

## Resource 5: Cold Chain Failure Response Procedures and Form

### Manitoba Health Cold Chain Failure Response Procedure and Form

The following document provides instruction on completing the required provincial *Cold Chain Failure Response Form* in the event of a cold chain failure involving vaccines and biologics obtained from Manitoba Health.

**When a cold chain failure occurs, all sections of the *Cold Chain Failure Response Form* must be completed and faxed to Communicable Disease Control (CDC), Manitoba Health at: (204) 948-2040.**

If you do not have a copy of the form, contact Manitoba Health at (204) 788-6737 to receive a copy by fax or email. The form is also available on the Manitoba Health website at: <http://www.gov.mb.ca/health/publichealth/cdc/coldchain.html>

#### Steps for Completing the Cold Chain Failure Response Form:

##### Section A: Contact Information and Health Care Setting Description

- Enter the date the form was completed and all contact information.

##### Section B: Description of Exposed Vaccines and Biologics

- Outline all vaccines and biologics that were exposed to the cold chain failure by completing the table.
- Clearly identify any vaccines and biologics that have previously been exposed to a cold chain failure, but were subsequently deemed useable. Communicate this to the manufacturer(s), as this could assist in determining if the products are useable.
- Contact the manufacturer(s) of the vaccines and biologics to explain the details of the cold chain failure and request a recommendation on the stability of the vaccines and biologics.
- All recommendations from the manufacturer(s) should be recorded on the table.
- Whenever possible ask the manufacturer(s) to provide their recommendation in writing.
- Include any written responses from the manufacturer(s) with the completed form.

##### Section C: Description of Occurrence and Temperatures

- Identify the date, time, current temperature, and the min/max temperatures when the cold chain failure was discovered.
- Identify the date, time, current temperature, and the min/max temperatures when the temperature was last checked and recorded.
- Indicate the estimated time of exposure outside the manufacturer's recommended storage conditions.  
\*\*This is the number of hours since the last temperature was checked and the time of discovery.
- Check the appropriate box to indicate the cause of the cold chain failure.

## **Section D: Temperature Monitoring/Refrigerator Information**

- Complete all areas as outlined on the form to describe the temperature monitoring practices that occur at the health care facility and indicate the type of refrigerator or cooler on site.
- If the failure occurred on route to and during off-site clinics, complete the sections with the details of the type of cooler used and the results of the cold chain monitor used.

## **Section E: Actions Taken Following Recognition of Occurrence**

- Provide details on how the situation was rectified and any steps taken to prevent further occurrences.

**NOTE:** Once the form has been faxed to Manitoba Health, consultation with the Manitoba Health Inventory Management Administrative Officer at (204) 788-6737 is required in order to review the occurrence, determine if products should be returned to the provincial vaccine warehouse or discarded, and for approval to order replacement product.

For additional information on cold chain maintenance of vaccines and biologics, please see the National Vaccine Storage and Handling guidelines at:

- <http://www.phac-aspc.gc.ca/publicat/2007/nvshglp-ldemv/index-eng.php>
- <http://www.phac-aspc.gc.ca/publicat/cig-gci/p01-08-eng.php>

To address any specific questions or concerns, please contact Manitoba Health at (204) 788-6737.



## Manitoba Health Cold Chain Failure Response Form

Page 2

### Section D: Temperature Monitoring/Refrigerator Information

Is refrigerator temperature monitored?  No  Yes

If yes, type of thermometer used:  Household mercury thermometer  Min/Max thermometer  
 Continuous temp data logger

Is temperature recorded?  No  Yes

Frequency of temp. monitoring  Twice daily on working days  From time to time  
 Daily on working days  Other specify: \_\_\_\_\_

Type of fridge:  Lab style  Bar style  Domestic  Other Specify: \_\_\_\_\_ Fridge age in years: \_\_\_\_\_

**Cold Chain Failure During Transport to and During Off-Site Clinics** Type of carrier (cooler): \_\_\_\_\_

Type of cold chain monitor used:

Chemical temperature mark (indicate results):

Cold Mark: Clear  Pink/Cloudy

Warm Mark: How many round indicator windows are partially or completely pink/red?  
 0  1  2  3 (all)

OR  Continuous temperature data logger:

Max. Temp.: \_\_\_\_\_ Min. Temp.: \_\_\_\_\_

Duration of Exposure (in estimated hours):  
\_\_\_\_\_

### Section E: Actions Taken Following Recognition of Occurrence

**Action 6:** Vaccines and biologics deemed useable must be clearly identified as having been exposed to a cold chain failure and used first.

**Action 7:** Consultation with the Manitoba Health, Inventory Management Administrative Officer at (204) 788-6737 is required to discuss the occurrence, to review what products can be returned to the Provincial Vaccine Warehouse or discarded into an appropriate biological waste container, and for approval to order replacement product. If product can be returned contact the Provincial Vaccine Warehouse for return instructions. Phone: (204) 948-1333 or Toll-Free (855) 683-3306.

What actions have been taken to rectify the cause of the cold chain failure and/or any preventative measures that have been put into place? \_\_\_\_\_

Supplementary Information \_\_\_\_\_

**Action 8:** Fax Completed Form to: Communicable Disease Control Branch, Manitoba Health, Fax: (204)-948-2040.

**For more Information:** See National Vaccine Storage and Handling Guidelines for Immunization Providers (2007): <http://www.phac-aspc.gc.ca/publicat/2007/nvshg/ldemv/index-eng.php>