

Vaccine Storage and Handling Guidance Document

This document is in support of the *Vaccine Storage and Handling Protocol* under the *Ontario Public Health Standards*

**Public Health Protection and Prevention Branch
Public Health Division
Ministry of Health and Long-Term Care
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Section 1. Introduction

The *Ontario Public Health Standards*¹ (*OPHS*) specify the minimum public health programs and services that all boards of health are required to provide (“the what”). Legal authority for the *OPHS* is established under Section 7 of the *Health Protection and Promotion Act*² (*HPPA*), which grants authority to the Minister of Health and Long-Term Care to: “publish guidelines for the provision of mandatory health programs and services and every board of health shall comply with the published guidelines” (R.S.O. 1990, c. H.7, s.7(1)). Where there is a reference to the *HPPA* in this document, the reference includes the *HPPA* and its regulations.

The Program Standards are supported by related protocols that further delineate expectations for carrying out the Standards’ requirements (“the how”). **Boards of health are accountable for following the procedures as outlined in the protocols.** The *Vaccine Storage and Handling Protocol*³ is part of the Vaccine Preventable Diseases Program Standard. The purpose of the *Vaccine Storage and Handling Protocol* is to achieve greater standardization in the management of provincial vaccine inventories to ensure the proper storage and handling of vaccines, strengthen quality assurance activities, and provide education strategies in an effort to minimize and reduce provincially funded vaccine wastage and promote vaccine safety and effectiveness.

a. Development of the Ministry’s Guidance Document

The ministry has worked collaboratively with local public health experts to create this guidance document. This guidance document will assist the staff at boards of health to identify issues and approaches for local consideration and implementation of the standards. While the *OPHS* and associated protocols published by the Minister under Section 7 of the *HPPA* are legally binding, guidance documents that are not incorporated by reference into the *OPHS* are not enforceable by statute. **These guidance documents are intended to be resources to assist professional staff employed by local boards of health as they plan and execute their responsibilities under the *HPPA* and the *OPHS*.** This particular guidance document provides specific advice about the *OPHS* requirements related to vaccine storage and handling.

b. The Importance of Vaccine Storage and Handling and the Cold Chain

The continued success of immunization programs requires a comprehensive, effective and efficient vaccine safety system. Effectiveness of the immunization program depends on high immunization coverage of the target group and vaccine inventory management, including proper storage and handling of vaccines. The term ‘cold chain’ is a system of all equipment and procedures used to maintain optimal conditions during the transport, storage and handling of vaccines, starting at the manufacturer and ending with administration of the vaccine to the client. Manufacturers and the Biologics and Genetic Therapies Directorate (BGTD) of Health Canada require that all refrigerated vaccines be stored at temperatures between +2°C to +8°C at all times.

c. Content Overview

Section 2 - Heat and Cold: an evidence based summary of the effects of heat and cold on vaccine potency.

Section 3 - Components of the Cold Chain Monitoring System: an explanation of the types of refrigerators, temperature monitoring devices, and vaccine transport systems used for vaccine storage and handling.

Section 4 - Vaccine Order, Return and Distribution Process and Inventory Management: a description of procedures for transporting and shipping vaccines, inventory management and practices for returning vaccines.

Section 5 - Cold Chain Incidents and Inspections: instruction for the investigation of refrigerator failures, incident inspection, electricity disruption, equipment failure, and human errors. A guide to troubleshooting and an algorithm to use when investigating a cold chain incident are also included.

Section 6 - Routine (Annual) Inspections: a summary of the steps required to prepare for inspections, the process to follow and how to follow-up after an inspection.

Section 7 - References

d. Intended Audience and Purpose

This guidance document is intended to be a resource that identifies key concepts and practical resources that boards of health may use in assisting health care providers and public health unit staff with vaccine storage and handling requirements. It provides advice and guidance to both managers and front-line staff in supporting a comprehensive approach to fulfill the *OPHS* and the *Vaccine Storage and Handling Protocol* requirements at the public health unit and at health care providers' premises.

e. Disclaimer

This guidance document is not intended to provide legal advice or to be a substitute for the professional judgment of public health staff or legal counsel. Public health staff should consult with their manager and/or legal counsel as appropriate. Where there is a conflict between this guidance document and the *Vaccine Storage and Handling Protocol*, the *OPHS*, the *HPPA*, or its regulations, the *Vaccine Storage and Handling Protocol*, *OPHS*, *HPPA* or regulations, as the case may be, shall prevail.

Section 2. Heat and Cold

This section provides an evidence-based summary of the effects of heat and cold on vaccine potency. Stability information for specific publicly funded vaccines is included in the *Canadian Provincial/Territorial Vaccine Stability Chart*. General vaccine storage and stability information is included in the product monograph of every vaccine.

Implementing proper vaccine storage, handling and administration practices ensures that vaccines retain their optimal potency. To maintain maximum potency, all publicly funded vaccines currently in Ontario must be kept between +2°C to +8°C at all times. Failure to adhere to cold chain requirements may result in reduced vaccine potency, resulting in an inadequate immune response to vaccine preventable diseases and/or increased local reactions after administration of vaccine.⁴ Even when vaccines have been maintained at the required storage temperature, vaccines are subject to gradual loss of potency from deterioration and denaturation (a molecular structure change resulting in biological activity loss).⁵

Vaccine potency loss is accelerated when vaccines are exposed to temperatures outside the recommended storage conditions. The loss of vaccine effectiveness due to exposures to adverse conditions is cumulative, permanent and irreversible. Vaccines involved in temperature excursions must be assessed individually due to differences in stability profiles, other vaccine characteristics and external conditions.

2.1 Heat Exposures

All publicly funded vaccines (including reconstituted vaccines) are heat sensitive. Some vaccines are heat and light sensitive. Refer to the *Canadian Provincial/Territorial Vaccine Stability Chart* for additional information.

2.1.1 Vaccines

Depending on the stability data, most publicly funded vaccines will maintain stability if they are briefly exposed to temperatures above +8°C. The rate of loss of potency at elevated temperatures depends on:

- a. Degree of temperature elevation.
- b. Duration of the elevated temperature exposure.
- c. Duration of the light exposure (some vaccines only, refer to the *Canadian Provincial/Territorial Vaccine Stability Chart*).

The risk of potency loss is increased when vaccines are exposed to high temperatures for longer periods of time.

Reconstituted Vaccines

Storage conditions differ once vaccines have been reconstituted. When vaccines are reconstituted they become even more heat-sensitive than in their lyophilized states.⁶ Reconstituted vaccines should be used immediately, as they are very unstable and quickly lose potency at room temperature after reconstitution.

However, some reconstituted vaccines can be stored between +2°C to +8°C for a limited time period. Refer to the vaccine product monographs for reconstituted vaccine storage guidelines. Before administering reconstituted vaccines, they should be checked for signs of deterioration, such as a change in colour or clarity.

2.1.2 Diluents

Diluents should be stored with vaccines and be kept within +2°C to +8°C. To conserve refrigerator space, some diluents may be stored at room temperature ($\leq +25^{\circ}\text{C}$) (refer to the product monographs). Before reconstitution, diluents should be refrigerated and be the same temperature as the vaccine, as reconstituting vaccines with warm diluents may affect potency.⁷

2.2 Cold Exposures

All vaccine diluents and most publicly funded vaccines (including reconstituted vaccines) are cold sensitive and cannot be frozen (exposed to temperatures $<0^{\circ}\text{C}$) (refer to the *Canadian Provincial/Territorial Vaccine Stability Chart*).

2.2.1 Vaccines

Although the potency of most publicly funded vaccines can be affected by storage temperatures that are warmer than +8°C, these effects are usually more gradual, predictable, and smaller in magnitude than losses from temperatures that are colder than 0°C.

Freezing refers to a situation where vaccines experience temperatures of $<0^{\circ}\text{C}$. When an ampoule, vial or syringe of a freeze-sensitive inactivated vaccine is exposed to freezing temperatures, the glass may develop hairline fractures. This is due to the contraction and subsequent thawing of the glass which causes the ampoule, vial or syringe to expand back to its original size. These hairline fractures contribute to contamination, which can affect vaccine sterility and potency.⁸ Vaccines should be assessed for signs of freezing (e.g. granular particles, cloudiness, etc.). However, it is important to remember that a previously frozen vaccine may not always show physical signs of freezing. Most vaccines do not appear different or 'frozen' even when they may have been damaged at temperatures $<0^{\circ}\text{C}$ and may be easily drawn up. Vaccines should not be used if exposed or potentially exposed to temperatures below 0°C even if signs of freezing are not present.

Although some publicly funded vaccines (including live-virus vaccines such as varicella and MMR) may be frozen, they cannot be used if their diluents may have been frozen (see section 2.2.2). The vaccine can only be used if the frozen diluent can be replaced by the Ontario Government Pharmaceutical and Medical Supply Service (OGPMSS).

Vaccines Adjuvanted with Aluminium

Although there are various types of vaccine adjuvants, most adjuvanted vaccines are adjuvanted with aluminium hydroxide or aluminium phosphate to enhance the

immune response in the recipient. The immunogens are adsorbed onto the adjuvant molecular structure. Freezing damages adjuvanted vaccines as this produces changes in the adjuvant's form and structure, by causing adjuvants to separate out of the vaccine and by producing undetectable cracks in the vaccine ampoule or vial.⁹ This results in the loss of vaccine potency and/or risk for contamination. Freezing also causes the development of granular forms or floccules, which produces an increase in sedimentation rate. The larger granules tend not to form a homogenous suspension even after vigorous shaking.

2.2.2 Diluents

Vaccine diluents must be discarded if there is a possibility of having been exposed to temperatures $<0^{\circ}\text{C}$. Freezing can cause the liquid diluent to expand in volume, which may result in undetectable hairline cracks in the ampoule or vial, leading to possible contamination. Frozen diluents may also result in a loss of diluent volume available for reconstitution or an inability of the diluent to provide a homogenous vehicle from which the vaccine suspends.

Section 3. Components of the Cold Chain Monitoring System

This section addresses the following sections of the *Vaccine Storage and Handling Protocol* :

- Section 5) Vaccine storage and handling equipment; and
- Section 6) Vaccine transport.

For specific public health unit requirements please refer to the *Vaccine Storage and Handling Protocol*.

3.1 Vaccine Refrigerators

There are many different types of refrigerators used for vaccine storage. Knowing the functions and components of the refrigerators should help in understanding why only certain types of refrigerators are recommended for vaccine storage.

3.1.1 Comparison Between Purpose-Built, Domestic and Bar Refrigerators

The three most common refrigerators currently used for vaccine storage are the purpose-built refrigerator (used in public health units, hospitals), domestic (used in health care providers premises) and bar refrigerators (used in health care providers premises). This chart provides a comparison between purpose-built, domestic and bar refrigerators.

Technical Features	Purpose-Built Refrigerator	Domestic Refrigerators	Bar Refrigerators
Also Known as	<ul style="list-style-type: none"> • Pharmacy refrigerator • Lab-style refrigerator • Laboratory grade refrigerator 	<ul style="list-style-type: none"> • Kitchen-style refrigerator: <ul style="list-style-type: none"> • Cyclic or manual defrost; or • Frost-free 	<ul style="list-style-type: none"> • Bar-style refrigerator • Mini-refrigerator
Temperature Regulation	<ul style="list-style-type: none"> • Very tight temperature tolerance. • Alarmed with quick reaction time to temperatures outside of the set range. 	<ul style="list-style-type: none"> • Large fluctuations in temperatures. • Temperature varies significantly every time the door is opened. • Unit is cooled by air blown at below 0°C and vaccines placed close to vents could experience below 0°C temperatures. 	Any small single-door refrigerator are not recommended because of the risk of: <ul style="list-style-type: none"> • Freezing temperatures; • Temperature instability; and • Susceptibility to external temperatures.

Technical Features	Purpose-Built Refrigerator	Domestic Refrigerators	Bar Refrigerators
Defrost Mechanism	<ul style="list-style-type: none"> • Has a mechanism to defrost ice from the evaporator without raising the temperature. • This method of regular defrosting also prevents fluctuations of temperatures. 	<ul style="list-style-type: none"> • Temperature rises during defrosting cycle. • Defrost cycle can cause temperature fluctuations. 	<p>If a bar refrigerator is used for vaccine storage modifications are required to reduce the risk of adverse vaccine storage events (see section 3.1.3).</p>
Spatial Temperature Differential	<ul style="list-style-type: none"> • Spatial temperatures are tightly controlled. • Constant fan-forced air circulation within the refrigerated compartments. • Temperatures do not vary within the storage area from the set point. 	<ul style="list-style-type: none"> • Various temperature zones for multiple storage functions. • No air is circulated when the compressor is off. • Transfer of cool air from the freezer to the refrigerator which could result in vaccines being exposed to freezing temperatures. 	
Effects of Changes in External Temperature	<ul style="list-style-type: none"> • Forced air circulation helps to keep internal temperatures within an even range when the external temperature changes. 	<ul style="list-style-type: none"> • When the external temperature rises, the compressor operates more frequently, and the vaccines inside the refrigerator can be exposed to cooler air. 	
Temperature Recovery	<ul style="list-style-type: none"> • Temperature is digitally managed and any deviation in temperatures from the pre-set one is sensed very rapidly. 	<ul style="list-style-type: none"> • Temperature setting using a dial is inaccurate as there is no digital indication of set temperature. • Thermostats are generally slow to react to increase in temperatures and have a wide temperature tolerance. 	

Technical Features	Purpose-Built Refrigerator	Domestic Refrigerators	Bar Refrigerators
Comments	<p>A purpose-built vaccine refrigerator is the standard for public health units and the preferred choice for health care providers to store inventories of vaccines due to the technical features outlined above.</p> <p>Note: As a result of the glass door design of the purpose built refrigerators, extra effort must be taken to protect vaccines from light exposure at all times. It is important to be aware that purpose-built refrigerators may not provide good insulation in the event of a power interruption, resulting in a rapid rise in temperature.</p>	<p>Cyclic or manual defrost refrigerators are not recommended for vaccine storage because they produce wide fluctuations in the internal temperatures with regular internal heating.</p> <p>If a domestic refrigerator is used for vaccine storage, modifications are required to reduce the risk of adverse vaccine storage events (see section 3.1.3).</p>	

3.1.2 Purpose-Built Refrigerator Specifications

Public health units must use a purpose-built vaccine refrigerator for storing vaccine. It is also recommended that health care providers use a purpose-built vaccine refrigerator especially if large inventories of vaccine should be stored. Health care providers who choose to purchase a purpose-built refrigerator should select a model that meets the following specifications:

Technical Features	Description
Interior	<ul style="list-style-type: none"> • At least four (4) fully adjustable, full extension roll-out drawers. • Optional one (1) or more fixed stainless steel shelving. • Resistant to cleaning solutions. • Walls are smooth, scratch and corrosion resistant interior surfaces. • Fan is either encased or removed from the chamber. • Fan auto shut-off when door is opened.
Exterior	<ul style="list-style-type: none"> • Walls are smooth, scratch and corrosion resistant exterior surfaces.
Refrigeration System	<ul style="list-style-type: none"> • Heavy duty, hermetically sealed compressors. • Refrigerant material should be R400 or equivalent. • Advanced defrost sensor(s) to manage the defrost cycle and minimize trace amounts of frost build-up. • Evaporator operates at +2°C, preventing vaccine from freezing.
Doors	<ul style="list-style-type: none"> • Full view non-condensing, glass door(s), at least double pane construction. • Glass doors should be coated with UV reflective material. • Spring-loaded closures include $\geq 90^\circ$ stay open feature and $< 90^\circ$ self closing feature. • Door locking provision. • Option of left or right hand opening. • Interior cabinet lights with door activated on/off switch, as well as an independent external on/off.
Temperature Regulation	<ul style="list-style-type: none"> • The external digital built-in thermometer (which allows for the temperature to viewed without opening the door) should be set at the factory to +5°C with a control range between +2°C to +8°C but this could be done at the time of delivery/installation. • The external digital built-in thermometer's set point (+5°C) and control range (+2°C to +8°C) cannot be altered. • The digital temperature feedback system must ensure a narrow tolerance with internal temperatures and be able to handle external temperature changes. • Ongoing positive forced fan air circulation to ensure temperature uniformity at all shelf levels. • During an electrical power failure, the refrigerator must be able to maintain the required temperature range (+2°C to +8°C) for a minimum of 30 minutes.

Technical Features	Description
Thermometer	<ul style="list-style-type: none"> • A digital automatic temperature recording and monitoring device with battery backup. • The equipment required to download the information from the digital automatic temperature recording and monitoring device (if necessary). • An external built-in visual digital display thermometer independent of the temperature recording and monitoring device which has a digital temperature display in Celsius and temperature increment readings of 0.1°C. • The external built-in digital thermometer must also be able to record and display the maximum, minimum and current temperatures and allow the user to easily check and reset these recordings as required. • The automatic temperature recording and monitoring device and digital display thermometer must be calibrated within +/- 0.5°C or better.
Alarm Condition Indicator	<ul style="list-style-type: none"> • Audible and visual warnings for over-temperature ($\geq +7^{\circ}\text{C}$), under-temperature ($\leq +3^{\circ}\text{C}$) and power failure. • Remote alarm contacts. • Door ajar enunciator. • Alarm testing system.
Top or Bottom Mounted Compressor/ Condensers	<ul style="list-style-type: none"> • Compressor mounted at top or bottom but not in rear.
Noise Levels	<ul style="list-style-type: none"> • The noise produced by the operation of the purpose-built refrigerator should not exceed 85 decibels of noise at one metre. • Noise level should be measured in decibels of sound at one metre from the purpose-built refrigerator.
Locking Plugs	<ul style="list-style-type: none"> • Power supply must have a locking plug.
Castors	<ul style="list-style-type: none"> • Heavy duty locking castors either installed at the factory or upon delivery.
Voltage Safeguard	<ul style="list-style-type: none"> • Voltage safeguard device capable of protecting against power surges related to the resumption of power to the purpose-built refrigerator.

Technical Features	Description
Electrical Equipment	<ul style="list-style-type: none"> • All electrically operated equipment should be UL, CSA and/or Electrical Safety Authority approved and bear a corresponding label. • The equipment should specify the electrical plug type, voltage and wattage rating, and the recommended breaker size for the circuit connection.

3.1.3 Modifying Domestic and Bar Refrigerators for Vaccine Storage at a Health Care Provider Premises

Although it is not recommended, it is possible and very complex to manage domestic and bar refrigerators to reduce the risk of heating and/or freezing the vaccines. Domestic and bar refrigerators are unsuitable for vaccine storage if the health care provider does not diligently undertake appropriate vaccine storage procedures. Health care providers who are using domestic and/or bar refrigerators to store vaccine should ensure the following:

- a. Have an understanding on how the refrigerator works i.e. how does the unit get cooled, where are the air vents located in the cabinet and how to adjust the thermostat.
- b. Modify and stabilize the temperature of the vaccine refrigerator between +2°C to +8°C (strive for +5°C) before stocking vaccine. This should minimize the effect of temperature variations on vaccines. Temperatures should be monitored for 7 consecutive days during regular business hours and the maximum, minimum and current temperatures need to be recorded twice daily and must be within the required storage temperature range prior to receiving and storing vaccine.
- c. Refrigerator should be optimally placed (see the rationale column in the table in section 6.4.1, part 6a)
 - i. In an area that is well ventilated;
 - ii. Out of direct sunlight; and
 - iii. Away from external walls.
- d. Vaccines must be secured. Vaccine refrigerators should be equipped with a lockable door or the vaccine refrigerator should be stored in a room with a lockable door. For those refrigerators without built-in locks, a latch or padlock should be installed. Designated staff must lock the refrigerator and/or the room that vaccine is housed in after office hours (see the rationale column in the table in section 6.4.1, part 6b).

- e. To help prevent the refrigerator from being accidentally unplugged or turned off, ensure that the refrigerator electrical outlet is (see the rationale column in the table in section 6.4.1, part 6c):
 - i. Covered by a metal cage; or
 - ii. Not easily accessible; or
 - iii. Accessible but has the 'do not unplug' sticker sign posted beside/above the refrigerator electrical outlet.
- f. Fill the drawers and the door shelves with plastic water bottles to help stabilize refrigerator temperatures (see the rationale column in the table in section 6.4.1, part 4j). When conditioning the refrigerator for vaccine storage (the refrigerator does not contain vaccine yet), plastic water bottles should be temporarily placed in the interior shelves as well to imitate vaccines as refrigerator temperatures differ when empty.
- g. Map the refrigerator by recording and monitoring temperatures throughout the refrigerator.
 - i. This can be done by placing temperature monitoring and recording devices in all areas of the refrigerator noting the different temperatures before commencing vaccine storage.
 - ii. The minimum time for monitoring in each position is 24 hours, as this should allow the capture of all the fluctuations that may occur in domestic and bar refrigerators.
 - iii. The key areas to monitor are on each shelf from top to bottom, front to back and side to side (the coldest area is often near a cold air outlet or the cooling plate).
 - iv. It is important to identify cold spots so freeze-tolerant vaccines can be placed in the shelves identified as being the coldest and freeze-sensitive vaccines on shelves identified as having more stable temperatures.
- h. Vaccines should be (see the rationale column in the table in section 6.4.1, parts 4a to 4f):
 - i. Stored in the middle of the refrigerator away from the walls, floors and cold-air vents;
 - ii. Stored on the internal shelves of the refrigerator (not stored in the door or in drawers);
 - iii. Stored with space left between each box of vaccine;
 - iv. Grouped by vaccine product type;
 - v. Protected from light (if required); and
 - vi. Arranged with the vaccines with the latest (or longest) expiry date at the back.

- i. Perform regular refrigerator maintenance by (see the rationale column in the table in section 6.4.1, part 6d):
 - i. Defrosting freezer compartment when the ice is >1 cm thick;
 - ii. Cleaning and dusting the back (includes coils), top and bottom of refrigerator if required and at least once annually;
 - iii. Tightening door hinges if the door is not sealing;
 - iv. Replacing door seals if the door is not sealing properly; and
 - v. Installing Velcro door latch to prevent the door from accidentally being left opened (if required).
- j. Place a map of vaccine locations on the outside of the refrigerator door so health care providers can go directly to the needed vaccine when the door is opened.
- k. Keep refrigerator door openings to a minimum. Reducing door opening helps to keep internal temperatures stable.
- l. One key person should be responsible for vaccine management (see the rationale column in the table in section 6.4.1, part 6e).
- m. Be aware of seasonal variations in room temperature that may affect the refrigerator temperature.
- n. Refrigerator must be dedicated for storage of vaccines only. Food, beverages or medical/laboratory specimens should not be stored in a vaccine storage unit because this practice results in frequent door openings and destabilization of the temperature (see the rationale column in the table in section 6.4.1, part 4i).
- o. The refrigerator needs to have enough capacity to accommodate vaccine inventory (see the rationale column in the table in section 6.4.1, part 4k). Take into consideration times of the year when a large inventory of vaccine must be stored in the refrigerator (i.e. influenza season). Premises should not store more than one month's inventory at any given time (see the rationale column in the table in section 6.4.1, part 4l), however depending on the size of the refrigerator, inventory may need to be reduced to a 2 week supply to prevent overcrowding.
- p. If storing large quantities of publicly funded vaccine, it is recommended that the refrigerator be alarmed.
- q. Keep equipment logbooks for each piece of vaccine storage and handling storage equipment. This logbook should be a record of the serial numbers of each piece of equipment, the date each piece of equipment was installed, the dates of routine maintenance tasks and the dates of any repairs or servicing.
- r. Have alternate storage in the event of regular refrigerator maintenance (i.e. defrosting freezer unit) or emergency. Vaccine security requires backup

equipment (such as a generator) and backup plans (see the rationale column in the table in section 6.4.1, part 6h).

3.2 Temperature Monitoring Devices for Vaccine Refrigerators and for Vaccine Transport

A temperature monitoring device is an essential requirement for temperature monitoring of vaccines. All temperature monitoring devices are calibrated during manufacturing. Not all models of temperature monitoring devices are calibrated with the same scale and may have different accuracies and resolutions.

Calibration should be accurate within $\pm 1^{\circ}\text{C}$. Avoid using temperature monitoring devices that have not been calibrated to be accurate within $\pm 1^{\circ}\text{C}$. As all temperature monitoring devices lose their accuracy over time, they should be checked for accuracy on an annual basis (see section 3.3).

3.2.1 Data Loggers

Digital data loggers are miniature, battery-powered, stand-alone temperature monitors that record temperature readings. Data loggers **do not replace** the need for a twice daily observation and recording of the refrigerator temperatures or the installation of an alarm system which should alert staff within and outside of work hours when there is a temperature excursion. Multiple-use digital data loggers are accompanied by software that is installed in a computer. This software allows the user to set the frequency of the temperature readings, download data from the device, and calculate temperature averages, minimums, and maximums, as well as the duration of time at each temperature. Keep data logger recordings as a permanent record of the performance of the vaccine storage unit. The data logger display should be equipped with a digital display screen so the temperature can be visually checked whenever going into the refrigerator and troubleshooting can occur if temperatures are at $+3^{\circ}\text{C}$ or $+7^{\circ}\text{C}$. In addition it is recommended that the data logger have temperature increment readings of 0.1°C .

Advantages of Data Loggers

- Temperatures are recorded continuously, 24 hours a day.
- Data loggers with a minimum, maximum and current display feature are easy to read because they display a number indicating the temperature and do not require interpretation.
- Record data during power outages.
- Decreases the human error element of collection and recording of temperature data, as errors can be made in setting parameters to be measured or in the interpretation of data.
- Provide data on the duration of the temperature excursion.
- Eliminate false documentation.
- Provide a permanent record of temperature readings.
- Provide accurate data.

- Can be used for troubleshooting when premises are unable to maintain the required temperatures or after a cold chain incident (see section 5.3, part j).

Disadvantages of Data Loggers

- Requires staff training to implement.
- Involves data to be downloaded into a computer.
- Data that is not downloaded may be deleted if there is no additional memory space to store data.
- Recording and checking temperature requires the opening of the refrigerator.

Placement of Data Loggers in Refrigerator

- While each manufacturer might have specific recommendations, as a general rule, data loggers should be placed in the centre of the refrigerator.
- Data loggers should not be placed in the refrigerator door or near the side of the refrigerator walls and not close to the freezer portion of the refrigerator.

Recording Maximum, Minimum and Current Temperatures and Downloading Data

- When an out of range temperature occurs the data from the data logger should be downloaded immediately to determine the duration of the cold chain incident and to determine if vaccine is suitable for use or if it should be discarded.
- For data loggers that are utilized to record the minimum, maximum and current temperatures twice daily, data must be downloaded after the temperature recordings in order to reset the minimum, maximum and current temperature readings from the previous readings.
- For data loggers that are utilized in conjunction with a maximum-minimum thermometer, data can be downloaded on a weekly basis (if no out of range temperatures occur) provided that the minimum, maximum and current temperature readings are documented from the maximum-minimum thermometer.

Recommended uses of Data Loggers

- Troubleshooting refrigerators that are not able to maintain the required temperature range and the identification of temperature fluctuations indicating when vaccine may have been at risk of damage as a result of excess heat or cold.
- Assistance in making decisions as to whether or not vaccine can be deemed suitable for use or wasted in the event of a temperature excursion.
- Monitoring of vaccine temperatures during transportation of vaccine.
- Determining the reliability and ability of vaccine refrigerator to store vaccine.
- Mapping vaccine refrigerators (see section 3.1.3, part g).

3.2.2 Chart Recorders

Chart recorders consist of a graph wheel with replaceable graph paper and ink pens. The pens mark the temperature on the graph paper as the wheel turns. The graph paper has a Fahrenheit or Celsius scale on it and the temperature is read where the ink line falls on the scale. The date should be recorded manually on the graph paper when it is placed onto the graph holder and when the graph paper is removed or changed. Keep old graphs as a permanent record of the performance of the vaccine storage unit. As with other temperature recording devices, temperature readings should be checked and recorded at least twice daily. The chart recorder graph should also be checked whenever going into the refrigerator.

Advantages of Chart Recorders

- Temperatures are recorded continuously, 24 hours a day.
- Decreases the human error element of collection and recording of temperature data, as errors can be made in setting parameters to be measured.
- Provide data on the duration of the temperature excursion.
- Eliminates false documentation.
- Provide a permanent record of temperature readings.
- Temperature can be recorded without opening refrigerator.

Disadvantages of Chart Recorders

- Graph paper must be changed when it completes a full circle, usually weekly.
- Chart recorders are more difficult to read than digital temperature recording devices because they require interpretation of the temperature graph.
- Chart recorders are built in units that are used only in purpose-built refrigerators.

Placement of Chart Recorder

- Chart recorders are placed in the front of purpose-built refrigerators.
- For accessibility it is recommended that the chart recorder is located above the glass doors.

Recording Maximum, Minimum and Current Temperatures

- Chart recorder can be utilized to record the minimum, maximum and current temperatures twice daily.
- If the chart recorder is utilized in conjunction with a minimum-maximum thermometer, the minimum, maximum and current temperature reading can be documented from the maximum-minimum thermometer.

Recommended uses of Chart Recorders

- Identification of temperature fluctuations indicating when vaccine may have been at risk of damage as a result of excess heat or cold.

- Assistance in making decisions as to whether or not vaccine can be deemed reusable or wasted in the event of a temperature excursion.
- Determining the reliability and ability of a vaccine refrigerator to store vaccine.

3.2.3 Digital Maximum-Minimum Thermometers

Digital maximum-minimum thermometers show the current temperature and the minimum and maximum temperatures that have been reached since the last time the maximum-minimum thermometer was reset. Digital maximum-minimum thermometers should have a screen in which the temperature is displayed in Fahrenheit or Celsius. The maximum-minimum thermometer sensor should be placed on the middle refrigerator shelf inside an empty vaccine box to help to stabilize the temperature readings and to protect the sensor from exposures to sudden breezes of cold or warm temperatures. In addition, it is recommended that temperature increment readings should be by +0.5°C.

Advantages of Digital Maximum-Minimum Thermometers

- Temperature can be recorded without opening refrigerator.
- Digital maximum-minimum thermometers have a minimum/maximum feature and are easy to read because they display a number indicating the temperature and do not require interpretation.
- Temperature fluctuations outside the recommended range can be detected by reading to the minimum and maximum temperature values.

Disadvantages of Digital Maximum-Minimum Thermometers

- Readings do not indicate when the exposure occurred and the exact length of time the vaccines were exposed to the out of range temperatures.
- The maximum-minimum thermometer must be manually reset regularly (after properly recording temperatures) for accurate temperature recording for the specific time period.

Placement of Digital Maximum-minimum Thermometer

Each digital maximum-minimum thermometer has slightly different operating instructions and the instructions should be followed to ensure that the maximum-minimum thermometer functions properly. In general, a digital maximum-minimum thermometer can be set up by:

- Attaching the maximum-minimum thermometer to the outside wall of the refrigerator using double-sided tape.
- Securing the cable to the centre of the middle shelf inside the refrigerator.
- Placing the maximum-minimum thermometer sensor inside an empty vaccine box that is stored on the middle shelf of the refrigerator - this should reduce the likelihood of the sensor measuring brief temperature fluctuations when the refrigerator door is opened.
- Do not place the sensor into fluid, unless instructed by the manufacturer.

- If the maximum-minimum thermometer has an IN-OUT switch, make sure it is always in the **OUT** position.
 - The OUT position actually reads the temperature *inside* the refrigerator, which is detected by the sensor at the end of the cable.
 - The IN position reads the temperature *outside* the refrigerator, which is detected by the built-in sensor.

Recording Maximum, Minimum and Current Temperatures

- It is important to manually reset the minimum and maximum temperatures after each time the temperatures are recorded.
- Follow the manufacturer's directions on how to reset the digital maximum-minimum thermometer.

Recommended uses of Digital Maximum-Minimum Thermometers

- Identification of temperature fluctuations indicating when vaccine may have been at risk of damage as a result of excess heat or cold.
- Assistance in making decisions as to whether or not vaccine can be reusable or need to be discarded in the event of a temperature excursion.

3.3 Checking the Accuracy of a Temperature Monitoring Device

Checking the temperature monitoring device for accuracy is recommended to ensure that temperature measurements are accurate and cables or sensors are not damaged. Temperature monitoring devices should be checked for accuracy after:

- a. The battery is changed (every 6 months with the time change) as a low functioning battery may give false temperature readings;
- b. A cold chain incident occurs; and
- c. One year of device use.

The following tests can be used to check the accuracy of temperature monitoring devices:

3.3.1 Sending Temperature Monitoring Devices to the Manufacturer for Recalibration

The most reliable and accurate method to ensure that the device is accurate is to send the temperature monitoring device back to the manufacturer for recalibration. When possible this should be encouraged.

3.3.2 Using the Slush Test to Check the Accuracy of Maximum-Minimum Thermometers

The following steps can be taken when checking the accuracy of a maximum-minimum thermometer using the slush test (please ensure that the maximum-minimum thermometer sensor can be submerged in water):

- a. Fill a polystyrene or plastic cup two-thirds with cold water.

- b. Place the cup in the freezer until a fine layer of ice forms on top and a small section of ice forms within the fluid (about 2 hours).
- c. If ice is present, this ensures the mixture is 0°C.
- d. Push the temperature sensor into the middle of the container and be careful not to let the sensor touch the container (keep the sensor one inch away from the bottom or sides of the container).
- e. After submersion of the sensor into the container, observe the display screen on the maximum-minimum thermometer. The temperature should drop to 0°C within 1-2 minutes.
- f. While a maximum-minimum thermometer with 100% accuracy should read 0°C, most maximum-minimum thermometers have degrees of accuracy ranging between $\pm 0.5^{\circ}\text{C}$ to $\pm 1.0^{\circ}\text{C}$. Check with the maximum-minimum thermometer manufacturer about the degree of accuracy of the device.
 - i. For maximum-minimum thermometers that are accurate within $\pm 0.5^{\circ}\text{C}$, this check could result in readings ranging from $+0.5^{\circ}\text{C}$ to -0.5°C .
 - ii. For maximum-minimum thermometers that are accurate within $\pm 1^{\circ}\text{C}$, this check could result in readings ranging from $+1^{\circ}\text{C}$ to -1°C .
- g. Read the temperature after 2 minutes:
 - i. For maximum-minimum thermometers that are accurate within $\pm 0.5^{\circ}\text{C}$, if the temperature reading is greater than $+0.5^{\circ}\text{C}$ or less than -0.5°C replace the battery and test again. If still not within range, replace the maximum-minimum thermometer.
 - ii. For maximum-minimum thermometers that are accurate within $\pm 1^{\circ}\text{C}$, if the temperature reading is greater than $+1^{\circ}\text{C}$ or less than -1°C replace the battery and test again. If still not within range, replace the maximum-minimum thermometer.
- h. Record the results of the accuracy check on the [Vaccine Cold Chain Maintenance Inspection Report \(VCCMIR\)](#) (if completed during the routine (annual) inspection) or on the [Vaccine Cold Chain Incident Exposure/Wastage Report \(VCCIEWR\)](#) (if completed during a cold chain incident inspection).

3.3.3 Testing the Accuracy of a Temperature Monitoring Device Against a Calibrated Temperature Monitoring Device

Another method of testing a thermometer's accuracy is to measure a temperature monitoring device against a reference calibrated temperature monitoring device but this is the least reliable of the three methods. Select the most appropriate testing of accuracy method based on the temperature monitoring devices:

- a. **Testing the Accuracy of a Maximum-Minimum Thermometer Against a Calibrated Maximum-Minimum Thermometer**
 - Place the calibrated maximum-minimum thermometer into the premises' refrigerator.

- Place the calibrated and the premises' maximum-minimum thermometer sensors in the same vaccine box.
- Let the calibrated maximum-minimum thermometer stabilize to the temperature of the refrigerator (this should take approximately 5-10 minutes depending on the refrigerator and thermometer).
- After the calibrated maximum-minimum thermometer's temperatures have stabilized, compare the current temperature readings from the calibrated maximum-minimum thermometer against the premises' maximum-minimum thermometer. If the current temperature readings of the premises' maximum-minimum thermometer is greater than +/- 2°C (see note) when compared to the calibrated maximum-minimum thermometer change the battery and repeat the test.
- If the premises' maximum-minimum thermometer is still reading at greater than +/-2°C when compared to the calibrated maximum-minimum thermometer, the premises' maximum-minimum thermometer should be replaced.

Note: if the calibrated maximum-minimum thermometer is accurate within +/- 1°C and the premises' maximum-minimum thermometer is accurate within +/- 1°C, the readings between the two maximum-minimum thermometers can differ by +/- 2°C. For example, if the actual temperature reading is +5°C, the calibrated maximum-minimum thermometer could have a reading of +6°C (this indicates the calibrated maximum-minimum thermometer is varying by plus 1°C) and the premises' maximum-minimum thermometer could have a reading +4°C (this indicates the premises maximum-minimum thermometer is varying by minus 1°C).

b. Testing the Accuracy of a Maximum-Minimum Thermometer Against a Calibrated Data Logger

- Place the calibrated data logger into the premises' refrigerator.
- Place the calibrated data logger in the vaccine box beside the premises' maximum-minimum thermometer's sensor.
- Let the calibrated data logger stabilize to the temperature of the refrigerator (this should take approximately 5-10 minutes depending on the refrigerator and data logger).
- After the calibrated data logger's temperatures have stabilized, compare the current temperature readings from the calibrated data logger against the premises' maximum-minimum thermometer.
- If the current temperature readings of the premises' maximum-minimum thermometer are greater than +/-1.5°C (see note) when compared to the calibrated data logger change the battery and repeat the test.
- If the temperature readings of the premises' maximum-minimum thermometer are still reading at greater than +/-1.5°C when compared to the calibrated data logger, the premises' maximum-minimum thermometer should be replaced.

Note: if the calibrated data logger is accurate within $\pm 0.5^{\circ}\text{C}$ and the premises' maximum-minimum thermometer is accurate within $\pm 1^{\circ}\text{C}$, the readings between the two devices can differ by $\pm 1.5^{\circ}\text{C}$. For example, if the actual temperature reading is $+5^{\circ}\text{C}$, the calibrated data logger could have a reading of $+5.5^{\circ}\text{C}$ (this indicates the calibrated data logger is varying by plus 0.5°C) and the premises' maximum-minimum thermometer could have a reading of $+4^{\circ}\text{C}$ (this indicates the premises maximum-minimum thermometer is varying by minus 1°C).

c. Testing the Accuracy of a Data Logger Against a Calibrated Data Logger

- Program the calibrated data logger and the non calibrated data logger(s) to the following specifications:
 - Measuring (recording) frequency: every 1 minute.
 - When to start recording: Push “start” button to start recording.
- When all of the data loggers have been programmed, place the data loggers in an enclosed area where they should not be disturbed (e.g. a box sitting in the refrigerator or on a desk at room temperature) and let the data loggers stabilize to the temperature of the enclosed area (this should take approximately 5-10 minutes).
- Press the “start” button. Let the data loggers sit undisturbed for 10-20 minutes.
- After 10-20 minutes, download the temperature logs from the data loggers.
- Create a file to store the data logger readings.
- Compare the temperature logs of the calibrated data logger to the temperature logs from the non calibrated data logger.
- If the non calibrated data logger is reading at greater than $\pm 1^{\circ}\text{C}$ (see note) when compared to the calibrated data logger, change the battery and repeat the test.
- If the non calibrated data logger is still reading at greater than $\pm 1^{\circ}\text{C}$ when compared to the calibrated data logger, the data logger must be sent to manufacturer for recalibration or be replaced.

Note: if the calibrated data logger is accurate within $\pm 0.5^{\circ}\text{C}$ and the non calibrated data logger is accurate within $\pm 0.5^{\circ}\text{C}$, the readings between the two devices can differ by $\pm 1^{\circ}\text{C}$. For example, if the actual temperature reading is $+5^{\circ}\text{C}$, the calibrated data logger could have a reading of $+5.5^{\circ}\text{C}$ (this indicates the calibrated data logger is varying by plus 0.5°C) and the non calibrated data logger could have a reading of $+4.5^{\circ}\text{C}$ (this indicates the non calibrated data logger is varying by minus 0.5°C).

3.4 Insulated Containers

An insulated container is a solid-walled container with a tight lid. The required temperatures inside the insulated container are maintained by ice pack(s) and/or

gel pack(s). Vaccines must be stored and transported in insulated containers supplied by the OGPMS with the appropriate packaging material and packing configuration. Public health units may choose to use alternative insulated containers for vaccine transport and storage however must provide the ministry with documentation that specifies that the insulated container is capable of meeting cold chain requirements. Please see section 6b in the *Vaccine Storage and Handling Protocol* for specific requirements.

Public health units should ensure that they and health care providers use insulated containers with the appropriate packaging material and packing configuration to ensure that vaccines are maintained within the +2°C to +8°C temperature range for the maximum length of time that might be required for transport and/or storage. Public health units can order insulated containers from the OGPMS for public health unit use or provide these containers to health care providers.

Insulated containers are not adequate for the transport and/or storage of vaccines for prolonged periods as their cold life (the container's ability to maintain the required temperature range) is limited. Most insulated container can maintain the required temperatures for a maximum of 4 hours. However the external temperature, the number of times the insulated container is opened and closed, the amount of vaccine that is being stored and the type of packaging material used may reduce the amount of time vaccines can be stored in the insulated container. If vaccines will be stored and/or transported for more than 4 hours in the insulated container, the ice pack(s) and/or gel pack(s) should be removed and replaced with a new set of conditioned frozen and/or refrigerated ice pack(s) and/or gel/pack(s).

3.5 Conditioning Frozen Ice Packs and Frozen Gel Packs

Conditioning is a term which refers to leaving the ice pack(s) (including flexible ice blankets) and gel pack(s) at room temperature to allow the ice or gel at the core to rise to about 0°C. This minimizes the risk of exposing vaccines to freezing temperatures.

3.5.1 Ice Packs

Ice packs (including the flexible ice blankets) are water-filled and come out of the freezer at a temperature of about -18°C. It normally requires at least 24 hours in a freezer for an ice pack to be frozen and brought down to the temperature in the freezer.

Condition frozen ice packs by:¹⁰

- a. Removing ice packs from the freezer.
- b. Laying out the ice packs leaving 5 cm around each ice pack to allow maximum air exposure to reduce the conditioning time.
- c. Waiting until the ice packs begin to sweat. This should take up to one hour at +20°C and less at higher temperatures.
- d. The ice pack is conditioned as soon as water begins to 'slosh' slightly inside the ice pack.

3.5.2 Gel Packs

There are a number of different types of gel packs that contain chemicals that depress the melting point and ensure the gel remains colder than 0°C for longer than water-filled ice packs. They tend to have freezing points below 0°C and present a risk of freezing vaccines unless they are appropriately conditioned for use in the insulated container.

Condition frozen gel packs by:

Usually gel packs should take longer than ice packs to condition so that they are safe to use for vaccine transport. There is no one rule that fits the conditioning of the available gel packs, however the following guidelines may be used:

- a. Storing the gel packs in the freezer at -20°C for approximately 36 hours.
- b. Conditioning gel packs weighing less than 750 grams:
 - If room temperature is over +15°C condition for 45 minutes before use.
 - If external temperature is less than +15°C condition for 1 hour before use.
- c. Conditioning gel packs weighing more than 750 grams:
 - If room temperature is over +15°C condition for 1 hour before use.
 - If external temperature is less than +15°C condition for 1½ hours before use.

3.6 Packing the Insulated Container for Vaccine Transport

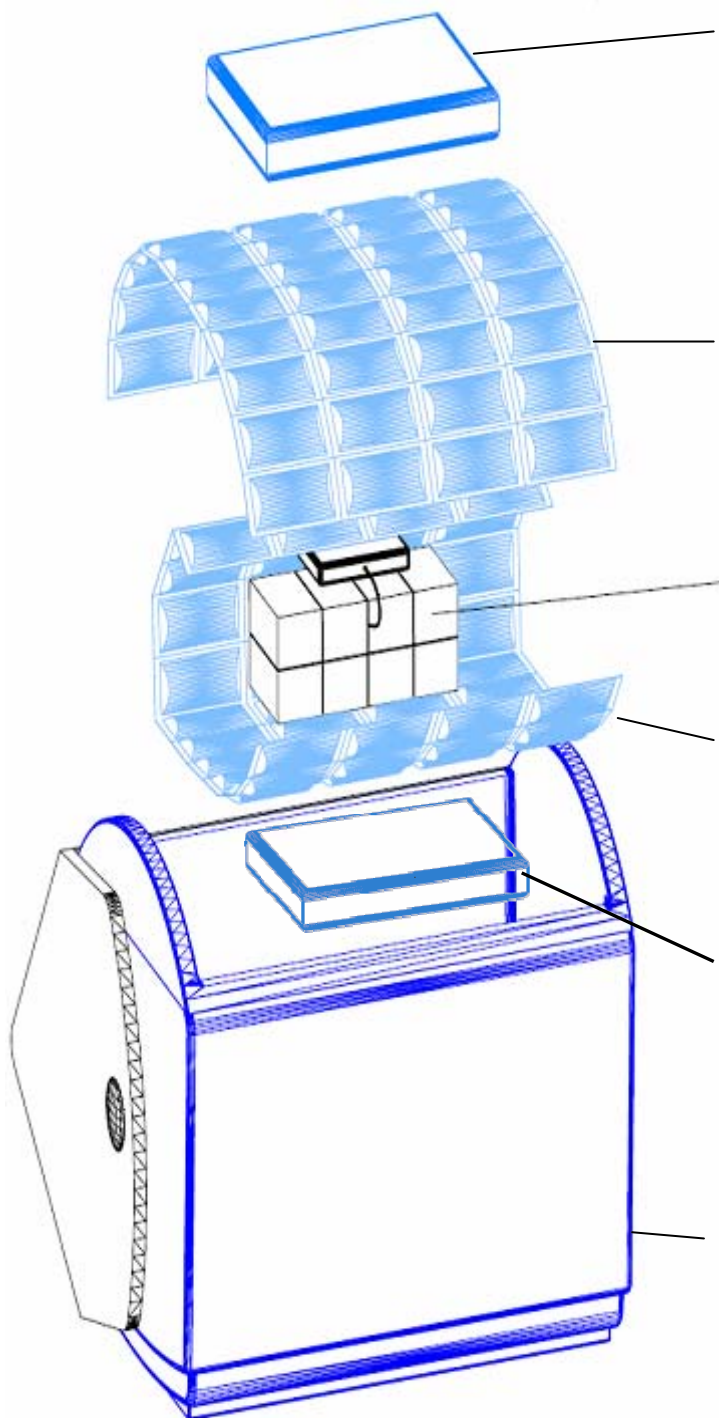
Freezing episodes happen very easily in all insulated containers, usually in the first 2 hours after packing. To ensure vaccines arrive at the destination safely:

- a. Chill the inside of the insulated container prior to use by placing frozen ice pack(s) and/or gel pack(s) in it for a few hours. Prior to packing the insulated container with the vaccines these frozen ice pack(s) and/or gel pack(s) should be removed from the container.
- b. Condition all frozen ice pack(s) and/or frozen gel pack(s) by following section 3.5.
- c. Place the conditioned ice pack(s) and/or gel pack(s) on the top and on the bottom of the insulated container. Wrap the flexible ice blanket around the vaccine to prevent the vaccines from coming into contact with the ice pack(s) and/or gel pack(s) and to minimize the potential of freezing the vaccine. Experiment to find the correct combination of ice pack(s) and/or gel pack(s) to ensure that the insulated container is able to maintain the required temperature range for:
 - i. The maximum length of time the vaccine might have to be in the insulated container;
 - ii. The amount of vaccines to be transported; and

- iii. The given external temperatures (e.g. winter climate vs. summer climate).
- d. Pack the freeze-sensitive vaccines in the centre of the container and the freeze tolerant vaccine closest to the ice pack(s) and/or gel pack(s).
- e. Place a temperature monitoring device in the centre of the vaccine stock.
- f. Place bubble wrap, Styrofoam chips, crumpled or shredded newspaper or other suitable insulating material inside (bottom, top and sides) the insulated container. This will:
 - i. Eliminate hot and cold spots;
 - ii. Ensure the contents of the insulated container are packed securely so they cannot move around during transport; and
 - iii. Allow cold air to circulate.
- g. Clearly mark all insulated containers storing vaccine with the following label: "VACCINES-REFRIGERATE IMMEDIATELY".
- h. Remove vaccines from the insulated container only as they are required.
- i. Insulated containers storing vaccines should not be transported in the trunk of a car due to the extreme temperatures that can occur.

3.6.1 Packing Instructions Using a 16 Quart Insulated Hard Sided Insulated Container

Packing instructions for the insulated containers supplied by OGPMS:



Gel pack(s)

- Winter transport may require gel pack(s) to be conditioned from the refrigerator at +2°C to +8°C.
- Summer transport may require gel pack(s) to be conditioned from the freezer at -10°C to -20°C.
- Place gel packs on top of outer flexible ice blanket.

Outer flexible ice blanket

- Condition in refrigerator at +2°C to +8°C.
- Wrap outer flexible ice blanket around vaccines and inner flexible ice blanket.

Vaccines and temperature monitoring device

- Vaccines in refrigerator between +2°C to +8°C.
- Position maximum-minimum thermometer sensor inside a vaccine box.

Inner flexible ice blanket

- Conditioned in refrigerator between +2°C to +8°C.
- Wrap inner flexible ice blanket around vaccines.

Gel pack(s)

- Winter transport may require gel pack(s) to be conditioned from the refrigerator at +2°C to +8°C.
- Summer transport may require gel pack(s) to be conditioned from the freezer at -10°C to -20°C.
- Place gel packs on top of outer flexible ice blanket.

Insulated hard sided container

- Pre-chill insulated container with gel packs from the freezer for a few hours or by placing the container in a refrigerator until a temperature between +2°C to +8°C is reached prior to placing vaccines into the container.

Note: Additional ice packs may be required depending on cold-life needed for the length of transport. Additional insulating material (e.g. bubble wrap, Styrofoam chips, crumpled or shredded newspaper) should be placed inside (bottom, top and sides) the insulated container to allow for cool air circulation.

3.7 Temperature Monitoring for Insulated Containers during Vaccine Transport

It is requirement when transporting vaccines in an insulated container to monitor temperatures during vaccine transport. The frequency of the checking and the recording of temperatures are dependent on the amount of time the vaccine should be stored and transported in the insulated container.

3.7.1 Health Care Providers

Health care providers should monitor and record temperature readings in the insulated container:

- a. Before leaving the public health unit with the insulated container.
- b. After 1 hour of travel.
- c. Upon arrival at the premises but before the vaccines are placed back into the refrigerator:
 - i. Place vaccine into inventory for use if the temperature monitoring device(s) indicates that the cold chain was maintained between +2°C to +8°C.
 - ii. If the temperature monitoring device(s) indicates an out-of-range reading, health care providers should place the vaccine under quarantine in the refrigerator and should immediately report the incident to their public health unit. The vaccines must be kept refrigerated and should not be used until the public health unit provides further direction (see section 5.2.2 for assessing cold chain incidents).

3.7.2 Public Health Unit Immunization Clinics

Health care providers should monitor and record temperature readings in the insulated container:

- a. Before leaving the public health unit with the insulated container.
- b. Upon arrival at the clinic, but prior to the immunization clinic.
- c. Record temperatures at least every three hours (however it is strongly encouraged to record temperatures hourly) during the immunization clinic.
- d. Upon completion of the clinic but before transport back to the public health unit.
- e. Upon arrival to the public health unit:
 - i. Place vaccine into inventory for use if the temperature monitoring device(s) indicates that the cold chain was maintained between +2°C to +8°C.
 - ii. If the temperature monitoring device(s) indicates an out-of-range reading, public health units should place the vaccine under quarantine in the refrigerator and immediately assess the cold chain incident using the *Canadian Provincial/Territorial Vaccine Stability Chart* (see section 5.2.3 for assessing cold chain incidents).

In addition, to the above required temperature monitoring and recordings in the insulated container, the temperature monitoring device should be visually inspected each time the insulated container is opened.

3.7.3 Courier Transport Services

Public health units should advise courier transport services contracted to transport vaccine that vaccines are perishable, must be refrigerated immediately upon receipt, and must be transported under required cold chain conditions. Education and training should be completed with courier services to ensure that the delivery personnel are knowledgeable regarding vaccine storage and handling practices. As courier transport services are responsible for the storing and handling of vaccine, it is recommended that a routine inspection be completed annually with courier transport services (see section 6.1).

A temperature monitoring device should be placed in each insulated container. Once a health care provider receives the insulated container from the courier, the health care provider should:

- a. Immediately open all the transport containers and assess the temperature monitoring device(s).
- b. Confirm that the number of containers received in the shipment matches the number of containers on the manifest.
- c. Examine the shipment for any evidence of damage.
- d. If there are any cold chain discrepancies or obvious damage, health care providers should inform the courier and make a notation of the issue on the manifest.
- e. Once the courier leaves, the health care providers should:
 - i. Unpack the shipment and place the vaccines in the refrigerator.
 - ii. Review the order against the packing slip(s) to confirm that the order is correct.
 - iii. Receive vaccine into inventory for use if the temperature monitoring device(s) indicates that the cold chain was maintained between +2°C to +8°C.
 - iv. If the temperature monitoring device(s) indicates an out-of-range reading, health care providers should place the shipment under quarantine in the refrigerator and immediately report the incident to their public health unit. The order must be kept refrigerated and should not be used until the public health unit provides further direction (see section 5.2.2 for assessing cold chain incidents).
 - v. If there are any problems with the vaccine order, the health care provider should contact the public health unit.

Section 4. Vaccine Order, Return and Distribution Process and Inventory Management

This section addresses the following sections of the *Vaccine Storage and Handling Protocol* :

- Section 1) Inventory management;
- Section 2) Vaccine order process; and
- Section 3) Vaccine return process.

For specific public health unit requirements please refer to the Vaccine Storage and Handling Protocol.

4.1 Staff Designated to Monitor Vaccine Storage and Handling Practices

All staff handling vaccines need to receive education and training on how to manage vaccines so the vaccines remain safe and effective. This involves all staff members whose roles may affect safe vaccine storage at any stage during the cold chain.

4.1.1 Public Health Unit

Public health units are responsible for maintaining their supply of publicly funded vaccine through proper vaccine storage and handling practices and proper inventory management. It is recommended that each public health unit establish the following:

- a. Designate at least one staff member the responsibility for vaccine ordering, inventory, storage, distribution and return in each location where publicly funded vaccine is stored.
- b. One person should be the designated lead for the public health unit, responsible for updating and maintaining policies and procedures related to the storage and handling of vaccines and ensuring that these reflect current best practices.
- c. Provisions for an alternate individual to cover these responsibilities must be designated in advance.
- d. Orient responsible staff to the program to ensure they are aware of requirements for vaccine storage and handling, product sensitivities and inventory management procedures.
- e. All public health unit staff must also be aware of the relevant expectations for health care providers who store publicly funded vaccine, as stated in the *Vaccine Storage and Handling Protocol* .

4.1.2 Health Care Providers' Premises

Health care providers storing and handling publicly-funded vaccines require knowledge of:

- The importance of the cold chain;
- Vaccine storage and handling practices;
- How to recognize a cold chain incident; and
- The appropriate action to be taken in the event of a vaccine exposure.

One person in each premise should be designated to monitor vaccine storage and handling practices, and to ensure that vaccines are kept at the required temperatures. This person should have a back-up person who can continue to monitor vaccine storage and handling responsibilities. However, all staff members should be trained in reading the vaccine refrigerator thermometers, and documenting and monitoring the vaccine storage temperatures to provide 'back up' in the event of staff vacations or other absence.

4.2 Vaccine Ordering

For ordering of publicly funded vaccines, please see section 2 of *the Vaccine Storage and Handling Protocol*.

Health care providers are required to understand and to be aware of the *Vaccine Storage and Handling Guidelines*¹¹ and have a documented routine (annual) inspection that meets the requirements of the *Vaccine Storage and Handling Protocol*³ prior to receiving publicly funded vaccine.

4.2.1 Vaccine Order Forms for Routine Immunizations

The following forms must be used to order vaccine from OGPMS:

- a. [Public Health Unit Requisition for Biological Supplies \(2255-64\)](#)
- b. [Toronto Clients Requisition for Biological Supplies \(for use in M postal code areas only\) \(2203-64\)](#)

4.2.2 Vaccine Order Forms for Non Routine Immunizations

Specific order forms must be used for ordering the following products:

- a. [Requisition for Vaccines for School-based Programs - Public Health Unit \(4586-64\)](#)
- b. Hepatitis A vaccine for outbreak control (contact the Public Health Division (PHD)).
- c. Hepatitis B for renal dialysis clients (contact the OGPMS).
- d. Meningococcal ACWY polysaccharide and conjugate vaccines for high risk clients (contact the PHD).
- e. Clostridium botulinum antitoxin (contact the PHD).
- f. Diphtheria antitoxin (contact the PHD).

4.3 Inventory Management

For detailed inventory management information please see section 1 of the *Vaccine Storage and Handling Protocol*.

4.4 Receiving Vaccines

Trained designated public health unit staff or their back-up must be available to receive and store vaccines when they are expected to arrive. OGPMSS packs vaccines in vaccine transport containers. A temperature monitoring device is packed in each transport container delivered by refrigerated trucks and by air to the public health units.

4.4.1 Public Health Unit Staff Receiving the Monitored Shipment by Refrigerated Truck

Public health unit staff should review the temperature monitoring devices and verify the contents of the order while the driver is present as follows (see the algorithm in section 4.4.4):

- a. Immediately open all the transport containers and assess the temperature monitoring device(s).
- b. Confirm that the number of containers received in the shipment matches the number of containers on the manifest.
- c. Examine the shipment for evidence of damage.
- d. Print the name of the receiver, the date and time of receipt then sign the manifest to acknowledge the receipt of the order.
- e. If there are any cold chain discrepancies or obvious damage, should inform the driver and make a notation of the issue on the manifest.
- f. Once the driver leaves, public health unit staff should:
 - i. Unpack the shipment and place vaccines in the refrigerator.
 - ii. Review the order against the packing slip(s) to confirm that the order is correct.
 - iii. Receive and record vaccine into inventory for use if the temperature monitoring device(s) indicates that the cold chain was maintained between +2°C to +8°C.
 - iv. If the temperature monitoring device(s) indicates an out-of-range reading, the shipment should be placed under quarantine in the refrigerator and should immediately report the incident to the nurse consultant at the PHD at 416-327-7419. OGPMSS should also be notified at 416-327-0837. The order must be kept refrigerated at the public health unit until PHD provides further direction.
 - v. Determine if there are any problems with the vaccine order. The public health unit should contact OGPMSS at 416-327-0837 within 72 hours of the receipt of the shipment if this occurs, otherwise the order will be considered to be complete and correct.

4.4.2 Health Care Providers who Receive Monitored Vaccine Delivery Directly from OGPMS by Refrigerated Truck

Health care providers who receive vaccine delivery directly from OGPMS should verify the contents of the order while the driver is present as follows:

- a. Confirm that the number of containers received in the shipment matches the number of containers on the manifest.
- b. Examine the shipment for evidence of damage.
- c. Print the name of the receiver, the date and time of receipt then sign the manifest to acknowledge the receipt of the order.
- d. If there is any obvious damage, inform the driver and make a notation of the issue on the manifest.
- e. Once the driver leaves, staff should:
 - i. Review the order against the packing slip(s) to confirm that the order is correct
 - ii. Receive vaccine into inventory for use.
 - iii. Determine if there are any problems with the vaccine order. If this occurs, health care provider should contact OGPMS at 416-327-0837 within 72 hours of the receipt of the shipment, otherwise the order will be considered to be complete and correct.
- f. If an incorrect order is shipped, the health care provider should contact the public health unit who will assess whether the premises that received the vaccine has a refrigerator that maintained the cold chain of +2°C to +8°C. If the cold chain was maintained, the public health unit should contact PHD. If the vaccine can be returned to OGPMS, PHD will coordinate with OGPMS to arrange for the order to be picked up by OGPMS as soon possible.

4.4.3 Public Health Unit Staff Receiving the Monitored Shipment by Air

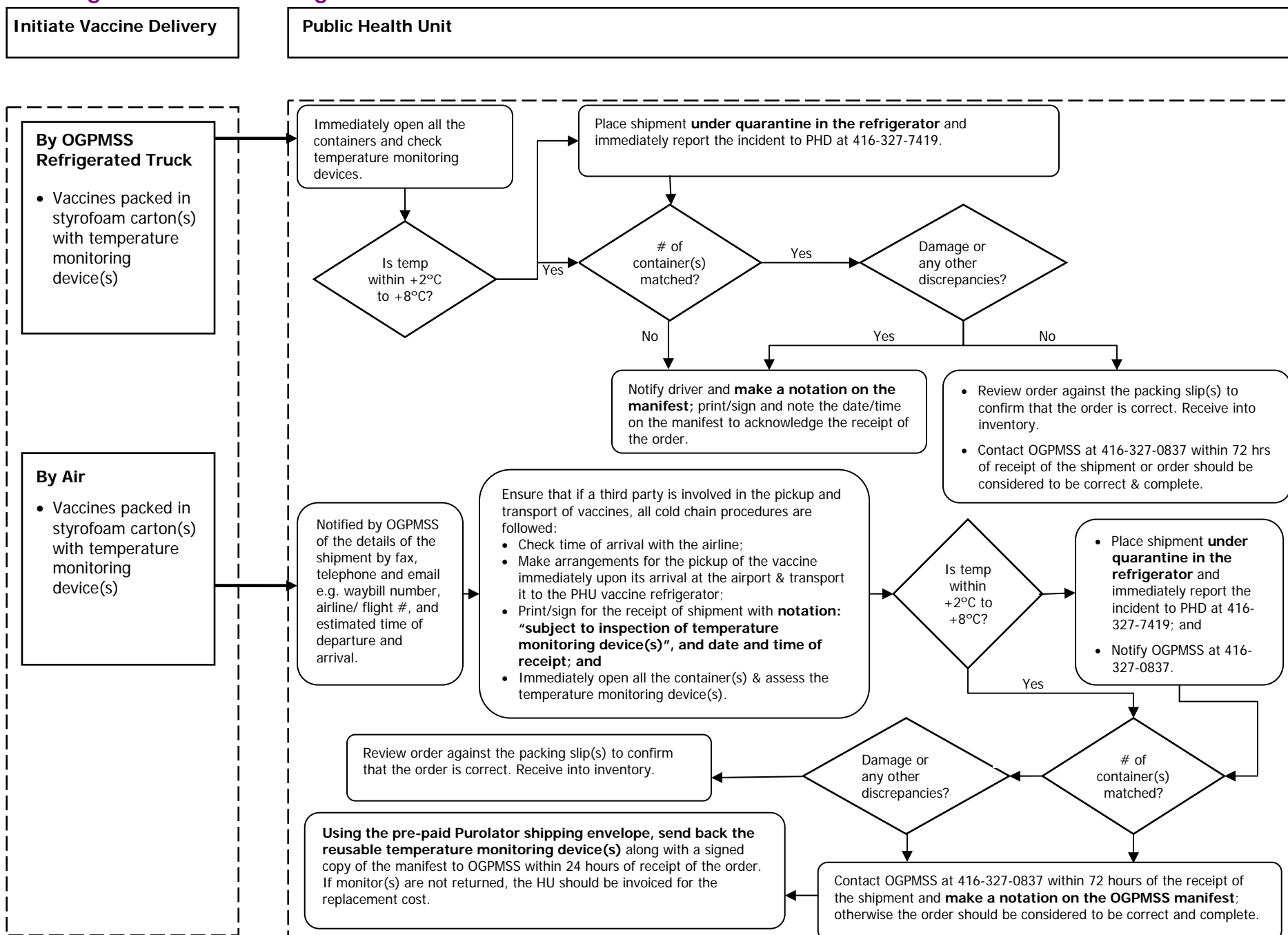
Public health unit staff will be notified by OGPMS of the following details: the number of boxes, the value of the vaccines, the waybill number, the airline, the flight number, and estimated time of departure and arrival of the shipment by fax, telephone and email. From the time of this notification, the public health unit should be responsible for all further arrangements for the receipt of vaccines (see the algorithm in section 4.4.4).

- a. The public health unit must check the time of the arrival with the airline. OGPMS monitors the flight status throughout the day up to the flights departure and the air carrier will also notify OGPMS if there any flight delays or cancellations. OGPMS will go to the airport and bring back the order if the flight is cancelled and the vaccine order would be re-booked for the next day if this is possible. OGPMS will notify the public health unit if this occurs. In addition, if the flight is delayed or cancelled, the airline should also be able to advise the public health unit if the package is on that flight or another flight (if available) by referencing the waybill number.

- b. The public health unit must make arrangements for the pickup of the vaccine immediately upon its arrival at the airport and transport it to the public health unit's vaccine refrigerator to ensure that the cold chain is maintained. The public health unit should ensure the number of containers(s) received matches the number of container(s) on the waybill. When the public health unit signs for the receipt of a shipment, a notation must be made on the receiving slip as follows: subject to inspection of temperature monitoring device(s) and the date and time of receipt.
- c. **If the order does NOT arrive at the airport**, public health unit staff must notify OGPMS:
 - i. Before 4 pm EST: contact the shipping supervisor at 416-314-2623. If the shipping supervisor is not available call the assistant warehouse manager at 416-327-0841, or the warehouse manager at 416-327-0826. If directed to the voice mail, press "0" for the receptionist and request a page for the distribution centre.
 - ii. After 4 pm EST: call the warehouse manager's cell phone at 416-818-8731, or the assistant warehouse manager's cell phone at 416-710-5153.
 - iii. When leaving a message after hours, a contact name and telephone number of the public health unit staff must be included in the message.
 - iv. If OGPMS distribution centre is notified by the public health unit that the flight is cancelled, OGPMS will follow up with the Pearson International Airport.
- d. If a third party (i.e. courier service) is involved in the pick-up of the vaccine from the airport and transport of vaccine to the public health unit, it is the responsibility of the public health unit to provide education regarding all cold chain requirements.
- e. The public health unit, upon receiving the vaccine shipment must immediately open all the container(s) and assess the temperature monitoring device(s).
- f. If the temperature monitoring device(s) indicates that the cold chain was maintained, the vaccines can be received into inventory for use.
- g. If the correct temperature was not maintained throughout the shipping process, the shipment should be placed under quarantine in the refrigerator. Public health unit staff should immediately report the incident to the nurse consultant at the PHD at 416-327-7419. OGPMS should also be notified at 416-327-0837. The order should be kept refrigerated and quarantined until further direction is provided by PHD.
- h. If there are any problems with the order, public health unit should contact OGPMS at 416-327-0837 within 72 hours of the receipt of the shipment and make a notation on the OGPMS manifest.

- i. A pre-paid Purolator shipping envelope is placed inside the container, along with the Purolator waybill, packing slip, a copy of the manifest and any other paperwork (e.g. flyers). Using the pre-paid Purolator shipping envelope, the reusable temperature monitoring device, along with a signed copy of the manifest should be sent back to OGPMS within 24 hours of receipt of the order. If the monitor(s) are not returned, the public health unit will be invoiced for the replacement cost.

4.4.4 Algorithm for Receiving Vaccines at Public Health Units



4.5 Assessing the Appropriateness of an Order

Public health unit and OGPMS staff are encouraged to:

- a. Review the health care provider's historical ordering and usage data.
- b. Review the health care provider's inventory reports when orders are submitted.
- c. Review the health care provider's success with vaccine storage and handling quality assurance and related vaccine ordering and accountability.
- d. For health care providers ordering vaccine directly from OGPMS, the public health unit should advise OGPMS if there are issues related to vaccine handling quality assurance and may request that orders for the health care provider be held.

4.6 Distributing Publicly Funded Vaccines to Health Care Providers

Public health units and OGPMS are stewards of publicly funded vaccine stored and are the point of contact for health care providers ordering publicly funded vaccines. Public health units and OGPMS are also the point of contact for all health care provider quality assurance and accountability activities.

Public health unit and OGPMS staff:

- a. Should review health care provider orders for appropriateness (i.e. timing of ordering, size of order, vaccines ordered etc.).
- b. May approve orders as submitted by health care providers or hold order for review:
 - i. If the public health unit or OGPMS determines the order is incorrect or not appropriate, the public health unit or OGPMS should hold the vaccine order for review, discuss the order with the health care provider and adjust the order accordingly.
 - ii. For health care providers who order vaccine directly from OGPMS, OGPMS may consult with the public health unit to determine the appropriateness of orders.
- c. Should determine a regular order schedule for health care providers. Primary ordering schedules are once a week, every two weeks or monthly. Air transport schedules may vary seasonally.
- d. Should work with health care providers to determine the best inventory levels to maintain based on storage capacity, recommended order frequency, and other factors deemed appropriate by the public health unit or OGPMS. For health care providers who order vaccine directly from OGPMS, OGPMS may consult with the public health unit to determine the optimal inventory levels.

- e. Can allow exceptions (emergency orders) to the established schedule and pattern under special circumstances when necessary to prevent the disruption of immunization services. Emergency orders should be verified by the public health unit prior to processing an order. Repeated emergency orders due to inadequate order planning, storage and handling issues, or other vaccine quality assurance problems may result in the public health unit arranging a site visit for a vaccine storage and handling best practice assessment. For health care providers who order vaccine directly from OGPMS, OGPMS will notify the public health unit if the emergency ordering option is being abused and if inventory management issue needs to be addressed.
- f. In addition, public health unit staff may also review health care provider compliance of vaccine storage and handling with submission of accountability reports, i.e., *Temperature Log Book*, when determining how to process each order.

4.7 Vaccine Return Procedures to OGPMS

For the return of all publicly funded vaccines, please see section 3 of the *Vaccine Storage and Handling Protocol*.

4.7.1 Vaccine Return Forms

The following forms must be used to return vaccine to OGPMS:

- a. [Reusable Vaccine Return Record - Public Health Unit \(3151-64\)](#)
- b. [Non-Reusable Vaccine \(spoiled or expired\) Return Record - Public Health Unit \(3150-64\)](#)
- c. [Non-Reusable Vaccine \(spoiled or expired\) Return Record Toronto Clients \(3296-64\)](#)

Section 5. Cold Chain Incidents and Inspections

This section addresses the following sections of the *Vaccine Storage and Handling Protocol* :

- Section 7) Information and education strategies;
- Section 8) Cold chain inspections – Cold chain incident inspections;
- Section 9) Cold chain incidents; and
- Section 10) Contingency planning within the board of health.

For specific public health unit requirements please refer to the *Vaccine Storage and Handling Protocol*.

5.1 Electricity Disruptions (Power Outages)

Electricity disruptions have substantial implications on vaccine storage and handling practices. In Ontario, interruptions in electricity distribution occur most often in rural areas due to inclement weather conditions. Metropolitan areas are more prone to experience disruptions due to flooding and equipment failure, as large portions of their distribution lines are located underground. Disruptions tend to occur most frequently during the months of May to October based on past observances in Ontario. For most local disruptions, electricity is restored within two to three days, however in rare cases extended and/or widespread disruptions may occur, particularly when electricity transmission systems are involved.

In August 2003, a widespread electricity disruption which affected most of Ontario and the north eastern U.S.A. caused a significant loss of publicly funded vaccines. This unprecedented event provided first hand insight into the issue of potential vaccine wastage, and underscored the need for advance preparation, as well as systematic and timely communication processes during emergency situations. In the wake of this occurrence, it is imperative that all parties involved in the storage, handling and distribution of publicly funded vaccine are familiar with the Urgent Vaccine Storage and Handling Practices to be followed in the event of an electricity disruption.

5.1.1 Public Health Units

a. Prior to an Electricity Disruption

It is the public health unit's responsibility to have a documented and operational contingency plan in the event of an electricity disruption. This document should be posted on or close to the vaccine refrigerators. All public health unit refrigerators must be connected to a temperature alarm monitoring system in order to minimize potential loss of vaccine during electricity disruptions and/or other circumstances which may result in compromised vaccine potency. Where possible, public health units should also have access to a backup power supply. If a backup power supply (i.e. generator) is not available, the contingency plan must include detailed

instructions for transporting vaccine to an alternate storage site (e.g. hospital or long-term care facility) that has an emergency backup power supply and appropriate vaccine storage capacity (i.e. functioning refrigerator with temperature monitoring device). Where possible, a written agreement should be established with the alternate storage facility.

Designate primary and back-up contact personnel to set up and maintain a monitoring and/or notification system to ensure proper storage and handling of vaccines. An updated list of these contacts should be maintained.

Public health unit staff may take additional steps to prepare for unexpected electricity disruptions, such as, following general electricity consumption practices and having contact information for the local electricity distributor on hand. Storing a battery operated portable radio and extra batteries should allow staff to receive emergency information during an electricity disruption. Public health units should also keep emergency supplies on hand, as follows:

List of Emergency Supplies Required
• Insulated containers
• Insulating material: crumpled paper, bubble wrap, Styrofoam pellets
• Packaging material: ice pack(s) (including ice blankets) and/or gel pack(s)
• Calibrated temperature monitoring devices
• Flashlight(s)
• Spare batteries

b. During an Electricity Disruption

- i. When an electricity disruption occurs, document the time and the maximum, minimum and current temperature of the refrigerator in the *Temperature Log Book* and reset the maximum-minimum thermometer (if applicable).
- ii. Contact the local hydro facility and listen to the radio for information concerning the estimated time before electricity should be restored.
- iii. Most refrigerated vaccines will remain stable at elevated temperatures for a limited period of time. Purpose-built refrigerators, especially those with glass doors, may not be able to maintain temperatures for longer than 30 minutes. Factors including the amount of vaccine being stored in the refrigerator, the external temperatures (e.g. summer vs. winter) and the type, model and age of the vaccine refrigerator will affect the duration of time vaccines within the unit will be kept within the +2°C to +8°C range. It is therefore important to 'know your vaccine refrigerator' to facilitate a timely response and minimize potential vaccine loss.

- iv. Do not allow the vaccine to remain in a non functioning unit for an extended period of time. If it is unsure that the problem can be corrected in time to maintain an appropriate temperature, initiate the public health unit's Urgent Vaccine Storage and Handling Practices which should include:
- Transferring vaccines to alternative storage facility (that is connected to a generator) by:
 - Contacting the alternate vaccine storage facility to notify them of the public health unit's refrigerator failure and the need to store vaccine at their location.
 - Conducting an inventory of vaccines while packing all vaccines, using insulated containers with appropriate packing materials and temperature monitoring devices.
 - Ensuring that the maximum-minimum thermometer sensor (if applicable) is in a vaccine box when placed in the insulated container(s).
 - Recording the time and insulated container temperature before leaving the public health unit.
 - Transporting vaccines to the alternate storage facility.
 - Recording the time and insulated container temperature upon arrival to the alternate storage site and ensure that vaccines are properly stored.
 - Continuing to read and record the maximum, minimum and current refrigerator temperature twice daily.
 - If an alternative storage facility cannot be identified within a reasonable distance, place the vaccine in insulated containers with appropriate packaging material and temperature monitoring devices and record the temperature at the public health unit by:
 - Labelling the insulated containers and place the container back in the refrigerator.
 - Continuing to monitor the temperatures inside the insulated container at 30 minute intervals if the temperature monitoring device allows temperature monitoring **without** opening the insulated container.

- v. If it is a **scheduled or a time-limited** power outage and you are **certain** the power should be restored before the vaccine refrigerator temperature rises above the recommended range, take the following steps:
- The refrigerator door should be kept **closed until the power is restored** to maintain an acceptable temperature range for as long as possible.
 - Seasonal influences may also dictate the most appropriate response:
 - In colder climates, adding chilled water bottles to refrigerator and keeping the external room temperatures warm may increase the duration of time before exposure to temperatures above +8°C.
 - In warmer climates, adding ice packs to the refrigerator and keeping the external room temperatures low (i.e. closing blinds) may increase the duration of time before exposure to temperatures above +8°C.
 - Record maximum, minimum and current temperatures:
 - Continue to monitor the temperatures inside the vaccine storage unit at 30 minute intervals if the temperature monitoring device allows temperature monitoring **without** opening the storage unit doors.

c. When the Electricity Supply to the Refrigerator has been Restored

- i. Document the following information once the electrical power supply has been restored:
- Maximum, minimum and current temperatures inside the vaccine storage units;
 - Length of time the power has been off; and
 - Time when the electricity supply is restored;
- ii. If the vaccine refrigerator and insulated container were able to maintain the required +2°C to +8°C temperature range, maintain the vaccines in the refrigerator or remove the vaccines from the insulated container and place them into the refrigerator and resume regular vaccine storage and handling practices.
- iii. If the insulated container was able to maintain the required +2°C to +8°C temperature range, but the vaccine refrigerator was unable to maintain the required storage range, maintain the vaccines in the insulated container and continue to monitor temperatures inside the container. Chilled plastic water bottles should be placed into the refrigerator until the refrigerator temperatures returns to between +4°C

to +5°C. Vaccines can be returned to the refrigerator once temperatures have returned to between +4°C to +5°C.

- iv. If the vaccines in the vaccine storage units (refrigerator(s) or insulated container(s)) were unable to maintain the required temperatures:
 - The public health unit must calculate the maximum length of time the temperature was outside 0°C to +8°C.
 - Assess vaccines involved in the cold chain incident using the *Canadian Provincial/Territorial Vaccine Stability Chart* to determine if the vaccine is usable or wastage. If cold chain incident conditions are not provided in the *Canadian Provincial/Territorial Vaccine Stability Chart*, or if the vaccines have been exposed in a previous incident, public health unit should contact the product manufacturer.
 - Mark (i.e. red dot) vaccines involved in a cold chain incident that have been determined to be usable in order to identify them in case of a second exposure.
 - The public health unit must return unusable/wasted vaccines to OGPMS using the *Non-Reusable Vaccine (spoiled or expired) Return Record - Public Health Unit*.
 - The public health unit should place chilled plastic water bottles into the refrigerator until the refrigerator temperatures returns to between +4°C to +5°C.
 - Vaccines can be returned to the refrigerator once temperatures have returned to between +4°C to +5°C.

d. Recurring Electricity Disruptions

- i. When an electricity disruption occurs, document the time and the maximum, minimum and current temperature of the refrigerator in the *Temperature Log Book* and reset the maximum-minimum thermometer (if applicable).
- ii. If possible contact the local hydro facility or radio for information concerning the estimated time before electricity should be restored.
- iii. Determine if the vaccines can be maintained in the refrigerator or if public health unit's Urgent Vaccine Storage and Handling Practices (i.e. vaccines need to be transferred to insulated containers or transferred to an alternative storage facility) need to be implemented.

5.1.2 Health Care Provider Premises

During electricity disruptions, the public health unit should help health care providers minimize the potential loss of vaccines. It is recommended that public health units work with health care providers in their jurisdiction to develop operational contingency plans. Public health unit staff must also ensure that

health care providers are aware of the practices to follow in the event of an electricity disruption (see section 5.1.1, parts a to b).

When an electricity disruption occurs, public health units should determine the extent of the electricity disruption (i.e. geographic area affected) and an estimated time before electricity should be restored where possible. This may involve contacting the local power supplier to obtain a power grid. Health care providers are directed to contact their public health unit for assistance in the identification and assessment of cold chain incidents after an electricity disruption (see section 5.1.1, part c). However, where possible, public health unit staff may initiate contact with health care provider premises.

5.1.3 Communication Processes During Extended/Widespread Electricity Disruptions

In order to maintain communication between relevant staff at the provincial and regional levels, the ministry and/or the OGPMS may contact public health units using one or more of the following methods:

- Fax letter to Medical Officers of Health (which may include a Dear Doctor Communication for distribution to health care providers).
- Information posted on [Public Health Portal](#)
- Telephone information service (hotline) which may include directives for ordering replacement vaccine and returning wasted vaccine.
- Media communications from the ministry or electricity distributors which may contain information regarding power advisories, warnings and emergencies.

During extended electricity disruptions (i.e. more than four hours), public health units are encouraged to develop a process to facilitate communication/messaging to health care providers within their jurisdiction. In addition, it is strongly recommended that a process to facilitate the ordering of replacement vaccines and pick up of wasted vaccines be established.

5.2 Cold chain Incident Inspections

The purposes of cold chain incident inspections are to:

- Determine whether vaccine can be used by the health care provider or returned to the public health unit;
- Investigate the cause of the cold chain incident, provide follow-up education in order to prevent the occurrence of future incidents; and
- Ensure that adequate cold chain conditions can be maintained prior to continuing the vaccine supply to the health care provider.
- Develop office policies for designated staff to follow.

5.2.1 Vaccine Cold Chain Incident Exposure/Wastage Report Form for Cold Chain Inspections

The [Vaccine Cold Chain Incident Exposure/Wastage Report \(VCCIEWR\)](#) form must be used if vaccine is wasted or exposed when conducting cold chain inspections. A copy of the forms should be submitted to the PHD at 416-327-7439 or at VSH.MOH@ontario.ca after the investigation of cold chain incident in which vaccine was exposed or wasted.

5.2.2 Cold Chain Incidents in Premises Storing Publicly Funded Vaccines

To ensure viability of vaccine, any reported cold chain incidents must be reported to the public health unit immediately. Public health unit staff should respond to all reports of cold chain incidents to provide consultation and technical assistance to health care providers:

- a. Once notification of a suspected cold chain incident is received by the public health unit, the public health unit must investigate within 24 hours (or the next business day) to determine if a cold chain incident has occurred.
- b. A preliminary evaluation of the incident should include:
 - i. The maximum and minimum temperatures the vaccines were exposed to; and
 - ii. The duration of time the vaccines were exposed to the maximum and/or minimum temperature(s).
- c. If the premises' refrigerator temperature was below 0°C or above +8°C, a cold chain incident inspection must occur:
 - i. Public health unit should request the premises to forward the following information as soon as possible:
 - Copy of previous two weeks of temperature logs; and
 - Inventory of affected vaccines, including information regarding previously exposed vaccines.
 - ii. Advise the premises that the exposed vaccines should no longer be used until an investigation is completed to determine vaccine viability. Have the premises bag the vaccines and label the bag "DO NOT USE." Move the bag to a monitored refrigerator or insulated container that meets the required temperature storage conditions until the public health unit determines which vaccines are usable and which vaccines must be replaced.
- d. When vaccine are exposed to temperatures between 0°C to +1.9°C, a cold chain incident inspection should be conducted (as specified in part c above) and troubleshooting measures should be implemented, as vaccines must be stored between +2°C to +8°C. When vaccines are exposed temperatures between 0°C to +1.9°C the following should be considered when determining if vaccines should be used:

- i. Assessing if the vaccine has been frozen;
 - ii. When the temperature monitoring device's batteries were replaced as the device may become less accurate if the batteries are low and;
 - iii. The accuracy of the premises' temperature monitoring device (for example, if the device is accurate within +/-1°C, a temperature reading of +0.5°C, could actually be a temperature of -1.5°C); and
 - iv. The health care provider's vaccine handling and storing practice history.
- e. Determine the cause for the cold chain failure (equipment malfunction, human error, refrigerator malfunction, power failure, etc.).
- f. Public health unit must determine whether an on-site cold chain incident inspection is required at the premises or whether the investigation can adequately be handled over the telephone. It is recommended that on-site inspections be conducted following cold chain incidents that are related to non-compliance with vaccine storage and handling requirements.
- g. The public health unit must calculate the maximum length of time the temperature was outside 0°C to +8°C (or 0°C to +1.9°C if applicable). If specific time/temperature details are not available, assume the refrigerator malfunctioned immediately after the last temperature monitoring device check.
- h. Assess vaccines involved in the cold chain incident and provide advice for use/return based on the recommendations on the *Canadian Provincial/Territorial Vaccine Stability Chart*. If cold chain incident conditions are not provided in the *Canadian Provincial/Territorial Vaccine Stability Chart*, or if the vaccines have been exposed in a previous incident, public health unit should contact the product manufacturer.
- i. Mark vaccines involved in a cold chain incident that have been determined to be usable in order to identify them in case of a second exposure. These vaccines must be distributed and/or administered before unexposed products.
- j. For health care providers who order directly from the public health unit: Health care providers must return vaccines involved in a cold chain incident that have been determined to be unusable to the public health unit. These vaccines do not require refrigeration. The public health unit must return these vaccines to OGPMS using the *Non-Reusable Vaccine (spoiled or expired) Return Record - Public Health Unit*.
- k. For health care providers who order directly from OGPMS: Health care providers must return vaccines involved in a cold chain incident that have been determined to be unusable to the OGPMS. These vaccines

do not require refrigeration. The health care provider must return these vaccines to OGPMS using the *Non-Reusable Vaccine (spoiled or expired) Return Record - Toronto Clients*.

- l. The [VCCIEWR](#) Form must be completed and sent to the PHD at 416-327-7439 or at VSH.MOH@ontario.ca after the investigation of an incident in which vaccine was exposed or wasted. A record of cold chain incident(s) should be maintained by the public health unit.
- m. The public health unit must communicate in writing the:
 - i. Public health unit's assessment of the cold chain incident, or issues related to non-compliance;
 - ii. Value of the returned vaccine;
 - iii. Required remediation strategy(ies) to health care providers who are non-compliant with the minimum vaccine storage and handling requirements or have experienced a cold chain incident; and
 - iv. Specified remediation time frame should be established with the health care providers.
- n. Depending on the severity of the cold chain incident and issues related to non-compliance, it is recommended that the premises monitor the refrigerator that experienced the cold chain incident for one week before using the refrigerator unit again to store vaccines and before any new vaccine should be released by the public health unit. The public health unit should inform the premises that one week of temperatures must be kept and reported to the public health unit. The temperatures need to be monitored for 7 consecutive days during regular business hours and the maximum, minimum and current temperatures need to be recorded twice daily and must be within the required storage temperature range prior to the release of publicly funded vaccine.
- o. Ensure that compliance with the required remediation strategy(ies) has occurred.
 - i. Follow-up by telephone or onsite visit following incident to ensure adequate vaccine storage and handling practices are being maintained.
- p. After follow-up with the health care provider, if all remediation strategies have not been met, withhold vaccines until compliance issues have been resolved. For health care providers who order vaccines directly from the OGPMS, the public health unit should instruct the OGPMS to discontinue further vaccine deliveries to the health care provider premises until the requirements have been met.
- q. Consider issuing an advisory from the medical officer of health (or designate) to the health care provider's premises advising that access to publicly funded vaccines has been suspended due to non-compliance with

the required remediation strategy(ies) or repeated cold chain incidences have occurred. Once remediation activities have been undertaken as recommended by the public health unit, vaccine supply can be restored. For health care providers who order vaccines directly from the OGPMS, the public health unit should instruct the OGPMS to resume processing orders for health care providers.

5.2.3 Cold Chain Incidents at a Public Health Unit

For cold chain incidents occurring at the public health unit, see section 5.2.2 and follow parts d to l.

Alarm Systems at Public Health Units

Public health units should have an alarm system that notifies staff in the event that refrigerator temperatures fall below +3°C or rise above +7°C. This should provide adequate response time to respond to the alarm and implement troubleshooting measures prior to temperatures falling above or below the recommended temperature range.

5.2.4 Cold Chain Incidents During Vaccine Deliveries from OGPMS to Public Health Units

See section 4.4.1, part f for cold chain incidents that occur when vaccine is delivered from OGPMS to public health units using a refrigerated truck and see section 4.4.3, part g for cold chain incidents that occur when vaccine is delivered from OGPMS to public health units by air.

5.2.5 Cold Chain Incident Evaluations

This table provides a description of the common occurrences of cold chain incidents, the recommended remediation strategy and time frame and the suggested time frame for follow up.

1. Equipment Malfunction	Remediation Strategy	Remediation Time Frame	Follow-Up
a. Temperature monitoring device is not present	<ul style="list-style-type: none"> <input type="checkbox"/> Premises given a temperature monitoring device or advised to obtain a temperature monitoring device. <input type="checkbox"/> Conduct a cold chain incident inspection, see section 5.2.2. <input type="checkbox"/> Follow the troubleshooting algorithm in section 5.3.1. 	Now	Within 2-3 weeks of initial visit conduct: <ul style="list-style-type: none"> • On site visit (recommended); or • Telephone call.

1. Equipment Malfunction	Remediation Strategy	Remediation Time Frame	Follow-Up
<p>b. Temperature monitoring device is not functioning properly</p> <p>OR</p> <p>c. Temperature monitoring device's batteries have not been replaced within the past 6 months</p> <p>OR</p> <p>d. Temperature variance between the public health unit's temperature monitoring device and premises' temperature monitoring device is greater than +/- 2°C</p> <p>OR</p> <p>e. Maximum-minimum thermometer sensor not properly located</p>	<ul style="list-style-type: none"> <input type="checkbox"/> Replace the batteries. <input type="checkbox"/> Place maximum-minimum thermometer sensor (if applicable) on the middle refrigerator shelf inside an empty vaccine box. <input type="checkbox"/> Check the accuracy of the premises' temperature monitoring device with the public health unit's temperature monitoring device: <ul style="list-style-type: none"> <input type="checkbox"/> If the premises temperature monitoring device is not within +/- 2°C (or less – this is dependent on the devices that are being tested for accuracy, see the notes in section 3.3.3 parts a to b) accuracy the temperature monitoring device should be checked using the slush test. <input type="checkbox"/> After checking the premises' device for accuracy using the slush test, if is determined that the device is not accurate the device should be sent to the manufacturer for recalibration or be replaced. <input type="checkbox"/> When refrigerator is checked using the premises or public health unit's calibrated temperature monitoring device and the temperatures are not within range: <ul style="list-style-type: none"> <input type="checkbox"/> Conduct a cold chain incident inspection, see section 5.2.2. <input type="checkbox"/> Follow the troubleshooting algorithm in section 5.3.1. 	<p>Now</p>	<p>Within 2-3 weeks of initial visit conduct:</p> <ul style="list-style-type: none"> • On site visit (recommended); or • Telephone call.

1. Equipment Malfunction	Remediation Strategy	Remediation Time Frame	Follow-Up
f. Alarm has not been tested within the past year	<ul style="list-style-type: none"> <input type="checkbox"/> Technician is required to ensure that alarm is connected and functioning properly. <input type="checkbox"/> Conduct a cold chain incident inspection, see section 5.2.2. <input type="checkbox"/> Alarm maintenance agreements need to be developed and kept. 	Servicing - within 1 week Alarm agreement established - within 1 week	Within 1 week of initial visit conduct: <ul style="list-style-type: none"> • Telephone call.
2. Refrigerator Malfunction	Remediation Strategy	Remediation Time Frame	Follow-Up
a. Refrigerator is broken	<ul style="list-style-type: none"> <input type="checkbox"/> Ensure that the unit is plugged in. <input type="checkbox"/> Leave refrigerator door closed and determine how long it should take to have the refrigerator repaired. <input type="checkbox"/> Depending on the amount of time required to have the refrigerator serviced by a technician proceed as if an electrical disruption has occurred (see section 5.1.1, part b). <input type="checkbox"/> When the refrigerator has been repaired, follow the algorithm in section 5.3.1. 	Servicing - within 1 week	Within 2-3 weeks of initial visit conduct: <ul style="list-style-type: none"> • On site visit (recommended); or • Telephone call.

2. Refrigerator Malfunction	Remediation Strategy	Remediation Time Frame	Follow-Up
<p>b. Domestic/bar refrigerators: regular maintenance of refrigerators has not been performed annually</p>	<ul style="list-style-type: none"> <input type="checkbox"/> Advised to: <ul style="list-style-type: none"> <input type="checkbox"/> Defrost freezer if more than 1 cm of frost is present. <input type="checkbox"/> Clean and dust the back (including coils, if applicable), top and sides of the refrigerator. <input type="checkbox"/> If the door is not sealing properly: <ul style="list-style-type: none"> <input type="checkbox"/> Replace door seals. <input type="checkbox"/> Install Velcro latch. <input type="checkbox"/> Tighten door hinges. <input type="checkbox"/> Conduct a cold chain incident inspection, see section 5.2.2. <input type="checkbox"/> Follow the troubleshooting algorithm in section 5.3.1. <input type="checkbox"/> Maintenance records need to be developed and maintained. 	<p>Within 1 week</p>	<p>Within 1 week of initial visit conduct:</p> <ul style="list-style-type: none"> • Telephone call.
<p>c. Purpose-built refrigerators: annual maintenance of refrigerator has not been performed annually</p>	<ul style="list-style-type: none"> <input type="checkbox"/> Technician is required to conduct annual maintenance including the checking the temperature monitoring device for accuracy. <input type="checkbox"/> Conduct a cold chain incident inspection, see section 5.2.2. <input type="checkbox"/> Follow the troubleshooting algorithm in section 5.3.1. <input type="checkbox"/> Maintenance agreement to be established and maintenance records need to be developed and kept. 	<p>Servicing - within 1 week</p> <p>Maintenance agreement established - within 1 week</p>	<p>Within 2-3 weeks of initial visit conduct:</p> <ul style="list-style-type: none"> • On site visit (recommended); or • Telephone call.

3. Human Error	Remediation Strategy	Remediation Time Frame	Follow-Up
a. Door left opened	<ul style="list-style-type: none"> <input type="checkbox"/> Velcro latch to be installed to prevent the door from accidentally being left opened. <input type="checkbox"/> Conduct a cold chain incident inspection, see section 5.2.2. <input type="checkbox"/> Follow the troubleshooting algorithm in section 5.3.1. 	1 – 2 days	<p>Within 1 week of initial visit conduct:</p> <ul style="list-style-type: none"> • Telephone call.
b. Minimum-maximum thermometer is not being reset or recorded twice daily	<ul style="list-style-type: none"> <input type="checkbox"/> Provide education regarding resetting the maximum-minimum thermometer and recording the temperatures twice daily. <input type="checkbox"/> Conduct a cold chain incident inspection, see section 5.2.2. <input type="checkbox"/> Follow the troubleshooting algorithm in section 5.3.1. 	Now	<p>Within 1 week of initial visit conduct:</p> <ul style="list-style-type: none"> • On site visit (recommended); or • Telephone call.
c. Temperature controls were adjusted too high/too cold	<ul style="list-style-type: none"> <input type="checkbox"/> One office staff member assigned the responsibility for temperature adjustment. <input type="checkbox"/> Conduct a cold chain incident inspection, see section 5.2.2. <input type="checkbox"/> Follow the troubleshooting algorithm in section 5.3.1. 	Now	<p>Within 1 week of initial visit conduct:</p> <ul style="list-style-type: none"> • On site visit (recommended); or • Telephone call.

4. Human Error	Remediation Strategy	Remediation Time Frame	Follow-Up
a. Refrigerator left unplugged	<ul style="list-style-type: none"> <input type="checkbox"/> Refrigerator electrical outlet is covered by metal cage or relocate refrigerator so the electrical outlet is not easily accessible or place the 'do not unplug' sticker beside the refrigerator outlet. <input type="checkbox"/> Conduct a cold chain incident inspection, see section 5.2.2. <input type="checkbox"/> Follow the troubleshooting algorithm in section 5.3.1. 	Installation of cage or make the electrical outlet not easily accessible - within 1 week Placement of the 'do not unplug' sticker – now	Within 1 week of initial visit conduct: <ul style="list-style-type: none"> • On site visit (recommended); or • Telephone call.
b. Vaccine left outside of refrigerator/insulated container for extended time periods	<ul style="list-style-type: none"> <input type="checkbox"/> Provide education regarding vaccine storage and handling requirements. <input type="checkbox"/> Conduct a cold chain incident inspection, see section 5.2.2. <input type="checkbox"/> Follow the troubleshooting algorithm in section 5.3.1. 	Now	Within 1 week of initial visit conduct: 5. Telephone call.
c. Vaccines transported in the trunk of the car	<ul style="list-style-type: none"> <input type="checkbox"/> Provide education regarding vaccine storage and handling requirements. <input type="checkbox"/> Conduct a cold chain incident inspection, see section 5.2.2. <input type="checkbox"/> Follow the troubleshooting algorithm in section 5.3.1. 	Now	Within 1 week of initial visit conduct: <input type="checkbox"/> Telephone call.
d. Storing food, beverages and medical/laboratory specimens in the refrigerator	<ul style="list-style-type: none"> <input type="checkbox"/> Ensure food, beverages and medical/laboratory specimens are removed from the refrigerator. <input type="checkbox"/> Conduct a cold chain incident inspection, see section 5.2.2. <input type="checkbox"/> Follow the troubleshooting algorithm in section 5.3.1. 	Now	Within 1 week of initial visit conduct: 2. Telephone call.

5. Power Outage	Remediation Strategy	Remediation Time Frame	Follow-Up
a. No contingency plan	<ul style="list-style-type: none"> <input type="checkbox"/> Develop contingency plan which includes detailed instructions for: <ul style="list-style-type: none"> <input type="checkbox"/> Transporting vaccine to an alternate storage facility that has an emergency backup power supply and appropriate vaccine storage capacity. <input type="checkbox"/> Maintaining the appropriate insulated containers and packaging materials to temporarily and safely store the vaccines at the premises, if an alternative storage facility cannot be arranged. 	Within 1 week	Within 1 week of initial visit conduct: <ul style="list-style-type: none"> <input type="checkbox"/> Telephone call.
b. Power outage	<ul style="list-style-type: none"> <input type="checkbox"/> See section 5.1.1, part c, for information regarding when the Electricity Supply to the Refrigerator has been restored. 		Within 1 week of initial visit conduct: <ul style="list-style-type: none"> <input type="checkbox"/> Telephone call.
c. Insulated container and packaging material: <ul style="list-style-type: none"> <input type="checkbox"/> No insulated container and no packaging material OR <input type="checkbox"/> Insulated container without appropriate packaging material OR <input type="checkbox"/> Packaging material without appropriate insulated container 	Obtain or provided: <ul style="list-style-type: none"> <input type="checkbox"/> Insulated container(s). <input type="checkbox"/> Packaging material (e.g. ice pack(s), gel pack(s)). <input type="checkbox"/> Additional temperature monitoring device (if required). <input type="checkbox"/> Conduct a cold chain incident inspection, see section 5.2.2. <input type="checkbox"/> See sections 3.4 to 3.6 for vaccine transport/storage and insulated container requirements. 	Within 1 week	Within 1 week of initial visit conduct: <ul style="list-style-type: none"> <input type="checkbox"/> Telephone call.

5.3 Troubleshooting when a Refrigerator does not Maintain the Required Temperatures

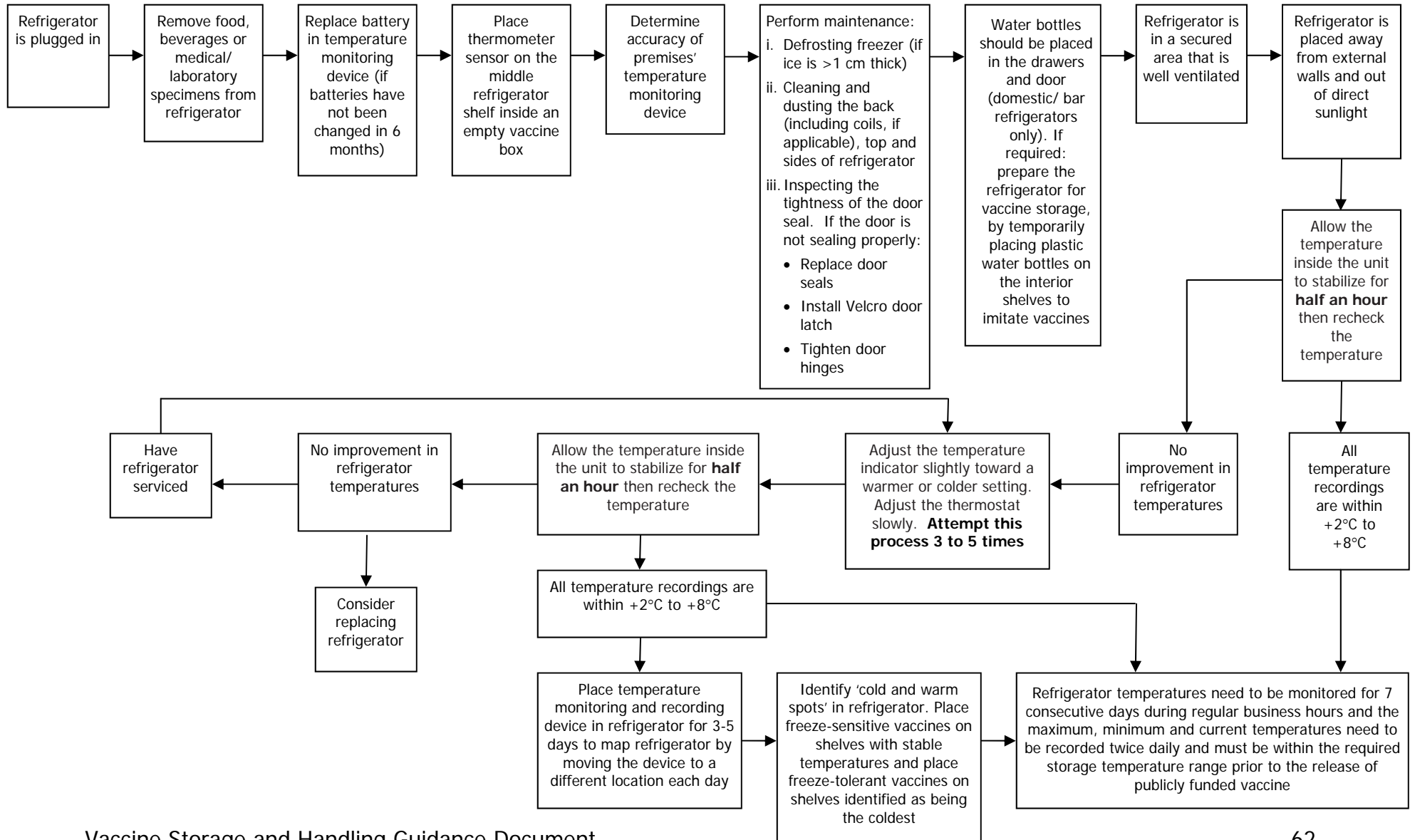
When a refrigerator is having trouble maintaining within-range storage temperatures ensure the following troubleshooting measures are implemented:

- a. Ensure the refrigerator is plugged in and the power outlet is working properly.
- b. Remove any food, beverages or medical/laboratory specimens from the refrigerator.
- c. Replace the batteries in the temperature monitoring device.
- d. Ensure the maximum-minimum thermometer sensor (if applicable) is placed on the middle refrigerator shelf inside an empty vaccine box.
- e. Temperature monitoring devices should be checked for accuracy annually to ensure that the temperature readings are accurate. See section 3.3 for checking a temperature monitoring device for accuracy.
- f. Perform maintenance including:
 - i. Defrosting the freezer - freezers should have no more than 1 cm of ice.
 - ii. Cleaning and dusting the back (including the coils, if applicable), top and sides of the refrigerator.
 - iii. Inspecting the tightness of the door seal. If the door is not sealing properly:
 - Replace the door seals.
 - Install a Velcro latch.
 - Tighten door hinges.
- g. Fill the empty space (shelves, door) with chilled plastic water bottles (for domestic and bar refrigerators only). If the refrigerator is being prepared for vaccine storage, temporarily place plastic water bottles interior shelves to mimic the vaccines.
- h. Check refrigerator location. The refrigerator should be optimally located in a secure and well ventilated area and be placed away from direct sunlight and external walls.
- i. Adjust the refrigerator temperature slightly up or down as indicated by the refrigerator logs provided by the premises.
- j. Map the refrigerator by placing a temperature monitoring and recording device (e.g. data logger) in the refrigerator. This provides a visual map of the refrigerator that can aid in determining what the problem likely is (see section 3.1.3, part g for instruction on refrigerator mapping).

- k. The premises should be prepared to make alternative vaccine storage arrangements until refrigerator temperatures are stable.
- l. When all troubleshooting strategies have been implemented, refrigerator temperatures should be monitored for 7 consecutive days during regular business hours and the maximum, minimum and current temperatures need to be recorded twice daily and must be within the required storage temperature range prior to the release of publicly funded vaccine to the health care provider.
- m. Sometimes refrigerators still have trouble maintaining temperatures despite all necessary precautions being taken. If all troubleshooting strategies have been exhausted please consider having the refrigerator serviced and/or replaced.

5.3.1 Refrigerator Troubleshooting Algorithm

The flowchart provides a step by step approach to troubleshooting when Refrigerator temperatures are $< +2^{\circ}\text{C}$ to $> +8^{\circ}\text{C}$:



Section 6. Routine (Annual) Inspections

This section addresses the following sections of the *Vaccine Storage and Handling Protocol*.

- Section 7) Information and education strategies; and
- Section 8) Cold chain inspections – Routine Inspections.

For specific public health unit requirements please refer to the *Vaccine Storage and Handling Protocol*.

6.1 Routine Inspections

Routine inspections should be conducted on an annual basis, regardless of whether or not a cold chain incident inspection has been conducted in that year. Prior to the release of publicly funded vaccine, public health units should conduct a routine inspection using the [Vaccine Cold Chain Maintenance Inspection Report \(VCCMIR\)](#) form for:

- a. Established health care providers:
 - At least on an annual basis;
 - With new vaccine refrigerator(s); and
 - Who have relocated their vaccine refrigerator within their premises.
- b. New health care providers.
- c. New courier transport service company that has been contracted to deliver vaccines (if applicable).
- d. Existing courier transport service company that has been contracted to deliver vaccines on an annual basis (if applicable).

6.1.1 Vaccine Cold Chain Maintenance Report Form for Routine Inspections

The [Vaccine Cold Chain Maintenance Inspection Report \(VCCMIR\)](#) form must be used when conducting routine inspections. A copy of the forms should be provided to health care providers and submitted to the PHD by mail at Ministry of Health and Long-Term Care, Vaccine Program, 1075 Bay Street, 11th floor, Toronto, ON, M5S 2B1 or by fax at 416-327-7439 once annually.

6.2 Purpose of Routine Inspections

The purpose of these inspections is to:

- Assess the health care providers' level of compliance with vaccine storage and handling requirements, including cold chain requirements; and
- Provide public health unit staff an opportunity to provide information and resources regarding the recommended practices for storage and handling of

vaccines and the required temperature monitoring systems that should be in place to optimize vaccine potency.

6.3 Preparation

All health care providers who are involved in the storage or handling of vaccines should be familiar with the *Vaccine Storage and Handling Guidelines*. They should receive education on why cold chain maintenance of vaccines is essential in order to ensure that the administered vaccines remain potent and to reduce the cost of vaccine wastage due to improper vaccine storage and handling practices.

When conducting a routine inspection of the cold chain requirements in premises where publicly funded vaccines are stored, designated public health unit staff should ensure the following steps are taken in preparation:

- a. Develop a public health unit plan for conducting the routine inspections to ensure that each premises where publicly funded vaccine is stored is inspected at least once annually.
- b. Prior to an individual site inspection, contact the staff at the premises involved in advance, and make efforts to accommodate their schedule when setting a date and time for the inspection.
- c. If a premises has been previously non-compliant in the previous inspection and has had issues with cold chain, an unannounced visit may be considered.
- d. Bring cold chain equipment (e.g. temperature monitoring devices, batteries, etc.) and materials (e.g. *Vaccine Storage and Handling Guidelines*, magnets, stickers, *Temperature Log Book*, etc.) to the inspection, in case the health care providers would like to, or need to, obtain them.

6.4 Conducting the Routine Inspection

The [VCCMIR](#) form should be completed and reviewed during the routine inspection. The table in section 6.4.1 specifies the information and education that should be provided in each of the cold chain requirements sections on the [VCCMIR](#) form.

6.4.1 Reviewing the VCCMIR Form

When conducting routine inspections all cold chain requirements sections should be reviewed with the health care provider.

1. Vaccine Refrigerator Temperatures and Readings	Strategies	Rationale
a. Temperature monitoring device is present and is able to record maximum, minimum and current temperatures	<ul style="list-style-type: none"><input type="checkbox"/> Premises given a temperature monitoring device or advised to obtain a temperature monitoring device.<input type="checkbox"/> Conducted a cold chain incident inspection (if necessary), see section 5.2.2.<input type="checkbox"/> Followed the troubleshooting algorithm in section 5.3.1.	<ul style="list-style-type: none">• A temperature monitoring device is used to document refrigerator temperatures and to ensure that vaccines are stored within the required temperature range.• See section 2 for education regarding the effects of heat and cold on vaccines.

1. Vaccine Refrigerator Temperatures and Readings	Strategies	Rationale
<p>b. Current temperature of refrigerator using premises' temperature monitoring device: _____ °C</p> <p>Current temperature of refrigerator using public health unit's temperature monitoring device: _____ °C</p>	<ul style="list-style-type: none"> <input type="checkbox"/> Temperature variance between public health unit's temperature monitoring device and premises' temperature monitoring device was + / - ____ °C: <input type="checkbox"/> Replaced premises' temperature monitoring device's battery. <input type="checkbox"/> Accuracy of the premises' temperature monitoring device was checked using the slush test. <input type="checkbox"/> Replaced premises' temperature monitoring device. 	<ul style="list-style-type: none"> • It is important to ensure that the temperature monitoring device is accurate as refrigerator temperature reading and recordings are dependent on the device. • It is recommended that temperature monitoring devices are accurate with +/- 1°C. • The temperature monitoring device may become less accurate (which may result in wastage of potent vaccine) if the batteries are low and as the device becomes older. To ensure optimum function of the device, the batteries should be changed every 6 months and the device should be checked for accuracy on an annual basis (or more often if recommended by the manufacturer).
<p>c. Temperature variance between public health unit's temperature monitoring device and premises' temperature monitoring device is no greater than +/-2°C (the degree of variability is dependent on the devices that are being checked for accuracy, see the notes in section 3.3.3 parts a to b)</p>	<ul style="list-style-type: none"> <input type="checkbox"/> Conducted a cold chain incident inspection (if necessary), see section 5.2.2. <input type="checkbox"/> Followed the troubleshooting algorithm in section 5.3.1. 	<ul style="list-style-type: none"> • See section 3.3 on how to check the accuracy of a temperature monitoring device.

1. Vaccine Refrigerator Temperatures and Readings	Strategies	Rationale
d. Maximum-minimum thermometer sensor properly located (<i>if applicable</i>)	<ul style="list-style-type: none"> <input type="checkbox"/> Placed maximum-minimum thermometer sensor on the middle shelf inside an empty vaccine box. <input type="checkbox"/> Labelled the vaccine box as empty. <input type="checkbox"/> Conducted a cold chain incident inspection (if necessary), see section 5.2.2. <input type="checkbox"/> Followed the troubleshooting algorithm in section 5.3.1. 	<ul style="list-style-type: none"> • Placing the maximum-minimum thermometer sensor inside an empty vaccine box allows the sensor to measure the air temperature closest to where the vaccine vials would be located. This would best simulate vaccine temperature. • This will help regulate temperatures as the vaccine box provides protection from very short term temperature fluctuations e.g. after the door is opened and closed. • An empty vaccine box is used so that the sensor does not get misplaced when vials are used. • Label the vaccine box as 'empty' so the sensor will not be inadvertently moved.
2. Log Book Review	Strategies	Rationale
a. <i>Temperature Log Book</i> present	<ul style="list-style-type: none"> <input type="checkbox"/> Given <i>Temperature Log Book</i>. 	<ul style="list-style-type: none"> • The <i>Temperature Log Book</i> is the documentation of refrigerator temperature readings.

2. Log Book Review	Strategies	Rationale
<p>b. Maximum, minimum temperatures are checked twice daily and documented in the <i>Temperature Log Book</i></p>	<ul style="list-style-type: none"> <input type="checkbox"/> Instructed to record maximum, minimum and current temperatures twice daily (once in the morning and once in the afternoon) and the time the temperatures were taken in <i>Temperature Log Book</i>. <input type="checkbox"/> Conducted a cold chain incident inspection (if necessary), see section 5.2.2. 	<ul style="list-style-type: none"> • Twice daily temperature checks (at the beginning and end of each day) will give a better indication of any problems in the refrigerator's function and temperature fluctuations over the course of the day. • The <i>Temperature Log Book</i> is the written record that enables staff to monitor and take action if temperatures go outside the recommended range. • Recording and checking the temperatures before using vaccine enables the identification of problems before vaccine is given. • The temperature should be viewed every time the refrigerator is opened. This will allow for troubleshooting if required.
<p>c. Maximum and minimum temperatures are maintained between +2°C to +8°C</p>	<ul style="list-style-type: none"> <input type="checkbox"/> Instructed premises to notify the public health unit when temperatures are outside the required range. <input type="checkbox"/> Conducted a cold chain incident inspection, see section 5.2.2. <input type="checkbox"/> Followed the troubleshooting algorithm in section 5.3.1. <input type="checkbox"/> Suspended vaccine ordering for _____ days. 	<ul style="list-style-type: none"> • If refrigerator temperatures are < +2°C or > +8°C the public health unit should be notified. • The temperature recordings in the <i>Temperature Log Book</i> will allow the public health unit to assess cold chain incidents in order to determine which vaccines can be deemed useable. • Public health units should also provide education and troubleshooting assistance with cold chain incidents to prevent the occurrence of additional exposures.

2. Log Book Review	Strategies	Rationale
d. Maximum-minimum thermometer is being reset twice daily (<i>if applicable</i>)	<input type="checkbox"/> Provided education regarding the importance of resetting the maximum-minimum thermometer twice daily after recording minimum and maximum temperatures. <input type="checkbox"/> Conducted a cold chain incident inspection, see section 5.2.2.	<ul style="list-style-type: none"> • The maximum-minimum thermometer should be reset after the temperature is checked in order to record the new maximum and minimum temperatures for the next time period.
e. Office staff demonstrates resetting or downloading data from the temperature monitoring device	<input type="checkbox"/> Provided temperature monitoring device resetting or downloading instructions/demonstration. <input type="checkbox"/> Conducted a cold chain incident inspection, see section 5.2.2.	<ul style="list-style-type: none"> • Knowing how to reset the temperature monitoring device is essential to ensure the temperature recordings from the previous reading are reset and a new set of temperature readings are recorded. • Data should be downloaded on a regular basis from the temperature monitoring device to ensure that the memory does not become full and is unable to record additional temperature readings or records over previous temperature readings.
f. Office staff demonstrates reading the temperature monitoring device	<input type="checkbox"/> Provided temperature monitoring device reading instructions/demonstration. <input type="checkbox"/> Conducted a cold chain incident inspection, see section 5.2.2.	<ul style="list-style-type: none"> • As temperatures need to be recorded twice daily and viewed when the refrigerator door is opening, knowing how to read the temperature monitoring device is essential.

3. Ministry Cold Chain Material	Strategies	Rationale
<p>a. <i>How to monitor your refrigerator temperature</i> magnet is mounted on exterior of vaccine refrigerator</p>	<p><input type="checkbox"/> Given <i>How to monitor your refrigerator temperature</i> magnet and placed on exterior of vaccine refrigerator.</p>	<p>This magnet provides important reminders on how to monitor vaccine refrigerator temperatures including:</p> <ul style="list-style-type: none"> • Recording the maximum, minimum and current temperature twice daily. • Resetting the maximum-minimum thermometer after a temperature reading. • Calling the public health unit when vaccines are exposed to temperatures outside the required storage range.
<p>b. <i>Protect your vaccines – Protect your patients</i> poster is mounted in exterior of vaccine refrigerator</p>	<p><input type="checkbox"/> Given <i>Protect your vaccines – Protect your patients</i> poster and placed on exterior of vaccine refrigerator.</p>	<p>This poster reinforces the following practices:</p> <ul style="list-style-type: none"> • Maintaining vaccines between +2°C to +8°C. • Documenting refrigerator temperatures twice daily. • Reporting any vaccines that have been exposed to temperatures below +2°C or above +8°C to the public health unit. • Never administering or discarding exposed vaccine until the public health unit has assessed the situation • Contact information for the public health unit.

3. Ministry Cold Chain Material	Strategies	Rationale
c. <i>Vaccine Storage and Handling Guidelines</i> is on hand	<input type="checkbox"/> Given <i>Vaccine Storage and Handling Guidelines</i> .	<ul style="list-style-type: none"> The <i>Vaccine Storage and Handling Guidelines</i> provides essential information for health care providers on the required vaccine storage and handling practices.
d. Insulated vaccine container(s) with packing material and a temperature monitoring device is: <ol style="list-style-type: none"> present used when transporting vaccines used for contingency planning 	<input type="checkbox"/> Given or advised to obtain insulated vaccine container(s) with packing material (i.e. ice packs) and temperature monitoring device(s).	<p>The insulated container(s) and packaging material are essential for:</p> <ul style="list-style-type: none"> Power outages. Refrigerator/equipment malfunctions. Transportation of vaccines. Defrosting refrigerators. Storing vaccine during community clinics. <p>The number of insulated containers and packing material that should be maintained by a premises must be able to accommodate the entire vaccine inventory.</p>
4. Organization of Refrigeration	Strategies	Rationale
a. Vaccines are stored in the middle of the refrigerator away from the walls, floors and cold air vents	<input type="checkbox"/> Placed vaccines in the middle of the refrigerator away from the walls, floor and cold air vents.	<ul style="list-style-type: none"> Storage of vaccine against refrigerator walls, floors and cold air vents increases the risk of exposing vaccines to temperatures below +2°C.

4. Organization of Refrigeration	Strategies	Rationale
b. Vaccines are stored on internal shelves of the refrigerator (not stored in the door or in drawers)	<input type="checkbox"/> Removed vaccines from the refrigerator door and placed in the middle of the refrigerator.	<ul style="list-style-type: none"> • The refrigerator doors and drawers get too warm for safe vaccine storage. • The refrigerator door is unable to maintain consistent temperatures when the door is opened and closed. • The refrigerator drawers do not allow for air circulation and the vaccines would be at an increased risk of being exposed to elevated temperatures.
c. Vaccines are organized by product	<input type="checkbox"/> Organized vaccines by product.	<ul style="list-style-type: none"> • Storage of vaccines in their original packaging by product allows easy identification of vaccines and minimizes the time spent with the door opened searching for vaccines.
d. Space is maintained between each vaccine product	<input type="checkbox"/> Ensured space is maintained between vaccine products to allow for air circulation. <input type="checkbox"/> Removed excess vaccine. <input type="checkbox"/> Instructed to obtain a larger refrigerator to accommodate required stock or instructed to order and stock less vaccine.	<ul style="list-style-type: none"> • Space between vaccine products is necessary to allow for adequate air circulation around the vaccine.
e. Vaccines that are sensitive to light are protected	<input type="checkbox"/> Protected the vaccines that are sensitive to light.	<ul style="list-style-type: none"> • Some vaccines are sensitive to light and will lose potency if they are exposed to light. • Storage of vaccines in their original packaging will protect vaccines from light.

4. Organization of Refrigeration	Strategies	Rationale
f. Vaccine with the longest expiry dates are placed behind shorter-dated vaccines	<input type="checkbox"/> Placed vaccines with the longest expiry dates behind shorter-dated vaccines.	<ul style="list-style-type: none"> • Longest expiry dates are placed behind shorter-dated vaccines to ensure that the shorter-dated vaccines are used first and shorter-dated vaccines are not wasted due to expiry.
g. Use vaccine that been previously exposed to a cold chain incident first	<input type="checkbox"/> Instructed to use vaccines that have been previously exposed to a cold chain incident first.	<ul style="list-style-type: none"> • Vaccine previously exposed to a cold chain incident should be used first, as most of these vaccines would need to be wasted if exposed to a second cold chain incident.
h. Only current dated vaccine present in refrigerator (no expired vaccine)	<input type="checkbox"/> Return expired vaccines to the public health unit or OGPMS.	<ul style="list-style-type: none"> • Expired vaccines should be removed from the refrigerator and returned to the public health unit to avoid inadvertent administration of expired vaccine.
i. Only vaccines (no food, beverages and/or medical/laboratory specimens) are stored in the refrigerator	<input type="checkbox"/> Removed food, beverages and/or medical/laboratory specimens from the vaccine refrigerator.	<ul style="list-style-type: none"> • Food, beverages or medical/laboratory specimens should not be stored in a vaccine storage unit because this practice results in frequent door openings and destabilization of the temperature. • This also affects the air flows in the refrigerator and takes up space that could be filled with cold mass (e.g. plastic water bottles).

4. Organization of Refrigerator	Strategies	Rationale
j. Water bottles placed on empty shelves and in refrigerator door	<input type="checkbox"/> Placed water bottles in the refrigerator's empty shelves and doors.	<ul style="list-style-type: none"> • Using plastic water bottles will help stabilize the temperature by keeping the temperature inside the refrigerator more stable and reducing warming periods when the refrigerator is opened. • The plastic water bottles will add additional cold mass to refrigerator and will assist with stabilizing temperatures longer in the event of a power failure. • To prevent the consumption and removal of the plastic water bottles from the refrigerator, the water bottles should be clearly labelled with 'do not remove' and 'do not drink' and the water bottle opening should be securely sealed with tape.
k. Refrigerator is of sufficient size to accommodate required stock	<input type="checkbox"/> Advised to obtain a larger refrigerator to accommodate required stock or instructed to order and stock less vaccine.	<ul style="list-style-type: none"> • Overstocking of vaccines will place all vaccines at risk as cold air circulation will be impeded and consistent, stable temperatures throughout the refrigerator will be difficult to achieve.
l. No more than a 1 month stock is on hand	<input type="checkbox"/> ____months stock is on hand, inventory control measures have been taken by public health unit.	<ul style="list-style-type: none"> • It is important to keep vaccine stock to a minimum by regularly ordering only the quantity of vaccine required for the period until the next delivery.

5. Vaccine Handling Review	Strategies	Rationale
a. Office staff know to remove vaccine from refrigerator for immediate use	<input type="checkbox"/> Instructed to only remove vaccines from the refrigerator for immediate use.	<ul style="list-style-type: none"> • Vaccines should only be removed from refrigerator for immediate use. This will reduce the potential for the vaccine to become exposed to elevated temperatures. • Removing vaccine from the refrigerator can potentially result in a cold chain incident and vaccine wastage.
b. Multi-dose vials (if present in vaccine refrigerator) are marked with the date opened and discarded within 30 days or as per manufacturer's instructions	<input type="checkbox"/> Instructed to mark multi-dose vials with the date opened and dispose as per manufactures' instructions.	<ul style="list-style-type: none"> • As multi-doses have a defined time period which it must be used after it has been punctured, the date the multi-dose vial was first punctured and the revised expiry date (as indicated on the product monograph) should be placed on the vial. • If this information is not placed on the multi-dose vial, the vial should not be used and will result in wastage. • Unused portions of multi-dose vials may be refrigerated at +2°C to +8°C and used until it has expired, provided it is not contaminated. • Place multi-dose vials back into the original package.

6. General	Strategies	Rationale
<p>a. Refrigerator should be optimally placed:</p> <ul style="list-style-type: none"> i. In an area that is well ventilated ii. Out of direct sunlight iii. Away from external walls 	<ul style="list-style-type: none"> <input type="checkbox"/> Instructed to relocate refrigerator: <ul style="list-style-type: none"> <input type="checkbox"/> To an area that is well ventilated. <input type="checkbox"/> Out from direct sunlight. <input type="checkbox"/> Away from external walls. 	<ul style="list-style-type: none"> • Placing the refrigerator in direct sunlight, near heat sources, in a room with inadequate ventilation or an external wall (which can be subject to hot and cold temperatures as the weather changes) increases the potential for higher and/or colder temperatures, will require the refrigerator to work harder and may increase the potential for out of range temperatures. • To prevent heat build up around the refrigerator, which will require the unit to work harder, some refrigerators also need to have clearance at the side and back. • Many refrigerators become warmer in hotter weather and colder in cooler weather but some refrigerators become colder in hotter weather and warmer in cooler weather. Be aware of what happens if the heat and/or air conditioner are turned off overnight and on weekends and holidays.
<p>b. Refrigerator door OR refrigerator room is locked at the end of the day</p>	<ul style="list-style-type: none"> <input type="checkbox"/> Instructed to install lock on vaccine refrigerator or refrigerator room door. 	<ul style="list-style-type: none"> • The vaccine refrigerator should be placed in a secure area or should be locked to minimize the risk of unnecessary door openings, power being switched off at the power point and tampering with vaccine.

6. General	Strategies	Rationale
<p>c. Refrigerator electrical outlet is:</p> <ul style="list-style-type: none"> i. Covered by metal cage; OR ii. Not easily accessible; OR iii. Accessible but has the <i>Do not unplug</i> sticker sign is posted beside refrigerator electrical outlet 	<ul style="list-style-type: none"> <input type="checkbox"/> Ensured refrigerator's electrical outlet is covered by metal cage or is not easily accessible. <input type="checkbox"/> Given 'do not unplug' sticker and placed beside refrigerator electrical outlet. 	<ul style="list-style-type: none"> • The refrigerator can be wired so that there is a lockable plug to prevent the accidental disconnection from the power source which can cause the vaccines to be exposed to elevated temperatures, particularly if the refrigerator was left unplugged for a long period of time. • The power source can be protected by placing a sticker above the power plug.
<p>d. Refrigerator maintenance is performed:</p> <ul style="list-style-type: none"> i. Freezer has been defrosted and ice is < 1 cm thick ii. Back (including the coils, if necessary), top and sides are cleaned and dusted iii. Door is sealed tightly and properly and has: <ul style="list-style-type: none"> • Adequate door seals • Velcro door latch installed • Tight door hinges 	<ul style="list-style-type: none"> <input type="checkbox"/> Instructed to: <ul style="list-style-type: none"> <input type="checkbox"/> Defrost refrigerator and move vaccines to a monitored and insulated container while defrosting. <input type="checkbox"/> Dust and clean the back (including the coils, if necessary), top and sides of the refrigerator. <input type="checkbox"/> Replace door seals. <input type="checkbox"/> Install Velcro door latch. <input type="checkbox"/> Tighten door hinges. 	<p>Maintenance of the vaccine refrigerator includes:</p> <ul style="list-style-type: none"> • Regularly checking the refrigerator seals and tightening door hinges to ensure a tight seal is maintained. • Replace the seals or tighten door hinges if they are damaged to prevent cold air from leaking. • Defrost refrigerator regularly, to prevent build-up of ice which will result in unstable temperatures. Regular defrosting also aids in the efficient functioning of the refrigerator. • Installing a Velcro door latch will prevent the door from accidentally being left opened and will ensure a tight door seal. • If there are exposed coils on the back of the refrigerator keep them clean to improve operating efficiency.

6. General	Strategies	Rationale
e. One office staff member is responsible for vaccine management	<input type="checkbox"/> Assigned one office member and a backup person the responsibility of vaccine management.	<ul style="list-style-type: none"> • One key person in each premises should be responsible for cold chain management to enable consistency. • A back up staff member should be trained to ensure that continuous monitoring is maintained. • All premises should have documented protocols and procedures to ensure staff awareness regarding vaccine storage and handling practice.
f. Office staff know to contact public health unit immediately if vaccines are exposed to temperatures below +2°C or above +8°C	<input type="checkbox"/> Instructed to: <ul style="list-style-type: none"> <input type="checkbox"/> Report cold chain incidents to the public health unit. <input type="checkbox"/> Place vaccine involved in a cold chain incident in a bag marked 'Do Not Use'. <input type="checkbox"/> Move this bag of vaccines into a monitored refrigerator or monitored insulated container until evaluated by the public health unit. 	<p>In order to ensure that effective vaccine is administered it is important to promptly identify and manage cold chain incidents. This will minimize the risks of ineffective vaccine being administered, which may result in reimmunization. All staff should be made aware that if a cold chain occurs they are to:</p> <ul style="list-style-type: none"> • Report cold chain incidents to the public health unit; and • Place vaccine involved in a cold chain incident in a bag marked 'Do Not Use'. Move this bag of vaccines into a monitored refrigerator or insulated container until evaluated by the public health unit.
g. Office staff know to return expired, damaged and wasted vaccines to the public health unit (in the City of Toronto – OGPMSS) for disposal	<input type="checkbox"/> Instructed to return expired vaccines to the public health unit or OGPMSS for disposal.	<ul style="list-style-type: none"> • Expired vaccines should be removed from the refrigerator and returned to the public health unit to avoid inadvertent administration of expired vaccine.

6. General	Strategies	Rationale
<p>h. Contingency (emergency) plan developed in the event of a vaccine refrigerator malfunction, power failure or other emergencies</p>	<ul style="list-style-type: none"> <input type="checkbox"/> Discussed a contingency plan. <input type="checkbox"/> Premises instructed to establish a contingency plan. 	<p>It is important to establish a contingency plan in the event of a vaccine refrigerator malfunction, power failure, natural disaster, or other emergency that may compromise vaccine storage conditions. The plan should include:</p> <ul style="list-style-type: none"> • Maintaining the vaccines within the premises if the vaccine refrigerator is connected to a generator; • Establishing in advance at least one alternative storage facility where vaccine can be appropriately stored and monitored if the premises does not have a generator. The facility should also have adequate vaccine storage capacity. In situations where an alternative vaccine storage facility cannot be identified within a reasonable distance, maintain the appropriate packing materials to temporarily and safely store vaccine at the premises; and • Ensuring that appropriate staff have training so that they understand the contingency plan.

6.5 The VCCMIR Form and Pass, Conditional and Fail Ratings

Note: One criteria is equivalent to one box (☐) on the [VCCMIR](#) form.

Section	Results of Routine Inspection		
	Pass Requirements	Conditional Requirements	Fail Requirements
1. Vaccine Refrigerator Temperatures and Readings Number of criteria (or ☐) in this section is 4	All criteria are in compliance	1 criterion is not in compliance Note: 1a must be in compliance	2 - 4 criteria are not in compliance If 1a is not in compliance this will result in an automatic final rating of a fail
2. Log Book Review Number of criteria (or ☐) in this section is 6	All criteria are in compliance	1 criterion is not in compliance Note: 2b must be in compliance	2 - 6 criteria are not in compliance If 2b is not in compliance this will result in an automatic final rating of a fail
3. Ministry Cold Chain Material Number of criteria (or ☐) in this section is 6	All criteria are in compliance OR 3a and/or 3b are not in compliance		3 - 6 criteria are not in compliance If 3c, 3di OR 3dii are not in compliance this will result in an automatic final rating of a fail
4. Organization of Refrigerator Number of criteria (or ☐) in this section is 12	0 - 2 criteria are not in compliance	3 criteria are not in compliance	4 - 12 criteria are not in compliance
5. Vaccine Handling Review Number of criteria (or ☐) in this section is 2	0 - 2 criteria are not in compliance		
6. General Number of criteria (or ☐) in this section is 16	0 - 2 criteria are not in compliance	3 criteria are not in compliance	4 - 16 criteria are not in compliance

6.5.1 Determining a Health Care Provider’s Compliance with the VCCMIR Form

After the [VCCMIR](#) form is completed the public health units should indicate the premises’ compliance with each of the cold chain requirements and develop a follow up plan if required.

To determine the final rating (pass, conditional or fail) using the table in section 6.5:

- a. After the routine inspection, determine the number of criteria (one criteria is equivalent to one box (☐) on the [VCCMIR](#) form) that are not in compliance by section.
- b. Compare the inspection results for each of the sections with corresponding section in the table in section 6.5. (e.g. compare section 1 of the inspection results with section 1 of the table).
- c. For each of the 6 sections, select the rating based on the inspections results.
- d. After determining the ratings for all of the 6 sections, the final rating would be selected based on the lowest rating of the 6 sections.

Example #1

Results of the Inspection	Rating According to Table in Section 6.5
Section 1: 1 criterion is not in compliance	Conditional
Section 2: All criteria are in compliance	Pass
Section 3: All criteria are in compliance	Pass
Section 4: 3 criteria are not in compliance	Conditional
Section 5: 1 criterion is not in compliance	Pass
Section 6: 3 criteria are not in compliance	Conditional
Final rating	Conditional

Example #2

Results of the Inspection	Rating According to Table in Section 6.5
Section 1: 2 criteria are not in compliance	Fail
Section 2: 1 (2a) criterion is not in compliance	Conditional
Section 3: 2 (3a and 3b) criteria are not in compliance	Pass
Section 4: 2 criteria are not in compliance	Pass
Section 5: 2 criteria are not in compliance	Pass
Section 6: 3 criteria are not in compliance	Conditional
Final rating	Fail

6.6 Follow Up Plans

Based on the final rating (pass, conditional or fail) of the routine inspection, a plan should be developed to ensure that the issues that were identified have remediation strategies and a resolution timeline is established. The premises' previous history of cold chain incidents and routine inspections should be taken into consideration when follow up plans are being developed.

Final Rating	Type of Inspection	Strategies	Follow Up Plans
Pass	Routine Inspection	<ul style="list-style-type: none">• Issues should be corrected (when possible) at the time of inspection.• Provide ongoing education, resources and support to ensure the continual compliance of vaccine storage and handling requirements.	Not required, however a telephone call within 1-2 weeks after initial inspection may be conducted.

Final Rating	Type of Inspection	Strategies	Follow Up Plans
Conditional	Routine inspection	<ul style="list-style-type: none"> • A collaborative, supportive approach should be used in assisting premises to meet the cold chain requirements. • Issues should be corrected (when possible) at the time of inspection. • Develop and document a follow up plan on the <i>VCCMIR</i> form outlining the: <ul style="list-style-type: none"> ○ Nature and significance of the identified issues; ○ Remediation strategies; ○ Resolution timelines; and ○ If the premises does not become compliant, publicly funded vaccine may be withheld from the premises. • Depending on the identified issues: <ul style="list-style-type: none"> ○ Prior to the release of additional vaccine, <i>Temperature Log Book</i> readings should be submitted to the public health unit for 7 consecutive days during regular business hours and the maximum, minimum and current temperatures need to be recorded twice daily and must be within the required storage temperature range; and ○ Control of vaccine inventory (releasing only small amounts of vaccine) for 7 days. • Provide the necessary education, resources, and support required for the premises to meet the requirements in a timely manner. 	<p>Depending on the issues identified during the routine inspection a telephone call or a re-inspection be completed at the end of the timeline given (approximately 1-2 weeks after the inspection) to determine whether the required remediation strategies have been fulfilled.</p>
	Re-inspection or telephone call	<ul style="list-style-type: none"> • If the issues have been corrected and the premises can meet the criteria for a pass, document that the corrective actions have been completed on the <i>VCCMIR</i> form. • Provide ongoing education, resources and support to ensure the continual compliance of vaccine storage and handling requirements. 	<p>Follow up is not required, but a follow up telephone call within 1-2 weeks after the re-inspection is recommended.</p>

Results	Type of Inspection	Strategies	Follow Up Plans
Conditional	Re-inspection or telephone call	<ul style="list-style-type: none"> • If all or some issues have not been corrected, document the following information on the <i>VCCMIR</i> form: <ul style="list-style-type: none"> ○ Corrective actions were not completed; ○ Revised resolution timelines; ○ Removal of all publicly funded vaccine from the premises; and ○ Vaccine suspension. • A notice from the public health unit detailing the reasons for the vaccine suspension and the required remediation timelines should be provided. • Continue with the submission of <i>Temperature Log Book</i> and vaccine inventory control until the premises is compliant. • Provide the necessary education, resources, and support required for the premises to meet the requirements required for a pass in a timely manner. • Consultation with the Medical Officer of Health or Associate Medical Officer of Health. 	<p>Re-inspect the premises when the premises has informed the public health unit that they have completed the remediation strategies as specified by the public health unit.</p> <p>After the premises meets all criteria to pass, additional periodic on site visits or telephone follow up is strongly recommended.</p>

Results	Type of Inspection	Strategies	Follow Up Plans
Fail	Routine inspection	<ul style="list-style-type: none"> • A collaborative, supportive approach should be used in assisting premises to meet the cold chain requirements. • Issues should be corrected (when possible) at the time of inspection. • Develop and document a plan on the <i>VCCMIR</i> form outlining the: <ul style="list-style-type: none"> ○ Nature and significance of the identified issues; ○ Remediation strategies; ○ Resolution timelines; ○ Removal of all publicly funded vaccine from the premises; and ○ Vaccine suspension. • A notice from the public health unit detailing the reasons for the suspension of vaccine and the required remediation timelines. • <i>Temperature Log Book</i> readings should be submitted to the public health until the premises is compliant during regular business hours and the maximum, minimum and current temperatures need to be recorded twice daily and must be within the required storage temperature range. • Control of vaccine inventory (releasing only small amounts of vaccine) until the premises is compliant. • Provide the necessary education, resources, and support required for the premises to meet the requirements in a timely manner. 	<p>Re-inspection should be completed at the end of the resolution timeline given (approximately 1-2 weeks after the inspection) to determine whether the required remediation strategies have been fulfilled.</p>

Results	Type of Inspection	Strategies	Follow Up Plans
Fail	Re-inspection	<ul style="list-style-type: none"> • If the issues have been corrected and the premises can meet the criteria for a pass, document that the corrective actions have been completed on the <i>VCCMIR</i> form. • Continue with the premises submitting <i>Temperature Log Book</i> readings and vaccine inventory control for an additional 7 days (or more). • Provide ongoing education, resources and support to ensure the continual compliance of vaccine storage and handling requirements. 	<p>A re-inspection should be completed within 1-2 weeks after the first re-inspection visit to ensure continual compliance.</p> <p>Additional periodic on site visits or telephone follow up is strongly recommended.</p>
	Re-inspection	<ul style="list-style-type: none"> • If all or some issues have not been corrected, document the following information on the <i>VCCMIR</i> form: <ul style="list-style-type: none"> ○ Corrective actions were not completed; ○ Revised resolution timelines; and ○ Continuation of vaccine suspension. • Continue with the premises submitting <i>Temperature Log Book</i> readings and vaccine inventory control until premises is compliant. • Provide the necessary education, resources and support required for the premises to meet the requirements for a pass in a timely manner. • Consultation with the Medical Officer of Health or Associate Medical Officer of Health as required. 	<p>Re-inspect the premises when the premises has informed the public health unit that they have completed the actions specified by the public health unit.</p> <p>After the premises meets all criteria to pass the routine inspection, additional periodic on site visits or telephone follow up is strongly recommended.</p>

6.7 When to Conduct Cold Chain Incident Inspections During Routine Inspections

During the routine inspection process a cold chain incident inspection should be completed if:

- a. A review of the log book temperatures are outside the +2°C to +8°C range.
- b. The public health unit temperature monitoring device indicates a temperature outside the +2°C to +8°C range.
- c. There is a “questionable cold chain” resulting from the premises’ lack of or unreliable temperature monitoring.
- d. See section 5.2.2 for information on how to conduct a cold chain incident inspection.

Section 7: References

1. Ontario. Ministry of Health and Long-Term Care. [Ontario public health standards](#). Toronto, ON: Queen's Printer for Ontario; 2008.
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11. Ontario. Ministry of Health and Long-Term Care. [Vaccine storage and handling guidelines](#). Toronto, ON: Queen's Printer for Ontario; 2009. Retrieved June 17.