THIS CHAPTER MEETS THE FOLLOWING IMMUNIZATION COMPETENCIES FOR HEALTH PROFESSIONAL (PHAC, 2008): http://www.phac-aspc.gc.ca/im/pdf/ichp-cips-eng.pdf

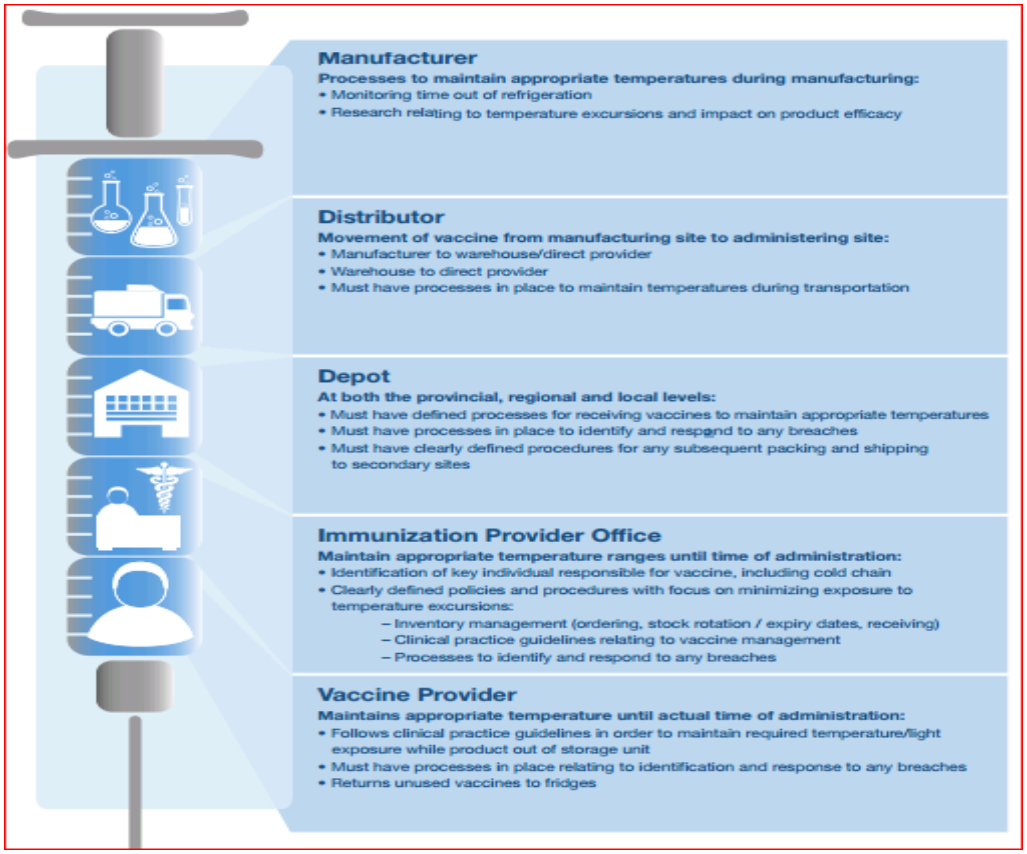
#7: Storage and Handling of Immunization Agents

- Competency: Implements Canadian guidelines when storing, handling, or transporting vaccines.

1.0 THE COLD CHAIN

'Cold chain' refers to the processes to maintain optimal temperature conditions during the transport, storage and handling of biological products, starting at the manufacturer and ending with administration of the product to the client. The proper storage and handling of biological products like vaccines and immunoglobulins are key components in maintaining the effectiveness of immunization programs. Appropriate biological product management is a shared responsibility from the time the biological product is manufactured until it is administered to the client. In this chapter, the use of the words 'vaccine' or 'vaccines' will also refer to biological products like immunoglobulins.

The optimum temperature for refrigerated vaccines is between 2°C - 8°C (36°F – 46°F). The optimum temperature for frozen vaccines is -15°C to -50°C (+5°F to -58°F). In addition, protection from light is necessary for some products. Proper storage temperatures must be maintained at every link in the chain:



(Source: *National Vaccine Storage and Handling Guidelines for Immunization Providers,* PHAC, 2015)

The objective of the chapter guidelines is to provide consistent and evidence-based recommendations for vaccine storage and handling for all health-care providers in Saskatchewan. These guidelines are adapted from the *National Vaccine Storage and Handling Guidelines for Immunization Providers* (PHAC, 2015), available at: http://healthycanadians.gc.ca/publications/healthy-living-vie-saine/vaccine-storage-entreposage-vaccins/alt/vaccine-storage-entreposage-vaccins-eng.pdf and the *Vaccine Storage & Handling Toolkit* (CDC, 2016), available at: http://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf.

1.1 Importance of Maintaining the Cold Chain

All biological products used in publicly funded programs for immunization, testing and screening programs in the province of Saskatchewan are provided free of charge to the public. It is essential that the utmost care be taken in the transport, storage and administration of these products, in order to minimize wastage and protect the potency of the vaccine. Cold chain break incidents must be reported to the Ministry of Health as soon as discovered.

The majority of vaccine storage and handling mistakes are easily avoidable. Three elements are essential to ensure proper vaccine cold chain:

1. Efficient biological product management procedures.
2. Fully trained personnel.
3. Proper storage and transportation equipment.

Vaccines are sensitive biological products that may become less effective or destroyed when exposed to temperatures outside the recommended range. Vaccines exposed to temperatures above or below the recommended temperature range may experience some loss of potency with each episode of exposure. Cold sensitive vaccines experience an immediate loss of potency following freezing. Repeated episodes of exposure to heat results in a cumulative loss of potency that is irreversible. Product stability data is not always available from manufacturers, so it can be difficult to assess the potency of a vaccine that has endured a cold chain break.

Maintaining the potency of vaccines is important for several reasons:

- There is a need to ensure that an effective product is being used. Vaccine failures caused by administration of compromised vaccine may result in the re-emergence or occurrence of vaccine preventable disease.
- Careful management of resources is important. Vaccines are expensive and can be in short supply. Loss of vaccine may result in the cancellation of immunization clinics, resulting in lost opportunities to immunize.
- Revaccination of clients who received an ineffective vaccine may cause loss of public confidence in vaccines and/or the health-care system.

When a cold chain break has been identified after a vaccine has been administered, the duration and temperature of the exposure is taken into account to assess a product's viability. Serological testing or revaccination may be suggested.

1.2 Protecting Vaccines During Immunization Clinics

Following these steps will ensure that the vaccines are maintained at the required temperature throughout the process and that the vaccines that are returned to the refrigerator have not been exposed to temperatures below 2°C (36°F) or above 8°C (46°F).

- Pack only the amount of vaccine you expect to use during the immunization clinic.
- Maintain the vaccines at the required temperature (between 2°C - 8°C (36°F – 46°F)) during the immunization clinic.
- Minimize the number of times that the cooler is opened during the immunization clinic.
- Monitor temperature readings in the insulated cooler often with a digital read out thermometer if available.

1.3 General Recommendations

1.3.1 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. 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.

1.3.2 Training Personnel

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

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 and be required to submit a vaccine cold chain report to the Ministry.

2.0 VACCINE STORAGE EQUIPMENT AND MAINTENANCE

The essential cold chain equipment needed to transport and store vaccines include:

- A dedicated refrigerator for storing biological products.
- A dedicated refrigerator for gel packs.
- A freezer for storing ice packs.
- Temperature monitoring devices.
- Insulated containers (coolers).
- Ice packs (frozen).
- Gel packs (stored at biological refrigerator temperatures).
- Insulating material.

Vaccine storage units must be selected carefully, used properly and maintained regularly. A refrigerator or freezer used for vaccine storage must:

- Be dedicated to the storage of vaccine only.
- Be able to maintain the required vaccine storage temperatures through all seasons.
- Be large enough to hold the year's highest monthly inventory, including influenza vaccine.
- Have a calibrated thermometer or data logger inside each refrigerator and freezer unit.
- Be placed in a secure location away from unauthorized and public access.

2.1 Protecting Vaccine Supplies

- Continued maintenance of all equipment is recommended to maintain optimal functioning. Keep maintenance log books for all pieces of vaccine storage equipment. Check equipment according to manufacturer's maintenance specifications to meet warranty requirements.

- Ensure that the power supply to the vaccine storage unit is protected. Label fuses and circuit breakers, and post signs to make others aware not to unplug the unit's cord from the electrical outlet.
- Label the vaccine refrigerator's power breaker switch in the electrical panel box: "**VACCINE REFRIGERATOR - DO NOT DISCONNECT/DO NOT SWITCH OFF**".
- Connect the refrigerator to a dedicated circuit that is not used for other appliances. Avoid using power outlets with built-in circuit switches (they have little red reset buttons), outlets that can be activated by a wall switch, or power strips. These can be tripped or switched off, resulting in loss of electricity to the storage unit.
- Use a plug guard on the electrical outlet for the refrigerator to prevent accidental disconnection from power.
- Facilities storing large vaccine inventories should install continuous monitoring temperature alarm systems with round-the-clock notification of appropriate personnel.
- Install back-up power generators to automatically provide power and maintain the ideal storage temperatures. Back-up generators should be of a 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. The generators should be regularly tested as per the manufacturer's instructions.
- As with any back-up system, periodic evaluation of the operational performance of the alarm and response will ensure that the contingency plan is effective.

2.2 Refrigerators and Freezers

The refrigerator compartment should maintain temperatures between 2°C - 8°C (36°F – 46°F). Set the temperature mid-range to achieve an average of about 5°C (41°F) (**'Strive for 5'**). This temperature setting will provide the best safety margin of temperature fluctuations within the 2°C to 8°C (36°F – 46°F) range. **Vaccines that must be frozen should be maintained in freezers at temperatures between -15°C to -50°C (+5°F to -58°F).**

Recommendations:

- Choose an appropriate refrigerator size:
  - Consider the amount of vaccine that will be used in your monthly order period; and
  - Consider seasonal fluctuations when more vaccine may be required (e.g., influenza season, school immunization programs).
- Newly installed or repaired vaccine storage unit must have 1 week of twice daily temperature recordings before using it to store biological products.
- Vaccine storage unit must have separate electrical circuits if possible.
- Ensure the room is well ventilated. Leave at least 10 cm of space (or as recommended by the manufacturer) between the back of the unit and the wall for air circulation around the vaccine storage unit.
- Ensure nothing blocks the cover of the motor compartment.
- Ensure vaccine storage units stand firmly and level, 2.5 to 5 cm above the floor.
- Never place the vaccine storage unit in direct sunlight, near a heat source, or along an outside wall where the temperature of the wall can vary.
- Ensure the room in which the vaccine storage unit is placed has a thermostat or thermometer to measure the room temperature.
- Always lock the refrigerator, or place the refrigerator in a room that can be locked, to prevent unauthorized access, product handling or refrigerator tampering.
- Ensure the vaccine storage unit door closes tightly. Installing a Velcro latch can help ensure that the door isn't accidentally left ajar during the day, or after hours.
- Never store items such as food and beverages in vaccine refrigerators, to prevent unnecessary opening of the refrigerator.

- Storage of laboratory specimens in a separate refrigerator is recommended. If laboratory specimens must be stored in a vaccine refrigerator, these specimens should be stored in separate, clearly-marked containers.

2.2.1 Purpose-Built Refrigerators

A purpose-built (lab or pharmacy grade) refrigerator is the standard for storing large inventories of vaccines for several reasons:

Temperature regulation

The temperature regulation mechanism in a purpose-built refrigerator has a very tight temperature tolerance and a quick reaction time to temperatures outside of 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.

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 period of time needed for defrosting in other refrigerator designs. This method of regular defrosting also prevents fluctuations of temperatures within the unit.

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.

Effects of changes in ambient temperature

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

Temperature recovery

The temperature is digitally managed in purpose built refrigerators. Any deviation in temperatures from the pre-set one is sensed very rapidly. It is important to note one limitation of these refrigerators: the glass doors do not provide good insulation in the event of a power interruption, resulting in a rapid rise in internal temperature. **These refrigerators should have a reliable long-lasting back-up power supply.**

2.2.2 Domestic Refrigerators

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 temperatures may occur depending on the point at which the compressor turns on and the time it takes to cool the unit. This will vary depending on 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 experience 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.

Defrost mechanism

Depending on the type of domestic refrigerator, there are two main mechanisms for defrosting:

- **A domestic frost-free refrigerator** relies on 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. **In a manual and cyclic defrost refrigerator**, the freezer defrosts manually and the refrigerator relies on natural melting or off-cycle heating of the evaporator when the compressor is off.

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

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. In turn, this could result in vaccines being stored in suboptimal conditions.

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.

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.

2.2.3 Bar Fridge Units

Bar fridge units are not acceptable for vaccine storage. With combined refrigerator and freezer units, the freezer compartments of bar fridge units are incapable of maintaining temperatures cold enough to store freezer-stable vaccine. 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 that of the air in the compartment, resulting in varying temperatures in the refrigerator as the ambient temperature changes.

2.2.4 Freezers

Vaccines should be stored away from the freezer walls and vents in the part of the freezer best able to maintain the required temperature range -15°C to -50°C (+5°F to -58°F). Vaccines must not be stored in the freezer door. The temperature in the door is unstable and differs from that inside the unit. Frozen cold packs can be stored in the freezer door.

2.3 Insulated Containers/Ice Packs/Gel Packs/Insulating Materials

2.3.1 Insulated Containers

Vaccines should be transported in insulated containers that have been qualified to ensure that they are capable of maintaining the vaccine temperature of 2°C - 8°C for the necessary duration.
The cooler should meet the following criteria:

- It is large enough to store vaccines, ice/gel packs, and insulating material during transport.
- The external surface material is strong and durable.
- The cooler insulation thickness is 30 mm to 80 mm.
- The lid is tight fitting.
- It has strong handles for carrying or wheels for transport.

Acceptable containers:

- Hard-sided plastic insulated coolers.
- Soft-sided vaccine bags.
- Shipping containers the vaccines arrived in from the manufacturer.
- Newer Styrofoam coolers with at least 2-inch thick walls.

Unacceptable containers (cannot reliably maintain appropriate temperatures):

- Banged-up old Styrofoam containers.
- Thin-walled Styrofoam coolers (such as those to hold beverages).

NOTE: Extra minimum/maximum thermometers should be available for use in coolers that are being used to store vaccines for several hours (e.g., for use at an off-site mass clinic). It is not necessary to use a thermometer in insulated coolers being used to transport vaccine for a short duration (e.g., from the health unit to physician's office) or in small coolers used at a clinic work station.

2.3.2 Ice Packs and Gel Packs

The temperature inside the cooler is maintained with ice/gel packs, and insulating materials. Keep enough ice packs frozen or gel packs refrigerated (at +2°C to +8°C) and ready to meet the vaccine transport needs of your clinic or health unit. Ensure that ice packs are completely frozen before use.
There are two main types of cooling packs:

- Refrigerator-conditioned (e.g., gel packs).
- Frozen packs:
    - **Note:** Ice packs filled with tap water are the safest type for maintaining the recommended vaccine storage temperature of 2°C - 8°C inside a cold box.
    - Gel coolant packs may have a freezing point below 0°C and may pose a risk of freezing vaccines.
    - Information about the product's cold life and instructions on how to freeze and condition the product before use should be asked of the manufacturer before purchasing coolant products.
    - Never use bagged or loose ice to transport vaccines.
    - If possible, set ice packs on their edge and allow space between them for air circulation in the freezer. Stacking icepacks on top of each other in the freezer may result in uneven or partial freezing, and decrease the efficacy of the icepacks.

2.3.3 Insulating Materials

Insulating materials are used as a barrier to prevent direct contact between vaccines and frozen packs. **A layer of paper towelling is not sufficient as a barrier to protect vaccines from contact with frozen material.**

Insulating materials include:

- Flexible insulating blankets (e.g., water blankets) and gel packs (refrigerated temperature is preferable).
- Crumpled packing paper, paper rolls, cardboard.
- Bubble wrap, Styrofoam peanuts.

2.4 Vaccine Storage Unit Maintenance

Regular maintenance is required to ensure proper functioning of the equipment and to extend the useful life of the appliance. Check equipment according to manufacturer's maintenance specifications to meet warranty requirements**.** The following maintenance schedule provides guidelines that should be considered when establishing local policies.

2.4.1 Daily Maintenance Tasks

- Clean spills immediately inside refrigerator compartments to prevent the growth of bacteria and fungi.
- Check the internal temperature.
- Minimum/maximum temperatures must be read and documented twice daily, during the week.
- More frequent temperature monitoring is required following thermostat adjustments.
- Check that the doors are closed. Improperly closed doors impact internal refrigerator temperatures. The doors should be checked at the end of the day to make sure that they are properly closed and sealed. Installing a Velcro™ latch can help to ensure the door is secure.

2.4.2 Weekly Maintenance Task

Check ice build-up in the freezer (manual and cyclic frost units only).

- When frost has accumulated to a thickness of 1 cm, the unit requires defrosting. Consult the manufacturer's direction for defrosting. Ensure that all vaccines are moved into a temperature controlled and monitored cooler or alternate temperature controlled and monitored refrigerator prior to defrosting. Ensure that the fridge temperature is stable between 2°C - 8°C before moving vaccines back into the fridge.

2.4.3 Quarterly Maintenance Tasks

Have a refrigeration company clean the coils and motor:

- Unplug the unit and use a soft brush, cloth or vacuum cleaner to remove dust from the surface of the coils.
- After cleaning, plug in the unit and document that the procedure has been done and that power was restored.
- As it only takes a few minutes to complete this procedure, it isn't necessary to transfer the vaccine to another storage unit as long as the doors remain tightly sealed for the duration and power is reconnected immediately following the procedure.
- Check the door seal using this method. With the fridge door open, place a thin paper strip against the front surface of the fridge cabinet that the seal closes against. Close the door. Move the paper strip between the seal and the fridge cabinet all the way around the door. If it moves easily or falls away by itself, the seal needs to be adjusted. Pay particular attention to the corners. Based on this assessment, if problems with the door seal or hinges are suspected, contact a trained repair technician and monitor the refrigerator temperatures frequently until the problem is fixed.

2.4.4 Annual Maintenance Task

All thermometers should be checked to ensure:

- Accurate temperature measurements.
- Batteries are functioning – consider an annual battery change for all battery operated equipment and note the date they are changed.
- Cables or probes are not damaged.
- An adequate supply of graph paper and ink pens is available for chart recorders.

2.5 Temperature Monitoring Devices

The CDC (2016) recommends thermometers with the following characteristics:

1. Provide continuous monitoring information with an active display.
2. Be a digital thermometer with a probe in a glycol-filled bottle. Standard air probes can be easily affected by short fluctuations in air temperature in the unit such as cycling and frequent opening and closing of the unit door during busy workdays.
3. Include an alarm for out-of-range temperatures.
4. Have a reset button if using a data logger with a min/max display.
5. Be capable of showing current temperature as well as minimum and maximum temperatures.
6. Be calibrated to be accurate within +/- 0.5°C (+/- 1°F). Recalibrate it if it has been dropped or purchase a new thermometer.
7. Have a low battery indicator.

Place thermometers away from the coils, walls, door, floor, and fans. In refrigerators place the thermometer on the middle shelf. In the freezer, place the thermometer on a box adjacent to the vaccine so that it is in the middle of the compartment. Have extra batteries for the thermometer on hand.

2.5.1 Continuous Temperature Recorders

Continuous temperature recorders are recommended as they provide accurate information about the occurrence time and length of a cold chain break. Continuous temperature recorder readings should be checked and recorded a minimum of twice daily (refer to this chapter, Section 2.6).

- **Data loggers** are strongly recommended. They are accurate, battery powered, and portable with a large internal memory. Choose a model that is capable of displaying the current temperature, as well as the minimum and maximum temperatures and should be read twice per day. Some models have an alarm that can be set to ring at a specified temperature. The internal memory is read with computer software and the records can be stored on computer. Go to: http://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf for further information.
- **Chart recorders** recorded continuously, 24 hours a day but are more difficult to read than digital thermometers because they require interpretation of the temperature graph. In addition, the chart paper must be changed when it is filled (usually weekly) and there is insufficient room to record readings. Failure to change the chart paper will result in unusable temperature data. Record the date on the graph paper when it is fitted and when you remove the graph paper.

2.5.2 Minimum and Maximum Thermometers

Digital min/max thermometers (with probes) show the current temperature and the minimum and maximum temperatures that have been reached since the last time the thermometer was reset. Temperature fluctuations outside the recommended range can be detected by referring to the minimum and maximum temperature readings. It is important to manually reset the minimum and maximum temperatures to the current temperature each time the temperatures are recorded for meaningful readings.

2.5.3 Temperature Indicator Cards

- WarmMark 2™ (ShockWatch) indicators show whether internal temperature of the vaccine package has risen above 10°C.
- Freeze Watch™ (3M) indicators show whether internal temperature of the vaccine package has fallen below 0°C. The manufacturer has confirmed that these monitors may be reused as long as they have not been activated or expired.

These monitors are intended only for use when transporting vaccines. The readings are irreversible; once the monitor has been activated, a coloured dye will be visible on the monitor indicating exposure to out of range temperatures.

2.6 Checking and Recording Temperatures

1. Post a temperature recording log on the vaccine storage unit door.
   a) **Temperatures must be read and recorded a minimum of twice per day.**
   b) Record the minimum and maximum temperatures reached since the last monitoring, on the Vaccine Temperature Log Form shown as Form 5.6 at the end of this chapter.
      i. In the morning before the door is opened for the first time.
      ii. At the end of the clinic day just after the door is closed for the last time.
   c) Reset the minimum/maximum thermometer once you have recorded the temperatures.
   d) Include the date and time of recordings, initials of the person recording and comments, if appropriate.

   NOTE: All vaccine storage unit temperatures must be read and recorded twice per day, even when a continuous temperature recording device is used, or when the refrigerator is connected to an alarmed temperature monitoring system. Monthly review of the continuous monitoring devices recording strip does not allow for timely notification and response to cold chain interruption and increases the risk that ineffective vaccine may have been administered to clients.
2. Record the current refrigerator temperature and ambient (room) temperature. Room temperatures may be read with a standard household thermometer.
3. If a temperature reading is missed, the log entry must remain blank.
4. If the temperature in either the refrigerator or freezer falls outside the recommended range for vaccine storage, the incident must be reported immediately to the regional Immunization Coordinator or designate. **Refer to Section 4.0, *Management of Cold Chain Incidents* in this chapter for direction.**

2.7 Reviewing and Storing Temperature Logs

If other staff are monitoring and recording the temperatures, the designated facility vaccine coordinator should review the logs on **a monthly basis** to ensure proper temperature recording and to note trends in refrigerator and freezer temperatures. Maintaining an ongoing file of temperature logs and equipment failures will help to track recurring problems for vaccine storage units. Retain completed forms (and the weekly recording wheel from the continuous data logger, if used) in order to have a history of temperature maintenance for refrigerated biological products. This process will also contribute to quality assurance assessment. Completed logs should be stored for legal purposes for the period of time determined by the health region/jurisdiction.

3.0 MANAGEMENT OF BIOLOGICAL PRODUCTS

3.1 Storage Principles - Refer to Appendix 9.1: *Store Biological Products Properly*.

3.1.1 Vaccine Principles

- Never leave vaccine outside of the refrigerator (e.g., on counters or in coolers after finishing a clinic**). Scan the environment carefully to prevent cold chain breaks due to human error.**
- Store all vaccine between 2°C - 8°C.
- Consider grouping vaccines by type: pediatric, adolescent, adult and seasonal.
- Place vaccines in mesh baskets and clearly label the front of the baskets by the vaccine agent;
- Keep all vaccines in their original boxes until they are ready to be used.
- Keep vaccines in the refrigerator or in a cooler until ready to administer.
- Only take or withdraw the actual number of doses required.
- Use vaccines that have experienced a cold chain incident and have been determined to be usable at the first opportunity.
- Keep a separate tray or container in the refrigerator for products that have been partially used or taken to a clinic (protect from light, if applicable). **Use these vaccines before opening new vials or packages**.
- Keep a digital minimum/maximum thermometer in refrigerator and record temperatures twice per day.
- Contact your regional immunization coordinator for advice when vaccine has been exposed to temperatures outside of 2°C - 8°C (e.g., human error, power failure).
- Develop a back-up plan for power outage/refrigerator failure (refer to Form 5.1, *Emergency Event Recovery Plan Form*).

3.1.2 Expiry Date Principles

- The expiry date is the date by which a vaccine or diluent should be used. When the date is marked as a month and year, the vaccine or diluent may be used up to and including the last day of the month. **Always check the expiry dates of the vaccines (and diluents) prior to administering the vaccine to avoid a medication error.**
  - **Note:** Component vaccines and diluents may be assembled into one package with a labelled expiry date on the outer carton. This date is the shorter of the two dates of either the component vaccine or the diluent in the package.
  - **Note:** The Ministry of Health will provide information when the original expiry date has been changed by the vaccine manufacturer.
- Check biological products inventory on the last working day of each month when inventory counts are done in Panorama. Check for and remove expired products. This is important in order to avoid the administration of expired products to clients.
- Check for product(s) that will expire within three months and rotate stock in kanbans accordingly. If use is unlikely within that time in the local office, determine if another office within the region could use the product.

3.1.3 Multidose Vial Principles

- Strict aseptic technique must be maintained each time a multidose vial is used and punctured.
- Multidose vaccine vials contain bacteriostatic agents that prevent the growth of bacteria.
- Multidose vials must be dated when first opened, and used within 30 days of first puncture unless the product monograph specifies a shorter or longer time period for use.
- Check for previously opened multidose vials before opening a new multi-dose vial to avoid product wastage. Remember to check the date opened before administering the vaccine to a client.
- Previously punctured multi-dose vials that are involved in a cold chain incident must not be used. They must be immediately disposed of and a wastage report submitted to the Ministry.

3.1.4 Storage Principles

- If room allows, place full plastic water bottles or thawed ice packs on the bottom and empty shelves (and in domestic refrigerator door) to function as a thermal ballast and maintain a constant storage temperature in all refrigerator models. This will delay the internal refrigerator temperature from rising in the event of a refrigerator or power failure.
- Do not store vaccines in refrigerator doors, vegetable crispers, on the refrigerator floor, or near the cooling units, as these areas are more susceptible to temperature fluctuations.
- Store vaccines only on the upper and middle shelves of the refrigerator.
- Leave space between products in the refrigerator to allow air to circulate.
- Keep vaccines away from cold air vents. The vents blow in cold air that could freeze vaccines.
- Open refrigerator doors ONLY as required, and for only as long as is necessary to replace or remove the product.

3.1.5 Other Principles

- Store flexible insulating blankets or gel packs used as insulating material in the refrigerator.
- Store diluents at room temperature to conserve refrigerator space, unless the product insert specifies refrigeration or is included in the vaccine packing box.
- **Store diluents and epinephrine at room temperature** (15°C to 30°C) (59°F to 86°F) and protect from heat, light and moisture.
- Dispose of all vials, ampoules and syringes used for biological products in sharps containers to comply with biohazardous waste guidelines.

3.2 Managing Biological Stock - Roles of Stakeholders

Inventory management ensures that appropriate vaccines are available and general wastage is minimized. This section provides information on the roles of the various stakeholders in the management of biologicals.

3.2.1 Facility Vaccine Coordinator

- Manage stock on hand and order products via Panorama.
- Rotate stock ensuring product with the shortest expiry date is used first. In instances where expiry dates are the same, use items that have been on-hand the longest, first.
- Conduct a monthly inventory report and reconciliation, and remove product that has expired.
- Ensure medications are available for the management of anaphylaxis:
  - Epinephrine 1:1000; and
  - *Diphenhydramine Injectable (Benadryl®) 50 mg/mL.

  ***Note: Diphenhydramine products cannot be ordered from the Roy Romanow Provincial Laboratory (RRPL).**

3.2.2 Regional Immunization Coordinator or Designate

- Order product via Panorama.
- Make arrangements for emergency shipments as necessary.
- Ensure regional demands are being met by monitoring kanban levels.
- Ensure appropriate use of products within the region.
- Receive shipments from the RRPL.
- Return gel packs, cooler boxes and data loggers to the RRPL within 2 business days.

3.2.3 Saskatchewan Ministry of Health (via the RRPL)

- Ensure adequate stock of to meet seasonal and ongoing needs of the population (within the constraints of contractual obligations and manufacturer abilities).
- Fill orders on schedule. Special arrangements must be made if unusual circumstances or emergencies arise.

3.2.4 Impact of Manufacturer Delays

- Supply of vaccine is dependent on the ability of manufacturers to meet the demands of the market.
- When market demands are high, the impact of product allocation by the manufacturer may be most apparent at the front line by an interruption of services.
- There may be delays in licensing of products, which can cause limited supply or a delay in the distribution of the vaccine causing a potential interruption or delay in service delivery.

3.3 Managing Biological Stock – Ordering, Receiving, Storing and Shipping Vaccines

Managing product inventory is a key to ensure appropriate vaccines are available and used. The following sections provide recommendations that should be used to guide the management of biologicals. Proper storage and handling procedures include but are not limited to the following:

- Twice daily minimum and maximum temperature monitoring and recording of the refrigerator(s), as well as the room temperature on the refrigerator temperature logs. Refer to Section 2.6, *Checking and Recording Temperatures*.
- Responding to storage temperatures outside the recommended range immediately upon discovery. Refer to Section 4.0, *Management of Cold Chain Incidents*.
- 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 specified kanban levels (or quantity sufficient to meet seasonal or outbreak demands).
- Overseeing proper receipt, storage, and transport of vaccine.
- All vaccines should be stored with the protective caps on, in their original boxes until they are needed. Light exposure may cause loss of potency in vaccines and other biologics; therefore, these products should be protected from light exposure at all times.

The best assurance of vaccine efficacy is to minimize the number of times vaccines are handled and transported. Inventory management is important for vaccine quality management. Proper inventory management means knowing the following:

- Quantities of vaccines and diluents that have been received;
- Quantities of vaccines and diluents that have been administered, wasted, or expired;
- Vaccines and diluents, and the quantities that are currently in stock and are available for administration;

- Vaccines and diluents, and the quantities that are currently in quarantine awaiting follow-up directions;
- Vaccines and diluents that should be used first;
- Vaccines and diluents that are expired and that must not be administered; and
- Vaccines and diluents that need to be ordered.

3.3.1 Ordering Vaccine Stock

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

- **Order set minimum inventory levels (kanbans) to ensure there is an adequate supply to meet the needs of the population served.** Consult your regional immunization coordinator for recommendations on vaccine inventory.
- **Do not over order vaccines.** Stockpiling of vaccines increases the chances of vaccine waste if unused vaccine expires or is involved in a cold-chain break.
- **Alert office staff** that an order has been placed. The designated vaccine coordinator 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.

3.3.1.1 Procedure

- Order biological products via the Panorama Inventory module: https://www.ehealthsask.ca/services/panorama**.**
- NOTE: Urgent requests should be telephoned to the RRPL at 306-787-7638 or 306-787-0415 and refer to the Urgent Biologicals Product Requests Policy on the eHealth Panorama site. Arrangements will be made for the most efficient delivery. **After hours/weekend request should be directed to 1-800-713-2436.**

3.3.2 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 of the arrival of the vaccine shipment so that it can be handled and stored appropriately.

3.3.2.1 Checking and Documenting the Condition of a Shipment

When the vaccine shipment is received, it should be examined and refrigerated immediately. Please follow these guidelines:

1. Document the time of the delivery.
2. Open and examine the shipping container and its contents for any signs of physical damage.
3. Read the temperature-monitoring devices upon receipt to determine if they have been activated. **Note:** that if the interval between shipment from the supplier and arrival at its destination was more than 48 hours, there is an increased chance of a cold chain break. **If there is any indication of a cold chain break, contact the** RRPL **at 306-787-0415 or 306-787-7638.**
4. Verify the contents of the vaccine package with what the packing slip indicates. If there is any discrepancy between the packing slip and product received, please call the RRPL at 306-787-7638 or fax 306-798-0071.
5. Ensure all contents of the shipping container have been removed before returning or storing the shipping container.
6. Check the vaccine expiration dates. Be sure to place vaccine in the refrigerator according to expiry date.
7. Examine the vaccine and diluent for heat or cold damage:
   - Refrigerated packs should still be cold.

Vaccines should not be in direct contact with refrigerated or frozen ice packs. There should be an insulating barrier between the vaccine and the refrigerated packs, such as bubble wrap or newsprint.

- Check that inactivated vaccines are cold but not frozen. Visually inspect the products.
- Check that diluent is cool or at room temperature. Diluent should not be in direct contact with refrigerated or frozen packs. There should be an insulating barrier between the diluent and the refrigerated or frozen packs.

8. Vaccines received must be entered into an inventory management system (Panorama) for monitoring stock **if order forms and packing slips are not kept**. This should include the date received, the vaccine name, lot number, expiry date, the number of doses received, the number of doses used and the balance.
9. If there are any concerns about the shipment, mark the vaccine and diluent as "DO NOT USE" and store it under appropriate conditions apart from other vaccine supplies until the integrity of the vaccine and diluent is determined. Refer to Section 4.0, *Management of Cold Chain Incidents.*

3.3.3 Shipping Vaccines

If vaccine transportation to another location is required, it is critical that the cold chain is maintained at all times to ensure vaccine potency.

- When transporting vaccines using a personal vehicle:
  - Do not place vaccine inside the trunk of the vehicle (the temperature inside the trunk cannot be regulated);
  - Avoid placing in direct sunlight, or directly in line with air from the vehicle's heater and air conditioner; and
  - 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. Ensure you are aware of jurisdictional guidelines regarding transporting open multi-dose vials. Many facilities do not accept open multidose vials due to potential contamination.
- Diluents that can be stored at room temperature may be transported either at room temperature or inside the same insulated cooled container as its corresponding vaccine; and
- If transported inside cooled containers with vaccine:
  - Diluent must not be in direct contact with refrigerated/frozen packs; and
  - Diluent must be refrigerated at least 24 hours in advance to prevent raising the temperature of the cooler and the refrigerated vaccines.

3.3.4 Packing Vaccine for Transport to Off-Site Clinics

Variables to consider when packing vaccines for transportation include:

- Ambient temperature;
- Distance and time in transit;
- Mode of transportation ; and
- Vaccine amounts being packaged.

Quality testing should be done to determine the packing materials and configurations that are suitable for your transporting containers. Refer to Section 2.3, *Insulated Containers/Ice Packs/Gel Packs/Insulating Materials* for more information. A consistent approach to packing vaccines must be developed and qualified.

Some of the basic principles include:

- An insulated and temperature monitored container must be used when transporting vaccines;
- Pack 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, and the volume of vaccine;
- Insulating material should be placed between the vaccine(s) and the cooling packs; and
- Do not pack vaccine tightly; ensure adequate air flow around the product.

WarmMark™ Indicators and Freeze Watch™ indicators should be used whenever a shipment is being made via a third party (non public health staff, i.e. bus, courier, community member). It should also be used when it will be > 1 hour before vaccine is unpacked. **Note:** WarmMark™ indicators should be used in all of these shipments. Freeze Watch™ indicators should be used when the temperature is 0°C or lower during shipment or if the shipment will be in transport overnight at times when the temperature drops below 0°C overnight.

3.3.5 Seasonal Variations

Summer packing configurations might include insulated material on the bottom of the insulated container, ice packs (preconditioned according to manufacturer's recommendations), gel packs preconditioned to +5°C, insulating barrier, temperature-monitoring device and vaccine, insulating barrier, gel pack preconditioned to +5°C, ice pack (preconditioned according to manufacturer's recommendations), insulating material on top, and frozen ice packs on top with an insulated cover.

Winter packing configurations may include the same materials as the summer configuration, except top packs are not frozen but refrigerated packs, preconditioned to 5°C. In extreme conditions, frozen ice packs may not be used at all.

3.3.6 Maintaining Temperatures during Off-Site Clinics

Vaccine must be maintained between 2°C - 8°C during an off-site clinic and should be stored in an insulated container.

- Pack 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, the volume of vaccine and 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 - 8°C during an off-site clinic.
- Only take vaccine stock that is anticipated to be used at that clinic.
- Keep the container closed as much as possible.

- Ideally, minimum/maximum thermometer should be used for each cooler used for clinics outside of health centre settings (e.g., school clinics). The external placement of the thermometer ensures that the temperature can be easily monitored. The probe must be kept in the middle of the container with the vaccines, but buffered from direct contact with ice packs and gel packs. Temperatures must be checked and recorded periodically to ensure that the cold chain is not broken. Record temperatures before leaving the facility, hourly during the clinic and upon return to the office, as per jurisdictional recommendations.

3.4 Managing Biological Stock – Expiry Dates, Wastage, Returns and Disposal

3.4.1 Interpreting Expiration Dates

The expiration date is the date (up to and including this date) by which the vaccine or diluent should be used. 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. All vaccine and diluent vials, ampoules, etc. and their containers (boxes) have an expiration date. **Expired vaccine and diluent must never be administered to a client, even if it is one day past the expiration date.**

3.4.1.1 Exceptions to the Expiration Date

- The labelled expiration date is only valid if proper storage and handling conditions are maintained at all times. Interruptions to storage requirements may reduce its potency **before** the expiration date is reached.
- The manufacturer labelled expiration date may also be invalidated after the vial is opened or reconstituted. The Ministry of Health will communicate expiry dates changes upon direction of the manufacturer.

3.4.1.2 What to Do with Expired Vaccines or Diluent

- Promptly remove expired vaccines and diluent from the refrigerator.
- Products being returned must meet the following criteria:
  - Must be date expired.
  - Must be returned as soon as possible post-expiry date.
  - Must be in original and unopened vials/ampoules/syringes/packages.
  - Package must be in good condition. Do not return any products that have been written on or have damaged packaging (e.g., broken seal).
  - Must have been maintained under the proper storage conditions.
- Products deemed as wastage must be documented on the Product Wastage Report form and submitted to RRPL. The following products are unacceptable for return and must be disposed of locally as per regional policy for biohazardous waste:
  - Any Sanofi Pasteur biological product.
  - Rabies vaccine (any brand).
  - Immune Globulins including: Tetanus Immune Globulin (TIg); Rabies Immune Globulin (RIg); Immune Globulin (Ig).
  - Epinephrine.
  - STI antibiotics.
- Please complete Vaccine Return Form and send with returned product; and
- If you need assistance with returning vaccines please contact the RRPL at 306-787-7638.

3.4.2 General Wastage

General wastage is any vaccine that cannot be used and excludes those that have been exposed to a cold chain break incident. For example, a multidose vial that has not been used up within the timeframe specified by the manufacturer, or reconstituted vaccine that has not been used.

3.4.2.1 Ways to Reduce General Wastage

- Mark multidose vials with the date of puncture. Opened multi-dose vials that are undated must be discarded.
- Use multidose vials that have already been opened before opening another one.
- Do not preload syringes – once reconstituted, use vaccine immediately. If this is not possible, consult the package insert for the most up-to-date information about expiration times and dates.
- Do not uncap single dose vials until you are ready to use the vaccine. **Single dose vials without their protective caps should be discarded at the end of the clinic day.**
- Use vaccine with the shortest expiry first.

3.4.2.2 Reporting General Wastage

- Report all vaccines wasted **(excluding those involved in a cold chain break)** to the RRPL using the Product Wastage Report Form.
- Fax these completed forms monthly to the Vaccine Management Program at 306-798-0071.
- Vaccines involved in a cold chain interruption with the recommendation of 'discard' or 'dispose' should not be reported on the wastage report form.

3.4.3 Vaccine Returns:

- **Do not return unexpired vaccines without consultation and approval by the RRPL.**
- Upon return approval:
  - The RRPL will approve courier delivery services to pick up vaccine from the centre.
  - Regions must properly pack the vaccine for shipment according to protocol, and must submit a completed a Vaccine Return Form in the cooler.

3.4.4 Vaccine Disposal:

- The vaccine that is wasted must be disposed of locally. Refer to regional/jurisdictional bio-medical waste guidelines.

3.5 Temperature Indicators

Temperature Indicator Cards are visual markers, sensitive to either warm or cold exposures. The RRPL uses WarmMark 2™ indicators that activate after exposure to temperatures greater than 10°C. The RRPL use Freeze Watch™ indicators with a threshold set point of 0°C.

3.5.1 WarmMark 2™ Time Temperature Indicators

The WarmMark™ indicators monitor temperature exposure, not product integrity. Their purpose is to signal when product integrity should be checked. WarmMark™ indicators are ideal for monitoring biological products which run the risk of being damaged when exposed to warmer-than acceptable temperatures during shipping and storage. WarmMark™ indicators are guaranteed to produce a highly accurate reading, within +/- 1°C of the response temperature.

When exposed to temperatures beyond a certain threshold, the blue-dyed compound inside the WarmMark™. Indicator liquefies, and a blue colour moves through the indicators windows over a period of time. If the temperature remains above the response temperature, the colour gradually continues to move through the windows. If the temperature returns to below the threshold, the colour stops moving. In this way, you have an indication as to how long the product was exposed above the threshold temperature.

Directions for Use:

1. Peel the liner off the back of the indicator and adhere it to a clean, dry surface such as a piece of paper. This paper should also be conditioned at the appropriate temperature.
2. To activate, push the button on the indicator.
3. Place the indicator in the middle of the shipping contents, away from ice packs.
4. To detect if the product has been exposed to warmer than acceptable temperatures, observe the WarmMark™ indicator windows for any blue colouration. If the indicator remains white, there is no concern.
5. If the indicator windows show blue, place vaccine in a separate bag in the refrigerator, mark it **DO NOT USE** and contact the Ministry of Health for further instructions.

3.5.2 Freeze Watch™ Indicators

The Freeze Watch™ indicators monitor temperature exposure, not product integrity. Their purpose is to signal when product integrity should be checked. Freeze Watch™ indicators are ideal for monitoring biological products that run the risk of being damaged when exposed to freezing temperatures during shipment and storage.

Freeze Watch™ indicators are available at two temperature levels, -4°C and 0°C, to accommodate differing product sensitivities. When exposed to sub-freezing temperatures, the liquid in the ampoule freezes, causing the ampoule to fracture and stain the indicator paper.

Directions for Use:

1. Attach the Freeze Watch™ indicator by peeling the release liner off the back and adhere the indicator to a clean, dry surface.
2. To detect if the product has been exposed to freezing temperatures, observe the Freeze Watch™ indicator. If the indicator paper is stained with color, your product has been exposed. Place vaccine in a separate bag in refrigerator, mark it and contact the Ministry of Health for further direction.

3. If the indicator paper shows no color indication, remove indicator from the surface to which it is attached. Vigorously tap the bottom edge of the indicator three times on a hard surface. Tapping will not cause colour staining in an unexposed indicator. If the paper becomes stained, your product was exposed to freezing temperatures. Place vaccine in a separate bag in the refrigerator, mark it **DO NOT USE** and contact the Ministry of Health for further instructions.

3.5.3 Data Loggers

The RRPL inserts data loggers into all vaccines shipments. Upon receipt of vaccine shipment from the RRPL :

1. Check if the WarmMark™ or Freeze Watch™ indicators have been activated. If they have, contact the RRPL immediately and return the data logger, charged to the RRPL account.
2. Region should document the time vaccine was received, and the time vaccine was unpacked.
3. Region should isolate vaccine in fridge and submit a cold chain break to the Ministry of Health.
4. The RRPL will read the data logger, and the Ministry will if the products are suitable for use.
5. If WarmMark™ or Freeze Watch™ indicators are not activated, the region shall return data logger in coolers and return to the RRPL as regular practices.

4.0 MANAGEMENT OF COLD CHAIN INCIDENTS

WHEN A COLD CHAIN BREAK IS SUSPECTED, quarantine products under cold chain conditions and immediately consult the regional Immunization Coordinator. Do not discard vaccine or diluent until the Ministry of Health determines the product integrity.

A cold chain interruption (break) is any circumstance where a biological product is exposed to temperatures outside of the 2°C - 8°C range. The stability of various immunizing agents can vary considerably. For example, some can tolerate long periods of exposure to heat without exhibiting serious degradation of vaccine components. But for others, exposure to a higher temperature translates into degradation in their activity and each exposure produces a cumulative effect. Most immunizing agents are unstable when exposed to freezing.

Immunizing agents affected by a break in the cold chain must:

- Be placed in cold quarantine (packaged separately);
- Identified on bag as "**DO NOT USE";** and
- Stored in a refrigerator at between 2°C and 8°C separately from immunizing agents in current use, until recommendations are received from the Ministry of Health.

4.1 Role of Person Discovering the Cold Chain Interruption

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

1. Promptly report the incident to the regional Immunization Coordinator or designate.
2. Complete the Cold Chain Break Report Form.
3. Document the inventory of the vaccines affected by the event. Include vaccine name, lot number, expiry date and quantity.
4. Isolate and quarantine the affected vaccines and mark "DO NOT USE."
5. Store the affected vaccines under appropriate conditions until the integrity of the vaccine is determined. If your vaccine storage unit is not maintaining the appropriate storage conditions, activate your urgent vaccine storage and handling protocols.
6. Submit the completed report form and the temperature-recording log to the regional Immunization Coordinator or designate.
7. Implement the recommendations made by the Immunization Coordinator and the Ministry of Health.
8. Manage the affected biologicals as directed.

4.1.1 Role of the Regional Health Authority/Jurisdiction

1. Ensure a designated regional contact is available to review and respond to cold chain interruptions.

4.1.2 Role of the Regional Immunization Coordinator or Designate

1. Receive the report.
2. Review for cause of interruption (such as equipment malfunction or personnel practice issue) and make recommendations and/or take measures to rectify the problem and prevent recurrence.
3. Document recommendations on the report form and fax pieces of incident report to the Ministry of Health Public Health Nursing Consultant at 306-787-3237 for vaccine specific recommendations. **NOTE: The Ministry of Health is responsible for providing recommendations only for vaccines/ biologicals that are supplied by the RRPL.** For vaccines/biologicals received through another source, the region/jurisdiction must contact the source directly for recommendations on the suitability of this product.
4. Relay information received from the Ministry of Health to the facility.
5. Ensure ongoing training and compliance of staff on cold chain policies and procedures.

NOTE: Failure to follow cold-chain recommendations and implement steps to prevent future cold chain breaks may result in the removal of publicly funded vaccines from the facility.

4.1.3 Role of the Ministry of Health

1. Receive report.
2. Review for cause and region/jurisdiction's recommendations.
3. Provide recommendations about the viability of the vaccines involved in the incident within 3 working days.
4. Determine the value of wastage due to the cold chain incident.
5. Provide recommendations for avoidance of future cold-chain breaks.
6. Provide a report of value of wastage from cold chain incidents to regions upon request.

4.2 Urgent Vaccine Storage and Handling Protocols

- To protect the vaccine inventory and to minimize potential monetary loss, every facility that stores vaccine should have a written Emergency Event Recovery Plan. If a problem is short term (usually 2 hours or less) and depending on ambient room temperature, the storage temperature can probably be maintained with the water containers in the refrigerator, with frozen coolant packs in the freezer, and by keeping the storage unit door(s) closed.
- Various situations may compromise vaccine storage conditions (e.g., new equipment, power outages, or natural disasters).
- Ensure that all new and current staff understands the urgent vaccine storage and handling protocols and their responsibility in maintaining the cold chain.
- Review and update the contact lists in the plan 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.

Activities may include:

Assigning a designated biological coordinator to:

- Monitor the operation of vaccine storage equipment.
- Track inclement weather conditions.
- Set up and maintain a monitoring and notification system in anticipation of inclement weather or other conditions that may cause a power outage.
- Ensure the appropriate handling of the vaccine during a disaster or power outage.

- Ensure that designated staff who attend to after-hours emergencies have 24-hour access to the building and vaccine storage unit.
- Ensure that sufficient fuel and/or battery power are on hand to continuously run a backup generator for at least 72 hours if the facility has one.

Arranging alternative vaccine storage facilities:

- By establishing working agreements with at least one alternative storage facility with a backup generator where vaccine can be appropriately and securely stored and monitored for the interim.
- By making advance arrangements with the facility to store your vaccine when weather predictions call for inclement weather conditions, when your vaccine storage equipment cannot be repaired, or when the power cannot be restored before the vaccine storage unit temperature unit rises above the recommended range.

Writing protocols for transporting vaccine to and from the alternative storage facility:

- Consider renting a refrigerated truck to transport vaccines if the alternative storage location is far away or if you have a large quantity of vaccines.
- Make advance arrangements with a local refrigeration company and an alternative facility and record the contact information.

Writing instructions for entering your facility and vaccine storage spaces in an emergency if the building is closed or it is after hours. These instructions should include the building security and after-hours access procedure and location of the following:

- doors
- flashlights
- spare batteries
- light switches
- keys
- locks
- alarms
- packing materials

Ensuring appropriate packing materials are available to store vaccines:

- Refer to Section 2.3, *Insulated Containers/Ice Packs Gel Packs/Insulating Materials* for further detailed information; and
- If a backup generator is not available, maintain the appropriate packing materials to temporarily and safely store vaccine at your facility.

4.3 Emergency Event Recovery Plan

In advance of a potential event, all providers should:

1. Identify an alternative storage facility with backup power where the vaccine can be properly stored and monitored for the interim.
2. Ensure the availability of staff to pack and move the vaccine.
3. Maintain the appropriate packing/insulating materials.
4. Ensure a means of transportation for the vaccine to the alternative storage facility.
5. Train staff and post information about these emergency procedures.

Refer to Section 5.1 of this chapter and complete the *Emergency Event Recovery Plan Form* as soon as possible. This plan may be adapted for regional use as it offers guidance to follow when the refrigerator fails or there is a power outage.

Things to do now before it's too late!

- Post your recovery plan on or near the vaccine storage equipment. Ensure that all staff (both current and new) read the plan and understand it as part of their orientation.
- Fill the empty space in your refrigerator with jugs/bottles of water and line the bottom of your freezer with ice packs. In the event that your refrigerator/freezer is out of order, this practice will help maintain the temperature for a longer period of time.

(Adapted from the Nova Scotia Immunization Manual, no date).

5.0 FORMS

5.1 Emergency Event Recovery Plan

A. Emergency phone numbers, companies, and points of contact

1. List the designated person(s) responsible for:
   - Monitoring the operation of the vaccine storage equipment and systems daily;
   - Tracking inclement weather conditions; and
   - Assuring the appropriate handling of the vaccine during the emergency event.

Name of employee	Work phone	Home phone	Cell phone

2. Determine if your refrigerator is having a mechanical failure or if the building has lost electrical power.
   - Check with the building maintenance to ensure that the generator is operational and has been activated.

Building maintenance	Time of contact	Work phone	Emergency phone

3. Contact the designated company responsible for restoring power to the location in the event of a power failure.

Power company	Time of contact	Work phone	Emergency phone

4. Contact the designated company responsible for repair where the compressor or the refrigeration equipment has been destroyed or you need emergency maintenance.

Repair company	Time of contact	Telephone number

5. If a time frame for the restoration cannot be determined, implement the following procedures for transferring the vaccines to an alternative storage facility with backup power.

B. List emergency phone numbers and points of contact for location with a backup generator.
This may be the local hospital, LTC facility, etc. Make arrangements with the site to store your vaccine there when weather predications call for inclement weather or when your vaccine storage equipment cannot be fixed or the power cannot be restored **within 4-6 hours**. Before moving your vaccine, call the location to ensure that their backup generator is working.

Alternative facility	Time of contact	Work phone	Emergency phone

C. Describe how to enter the building and vaccine storage spaces in an emergency if closed or after hours. Include a floor diagram and the locations of the following:

Item	Location(s)
Doors	
Flashlights	
Spare batteries	
Light switches	
Keys	
Locks	
Alarms	
Packing/insulating materials	

D. If possible, conduct an inventory before you move the vaccine.

E. Package the vaccine as per packing instructions.

F. Move vaccine to backup storage according to prearranged plans.

5.2 Cold Chain Break Report Form (Page 1 of 2)

Pharmacists: Fax form to 306-787-3237.
Others: Fax form to regional immunization supervisor.

Complete for all Saskatchewan Health publicly funded products. Do not assume that products must be wasted.

Section 1

Date of Break: *(yyyy-mm-dd)* | Date of Report: *(yyyy-mm-dd)* | Reporter Name:

Telephone Number: | Fax Number: | Reporter Email Address: *(optional)*

Location of Break (AHA, SHA, FNJ / City / Town) | Facility Name:

Facility type:

☐ Public Health ☐ Pharmacy ☐ Physician office ☐ Long-Term Care ☐ Acute Care ☐ Employee Health ☐ Other _____

Are products: Quarantined, Labeled: DO NOT USE, and stored on cold chain? ☐ Yes ☐ No *(attach explanation)*

Section 2

Check box for type of break and fill out corresponding category:

☐ Vaccine left out of fridge:

☐ in cooler with cold packs ☐ in cooler with no cold packs ☐ in package on counter ☐ not in package on counter

Vaccine returned to storage between 2°C and 8°C on date _____ at (time) _____

Length of time outside recommended temperature range of 2 - 8 °C _____

Room temperature at time of break _____ °C on date _____ at (time) _____

☐ Fridge temperature excursion

Fridge temperature when break identified: _____ °C on date _____ at (time) _____

Max. temp recorded during break interval _____ °C Min. temp recorded during break interval _____ °C

Length of time outside recommended temperature range of 2 - 8 °C _____

Last fridge temperature record before the break _____ °C on date _____ at (time) _____

Room temperature before the break _____ °C on date _____ at (time) _____

Is temperature log being submitted? ☐ Yes ☐ No If No, indicate why: _____

Refrigerator type:

☐ Lab or Biological Fridge(any size) ☐ Domestic Fridge

☐ Bar Fridge ☐ Other _____

Thermometer/Monitor Type (Not Brand Name):

☐ Digital Min/Max ☐ Chart / Wheel Recorder

☐ Warm/Cold Mark ☐ No Monitor ☐ Other _____

Date last serviced: _____

☐ Break during transportation

Vehicle type (e.g. car/courier) _____ Time delivery received: _____

Specify: ☐ Provincial Depot to RHA/FNJ/ wholesaler ☐ Public Health to community ☐ Intraregional

Was there a data logger included in the cooler? ☐ Yes ☐ No If yes, is it being sent back to SDCL? ☐ Yes ☐ No

Was there a warm/cold marker in cooler? ☐ Yes ☐ No If yes, was it activated? ☐ Yes ☐ No Reading: _____

Section 3

☐ Other situation: provide description

Description of break:

Cause of cold chain break:

☐ Human error ☐ Power outage ☐ Other _____

☐ Thermometer malfunction ☐ Refrigerator malfunction

☐ Transportation ☐ Backup generator failed

Corrective action details and additional comments:

Have any affected products been administered to clients? ☐ Yes ☐ No

- If yes, indicate the date the Medical Health Officer was notified: _____
- If yes, identify these products using a separate page if necessary.

Adapted with permission from Alberta Health Services (August 2016) revised June 2018

5.2 Cold Chain Break Report Form (Page 2 of 2)

Complete for all Saskatchewan Health publicly funded products. Do not assume that products must be wasted.

Go to http://www.ehealthsask.ca/services/manuals/Documents/sim-chapter9.pdf for further instructions.

Vaccine Brand or Abbreviation	Manufacturer	Count (# of Doses)	Lot Number	Expiry date	Open multi-dose vial?	Previous cold chain break?	SK Health USE ONLY	
							Viable	Discard
					☐ Yes ☐ No	☐ Yes ☐ No		
					☐ Yes ☐ No	☐ Yes ☐ No		
					☐ Yes ☐ No	☐ Yes ☐ No		
					☐ Yes ☐ No	☐ Yes ☐ No		
					☐ Yes ☐ No	☐ Yes ☐ No		
					☐ Yes ☐ No	☐ Yes ☐ No		
					☐ Yes ☐ No	☐ Yes ☐ No		
					☐ Yes ☐ No	☐ Yes ☐ No		
					☐ Yes ☐ No	☐ Yes ☐ No		
					☐ Yes ☐ No	☐ Yes ☐ No		
					☐ Yes ☐ No	☐ Yes ☐ No		
					☐ Yes ☐ No	☐ Yes ☐ No		
					☐ Yes ☐ No	☐ Yes ☐ No		
					☐ Yes ☐ No	☐ Yes ☐ No		
					☐ Yes ☐ No	☐ Yes ☐ No		
					☐ Yes ☐ No	☐ Yes ☐ No		
					☐ Yes ☐ No	☐ Yes ☐ No		
					☐ Yes ☐ No	☐ Yes ☐ No		
					☐ Yes ☐ No	☐ Yes ☐ No		
					☐ Yes ☐ No	☐ Yes ☐ No		

Ministry of Health reviewer: _____ Date: _____

Total cost of wastage: $_____ *(Ministry use only)*

5.2A How to Complete the Cold Chain Break Report Form

Section 1

Complete all components of this section. The Reporter is the person who discovered the cold chain break or is responsible for reporting the cold chain break. Their contact information is important to facilitate follow up.

Section 2

There are four categories in this section. The Reporter **only** needs to **fill out the one category** that is most applicable to the cold chain break:

1. **Vaccine left out of fridge** – in cooler, box, on counter, etc.
2. **Fridge temperature excursion** – when fridge thermometer indicates temperatures outside of cold chain maintenance (2 to 8°C).
3. **Break during transportation** – Temperature indicator card and/or data logger indicates break in cold chain during transport from one facility to another (includes vaccine from Roy Romanow Provincial Laboratory [RRPL] and intra-regional transport) **
4. **Other situation** – any situation not covered in the three scenarios above. Include as much information about the situation including time, temperature and cause.

All products must be immediately quarantined when involved in a cold chain break.

****Data loggers** that are in the coolers of vaccine found to be in a cold chain break should be sent into RRPL and marked with the name of the former Regional Health Authority (RHA), Athabasca Health Authority (AHA) or First Nations Jurisdiction (FNJ); facility; date of cold chain break and contact person. The data logger should then be put in an envelope and placed back in the cooler to be sent to **Roy Romanow Provincial Laboratory at 5 Research Drive, Regina SK. S4S 0A4 NOTE:** This does not apply to vaccines sent from wholesalers to community pharmacies.

Section 3

- **Description of Break:** Provide as much detail as possible regarding the cold chain break including how and why the break occurred.
- **Cause of cold chain break:** Please check off the cause that is most applicable. Provide details of the corrective action or plan.
- **Have any affected products been administered to clients?** Please check off yes or no, and answer subsequent questions as appropriate.

Section 4 (Page 2)

- Print all vaccine information clearly using one line per lot number. List open vial vaccines on separate lines even if lot number is the same. Use appropriate vaccine and manufacturer abbreviations.

- Circle the applicable answer for "open multidose vial" and "previous cold chain break."

- Page 2 will be faxed back to the SHA, AHA or FNJ Immunization Supervisor/ Designate or Community Pharmacist indicating whether the vaccine is:
    - Viable – usable – maintain in cold chain and use as soon as possible; **OR**
    - Discard – not to be used. Discard as per organizational policy.

NOTE: The Ministry of Health will fax recommendations to Immunization Supervisor/Designate or reporting Community Pharmacy as appropriate

5.3 Product Wastage Report Form

DO NOT REPORT COLD CHAIN WASTAGE ON THIS FORM.

- **USE FOR: all vaccines, Tubersol™, TIg, Ig, RabIg, azithromycin, amoxicillin, benzathine penicillin (bicillin), cefixime, ceftriaxone, ciprofloxacin, doxycycline, erythromycin, rifampin, epinephrine and lidocaine. Diluents for MMR, Var and MMRV do not need to be reported.**

Submit to: Roy Romanow Provincial Laboratory
Provincial Vaccine Depot
5 Research Drive
Regina, SK, S4S 0A4
Fax: 306-798-0071
Phone: 306-787-7638

SHA, AHA or FNJ site/Pharmacy/Wholesaler submitting report: _____

Reporter name: _____ Date: _____

Phone #: _____ Fax #: _____

					Indicate only 1 reason for wastage			
Product Name	Manufacturer	Lot Number	Expiry date	# of Doses	EXPIRED OPENED	EXPIRED UNOPENED	Not administered	Defective or damaged (Note: Vaccine Problem Report must also be submitted)
					☐	☐	☐	☐
					☐	☐	☐	☐
					☐	☐	☐	☐
					☐	☐	☐	☐
					☐	☐	☐	☐
					☐	☐	☐	☐
					☐	☐	☐	☐
					☐	☐	☐	☐
					☐	☐	☐	☐

5.3A Product Wastage Reporting Form Visual Tool

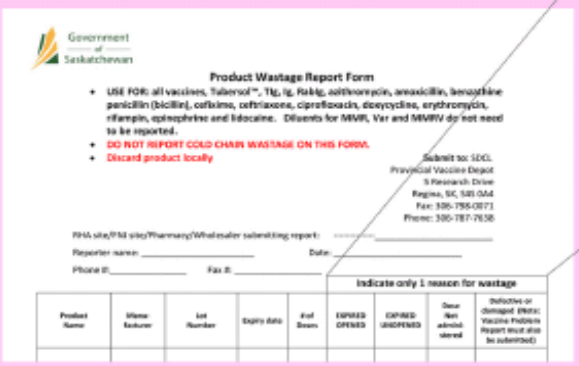
PRODUCT WASTAGE REPORTING

REPORT WASTED PRODUCTS IF THEY ARE:

expired OR not administered OR defective AND NOT involved in a cold chain break AND non-returnable

1 COMPLETE THE *PRODUCT WASTAGE FORM*

Indicate only 1 reason for wastage



Government of Saskatchewan

Product Wastage Report Form

- USE FOR: all vaccines, Tubersol™, TIg, Ig, Rabig, azithromycin, amoxicillin, benzathine penicillin (bicillin), cefixime, ceftriaxone, ciprofloxacin, doxycycline, erythromycin, rifampin, epinephrine and lidocaine. Diluents for MMR, Var and MMRV do not need to be reported.
- DO NOT REPORT COLD CHAIN WASTAGE ON THIS FORM.
- Discard product locally

Submit to: SDCL
Provincial Vaccine Depot
5 Research Drive
Regina, SK S4S 0A4
Fax: 306-798-0871
Phone: 306-787-7638

RHA site/FNI site/Pharmacy/Wholesaler submitting report: _____

Reporter name: _____ Date: _____

Phone #: _____ Fax #: _____

Indicate only 1 reason for wastage

Product Name	Manufacturer	Lot Number	Expiry date	# of Doses	EXPIRED OPENED	EXPIRED UNOPENED	Dose Not administered	Defective or damaged (Note: Vaccine Problem Report must also be submitted)

ALWAYS INDICATE THE REASON FOR WASTAGE

- **EXPIRED & OPENED**
  - expiry date on product has passed
  - product is in opened/ punctured/marked vials/ ampoules/syringes/packages as applicable
- **EXPIRED & UNOPENED (NON-RETURNABLE)**
  - expiry date on product has passed
  - product is in original unopened /unpunctured/unmarked vials/ ampoules/syringes/packages as applicable
- **DOSE NOT ADMINISTERED**
  - dose was not administered to client *regardless of reason*
- **DEFECTIVE OR DAMAGED**
  - issue with product integrity or function

*COMPLETE THE PRODUCT WASTAGE REPORT FORM AND SUBMIT WITH ORIGINAL PRODUCT (E.G., VIAL OR PREFILLED SYRINGE).

2 SUBMIT *MONTHLY*

(must be received by the 5th of the next month)

3 DISCARD PRODUCTS LOCALLY

Government of Saskatchewan

5.4 Vaccine Returns Form

Government of Saskatchewan

Vaccine Returns Form

Roy Romanow Provincial Laboratory
Provincial Vaccine Depot
5 Research Drive
REGINA SK S4S 0A4
PH: 306-787-7638 FAX: 306-798-0071

NOTE: The following products are NOT returnable - All immune globulins (including Ig, RabIg, TIg); rabies vaccine (all brands); IPV (IMOVAX Polio); Td (Td Adsorbed); Td-IPV; Tubersol; any vaccine diluents; epinephrine; and all STI meds.

RHA/FNJ/Pharmacy/Wholesaler: _____

Date: _____

Vaccine	Manufacturer	Lot Number	Expiry date	Number of Doses	Reason for Return

Report submitted by: _____ Phone No: _____ Fax No: _____

Revised Aug. 2018

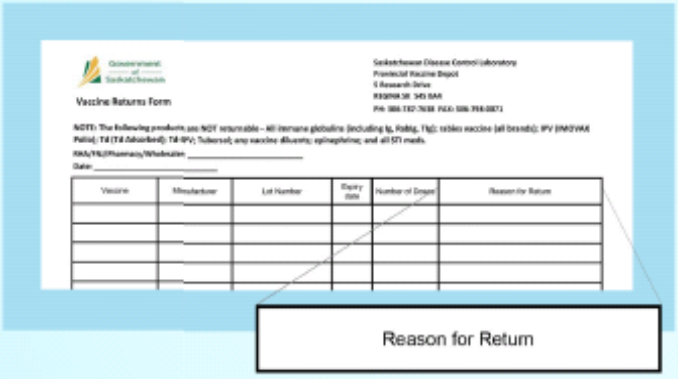
5.4A Vaccine Product Returns Form Visual Tool

VACCINE PRODUCT RETURNS

RETURN PRODUCTS ONLY IF THEY ARE:

expired OR recalled AND in original intact unopened unmarked packaging

1 COMPLETE THE *VACCINE RETURNS FORM*



ALWAYS INDICATE THE REASON FOR RETURN
(either EXPIRED or RECALLED)

Most are returnable EXCEPT for the following products:
- Any immune globulins
- Any rabies vaccines
- IPV (IMOVAX® Polio)
- Td Adsorbed
- Td-IPV
- Tubersol™
- Any vaccine diluents
- Epinephrine & lidocaine
- Any antibiotics

2 SUBMIT FORM AND PRODUCTS *IN ORIGINAL INTACT UNOPENED UNMARKED PACKAGING*

REMEMBER TO SEND PRODUCTS:
- in good condition
- off cold chain
- by interoffice or regular mail

3 SUBMIT *MONTHLY*

(must be received by the 5th of the next month)

Government of Saskatchewan

5.5 Vaccine Temperature Log

Government of Saskatchewan

TEMPERATURE LOG FOR VACCINES

Record all temperatures *twice* daily for all vaccine storage units. Retain records per your schedule.

Post on or beside refrigerator.

Location/Pharmacy:

Day	AM						PM						Comments
	Vaccine Storage Unit						Vaccine Storage Unit						
	Time	Current	Min	Max	Room Temp	Initial	Time	Current	Min	Max	Room Temp	Initial	
1													
2													
3													
4													
5													
6													
7													
8													
9													
10													
11													
12													
13													
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Revised October 2016

Check fridge temperature at the beginning and end of each day. Vaccines must be stored between 2° – 8° C at all times. Take immediate action if they have been exposed to temperatures outside of normal storage range

Take immediate action if products have been exposed to temperatures outside of 2°–8°C. **DO NOT DISCARD PRODUCTS!** Quarantine products, label **DO NOT USE** and maintain between 2°–8°C while awaiting direction from the regional Immunization Supervisor/Ministry of Health.

5.6 Vaccine Problem Supply Report Form

Vaccine Supply Problem Report
Mail completed report and defective product to:
Public Health Nursing Consultant
3475 Albert Street, Regina, SK S4S 6X6

- **Reported by:** [name, title, jurisdiction] ……

  ……..

- **Date of report:** [year/month/day] ……

- **Vaccine:**
  - **Type**: ……..
  - **Brand Name**: ……..
  - **Manufacturer**: ……..
  - **Format**: ……..

- **Lot number:** ……..

- **Supplier:** ……..

- **Contract number (Ministry to complete):** ……

- **PSPC contract or direct with supplier? (Ministry to complete)** ……

- **Nature of the problem experienced:** [Attach additional page if necessary.]

  ……

  ……

- **Delivery:**

	Out of stock
	Delayed or incomplete delivery
	Cold chain breach
	Product damaged in delivery
	Short expiry date
	Other

Administration / Packaging

	Dull needle
	Needle separates from syringe
	Contents cloudy or contains particles
	Label concerns (e.g. can't read Lot #)
	Other

- **Details:** [Please provide details of the problem experienced; including when experienced and frequency / extent of problem. Attach additional page if necessary.]

  ……

  ……

- **Was the problem satisfactorily resolved?** [Yes or No] …….

- **How was the problem resolved?** [e.g. directly with the manufacturer; via PWGSC; etc. Attach additional page if necessary.]

  ……

  ……

- **Additional comments?** [Attach additional page if necessary.]

  ……

  ……

FOR YOUR INFORMATION: PURPOSE OF THE VACCINE SUPPLY PROBLEM REPORT

The Vaccine Supply Problem Report is intended to allow for the central collection of information on problems experienced in the procurement and/or use of vaccines, even if the problem has been satisfactorily resolved by the supplier. A summary of problem reports will be shared with all jurisdictions. Where necessary, the problems identified will be formally reported to PWGSC or to Health Canada.

If appropriate, and if agreed to by the VSWG, the information collected may be considered in the evaluation of bids and the awarding of future contracts.

Problem reports will be collected and collated and a summary distributed once a month to the VSWG. A brief discussion of problem reports will be added as a standing item on each VSWG monthly teleconference.

Please note that the Vaccine Supply Problem Report (VSPR) is not intended to be used for the reporting of adverse events following immunization (AEFI).

6.0 REFERENCES

BCCDC (2016). *Communicable Disease Control Manual, Immunization Program*. Available at: http://www.bccdc.ca/dis-cond/comm-manual/CDManualChap2.htm

Centres for Disease Control and Prevention (2016). *Vaccine Storage &Handling Toolkit*. Available from: http://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf

Government of Nova Scotia (No date). *Nova Scotia Immunization Manual.* Available at: http://www.gov.ns.ca/hpp/publications/13067_ns_immunizationmanual.pdf

PHAC (2015). *National Vaccine Storage and Handling Guidelines for Immunization Providers*. Available at: http://healthycanadians.gc.ca/publications/healthy-living-vie-saine/vaccine-storage-entreposage-vaccins/alt/vaccine-storage-entreposage-vaccins-eng.pdf

Testo Home Page (No Date). *Data Loggers*. Accessed April 18, 2011 from: http://www.testosites.de/datalogger2011/en_US/index.html#/174t

7.0 APPENDICES

Appendix 9.1: Store Biological Products Properly

Store Biological Products Properly!

Ordering Products

- Keep only 1 month's supply of products on hand.
- Complete a product inventory once a month.
- Check expiry dates monthly.

Storage of Products

- Always store refrigerated biological products between 2°C and 8°C, and frozen biological products at -15°C or colder.
- Use a digital min-max thermometer in the refrigerator and record the temperature twice daily.
- Immediately contact the regional Immunization Coordinator when product has been exposed to temperatures outside of 2°C - 8°C. Place the vaccines in a bag labelled "DO NOT USE" and store the bag in a temperature monitored refrigerator until recommendations are received from the Ministry of Health.
- Develop a back-up plan for potential power outages or refrigerator failure. Post this plan near the fridge and ensure all staff is familiar with it.
- Secure and label the refrigerator plug to prevent it from accidentally getting unplugged.
- Never store biological products in refrigerator or freezer doors.
- Store full water bottles on empty shelves and in the door of the refrigerator to maintain consistency in temperature.
- Never use a bar or half-sized refrigerator for product storage.
- **Always use products with the nearest expiry dates first including previously opened vials.** Place products with the farthest expiry dates behind those with the nearest expiry dates.
- Only store biological products in the refrigerator.
- Only open the refrigerator door when necessary.
- Always ensure the refrigerator door is fully closed after opening.
- Leave space between product trays to allow air to circulate in the refrigerator.
- Unpack all vaccine deliveries prior to placing in fridge (do not place vaccine in container with ice pack in fridge as vaccine will freeze).

Handling Products

- Take only the exact biological products and number of doses that are required for a scheduled clinic from the fridge.
- Mark the date on multi-dose vials when they are opened and use all doses within the timeframe specified by the manufacturer.
- Always use previously opened multidose vials before opening a new multi-dose vial.
- Refer to package inserts to determine how long a multi-dose vial can be kept for use after the first dose is withdrawn.
- **Do an environmental scan of the clinic area when you are finished and ensure that vaccine is always placed back into the refrigerator when you have completed a clinic.**

Transporting Products

- Use insulated containers with tight fitting lids and ice packs when transporting biological products.
- Keep ice packs in your freezer for use during transport of biological products.
- Allow ice packs to sweat before adding vaccine to the cooler.
- Never put biological products directly on ice packs.
- Always place bubble wrap or crumpled newspaper between the ice pack and the biological product.
- Keep biological products in their original packages.
- Place a thermometer or other temperature indicator in the cooler during transportation.

Disposing of Products

- **Do not return vaccines to the Ministry of Health without prior consultation and approval.**
- All biological products expire at the end of the month (e.g. June/13 or 06/13 means June 30, 2013) or as specified.
- All products must be disposed of as per regional or jurisdictional policy.