NATIONAL VACCINE STORAGE AND HANDLING GUIDELINES

FOR IMMUNIZATION PROVIDERS 2015

PROTECTING CANADIANS FROM ILLNESS

Public Health Agency of Canada
Agence de la santé publique du Canada

Canada

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The objective of the National Vaccine Storage and Handling Guidelines for Immunization Providers - 2015 is to provide recommendations for vaccine storage and handling for immunization providers. Specific recommendations for vaccine storage and handling procedures may vary among public health offices and immunization programs, therefore the document is meant to supplement existing policies rather than replace them.

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SECTION 1 **Cold Chain**

National Vaccine Storage and Handling Guidelines for Immunization Providers

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1.1 The Cold Chain

1.1.1 What Is the Cold Chain?

Excessive heat or cold exposure can damage vaccines. The "cold chain" refers to the process used to maintain optimal conditions during the transport, storage, and handling of vaccines, starting at the manufacturer and ending with the administration of the vaccine to the client (1). The optimum temperature for refrigerated vaccines is between +2°C and +8°C (+35°F and +46°F) (2). For frozen vaccines the optimum temperature is –15°C (+5°F) or lower. In addition, protection from light is a necessary condition for some vaccines (see *Section 1.2.1: A Note on Light Exposure*).

1.1.2 The Effective Cold Chain

Three key elements combine to achieve proper vaccine transport, storage, and handling:

- Trained personnel.
- Proper transportation and storage equipment.
- Efficient vaccine management procedures.

Each of these elements will be addressed in subsequent sections.

Proper storage temperatures must be maintained at every link in the chain or vaccine may be damaged and unsuitable for administration.

Appropriate storage temperatures and light requirements must be maintained at each step of the way in order to ensure that the products used in immunization will provide the client with the expected protection.

FIGURE 1: COLD CHAIN DIAGRAM

Manufacturer

Processes to maintain appropriate temperatures during manufacturing:

- Monitoring time out of refrigeration
- Research relating to temperature excursions and impact on product efficacy

Distributor

Movement of vaccine from manufacturing site to administering site:

- Manufacturer to warehouse/direct provider
- Warehouse to direct provider
- Must have processes in place to maintain temperatures during transportation

Depot

At both the provincial, regional and local levels:

- Must have defined processes for receiving vaccines to maintain appropriate temperatures
- Must have processes in place to identify and respond to any breaches
- Must have clearly defined procedures for any subsequent packing and shipping to secondary sites

Immunization Provider Office

Maintain appropriate temperature ranges until time of administration:

- Identification of key individual responsible for vaccine, including cold chain
- Clearly defined policies and procedures with focus on minimizing exposure to temperature excursions:
  - Inventory management (ordering, stock rotation / expiry dates, receiving)
  - Clinical practice guidelines relating to vaccine management
  - Processes to identify and respond to any breaches

Vaccine Provider

Maintains appropriate temperature until actual time of administration:

- Follows clinical practice guidelines in order to maintain required temperature/light exposure while product out of storage unit
- Must have processes in place relating to identification and response to any breaches
- Returns unused vaccines to fridges

1.2 Importance of Maintaining the Cold Chain

Temperatures falling outside the recommended range require immediate action to avoid loss of product.

Vaccines are sensitive biological products that may become less effective, or even destroyed, when exposed to temperatures outside the recommended range. An immediate loss of potency of cold-sensitive vaccines may occur following freezing. For vaccines exposed to temperatures above the recommended temperature range, there is some loss of potency with each episode of exposure. Repetitive exposure to heat episodes could result in a cumulative loss of potency that is not reversible (3, 4).

The proper storage and handling of vaccines is important for several reasons:

If an ineffective product is used, recipients may not be protected against vaccine-preventable diseases, and this may result in re-emergence or occurrence of those diseases.

- In the past, many studies have shown that health care providers accidentally expose vaccines to improper storage temperatures outside of the +2°C to +8°C (+35°F to +46°F) range and do not monitor refrigerator temperatures regularly (5).
- There is a need to ensure that an effective product is being used, otherwise recipients may not be protected against vaccine-preventable diseases; this could result in the re-emergence or occurrence of those diseases.
- Loss of vaccine effectiveness may result in the cancellation of immunization clinics and thus lost opportunities to immunize, as well as increased costs to the program.
- Revaccination of people who have received an ineffective vaccine may cause a loss of public confidence in vaccines and/or the health care system. A shortage of vaccine supply could be created by increased demand in a mass revaccination scenario.

Vaccines are sensitive biological products that may become less effective, or even destroyed, when exposed to temperatures outside the recommended range and/or to direct sunlight or fluorescent light (1).

When a cold chain break is identified after a vaccine has been administered, consult your jurisdictional/local public health office or immunization program for advice. The type and cost of the vaccine and the duration and temperature of the exposure will be taken into account when the situation is assessed. Serological testing or revaccination may be recommended (3).

1.2.1 A Note on Light Exposure

Exposure to light can reduce the potency of some vaccines (2, 3). Studies have shown that both UV light and fluorescent light cause damage to certain vaccines (5, 6). As with exposure to adverse temperatures, the deleterious effects of light exposure on light-sensitive vaccines are cumulative (3). Refer to the product monograph of each vaccine to determine light exposure restrictions.

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SECTION 2 **Vaccine Personnel and Vaccine Storage and Handling Protocols**

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2.1 General Recommendations

- All health care providers who administer vaccines should evaluate their cold chain procedures to ensure that vaccine storage and handling guidelines are being followed.
- Each immunization provider office should develop detailed written protocols as follows:
  - **Routine Vaccine Storage and Handling** for day-to-day operations (see *Section 4: Vaccine Storage Practices* for more details);
    - This includes the use of vaccine bags.
  - **Urgent Vaccine Storage and Handling** in the event of refrigerator or freezer malfunctions, power failures, natural disasters, or other emergencies that might compromise vaccine storage conditions;
  - **Management of Inappropriate Vaccine Storage Conditions** leading to cold chain breaks (see *Section 7: Cold Chain Breaks*), for instance, lack of attention to refrigerator conditions or human error (see *Section 6: Storage Troubleshooting* and *Section 7: Cold Chain Breaks* for more details).
- All staff members who administer or handle vaccines in any way should be familiar with all protocols.
- The protocols should be updated and placed in an area accessible by all staff members who handle vaccines or provide immunizations, preferably near the vaccine storage units.

All immunization clinics should develop detailed written protocols for routine vaccine storage and handling, for urgent vaccine storage and handling, and for cold chain breaks.

2.2 Staff and Training Personnel

2.2.1 All Staff

Ensure that all staff members (current and new) have received appropriate training so that they understand the protocols for routine and urgent vaccine storage and handling and their responsibility in maintaining the cold chain. Also ensure that maintenance staff, janitorial staff, and security staff members are aware of the plan and know the procedures for notifying designated personnel about any problems with vaccine storage equipment. The plans and procedures should be clear and easily accessible to all staff.

2.2.2 Designated Vaccine Coordinators

Each site should designate one staff member to be the primary vaccine coordinator and another staff member as a backup (delegate) in case the primary coordinator is unavailable (1). The designated vaccine coordinators should be fully trained in routine and urgent vaccine storage and handling protocols, and in procedures for managing cold chain breaks. They will be responsible for ensuring that all vaccines and diluents are handled correctly, that procedures are documented, and that all personnel receive appropriate cold chain training.

Each site should designate one staff member to be the primary vaccine coordinator and another staff member as a backup or delegate in case the primary coordinator is unavailable.

Duties of the Designated Vaccine Coordinators and Delegates

- Monitor the operation of the vaccine storage equipment and systems twice daily.
- Ensure that protocols and training are in place for the appropriate handling of the vaccine during a disaster or power outage.
- Arrange for designated staff members to have 24-hour access to the building and vaccine storage unit(s).
- Track inclement weather conditions.
- Wherever possible, set up and maintain a monitoring and notification system in anticipation of times of inclement weather or other conditions that might cause a power outage (a continuous-monitoring temperature alarm and notification system should be considered, especially for sites with large inventories).
- If the facility has a backup generator, ensure that sufficient fuel and/or battery power is on hand to continuously run the generator for at least 72 hours. Arrange for someone to be designated to turn the generator on in the event of a power outage.
- If the facility has an uninterruptible power supply (UPS), confirm that it is in working order and that the length of the battery life is known, so that appropriate actions can be taken once the power supply runs out.
- **NOTE:** in the event of a sustained power outage or emergency, decisions about relying on backup power for a length of time will have to be considered jurisdictionally; thus, vaccine coordinators and delegates should refer to the jurisdictional/local public health protocol.
- If backup power in the form of a generator or UPS is not available, plans should be put in place for vaccines to be moved to another location with access to a backup power supply for the duration of the event.

2.2.3 Other Staff

All staff members should be familiar with their site's policies and procedures for vaccine storage and handling.

All staff members (including support staff who accept vaccine shipments, program manager(s), immunization coordinator(s), public health nurses, physicians, pharmacists, physician office staff, administration staff, janitors, security staff) should be familiar with the site's policies and procedures for vaccine storage and handling (2).

All policies and procedures should be available in writing and kept near the vaccine storage units for easy reference.

2.2.4 Training Personnel

All new staff members who handle or administer vaccines should be trained in proper vaccine storage and handling practices. All other new staff should have an understanding of the importance of cold chain maintenance and basic practices so that they are aware of their responsibilities relating to the cold chain. A refresher training session should be held annually for all staff. Staff members who monitor and record temperatures of vaccine storage units should immediately report inappropriate storage conditions (including exposure to inappropriate temperature or light exposures) to the designated vaccine coordinator or delegate (see *Section 1: Cold Chain* for more information on inappropriate temperature and light exposure).

2.3 Routine Vaccine Storage and Handling Protocols

Routine protocols should include all aspects of day-to-day vaccine management, from ordering vaccines and controlling inventory to handling vaccines and monitoring storage conditions. Please see *Appendix A: Routine Vaccine Storage and Handling Protocols Checklist* for a tool to use or adapt to ensure that routine protocols include all the recommended information. A sample contact list is also provided in *Appendix B: Routine Vaccine Storage and Handling Contact List*, which may be useful in developing and organizing routine protocols and plans.

2.3.1 Routine Protocol Requirements

The following information should be included with the routine vaccine storage and handling protocols:

- Up-to-date contact information for the following:
  - Designated vaccine coordinators and delegates who are responsible for routine vaccine storage and handling;
  - Provincial, territorial, local, or other jurisdictional public health office or immunization programs;
  - Refrigerator and freezer maintenance and repair companies;
  - Vaccine storage unit alarm companies (if applicable);
  - Sources of packing materials and calibrated thermometers.
- Descriptions of the roles and responsibilities of the designated vaccine coordinators, delegates, and other staff members.
- Summaries of the storage requirements for each vaccine and diluent in the inventory.
- Samples of the vaccine management forms used in each immunization program.
- Information on the routine protocol topics covered in section 2.3.2.

2.3.2 Routine Protocol Topics

The following is a list of topics that the routine vaccine storage and handling protocols should cover:

- Vaccine storage unit temperature monitoring.
- Vaccine storage equipment maintenance.
- Placement of vaccine within storage units.
- Response to vaccine storage and handling problems, including off-site clinics.
- The proper use and packing of vaccine bags/coolers (can be off-site or on-site).
- Vaccine inventory management.
- Packaging, transporting, and receiving vaccine shipments.
- Disposal of vaccines and diluents as directed by jurisdictional policy or guidelines (see *Section 10: Vaccine Disposal* for more information).

2.4 Urgent Vaccine Storage and Handling Protocols

Various situations may compromise vaccine storage conditions, for example, equipment failures, power outages, or natural disasters. Clear and concise procedures should be posted in a visible and accessible area to aid staff in the event of an excursion. These procedures should contain a contact list that is reviewed and updated as staffing changes occur. Review and update the entire protocol annually.

When immunization providers have reasonable cause to believe that weather conditions, natural disasters, or other emergencies might affect vaccine storage conditions, urgent procedures should be implemented in advance of the event.

Urgent protocols should be clearly labelled and posted in a prominent place.

2.4.1 What to Include with the Urgent Protocols

See the list below for details on what is to be included with the urgent vaccine storage and handling protocols. Please see *Appendix C: Urgent Vaccine Storage and Handling Protocols Checklist* for a summary and additional detail. A sample contact list is also provided in *Appendix D: Urgent Vaccine Storage and Handling Contact List*.

When immunization providers have reasonable cause to believe that weather conditions, natural disasters, or other emergencies might affect vaccine storage conditions, urgent procedures should be implemented in advance of the event.

Contact Lists

- Current emergency staff contact list, in order of contact preference;
- Current contact information for all possible players in the event of an emergency (see *Appendix D: Urgent Vaccine Storage and Handling Contact List*).

Vaccine Coordinator Responsibilities

- Designated duties of the vaccine coordinators and delegates (see section 2.2.2).

Power Outages

- A list of the most common causes of power interruption for your facility:
  - Include procedures to follow in each circumstance;
  - Include considerations for varying lengths of time during which the power may be out.

Storage Units

- Vaccine storage unit specifications and records in case of an equipment failure (3):
  - For each vaccine storage unit in your facility, document the type of unit (e.g. refrigerator, freezer, combination refrigerator and freezer), the brand name, the model number, the serial number, and its location, as well as a full maintenance history. These records may be useful for the repair company.

Storage Facilities

- Alternative vaccine storage facility or facilities (3):
  - Establish working agreements with at least one alternative storage facility with a backup generator or UPS where vaccine can be appropriately and securely stored and monitored for the interim, on short notice if necessary (e.g. local health units, provider offices, hospital pharmacies, provincial or territorial depots, local pharmaceutical warehouses, or distributors that could offer or meet both refrigeration and freezer requirements);
  - If you do not have a 24-hour monitored and alarmed refrigerator and a reliable backup power supply, make advance arrangements with an alternative facility to store your vaccine when weather forecasts call for inclement conditions, when your vaccine storage equipment cannot be repaired, or when the power cannot be restored before the vaccine storage unit temperature rises above the recommended range;
  - Record the name of the alternative storage facility/facilities, the name of the contact person(s), and the telephone number(s) (see *Appendix D: Urgent Vaccine Storage and Handling Contact List*). Instructions should include details on 24-hour access.
- Written protocols, vehicles, and drivers for transporting vaccine to and from the alternative vaccine storage facility:
  - Develop written protocols for transporting vaccine to and from the alternative vaccine storage facility (see *Section 9: Vaccine Distribution* for further information);
  - If the vaccine can be moved to the alternative facility before the vaccine storage temperature goes outside the recommended range, it may be transported in appropriately insulated and packaged containers or coolers within ordinary vehicles inside the passenger compartment, not in a truck bed or trunk (which is not climate-controlled and may expose vaccines to extreme temperatures);
  - Make advance arrangements for a primary and backup vehicle and a driver, and record the contact information (see *Appendix D: Urgent Vaccine Storage and Handling Contact List*);
  - If the alternative vaccine storage facility is far away or if you have a large quantity of vaccine, consider other storage or modes of transport and factor these considerations into the procedures. For example, renting a refrigerated truck to transport the vaccine is a consideration but may not be feasible or the best option in all cases. Likewise, for remote locations, flying the vaccine may be an option, but also not feasible in all cases;

  - Make advance arrangements with a local refrigerated transport company, as well as an alternative storage company, and record the contact information (see *Appendix D: Urgent Vaccine Storage and Handling Contact List*);
  - Document procedures for loading the vehicle;
  - Have pre-selected routes to take (and alternative routes if necessary);
  - Determine the estimated time en route (4) – this will ensure that your planned packing procedures and containers are acceptable.
- Urgent vaccine storage and handling protocols should include written and accessible instructions for entering your facility and vaccine storage spaces in an emergency if the building is closed or if the emergency occurs after hours:
  - Consider that posting the instructions outside of the facility may not be appropriate and posting them inside the building may make them inaccessible after hours – those responsible for entering the building after hours may therefore need the instructions at home or available electronically. Use the best/most appropriate means for your facility or jurisdiction to make the instructions accessible;
  - These instructions should include the building security and after-hours access procedure, a floor diagram, and the locations of the following:
    - Alarms (including passwords and instructions for use);
    - Doors;
    - Flashlights;
    - Spare batteries;
    - Light switches;
    - Keys;
    - Locks;
    - Circuit breakers;
    - Vaccine coolers and packing materials (cold packs, insulated blankets).

Vaccine Storage at Alternative Facilities

- Urgent vaccine storage and handling protocols should include a written protocol for appropriately storing vaccine at the alternative vaccine storage facility:
  - Refrigerator-stable vaccines should be stored in the refrigerator at +2°C to +8°C (+35°F to +46°F). Vaccines that are frozen should be stored at –15°C (+5°F) or colder;
  - There should be adequate cold air circulation around the vaccines;
  - Each alternative vaccine storage unit should have a functioning calibrated temperature monitor in each compartment;
  - Temperatures inside the storage units and the room temperature should be monitored and recorded at least twice a day at the start and close of business for as long as vaccine is stored in this location.

Vaccine Packaging Protocols

- Urgent vaccine storage and handling protocols should include an appropriate written protocol for vaccine packing (1):
  - Every facility has access to different types of shipping materials and coolers, so each facility should develop its own standard operating procedures (SOP) for packing vaccine based on the facility's experience using the materials and/or guidance provided by its jurisdictional/local public health office or immunization program. These instructions should be readily available for staff unfamiliar with vaccine packing procedures.
- Appropriate packing materials to safely transport or temporarily store vaccine may include the following:
  - Insulated containers;
  - Refrigerated packs;
  - Frozen packs (may be gel or ice);
  - Dry ice if product must be frozen;
  - Insulating barrier materials or materials used as barriers between the vaccine and refrigerated/frozen packs and as filler.
- If an alternative vaccine storage facility with a backup generator or UPS cannot be identified within a reasonable distance, plans should be made for ongoing maintenance of the appropriate packing materials to temporarily and safely store vaccine at your facility. Record the contact information for sources of these materials (see *Appendix D: Urgent Vaccine Storage and Handling Contact List*).
- See *Section 9: Vaccine Distribution* for more details on vaccine packing protocols and materials.

Temperatures inside the storage units and the room temperature should be monitored and recorded at least twice a day at the start and close of business for as long as vaccine is stored in this location.

Refrigerated and Frozen Vaccines

- Urgent vaccine storage and handling protocols should include appropriate guidelines for maintaining the temperature of both refrigerated vaccines and frozen vaccines:
  - Document the vaccine storage unit temperature at the time the vaccine is removed for transport;
  - Pack the refrigerated vaccines first, using enough refrigerated and/or frozen packs to maintain the cold chain. The number and placement of refrigerated or frozen packs inside the container will depend on container size, outside temperature, and jurisdictional variations (see *Section 9: Vaccine Distribution* for more details;
  - Vaccines should be packed in layers using the following materials: refrigerated or frozen packs, insulating barrier, vaccine, a temperature monitor, and filler materials (may be the same as those used as insulating barriers) to prevent shifting of the contents during transport (see *Section 9: Vaccine Distribution* for more details);
  - Vaccines should never be directly placed next to the ice pack or refrigerated pack. Be sure to place an insulating barrier between the refrigerated or frozen packs and the vaccines to prevent accidental freezing;
  - Use properly placed temperature monitors to assess whether the cold chain has been broken. The temperature-monitoring device should be placed in the middle of the vaccines (an empty vaccine box can be used to hold the device to prevent movement during transport) and should not come in contact with the refrigerated or frozen packs;
  - Record the vaccine type(s), lot numbers, brand names, quantity, expiry date, packing date and time, and originating facility on a packing slip included inside the container, especially if moving the vaccine by a third party;
  - Attach labels to the outside of the container to clearly identify the contents as valuable and fragile vaccines, especially if moving the vaccine by a third party. Labels should include special instructions to refrigerate immediately upon arrival.

- For frozen vaccines:
  - Document the temperature of the vaccine storage unit at the time the vaccine is removed for transport;
  - Pack the frozen vaccines last, using a separate insulated container;
  - Pack with dry ice immediately before they are to be transported. At least 2.7 kg (6 lbs.) of dry ice should be used in the container to maintain vaccines in their frozen state (depending on the size of the container);
  - Use properly placed temperature monitors to assess whether the cold chain has been broken. The temperature monitors should be placed next to the vaccine and should not come into contact with frozen packs;
  - Record the vaccine type(s), lot numbers, brand names, quantity, expiry date, packing date and time, and originating facility on a packing slip included inside the container, especially if moving the vaccine by a third party;
  - Attach labels to the outside of the container to clearly identify the contents as valuable and fragile vaccines, especially if moving the vaccine by a third party. Labels should include clear instructions to "keep frozen."
- See *Section 9: Vaccine Distribution* for more details on packing requirements for refrigerated and frozen vaccines.

General Principles

- Key steps that should be reflected in all SOPs (2):
  - Open the refrigerator and/or freezer doors only when absolutely necessary and only after all preparations for packing and moving the vaccine to the alternative storage location have been made;
  - Use properly insulated containers to transport the vaccine. These containers should be qualified, as described elsewhere (4), to ensure that they are capable of maintaining the vaccine at the correct temperatures. Thin-walled recreational-use Styrofoam coolers, such as those purchased to hold beverages, are not acceptable.
- See *Section 4: Vaccine Storage Practices* and *Section 9: Vaccine Distribution* for more details on day-to-day general principles to include in SOPs.

2.5 Emergency Actions

The following emergency procedures should be implemented in advance of the event whenever possible:

- Suspend immunization and other activities. This will allow sufficient time for packing and transporting vaccine.
- If the vaccine is to be moved, notify staff at the alternative vaccine storage facility beforehand so they can ensure that their backup generator or UPS is working and that they have sufficient storage capacity.
- Conduct an inventory of the vaccines and record the actions taken. See *Appendix E: Vaccine Stock Record and Tally Sheet* for examples of forms that may be used or adapted to record inventory.
- Follow established vaccine transport procedures for moving vaccine.
- If a cold chain failure occurs or is suspected, fill out the necessary documentation required by your jurisdictional/local public health office or immunization program. Sample reports can be found in *Appendix F: Cold Chain Failure Reports*, which may be used or adapted. See *Section 7: Cold Chain Breaks* for more details.

Whenever there is a question about vaccine integrity after an urgent event, contact your jurisdictional/local public health office or immunization program for advice.

2.5.1 Mass Immunization and Pandemic Plans

It is important for all jurisdictions to have a mass immunization plan in the event that an outbreak or a pandemic occurs. These are developed according to jurisdictional needs. It is beyond the scope of this document to provide further information; however, it is important that vaccine management be clearly defined in this plan. Refer to your local pandemic plan and/or the appropriate provincial or territorial pandemic plan for further information.

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SECTION 3 **Vaccine Storage Equipment**

National Vaccine Storage and Handling Guidelines for Immunization Providers

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3.1 General Requirements

Vaccine storage units must be selected carefully and used properly. Any refrigerator or freezer used for vaccine storage must have the following features:

- Be able to maintain the required vaccine storage temperatures through all seasons.
- Be large enough to hold the year's highest monthly inventory, including vaccines for influenza season and any school-based immunization programs.
- Have a calibrated temperature-monitoring device inside each storage compartment.
- Be dedicated to the storage of vaccines only.
- Be placed in a secure location away from unauthorized and public access.
- Be on a dedicated circuit.

3.2 Backup Equipment

No piece of vaccine storage equipment is infallible. At some point, equipment failure will occur because of a power failure, breakdown, or normal wear and tear. Vaccine security requires that these failures be anticipated and that reliable backup equipment and/or backup plans be available. Regular maintenance of all equipment is recommended to maintain optimal functioning.

3.3 Routine Equipment Maintenance Logbooks

An equipment logbook should contain the following records of each piece of equipment:

- Date of installation, serial number, and model number.
- Equipment instructions and list of routine maintenance tasks.
- Dates of any routine tasks performed (e.g. cleaning).
- Dates of repairs or servicing, including invoices.
- The name of the person, company, and contact information (operational and after hours) of the company providing the service.

3.4 Refrigerators and Freezers

3.4.1 Technical Requirements for Refrigerators

There are many different types of refrigerators and freezers available. Knowing their functions and components will help in understanding why certain types are recommended for vaccine storage. The technical features of refrigerators that can affect the safe storage of vaccines are outlined in Table 1 (1).

TABLE 1. TECHNICAL REQUIREMENTS FOR REFRIGERATORS

FUNCTION	COMPONENT	TECHNICAL REQUIREMENTS FOR VACCINE STORAGE REFRIGERATORS
1) Temperature Regulation	The **compressor** functions to cool the inside of the refrigerator. The compressor is controlled by either a thermostat or a digital controller, depending on the type of fridge. When the temperature exceeds the set temperature of the thermostat, the compressor turns on and operates to cool the fridge. The point at which the compressor turns on depends on the design of the thermostat and fridge. Therefore, a thermostat that has a large differential between its switch points (on and off) will cause, in turn, long compressor on and off periods. This may produce large temperature fluctuations that are undesirable for the storage of vaccines.	A refrigerator used for vaccine storage must have a compressor with a short differential between its switch points (temperature fluctuations throughout the refrigerator due to compressor cycles ≤1°C/1.8°F) (1).
2) Defrost Mechanism	The cooling area in the refrigerator is called the **evaporator**. It consists of cooling coils usually located behind the surface of the wall at the back of the refrigerator or in the exposed area at the back of the refrigerator. Heat from the warm air inside the fridge transfers to the refrigerant in the coils. As warm air passes over the evaporator, water vapour in the air condenses and freezes on the evaporator. During the process of cooling the refrigerator, an icy buildup is created on the evaporator. The ice that forms may reduce the cooling capacity and efficiency of the system. Therefore, refrigerators must have a defrost cycle that allows the ice to melt off the evaporator.	The temperature must remain at the set point (within the range of +2°C to +8°C/+35°F to +46°F) during the defrost cycle of a refrigerator used for vaccine storage.

(continued on next page)

FUNCTION	COMPONENT	TECHNICAL REQUIREMENTS FOR VACCINE STORAGE REFRIGERATORS
3) Spatial Temperature Differential	**Spatial temperature differentials** are the differences in temperature within the internal fridge space.	Vaccine storage requires a uniform temperature distribution to prevent placement of vaccines outside the recommended temperature ranges. See *Section 4: Vaccine Storage Practices* for more information on organizing your refrigerator.
4) Control of Changes in Ambient Temperature	**Ambient temperature** is the temperature of the environment where the fridge is kept.	For vaccine storage, the aim is to have a refrigerator that can maintain a stable temperature within, even when the surrounding ambient temperatures change.
5) Temperature Recovery	**Temperature recovery** is the ability of the refrigerator to return to its set temperature after being exposed to elevated temperatures (e.g. after the door has been opened to remove vaccine).	A refrigerator used for vaccine storage must have the ability to quickly return to its set temperature when exposed to adverse temperatures. A single minimum number of minutes cannot be provided, as it depends on the temperature reached when the power supply is cut off and for how long the power is cut off.

3.4.2 Types of Refrigerators

While there are many different types of refrigerators and freezers available on the market, some are acceptable for use, and others are not. A summary of refrigerators that are the best, are acceptable, or are not recommended for vaccine storage can be found in Table 2.

TABLE 2. TYPES OF REFRIGERATORS FOR VACCINE STORAGE – A SUMMARY

RATING	TYPE OF REFRIGERATOR	DESCRIPTION
Best	**Purpose-Built Refrigerator**	A purpose-built vaccine refrigerator (also referred to as a pharmacy, lab-style, or laboratory grade refrigerator) is the best type for storing all inventories of vaccines. It has been shown to have the least temperature variations, maintaining temperatures more reliably within the desired range (1, 2). The defrost mechanism and fan-forced air circulation (see *Section 3.4.3: Refrigerators Appropriate For Use*) differentiate this type of refrigerator from domestic refrigerators, making it more suitable for vaccine storage.
Acceptable	**Domestic Frost-Free Refrigerator**	A combination of domestic refrigerator and freezer unit is acceptable but requires significant modifications to store vaccines. The refrigerator and freezer compartments must have separate external doors, and the unit must meet the criteria set out in these guidelines (3).
Not Recommended	**Manual Defrost Refrigerator / Cyclic Defrost Refrigerator**	Manual and cyclic defrost refrigerators are not recommended for vaccine storage because of the significant temperature variations and the risk of vaccines freezing. Generally, while the compressor is running, the area near the evaporator can be very cold whereas other areas are much warmer.
	Bar Refrigerator	Any style of small, domestic-use bar fridge is unpredictable in terms of maintaining temperatures and must not be used. With combined refrigerator and freezer units, the freezer compartment in this type of unit is incapable of maintaining temperatures cold enough to store freezer-stable vaccines (4).

3.4.3 Refrigerators Appropriate For Use

There are two types of refrigerator that are suitable for the storage of vaccines: purpose-built refrigerators and domestic frost-free refrigerators. For a comparison of the technical components of the two types of refrigerator please refer to *Appendix G: Technical Components of Purpose-Built and Domestic Frost-Free Refrigerator*s.

Purpose-Built Refrigerator

A purpose-built vaccine refrigerator (also referred to as a pharmacy, lab-style or laboratory grade refrigerator) is the best type for storing all inventories of vaccines for several reasons. The advantages of a purpose-built refrigerator, in terms of the technical features, are outlined below (1). For an example of a purpose-built vaccine refrigerator, see *Section 4.2: Organizing Your Refrigerator and Freezer, Figure 1.*

1) Temperature Regulation

The temperature regulation mechanism in a purpose-built vaccine refrigerator has a very tight temperature tolerance and a quick reaction time to temperatures outside the set range. A temperature probe for the temperature control is usually located in the path of the return airflow, thereby measuring the temperature of the warmest air in the refrigerator.

2) Defrost Mechanism

Purpose-built vaccine refrigerators have a mechanism to defrost ice from the evaporator without raising the temperature in the unit. There is a small heating element wrapped around the evaporator coils that has the capacity to melt the frost off the evaporator frequently. This feature prevents the lengthy periods of time needed for defrosting in other refrigerator designs. This method of regular defrosting also prevents fluctuations of temperatures within the unit.

3) Spatial Temperature Differential

The spatial temperatures are tightly controlled in purpose-built vaccine refrigerators. There is constant fan-forced air circulation within the refrigerated compartments. Generally, the temperature does not vary within the storage area from the set point.

4) Effects of Changes in Ambient Temperature

The forced air circulation helps to keep internal temperatures within a range even when the ambient temperature changes.

5) Temperature Recovery

The temperature is digitally managed in purpose-built refrigerators. Any deviation in temperature from the preset one is sensed very rapidly.

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. For example, it is best practice to keep the vaccines in their original packaging within the refrigerator or freezer to provide protection from light (see *4.3 Organizing Vaccine Inventory* in *Section 4: Vaccine Storage Practices* for more details). One limitation of purpose-built refrigerators is that glass doors do not provide good insulation in the event of a power interruption, resulting in a rapid rise in spatial temperature.

Purpose-Built Vaccine Refrigerator
ADVANTAGES
A digital feedback system achieves narrow tolerances within internal temperatures, thus providing an excellent temperature regulation system for vaccine storage.
Ongoing air circulation ensures that the temperature distribution is even.
A set-point temperature, within a +2°C to +8°C (+35°F to +46°F) range, is maintained.
Evaporator operates at +2°C (+35°F), which prevents vaccine from freezing.
Air circulation is fan forced.
Temperature recovery system is good.
Built to handle ambient temperature changes.
LIMITATIONS
Glass door design required extra effort to protect vaccines from light exposure.
Glass doors do not provide good insulation in the event of a power interruption.

Domestic refrigerators are designed for food storage and not for the requirements of vaccine storage. Precautions and fridge modifications are needed in order to store vaccines.

Domestic Frost-Free Refrigerator

A domestic frost-free combination refrigerator and freezer unit is acceptable but requires significant modifications to store vaccines. The refrigerator and freezer compartments must have separate external doors and the unit must meet the criteria set out in these guidelines.

A "frost-free" refrigerator refers to the freezer compartment, where food is supposed to stay relatively frost-free. The evaporator is located in the freezer (usually behind the rear wall). The evaporator defrosts automatically with a heater that dissipates the defrost water. When the compressor is on, a fan blows the cool air through vents to the freezer and then to the refrigerator. Thus, the air being circulated to the refrigerator may be below 0°C (+32°F). The cool air may freeze vaccines if they are placed near the vents.

For an example of an appropriate domestic refrigerator, see *Section 4.2: Organizing Your Refrigerator and Freezer, Figure 2*. The technical features of domestic frost-free refrigerators are outlined on the next page (1).

1) Temperature Regulation

The thermostat in domestic refrigerators detects temperature changes and controls the compressor's on and off function. When the temperature exceeds the set temperature of the thermostat, the thermostat sends a signal to the compressor to cool the unit. Large fluctuations in temperature may occur, depending on the point at which the compressor turns on and the time it takes to cool the unit. This will vary according to the specifications of the refrigerator.

Domestic refrigerators are designed to cool the unit by air blown at below 0°C (+32°F) from the evaporator into the refrigerator. Products placed close to vents will be exposed to these below 0°C (+32°F) temperatures.

Finally, temperature sensors are located in various areas of the refrigerator, depending on the model. The sensors may not measure the temperature where the vaccines are stored, thereby possibly exposing vaccines to temperatures outside the recommended range when the evaporator blows cold air into the refrigerator.

2) Defrost Mechanism

A frost-free refrigerator relies on heating coils wrapped around the evaporator in the freezer as the mechanism for defrosting. The heating coil is controlled by a timer and/or a sensor that determines when a predetermined temperature is reached and when the heating coil should be turned off. There is a risk of temperature fluctuations that may result in higher temperatures in the freezer and sections of the refrigerator.

The defrost mechanism in domestic refrigerators can cause temperature fluctuations within the unit. The combination of the compressor cooler, the defrost heating, and poor uniformity of temperatures throughout the compartments creates temperature variations that can affect vaccine storage.

3) Spatial Temperature Differential

Domestic refrigerators are designed to have various temperature zones for multiple storage functions. They are designed so that there is transfer of cool air from the freezer to the refrigerator. This could result in vaccines being stored in suboptimal conditions.

4) Effects of Changes in Ambient Temperature

In domestic refrigerators, the temperature sensor may be located in the freezer. As a result, when the ambient temperature rises, the compressor operates more frequently, and the refrigerator gets exposed to cooler air from the evaporator more frequently.

5) Temperature Recovery

In domestic refrigerators, temperature recovery depends on many factors, including the design of the refrigerant delivery system and temperature regulation system; the size of the compressor, evaporator, and fan; and the time it takes for the temperature sensor to detect a change in temperature. Domestic refrigerators may need to accommodate large loads or contain water bottles to keep the refrigerator's thermal mass higher in order to achieve efficient temperature regulation (5).

Domestic Refrigerator General Information
Thermostats are generally slow to react to an increase in temperatures and have a wide temperature tolerance.
It is difficult to accurately set temperature.
No air is circulated when the compressor is off.
The defrost function can cause temperature fluctuations.

The vaccine coordinator MUST KNOW the following information if a domestic refrigerator is going to be used to store vaccines:

The various temperature zones within compartments: vaccines can only be stored in certain areas, depending on the temperature zone.

The air vent location: the location of air vents differs by manufacturer. Vaccines should be kept away from the air vent to avoid potential freezing. Generally, the air from the evaporator is below 0°C (+32°F).

Ambient temperature: changes in ambient temperature affect internal temperature.

3.4.4 Refrigerators Inappropriate For Use

Manual and Cyclic Defrost Refrigerators

Other types of domestic refrigerators are manual and cyclic defrost refrigerators. For these types, the evaporator in the refrigerator automatically defrosts and/or relies on natural melting or off-cycle heating of the evaporator when the compressor is off, whereas the freezer needs to be manually defrosted. The evaporator is most commonly found as an exposed vertical plate at the back of the refrigerator. Manual and cyclic defrost refrigerators are not recommended for vaccine storage because of the significant temperature variations and the risk of vaccines freezing. Generally, while the compressor is running, the area near the evaporator can be very cold, whereas other areas are much warmer.

Any style of small, single-door (bar-style) fridge is unpredictable in maintaining temperatures and is not recommended for vaccine storage.

Bar Fridge Units

Studies show that bar-style refrigerators **are not capable of consistently maintaining temperatures within the 2°C to 8°C (+35°F to +46°F) range** (6). Any style of small, domestic use, single-door (bar-style) fridge is unpredictable in terms of maintaining temperatures and should **not be used**. With combined refrigerator and freezer units, the freezer compartment in this type of unit is incapable of maintaining temperatures cold enough to store freezer-stable vaccines. Even when the freezer temperature is not adjusted, the temperature in the refrigerator compartment will fall below the recommended range, potentially freezing the refrigerated vaccines. Temperatures vary inside the compartment. The temperature-control sensor reacts to the temperature of the evaporator rather than to that of the air in the compartment, resulting in varying temperatures in the refrigerator as the ambient temperature changes (1).

3.4.5 Freezers

Ideally, frozen vaccines should be stored in a separate, designated, frost-free freezer unit at –15° C (+5°F) or colder. However, the freezer compartment of domestic frost-free refrigerators may be used if it has a separate condenser. If a separate condenser is not present in the freezer compartment of a combination fridge/freezer unit the freezer should not be used for the storage of vaccines, as these units cannot maintain the recommended temperatures (7).

3.4.6 Equipment Placement

Good air circulation around the vaccine storage unit is essential for proper heat exchange and cooling functions. The unit should be placed in a well-ventilated room not accessible to the public and should have space around the sides, top, and back. Leave at least 10 cm/4 inches of space (or as recommended by the manufacturer) between the back of the unit and the wall. If the unit has coils on the back, measure 10 cm/4 inches from the coils to the wall. Nothing should be blocking the cover of the motor compartment, which is normally located at the back or the side of the unit. Make sure that the unit stands firmly and is level, and that the wheels or levelling legs are adjusted so that the bottom of the unit sits 2.5 cm/1 inch to 5 cm/2 inches above the floor. Do not place in direct sunlight, near a heat source, or along an outside wall, where the temperature of the wall can vary depending on the season (2). Vaccine storage units should ideally be on a dedicated circuit.

3.4.7 Recommended Temperature Range

Refrigerator

The refrigerator compartment should maintain temperatures between +2°C and +8°C (+35°F and +46°F). The temperature should never fall below +2°C (+35°F) or rise above +8°C (+46°F). Therefore, set the temperature mid-range to achieve an average of about +5°C (+41°F). This temperature setting will provide the best safety margin of temperature fluctuations within the +2°C to +8°C (+35°F to +46°F) range.

Freezer

Vaccines that must be frozen should be maintained at a temperature of –15°C (+5°F) or colder.

3.4.8 Setting and Stabilizing the Temperature

Only the vaccine coordinators or delegates should adjust the temperature of a vaccine storage unit.

Who Should Adjust the Temperature?

Only the designated vaccine coordinators or delegates should adjust the temperature of a vaccine storage unit. Limiting access to the thermostat reduces the risk that the temperatures will be adjusted inappropriately. If the thermostat requires adjustment, alert the designated vaccine coordinator or delegate.

A warning sign should be posted on the storage unit that says, "Do not adjust refrigerator or freezer temperature controls. Notify primary vaccine coordinator or the back-up/ delegate coordinator if adjustments are necessary."

Thermostats

Refrigerator and freezer thermostats are marked in various ways, depending on the brand. In general, thermostats do not show temperatures but, rather, the levels of coldness. For example, some have a series of numbers or letters on the control knob. Others may have "MIN," "MED," and "MAX" marked on the knob. The only way to know the temperature inside the unit is to measure it with a thermometer. In combination refrigerator and freezer units, the thermostat actually controls the volume of cold freezer-temperature air that goes into the refrigerator. Consult the manufacturer's guidelines for instructions on how to operate the thermostat.

How to Adjust the Temperature

Use caution in adjusting a thermostat. Normal defrost cycles and opening of the door can lead to slight temperature variations inside the unit that are not necessarily indicative of inappropriate vaccine temperatures (7). The goal should be to stabilize the freezer's temperature at –15°C (+5°F) or colder and the refrigerator's temperature at +5°C (+32°F).

To adjust the temperature:

- Be sure the unit is plugged into the power source.
- If necessary remove all vaccines and store appropriately.
- Check the temperatures inside the refrigerator and freezer compartments.
- Check the data from the temperature-monitoring device, to verify that a temperature reset is appropriate.
- Adjust the temperature indicator slightly toward a warmer or colder setting as necessary. Adjust the thermostat slowly so as not to exceed the recommended temperature range.
- Allow the temperature inside the unit to stabilize for **half an hour** then recheck the temperature. Adjust the thermostat again as necessary.
- Always strive for +5°C (+32°F) to stabilize the refrigerator temperature. Make sure the temperature does not fall below the lower limit or rise above the upper limit of the recommended refrigerator temperature range of +2°C to +8°C (+35°F to +46°F).[1]
- Be sure the temperature in the refrigerator has stabilized before returning vaccines that have been removed.

Combined domestic refrigerator and freezer units use a cooling system that directs cold air from the freezer compartment into the main refrigerator compartment. Therefore, be careful when adjusting the freezer temperature because this will affect the temperature of the air venting into the refrigerator compartment. Without careful and frequent temperature monitoring inside the refrigerator compartment, there is a danger of freezing the refrigerated vaccines. For this reason it is recommended that only the refrigerator compartment of a domestic combination unit be used for vaccine storage. Vaccine storage in the freezer compartment should be avoided (7), unless it is a purpose-built combination refrigerator and freezer unit.

Allow 1 week of twice daily refrigerator and freezer temperature recordings before using a newly installed or newly repaired refrigeration unit to store vaccines.

Frequent temperature monitoring of both the freezer and refrigerator compartments throughout the day, as well as at the beginning and end of the workday, is required whenever thermostats are adjusted. **The temperature in a newly installed or newly repaired refrigerator may take 2 to 7 days to stabilize within the recommended range of +2°C to +8°C (+35°F to +46°F). The temperature in a newly installed or newly repaired freezer unit may take 2 to 3 days to stabilize within the recommended range of –15°C (+5°F) or colder. Allow 1 week of twice daily refrigerator and freezer temperature recordings before using the unit to store vaccines.**

[1] In the event of a power outage, follow established procedures depending on the length of time of the power outage. See *Power Outages* in *Section 6.5: Storage Troubleshooting* for more details.

Consider re-loading the refrigerator with vaccines at the beginning of a work week. Monitor newly adjusted fridge temperatures closely after loading with vaccines. The presence of vaccines has a major impact on the temperature of the refrigerator, especially when domestic models are being used (8, 9).

To maintain the cold chain during any period when the refrigerator or freezer is out of service, vaccines should be temporarily stored in a temperature-monitored alternative vaccine storage unit until the temperature in the original unit can be stabilized within the recommended range. Another option is to store the vaccines in an appropriately packed cooler if the storage unit will be out of service for a short time and vaccine-appropriate temperatures can be maintained in the cooler for the time required. See *Section 9: Vaccine Distribution* for more details.

3.4.9 Factors Affecting Temperature Variations

Temperatures can vary in a vaccine storage unit according to the contents/load, seasonal temperature variation, how often the door is opened, and power interruptions. The only way to be sure the temperature in the storage unit has remained within the recommended range is to frequently monitor and record the temperature using a minimum and maximum (min/max) thermometer or data logger. See *4.2.3 Know the Refrigerator* in *Section 4: Vaccine Storage Practices* for more details.

Avoid unnecessarily opening the refrigerator door. Minimize door openings to not more than four times a day.

Opening the Door

Limit the number of times the vaccine storage unit doors are opened, and avoid letting the doors stand open unnecessarily as this can affect the temperature in the unit (which can affect the potency of some vaccines). Routinely check the doors throughout the day and at the end of the day to ensure that they are tightly closed. Some units have alarms to notify users that the door has been left open; ensure that the alarm feature is on at all times.

Stabilizing the Temperature with Water Bottles and Frozen Packs

You can help stabilize the temperature in the refrigerator by keeping containers of water inside it. Store the water bottles in the crisper area, in the door racks, and/or against the inside walls and floor of the refrigerator. You can help stabilize the temperature in the freezer by keeping frozen packs or ice trays inside. Store the frozen packs along the walls, back, and bottom of the freezer compartment and inside the racks of the freezer door. Not only will water bottles and frozen packs help maintain an even temperature in the compartments with opening and closing of the doors, they will also help keep the temperatures stable longer in the event of a power failure.

Vegetable Bins ("Crispers")

Consider removing the vegetable bins from the refrigerator if a domestic frost-free refrigerator is being used. Removing the bins not only provides extra space for storing containers of water but it also removes the temptation to use the bins for storage of food, beverages, or vaccines. Vaccines should never be stored near the floor of the refrigerator in the vegetable bins because the temperature in this area is different from that in the body of the refrigerator. See *4.2.3 Know the Refrigerator* in *Section 4: Vaccine Storage Practices* for more details.

When to Adjust the Temperature

The refrigerator and freezer temperatures should be adjusted if they are outside the recommended range or if, over time, the temperature appears to be moving toward the upper or lower temperature limit. See *Section 6: Storage Troubleshooting* for more details.

In some situations, the thermostat may need to be reset in summer and winter, depending on the ambient temperature.

3.5 Refrigerator and Freezer Maintenance

3.5.1 General Principles

The most important action to take if the vaccine storage unit is not working properly is to protect the vaccine supply.

Regular maintenance is required to achieve proper operation, to maintain required temperatures, and to extend the useful life of the appliance.

The most important action to take if the vaccine storage unit is not working properly is to protect the vaccine supply. Move the vaccine to a properly functioning storage unit with appropriate temperatures. After this has been accomplished, attempt to find the cause of the problem and correct it. See *Section 6: Storage Troubleshooting* for more details.

3.5.2 Daily Maintenance Tasks

Check The Internal Temperature

The temperature inside each compartment of the vaccine storage unit must be checked with a calibrated thermometer at least twice each day.

The minimum and maximum temperature inside each compartment of the vaccine storage unit must be checked with a calibrated thermometer and recorded numerically on a temperature log at least twice each day: in the morning before the fridge door is first opened and once at the end of the day when the door is closed for the last time. (See *Section 5: Temperature Monitoring* for more details, and see *Appendix I: Temperature Log for Vaccines and Vaccine Storage Troubleshooting Record* for an example of a temperature log that may be used or adapted.) More frequent temperature monitoring is required following thermostat adjustments. The temperatures should be recorded on a temperature log and/or charted on a graph for visual focus when it is outside the optimal temperature range. If the temperature is outside the recommended range, the designated vaccine coordinator or delegate should be notified without delay. **Immediate action must be taken**. To facilitate response in such circumstances, the cold chain break protocol should be posted in an accessible location on or adjacent to the refrigerator. See 6.1 *Steps in Handling Inappropriate Vaccine Storage Conditions (Light and Adverse Temperature Exposure)* in *Section 6: Storage Troubleshooting* for more details.

NOTE: There is a potential for equipment failure of automated temperature recorders, therefore it is recommended that staff check and record temperatures twice daily as a quality assurance measure.

Check That the Doors are Closed

To maintain internal temperatures within the recommended ranges, the doors of the vaccine storage unit must fit securely and tightly against the unit. The rubber-like seals that run around the inner edges of the doors contain magnets that help hold the doors closed and create tight seals, keeping cold air inside. Check that the doors are properly sealed by giving a gentle tug on the door handle or sliding door. The doors should also be checked at the end of each day to make sure that they are properly closed and sealed. Installing an inexpensive Velcro™ latch from a hardware store can help ensure that the door is not accidentally left ajar. See *6.3.1 Checking the Door Seal* in *Section 6: Storage Troubleshooting* for more details.

Check that doors are properly sealed each time they are closed and at the end of each day.

3.5.3 Quarterly Maintenance

Clean the Coils and Motor

The vaccine storage unit coils, if exposed, should be examined and cleaned at least quarterly. Dust and dirt buildup affects the transfer of heat from the coils and, therefore, the efficiency of the unit. Unplug the unit and use a soft brush, cloth, or vacuum cleaner with an attachment hose to remove any dirt or dust from the surface of the coils. After cleaning, plug in the unit and document that the power is restored and that the temperature has been maintained. Avoid cleaning the coils and motor at the end of the week. Accidentally damaging the coils will cause a problem that may not be detected until the start of the following week.

NOTE: This process should take only a few minutes; therefore, it is not necessary to transfer the vaccine to another storage unit as long as the doors remain tightly closed for the duration of the procedure.

Clean the Refrigerator and Freezer Compartments

Clean the refrigerator and freezer compartments quarterly or as needed. Remove the vaccines from the compartments and store them in an alternative storage unit. Unplug the unit or turn off the power and wash all inside surfaces and shelves with warm, slightly soapy water. Dry thoroughly; then plug in the unit or turn the thermostat back to an appropriately cold setting. Wait for the unit to reach and stabilize at the proper temperature range, monitoring and recording the temperature every half-hour for the next few hours. Restock each compartment with vaccine, continuing to monitor and record the temperature every half-hour for the next few hours.

Check the Door Seals

Quarterly, check the integrity of the rubber-like door seals. They should not be torn or brittle and there should be no gaps between the seals and the body of the unit when the doors are closed. The doors should open and close properly and fit squarely against the body of the refrigerator. For this to happen, the hinges must be correctly adjusted. If there are any problems with the door seals, consult a technician as necessary and monitor temperatures carefully. (See *6.3 Refrigerator and Freezer Door Problems* in *Section 6: Storage Troubleshooting* for more details.)

See *Appendix H: Refrigerator and Thermometer Maintenance and Monthly Vaccine Inventory* as an example form that may be used or adapted to record and summarize any maintenance that is completed.

3.6 Thermometers and Temperature Monitors

Always use a thermometer that has been calibrated within ±0.5°C (±1°F).

All thermometers are calibrated (given a temperature scale) during manufacture. Not all models of min/max thermometers are calibrated with the same scale and may have different accuracies and resolutions. Please check with the manufacturer for the accuracy of the thermometer.

Calibration should be accurate within ±0.5°C (±1°F). Avoid using thermometers that have not been calibrated to be accurate within ±0.5°C (±1°F). See *Section 3.7: Thermometer Maintenance* below for more details.

3.6.1 Temperature-Monitoring Devices

Overview

Immunization providers must be familiar with their jurisdiction's requirements for temperature-monitoring equipment. Each jurisdiction must make a decision about which type(s) of appropriate temperature-monitoring device(s) to use, depending on the needs and unique requirements of the site, the size and type of refrigerator and/or freezer used, and the amount of vaccine that the unit is to hold. The type of temperature-monitoring device will change with time, as new technology becomes available. Each jurisdiction must evaluate and decide which device(s) to use on the basis of current available evidence.

The only thermometers and temperature-recording devices recommended for monitoring the temperatures within vaccine storage units are thermometers that provide continuous recording or min/max thermometers that are properly monitored.

The only thermometers and temperature recording devices recommended for monitoring the temperatures within vaccine storage units are thermometers that provide continuous recording or min/max thermometers that are properly monitored. These types of thermometer are preferred because they provide an indication of the length of time a storage compartment has been operating outside recommended temperature ranges when a cold chain break occurs. The min/max thermometer must be reset regularly (after properly recording temperatures) for useful readings. See Table 3 for a summary of the major types of monitoring device available for use. Please note that specific models will have slight differences in their functionality and will need to be evaluated according to the program/jurisdictional needs.

TABLE 3. TYPES OF TEMPERATURE-MONITORING DEVICES – A SUMMARY

RATING	TYPE OF TEMPERATURE-MONITORING DEVICE	DESCRIPTION	RECOMMENDED USAGE
Recommended	**Digital data logger** ■ Single use ■ Ongoing use	A battery operated unit that continuously monitors the temperature; has an alarm alert. Data are downloaded with appropriate software. Depending on the jurisdictional program, this may be done at the site of delivery, or the data logger may need to be returned to the distributor. ■ Some single-use data loggers can be set to indicate specific conditions and have a process by which to access and interpret data directly.	Single use: ■ transport of vaccine; vaccine away from fridge for any reason Ongoing use: ■ vaccine storage units **NOTE:** may be used in conjunction with min/max thermometer.
	Digital min/max thermometer with a glycol-enclosed probe	A battery-operated monitoring unit that displays current temperature and minimum/maximum temperature since last reset. The glycol-enclosed probe attached to the monitoring unit by a 1 to 3 metre cable allows the temperature of the vaccine (not the air) to be read without opening the door. Has an alarm alert.	Monitoring vaccine storage unit temperatures. ■ Probe is placed in the centre of the vaccine storage unit and a screen is mounted outside of the storage unit: temperature should be recorded at least twice daily. ■ The unit must be reset after each reading.

(continued on next page)

RATING	TYPE OF TEMPERATURE-MONITORING DEVICE	DESCRIPTION	RECOMMENDED USAGE
Acceptable	**Digital min/max thermometer without glycol-enclosed probe**	A battery-operated monitoring unit that displays current temperature and minimum/maximum temperature since last reset. There may be a probe to enable the unit to be accessed outside of the vaccine storage unit. Has an alarm alert. ■ Measures air temperature inside unit vs temperature of vaccine, therefore less accurate measure.	Monitoring vaccine storage unit temperatures. ■ The unit must be reset after each reading. ■ Units without probe can only be read by opening the door.
	Cold chain monitors *(see Section 3.8)*	Heat or freeze single-use indicators that provide a visual indication when temperatures have been either above (heat) or below (freeze) preset temperatures.	Transport of vaccines
	Strip monitors	Battery-powered single use units that record continuous temperature readings on a paper strip.	Transport of vaccines
	Chart recorders	Unit containing graphs and pens that record temperatures on paper over time. Graph paper must be changed on a weekly or monthly basis. Other temperature-monitoring devices should be used for daily temperature monitoring.	Monitoring temperatures of vaccine storage units if access to computer and digital units is not feasible. ■ Harder to read and interpret temperatures.
Not Recommended for Vaccine Storage Unit Temperature Monitoring	**Fluid-filled biosafe liquid thermometers**	These devices can be difficult to read and only indicate the temperature at the precise time they are read. There is no memory, so any fluctuations of temperature will not be available.	Not recommended for use.
	Bi-metal stem thermometers		Not recommended for use.
	Household mercury thermometers		Acceptable for reading ambient room temperature only.

Temperature-Monitoring Devices Recommended and Acceptable For Use

1) Digital Thermometers

Digital thermometers have a screen in which the temperature is displayed in Fahrenheit and/or Celsius. When specific digital thermometers are being evaluated the best model to choose will have the following:

- A display of current, minimum, and maximum temperatures.
- Two components: a display that mounts to the outside of the unit and a glycol-enclosed probe on a cord (usually 1 to 3 metres long) that is placed in the centre of the vaccine storage unit, as this arrangement allows the temperature to be read without opening the door.
- An alarm that can be set to ring at a specified temperature. An alarm that rings outside the storage unit is preferable to one that rings inside it.

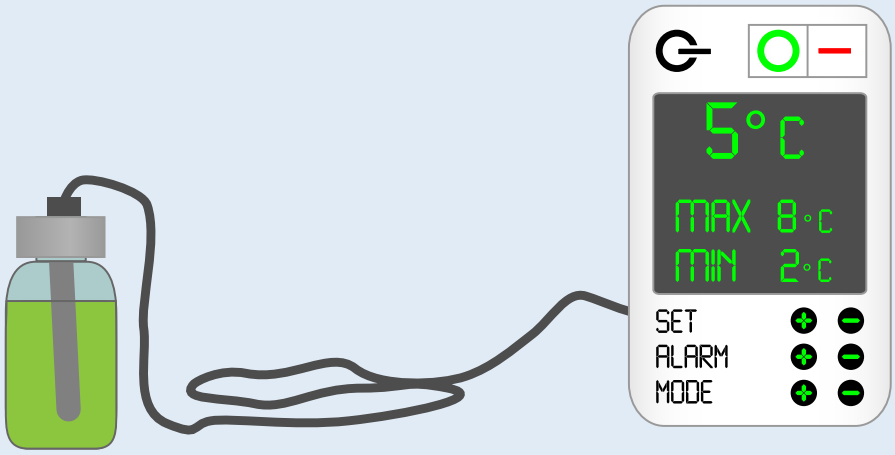
Fluid-filled biosafe liquid thermometers, bi-metal stem thermometers, and household mercury thermometers are NOT recommended for monitoring temperatures in vaccine storage units.

Digital thermometers with a min/max feature 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 referring to the minimum and maximum temperature readings. The digital thermometer must be reset after each properly recorded temperature for useful readings. Glycol-encased probes are preferred, as they more closely mimic vaccine temperatures and do not react to the short fluctuations in air temperature frequently associated with opening of the refrigerator door (7). This provides a more relevant reading and is therefore recommended as best practice.

A limitation of min/max thermometers is that readings do not indicate when the exposure occurred and the exact length of time the vaccines were exposed to the out-of-range temperatures.

NOTE: Many purpose-built refrigerators have built-in thermometers with minimum and maximum temperature settings.

FIGURE 1: MIN/MAX THERMOMETERS



2) Data Loggers

Digital data loggers are miniature, battery-powered, stand-alone temperature monitors that record hundreds or thousands of temperature readings. These are the ideal temperature monitors because they can indicate **when an adverse temperature exposure occurred and how long the vaccines were exposed to the min/max temperatures**. Data loggers may be for single use and used only in transport, or they may be for multiple use.

Single-use data loggers have an external alert (usually lights or symbols) that alert the user to out-of-range temperature events. Interpretation of the alert is specific to the data logger, and the manufacturer's guidelines will need to be followed. Each jurisdiction will have guidelines as to how single-use data loggers are used. Multiple-use digital data loggers are accompanied by special 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 time spent at each temperature. Data loggers should be replaced or re-calibrated annually.

Monitor for a visual alarm whenever going into the fridge. Each jurisdiction will have recommendations relating to use of a data logger; however, temperature should be documented at least daily. This can be accomplished by downloading data daily, i.e. each morning to monitor overnight temperatures or on a weekly basis (or as per jurisdiction guidelines) if using the data logger in combination with a min/max thermometer. A download should be done immediately if there is any indication that there has been a temperature excursion.

3) Cold Chain and Strip Monitors

Cold chain monitors and strip monitors are used to monitor temperatures during the transport of vaccines. Cold chain monitors are either heat or freeze indicators that change colour when exposed to temperatures either above or below the required range. See *Section 3.8: Cold Chain Monitors* below for more details. Strip monitors are battery-powered, single-use units that record continuous temperature readings on a paper strip.

4) Chart Recorders

Chart recorders consist of a graph (wheel or linear) with replaceable graph paper and ink pens. The pens mark the temperature on the graph paper over time. Temperatures are recorded continuously, 24 hours a day. 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 graph paper must be changed when it completes a full round, usually weekly or monthly. The chart recorder must be used as per the manufacturer's instructions: generally, the date is recorded on the graph paper when it is fitted and when the graph paper is removed or changed. Temperature monitoring records should be kept for a minimum of 3 years, unless local jurisdictions have other guidelines. As with other types of monitor, temperature readings should be checked and recorded twice daily.

Some chart recorders have temperature probes. Chart recorders are more difficult to read than digital thermometers because they require interpretation of the temperature graph.

Temperature-Monitoring Devices That Are Not Recommended for Monitoring Temperatures Inside Vaccine Storage Units

Fluid-filled biosafe liquid thermometers, bi-metal stem thermometers, and household mercury thermometers

Fluid-filled biosafe liquid (bottle) thermometers, bi-metal stem thermometers, and household thermometers **are not recommended** for temperature monitoring in vaccine storage units. They can be difficult to read and only indicate the temperature at the precise time they are read, therefore temperature fluctuations outside the recommended range may not be detected.

3.6.2 Thermometer Placement

The sensing device of the temperature monitor should be placed in the centre of the vaccine storage unit away from the coils, walls, door, floor, and fan. The monitor portion should be easily accessible, preferably mounted on the outside of the vaccine storage unit to minimize the number of times the door to the unit is opened.

When using units with probes, the probes should be suspended in the centre of the compartment or placed in a diluent or vaccine box. It is important to ensure that air flow around the sensor is not blocked.

3.7 Thermometer Maintenance

3.7.1 Checking the Accuracy of the Thermometer

Thermometers Should be Checked Every 6 Months to a Year to Establish the Following:

- Temperature calibration is accurate (see *Slush Test* below).
- Batteries are functioning. Maintain and change batteries as recommended by the manufacturer, keeping in mind warranty requirements. Batteries should be changed every 6 months to a year.
- Cables or probes are not damaged.
- Vials of fluid that the probes sit in are intact and have adequate volume.
- There is an adequate supply of graph paper and ink pens for chart recorders.

All of these may affect accuracy in temperature readings.

Slush Test

The accuracy of a thermometer can be checked using the following test:

1) Fill a polystyrene or plastic cup two-thirds full with cold water. 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). If ice is present, this ensures that the mixture is at 0°C (+32°F).
2) Place the temperature probe in the middle of the cup (do not touch the sides or bottom).
3) Observe the temperature after 2 minutes. The temperature should drop to 0°C (+32°F) within 2 minutes.

Most thermometers are calibrated to be accurate to ±1°C or better. If the temperature reading is more than 1°C (+34°F) above or below 0°C (+32°F) at 2 minutes, replace the battery and test again. If the thermometer is still not within range, contact your thermometer manufacturer for instructions regarding recalibration procedures or replace the thermometer. This test should be done at least once a year.

A less reliable method is to test thermometer accuracy against a reference thermometer. This is not recommended.

If the calibrated thermometer indicates an out-of-range temperature and if it is properly positioned, assume that it is accurate and take immediate steps to safeguard the vaccine. Once the vaccine has been safely stored under proper conditions, the accuracy (and batteries) of the thermometer can be checked. However, always check other causes of inappropriate storage temperatures first.

Use *Appendix H: Refrigerator and Thermometer Maintenance and Monthly Vaccine Inventory* to summarize maintenance completed.

3.8 Cold Chain Monitors

3.8.1 Using Cold Chain Monitors

Cold chain monitors (CCMs) are primarily used to monitor temperature thresholds when vaccine is shipped by manufacturers, commercial vaccine distributors, and government-managed vaccine depots. When the vaccine arrives at its destination, the CCMs should be checked immediately and the temperature inside the transport unit should be documented. If the CCM has been activated, the product should be quarantined in the fridge. **Do not assume that the exposed vaccine CANNOT be salvaged**. (See *Section 6: Storage Troubleshooting* for more details.)

3.8.2 General Principles

There are two basic types of cold chain monitor: those that indicate whether packages have reached temperatures that are too warm and those that indicate whether packages have reached temperatures that are too cold. These types of monitor are designed to be irreversible indicators of inappropriate temperatures once a temperature excursion has occurred above or below the activation set points. In general, CCMs are for single use only and should not be re-used.

Cold chain monitors should only be used during transport.

Cold chain monitors are not a substitute for twice-a-day temperature reading and recording. They should only be used to monitor the temperature of vaccine during transport.

NOTE: Each jurisdiction will decide which type(s) of appropriate cold chain monitor to use, depending on the needs and unique requirements of the site and the amount and type of vaccine that is to be shipped.

3.8.3 Types of Cold Chain Monitors

Heat Indicators

Heat indicators, also known as time and temperature indicators, are made for single use only. Heat indicators that are appropriate for vaccine shipping have an activation temperature of +10°C (+50°F) and a run-out time of 48 hours to 7 days.

A heat indicator releases a coloured dye into the windows of the device when the temperature has exceeded the threshold or activation temperature (indicated on the device). The dye gradually moves through the windows over time. Once activated, the process is irreversible. If the temperature drops below the threshold again, the dye stops moving but does not disappear. Therefore these indicators also show the length of time in hours or days that the temperature has exceeded the desired range. Response cards are used to interpret the time and temperature relationship for each indicator.

The heat indicator must be preconditioned **below** its threshold response temperature before use; check manufacturer specifications for the length of conditioning time and the appropriate conditioning temperature.

In general, heat indicators are preconditioned in the refrigerator. This ensures that the dye inside the indicator is in a solid state when the activation tab is pulled. The activation strip needs to be removed to start the monitor—this allows for the coloured marker to melt and stain the porous wick as it undergoes temperature excursions above its threshold temperature. If the dye is not in a solid state, it will start moving down the track of the indicator and through the windows, producing an inaccurate reading.

Always attach the indicator to a vaccine vial or box; do not attach it to the transport box. If the surface to which the indicator is attached is at a temperature above the threshold of the indicator, the indicator will activate prematurely. Once the indicator is preconditioned, pull the activation tab, and place it and the vaccine into the environment to be monitored. This allows the indicator strip and reservoir pad to come in direct contact with each other and begins the temperature monitoring process. Like vaccines, heat indicators will have an expiration date and should be checked for these dates routinely.

Freeze Indicators

Freeze indicators are made for single use only. Unlike heat indicators, freeze indicators do not indicate the length of time vaccine has been exposed to temperatures outside the recommended temperature range. Freeze indicators appropriate for vaccine shipping have an activation temperature of 0°C (+32°F) or below.

A freeze indicator uses coloured liquid to indicate exposure to freezing temperatures. In some models, the freeze indicator has a clear indicator bulb; when the temperature drops below the threshold freezing point, the indicator bulb irreversibly changes colour. The indicator does not require preconditioning and may be attached to any clean dry surface in the environment being monitored. There is no activation tab to pull; the indicator is working at all times.

Other freeze indicators use a specially designed ampoule filled with dye; when the temperature drops below the freezing threshold, the ampoule breaks and releases the dye that irreversibly stains the paper behind the ampoule. This type of freeze indicator requires preconditioning in a temperature above the freezing threshold; check the manufacturer's specifications for the duration of this preconditioning period. Leaving it out at room temperature will meet this requirement.

For freeze indicators that require preconditioning, attach the indicator after preconditioning to any clean dry surface in the environment being monitored. There is no activation tab to pull. To determine whether the product has been exposed to freezing temperatures, observe the paper behind the ampoule. If it is stained with colour, the product being monitored was exposed. If there is no colour, remove the indicator from the surface to which it is attached and gently but vigorously tap the bottom edge of the device three times on a hard surface. If the paper becomes stained, the product being monitored was exposed. Tapping will not cause colour staining in an unexposed indicator.

Like vaccines, freeze indicators have an expiration date that should be checked routinely.

3.9 Vaccine Security

3.9.1 Protecting the Power Supply

To protect vaccine supply within the proper range, the vaccine storage unit must be in good working condition and have power at all times.

To prevent problems with the power supply:

- It is preferred to have a dedicated circuit for the fridge (i.e. have nothing else plugged into the circuit). Avoid using power outlets with built-in circuit switches and outlets that can be activated by a wall switch.
- Use a safety-lock plug or an outlet cover.
- Post a warning sign at the plug and on the storage unit alerting others not to unplug the unit.
- Label the fuses and circuit breakers to alert others not to turn off the power to the vaccine storage unit.
- Consider installing a temperature alarm with 24 hour and 7 days a week monitoring, especially for large vaccine inventories.

3.9.2 Temperature Alarms

A continuous-monitoring temperature alarm or notification system should be considered, especially for vaccine storage units with large or expensive inventories, to help prevent substantial financial loss in the event of a cold chain break. These systems help alert staff to after-hours emergencies. Simple systems sound audible alarms when the temperatures inside the storage units exceed the recommended ranges. A system that sounds an audible alarm and alerts one or more designated person(s) at a specified ‘phone or pager number is preferable. For larger or centralized depots, alarms should be monitored 24 hours a day and 7 days a week by external sources that maintain a fan-out list of contacts. External monitoring services should be tested occasionally (like a fire drill) to ensure that the service is able to function properly in the event of an actual cold chain break. This drill should be done outside of operational hours, for example, during a weekend when regular staff are unavailable.

3.9.3 Backup Generators

Facilities storing large or expensive vaccine inventories should install backup generators that automatically provide power to the storage units and maintain the recommended storage temperatures in the event of power outages. Use of backup generators must be linked with 24 hour monitoring and SOPs in place for power outages. Backup generators should be tested quarterly and should receive maintenance at least annually (check the manufacturer's specifications for test procedures and maintenance schedules). Backup generators should be of sufficient capacity to run continuously for 72 hours if necessary. Plans should be made to ensure that an adequate supply of fuel is on hand. See both *2.3 Routine Vaccine and Storage Handling Protocols* and *2.4 Urgent Vaccine Storage and Handling Protocols* in *Section 2: Vaccine Personnel and Vaccine Storage and Handling Protocols* and *Section 6: Storage Troubleshooting* for more details.

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National Vaccine Storage and Handling Guidelines for Immunization Providers

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4.1 Appropriate Vaccine and Diluent Storage Conditions

Proper vaccine storage and handling procedures include (but are not limited to) the following:

- Monitoring the minimum and maximum temperature of the refrigerator(s) and freezer(s), as well as the room temperature, for a minimum of twice daily.
- Recording temperature data on the temperature logs for a minimum of twice daily, or, if using an automated recording system with alarm, downloading temperature data for a minimum of once weekly (**NOTE:** even if using an automated recording system, the real-time temperature must still be checked daily).
- Organizing staff to minimize the number of times the refrigerator is opened during the course of the day.
- Placing a latch on the fridge to ensure that the door is not accidentally left ajar.
- Planning for and responding to storage temperatures outside the recommended range.
- Maintaining storage and handling equipment, and records.
- Rotating vaccine stock so that vaccine closer to its expiration date will be used first.
- Monitoring expiration dates on vaccines and ensuring that expired vaccine is not administered to clients.
- Ordering vaccines to maintain an appropriate supply (generally no more than a 1-month supply or a sufficient quantity to meet seasonal or outbreak demands).
- Establishing a clear structure for oversight of proper receipt, storage, and transport of vaccine.

4.1.1 Maintaining and Updating Vaccine Information

It is recommended that all facilities maintain a resource binder or chart that outlines the basic shipping and handling information for each vaccine provided by the facility. The information should be updated regularly.

It is recommended that all facilities maintain a resource binder or chart that outlines the basic storage and handling information for each vaccine provided by the facility. This should be updated when new information and products become available. This information should be readily accessible to all providers.

Basic information on each vaccine should include the following:

- Shipping requirements (if applicable).
- Storage requirements.
- Shelf life (expiry date).
- Instructions for reconstitution (if applicable).
- Shelf life (expiry date) of multidose vaccines after opening.
- Special instructions.

4.1.2 Light Exposure

All vaccines should be stored with the caps on in their original boxes until they are needed, to protect them from sunlight and fluorescent light exposure. Studies have shown that both ultraviolet light and fluorescent light cause damage to certain vaccines (1, 2). As with exposure to adverse temperatures, the deleterious effects of light exposure on light-sensitive vaccines are cumulative (3). Therefore, vaccine products should be protected from light exposure at all times (see *Section 1: Cold Chain* for references regarding light-sensitive vaccines).

4.1.3 Refrigerated Vaccines

Most vaccines are refrigerator-stable products and should be stored in a refrigerator at +2°C to +8°C (+35°F to +46°F), with a desired average temperature of +5°C/+41°F (mid-point that allows for a ±3°C/±5.4°F buffer). Refrigerator-stable vaccines are sensitive to both excessive heat and freezing. Exposure to temperatures outside of the allowed range may result in decreased vaccine potency and increased risk of vaccine-preventable diseases. For vaccines requiring refrigeration, as with all vaccine products, always refer to the product monograph for the most up-to-date information on storage information.

4.1.4 Frozen Vaccines

While most live vaccines are licensed as refrigerator-stable products in Canada, some live vaccines must be stored in a continuously frozen state at –15°C (+5°F) or colder until administration. If the vaccine requires storage in a frozen state and is received frozen from the vaccine supply source, it must be stored in the freezer. Do not refreeze vaccines unless refreezing is allowed by the vaccine manufacturer (for example, unreconstituted lyophilized [freeze-dried] vaccines are not affected by repeat exposures to freezing temperatures). However, it is best practice to always refer to the product monograph for the most up-to-date information on storage information.

4.1.5 Diluents

Use only the diluent provided by the manufacturer with its corresponding lyophilized product. Diluents are not interchangeable.

Some vaccines are packaged separately in two different parts – a lyophilized (freeze-dried, powdered) component and a liquid diluent. The two parts must be reconstituted (mixed) before administration. There are different types of diluent, each specific to the vaccine that it accompanies. It is essential that only the diluent provided by the manufacturer for each specific vaccine be used with the corresponding lyophilized product.

If the incorrect diluent is used with the lyophilized component, contact the vaccine manufacturer to determine what steps should be taken. Depending on the situation and the vaccine, re-immunization may or may not be necessary.

Often the diluent consists of sterile water or a sodium chloride solution and may not require refrigeration, but some liquid diluents contain live vaccine and thus must be kept in the refrigerator. Always refer to the product monograph for information on the proper storage of diluents.

Diluent that consists only of sterile water can be stored at room temperature or in the refrigerator. To conserve space, these diluents may be stored in the door of the domestic refrigerator.

Diluent that has been frozen should not be used because of the risk of fractures in the vial that may cause contamination. Appropriate actions should be taken to isolate and dispose of the vials according to your jurisdictional/local public health office or immunization program recommendations (refer to *Section 10: Vaccine Disposal* for more information).

4.1.6 Stability Guidelines

New vaccine development has increased dramatically in recent years. The increasing number of and changes in licensed products make it very difficult to keep a table of vaccines and their stability guidelines current. The availability of specific recommendations may vary at any given time. For the latest information about product storage and handling, vaccine providers are asked to consult their jurisdictional/local public health office or immunization program.

4.2 Organizing Your Refrigerator And Freezer

The organization of a refrigerator and freezer must take into account vaccine requirements, convenience for staff, and the technical features of the refrigerators and freezers.

4.2.1 Refrigerated Vaccines

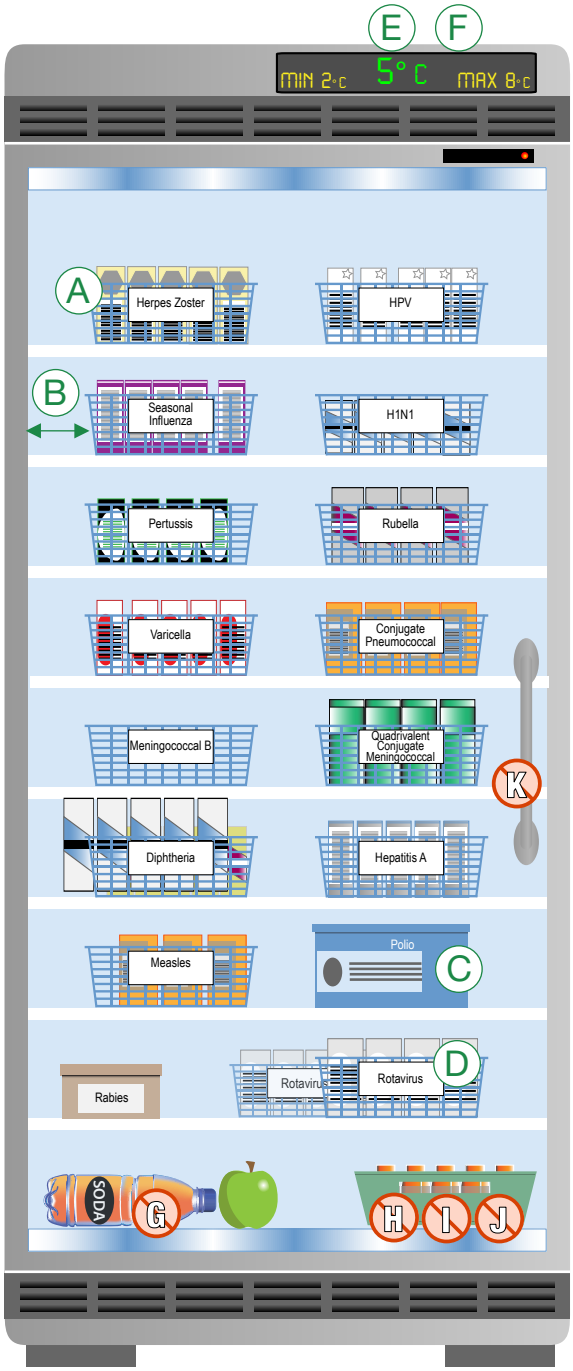
In the refrigerator, vaccine should be stored in the middle of the compartment away from the coils, walls, floor, and cold-air vent. The temperature near the floor of the refrigerator is not stable and differs from that in the middle of the compartment. For this reason, **vaccines should never be stored in the vegetable bins** of a domestic refrigerator. **Additionally, vaccines should not be stored in the refrigerator door.** The temperature in the door is not stable because door openings subject products in this location to frequent temperature fluctuations. If a freezer compartment is present in the unit, refrigerated vaccines should always be stored far enough away from the air venting from the freezer compartment to avoid freezing.

Figure 1 summarizes how a purpose-built refrigerator should be organized.

Figure 2 provides the same information for domestic refrigerators.

Figure 3 summarizes the *Do's* and *Don'ts* for each.

FIGURE 1: ORGANIZING THE PURPOSE-BUILT REFRIGERATOR



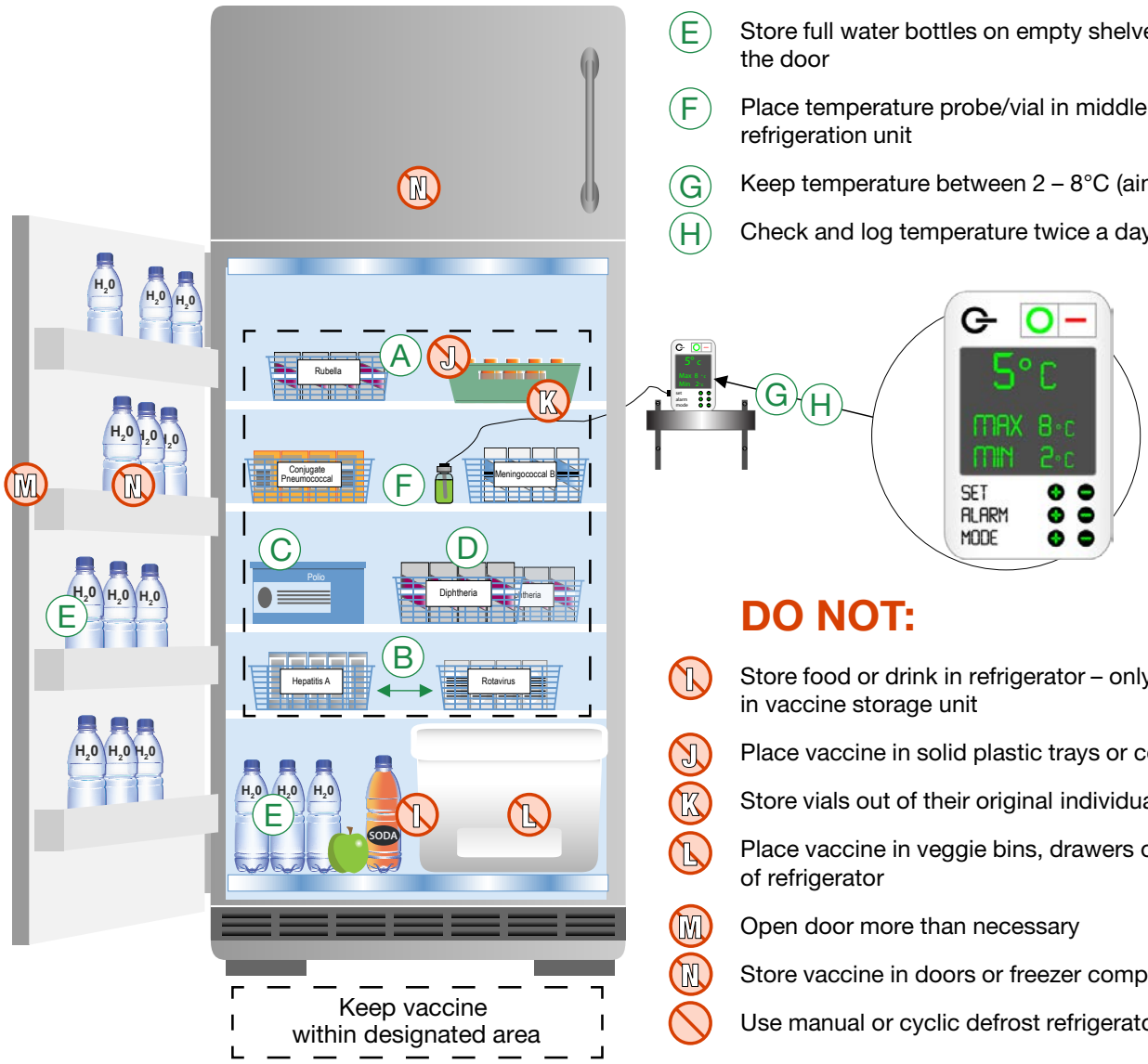
DO:

- (A) Place vaccine in breathable plastic mesh baskets and clearly label baskets by type of vaccine
- (B) Keep baskets 5 – 8 cm from walls and other baskets
- (C) Keep vaccine in their original boxes until you are ready to use them
- (D) Keep vaccines with shorter expiration dates to the front of the shelf/basket
- (E) Keep temperature between 2 – 8°C (aim for 5°C)
- (F) Check and log temperature twice a day

DO NOT:

- (G) Store food or drink in refrigerator – only vaccine in vaccine storage unit
- (H) Place vaccine in solid plastic trays or containers
- (I) Store vials out of their original individual packaging
- (J) Place vaccine in drawers or on floor of refrigerator
- (K) Open door more than necessary

FIGURE 2: ORGANIZING THE DOMESTIC REFRIGERATOR



DO:

- (A) Place vaccine in breathable plastic mesh baskets and clearly label baskets by type of vaccine
- (B) Keep baskets 5 – 8 cm from walls and other baskets
- (C) Keep vaccine in their original boxes until you are ready to use them
- (D) Keep vaccines with shorter expiration dates to the front of the shelf/basket
- (E) Store full water bottles on empty shelves and on the door
- (F) Place temperature probe/vial in middle of refrigeration unit
- (G) Keep temperature between 2 – 8°C (aim for 5°C)
- (H) Check and log temperature twice a day

DO NOT:

- (I) Store food or drink in refrigerator – only vaccine in vaccine storage unit
- (J) Place vaccine in solid plastic trays or containers
- (K) Store vials out of their original individual packaging
- (L) Place vaccine in veggie bins, drawers or on floor of refrigerator
- (M) Open door more than necessary
- (N) Store vaccine in doors or freezer compartment
- Use manual or cyclic defrost refrigerators

FIGURE 3: SUMMARY OF "DO'S & DON'TS"

"DOs & DON'Ts" for purpose-built and domestic refrigeration units
DO
Place vaccine in breathable plastic mesh baskets and clearly label baskets by type of vaccine.
Keep baskets 5 – 8 cm from walls and other baskets.
Keep vaccine in their original boxes until you are ready to use them.
Keep vaccines with shorter expiration dates to the front of the shelf/basket.
Place temperature probe/vial in middle of refrigeration unit.
Keep temperature between 2 – 8°C (aim for 5°C).
Check and log temperature twice a day.
DO NOT
Store food or drink in refrigerator – only vaccine in vaccine storage unit.
Place vaccine in solid plastic trays or containers.
Store vials out of their original individual packaging.
Place vaccine in veggie bins, drawers or on floor of refrigerator.
Open door more than necessary.
Special notice for domestic refrigerators
DO store full water bottles on empty shelves and on the door.
DO NOT store vaccines in doors.
DO NOT use manual or cyclic defrost refrigerators.

Organization of your refrigerator and freezer must take into account vaccine requirements, convenience for staff, and the technical features of the refrigerator. In the refrigerator, vaccine should be stored in the middle of the compartment away from the coils, walls, floor, and cold-air vent. In the freezer, vaccine should be stored in the middle of the compartment away from the walls, coils, and peripheral areas.

4.2.2 Frozen Vaccines

Ideally, frozen vaccines should be stored in a separate, designated, freezer unit. However, for domestic refrigerators having a separate freezer compartment, frozen vaccine may be stored in the middle of the compartment away from the walls, coils, and floor. Vaccines should not be stored in the freezer door. The temperature in the door is not stable because door openings subject products in this location to frequent temperature fluctuations.

Frozen vaccines must be stored in a frost-free freezer at –15°C (+5°F) or colder. Freezers should be defrosted regularly. Vaccine products must not be stacked or placed so closely together that air circulation inside the freezer compartment is impeded.

It is important to know your refrigerator. Knowing the temperature gradients will help you to place your vaccines properly within the refrigerator. It is also important to know the factors that affect fluctuations in temperatures in the refrigerator.

4.2.3 Know The Refrigerator

Refrigerator technology can vary; it is thus not possible to make generalized statements on how to manage vaccines for all refrigerators. It is important that vaccine management staff "know the refrigerator" (4).

Most refrigerators have a temperature gradient, meaning that there is a gradual difference in temperature from one part of the refrigerator to another (5), for example, from top to bottom, side to side, and front to back. It is important to know each refrigerator's temperature gradients. The gradients will depend on how the refrigerator is cooled and/or where the plate evaporator is located. See *Section 3: Vaccine Storage Equipment* for more information on refrigerator temperature gradients.

To determine the gradients within your refrigerator, a recording device, such as a data logger, should be placed in each position for a minimum of 24 hours, preferably with at least two other recorders simultaneously placed in other parts of the unit. Depending on the type and number of recorders available, this could take some time and is best done when there is no vaccine in the fridge but, instead, with some sort of "cold mass" (e.g. cooled water bottles) to simulate a batch of vaccine. Knowing the temperature gradients (i.e. the "cold spots") will help you to place your vaccines properly within the refrigerator.

Temperatures for each location of the refrigerator can also fluctuate at any given time. For frost-free refrigerators, the defrost cycle can affect the temperature. Environmental factors may also affect the temperature, for example, the surrounding room temperature and the location of the refrigerator with reference to windows, heat sources, or air conditioning. It is also important to know what happens when there are changes in the weather, or a decrease or increase in use compared with usual daily activities, such as during holidays.

4.2.4 Vaccine Spacing

Overpacking the unit should be avoided, as this would prevent proper airflow.

Vaccine should be grouped by product, taking note to place products close to expiry near the front of the group for more immediate use. There should be space between the vaccine and the compartment wall, and space between each large vaccine box, tray, or container to allow for cold-air circulation around the vaccine. Overpacking the unit should be avoided, as this would prevent proper airflow. Adequate cold-air circulation helps each vaccine to reach a consistent temperature throughout its mass and is necessary for the storage unit to maintain a consistent temperature inside the compartment (6). Packing any vaccine storage unit too tightly will affect the temperature. Likewise, packing too much vaccine in one unit will affect the temperature (e.g. during peak flu season).

4.2.5 Placement of Vaccines

Vaccine products that have similar packaging should be stored in different locations to avoid confusion and medication errors. For example, if you have pediatric and adult versions of the same vaccine, storing them in different locations lessens the chance that someone will inadvertently choose the wrong vaccine.

Likewise, vaccines that have similar sounding names should be stored in different locations. For example, Tdap and Td vaccines might be easily confused, as could Hib and HB vaccines.

Vaccine formulations from different manufacturers are also best kept separate to avoid administration of an incorrect dose if the dosing schedule or series differs among brands of the same antigen.

4.3 Organizing Vaccine Inventory

4.3.1 Storage

Ensure that there is good air circulation in the vaccine storage unit by using vented trays and containers, and by adequately spacing them.

Vaccine and diluent should be stored in their original packaging. Storing loose vaccine vials makes inventory management more difficult and administration errors more likely, and it exposes the vaccines to light.

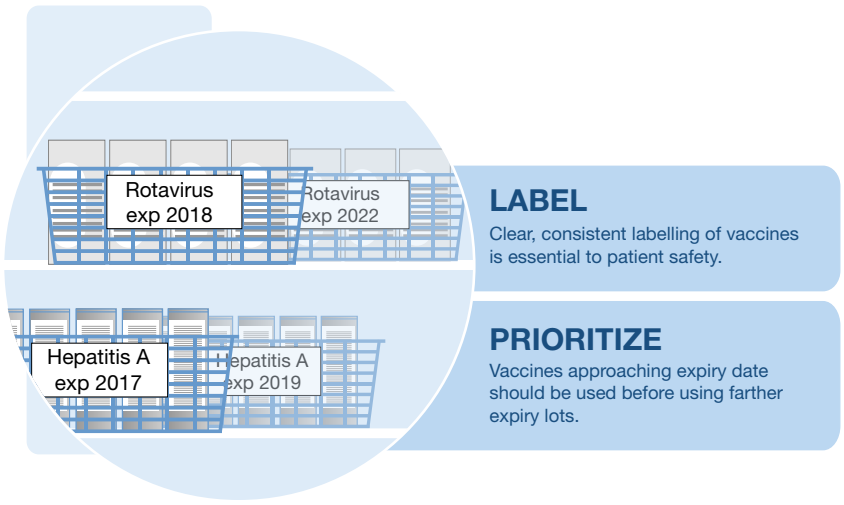
Trays and uncovered containers (including mesh baskets and vented bins) may be used to organize vaccine and diluent packages. Each tray or uncovered container should only store vaccine of the same type. Other medications and biological products, if they must be stored in the vaccine storage unit, must not be stored in the same trays or containers as the vaccines to avoid medication errors. Clearly label trays or containers.

Trays and containers may be stacked but must not be stacked or placed so closely together that air circulation inside the vaccine storage unit compartment is impeded. Trays and containers should be vented to allow air circulation. Never use air-tight containers.

4.3.2 Labelling

Clear, consistent labelling of vaccines is essential to patient safety.

The designated location of each specific vaccine inside the storage unit should be clearly labelled. This can be accomplished by attaching labels directly to the shelves on which the vaccines are placed or by labelling trays or containers in which packages of the same vaccine type are placed (3, 6). The labelling should be done in a reliable, consistent manner, using the appropriate brand name or national abbreviation. Storing each vaccine in its own specifically labelled section (including trays, containers, baskets, or bins) of the refrigerator or freezer helps decrease the chance that someone will mistakenly select the wrong vaccine. Each section should contain only one type of vaccine.



In addition to labelling the location of vaccines, mark each opened multidose vial with the **date** it was first punctured (either the date of puncture or the revised expiration date, depending on jurisdictional guidelines). Clearly mark reconstituted vaccine with the **date and time** it was reconstituted. Dating these vials is important for two reasons:

1) Some vaccines expire within a certain time after puncturing or after reconstitution. This may not correspond to the expiration date printed on the vial by the manufacturer. Follow manufacturer recommendations or jurisdictional guidelines for use of multidose vials and reconstituted vaccine.
2) Dating punctured or reconstituted vials helps manage vaccine inventory by identifying vials that should be used first.

Whenever possible, use all the vaccine in a punctured multidose vial before opening another vial. Use all the reconstituted vaccine in one vial before reconstituting another vial to reduce vaccine waste.

Store punctured multidose vials in a designated, labelled container so that they are easily recognized. Remember to store these vials in their original boxes to prevent light exposure.

Diluents should also be clearly labelled to ensure that the correct diluentis used with the corresponding vaccine.

Diluents should be clearly labelled, whether they are stored at room temperature or in the refrigerator. Label the boxes of corresponding vaccines and diluents from the same manufacturer so that they will be used together. This avoids confusion and helps to ensure that only the specific diluent provided by the manufacturer is used for each type of lyophilized (freeze-dried) vaccine. This is particularly important if you store two or more lyophilized vaccines that use different diluents.

4.4 Storage of Non-Vaccine Products

Never store food or beverages inside vaccine storage units.

Never store food, beverages, or biological specimens inside vaccine storage units. As well, whenever possible, medications and/or other biological products should not be stored with vaccines. Storing non-vaccine items in the vaccine storage unit results in frequent opening of the storage unit door. This allows for a greater chance of temperature instability and excessive exposure to light. It may also result in spills and contamination inside the compartment. Introduction of other items also impedes airflow and introduces varying temperatures to the unit.

See *Appendix L: Checklist for Safe Vaccine Storage and Handling* for ways to safeguard vaccines.

4.5 References

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SECTION 5 **Temperature Monitoring**

National Vaccine Storage and Handling Guidelines for Immunization Providers

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5.1 Checking and Recording Temperatures

Record the temperature in the refrigerator, freezer, and room twice daily. Remember to record the current, minimum, and maximum temperatures for the refrigerator and freezer.

- Post a temperature log on the vaccine storage unit door. Use or adapt *Appendix I: Temperature Log for Vaccines and Vaccine Storage Troubleshooting Record*, or use the temperature log provided by the jurisdictional/local public health office or immunization program.
- Read the thermometers in both the refrigerator and freezer twice a day (in the morning and again at the end of the day) for all storage units, including those with continuous temperature monitoring and recording devices. Remember: min/max thermometers must be reset after properly recording every temperature reading (see *Section 3: Vaccine Storage Equipment* for more details.) The room temperature should also be read and recorded at the same time to establish awareness of how ambient temperature affects the vaccine storage. Room temperatures may be read with a standard household thermometer or digital thermostat.
- Record the current, minimum, and maximum temperatures in Celsius or Fahrenheit as appropriate on the temperature log for the refrigerator, freezer, and the room. Also include:
  - Date and time;
  - Initials of the person recording;
  - Comments, if appropriate.
- When a temperature reading is missed, retain the log entry as a blank.
- Take corrective action when the temperature in either the refrigerator or the freezer begins to trend towards the outer limits of the acceptable temperature range. Ideally, refrigerated vaccine should remain consistently at 5°C/41°F.

Take immediate action when the temperature in either the refrigerator or the freezer is outside the recommended range for vaccine storage.

- **Take immediate action** when the temperature in either the refrigerator or the freezer is outside the recommended range for vaccine storage. Document the action taken. See *Section 1: Cold Chain* for ideal temperature ranges of the refrigerator and freezer, and *Section 6: Storage Troubleshooting* for steps to address the occurrence of temperatures outside of the recommended ranges. *Appendix I: Temperature Log for Vaccines and Vaccine Storage Troubleshooting Record* may also be used to document vaccine storage temperatures and any actions taken when the temperature is outside the recommended ranges.

5.2 Reviewing Temperature Logs

The designated vaccine coordinator or delegate should review the log weekly to ensure that there has been proper temperature recording and to note trends in refrigerator and freezer temperatures.

If other staff are monitoring and recording the temperatures, the designated vaccine coordinator or delegate should review the log weekly to ensure that there has been proper temperature recording and to note trends in refrigerator and freezer temperatures. In some jurisdictions log books must be submitted prior to ordering vaccine.

5.3 Noting Equipment Failures and Room Temperatures

If a mechanical malfunction or power outage has occurred, the room temperature where the vaccine storage unit is kept should also be recorded.

When a mechanical malfunction or power outage occurs, record the following:

- Date and time when the event was discovered, as well as the duration of the malfunction, to the best of your knowledge.
- Current, minimum, and maximum storage unit and room temperatures during this event.
- Cause of the problem.
- Actions taken.
- Results.
- Initials of vaccine coordinator or delegate.

Record the information on the temperature log or on a jurisdictionally determined document. Refer to *Section 6: Storage Troubleshooting* for more information. Use or adapt *Appendix I: Temperature Log for Vaccines and Vaccine Storage Troubleshooting Record*, or use the temperature log provided jurisdictionally. See *Appendix J: Online Resources* for a list of links to jurisdictional websites.

5.4 Maintaining Temperature Logs

Maintaining an ongoing file of temperature logs and equipment failures will help to track recurring problems for vaccine storage units. It will also contribute to quality assurance assessment. Completed logs should be stored for legal purposes for the period of time determined by the jurisdictional/local public health office or immunization program.

5.5 Using Alarm Systems

Facilities storing large vaccine inventories should consider installing continuous monitoring temperature alarm systems with round-the-clock notification of appropriate personnel to help prevent substantial financial loss. Even if alarm systems are used, temperatures must be checked and recorded daily. A backup power supply (such as a generator or uninterruptible power supply) should also be considered to help protect vaccine inventories. See *Section 3.9: Vaccine Security* in *Section 3: Vaccine Storage Equipment* for more information on alarm systems and backup power supplies.

SECTION 6 **Storage Troubleshooting**

National Vaccine Storage and Handling Guidelines for Immunization Providers

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6.1 Steps in Handling Inappropriate Vaccine Storage Conditions (Light and Adverse Temperature Exposure)

If you become aware of inappropriate vaccine storage conditions,[2] the following steps should be taken immediately:

1) As quickly as possible, store the affected refrigerated vaccines between +2°C and +8°C (+35°F and +46°F) and frozen vaccines below –15°C (+5°F) until the integrity of the vaccine is determined. If your vaccine storage unit is not maintaining the appropriate storage conditions, activate the Urgent Vaccine Storage and Handling Protocols. See *Section 2: Vaccine Personnel and Vaccine Storage and Handling Protocols* for more details; *Appendix C: Urgent Vaccine Storage and Handling Protocols Checklist* may be used or adapted.
2) Notify the designated vaccine coordinator or delegate.
3) Record the following information:
   - Date and time of incident.
   - The issue (e.g. inappropriate temperature and/or exposure to light).
   - Length of time the vaccine may have been exposed to inappropriate conditions.
   - The temperature of the room where the vaccine storage unit is located:
     - A standard household thermometer may be used;
     - Do not use the thermometer from the vaccine storage unit;
     - Do not rely on the temperature displayed by the room thermostat.
   - Current temperature inside the vaccine storage unit.
   - Minimum and maximum temperature readings inside the vaccine storage unit.
   - Presence of water bottles and/or cold packs in the refrigerator.
   - Presence of frozen packs in the freezer.
   - Action that has been taken to protect the vaccines.
   - Action that has been taken to correct the issue.

   See *Appendix F: Cold Chain Failure Reports* for sample report templates that may be used or adapted. Many jurisdictions also have their own report templates, which may be referred to.
4) Document the inventory of the vaccines affected by this event. Include vaccine name, lot number, expiry date, and quantity. Note whether the vaccines have previously been exposed to cold chain failure. See *Appendix F: Cold Chain Failure Reports* for sample report templates that may be used or adapted to help you organize your response. Consult your jurisdictional/local public health office or immunization program for related forms that you may use, as well as any special instructions or forms.
5) Isolate and quarantine the affected vaccines and mark them as "DO NOT USE."

Do not assume that vaccine inappropriately exposed to light or to excessive temperatures cannot be salvaged. Contact your local public health office or immunization program for further guidance.

[2] Inappropriate vaccine storage conditions are those in which vaccine storage temperatures fall outside +2°C and +8°C (+35°F and +46°F) for refrigerated vaccines and above –15°C (+5°F) for frozen vaccines. In addition, protection from light is a necessary condition for some vaccines. *See Section 1: Cold Chain* for more details. Inappropriate vaccine storage conditions can arise through numerous circumstances.

6.2 Dealing with Vaccine Storage Unit Failure

6.2.1 General Instructions

The most important step to take if the vaccine storage unit is not working properly is to protect the vaccine supply and continuously monitor the temperature of the vaccine.

The most important step to take if the vaccine storage unit is not working properly is to protect the vaccine supply. **Do not allow the vaccine to remain in a unit that cannot perform its function as intended: move the vaccine to an alternative appropriate location until the issue is resolved. Follow your office plan, and continuously monitor the vaccine temperature.**

See *2.4 Urgent Vaccine Storage and Handling Protocols* in *Section 2: Vaccine Personnel and Vaccine Storage and Handling Protocols*, and *Appendix C: Urgent Vaccine Storage and Handling Protocols Checklist* for more details.

6.2.2 Vaccine Storage Unit Problems

Vaccine Storage Unit Temperature Is Not Appropriate

- Check the following (see *3.4.8 Setting and Stabilizing the Temperature* in *Section 3: Vaccine Storage Equipment* for more details):
  - Unit is plugged in and turned on;
  - If the control knob is not set properly, readjust as appropriate.
    NOTE: only the designated vaccine coordinator or delegate should adjust the control knob;
  - The door is closing properly;
  - The thermometer is properly located;
  - The freezer compartment is free of thick frost (< 1 cm);
  - There is good air circulation inside and outside the unit;
  - Exposed coils and the motor are free from dust;
  - The room temperature is appropriate.
- Call a refrigeration technician to assess the equipment if necessary.

Vaccine Storage Unit Is Too Noisy

- If the unit is making an unusual noise, contact a refrigeration technician to assess the equipment.

Vaccine Storage Unit Has Stopped

- Check for the following:
  - The electrical cord is undamaged;
  - The unit is plugged in and turned on;
  - The wall outlet is operative; appropriate personnel should check fuses and circuit breakers.
- Call a refrigeration technician to assess the equipment if necessary.

Document all the checks you made and the actions taken in the vaccine storage unit logbook. See *3.3 Routine Equipment Maintenance Logbooks* in *Section 3: Vaccine Storage Equipment* for more details.

Appendix K: Algorithms to Assess Problems in Temperature Readings Outside the Recommended Ranges may be used or adapted. Two algorithms are contained in this appendix that summarize actions to take if the refrigerator temperature reading is less than +2°C (+35°F) or greater than +8°C (+46°F).

6.3 Refrigerator and Freezer Door Problems

6.3.1 Checking the Door Seal

To check that the vaccine storage unit door is sealing properly:

1) Place a thin paper strip against the fridge's door seal.
2) Close the door.
3) Pull the paper strip. If it moves easily or falls away by itself, the door and the rubber-¬like seal need to be adjusted or replaced.
4) Check all the way around the door with the paper strip. Pay particular attention to the corners.

Installing an inexpensive Velcro™ latch from a hardware store can help ensure that the door is not accidentally left ajar and that it seals properly.

6.3.2 Adjusting the Door Seal

If you have checked the door seal and determined that the refrigerator door is not closing properly, call a technician.

6.4 Thermometer Problems

6.4.1 Checking Thermometer Placement

If the thermometer indicates a temperature outside the recommended range, check that the thermometer is appropriately situated in the centre of the storage unit compartment, adjacent to the vaccine. If the thermometer is placed near the coils, walls, floor, door, or fan, it may indicate colder or warmer temperatures than a thermometer appropriately placed in the centre of the compartment where the vaccines should be kept.

6.4.2 Checking Whether the Thermometer Works and is Accurate

A slight variation in temperature may be seen from one thermometer reading to another, even when the vaccine storage unit thermostat is set at a particular temperature. If the thermometer reading does not fluctuate at all over several readings or, on the other hand, if it shows extreme temperature fluctuations or does not seem to be accurate, this may indicate that the thermometer is not functioning properly. Temporarily remove the thermometer from the storage unit and place it outside the unit at room temperature, and check whether the temperature reading rises. If no change in the temperature reading occurs, check the batteries. Batteries should be changed every 6 to 12 months. If the batteries and thermometer appear to be in good working order but there is still concern regarding the accuracy of the reading, the slush test can be used to test the accuracy of the thermometer (see *Section 3.7.1, Checking the Accuracy of the Thermometer*). If there continues to be a problem with the thermometer, call the manufacturer. The thermometer may be faulty and need to be replaced. See *3.7 Thermometer Maintenance* in *Section 3: Vaccine Storage Equipment* for more details.

Thermometers should be checked every 6 months to a year to ensure that the following apply:

- Temperature calibration is accurate.
- Batteries are functioning.
- Cables or probes are not damaged.
- Vials of fluid that the probes sit in are intact and have adequate volume.
- Adequate supplies of graph paper and ink pens are available for chart recorders.

6.5 Power Outages

6.5.1 Advance Preparations

When there is reasonable cause to believe that a power outage may occur, emergency procedures should be implemented in advance of the event.

When there is reasonable cause to believe that a power outage may occur, emergency procedures should be implemented **in advance of the event**.

See *2.4 Urgent Vaccine Storage and Handling Protocols* in *Section 2: Vaccine Personnel and Vaccine Storage and Handling Protocols* and *Appendix C: Urgent Vaccine Storage and Handling Protocols Checklist* for more details.

6.5.2 Temperature Considerations

Most refrigerated vaccines will remain stable at elevated temperatures for limited periods of time. Knowledge of a vaccine's stability, especially the rate of decline in potency at a given temperature, can be helpful in determining the impact on expiry date and use of product after a temperature excursion has occurred. Consult the product monograph, your jurisdictional/local public health office or immunization program and, if necessary, the vaccine manufacturer for product-specific, up-to-date stability data.

6.5.3 Power Outage Procedures

The information below is provided as a guideline. Consult your local/jurisdictional public health office or immunization program for any special instructions or forms.

If there is an ongoing power outage, **do not allow the vaccine to remain in a non-functioning unit**. If you are unsure whether the power will be restored in time to maintain an appropriate temperature, activate the Urgent Vaccine Storage and Handling Protocols. See *2.4 Urgent Vaccine Storage and Handling Protocols* in *Section 2: Vaccine Personnel and Vaccine Storage and Handling Protocols* and *Appendix C: Urgent Vaccine Storage and Handling Protocols Checklist* for more details.

NOTE: Purpose-built fridges, especially those with glass doors, may not be able to maintain temperatures for longer than 30 minutes. In fact, purpose-built refrigerators with glass doors have been shown to exceed recommended temperatures faster after a power outage than domestic dual-door refrigerators, as glass is a poor insulator (1). Knowing the technical details of the refrigerator will help in the assessment. See *Section 3: Vaccine Storage Equipment* and *Section 4: Vaccine Storage Practices* for more details.

In the event of a scheduled power outage, do not open the door of the vaccine storage unit until the power is restored, and continuously monitor the temperature of the unit.

In power outage simulations performed by the National Institute of Standards and Technology (1), vaccine vials exceeded recommended temperatures within 45-60 minutes (no water bottles in the refrigerator) or within 60-120 minutes (water bottles in the refrigerator), highlighting the importance of the presence of cold mass in the cooling unit. In this same study, it was found that purpose-built refrigerators can take up to 7 hours and domestic refrigerators up to 12 hours to return to the pre-set temperature after a power outage. Therefore, it is important to keep monitoring the temperature inside the cooling unit during the hours following the power outage.

If the power outage is scheduled and time-limited, and the power will be restored before the vaccine storage unit temperature rises above the recommended range, proceed as follows:

1) **Do not open the refrigerator or freezer door** until the power is restored.
2) **Continuously monitor the temperatures** inside the vaccine storage unit if the thermometer allows temperature monitoring without opening the storage unit doors.
3) The following steps should also be followed in the event of a **scheduled, time-limited** power outage and you are **certain that** the power will be restored before the vaccine storage unit temperature rises above the recommended range:
   - Record the room temperature and the temperature(s) inside the unit(s) prior to the outage, as well as the minimum and maximum temperatures reached inside the unit(s) during the power outage.
   - Record the room temperature and the temperatures inside the vaccine storage units as soon as possible after power has been **restored**. Note the length of time the power has been off and the maximum temperature observed.
   - If the temperature is approaching +8°C (+46°F), arrangements should be made to move the vaccine to coolers or an alternative location (see Section 2.4)
   - If the temperature inside the refrigerator has exceeded the recommended +8°C (+46°F) or if the temperature inside the freezer has risen above –15°C (+5°F), record the duration of inappropriate temperature exposure and follow the procedures in *6.1 Steps in Handling Inappropriate Vaccine Storage Conditions (Light and Adverse Temperature Exposure)* earlier in this section.

6.6 References

(1) Chojnacky M, Miller W, Ripple D, Strouse G. Thermal Analysis of Refrigeration Systems Used for Vaccine Storage. United States: National Institute of Standards and Technology, 2009. Available at: http://www.nist.gov/pml/div685/grp01/upload/NISTIR7656-Thermal-Analysis-of-Dorm-style-Refrigerator-and-Freezerless-Refrigerator-for-Vaccine-Storage.pdf

SECTION 7 **Cold Chain Breaks**

National Vaccine Storage and Handling Guidelines for Immunization Providers

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7.1 Protecting the Vaccine Supply

Maintaining the vaccine cold chain from vaccine production to administration is a vital component of establishing vaccine efficacy (1) (see *Section 1: Cold Chain* for more details). However, several events can occur during transportation or storage that may compromise the cold chain, thus exposing the vaccine to adverse conditions (temperatures outside the recommended range or adverse light exposure): delays during shipping, storage unit malfunctions, vaccines mistakenly stored at inappropriate temperatures, etc.

In the case of a cold chain break, **protecting the vaccine supply** is fundamental. Depending on the duration and intensity of the exposure, the vaccine may still be viable if immediately removed from the adverse environment. Do not assume that exposure to adverse events has rendered the vaccines unusable, and do not discard vaccines or diluent before determining their integrity. **When a cold chain break is suspected**, consult your jurisdictional/local public health office or immunization program for vaccine-specific direction relating to the break, because jurisdictions have access to more detailed and jurisdictionally approved stability guidelines to aid in the assessment of cold chain breaks.

7.2 Instructions for Cold Chain Breaks

In the event of a cold chain failure, the following steps should be taken (2, 3):

- Notify the vaccine coordinator or delegate immediately. He/she will implement the Urgent Vaccine Storage and Handling Protocols (see *2.4: Urgent Vaccine Storage and Handling Protocols* in *Section 2: Vaccine Personnel and Vaccine Storage and Handling Protocols* for more details).
- Quarantine the affected vaccines within a functional storage unit or cooler, grouping them together and labelling them with a "Quarantine" sign and the date on which the cold chain break occurred. Alert staff members of the situation to avoid the administration of these vaccines.
- Protect the vaccine supply by keeping it at appropriate temperatures (between +2°C and +8°C [+35°F to +46°F] for refrigerated vaccines and –15°C [+5°F] or colder for frozen vaccines). Continue to monitor the storage conditions.
- If a faulty storage unit is the source of the cold chain failure, transfer the supply to an alternative storage unit or a cooler (see *Section 9: Vaccine Distribution* for instructions on packing a vaccine cooler). Once the vaccines have been relocated, identify the source of the malfunction (see *Section 6: Storage Troubleshooting* for more details). Take appropriate actions to rectify the situation.
- Fill out the appropriate forms to report the cold chain break to your jurisdictional/local public health office or immunization program. See *6.1 Steps in Handling Inappropriate Vaccine Storage Conditions (Light and Adverse Temperature Exposure)* in *Section 6: Storage Troubleshooting* for more details). The information requested on these forms may include the following:
  - Date and time the breach occurred (or was first noticed);
  - Type of adverse exposure;
  - Duration of adverse exposure;
  - Site of the exposure (e.g. storage unit, transportation);
  - Temperature inside the storage unit;
  - Estimated temperature outside the storage unit (a household thermometer may be used);
  - Whether water bottles in the storage unit are still cold;
  - Inventory of the vaccines affected and their expiration date;
  - Whether vaccines exposed to adverse temperature or light exposure were administered to patients;
  - Actions taken to remedy the situation.
- Contact your jurisdictional/local public health office or immunization program for further instructions. They will determine whether the vaccine is still safe to use or should be discarded, and whether re-administration of the vaccine to patients is necessary.

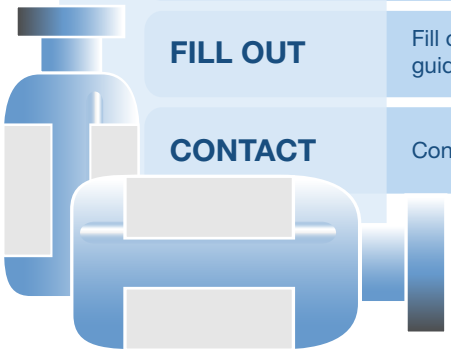
In the case of a suspected cold chain failure, do not discard vaccines unless instructed to do so by your jurisdictional/local public health office or immunization program.

7.3 Forms for a Suspected Cold Chain Break

Many jurisdictional/local public health offices have specific forms to fill out in the event of a suspected cold chain failure (see *Appendix J: Online Resources*); these may be found on their websites or on internal websites, depending on the jurisdiction. A copy of the forms should be kept with the Urgent Vaccine Storage and Handling Protocols (see *Section 2.4: Urgent Vaccine Storage and Handling Protocols* for more details).

Sample forms can be found in *Appendix F: Cold Chain Failure Reports*.

7.4 Summary of Actions to take in the Case of a Suspected Cold Chain Break



NOTIFY	Notify vaccine coordinator
ISOLATE	Isolate and label vaccines with “Quarantine” and date of cold chain break
STORE	Store the vaccine at appropriate temperatures and monitor the storage unit conditions
TRANSFER	Transfer vaccine to an alternative storage unit/cooler if storage unit has failed (breakdown, power outage, human error, etc.)
IDENTIFY	Identify the source of the failure (breakdown, power outage, human error, etc.)
FILL OUT	Fill out appropriate forms according to jurisdictional/local guidelines
CONTACT	Contact jurisdictional/local public health office for further guidance

7.5 References

(1) Page SL, Earnest A, Birden H, Deaker R, Clark C. Improving vaccination cold chain in the general practice setting. Aust Fam Physician. 2008 Oct;37(10):892-6.

(2) Centers for Disease Control and Prevention. Vaccine Storage and Handling Toolkit. National Center for Immunization and Respiratory Diseases, 2012. Available at: http://www.cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf

(3) Australian Government. National Vaccine Storage Guidelines – Strive for 5, 2nd edition. Department of Health and Ageing, 2013. Available at: http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/59F63C79DAFAFB38CA257B020002C371/$File/strive-for-5-guidelines.pdf

SECTION 8 **Vaccine Management**

National Vaccine Storage and Handling Guidelines for Immunization Providers

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8.1 Vaccine Management

Limit access to the vaccine supply to authorized personnel only, determined by the vaccine coordinator or delegate. This will help protect the vaccine supply by avoiding inappropriate removal of vaccine or inappropriate handling of vaccine and vaccine storage units by untrained personnel.

8.2 Expiration Dates

8.2.1 Interpreting Expiration Dates

All vaccines and diluents have expiration dates (date by which the vaccine or diluent should be used). This date is printed on all vaccine and diluent containers (e.g. vials, syringes, ampoules) and their package boxes.

Expiration dates vary by the type of vaccine or diluent and by the lot number. The vaccine or diluent may be used up to and including this date. For example, if the printed expiry date is Sept 1, 2015, the product expires at midnight on September 1, 2015. When the expiration date is marked with only a month and year, the vaccine or diluent may be used up to and including the last day of the month indicated on the vial. If the expiry date is Sept 2015, the vaccine may be used up to midnight on September 30, 2015.

8.2.2 What To Do with Expired and Mishandled Vaccine or Diluent

Expired vaccine and diluent, even if they are only one day past the expiration date, should not be administered.

Expired Vaccine

Expired vaccine and diluent, even if they are only one day past the expiration date, should not be administered. Record the lot number and expiry date of the immunizing agent and return it or dispose of it according to public health guidelines or policies.

If expired vaccine is inadvertently given, contact your jurisdictional/local public health office or immunization program for advice.

Mishandled Vaccine

Promptly move the mishandled vaccine and diluent into a separate area of the refrigerator or freezer and place in a container marked “DO NOT USE.” Consult your jurisdictional/local public health office or immunization program for specific policies regarding the disposition of mishandled or expired vaccine.

See *Section 10: Vaccine Disposal* for more information on the safe disposal of vaccine and vaccine products.

8.2.3 Exceptions to the Expiration Date

The expiration date labelling on each vial or box is valid only if proper storage and handling conditions are observed at all times, unless otherwise stated by the manufacturer. If vaccine has been inappropriately exposed to heat, cold, or light, its potency may be reduced **before** the expiration date is reached.

The only way to determine whether proper transport and storage conditions have been maintained is to monitor vaccine and diluent temperatures during every link in the cold chain and to safeguard light-sensitive vaccines from exposure to light. The manufacturer-labelled expiration date may also be invalid after the vial is opened or reconstituted. (See 8.2.5 *Expiration of Multidose, Single-Dose, and Select Vaccine Products* below, for details.)

8.2.4 Transferring Vaccine or Diluent that Cannot be Used Before Expiration

If it is determined that a product cannot be used before the expiry date, contact the jurisdictional/local public health office or immunization program for guidance. It may be possible to transfer the product under appropriate cold chain conditions to another facility, where it can be used before it expires.

8.2.5 Expiration of Multidose, Single-Dose, and Select Vaccine Products

Once punctured, multidose vials should be marked with the date of puncture or the date of expiration and should be used within the timeframe specified by the manufacturer.

Consult the product monograph before vaccine reconstitution for the most up-to-date information about vaccine expiration times and dates. Unused reconstituted vaccines kept beyond recommended limits should not be administered. The best way to avoid such waste is to reconstitute and draw up vaccines immediately before administration.

It is important to consult jurisdictional/local guidelines when developing protocols pertaining to vaccine expiration dates, as practice may vary from one jurisdiction to the next. As a general rule, multidose, premixed vaccine vials should be labelled with the date of puncture, according to jurisdictional labelling protocols (either today's date or the revised date of expiration). Once punctured, multidose vials should be maintained under appropriate storage conditions and be used within the timeframe specified by the manufacturer, unless otherwise indicated by the public health authorities.

Single-dose vials are meant for one-time use only. To avoid needless waste of vaccine, the vial or syringe must **always** be checked before removal of the cap to ensure that it is the correct vaccine type. The cap should only be removed at the time of vaccine administration. At the end of the clinic day, single-dose vials without a protective cap must be discarded.

8.3 Inventory Management

8.3.1 General Recommendations

The vaccine coordinator or delegate should arrange the vaccine and diluent supplies according to the expiration dates on a weekly basis and each time a vaccine shipment arrives.

Inventory management is important for vaccine quality management. Proper inventory management means knowing the following quantities:

- Vaccines and diluents that have been received.
- Vaccines and diluents that have been administered, wasted, expired, or spoiled.
- Vaccines and diluents: the quantities that are currently in stock and are available for administration.
- Vaccines and diluents: the quantities that are currently in quarantine awaiting follow-up directions.
- Vaccine and diluent vials that should be used first.
- Vaccines and diluents that need to be ordered on the basis of upcoming program demand.

The designated vaccine coordinator or delegate should arrange the vaccine and diluent supplies according to the expiration dates on a weekly basis and each time a vaccine shipment arrives. The vials and boxes in opened packages with the earliest expiration dates should be placed in the storage unit in front of other vials and boxes of the same type with later expiration dates. This practice avoids waste by ensuring that short-dated vaccine and diluent will be used first, thereby limiting the amount of unused vaccine that has passed its expiration date. Additionally, vaccines that have been exposed to adverse events but were deemed viable by the jurisdictional/local public health office or immunization program should be placed in front of unexposed vials.

8.3.2 Vaccine Inventory Calculations and Vaccine Ordering

Three main principles of ordering vaccines:

- **Order and stock only a 30-day supply to meet the needs of the population served.**
- **Do not stockpile vaccine.**
- **Alert office staff when an order has been placed.**

In general, there are three main principles to keep in mind when calculating the amount of vaccine supplies needed and when placing vaccine orders.

1) **Order and stock enough vaccine for a 30-day supply to meet the needs of the population served, including vaccine for seasonal programs** (though this may vary depending on shipping and delivery schedules). Consult your jurisdictional/local public health office or immunization program for recommendations on different supply levels, depending on local and seasonal use.
2) **Do not over-order or stockpile vaccines.** Ordering large amounts of vaccine can lead to vaccine wastage if they are unused before expiry date and to an unnecessarily increased risk of losing a large quantity of vaccines should there be a cold chain break. For these reasons, it is recommended that only a 30 day supply of vaccine be kept in stock.[3]
3) **Alert office staff when an order has been placed.** The vaccine coordinator or delegate (other designated individual responsible for receiving shipment) should be notified immediately upon arrival of a vaccine shipment so that the vaccine is stored under appropriate conditions and the cold chain is maintained. (See *9.2 Receiving and Unpacking Vaccine Shipments* in *Section 9: Vaccine Distribution* for more details.) Vaccine shipments must also be documented in the appropriate inventory record. Use the appropriate inventory form (for an example, see *Appendix H: Refrigerator and Thermometer Maintenance and Monthly Vaccine Inventory*). Many jurisdictions have their own pre-existing vaccine inventory sheets available for use.

[3] A vaccine supply of greater than 30 days may be necessary in remote areas with limited delivery schedules.

8.3.3 Inventory Management Tools

Maintaining complete and accurate inventory records is a critical component of inventory management to prevent over- or under-stocking of supplies and disruption to the immunization program.

Maintaining a complete and accurate hardcopy or electronic inventory of vaccines and diluents is critical to prevent over- or under-stocking of supplies and disruption to the immunization program. The information in the inventory also contributes to planning for seasonal fluctuations in vaccine needs, such as during an influenza program or school-based program. The balance of doses of both vaccine and diluent remaining in stock, as indicated on the inventory records, should be updated regularly, using a tally of doses administered, wasted, spoiled, or expired in that period.

Inventory records and tally sheets are examples of management tools that can be used to keep track of vaccine and diluent inventory.

A running tally sheet may be used to record vaccine doses and diluent that were removed from or returned to the vaccine storage unit. The tally sheet(s) can be used to keep inventory records updated.

Hardcopy or electronic inventory records can be used to keep track of the following information:

- Date each shipment arrived at the facility.
- Initials of the person who unpacked and checked the shipment upon arrival (the same individual will usually fill out the inventory records for this shipment).
- Condition of the shipment upon arrival (i.e. did the vaccine arrive in good condition at the proper temperature or was there a reason to question its integrity?).
- For each vaccine and diluent, it is suggested that the following information be recorded:
  - Manufacturer and lot number;
  - Quantity of units per lot number;
  - Balance remaining (in doses) after subtracting the amount used (i.e. administered, wasted, spoiled, or expired) from the amount previously received;
  - Expiration date for each lot (including the new expiration dates for punctured multidose vials and times for vaccines that have been reconstituted);
  - Type of container (i.e. single-dose vial, multidose vial, or manufacturer-filled syringe).

If you receive multiple vials of the same vaccine in the same type of container (i.e. single-dose vial, multidose vial, or manufacturer-filled syringe) from the same lot with the same expiration date, these **doses** may be recorded as one entry on the inventory record. Simply indicate the total number of doses of that particular vaccine (regardless of the number of vials or syringes the doses came in). See *9.2 Receiving and Unpacking Vaccine Shipments* in *Section 9: Vaccine Distribution* for details.

Appendix H: Refrigerator and Thermometer Maintenance and Monthly Vaccine Inventory has components that may be included on inventory records. Each jurisdiction may also have pre-existing vaccine inventory sheets and recommended standard operating procedures available for use.

If an electronic spreadsheet or inventory system is not available, **tally sheet(s)** can be used to keep inventory records updated. For example, place a tally sheet on the storage unit door and record the doses removed from the unit during the week. Tick marks can be used to record doses that have been removed from the storage unit. Alternatively, the initials of the person removing the dose may be used. Tally sheets should include information on doses that were administered, wasted, spoiled, or expired.

At the end of the week, the vaccine coordinator or delegate may add up the number of doses of each vaccine used and update the inventory records accordingly to determine the new inventory balance at the end of the week. Store used tally sheets in a file for future reference for the length of time determined by your jurisdiction.

See a sample tally sheet that may be used or adapted in *Appendix E: Vaccine Stock Record and Tally Sheet*. Jurisdictions may also have their own pre-existing vaccine tally sheets available for use.

8.3.4 Recording Administered, Wasted, Spoiled, and Expired Doses

Consult pertinent local policy for vaccine inventory management requirements for recording and reporting of vaccine use or reasons for non-use. Maintaining a tally sheet (or electronic method of tallying vaccines) in which each dose of vaccine is accounted for will help with inventory management.

8.3.5 Counting Inventory

An actual count of the number of doses of vaccine and diluent in the inventory is an important component of inventory management and is the responsibility of the designated vaccine coordinator or delegate.

- At the end of every month, make a summary of the amount of each vaccine and diluent used during that month and the amount of inventory still available at that time. This information is useful in determining how much vaccine to order and can be used to monitor the seasonality of vaccine use.
- At the end of every year, total the amount of each vaccine and diluent received and the amount used. This information is useful for determining the annual vaccine needs of the immunization centre.

SECTION 9 **Vaccine Distribution**

National Vaccine Storage and Handling Guidelines for Immunization Providers

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9.1 Standard Operating Procedures

It is important to establish a routine, systematic process for handling vaccine shipments and vaccine transport. Each facility should develop its own written standard operating procedures (SOP), covering every aspect of vaccine shipping: receiving, storing, packing, and transportation. Written SOPs are useful for reference, training, and evaluation and should be included in the Routine Vaccine Storage and Handling Protocols. See *Section 2: Vaccine Personnel and Vaccine Storage and Handling Protocols* and *Appendix A: Routine Vaccine Storage and Handling Protocols Checklist* for more details.

9.2 Receiving and Unpacking Vaccine Shipments

9.2.1 Receiving Vaccine Shipments

All staff members who accept vaccine deliveries must be aware of the importance of maintaining the cold chain and of the need to **immediately notify** the designated vaccine coordinator or delegate of the arrival of the vaccine shipment so that it can be handled and stored appropriately.

9.2.2 Checking and Documenting the Condition of a Shipment

When the vaccine shipment is received, it should be examined and refrigerated immediately.

When the vaccine shipment is received, it should be examined, unpacked, and refrigerated immediately.

- Open and examine the shipping container and its contents for temperature monitoring devices/indicators and for any signs of physical damage.
- Read and/or stop the recording of the temperature monitoring device upon receipt to determine whether it has been activated or alarmed. Check the monitor to see whether the vaccine or diluent has been exposed to temperatures outside the recommended range during transport. Do not delay temperature reading; a delayed reading could lead to false identification of a cold chain break.
- Rely on the temperature monitors to determine whether a cold chain break has occurred. Longer shipping times (i.e. longer than 48 hours) can increase the chance of a cold chain break but with proper shipping materials they do not in and of themselves represent a cause for concern.
- If a cold chain break is detected, examine the vaccine and diluent for heat or cold damage.
- If a cold chain break is detected, check that inactivated vaccines are cold but not frozen, and that frozen vaccines are frozen.

- Refrigerated packs should still be cold. Frozen packs can be melted but the package should still be cold. Vaccines and diluents should not be in direct contact with refrigerated or frozen packs. There should be an insulating barrier between the vaccine and the refrigerated or frozen packs.
- Crosscheck the contents with the packing slip to be sure they match. Remove **all contents** of the shipping container before returning or storing the shipping container to ensure that all vaccines have been removed and stored appropriately. If there are any discrepancies with the packing slip immediately notify the designated vaccine coordinator or delegate.
- Check the vaccine expiration dates. If the vaccine or diluent has expired, record the lot number and expiry date of the immunizing agent and return it or dispose of it according to public health guidelines or policies.
- Ensure that there is enough diluent with an expiry date greater than or equal to that of the vaccine it will be used with.
- If the vaccine or diluent is short dated, place it at the front of the vaccine storage unit to be used first. If short dated vaccine or diluent cannot be used before the expiry date, contact your jurisdictional/local public health department or immunization program to enquire whether the vaccine can be used in time elsewhere or whether it should be returned to the manufacturer for replacement.
- Ensure that frozen vaccines have been shipped separately from refrigerated vaccines and diluents.
- Ensure that lyophilized vaccines have been shipped with the correct type and quantity of diluent for reconstitution.
- Diluents that can be stored at room temperature may be transported either at room temperature or inside the same insulated cooled container as their corresponding vaccine. If there are any concerns about the shipment, segregate the vaccine and diluent within the appropriate storage unit and label with a “Quarantine” sign until the integrity of the vaccine and diluent has been determined. Contact your jurisdictional/local public health office or immunization program, as per protocol.

9.3 Transporting Vaccine to Off-Site Clinics

9.3.1 General Recommendations

The best assurance of vaccine efficacy is to minimize the number of times vaccines are handled and transported. If vaccine transportation to another location is required, it is critical to maintain the cold chain at all times.

The best assurance of vaccine efficacy is to minimize the number of times vaccines are handled and transported. If vaccine transportation to another location is required, it is critical that vaccine potency is protected by maintaining the cold chain at all times

When using a vehicle to transport vaccines, **do not place vaccine inside the trunk** of the vehicle. The temperature inside the trunk cannot be regulated. Avoid placing the vaccine in direct sunlight or directly in line with air from the vehicle's heater and air conditioner. Vaccine should not be left unattended in the vehicle. Staff should be instructed to deliver the vaccine directly to the appropriate personnel as soon as possible.

9.3.2 Basic Principles for Packing Vaccines

Ensure that everything in the shipping container is cooled prior to packing to avoid temperature fluctuations.

1) Ensure that everything in the container used for vaccine transportation is cooled before packing to avoid temperature fluctuations.
2) Vaccines should be packed in layers using the following materials: refrigerated and/or frozen packs, insulating barrier, vaccine, a temperature monitor, and filler materials (may be the same as those used as insulating barriers) to prevent shifting of the contents during transport. Refrigerated and frozen packs must first be "conditioned" prior to packing. Refrigerated packs should be conditioned in the refrigerator, and frozen packs are conditioned by leaving them at room temperature until the edges have defrosted and the packs look like they have been "sweating". However, it is best to follow manufacturer guidelines for conditioning of frozen gel packs. Frozen packs that are not conditioned can freeze vaccine (1). The number and placement of refrigerated or frozen packs inside the container will depend on container size, outside temperature, duration of transit, and jurisdictional variations in storage and handling materials.
3) Pack frozen vaccines last, using a separate insulated container. Pack frozen vaccines with dry ice immediately before they are to be transported. At least 2.7 kg (6 lbs.) of dry ice should be used in the container to maintain vaccines in their frozen state.

Place an insulating barrier between the refrigerated or frozen packs and the vaccines to prevent accidental freezing.

4) Be sure to place an insulating barrier between the refrigerated or frozen packs and the vaccines to prevent accidental freezing.
5) Pack vaccines in their original packaging on top of the barrier. Do not remove vaccine vials from boxes. Be sure to fill any spaces between vaccine boxes with filler to prevent shifting of contents in the insulated container.
6) Place a temperature-monitoring device in the middle of the vaccines (an empty vaccine box can be used to hold the device to prevent movement during transport) and ensure that it is not in contact with the refrigerated or frozen packs.
7) Record vaccine type(s), lot numbers, brand names, quantity, expiry date, packing date and time, and originating facility on a packing slip on the inside of the container.
8) Attach labels to the outside of the container to clearly identify the contents as being valuable, fragile, and temperature-sensitive vaccines that require refrigeration or freezing immediately upon shipment arrival.

FIGURE 1: PACKING SHIPPING CONTAINERS

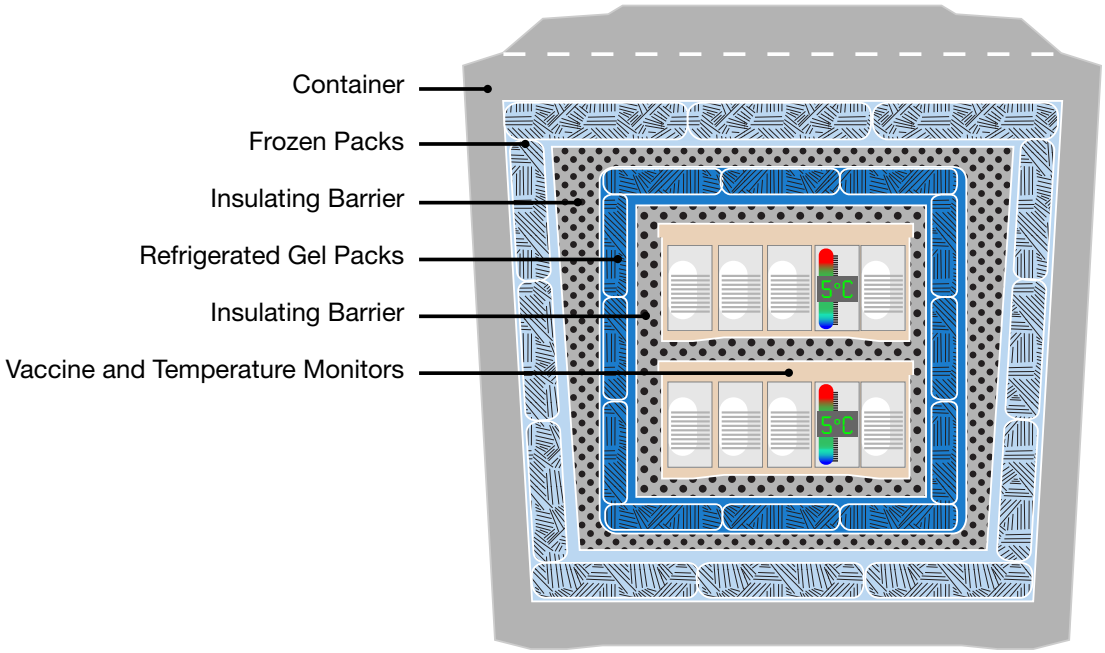

Figure 1 shows an example of how a shipping container can be packed. Note that packing configurations may vary according to time of year, length of shipment, and jurisdiction. See *2.4.1 Refrigerated and Frozen Vaccines* in *Section 2: Vaccine Personnel and Vaccine Storage and Handling Protocols* for additional details on packing vaccines.

9.3.3 Packing Vaccine for Transport to Off-Site Clinics

Never put frozen packs near vaccine.

In packing vaccines for transportation many variables must be considered, including the ambient temperature, the distance and time in transit, the mode of transportation, and the amount of vaccine being packaged. It is important to test and qualify[4] the method of packing vaccines in order to maintain the cold chain during transportation. The container and packing materials tested should take into account the aforementioned variables.

A consistent approach to packing vaccines must be developed and qualified, and a packing protocol established according to some basic principles:

- An insulated and temperature-monitored container must be used when transporting vaccines.
- Use enough refrigerated or frozen packs to maintain the cold chain.
- Do not use loose or bagged ice.
- The number and placement of refrigerated or frozen packs inside the container will depend on container size, the ambient temperature, the volume of vaccine, and the duration of transport.

Vaccines should be transported in insulated containers that have been tested and qualified to meet the specific transportation requirements of the region or jurisdiction, ensuring that they are capable of maintaining the vaccine at the correct temperatures for the necessary duration. Summer and winter packing configurations will vary by jurisdiction. Consult your jurisdictional/local public health office or immunization program for more information.

Packing Materials

The following table lists the various materials that are required when packing and distributing vaccines.

NOTE: The use of refrigerated and frozen packs for transporting vaccines will depend on the ambient temperature, the amount and type of vaccine, the size of the container, and the length of transport. For all packing materials and equipment, ensure that the specifications of each item are known and documented by checking with the manufacturer before purchasing or using.

[4] Qualified: previously tested, resulting in a high degree of assurance that a specific process will meet the pre-determined acceptance criteria of the facility (2).

TABLE 1. PACKING MATERIALS

MATERIAL		REQUIREMENTS
Container		Insulated containers must be used for transporting vaccine; these containers should be qualified to ensure that they are capable of maintaining the vaccine at the correct temperatures. The shipping containers that the vaccines arrived in from the manufacturer may be used if they meet the criteria. Alternatively, qualified hard-sided, plastic, insulated containers or Styrofoam coolers with at least 2-inch thick walls may be used. Qualified soft-sided, purpose-designated vaccine bags may also be used if they meet the criteria. Thin-walled, recreational-use Styrofoam coolers, such as those purchased to hold beverages, are not acceptable containers to use.
Refrigerated Gel Packs		These packs are refrigerated at +2°C to +8°C (+35°F to +46°F) and must be conditioned in the refrigerator for at least 24 hours.
Frozen Packs	**Ice Packs**	An ice pack is a plastic container designed to be 7/8 filled with water, frozen, and then used to keep vaccines at the recommended temperatures. Ice packs may have a removable lid for filling or be pre-filled and sealed. Ice packs should be conditioned before use, which is achieved by laying out the ice packs at room temperature until they begin to sweat. Ice packs are conditioned when water begins to slosh about slightly inside the pack (3).
	Frozen Gel Packs	There are many different types of frozen gel pack. They contain coolants that depress the melting point and ensure that the coolant remains cooler than 0°C (+32°F) for a long period (4). There are frozen gel packs that have freezing points below 0°C (+32°F) and may present a risk of freezing vaccines unless they are properly conditioned before use in the cooler (4). Therefore, before purchasing coolant products, request the following information from the manufacturer: ■ Validation of their claim about the product's cold life. ■ Clear instructions on how to freeze and condition the product before use, and how to use it to pack vaccines (3).
Insulation		Insulating and filler materials may consist of bubble wrap, crumpled paper, Styrofoam peanuts, or a number of other available packing materials. Insulating and filler material should not be stored in the same refrigerator as vaccines (whenever possible), since placing room temperature items in the refrigerator may affect the fridge's operating temperature and take up too much space.
Filler		

9.4 Maintaining Appropriate Temperatures During Off-Site Clinics

Vaccine must be maintained between +2°C and +8°C (+35°F to +46°F) during an off-site clinic and should be stored in a properly packed, insulated container. Use enough refrigerated or frozen packs to maintain the cold chain. The number and placement of refrigerated or frozen packs inside the container will depend on container size, the ambient temperature, and the volume of vaccine, taking into consideration jurisdictional variations. The combination of insulated container and packing material should be qualified to take into account these variables in order to maintain vaccines between +2°C and +8°C (+35°F to +46°F) during an off-site clinic.

Keep the container closed as much as possible. A process to monitor temperature must be in place to ensure that the cold chain is not broken. For example, an external digital thermometer probe could be kept in the container with the vaccines, and temperatures checked and recorded before leaving the facility, periodically during the clinic, and upon return to the office, as per jurisdictional recommendations.

9.5 References

(1) Centers for Disease Control and Prevention. Vaccine Storage and Handling Toolkit. National Center for Immunization and Respiratory Diseases, 2012. Available at: http://www.cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf

(2) Bishara RH. Qualification versus validation and good cold chain management practices. Pharmaceutical Manufacturing and Packing Sourcer. 2005:pp102,4,6.

(3) Australian Government. National Vaccine Storage Guidelines – Strive for 5, 2nd edition. Department of Health and Ageing, 2013. Available at: http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/59F63C79DAFAFB38CA257B020002C371/$File/strive-for-5-guidelines.pdf

(4) Kempe A. Bulk storage and transport of vaccine including outreach clinics. In: Langley A, Grant S, editors. Proceedings of the National Vaccine Storage Workshop. Brisbane, Australia: Queensland Health; 2004. Available at: http://www.gpqld.com.au/content/Document/3%20Programs/03_Immunisation/Vaccine_Management/Proceedings_of_the_National_Vaccine_Storage_Workshop_2004.pdf

SECTION 10 **Vaccine Disposal**

National Vaccine Storage and Handling Guidelines for Immunization Providers

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10.1 Unusable Vaccines

Vaccines and vaccine products (such as diluents) may be deemed unusable by local jurisdictions after assessment of exposure to adverse environmental conditions, such as the following:

- They have reached their expiry date and time.
- They have been reconstituted for longer than recommended.
- Multidose vials have been opened for longer than recommended.
- They may have been exposed to adverse environmental conditions.

10.1.1 Expired Vaccines

Vaccines degrade over time, resulting in a loss in potency. The expiration date provided by the manufacturer and displayed on the vaccine label ensures that unexpired vaccines will be administered at their full potency, provided the vaccine is stored at the recommended temperatures. Therefore, **expired vaccine must be discarded**.

In some situations, manufacturers may advise that the original expiry date for a specific product be extended, on the basis of further quality testing that they have conducted.

Expiration dates vary by the type of vaccine or diluent and by the lot number. The vaccine or diluent may be used up to and including this date. For example, if the printed expiry date is Sept 1, 2015, the product expires at midnight on September 1, 2015. When the expiration date is marked with only a month and year, the vaccine or diluent may be used up to and including the last day of the month indicated on the vial (1, 2). If the expiry date is Sept 2015, the vaccine may be used up to midnight on September 30, 2015.

10.1.2 Reconstituted Vaccines

Once vaccines have been reconstituted, they expire within a specific number of hours, independently of the expiration date provided by the manufacturer.

Labelling the vial after it has been reconstituted is of the utmost importance. As labelling practices may vary across jurisdictions (e.g. labelling the vial with the time it was reconstituted versus labelling it with the revised expiration time), local labelling practices must be made very clear and included in the routine protocols. See *Section 8.2 Expiration Dates* for more details on labelling.

10.1.3 Multidose Vials

Once multidose vials have been opened, they remain viable for the duration of a specific shelf life, as indicated by the manufacturer. The shelf life varies by vaccine type. Always check the product monograph for the prescribed shelf life. Mark the vial with the date it was reconstituted upon opening the vial, according to local guidelines, **and discard when the shelf life has expired**.

10.1.4 Adverse Environmental Exposures

When exposed to light or temperatures outside the prescribed range established by the manufacturer, vaccines may become unstable and lose potency. Consequently, adverse environmental exposures potentially result in a loss of vaccine effectiveness (3, 4). The jurisdictional/local public health office or immunization program can determine whether vaccines exposed to adverse environments are still viable or should be discarded. If indicated, the vaccine manufacturer may be contacted to assist in determining viability.

Please see *Section 7: Cold Chain Breaks* for guidelines on actions to take upon learning that products were exposed to adverse storage conditions.

10.2 Handling Unusable Vaccines

Protocols for handling unusable vaccine (either expired or subjected to adverse environmental exposure) vary greatly among jurisdictions. Consult the jurisdictional/local public health department or immunization program for directions on handling these vaccines.

The following are general recommendations on actions to take if vaccine doses have expired, or in the event of a suspected cold chain failure or other adverse exposure:

- Segregate the unusable vaccine within the refrigerated storage unit, and label with a "DO NOT USE" sign to avoid inadvertent administration of these doses.
- Contact the jurisdictional/local public health office or immunization program, as per protocol. In the event of a suspected adverse event, report the type of exposure and its duration. Keep the vaccine in the cold storage unit until further instructions from the public health department.

It is important to report expired vaccines to jurisdictional/local public health, as many jurisdictions keep track of vaccine waste. Additionally, report vaccines that are due to expire shortly if the administration of those vaccines before that date is unlikely. The public health authorities may be able to transfer the vaccines to another health care facility that would be able to administer them.

10.3 Procedure for Vaccine Disposal

If vaccine and/or diluent doses must be discarded, jurisdictional/local guidelines should be followed. Although the Office of Waste Management (Environment Canada) has published guidelines pertaining to disposal procedures for vaccines and immunization material (needles, syringes, etc.), waste management policies are under provincial and territorial jurisdiction and therefore vary widely depending on the location. Jurisdictional/local guidelines should be followed (see *Appendix J: Online Resources* for links to provincial and territorial guidelines), as they are usually more specific than nationwide guidelines, which represent the minimal standards (5).

Each health care facility should have a detailed, written procedure for biomedical waste management (based on federal and jurisdictional guidelines) and appoint a knowledgeable, trained individual to be responsible for the waste management program.

10.4 References

(1) National Advisory Committee on Immunization (NACI). Storing and handling of immunizing agents. In: Canadian Immunization Guide. 2013. Available at: http://www.phac-aspc.gc.ca/publicat/cig-gci/p01-08-eng.php

(2) Centers for Disease Control and Prevention. Vaccine Storage and Handling Toolkit. National Center for Immunization and Respiratory Diseases, 2012. Available at: http://www.cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf

(3) Page SL, Earnest A, Birden H, Deaker R, Clark C. Improving vaccination cold chain in the general practice setting. Aust Fam Physician. 2008 Oct;37(10):892-6.

(4) Australian Government. National Vaccine Storage Guidelines – Strive for 5, 2nd edition. Department of Health and Ageing, 2013. Available at: http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/59F63C79DAFAFB38CA257B020002C371/$File/strive-for-5-guidelines.pdf

(5) Canadian Council of the Ministers of the Environment. Guidelines for the Management of Biomedical Waste in Canada. 1992. Available at: http://www.ccme.ca/assets/pdf/pn_1060_e.pdf

APPENDICES

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APPENDIX A:

Routine Vaccine Storage and Handling Protocols Checklist

The following is a suggested checklist of items that may be included in the routine vaccine storage and handling protocols. The protocols should be available in an accessible area near the vaccine storage unit.

See Section 2 for details.

✓ ROUTINE VACCINE STORAGE AND HANDLING PROTOCOLS CHECKLIST

Ⓐ

	Up-to-date contact information for the following:
	• Designated vaccine coordinators and delegates who are responsible for routine vaccine storage and handling
	• Provincial, territorial, local or other jurisdictional public health office or immunization programs
	• Refrigerator and freezer maintenance and repair company
	• Vaccine storage unit alarm company (if applicable)
	• Sources of packing materials and calibrated thermometers
	Descriptions of the roles and responsibilities of the designated vaccine coordinators, delegates and other staff members
	Summaries of the storage requirements for each vaccine and diluent in your inventory
	Samples of the forms used in each immunization program

APPENDIX B:

Routine Vaccine Storage and Handling Contact List

The following is a table that may be used when developing routine vaccine storage and handling protocols.

See Section 2 for details.

ROUTINE VACCINE STORAGE AND HANDLING
CONTACT LIST

(B)

DESIGNATED VACCINE COORDINATORS

Title	Name	Phone #	Cell #	Pager #	Email
Primary coordinator					
Backup coordinator					

PROGRAM RESOURCE CONTACT LIST

Title	Name	Phone #	Cell #	Pager #	Email
Provincial/territorial immunization program					
Local immunization program					

OTHER

Title	Name	Phone #	Cell #	Pager #	Email

ROUTINE VACCINE STORAGE AND HANDLING
CONTACT LIST

B

SUPPLIER RESOURCE CONTACT LIST

Title	Name	Phone #	Cell #	Pager #	Email
Electric power company					
Refrigerator repair company					
Thermometer supplier					
Security alarm company					
Insulated containers or coolers					
Refrigerated or frozen cold packs					
Dry ice vendor					
Fillers (i.e. bubble wrap, Styrofoam)					

APPENDIX C:

Urgent Vaccine Storage and Handling Protocols Checklist

The following is a suggested checklist of the items that may be included in the urgent vaccine storage and handling protocols. The protocols should be available in an accessible area near the vaccine storage unit.

See Section 2 for details to be included under each item of the checklist.

✓	**URGENT** VACCINE STORAGE AND HANDLING **PROTOCOLS CHECKLIST** ©
	Contact list (see *Appendix D: Urgent Vaccine Storage and Handling Contact List*)
	• Emergency staff contact list in order of contact preference
	• Current contact information for all possible players in the event of an emergency:
	– Designated vaccine coordinators and delegates
	– Emergency staff contact list
	– Alternative vaccine storage facility or facilities
	– Provincial, territorial or local health department immunization program
	– Electric power company
	– Emergency generator repair company
	– Refrigerator and freezer maintenance and repair company
	– Vaccine storage unit/temperature alarm monitoring company (if applicable)
	– Security alarm company (if applicable)
	– Weather service
	– Sources of packing materials and calibrated thermometers
	– Local refrigeration company and alternative
	Designated vaccine coordinators'/delegates' responsibilities
	Power outages
	• A list of the most common causes of power interruption for your facility
	Vaccine storage unit specifications (type, brand, model number, serial number, location)
	Vaccine storage facilities
	• Alternative vaccine storage facility or facilities
	• Written protocols, vehicles and drivers for transporting vaccine to and from the alternative vaccine storage facility
	• Written, accessible instructions for entering your facility and vaccine storage spaces in an emergency if the building is closed or if it is after hours
	Vaccine storage at alternative facilities
	• Written protocol for appropriately storing vaccine at the alternative vaccine storage facility
	• Appropriate packing materials to safely transport or temporarily store vaccine
	• Written protocol for vaccine packing
	Refrigerated and frozen vaccines
	• Separate protocols for specific packing requirements of refrigerated and frozen vaccines
	General principles

APPENDIX D:

Urgent Vaccine Storage and Handling Contact List

The following is a table that might be used when developing urgent vaccine storage and handling protocols.

See Section 2 for details.

URGENT VACCINE STORAGE AND HANDLING CONTACT LIST

(D)

DESIGNATED VACCINE COORDINATORS

Title	Name	Office Phone # Home Phone #	Cell # Fax #	Pager #	Email
Primary coordinator					
Backup coordinator (delegate)					

EMERGENCY STAFF CONTACT LIST

Title	Name	Office Phone # Home Phone #	Cell # Fax #	Pager #	Email

URGENT VACCINE STORAGE AND HANDLING CONTACT LIST

(D)

(PAGE 2 OF 3)

DRIVER OF VEHICLE

Title	Name	Phone #	Cell # Fax #	Pager #	Email
Driver of vehicle					
Backup driver					

ALTERNATIVE VACCINE STORAGE FACILITIES

Title	Name	Phone #	Cell # Fax #	Pager #	Email

EMERGENCY RESOURCE CONTACT LIST

Title	Name	Phone #	Cell # Fax #	Pager #	Email
Provincial/territorial immunization program					
Local immunization program					

URGENT VACCINE STORAGE AND HANDLING @ CONTACT LIST

(D)

(PAGE 3 OF 3)

SUPPLIER RESOURCE CONTACTS

Title	Name	Phone #	Cell # / Fax #	Pager #	Email
Electric power company					
Emergency generator repair company					
Refrigerator/freezer repair company					
Vaccine storage unit/temperature alarm monitoring company					
Security alarm company					
Weather service					
Sources of packing materials and calibrated thermometers					
Local refrigeration company					

OTHER

Title	Name	Phone #	Cell # / Fax #	Pager #	Email

APPENDIX E:

Vaccine Stock Record and Tally Sheet

The following are examples of a Vaccine Stock Record and Tally Sheet that may be used or adapted.[1]

See Section 2 and Section 8 for details.

Vacccine Stock Record Instructions

The following information should be recorded for **each vaccine** inventory when it arrives. At the end of each week, the number of doses used should be recorded. At the end of the month the balance should be recorded.

At the end of each month conduct a physical check of the inventory and compare it with the recorded balance, looking for any discrepancies. If the cause of a discrepancy cannot be determined and corrected, make a note of this. Start a new stock record page by recording the physical count of the previous page. Use the correct physical count for the starting balance. Use the remaining lines to record new shipments of vaccines/diluents and weekly accounts of doses used.

Vaccine Tally Sheet Instructions

Place a copy of this sheet on the door of the refrigerator and freezer units in which you store vaccines. Record the week (by date and/or week number). Write the names of the vaccines/diluents and indicate the storage location of each vaccine/diluent in the refrigerator (R) or freezer (F). Record a tick mark for each dose of vaccine/diluent that you remove from a storage unit (i.e. for each dose that is administered, wasted, unusable, expired or transferred). At the end of the week, add the tick marks for each vaccine/diluent and update the appropriate stock record. Remove the completed tally sheet from each storage unit door and store in a file for future reference. Place a new copy of the tally sheet on the storage unit door.

1. These resources have been adapted from the Centers for Disease Control and Prevention Vaccine Storage and Handling Toolkit (2012), available at http://www.cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf.

VACCINE

STOCK RECORD

E

VACCINE TYPE							MONTH AND YEAR				
Date Received or Usage Tallied	Person Receiving Shipment *	Arrival Condition **	Vaccine or Diluent Name	Manufacturer	Vial Type ***	Lot Number	Expiration Date	Expiration Date After Reconstitution	Doses Received/Balance Forward	Doses Used §	Balance (Doses)
	BEGINNING BALANCE FOR THE MONTH									N/A	

Vaccine Totals			§§
Physical Stock Check (In Doses)			
Difference ("Balance" minus Physical Stock Check)			
Balance Carried Forward (In Doses)			

* The initials of the person who unpacked or checked the vaccines/diluents upon arrival.

** G = Vaccines/diluents arrived in good condition.
X = Condition of vaccine/diluents questionable; document details on reverse side of stock record; contact jurisdictional/local public health office or immunization program.

*** S = Single-dose vial
M = Multidose vial
Y = Pre-filled syringe.

§ Include the number of doses administered, wasted, spoiled, expired or transferred.

§§ Enter the sum of "total doses received or balance forward" minus "total doses used".

VACCINE

TALLY SHEET

E

WEEK (DATES):

Storage Location *	Vaccine or Diluent Name	Doses Administered	Doses Wasted	Doses Expired **	Doses Unusable	Doses Transferred (Viable) ***	Total

* R = Refrigerator
F = Freezer

** See Section 10: Vaccine Disposal for details regarding expired vaccine/diluent. If expired vaccine and/or diluent doses must be discarded, local/jurisdictional guidelines should be followed.

*** Viable vaccine doses transferred to your jurisdictional/local public health office or immunization program or another facility.

APPENDIX F:

Cold Chain Failure Reports

The following sample reports (Suspected Cold Chain Failure Exposure and Wastage Report, and Vaccine Inventory: Cold Chain Failure) may be used or adapted.

See Section 2 and Section 6 for details.

SUSPECTED COLD CHAIN FAILURE EXPOSURE AND WASTAGE REPORT

(F)

HEALTH UNIT, REGION NAME: FACILITY INFORMATION:			DATE:
Report completed by:		Contact name if other than reporter:	
Phone # : Fax # : email :		Phone # : Fax # : email :	
Was the failure detected during an annual inspection? Date of most recent inspection:			

BRIEF INCIDENT DESCRIPTION:				DISCOVERY DATE / TIME:	
Date and time of last known temperature consistently between +2°C and +8°C	Date: Time:	Temperature at time of discovery:	Min: Max: Current:	Estimated duration of exposure:	Hours: Days: Weeks:

Check the box that applies to the cold chain failure:	☐ Equipment malfunction (i.e. thermometer, alarm) ☐ Fridge malfunction (i.e., sensor, compressor) ☐ Power failure: How long was the power disrupted?_____ What time of day was the disruption?_____ What was the cause of disruption?_____ ☐ Human error (i.e. door left open, unplugged) ☐ Other (describe)	Was there any expired vaccine discovered at the facility? ☐ Yes ☐ No Describe the event briefly:

COMPLETE IF TRANSPORTATION INVOLVED	☐ Air ☐ Land	Date/time products were packed: Date/time products were un packed:	
Describe container:		Describe transport: (i.e. car courier, bus)	
Temperature exposed to during transport:		Condition of gel or ice packs on arrival: (i.e. number, frozen, cold or warm, left on counter)	
Describe filler used:		Temperature monitoring devices used:	

☐ Vaccine and diluent segregated within the appropriate storage unit and labelled with a "DO NOT USE" sign ☐ Jurisdictional/local public health office or immunization program contacted ☐ Vaccine/diluent stability confirmed with jurisdictional/local public health office or immunization program ☐ Usable vaccine and diluent marked to indicate exposure and to use first	Comments:

VACCINE INVENTORY

F

COLD CHAIN FAILURE

HEALTH UNIT, REGION NAME:
FACILITY INFORMATION:

Vaccine	# Vials/Units	# Doses per Vial/Unit	# Unopened Vials/Units	# Open Multidose Vials/Units	Lot #	Expiry Date	Previous Exposure Dates (if no exposure, enter "nil")	Suitable for Use; Mark as Exposed	Unsuitable for Use	Approximate Value of Exposed Vaccine(s)
APPROXIMATE VALUE OF RETURNED VACCINE									$	

APPENDIX G:

Technical Components of Purpose-built and Domestic Frost-free Refrigerators

The following table provides a comparative summary of the two types of refrigerator that are suitable for the storage of vaccines: purpose-built refrigerators and domestic frost-free refrigerators.

See Section 3 for details.

TECHNICAL COMPONENTS
OF PURPOSE-BUILT AND DOMESTIC FROST-FREE REFRIGERATORS

TECHNICAL COMPONENT	PURPOSE-BUILT REFRIGERATOR	DOMESTIC FROST-FREE REFRIGERATOR
1. Temperature Regulation	The temperature-regulation mechanism has • a very tight temperature tolerance • a quick reaction time to temperatures outside the set range. A temperature probe for the temperature control is usually located in the path of the return airflow, thereby measuring the temperature of the warmest air in the refrigerator.	The temperature-regulation mechanism (thermostat) detects temperature changes and controls the compressor's on and off function. When the temperature exceeds the set temperature of the thermostat, the thermostat sends a signal to the compressor to cool the unit. Large fluctuations in temperature may occur depending on the point at which the compressor turns on and the time it takes to cool the unit. **NOTE:** Products placed close to vents will be exposed to temperatures below 0°C (+32°F), since cold air is blown into the unit from the evaporator. As well, the temperature sensors may not measure the temperature where the vaccines are stored, thereby possibly exposing vaccines to temperatures outside the recommended range.
2. Defrost Mechanism	The defrost mechanism defrosts ice from the evaporator without raising the temperature in the unit, preventing fluctuations of temperatures within the unit. There is a small heating element wrapped around the evaporator coils that has the capacity to melt the frost off the evaporator frequently.	The defrost mechanism consists of heating coils wrapped around the evaporator in the freezer. The heating coil is controlled by a timer and/or a sensor that determines when a predetermined temperature is reached and when the heating coil should be turned off. There is a risk of temperature fluctuations that may result in higher temperatures in the freezer and sections of the refrigerator, creating temperature variations that can affect vaccine storage.
3. Spatial Temperature Differential	The spatial temperatures are tightly controlled, and there is constant fan-forced air circulation within the refrigerated compartments. The temperature does not vary within the storage area from the set point.	The spatial temperatures can vary greatly, as domestic refrigerators are designed to have various temperature zones for multiple storage functions. This can result in vaccines being stored in suboptimal conditions.
4. Control of Changes in Ambient Temperature	The constant fan-forced air circulation helps to keep internal temperatures within a range even when the ambient temperature changes.	In some models, the temperature sensor may be located in the freezer. As a result, when the ambient temperature rises, the compressor operates more frequently, and the refrigerator gets exposed to cooler air from the evaporator more frequently.
5. Temperature Recovery	The temperature is digitally managed; any deviation from the preset temperature is sensed very rapidly. **NOTE:** The glass doors of purpose-built refrigerators do not provide good insulation in the event of a power interruption, resulting in a rapid rise in spatial temperature.	Temperature recovery depends on many factors, including the design of the refrigerant delivery system and temperature regulation system; the size of the compressor, evaporator, and fan; and the time it takes for the temperature sensor to detect a change in temperature. Temperature regulation may be aided by large loads or the presence of water bottles to keep the refrigerator's thermal mass higher.

APPENDIX H:

Refrigerator and Thermometer Maintenance and Monthly Vaccine Inventory

The following forms may be used or adapted to record refrigerator and thermometer maintenance, and monthly vaccine inventory.

See Section 3 and Section 8 for details.

H

REFRIGERATOR AND THERMOMETER

MAINTENANCE

HEALTH UNIT, REGION NAME: FACILITY INFORMATION:	DATE:
Primary Vaccine Coordinator: Backup/Delegate Vaccine Coordinator:	

REFRIGERATOR MAINTENANCE

Refrigerator Type: _____ Year Received: _____

a) Cleaning

Motor and coils Date: _____ Completed by _____

Fridge and freezer Date: _____ Completed by _____

b) Door seals checked Date: _____ Completed by _____

c) Refrigerator Repairs Date: _____ Completed by _____

Details:

_____

_____

_____

_____

THERMOMETER MAINTENANCE

Thermometer Type: _____ Year Received: _____

a) Battery replaced or changed Date: _____ Completed by _____

b) Probes/cables checked Date: _____ Completed by _____

c) Calibration (slush test) Date: _____ Completed by _____

Results/Action taken:

_____

_____

_____

_____

_____

_____

_____

MONTHLY VACCINE **INVENTORY**

(PAGE 1 OF 2)

HEALTH UNIT, REGION NAME: FACILITY INFORMATION:	DATE:
Primary Vaccine Coordinator: Backup/Delegate Vaccine Coordinator: Completed by:	*** Record the vaccine and diluent together on the inventory sheet**

VACCINE	*	*	STORAGE CONDITIONS	DATE RECEIVED	LOT NUMBER	EXPIRY DATE		CURRENT NUMBER OF DOSES
						SINGLE DOSE	MULTI DOSE	
Diphtheria, tetanus, acellular pertussis, inactivated polio virus, and *Haemophilus influenzae* type b conjugate vaccine (DTaP-IPV-HiB)	V							
	D							
Diphtheria, tetanus, acellular pertussis, and inactivated polio virus vaccine (DTaP-IPV)	V							
	D							
***Haemophilus influenzae* type b conjugate vaccine (HiB)**	V							
	D							
Tetanus, diphtheria, acellular pertussis vaccine (Tdap)	V							
	D							
Tetanus, diphtheria, acellular pertussis and inactivated polio virus vaccine (Tdap-IPV)	V							
	D							
Hepatitis B vaccine (HB)	V							
	D							
Measles, mumps, and rubella vaccine (MMR)	V							
	D							

Varicella vaccine (Var)	V						
	D						
Measles, mumps, rubella and varicella vaccine (MMRV)	V						
	D						
Meningococcal C conjugate vaccine (Men-C)	V						
	D						
Meningococcal conjugate A, C, Y and W-135 vaccine (Men-C-A, C, Y, W-135)	V						
	D						
Pneumococcal conjugate 13 valent vaccine (Pneu-C-13)	V						
	D						
Pneumococcal polysaccharide 23 valent vaccine (PP23)	V						
	D						
Influenza vaccine (Inf)	V						
	D						
Human papillomavirus vaccine (HPV)	V						
	D						
Rotavirus vaccine (Rot)	V						
	D						
Zoster (Zos)	V						
	D						
Other	V						
	D						

APPENDIX I:

Temperature Log for Vaccines and Vaccine Storage Troubleshooting Record

The following sample reports (Temperature Log for Vaccines and Vaccine Storage Troubleshooting Record) may be used or adapted.

See Section 3 and Section 5 for details.

INSTRUCTIONS

Completing this temperature log: Check the min/max temperatures in both the freezer and the refrigerator compartments of your vaccine storage units at least twice each working day. Place an "X" in the box that corresponds with the temperature and record the ambient (room) temperature, the time of the temperature readings and your initials. Once the month has ended, save each month's completed form for as long as your jurisdiction requires.

If the recorded temperature is in the shaded zone: This represents an unacceptable temperature range. Follow these steps: 1. Store the vaccine under proper conditions as quickly as possible. 2. Notify the designated vaccine coordinator or delegate.
3. Document the action taken on the Vaccine Storage Troubleshooting Record.

TEMPERATURE LOG
FOR VACCINES

MONTH & YEAR:

DAYS 1 – 15

	Day of the Month	1		2		3		4		5		6		7		8		9		10		11		12		13		14		15			
	Record Twice Daily	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM		
	Staff Initials																																
	Room Temp																																
	Exact time																																
Too Warm	+11°C																																
	+10°C																																
	+9°C																																
REFRIGERATOR TEMPERATURE	+8°C																																
	+7°C																																
	+6°C																																
	AIM FOR +5°C																																
	+4°C																																
	+3°C																																
	+2°C																																
Too Cold	+1°C																																
	+0°C																																
	-1°C																																
Too Warm	-12°C																																
	-13°C																																
	-14°C																																
FREEZER	-15°C																																
	-16°C																																
	-17°C																																

TEMPERATURE LOG
FOR VACCINES

MONTH & YEAR:
DAYS 16 – 31

	Day of the Month	16		17		18		19		20		21		22		23		24		25		26		27		28		29		30		31	
	Record Twice Daily	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
	Staff Initials																																
	Room Temp																																
	Exact time																																
Too Warm	+11°C																																
	+10°C																																
	+9°C																																
REFRIGERATOR TEMPERATURE	+8°C																																
	+7°C																																
	+6°C																																
	AIM FOR +5°C																																
	+4°C																																
	+3°C																																
	+2°C																																
Too Cold	+1°C																																
	+0°C																																
	-1°C																																
Too Warm	-12°C																																
	-13°C																																
	-14°C																																
FREEZER	-15°C																																
	-16°C																																
	-17°C																																

VACCINES STORAGE

TROUBLESHOOTING RECORD

Date Time	Storage Unit Temperature	Room Temperature	Problem	Action Taken	Results	Initials

APPENDIX J:

Online Resources

Use the links on the next page to access provincial and territorial jurisdictional guidelines on vaccine storage and handling. Note that the links may be updated after the publication of these federal guidelines. Please use the most up-to-date versions of the following resources.

ONLINE RESOURCES

(J)

JURISDICTION	ONLINE RESOURCE
Alberta	http://www.health.alberta.ca/documents/AIP-General-Guidelines.pdf
British Columbia	http://www.bccdc.ca/dis-cond/comm-manual/CDManualChap2.htm
Manitoba	http://www.gov.mb.ca/health/publichealth/cdc/protocol/ccp.pdf
New Brunswick	http://www2.gnb.ca/content/gnb/en/departments/ocmoh/for_healthprofessionals/cdc/NBImmunizationGuide.html
Newfoundland and Labrador	http://www.health.gov.nl.ca/health/publichealth/cdc/health_pro_info.html#immunization
Northwest Territories	Contact public health department directly
Nova Scotia	http://novascotia.ca/hpp/cdpc/docs/Immunization-Manual.pdf
Nunavut	Contact public health department directly
Ontario	http://www.health.gov.on.ca/en/pro/programs/publichealth/oph_standards/docs/guidance/guide_vaccine_storage.pdf
Prince Edward Island	http://www.gov.pe.ca/photos/original/DHW_IPC_HC.pdf
Québec	http://publications.msss.gouv.qc.ca/acrobat/f/documentation/piq/chap5.pdf http://www.msss.gouv.qc.ca/sujets/santepub/vaccination/index.php?documentation_pro
Saskatchewan	http://www.health.gov.sk.ca/immunization-manual
Yukon	http://www.hss.gov.yk.ca/yipm.php

APPENDIX K:

Algorithms to Assess Problems in Temperature Readings Outside the Recommended Ranges

Use or adapt these algorithms to help assess problems in temperature readings outside the recommended ranges.

See Section 6 for details.

Prior to assessment of the problem, move vaccine to a backup refrigerator or activate the Urgent Vaccine Storage and Handling Protocols.

ALGORITHM 1: temperature reading is less than +2ºC (+35°F)

ALGORITHM 2: temperature reading is greater than +8ºC (+46°F)

ALGORITHM 1: TEMPERATURE READING IS LESS THAN +2°C (+35°F)

1. Is the thermometer properly placed and working?
   - NO → Move the thermometer/probe to the centre of the middle shelf. Change the battery, if necessary.
   - YES ↓
2. Is the thermostat set to an appropriate setting?
   - NO → Adjust the thermostat to a warmer setting. Recheck the temperature of the fridge every half hour until the temperature stabilizes at or around +5°C. Continue to monitor for several more hours.
   - YES ↓
3. Has the ambient temperature of the room become warmer?
   - YES → Adjust the temperature of the room so that it is not too warm. A warm room will cause the fridge to work harder, producing a cooler environment inside the fridge.
   - NO ↓
4. Is there good air circulation outside of the fridge?
   - NO → Ensure the refrigerator is set up according to the recommended clearance requirements and that nothing is impairing the air exchange around the unit.
   - YES ↓
5. Call a trained technician to check the fridge.

ALGORITHM 2: TEMPERATURE READING IS MORE THAN +8ºC (+46°F)

After ensuring that the fridge is plugged in, the outlet is working, and the cord is functioning properly:

1. Is there electrical power to the fridge?
   - NO → Check the fuse box then contact the electric or hydro company in your area if necessary.
   - YES ↓
2. Is the door closing properly?
   - NO → Check the levelling legs, door seals, door latch and hinges. Call a technician to repair as necessary.
   - YES ↓
3. Is the thermometer properly placed and working?
   - NO → Move the thermometer/probe to the centre of the middle shelf. Change battery if necessary.
   - YES ↓
4. Is the thermostat set to the appropriate setting?
   - NO → Adjust the thermostat to a colder setting. Recheck the thermometer every half hour until the temperature stabilizes at or around +5°C. Continue to monitor for several more hours.
   - YES ↓
5. Has the ambient temperature of the room become cooler?
   - YES → Adjust the temperature of the room so that it is not too cold. A cold room will cause a cool ambient temperature outside and a warm environment inside the fridge.
   - NO ↓
6. Is there good air circulation inside and outside the fridge?
   - NO → Rearrange vaccine trays to allow air to circulate around the vaccines. Ensure that nothing is impairing the air exchange around the unit.
   - YES ↓
7. Call a trained technician to check the fridge.

APPENDIX L:

Checklist for Safe Vaccine Storage and Handling

The following checklist may be used or adapted.

See Section 4 for details.

✓ CHECKLIST
FOR SAFE VACCINE STORAGE AND HANDLING (PAGE 1 OF 2)

ARE YOU DOING THEM ALL?

(PAGE 1 OF 2)

YES	NO	
		1. We have a designated vaccine coordinator.
		2. We have a designated back-up vaccine coordinator.
		3. All staff receive ongoing training.
		4. All new staff are trained at an appropriate level in proper storage and handling practices.
		5. A vaccine inventory log is maintained that documents:
		a) Vaccine name and number of doses received
		b) Date the vaccine was received
		c) Arrival condition of vaccine
		d) Initials of person unpacking shipment
		e) Vaccine manufacturer and lot number
		f) Vaccine expiration date
		g) Type of container of each vaccine
		h) Number of doses used
		i) Number of doses remaining
		6. Our refrigerator for vaccines is either a purpose-built or a domestic frost-free style, NOT a bar-style. The freezer compartment has a separate exterior door.
		7. We do NOT store any food, drink or specimens in the refrigerator or freezer.
		8. We store vaccines in the middle of the refrigerator or freezer, and NOT in the door.
		9. We stock and rotate our vaccine supply so that the newest vaccine of each type (with the longest expiration date) is placed behind the vaccine with the shortest expiration date.
		10. We check vaccine expiration dates and use those that will expire soonest first.
		11. We post a sign on the refrigerator door showing which vaccines should be stored in the refrigerator and which should be stored in the freezer.
		12. We always keep a min/max thermometer or data logger in the refrigerator and freezer.

✓ CHECKLIST
FOR SAFE VACCINE STORAGE AND HANDLING (PAGE 2 OF 2)

ARE YOU DOING THEM ALL?
(PAGE 2 OF 2)

YES	NO	
		13. The temperature in the refrigerator is maintained between + 2°C and + 8°C (+35°F and +46°F).
		14. We keep extra containers of water in the refrigerator in appropriate areas.
		15. The temperature in the freezer is maintained at –15°C (+5°F) or colder.
		16. We keep ice packs and other ice-filled containers in the freezer.
		17. We record the minimum and maximum temperatures of the refrigerator and freezer, and the room temperature twice daily, first thing in the morning and at clinic closing time.
		18. We know whom to call if the temperature is out of range.
		19. We calibrate the thermometer using the slush test at least once a year and change batteries in thermometer or data loggers on a regular basis.
		20. We defrost the refrigerator regularly.
		21. We have a **Do Not Unplug** sign next to the refrigerator's electrical outlet.
		22. We check that the door is properly closed and sealed.
		23. In the event of a refrigerator failure, we take the following steps:
		a) We ensure that the vaccines are maintained under appropriate conditions.
		b) We mark vaccines as having been exposed, and separate them from undamaged vaccines.
		c) We note the refrigerator or freezer temperature and the ambient temperature, and then always contact the local public health office or immunization program to determine how to handle the affected vaccines.
		d) We follow the local public health office or immunization program instructions. If the vials are useable, we mark them with the revised expiration date provided by the program.
		24. We have a detailed written protocol for routine and urgent vaccine storage and handling.