

Instructions for Completing the Cold Chain Incident Form

In order for a cold chain incident to be accurately assessed it is important that as much information as possible is provided regarding the incident. Ensure that all fields of the form are completed before submitting the form for recommendations as to the use of the vaccine(s) involved in the cold chain incident; failure to provide complete information can result in unnecessary back-and-forth and delay the provision of recommendations regarding the use of the vaccines involved in the cold chain incident. In addition, **incomplete forms will be returned**. Abbreviations should not be used unless the full name of a health unit/location/site is first spelled out in its entirety.

- 1. **Incident description and action taken.** It is important that as many specific details as possible are included to ensure a thorough and accurate assessment of the cold chain incident. If necessary, please include additional information in a Word document when submitting the cold chain incident form. Examples of some details that should be included:
 - a. Power outage: Include the duration of the power outage and whether it was a planned outage, i.e., scheduled by BC Hydro, or an unscheduled outage, if known. For the latter include any information as to the root cause of the outage, e.g., inclement weather or circuit breaker tripped.
 - b. Equipment malfunction: Identify the specific equipment that malfunctioned (e.g., refrigerator or back-up generator), any potential reasons for the malfunction and actions done to address the issue.
 - c. Handling error: Provide as much information as possible regarding the incident. For instance if the vaccine was left out overnight include the times the vaccines were discovered and the most likely time that the vaccine would have been in use, e.g., clinic ended at 2 pm and vaccine discovered next morning at 8 am in a cooler with thawed ice packs and vaccine was warm to touch.
 - d. Internal Health Authority transport: Include the names of the sending and receiving sites, the time of the shipment, the time the vaccine was received and the time in transit, and any pertinent details regarding the configuration of the shipment (i.e., specifics regarding how the vaccine was packed e.g., the number of refrigerated blankets, ice packs, positioning of the temperature monitoring device etc.).
 - e. Other: The vast majority of issues should be captured in one of the preceding categories. For incidents that don't fit into one of the other categories, a detailed description of the incident and cause of the incident should be included.
 - f. Examples of action taken include: Vaccine moved to a functioning refrigerator and quarantined, vaccine packed in coolers and transported to a back up site with a functioning refrigerator and quarantined, closed refrigerator door and monitored temperature to ensure it returned to the recommended temperature range, called to schedule servicing of the refrigerator or backup generator, reviewed internal processes for responding to a cold chain incident, reviewed packing configurations of coolers used for transporting/storing vaccines. Include the time for any actions that are done to address the incident while it is in progress, i.e., vaccine moved to functioning refrigerator at 9:45 am.
- 2. **Primary cause of the incident.** Please check only the ONE BOX that best describes the primary cause of the cold chain incident. Examples for the various causes are provided below.
 - a. Power outage: An incident resulting in the disruption of power to the refrigerator (or freezer).
 - b. Equipment malfunction: A refrigerator (or freezer) warms or cools to temperatures outside of the recommended storage temperature range (without another cause being identified such as

March 4, 2021

- the door being left ajar) or fails completely, a back-up generator or temperature monitoring device malfunctions.
- c. Handling error: Incidents such as leaving vaccine out after a clinic, not ensuring the door of the refrigerator (or freezer) is closed properly, failure to store vaccine promptly upon receipt of a new shipment.
- d. Internal Health Authority transport: Incidents occurring while transporting vaccine from one site to another within the health authority (or between health authorities). Note that the cold chain incident form is not intended for reporting incidents occurring in transit from the BCCDC/Delta Vaccine Distribution Centre, a vaccine manufacturer or a pharmacy wholesaler/distributor.
- e. Other: Any incident that can't be assigned to one of the preceding reasons.
- 3. Where did the incident happen? Please note that 'Pharmacy' refers to community pharmacies, not hospital pharmacies. Incidents arising at hospital pharmacies should be indicated as 'Other'. Some other examples of 'Other' include Long Term Care and Assisted Living Facilities.
- 4. **Temperature exposure information.** The minimum and maximum temperatures that the vaccine was exposed to during the incident. This information is essential for the provision of a recommendation regarding the use of the vaccine.
- 5. **Additional temperature information.** Please ensure that the dates and times that the vaccine was last stored at and returned to temperatures within the recommended temperature range are reported. This helps to ensure that the duration of the exposure is accurately determined.
- 6. **Duration of exposure.** The total time that the vaccine was outside of recommended storage temperatures.
- 7. **Temperature logs included?** Please indicate if temperature logs have been included for the incident under investigation. The inclusion of temperature logs will assist with verifying the duration of the incident. The temperature logs could be from twice daily monitoring of the refrigerator (or freezer) or the output from a data logger.
- 8. Accuracy of the temperature monitoring device. This information needs to be included to determine the precise temperature to which the vaccine may have been exposed during the incident. For example, if the temperature reading was +15°C with an accuracy of ±1°C, the vaccine may have been exposed to a temperature as high as +16°C. The worst case scenario is used when providing recommendations regarding the use of vaccine.
- 9. **How is the temperature monitored?** Please indicate the type of device used to monitor the temperature for the incident under investigation.
- 10. Vaccine information. Be sure to include all of the information for the vaccines involved in the incident. Please note, that the number of doses of vaccine should be reported, this includes when multi-doses vials of vaccine are involved in the incident; do NOT report the number of vials. For each vaccine, be sure to include the lot number and the corresponding expiry date. If the expiry date only includes the month and year, the last day of the month should be used when entering the information for day. When entering the previous exposure details, ONLY include details for a previous cold chain incident; do NOT include information for the current incident being reported. If the vaccine has been involved in more than one incident, include information (time and temperature) for all previous incidents; this information is necessary to provide a recommendation as cold chain incidents are cumulative in nature.

March 4, 2021