Date Approved: January 2017
Applicable to: All Immunization Providers

Purpose: This document provides instruction on completing the Manitoba Health *Adverse Storage Condition* (ASC) Form.

Policy: In the event that vaccines and biologics supplied by Manitoba Health are exposed to an Adverse Storage Condition* the facility is responsible for the notification of the incident to Manitoba Health via the *Adverse Storage Condition (ASC) Form.*

*Adverse Storage Condition is defined as an exposure outside of the manufacturers recommended storage conditions.

When an ASC occurs, all sections of the Adverse Storage Condition (ASC) Form must be completed and faxed to the Manitoba Health Inventory Management Officer at: 204-948-2190.

Steps for Completing the Adverse Storage Condition (ASC) Form:

Section 1: Contact Information

- Enter the date the report was completed as well as the contact information for the person who filled out the form.
- The Holding Point (HP) Code is the 5 digit number assigned to an Immunization Provider when they register as a New Immunization Provider with Manitoba Health.

Section 2: ASC Details

 Fill out the date and time the ASC began as well as when it ended. (Please note: the time must be filled in using a 24hr clock format). Calculate the total duration** of the ASC and fill in this information.

**This is the number of hours since the last temperature was checked and the time of discovery – assuming actions were taken to bring the products back to the manufacturers' recommended storage conditions after discovery.

Section 3: Cause of ASC

 Identify the cause of the ASC and write a short description of what happened in the space provided.

Section 4: Temperature Monitoring Information

- Check off whether or not the temperature in your refrigerator is being monitored and how often.
- Identify the date, time and last logged temperature from when the temperature was <u>last checked and</u> recorded.
- Identify the date, time and temperature of the refrigerator when the ASC was discovered, and the MAX/MIN temperatures during the interval.
- Check the appropriate box to indicate the type of monitor being used.



Section 5: Affected Products

- Outline all vaccines and biologics that were exposed to the ASC by completing the table.
- Clearly identify vaccines and biologics that have previously been exposed to an ASC, but were 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 corresponding vaccines and biologics and explain the details of the ASC incident and request a recommendation on the stability and usability 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 to Manitoba Health.

FAX COMPLETED FORM TO MANITOBA HEALTH INVENTORY MANAGEMENT OFFICER AT 204-948-2190

NOTE: Once completed and the form has been faxed to Manitoba Health, consultation with the Manitoba Health Inventory Administrative Officer at 204-788-6721 may be required to review the occurrence, determine if products should be returned to the Provincial Vaccine Warehouse or discarded, to ensure the situation is rectified, and obtain approval to order replacement product, if needed.

For information on cold chain maintenance of immunizing agents and biologics, see the Manitoba Health Cold Chain Resources Website at www.gov.mb.ca/health/publichealth/cdc/coldchain.html.

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



MANITOBA HEALTH ADVERSE STORAGE CONDITION (ASC) FORM



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	CONTACT INF	ORMATION							
Date of Report:	YYYY/MM/DD								
Reported By:		Contact Phone #:	()						
Holding Point (HP) Code:		Facility Name:							
ASC DETAILS									
ASC Start Date:	YYYY/MM/DD	ASC Start Time:	<u> </u>						
ASC End Date:	YYYY/MM/DD	ASC End Time:	<u>:</u>						
Recorded Duration of ASC:		minshrs	days						
	CAUSE OF ASC	(Check One):							
Electricity Disconnected	0	Refrigerator Malfunction	0						
Flood or Other Emergency	0	Temperature Breached in Transit - External	0						
Power Outage	0	Temperature Breached in							
- Tower Outage	V	Transit - Internal	<u> </u>						
Cause Description:									
TEMPERATURE MONITORING INFORMATION:									
Is the Refrigerator's Temperature Monitored?									
Yes	0	No	0						
Frequency of Temperature Monitoring:									
Twice Daily on Working Days:	0	From Time to Time:	0						
Daily on Working Days:	0	Other (Please Specify):							
Last Logged Date:	YYYY/MM/DD	Last Logged Time:	::						
Last Logged Temperature:	°C								
Discovery Date:	YYYY/MM/DD	Discovery Time:	:						
Temperature @ Discovery:	°C	_							
MAX. Temperature During Interval:	°C	MIN. Temperature During Interval:	°C						
Monitor Type (check one):	Cold Marke	0							
	Continuous Monitoring	\circ							
	Continuous Monitoring - T	0							
	Freeze Temperatur	0							
	Heat Time and Tempera	0							
	Household Mercury T	0							
	None	\bigcirc							
		II.							
	Thermometer - Digit	al MAX/MIN	0						

AFFECTED PRODUCTS (PLEASE ONLY INCLUDE THOSE PUBLICLY-FUNDED BY MANITOBA HEALTH) - PAGE 2

PRODUCT BRAND NAME	Manufacturer	Lot#	Expiry Date	# of Doses Affected	Previous Exposure (Y/N)	Recommendation from Manufacturer (Contact Information Found at Bottom of Page)	
PLEASE PRINT ADDITIONAL PAGES IF NEEDED							

VACCINES & BIOLOGICS DEEMED USEABLE MUST BE CLEARLY IDENTIFIED AS HAVING BEEN EXPOSED TO AN ADVERSE STORAGE CONDITION AND MARKED "USE FIRST".

IF YOU HAVE ANY QUESTIONS ON HOW TO FILL OUT THIS FORM CORRECTLY OR TO REVIEW WHAT PRODUCTS CAN BE RETURNED TO THE PROVINCIAL VACCINE WAREHOUSE, PLEASE CONTACT THE MANITOBA HEALTH INVENTORY ADMINISTRATIVE OFFICER AT 204-788-6721

IF PRODUCT CAN BE RETURNED, PLEASE CONTACT THE PROVINCIAL VACCINE WAREHOUSE AT 204-948-1333 OR TOLL FREE AT 855-683-3306 FOR RETURN INSTRUCTIONS.

MANUFACTURER CONTACT INFORMATION:

SANOFI: GRIFOLS: NOVARTIS: MERCK:

1-888-621-1146 1-866-482-5226 1-800-465-2244 1-800-567-2594

GSK: PFIZER:

1-800-387-7374 1-800-463-6001

FAX COMPLETED FORM TO: MB HEALTH INVENTORY MANAGEMENT OFFICER FAX: 204-948-2190