator is the standard for storing large inventories of vaccines. Alternatively, a pharmacy may choose to use a domestic frost-free refrigerator (i.e., food storage refrigerator), as long as the unit has certain qualities that meet the requirements in 2.4. to ensure the cold chain is maintained. **A bar fridge is not permitted.**

Best Practices: Vaccine Storage Equipment

There are many different types of refrigerators and freezers available. Knowing their functions and components will help in understanding why certain types are recommended for vaccine storage.

A purpose-built refrigerator (also referred to as a pharmacy, lab-style, or laboratory grade refrigerator) is the best type for storing vaccines. It has been shown to have the least temperature variations, maintaining temperatures more reliably within the desired range.

Note: the glass doors do not adequately protect light sensitive vaccines or provide adequate insulation in the case of a power interruption.

Domestic refrigerators are designed for food storage and not for the requirements of vaccine storage. Precautions and fridge modifications are needed in order to store vaccines. See PHAC section 3.4.3. Domestic Frost-Free Refrigerator for more information.

Studies show that bar-style refrigerators are not capable of consistently maintaining temperatures within the +2°C to +8°C range, therefore, bar fridges are not permitted to store vaccines.

Equipment placement: good air circulation around the vaccine storage unit is essential for proper heat exchange and cooling functions. Leave at least 10cm of space (or as recommended by manufacturer) between the back of the unit and the wall. Make sure the unit stands firm and level and adjust levelling legs so that the bottom of the unit sits 2.5cm to 5 cm above the floor. Do not place in direct sunlight, near a heat source, or along an outside wall. Vaccine storage units should ideally be on a dedicated circuit.

Source: [PHAC National Vaccine Storage and Handling Guidelines 2015](#), Section 3.4. Refrigerators and Freezers, [Administration by Injection FAQs](#).

2.4. The requirements for a vaccine storage unit are as follows:

2.4.1. For combination freezer and refrigerator units, there must be a separate external freezer and refrigerator door.

Best Practices: Equipment to Store Frozen Vaccines

Ideally, frozen vaccines should be stored in a separate, designated, frost-free freezer unit at -15°C or colder. However, the freezer compartment of domestic frost-free refrigerators may be used if it has a separate condenser. If a separate condenser is not present in the freezer compartment of a combination fridge/freezer unit the freezer should not be used for the storage of vaccines, as these units cannot maintain the recommended temperatures.

Source: [PHAC National Vaccine Storage and Handling Guidelines 2015](#), Section 3.4.5. Freezers

2.4.2. The unit must be a frost-free model, as this will ensure more uniform temperatures than manual/cyclic defrost models and reduce the risk of freezing vaccines.

Best Practices: Frost-Free Refrigerator

A “frost-free” refrigerator refers to the freezer compartment, where food is supposed to stay relatively frost-free. The evaporator is located in the freezer (usually behind the rear wall). The evaporator defrosts automatically with a heater that dissipates the defrost water. When the compressor is on, a fan blows the cool air through vents to the freezer and then to the refrigerator. Thus, the air being circulated to the refrigerator may be below 0°C. The cool air may freeze vaccines if they are placed near the vents.

Source: [PHAC National Vaccine Storage and Handling Guidelines 2015](#), Section 3.4.3. Refrigerators Appropriate for Use

- 2.4.3. The unit must be able to maintain required vaccine storage temperatures through all seasons.
- 2.4.4. The unit must be large enough to hold the year’s highest monthly inventory (e.g., vaccines for influenza season).
- 2.4.5. The unit must have a calibrated temperature-monitoring device inside each storage compartment capable of recording minimum, maximum and current temperatures.

Note: As required in Section 2.1.2.2. of the [Vaccine Storage, Handling and Transport Guidelines](#), pharmacies must record the current, minimum, and maximum storage unit temperatures and room temperature at least twice a day, even for continuous temperature monitors with alarms. The use of data loggers may help with continuous temperature monitoring (see Best Practice text box below).

Best Practices: Thermometers and Temperature Monitors

All thermometers are calibrated (given a temperature scale) during manufacture. Calibration should be accurate within $\pm 0.5^{\circ}\text{C}$. Avoid using thermometers that have not been calibrated to be accurate within $\pm 0.5^{\circ}\text{C}$. Check with the manufacturer for the accuracy of the thermometer.

The only thermometers and temperature recording devices recommended for monitoring the temperatures within vaccine storage units are thermometers that provide continuous recording (e.g. [data loggers](#)) or min/max thermometers that are properly monitored. These types of thermometers are preferred because they provide an indication of the length of time a storage compartment has been operating outside recommended temperature ranges when a cold chain break occurs. The min/max thermometer must be reset regularly (after properly recording temperatures) for useful readings.

Investing in a reliable thermometer is less expensive than replacing drugs which have been exposed to a cold chain break. See PHAC Guidelines section 3.6 for recommended options. In addition, cold chain breaks are recognized as a **public safety risk** as exposure to temperatures outside of the allowed range may result in decreased vaccine potency and increased risk of vaccine-preventable diseases.

Source: [PHAC National Vaccine Storage and Handling Guidelines 2015](#), Section 3.6

Also see [SIM](#), Chapter 9, Section 2.5 for recommendations on Temperature Monitoring Devices.

3. RELATED RESOURCES

- 3.1. Public Health Agency of Canada (PHAC) – [National Vaccine Storage and Handling Guidelines for Immunization Providers 2015](#) for best practice recommendations on vaccine storage equipment:
 - Section 3.4.1 technical requirements for refrigerators that can affect the safe storage of vaccines
 - Section 3.4.2 a summary of refrigerators that are the best, are acceptable, or are not recommended for vaccine storage
 - Section 3.4.3 detailed information on refrigerators appropriate for use
 - Section 3.4.6 equipment placement recommendations
 - Section 3.4.8 setting and stabilizing the temperature
 - Section 3.6 recommended thermometers and temperature monitors
- 3.2. Ministry of Health - [Saskatchewan Immunization Manual](#) (SIM)
- 3.3. SCPP - [Administration by Injection and Other Routes FAQs](#) for additional information on storage and cold chain management.

4. AUTHORITY

[The Pharmacy and Pharmacy Disciplines Act](#)

[Saskatchewan College of Pharmacy Professionals Regulatory Bylaws](#)