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1.0 THE COLD CHAIN

“Cold chain” refers to the process used to maintain optimal temperature conditions during the transport, storage and handling of vaccines, starting at the manufacturer and ending with the administration of the vaccine to the client.

Vaccines are sensitive biological products; protection of vaccine potency and stability is important. The recommended temperature for vaccine storage is, at all times, +2°C to +8°C. Biologicals may be inactivated by exposure to excess light or heat or freezing, depending on the nature of the product, the temperature reached and the duration of exposure. Freezing will reduce the potency of inactivated vaccines and exposure to heat and light can compromise the stability of live-virus vaccines. **Any loss of vaccine potency is permanent and irreversible. Damage from successive exposures to adverse conditions is cumulative.** It is important to know the correct storage conditions for each biological product and to ensure that each is kept under the recommended conditions.

As a general principle, **0°C to +2°C** is considered “refrigeration conditions”, with due regard to the accuracy of the temperature reading device: no product needs to be discarded for a validated temperature in this range for an exposure of any period of time, even for a series of exposures within the temperature range of 0°C to 2°C. Exposures in this range need **not** be reported as a “cold chain incident”. It is extremely important to have a thermometer calibrated to an accuracy of +/- 1°C or better; the thermometer probe should be placed centrally (in the middle of the middle shelf) in the refrigerator, not at the back or near the door.

When the temperature is in the 0°C to 2°C range, adjust the refrigerator temperature and restore the temperature to within the +2°C to +8°C range **immediately**. See [Section 5.0, Management of a Cold Chain Incident](#), for more information.

All biological products freeze at temperatures below 0°C; products that have been exposed to temperatures below 0°C should not be used. Consult with BCCDC Vaccine and Pharmacy Services, as there may be specific exceptions to this (e.g., lyophilized products.)

The Vaccine Stability Chart is a reference to guide product use when biologicals are exposed to temperatures outside the acceptable range. An addendum to the 2005 Stability Chart will be provided to the Biological Products Consultants in each Health Authority. This addendum contains updated stability information from the vaccine product monographs. No vaccine should be removed from cold chain conditions nor returned to BCCDC until it has been determined that the product cannot be used.



2.0 GENERAL RECOMMENDATIONS

To facilitate cold chain management:

- Designate one person, at the Health Service Delivery Area (HSDA) level, as a Biological Products Consultant (BPC) to be responsible for decision-making regarding safety and efficacy of vaccines following cold chain incidents. When the 2005 Vaccine Stability Chart and the 2009 Addendum to the Stability Chart does not contain sufficient information in order to make a determination about vaccine usage, the BPC will consult with BCCDC Vaccine and Pharmacy Services. The BPC will ensure that all staff who handle vaccines are trained in biological management procedures. The BPC will review documentation for vaccine storage and confirm that conditions comply with the criteria established by Vaccine and Pharmacy Services for vaccines that are to be returned to BCCDC for redistribution.
- Designate one person, at the Health Unit office level, as the Biological Products Monitor (BPM) to be responsible for ordering, receiving and storing all biological products, tracking exposure history for every exposed product, twice daily monitoring of the refrigerator internal temperature, and arranging for service calls and preventive maintenance for the biological refrigerators. The BPM will have documentation at the office level to support storage conditions for vaccines that are returned to BCCDC for redistribution.
- Designate a back-up individual for each role.
- Have written procedures for vaccine storage and handling available at each site to facilitate cold chain management by all staff.

Maintaining the quality of biological products is the shared task of manufacturers, vaccine handlers, and all health care professionals responsible for immunization delivery.

All staff must be aware of

- the importance of the cold chain and the implications of cold chain incidents
- standard vaccine storage and handling practices
- the immediate and appropriate action to be taken in the event of a vaccine exposure to temperatures outside the standard storage conditions



3.0 EQUIPMENT

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

1. A dedicated refrigerator for storing biological products
2. A freezer for storing ice or gel packs
3. Temperature monitoring devices
4. Insulated containers (coolers)
5. Ice packs/gel packs
6. Insulating material

3.1 Refrigerators

- Store biological products preferably in a purpose-built **refrigerator**, (also called a pharmacy, laboratory or industrial grade refrigerator.)
- See National Guidelines, Section 3, for detailed information on refrigerators.
<http://www.phac-aspc.gc.ca/publicat/2007/nvshgip-ldemv/section3-eng.php>
- Domestic frost free refrigerators can be used, with the precaution that temperatures may fluctuate in different compartments of the refrigerator, and vaccines can only be stored in certain areas. For details, refer to national guidelines above.
- Bar fridges are not adequate for biological products storage.
- Refrigerators are “Vaccine Use” only. Do not store items such as food and beverages in vaccine refrigerators, to prevent unnecessary opening of the refrigerator.
- It is preferable to store laboratory specimens in a refrigerator other than a refrigerator dedicated to vaccine storage. If laboratory specimens must be stored in a vaccine refrigerator, these specimens should be stored in a separate, clearly-marked container.
- Choose an appropriate refrigerator size:
 - Consider the amount of vaccine that your health unit will use in your monthly order period.
 - Choose a refrigerator that can hold vaccines in the middle and upper shelves without crowding.
 - Consider seasonal fluctuations when more vaccine may be required, for example, during influenza season and for school immunization programs.
- The room in which the refrigerator is placed should have a thermostat or thermometer to measure the ambient (room) temperature.
- Lock the refrigerator, or place the refrigerator in a room that can be locked, to prevent unauthorized access, product handling or refrigerator tampering.
- Close the refrigerator door tightly. Installing a Velcro latch can help ensure that the door isn’t accidentally left ajar during the day, or after hours.



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- Maintain the refrigerator temperature between +2°C to +8°C. Set the temperature at **+5°C** to provide a safety margin for temperature fluctuations.
 - Place the refrigerator away from the wall or surrounding structures (according to manufacturer's recommendations) to provide proper ventilation and air circulation on all sides.
 - Ensure the area around (including behind and under) the refrigerator is clean and dust free. This will help to ensure that the refrigerator is working at optimal levels.
 - Protect the refrigerator from direct sunlight.
 - Connect the refrigerator to a dedicated circuit that is not used for other appliances.
 - Use a plug guard on the electrical outlet for the refrigerator to prevent accidental disconnection from power.
 - Label the vaccine refrigerator's power-breaker switch in the electrical panel box: **"VACCINE REFRIGERATOR - DO NOT DISCONNECT / DO NOT SWITCH OFF"**.
 - Have a refrigerator maintenance check (cleaning coils, checking door seals) done regularly (at minimum, annually) and keep a record of maintenance service and repairs. Post the refrigerator maintenance repair telephone number on the refrigerator for easy accessibility.
 - Check refrigerator seals quarterly to ensure cold air cannot leak out. If seals are brittle or torn arrange for replacement.
 - When refrigerators are newly installed or just repaired, follow manufacturers' recommendations for establishing the appropriate temperature before placing vaccines into the unit.
 - See national guidelines for a "maintenance" checklist:
<http://www.phac-aspc.gc.ca/publicat/2007/nvshgjp-ldemv/resources-eng.php>

3.2 Temperature Monitoring

- Use a constant temperature-recording device or digital minimum/maximum thermometer (with probe) to monitor both the current refrigerator temperature and the minimum/maximum temperatures.
- Thermometers should be calibrated to be accurate within +/- 1° C or better.
- Check equipment annually, or according to manufacturer's specifications, to ensure thermometer measurement is accurate, batteries are functioning, and cables/probes are undamaged. Maintain and change batteries as recommended by the manufacturer, keeping in mind warranty requirements.
- See the national guidelines for detailed information on temperature monitoring devices: <http://www.phac-aspc.gc.ca/publicat/2007/nvshgjp-ldemv/section3-eng.php>
- Place the thermometer probe centrally (in the middle of the middle shelf) in the refrigerator, **not** at the back or near the door.
- Have extra thermometers (ideally minimum/maximum thermometers) 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.

- At the start and end of each workday, record the minimum and maximum temperatures reached since the last monitoring, on the Temperature Form (see 7.0, Resources.) Record the temperatures on the form even when there is a continuous temperature recording device in use, or when the refrigerator is connected to an alarmed temperature system. Also record the current refrigerator temperature, ambient (room) temperature, and refrigerator dial setting. Reset the min/max thermometer once you have recorded the temperatures.
- 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. Retain records for a minimum of three years, or for a period of time as determined by HA.

Many biologicals orders shipped from BCCDC to the field will contain an electronic monitoring device called a TempTale®. This device provides time and temperature data for vaccine shipments from BCCDC to the field. Instructions for handling a TempTale® are in 4.1 below.

Temperature Indicator Cards are visual markers, sensitive to either warm or cold exposures. The markers are activated and will change color when threshold temperatures are reached. The markers do **not** provide interpretation of product integrity.

- “Warm” indicators are available with different temperature threshold set points, and different run times (hours of use.) BCCDC Vaccine and Pharmacy Services uses markers that activate after exposure to temperatures > 10°C. When the temperature threshold is reached, the background film melts, discoloring the paper red. Each circular window is stained incrementally red in relation to the exposure time above the threshold (e.g. top circular window stained after 2 hours, middle window after 12 hours, and bottom window after 48 hours.)
- “Cold” indicators activate when exposed to temperatures at or below freezing. The liquid in the bulb freezes, cracks the bulb, and stains the white background red. BCCDC Vaccine and Pharmacy Services uses cold markers with a threshold set point of 0°C.
- Follow manufacturer's directions for using and reading cards.

Refer to Section 5.0 for management of vaccine exposures to temperatures outside of the appropriate range. No vaccine should be removed from cold chain conditions nor returned to BCCDC until it has been determined that the product should not be used. Do not return any vaccine unless directed to do so by your Biologicals Product Consultant and BCCDC Vaccine and Pharmacy Services.



3.3 Insulated Containers

- Insulated containers (coolers) are used to transport quantities of vaccine off-site during one working day, or to store quantities of vaccine needed for immunization on site during a working day, thus avoiding frequent opening of the refrigerator.
- The cooler must be able to maintain vaccine temperature of +2°C to +8°C during transport and throughout clinics.
- The temperature inside the cooler is maintained with ice/gel packs, and insulating materials.
- 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.

3.4 Ice packs/gel packs

- 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.
- Set ice packs on their edge and allow space between them for air circulation in the freezer. Stacking icepacks on top of each other in the freezer may result in uneven or partial freezing, and decrease the efficacy of the icepacks.
- Ensure that ice packs are completely frozen before use.

3.5 Insulating Materials

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



4.0 HANDLING BIOLOGICAL PRODUCTS

4.1 Vaccine Delivery to Health Units

Vaccine shipments require immediate attention.

- **Unpack and refrigerate biological products immediately upon their arrival.**
- The national guidelines provide a resource for tracking vaccine inventory. See <http://www.phac-aspc.gc.ca/publicat/2007/nvshqplp-ldemv/resources-eng.php> The Vaccine Tally Sheet may be used to document arrival of a product, lot number and expiration date.
- Check for evidence of physical damage, freezing or excessive heat. If you notice evidence of damage, label the products as “Do not use”, quarantine in the refrigerator, and contact your Biological Products Consultant for directions about vaccine use.
- Remove the TempTale® device from shipping box immediately.
- Press and hold the red “STOP” button located in the bottom right corner of the TempTale® for at least 3 seconds. A “Stop” icon will appear display when device has been stopped.
- A SUNSHINE icon on the top left corner indicates the shipment was shipped under cold chain conditions and is OK to use. A BELL (alarm) icon on the lower right corner indicates that the shipment may have been exposed to temperatures outside the range of +2°C to + 8° C. Quarantine shipment in the refrigerator when the alarm icon is showing
- Return the TempTale® monitoring device immediately in the prepaid bubble envelope (enclosed with shipment) to BCCDC.
- Inform your Biological Products Consultant when products have been quarantined and await instruction regarding use of the products from BCCDC Vaccine and Pharmacy Services.
- **Note:** if unsure of proper procedure for the TempTale® device, store the shipment and the TempTale® in the refrigerator until Biological Products Monitor or designate is available.

4.2 Vaccine Storage

- See 7.0, Resources: Instructions for Packing a Refrigerator, for diagram illustrating placement of biological products in the refrigerator.
- **“First in, first out”:** rotate vaccine stock according to expiry date (placing vaccine with the shortest expiry date at the front of the shelf, and longest expiry date at the back) so that vaccine closer to the expiration date will be used first.
- 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. Note: some component vaccines and diluents may be assembled into one package with a labeled 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.

- **Check biological products inventory on the last working day of each month:** Check for expired vaccines, and **remove expired products**. This is important in order to avoid the administration of expired product to a client.
- Check multidose vials which have been opened. Multidose vials are dated when first opened, and should be used within 30 days of first puncture unless the product monograph specifies a shorter time period for use (e.g. some influenza vaccine in multidose presentation must be used within 7 days of first puncture.)
- Return **all** expired products to BCCDC Vaccine and Pharmacy Services (See 7.0, Resources: Field Return Form). Do **not** discard expired products locally.
- Check for product(s) that will expire within three months and if use is unlikely within that time in the local office, determine if another office within the region could use the product.) If it is unlikely that the product can be used in the region prior to expiry, contact the Biologicals Desk, BCCDC for return authorization (see 7.0, Resources, Redistribution Form.) These products will require return under cold chain conditions.
- Vaccines that have experienced a cold chain incident and have been determined to be useable should be used **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 (remember to protect from light). Use these vaccines before opening new vials or packages.
- Group the same biological products together and space the products to allow air circulation between rows.
- Keep all vaccines in their original packaging prior to use.
- Store vaccines **only** on the upper and middle shelves in the refrigerator.
- Refrigerator door shelves and crispers should **never** be used for vaccine storage as these areas are more susceptible to temperature fluctuations.
- Store sealed bottles of water in the refrigerator to provide cold mass that will help to maintain internal temperatures and delay temperature changes in the event of a power or refrigerator failure.
- Store flexible insulating blankets or gel packs that will be used as insulating material during vaccine transport in the refrigerator.
- Diluent for vaccines can be stored at room temperature to conserve refrigerator space, unless the product insert specifies refrigeration.
- Store epinephrine at **room temperature** (15°C to 30°C) and protect from heat, light and moisture. Do not store epinephrine in the refrigerator.
- Open the refrigerator door **only** when necessary, and close it as soon as possible.



4.3 Vaccine Orders

- Review inventory on hand and order vaccines as per the shipping schedule provided by BCCDC Vaccine and Pharmacy Services for your office. Weekly ordering is recommended for large Health Unit offices, biweekly for medium-sized offices, and monthly for small and isolated offices. Place all orders on the Tuesday prior to delivery, according to the BCCDC Shipping Schedule.
- Establish a base order for all vaccines considering the following:
 - a) the size of the age cohort; i.e., the number of births in the community, or the number of students in a school-based program grade;
 - b) the doses in a “routine” immunization schedule (no seasonal fluctuations); i.e., two doses of MMR vaccine/infant;
 - c) seasonal and program demands (influenza clinics, school - based programs – Hepatitis B, meningococcal C, HPV, varicella, Tdap); and
 - d) small buffer amount to accommodate any unexpected increased demand.
- Review base order quantities quarterly, and revise as needed (for example, if there is a large supply of vaccine on hand on a regular basis, this may indicate over-ordering.) Base orders will need to be adjusted when there is a program change to the number of doses in a recommended immunization schedule (e.g., moving from a 4 dose to a 3 dose Prevnar schedule) or when a new combination vaccine is introduced (e.g., use of INFANRIX hexa™ rather than Pediacel® and hepatitis B vaccine.)
- Consider quantity on hand when ordering.

Example: monthly base order, minus quantity of the vaccine on hand = amount to order.

- For school-based programs, order only the quantity needed for the **first** dose in a vaccine series (grade 6 hepatitis B, HPV); order subsequent doses at a later date as needed according to series schedule. Consider coverage level reached with dose #1 to estimate vaccine amount needed for dose #2.
- Avoid over-ordering or early ordering. Do not stockpile vaccines. Any loss will be more costly in the event of a power outage or refrigerator failure, and the risk of wastage from expired product is increased.
- Alert staff when an order is placed, and when order is expected to arrive. All staff need to be aware of procedures to follow when a biologicals order is received and the Biological Products Monitor or designate is not available.
- For Public Health only, use the “Biologicals Requisition Form” (See 7.0, Resources) to order biological products from BCCDC. The form is available at



http://www.bccdc.ca/NR/rdonlyres/C98371DC-5305-45F4-B5B5-F5D42D601F68/0/PHARMACY_form_BiologicalReplenishment_20090529.pdf.

Physicians, private clinics and facilities order publicly-funded vaccines through their local health unit office.

4.4 Principles of Vaccine Handling

- Keep vaccines in the refrigerator or in a cooler until ready to administer.
- Use small coolers at work stations during mass immunization clinics. This will reduce the number of times that the refrigerator or larger cooler will be opened and closed during the day, thus reducing temperature fluctuations and exposures to adverse conditions (see 7.0, Resources: Mass Clinics – Vaccine Handling Tips.)
- Biological products are not hazardous waste. Empty multi-dose vials may be placed in the regular garbage for disposal.

4.5 Transportation and Management of Vaccines for Clinics

Consider the amount of vaccine to be transported, the external air temperature, and the length of time the vaccine will be in an insulated container. This will help to determine packing requirements.

Packing vaccines for clinic use:

- Keep vaccines in original packaging.
- Place a thermometer with the vaccine in the cooler when vaccine will be in the cooler for more than 4 hours. Note: A minimum/maximum thermometer is recommended for monitoring temperature inside large coolers during mass immunization clinics.
- Provide a protective barrier of insulating material such as a flexible insulating blanket, between the vaccines and the frozen packs.
- Place frozen packs at the top of the cooler.
- See 7.0, Resources: Instructions for Packing an Insulated Container. Specific packing configurations should be developed at the local level, considering locally available equipment and supplies.
- Consider local testing of packing configurations using available supplies and monitoring the temperatures in a cooler over time to determine the appropriate vaccine load and packing requirements that will maintain the temperature within the + 2°C to + 8°C range. Consider the length of times vaccines may be in the field in your specific region (locations of outside clinics and travel times to clinics.)
- Packing configurations will vary on a seasonal basis. It is most important that vaccines do not freeze. In winter conditions, less ice may be needed to maintain the required temperature; more ice may be needed for summer conditions.



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- Maintain the packing configuration when removing vaccines from or returning vaccines to the cooler.
 - Refrigerate diluent for 24 hours in the refrigerator if you are planning on transporting it in the cooler with the vaccines. Diluent that is not refrigerated before being placed in a cooler may warm the temperature in the cooler. If you have not refrigerated the diluent, transport diluent separately from vaccines.
 - Keep coolers out of direct sunlight. Do not place coolers in the trunk of the car where temperatures cannot be monitored. When weather temperatures are below +2°C, transport in a vehicle where the temperature can be kept higher than +2°C to avoid freezing. Do not place coolers by the car heater.
 - Check the temperature readings hourly to ensure the vaccines are maintained within cold chain parameters.

4.6 Mass Immunization Clinics

Monitor the temperature in large coolers used for mass clinics. Check the temperature in the large monitored cooler before removing vaccines. When there is concern that products may have been exposed to adverse temperatures, do not use the vaccine until you have received instructions from your Biological Products Consultant.

The British Columbia Mass Immunization Cold Chain Project (2005-2006) provided recommendations for insulated coolers that would maintain the cold chain during vaccine transport and handling in mass clinic settings. The project provided data for a small number of specific packing configurations and vaccine loads, under summer and winter conditions and over extended periods of time. These data will be useful if your circumstances (ambient temperatures and travel times) match those of the project. The project report is available on the BCCDC web site (see 7.0, Resources) and contains the specific packing configurations for large and small coolers for mass clinics under summer and winter conditions.

If vaccines are transported to mass clinics in numerous coolers, use all the vaccines in one cooler before opening the next cooler.

4.7 Returning Biological Products

- Check inventory and return products to BCCDC Vaccine and Pharmacy Services **monthly**.
- Return only BCCDC-supplied products.
- Encourage community immunization providers to return damaged/wasted vaccines to public health.



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- Complete a Field Return Form, (See 7.0, Resources) indicating the product, lot #, expiry date, reason for return, quantity, and the contact person at the Health Unit. Accurate and complete information is required to facilitate analysis of returns and determine vaccine wastage.

For products that do **not** require return under cold chain conditions:

- Fax the completed form to the Biologicals Desk at (604) 775-2718 to obtain a Field Return authorization number.
- The Biologicals Desk will fax the Field Return Form with the authorization number to the Health Unit Office.
- Enclose a copy of the Field Return Form with the authorization number in the vaccine shipment, and retain a copy in the Health Unit office.

For products that **do** require return under cold chain conditions:

- Follow the steps outlined above to obtain a return authorization number.
- Arrange with the Biologicals Desk for a TempTale® to be sent from BCCDC to the Health Unit Office to accompany the shipment.
- Return the vaccines in an insulated container with ice packs in a configuration specified by BCCDC and monitored with the TempTale® device
- For vaccines being returned for redistribution, complete and enclose the Redistribution Form, signed by the Biological Products Monitor **and** Biological Products Consultant, and follow the above steps for products requiring return under cold chain conditions

For surplus biological products only, the request to return to BCCDC for redistribution must meet **ALL** of the following criteria, compliance signatory by both the Biological Products Monitor and Biological Products Consultant, before an authorization is provided:

- The cold chain was maintained between +2°and +8°C for these products, throughout their storage at the site.
- Products were received directly from BCCDC, and were maintained at all times at the site, with no transfer to/from other site(s) prior to being shipped back to BCCDC.
- Products are in their original packaging, sealed, unopened and unused.
- Products were stored in a safe and secure location with no public access.
- The refrigerator temperature was logged at the start and end of each business day.
- The products have at least 3 month dating before the expiry date is reached.

See 7.0, Resources, for Biologicals Return and Redistribution Requirements Form.



To facilitate the tracking of vaccine returns, use the following “Reasons for Return” codes:

REASON	CODE
Product recall	G
Wrong product shipped/requested*	H *
Damaged	I
Expired	J
Overstocked: surplus with remaining shelf life*	K*
Cold chain failure (in transit)	L
Cold chain failure (refrigerator failure)	M

*Indicates product to be returned under cold chain conditions, with a temperature monitoring device.

5.0 MANAGEMENT OF A COLD CHAIN INCIDENT

All biological products are licensed for use under storage conditions of **+2°C to +8°C**.

As a general principle, **0°C to +2°C** is considered “refrigeration conditions”; with due regard to the accuracy of the temperature reading device, no product needs to be discarded for a validated temperature in this range for an exposure of any period of time, even for a series of exposures within the temperature range of 0 to 1.9°C.

With a thermometer calibrated for accuracy at +/- 1°C, a reading of 0.5°C could be as high as +1.5°C or as low as -0.5°C. The decision about use of the product will be based on the temperature range, and the “worst case scenario”, which in this example would be - 0.5°C.

Exposures in the 0° to +2° C range need **not** be reported as a “cold chain incident”. It is, however, extremely important to adjust the refrigerator temperature and restore the temperature to within the +2°C to +8°C range **immediately**, because further temperature declines to below zero could result in freezing of vaccines.

Any temperature outside of the +2°C to +8°C range requires immediate action.

- Check that your thermometer is working correctly; you may need to change the battery. Check manufacturer’s specifications for battery life.
- On the Temperature Log, record the date, time and three temperatures (the current refrigerator temperature, the minimum temperature reached since last check, and the maximum temperature reached since last check.) Also record



the refrigerator dial setting. Reset the thermometer after recording these temperatures.

- If the **current** refrigerator is malfunctioning, move all of the vaccines to a properly functioning, monitored refrigerator.
- Adjust your refrigerator temperature setting and monitor the effect of this measure, or have the refrigerator serviced, and check that the temperature is between +2°C to +8°C before returning any vaccine to the refrigerator.
- Place exposed vaccines in a container; clearly label as “**DO NOT USE**”, and mark the date and time. Place this container with the exposed vaccines back into a functioning refrigerator, ensuring that the exposed vaccines are separate from any non-exposed vaccines. It is important that the exposed vaccines are returned to acceptable temperatures (+2°C to +8°C) as soon as possible.
- Complete the Cold Chain Incident Form (See 7.0, Resources).
- Contact your Biological Products Consultant for direction about use of the vaccines.
- Do **not** discard any vaccines until this consultation and determination of use has been made.
- **Clearly label** biological products that have had a cold chain incident, but are subsequently deemed to be usable. Develop a system to track vaccines exposed to a cold chain incident, including the temperature and the duration of the exposure.
- Vaccines that have been exposed to a temperature outside the recommended range in transit from the manufacturer to BCCDC will be labeled with a **yellow** dot. BCCDC Vaccine and Pharmacy Services will provide the details of this initial exposure when these vaccines are shipped to the field.
- Vaccines that have been exposed to a temperature outside the recommended range in transit from BCCDC to the field should be labeled with a **red** dot. BCCDC Vaccine and Pharmacy Services will supply the temperature and duration information for this incident to the field.
- Develop a protocol within the HA for labeling products that have subsequent exposures to temperatures outside the 0°C to +8°C range.
- Any temperature outside of the 0°C to +8°C range should be treated as a cold chain incident and reported to BCCDC Vaccine and Pharmacy Services.
- Any cold chain incident provides an opportunity to review cold chain management and modify practices that may be contributing to cold chain incidents.
- Return to BCCDC the exposed vaccines that have been determined by the Biological Products Coordinator to be non-usable.



When the information in the Stability Chart is insufficient for decision – making, the Biological Products Consultant will contact BCCDC Vaccine and Pharmacy Services for assistance in determining if vaccines can be used.

Consult with Vaccine and Pharmacy Services when products have had a second exposure to temperatures outside of the recommended range.

5.1 Power Failure

- Establish an office-specific emergency plan for power failures or equipment malfunction.
- Identify a back-up refrigerator that is accessible, monitored and functional at all times.
- On the Temperature Form (see 7.0, Resources), record the refrigerator temperature (minimum, maximum and current), room temperature, and time, as soon as possible after the start of the power failure. Reset the thermometer.
- Place a “**DO NOT USE**” sign on the refrigerator. Do **NOT** open the refrigerator except to remove vaccines for alternate storage.
- On average, the temperature in a powerless refrigerator will increase approximately +1°C per hour. The refrigerator is insulated and able to maintain its temperature, especially if it contains cold ballast (bottles of water).
- If power is expected to be restored within four hours or less, keep the vaccines in the refrigerator and keep the refrigerator doors closed.
- If a longer power outage is expected, or if the refrigerator temperature is going out of range quickly, move vaccines to a cooler with ice packs and insulating material. Take the vaccines to a facility that has a functioning monitored refrigerator (i.e. that has power or a back up generator) as per the local emergency plan.
- Continue to monitor and record refrigerator temperatures for the duration of the outage. If power failures are a common occurrence, centralize vaccine storage to a more power-stable facility.
- Record the time and refrigerator temperatures (current, minimum and maximum) when the power is restored.
- Complete the Cold Chain Incident Form and contact your Biologicals Products Consultant if products have been exposed to temperatures outside of the 0°C to +8°C range.



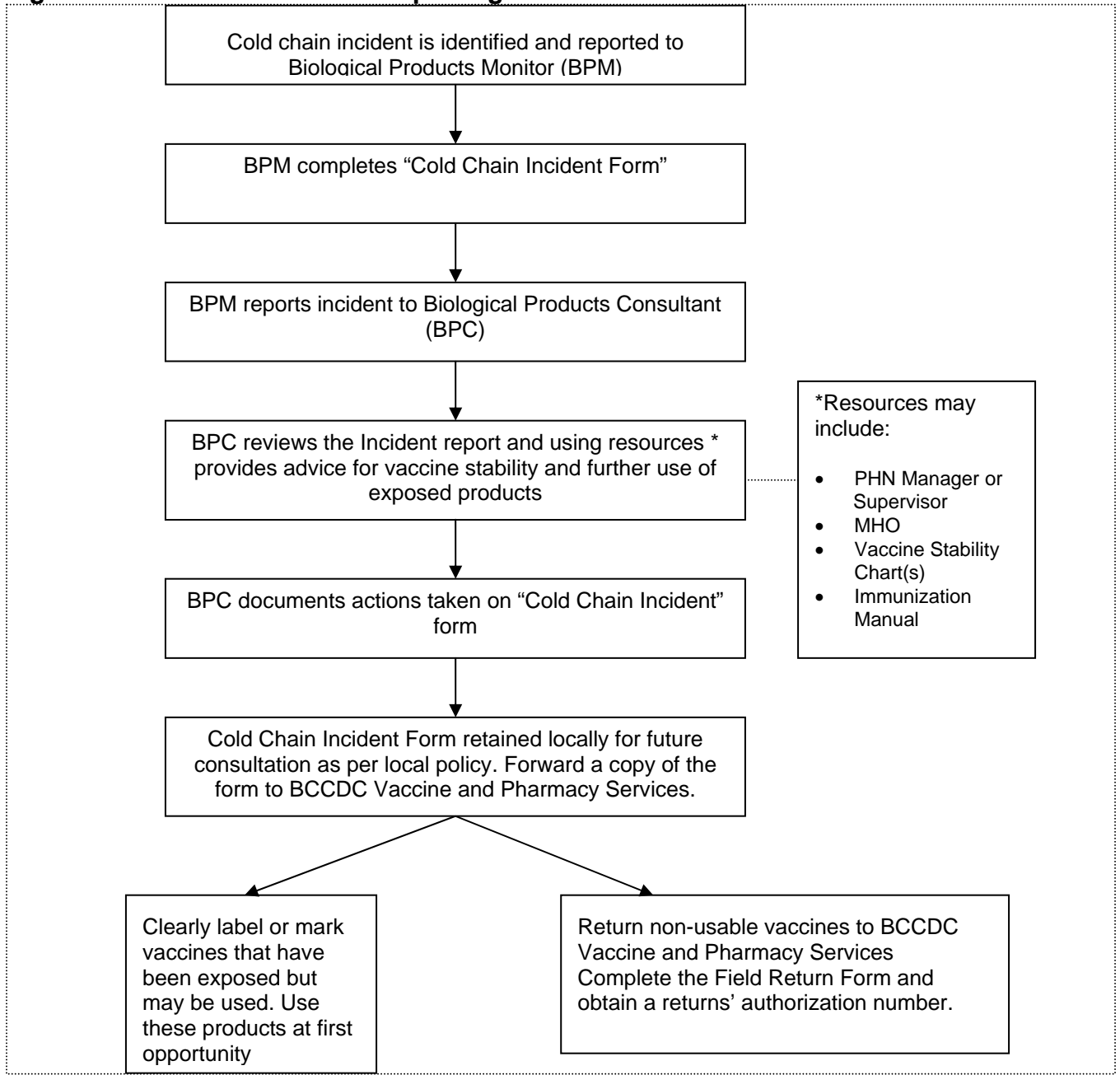
6.0 VACCINE STABILITY CHART INFORMATION

BCCDC has developed a Vaccine Stability Chart for **PUBLIC HEALTH USE ONLY**. It contains guidance for use of vaccines exposed to specific time/temperature scenarios.

Using the Vaccine Stability Chart (See Figure 1)

1. Staff person identifies that there has been a break in the cold chain.
2. Staff person contacts Biological Product Monitor (BPM).
3. BPM completes the Cold Chain Incident Form and contacts the Biological Products Consultant (BPC).
4. BPC reviews the completed Cold Chain Incident form and uses the Vaccine Stability Chart to determine whether vaccines are usable.
5. The completed "Cold Chain Incident Form," with actions taken, is retained by the health unit, and copied to BCCDC Vaccine and Pharmacy Services for analysis.
6. If the information contained in the Vaccine Stability Chart does not match the circumstances of the reported cold chain failure, the BPC can contact the BCCDC Vaccine and Pharmacy Services at (604)660-6000 and speak with a Pharmacist. A copy of the "Cold Chain Incident" form is needed by BCCDC Vaccine and Pharmacy Services to assist with the assessment of the stability of the vaccines in question.
7. Clearly label vaccines that have been exposed to a cold chain incident and have subsequently been determined to be usable. Use these products at the first opportunity.

Figure 1: Cold Chain Incident Reporting





7.0 RESOURCES

The following resources are available on the BCCDC web site at

<http://www.bccdc.ca/imm-vac/ForHealthProfessionals/VaccineAndPharmacyServices.htm>

1. Field Return Form
2. Biologicals Return and Redistribution Requirements Form
3. Cold Chain Incident Form
4. Temperature Form

The BCCDC web site has resource material for community vaccine providers and public health at

<http://www.bccdc.ca/imm-vac/ForHealthProfessionals/ColdChainInfo.htm>

Cold Chain Resources for Community Vaccine Providers

1. Handle Vaccines with Care
2. Packing an Insulated Cooler
3. How to Store Vaccines in the Refrigerator
4. What to do if the temperature is outside the 2°C to 8°C range
5. Temperature Form
6. Cold Chain Checklist

Cold Chain Resources for Public Health:

1. Handle Vaccines with Care
2. Packing an Insulated Cooler
3. How to store vaccines in the Refrigerator
4. TempTale® Directions for Use
5. Mass Clinic Project Report
6. Cold Chain Checklist
7. Mass Clinic – Vaccine Handling Tips



8.0 REFERENCES

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Department of Health and Ageing (2005) National Vaccine Storage Guidelines: Strive for Five. Canberra, Australia available at <http://www.health.gov.au/internet/immunise/publishing.nsf/content/provider-store>

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