

**Alberta
Vaccine Cold Chain Policy
MARCH 2015**

**Surveillance and Assessment Branch
Health System Accountability and Performance**

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TABLE OF CONTENTS

Contents

1. INTRODUCTION	5
2. DEFINITIONS	6
3. PURPOSE	7
4. OBJECTIVES	8
5. LEGISLATIVE AUTHORITY	8
6. POLICY SCOPE, IMPLEMENTATION AND EFFECTIVE DATE	8
7. ROLES AND RESPONSIBILITIES	9
7.1 <i>AHS</i>	9
7.2 <i>Community Providers</i>	10
8. VACCINE STORAGE AND HANDLING MANAGEMENT	11
9. VACCINE STORAGE REQUIREMENTS	11
10. VACCINE TRANSPORT	13
11. TEMPERATURE MONITORING	13
12. ALARMS	14
13. COLD CHAIN BREAKS	14
14. INFORMATION AND EDUCATION STRATEGIES	15
15. QUALITY ASSURANCE	16
16. CONTINGENCY PLANNING	17

17. VACCINE REPLACEMENT 17

18. POLICY UPDATES 17

19. EVALUATION OF THE POLICY 17

REFERENCES 18

APPENDIX A..... 19

 Sample Cold Chain Break Report Form

APPENDIX B..... 22

 Sample Temperature Monitoring Form

Superseded

1. INTRODUCTION

Alberta Health purchases, stores and distributes provincially funded vaccine from the Provincial Vaccine Depot (PVD) to 14 main vaccine depot stations in Alberta Health Services (AHS) referred to as “AHS Depot Sites” in this document. AHS administers the vaccine to clients or provides it to some Community Providers to administer. Alberta Health distributes the influenza vaccine to pharmacies through the Pharmacy Wholesale Distributors. Cold Chain accountability for pharmacists will reside with Alberta Health until further notice.

The recommended temperature for vaccine storage and handling is +2.0°C to +8.0°C and some vaccines also need to be protected from exposure to light.

Vaccines are sensitive biological products that may become less effective or destroyed when exposed to temperatures outside the recommended range and inappropriate exposure to light. Exposure to temperatures outside the recommended range results in loss of potency with each episode of exposure. Repeated exposures to heat results in a cumulative loss of potency that is not reversible. Cold-sensitive vaccines experience an immediate loss of potency following freezing. It is not possible to look at a vaccine vial to determine if it has experienced temperature excursions; monitoring of temperature during transport and storage is required. Loss of potency may result in failure to stimulate an adequate immunologic response, leading to lower levels of protection against disease.

For the purposes of this document the Alberta Vaccine Cold Chain Policy will be referred to as the AVCC Policy.

More detailed information on vaccine storage equipment, temperature monitoring, packing vaccine for transport, and vaccine management can be found in the 2007 *National Vaccine Storage and Handling Guidelines for Immunization Providers*.

2. DEFINITIONS

Alarmed Temperature Monitoring System	A continuously-monitored alarm system monitors temperature in vaccine refrigerators 24 hours a day and seven days a week. The alarm must be either a voice or electronic message that will be telephoned to on-call staff or security service or a recognizable audio tone that is monitored during office hours by staff and after hours by a security service. The alarmed temperature monitoring system should have a battery back-up system in case of an electricity disruption.
Alberta Health Services (AHS)	The regional health authority established under the <i>Regional Health Authorities Act</i> .
Alberta Health Services Depot Sites (AHS Depot Sites)	AHS sites where vaccine is shipped to and from the PVD. These sites then distribute the vaccine to other AHS sites and Community Providers. There are currently 14 sites.
Audit	An independent evaluation that will include some degree of quantitative and qualitative analysis.
Bar Refrigerator	Small single-door fridge.
Chart Recorders	A device in which the refrigerator temperature is marked by ink pens on graph paper continuously 24 hours a day.
Cold Chain	Refers to the process used to maintain optimal conditions during the transport, storage, and handling of vaccines, starting at the manufacturer and ending with the administration of the vaccine to the client.
Cold Chain Break	The vaccine has been exposed to light and/or to temperatures outside the recommended range.
Cold Chain Monitors	Single-use irreversible indicators of inappropriate temperatures once a temperature excursion has occurred above or below the activation set points.
Community Provider	An individual or group of individuals who are authorized to provide immunizations in the community and who are not employed directly by AHS. Types of Community Providers include, but are not limited to, pharmacists, private nursing agencies and physicians.

Continuous Temperature Recording Devices	An electronic device that measures temperatures and records the results. This can include devices such as a Chart Recorder and Data Logger.
Data Loggers	Miniature, battery-powered, stand-alone temperature monitors that record hundreds of temperature readings. They can indicate when the exposure occurred and how long the vaccines were exposed to the minimum/maximum temperatures. Multiple-use digital data loggers are accompanied by software that is installed in a computer allowing the user to set the frequency of the temperature readings, download data from the device, and calculate temperature averages, minimums and maximums, as well as the time spent at each temperature.
Domestic Refrigerator	Combination refrigerator and freezer units. Also referred to as kitchen-style refrigerators.
Laboratory Refrigerator	The standard for storing larger amounts of vaccine. Also referred to as pharmacy, purpose-built, laboratory, lab-style or industrial-quality refrigerators.
Minimum and Maximum Thermometers	Thermometers that show the current temperature and the minimum and maximum temperatures that have been reached since the last time the thermometer was reset.
Minister	Minister of Health
PVD	Provincial Vaccine Depot
Vaccine	Provincially funded vaccine
Vaccine Bags	Insulated bags used to transport vaccine.
Vaccine Suspension	Withholding of vaccine by AHS to Community Providers due to Cold Chain requirements not being met.

3. PURPOSE

The purpose of the AVCC Policy is to define:

- vaccine Cold Chain practices in Alberta, and
- the roles and responsibilities of AHS and some community providers in implementing the AVCC Policy.

4. OBJECTIVES

The objectives of the AVCC Policy are to:

- protect vaccine safety and efficacy, ultimately ensuring a potent and safe vaccine is administered;
- minimize and reduce the cost of vaccine wastage due to Cold Chain Breaks;
- strengthen quality assurance activities related to vaccine Cold Chain;
- improve knowledge of vaccine providers regarding vaccine Cold Chain maintenance; and
- specify how vaccine lost due to Cold Chain is replaced.

5. LEGISLATIVE AUTHORITY

The AVCC Policy is provided under the authority of section 10 and 12 of the *Public Health Act* (Act) and section 2 and 2.1 of the *Communicable Diseases Regulation* which states the Minister may provide biological agents for the prevention of communicable diseases, and determine:

- the conditions under which these agents are provided and administered; and
- the methods and protocols respecting distribution and storage and handling of these agents.

6. POLICY SCOPE, IMPLEMENTATION AND EFFECTIVE DATE

- 6.1 AHS may deliver Alberta's Vaccine directly or through another Community Provider. This AVCC Policy sets out requirements for AHS and for Community Providers in order to maintain the safety and efficacy of the vaccine.
- 6.2 AHS and the Community Providers shall implement the AVCC Policy to the greatest extent possible as soon as practicable and it must be fully implemented and effective 18 months after the AVCC Policy is approved.

7. ROLES AND RESPONSIBILITIES

7.1 AHS

- a) must designate prior to 18 months after the approval of the AVCC Policy, a senior executive with accountability for the AVCC Policy application;
- b) must develop, implement and monitor vaccine Cold Chain protocols and procedures in accordance with the AVCC Policy, as updated from time to time;
- c) must monitor and report on Cold Chain as outlined in the AVCC Policy (refer to Sections 13.4, 13.8, 15.9);
- d) may hold distribution of publicly funded vaccine to non-AHS community sites where there is inadequate vaccine storage or temperature monitoring until these are corrected to the satisfaction of AHS.
- e) must develop and submit to Alberta Health, prior to 18 months after the approval of the AVCC Policy, a plan which includes:
 - i) vaccine Cold Chain standards based on the AVCC Policy;
 - ii) an information and education strategy that meets the policies outlined in Section 13;
 - iii) the installation of vaccine storage equipment, temperature monitoring equipment, backup power and alarms as outlined in the AVCC Policy (refer to Sections 8, 10, 11, 15);
 - iv) a quality assurance plan for vaccine Cold Chain practices in accordance with the AVCC Policy (refer to Section 15).

7.2 COMMUNITY PROVIDERS

Community Providers must:

- a) comply with the requirements of the AVCC Policy as updated from time to time and include any further directions by AHS and/or Alberta Health;
- b) ensure that staff have received a vaccine Cold Chain orientation or training session;
- c) have written protocols for vaccine Cold Chain management as directed by AHS;
- d) have a dedicated vaccine refrigerator and appropriate thermometer for monitoring temperature;
- e) monitor and record refrigerator temperatures at the beginning and end of each business day and verify refrigerator temperatures on the business day immediately following any day the office/clinic/facility is closed;
- f) label and appropriately store any vaccine exposed to a Cold Chain Break and immediately report the incident to the AHS public health contact identified by AHS and/or Alberta Health;
- g) promptly return unstable vaccine to AHS in the time frame specified by AHS, as recommended by Alberta Health;
- h) co-operate with AHS/Alberta Health for periodic Audits and/or on-site inspections; and
- i) prior to 18 months after the approval of the AVCC Policy, all **new Community Providers** must submit a Cold Chain management plan to AHS/Alberta Health for review prior to receiving vaccine.

8. VACCINE STORAGE AND HANDLING MANAGEMENT

- 8.1 Each site storing vaccine must have detailed, written, and easily accessible vaccine Cold Chain protocols for routine day to day operations and for urgent situations including refrigerator malfunctions, power failures, natural disasters or other emergencies that might compromise vaccine storage conditions.
- 8.2 All personnel, including non-health professional staff, who handle vaccines in any way, must receive appropriate training.
- 8.3 Each site where vaccine is stored must have a designated vaccine coordinator and another staff member as a backup at all locations where vaccine is stored. The designated person is responsible for ensuring vaccines are handled correctly and that procedures are followed and documented. Sites should maintain no more than a one month supply of vaccine at any time. Avoid over-ordering or ordering early. Do not stockpile vaccines, as any loss will be more costly in the event of a power outage or refrigerator failure so that the risk of wastage from expired product is increased.

9. VACCINE STORAGE REQUIREMENTS

- 9.1 Vaccines must remain in the refrigerator, except when being administered or transported. In the case of a power or refrigerator failure or refrigerator maintenance, alternate storage that has the capacity to monitor Cold Chain is acceptable.
- 9.2 **Laboratory Refrigerators** are required for vaccine storage at sites where \$5,000 or more of vaccine is stored at a time. The advantages are:
 - a digital feedback system that ensures narrow tolerances with internal temperatures, thus providing an excellent temperature regulation
 - air circulation is fan-forced,
 - system for vaccine storage,
 - ongoing air circulation that ensures that the temperature distribution is even,
 - a set-point temperature is kept within a +2.0°C to +8.0°C range,
 - evaporator operates at +2.0°C, preventing vaccine from freezing,
 - temperature recovery system is appropriate, and
 - it is built to handle ambient temperature changes.

- 9.3 Domestic Refrigerators** may be used for storage of vaccine less than \$5,000. Acceptable domestic combination refrigerator and freezer units must have separate external doors for the freezer and fridge. Manual and cyclic defrost refrigerators should not be used due to the significant temperature variations and the risk of vaccines freezing. Some domestic frost free refrigerators can be used but may require modification to store vaccine. Vaccines can only be stored in certain areas of the refrigerator and Precautions should be taken as temperatures may fluctuate in different compartments of the refrigerator (i.e. not in the door or in vegetable bins).
- 9.4 Bar Refrigerator** units are **not** to be used for continuous vaccine storage (ie: eight hours or longer).
- 9.5** Refrigerators must be connected to a dedicated electrical circuit that is not used for other appliances.
- 9.6** Steps must be taken to protect the power supply (e.g. safety-lock plug, warning signs, labeling fuses and circuit breakers).
- 9.7** Refrigerators are “Vaccine Use only”. Do not store items such as food and/or beverages in vaccine refrigerators to prevent unnecessary opening of the refrigerator. For refrigerators where vaccines share space with other Cold Chain medications, consideration must be given to the frequency of access to these medications. Frequent access may compromise the temperature stability of that storage unit.
- 9.8** Refrigerators must have regular maintenance checks (cleaning coils, checking door seals). At a minimum, maintenance should be performed annually and records (i.e. a log book) should be kept. Documentation of maintenance will be critical when an equipment malfunction occurs.
- 9.9** Cold Chain must be maintained during clinics when vaccine is not stored in the refrigerator. Appropriately pack vaccine in Vaccine Bags including a temperature-monitoring device to ensure the Cold Chain is not broken.
- 9.9.1** Vaccine Bags must be replaced periodically based on usage (e.g. every 2 years), due to material break down and decreased effectiveness of maintaining temperature.
- 9.9.2** Vaccine Bags must be inspected for integrity prior to each use. If the vaccine bag is showing signs of wear due to material break down or damage, it must be replaced.
- 9.9.3** Vaccine Bags must be tested for their ability to maintain a stable temperature between +2.0°C and +8.0°C in accordance with AHS guidelines.

10. VACCINE TRANSPORT

- 10.1 The Cold Chain must be maintained during transport to another location.
- 10.2 Vaccines must be packed for transport taking into account the type of transport, the amount of vaccine to be transported, the external air temperature, and the length of time the vaccine will be in an insulated container. Packing configurations will vary on a seasonal basis. **It is most important to prevent vaccines from freezing.**
 - 10.2.1 Do not transport vaccine if outside temperatures are expected to reach -25.0°C and colder or $+25.0^{\circ}\text{C}$ and warmer unless there is an urgent need for vaccine delivery.
- 10.3 The temperature must be monitored during transport (e.g. Data Logger, Cold Chain Monitors or a Minimum and Maximum Thermometer), depending on the type of transport and the estimated time in transport.
- 10.4 Each site must have written standard operating procedures regarding receiving, storing, unpacking, packing and transporting vaccine shipments.
- 10.5 When a vaccine shipment is received, it must be examined and refrigerated immediately. Check for evidence of physical damage, freezing or excessive heat and read and/ or stop the recording of the temperature monitoring device upon receipt to determine if it has been activated or alarmed.
- 10.6 If there are any concerns about the shipment, mark each package/vial of vaccine and diluent as "DO NOT USE" and store in Cold Chain conditions, but apart from other vaccines, until the integrity of the vaccine and diluent is determined.
- 10.7 Staff responsible for packing vaccine for transport must receive appropriate training.
- 10.8 Dedicated insulated containers (coolers) able to maintain Cold Chain conditions with ice/gel packs and insulating materials must be used to transport vaccine.

11. TEMPERATURE MONITORING

- 11.1 All refrigerators where vaccine is stored must have at least a Minimum and Maximum Thermometer for temperature monitoring.
- 11.2 Thermometers must be calibrated within at least $\pm 1.0^{\circ}\text{C}$ by the manufacturer.
- 11.3 All thermometers must be checked at least annually to ensure the temperature measurement is accurate, batteries are functioning, cables or probes are not damaged and there is an adequate supply of graph paper and ink pens for Chart Recorders.

- 11.4 Fluid-filled bio-safe liquid (bottle) thermometers, bi-metal stem thermometers, and household thermometers are **not** acceptable.
- 11.5 At minimum, the temperature must be recorded at the beginning and end of each business day for each refrigerator storing vaccine even if chart recorders, Data Loggers or alarm systems are used.
- 11.6 Sites where \$5,000 or more of vaccine is stored at any time must have Continuous Temperature Recording Devices (e.g. Chart Recorders, Data Loggers) prior to one calendar year post-implementation of this policy.
- 11.7 Temperature logs and data recordings must be retained for the period of time as determined by Records Management Standards.

12. ALARMS

- 12.1 Sites where \$10,000 or more of vaccine is stored at a time must have alarms that are monitored 24 hours a day and seven days a week prior to 18 months after the approval of the AVCC Policy. An alarm temperature monitoring system can prevent substantial financial losses in the event of an equipment malfunction that occurs outside of regular working hours.
- 12.2 Alberta Health recommends alarm settings be programmed to alarm at: low 3.5°C; high 6.5°C. This ensures adequate time for action that may be required to prevent a Cold Chain Break. A stable temperature of 4.5°C to 5.0°C is the optimal environment for vaccine storage.

13. COLD CHAIN BREAKS

- 13.1 Staff who monitor and record vaccine storage temperatures must immediately report a Cold Chain Break to the designated site vaccine coordinator.
- 13.2 Affected vaccines must be isolated and marked as “DO NOT USE” as soon as a Cold Chain Break is discovered.
- 13.3 Do not assume that vaccine inappropriately exposed to light or to excessive temperature is unsalvageable. Affected vaccines must be returned to storage between +2.0°C to +8.0°C as soon as possible following a Cold Chain Break, and must remain in Cold Chain until the integrity of the vaccine is determined by Alberta Health.
- 13.4 All known exposures of vaccine to temperatures outside +2.0°C to +8.0°C or inappropriately exposed to light **must** be reported. Community Providers must provide information to the public health contact identified by AHS. AHS must

complete and send the Alberta Health Cold Chain Break Report Form (CCB Report Form) (Appendix A) to Alberta Health as soon as possible or within five business days of the occurrence. The CCB Report Form is periodically revised and AHS must ensure the current version is used when submitting a report.

- 13.5 Alberta Health will provide direction on the use of exposed vaccine.** The direction provided by Alberta Health is for the specific incident and must not be applied to other similar incidents since stability information may change. Each separate Cold Chain incident requires submission of an individual Cold Chain report.
- 13.6** When vaccines are involved in more than one Cold Chain Break, the Cold Chain Break report must include the dates and locations of the previous Cold Chain Breaks, in order for Alberta Health to accurately assess the time out of refrigeration.
- 13.7** Vaccines that have experienced a Cold Chain Break and have been determined to be usable must be clearly labeled and must be used **at the first opportunity, preferably within four weeks of the break**. They may need to be redistributed to higher use areas if it is anticipated they cannot be used within eight weeks. If the affected vaccine is not used within eight weeks of the break, Alberta Health must be consulted to reassess.
- 13.8** Following a Cold Chain Break greater than \$2,000, or repeated similar incidents (e.g. human error, refrigerator failures), AHS must provide a report separate to the cold chain break report to Alberta Health identifying the root cause of the break and corrective steps that have been taken; this report should be provided within one month of occurrence of the cold chain break.
- 13.9** All wasted vaccine must be returned to the PVD on a monthly basis, in a manner determined by AHS.

14. INFORMATION AND EDUCATION STRATEGIES

- 14.1** All staff handling vaccine must be made aware of:
- the importance of the Cold Chain and the implications of Cold Chain Break incidents;
 - recommended vaccine storage and handling practices; and
 - the immediate and appropriate action to be taken in the event of a vaccine exposure to temperatures outside the recommended storage conditions.
- 14.2** AHS must provide a comprehensive information and education strategy on vaccine Cold Chain maintenance for their staff.

- 14.3 Community Providers must ensure that all staff handling vaccines are provided with appropriate training on Cold Chain maintenance and updated on an annual basis.
- 14.4 AHS must provide educational materials to Community Providers regarding Cold Chain practices, recommended vaccine storage and handling and temperature monitoring equipment.

15. QUALITY ASSURANCE

- 15.1 AHS and Community Providers must regularly review storage conditions including vaccine refrigerator temperature logs and chart recordings.
- 15.2 AHS must investigate all reports of Cold Chain Breaks within eight hours (or next business day) of receiving a report of such an incident and determine if an on-site inspection is required.
- 15.3 Following a Cold Chain Break incident at a Community Provider's site, AHS must provide the reason for the break and the required remediation strategies. A specified time frame for correction shall be established with the Community Provider.
- 15.4 As of one calendar year post-implementation of the AVCC Policy, AHS must conduct, at minimum, annual on-site inspections of all **AHS depot sites** to assess Cold Chain.
- 15.5 AHS must provide orientation and on-site inspections of **new AHS sites** prior to distributing and storing provincially funded vaccine.
- 15.6 As of 18 months after the approval of the AVCC Policy, AHS must review Cold Chain management plans of **new Community Providers** prior to providing them with vaccine.
- 15.7 AHS may hold vaccine distribution to sites where vaccine handling equipment or practice is not in accordance with this policy, until these are corrected to the satisfaction of AHS.
- 15.8 AHS must conduct periodic Audits, which may include on-site inspections, as determined by AHS, of AHS sites to assess Cold Chain practices.
- 15.9 AHS must provide an annual report of Audits, inspections and Vaccine Suspensions to Alberta Health each year starting one calendar year post-implementation of the AVCC Policy.

16. CONTINGENCY PLANNING

- 16.1 AHS must establish standard operating procedures in the event of a vaccine refrigerator malfunction, power failure, natural disaster, or other emergency that may compromise vaccine storage conditions.
- 16.2 Sites where \$10,000 or more of vaccine is stored at any time must have backup power at the site or written agreement with an alternate storage facility with backup power that can provide storage units to maintain the recommended storage temperatures prior to 18 months after the approval of the AVCC policy.

17. VACCINE REPLACEMENT

- 17.1 Alberta Health will determine when and at what level AHS and some Community Providers will be required to replace vaccine lost in a Cold Chain Break.
- 17.2 In the interim, immediate vaccine replacement will be done by the PVD so there is no interruption in immunization services for Albertans.
- 17.3 AHS will be fiscally accountable for all vaccine discarded due to a Cold Chain Break that occurred in AHS public health. Alberta Health will assess accountability of Cold Chain Breaks at non-AHS public health sites on a case-by-case basis. Annual Cold Chain Break reporting will be completed by AHS.

18. AVCC POLICY UPDATES

The AVCC Policy is subject to change and will be reviewed annually. Questions related to the AVCC Policy may be directed to Alberta Health's Immunization Team administration: 780-427-4297.

19. EVALUATION OF THE POLICY

Community Providers may be contacted by AHS or Alberta Health for feedback on the AVCC Policy.

REFERENCES

Communicable Diseases Regulation, AR 238/1985, ss. 2 and 2.1.

Public Health Act, RSA 2000, c P-37, ss. 10 and 12.

Public Health Agency of Canada (PHAC). (2007). *Canadian Immunization Guide*. Retrieved from: www.phac-aspc.gc.ca/publicat/cig-gci/index-eng.php (PHAC 2007).

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ADDITIONAL RESOURCES / FURTHER READING

BC Centre for Disease Control. Communicable Disease Control, Immunization Manual; Section VI – Management of Biologicals. Retrieved from: www.bccdc.ca/dis-cond/comm-manual/CDManualChap2.htm

Department of Health and Ageing. Australia. *National Vaccine Storage Guidelines: Strive for Five – Second edition*. Retrieved from: www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/IMM77-cnt

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APPENDIX A

SAMPLE COLD CHAIN BREAK REPORT FORM

***Note: These forms are periodically updated.**

Superseded

SAMPLE: COLD CHAIN BREAK REPORT
Alberta Health Services Zone Vaccine Controller to fax completed form to
Alberta Health 780-422-6663
 Alberta Health Phone: 780-415-2802

Date Break Occurred: _____ Date of Report: _____	
Reporter Name: _____ Tel. _____ Fax: _____	
Location of Break (City/Town): _____ Facility Name: _____	
Facility Type: <input type="checkbox"/> Public Health <input type="checkbox"/> Physician Office <input type="checkbox"/> Acute Care <input type="checkbox"/> Pharmacy <input type="checkbox"/> LTC <input type="checkbox"/> Private Agency (e.g., VON, Shell) <input type="checkbox"/> Other _____	AHS Zone: <input type="checkbox"/> South <input type="checkbox"/> Calgary <input type="checkbox"/> Central <input type="checkbox"/> Edmonton <input type="checkbox"/> North
AHS Zone Vaccine Controller: _____ Tel. _____ Fax: _____	
Type of cold chain break: <input type="checkbox"/> Temperature excursion (less than 2.0°C and greater than 8.0°C) <input type="checkbox"/> Light Exposure	Description of Break (PLEASE PRINT) _____ _____ _____ _____
Are products now quarantined, labeled do not use, and back in cold chain <input type="checkbox"/> Yes <input type="checkbox"/> No (attach explanation)	
Last temperature recorded before the break: _____ °C at date _____ and time: _____ Temperature at time break identified _____ °C at date _____ and time: _____ Product returned to storage between 2.0°C and 8.0°C at date _____ and time: _____ Max. temp. recorded during interval: _____ °C Min. temp. recorded during interval: _____ °C Time out of cold chain (if different from above): _____ (Provide evidence in description or attachments e.g. chart tracing)	
Refrigerator Type: <input type="checkbox"/> Lab Fridge <input type="checkbox"/> Bar Fridge <input type="checkbox"/> Domestic Fridge <input type="checkbox"/> Other _____	
Thermometer/Monitor Type (NOT brand name): <input type="checkbox"/> Digital Min/Max <input type="checkbox"/> Chart Recorder <input type="checkbox"/> TT4 <input type="checkbox"/> Warm/Cold Mark <input type="checkbox"/> No monitoring <input type="checkbox"/> Other (describe) _____	Cause of Cold Chain Break: <input type="checkbox"/> Human Error <input type="checkbox"/> Thermometer Malfunction <input type="checkbox"/> Power outage <input type="checkbox"/> Refrigerator Malfunction <input type="checkbox"/> Other: _____
Products involved in previous breaks: <input type="checkbox"/> Yes <input type="checkbox"/> No If yes: Date _____ Location _____ Date _____ Location _____	If Transportation Involved: Type (e.g. car / courier) _____ Transportation between: <input type="checkbox"/> Provincial Vaccine Depot – Alberta Health <input type="checkbox"/> AHS – Public Health <input type="checkbox"/> AHS – Community Providers
Have any affected products been administered to clients? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes: clearly identify these products using a separate page if necessary.	

Date Break Occurred: _____ Location of Break: _____

This is a follow-up report Yes No If yes 1 month 2 month ___ month

PRODUCT Alberta Health funded vaccine ONLY	Count	Lot # If >2 lot numbers use separate page(s)	Count	Lot # If > 2 lot numbers use separate page(s)	Alberta Health USE ONLY	
					USE	DISCARD
Single Dose Preparations	Doses		Doses			
BOOSTRIX - dTap						
BOOSTRIX-POLIO – dTap-IPV						
INFANRIX-IPV+Hib - DTaP-IPV-Hib						
INFANRIX-IPV DTaP-IPV						
GARDASIL - HPV						
HIBERIX - HIB						
TWINRIX - Adult						
TWINRIX - Pediatric						
HAVRIX 1440 - Adult						
HAVRIX 720 - Pediatric						
RECOMBIVAX HB - Dialysis						
ENGERIX-B - Adult						
ENGERIX-B - Pediatric						
PROQUAD - MMRV						
M-M-R II – MMR						
MENJUGATE - C, Conjugate						
MENVEO A/C/Y/W-135 - Conjugate						
PNEUMOVAX 23 - Polysaccharide						
PREVNAR 13 - Conjugate						
IMOVAX Polio						
TD ADSORBED						
VARIVAX III						
GAMASTAN - (ISG)						
HYPERTET - (TIG)						
ROTARIX – Human Rotavirus						
ADACEL - dTap						
PEDIACEL - DTaP-IPV-Hib						
RECOMBIVAX HB - Pediatric						
RECOMBIVAX HB - Adult						
PRIORIX-TETRA - MMR & Varicella						
BEXSERO – Meningococcal B						
RABAVERT - Rabies						
IMOVAX Rabies						
HYPERRAB - (RIG)						
IMOGAM – (RIG)						
TYPHIM Vi - Typhoid						
QUADRACEL - DTaP-IPV						
AGRIFLU - Influenza						
FLUMIST - Influenza						
FLUAD - Influenza						
OTHER _____						
Multi-dose Preparations	Sealed Vials		Sealed Vials			
FLUVIRAL - Influenza # of open vials _____						
TUBERSOL (STU) # of open vials _____						

Please see Alberta Health Cold Chain Break Recommendation Report for complete evaluation.

APPENDIX B

SAMPLE TEMPERATURE MONITORING FORM

***Note: These forms are periodically updated.**

Superseded

SAMPLE: Temperature Log for Vaccine Storage

Location: _____

Month: _____ Day (1-15)

Record refrigerator minimum and maximum for each time frame

Day Of Month		Exact Time	Room Temperature	Refrigerator Min. Temp.	Between 2.0°C–8.0°C?		Refrigerator Max. Temp.	Between 2.0°C– 8.0°C?		Staff Initials
1	am				yes	no		yes	no	
	pm				yes	no		yes	no	
	eve				yes	no		yes	no	
2	am				yes	no		yes	no	
	pm				yes	no		yes	no	
	eve				yes	no		yes	no	
3	am				yes	no		yes	no	
	pm				yes	no		yes	no	
	eve				yes	no		yes	no	
4	am				yes	no		yes	no	
	pm				yes	no		yes	no	
	eve				yes	no		yes	no	
5	am				yes	no		yes	no	
	pm				yes	no		yes	no	
	eve				yes	no		yes	no	
6	am				yes	no		yes	no	
	pm				yes	no		yes	no	
	eve				yes	no		yes	no	
7	am				yes	no		yes	no	
	pm				yes	no		yes	no	
	eve				yes	no		yes	no	
8	am				yes	no		yes	no	
	pm				yes	no		yes	no	
	eve				yes	no		yes	no	
9	am				yes	no		yes	no	
	pm				yes	no		yes	no	
	eve				yes	no		yes	no	
10	am				yes	no		yes	no	
	pm				yes	no		yes	no	
	eve				yes	no		yes	no	
11	am				yes	no		yes	no	
	pm				yes	no		yes	no	
	eve				yes	no		yes	no	
12	am				yes	no		yes	no	
	pm				yes	no		yes	no	
	eve				yes	no		yes	no	
13	am				yes	no		yes	no	
	pm				yes	no		yes	no	
	eve				yes	no		yes	no	
14	am				yes	no		yes	no	
	pm				yes	no		yes	no	
	eve				yes	no		yes	no	
15	am				yes	no		yes	no	
	pm				yes	no		yes	no	
	eve				yes	no		yes	no	

Take immediate action if “no” is marked in shaded section. Excursions below 2.0°C and above 8.0°C must be reported to Zone Contact (who will report to Alberta Health) as per *Alberta Cold Chain Vaccine Policy* (13.4).

Completing this temperature log: Check the temperature in the refrigerator of vaccine storage units at least twice each working day. Vaccine must be stored between 2.0°C and 8.0°C. Record the minimum and the maximum temperatures for each time frame, the room temperature, the time of the temperature readings, and staff initials. At the end of each month, save and file the completed form (in Alberta, hard copy records must be kept for seven years).

If the recorded temperature is in the shaded zone: This represents an unacceptable temperature range. Follow these steps: 1) **Quarantine** the vaccine immediately. 2) **Return** the vaccine to proper cold chain as quickly as possible. 3) **Notify** your Zone Contact. 4) **Complete** cold chain report form and await Alberta Health recommendations.

SAMPLE: Temperature Log for Vaccine Storage

Location: _____

Month: _____ (Day 16-31)

Record refrigerator minimum and maximum for each time frame

Day Of Month	Exact Time	Room Temperature	Refrigerator Min. Temp.	Between 2.0°C–8.0°C?	Refrigerator Max. Temp.	Between 2.0°C– 8.0°C?	Staff Initials
16	am			yes	no	yes	no
	pm			yes	no	yes	no
	eve			yes	no	yes	no
17	am			yes	no	yes	no
	pm			yes	no	yes	no
	eve			yes	no	yes	no
18	am			yes	no	yes	no
	pm			yes	no	yes	no
	eve			yes	no	yes	no
19	am			yes	no	yes	no
	pm			yes	no	yes	no
	eve			yes	no	yes	no
20	am			yes	no	yes	no
	pm			yes	no	yes	no
	eve			yes	no	yes	no
21	am			yes	no	yes	no
	pm			yes	no	yes	no
	eve			yes	no	yes	no
22	am			yes	no	yes	no
	pm			yes	no	yes	no
	eve			yes	no	yes	no
23	am			yes	no	yes	no
	pm			yes	no	yes	no
	eve			yes	no	yes	no
24	am			yes	no	yes	no
	pm			yes	no	yes	no
	eve			yes	no	yes	no
25	am			yes	no	yes	no
	pm			yes	no	yes	no
	eve			yes	no	yes	no
26	am			yes	no	yes	no
	pm			yes	no	yes	no
	eve			yes	no	yes	no
27	am			yes	no	yes	no
	pm			yes	no	yes	no
	eve			yes	no	yes	no
28	am			yes	no	yes	no
	pm			yes	no	yes	no
	eve			yes	no	yes	no
29	am			yes	no	yes	no
	pm			yes	no	yes	no
	eve			yes	no	yes	no
30	am			yes	no	yes	no
	pm			yes	no	yes	no
	eve			yes	no	yes	no
31	am			yes	no	yes	no
	pm			yes	no	yes	no
	eve			yes	no	yes	no

Take immediate action if “no” is marked in shaded section. Excursions below 2.0°C and above 8.0°C **must** be reported to Zone Contact (who will report to Alberta Health) *Alberta Cold Chain Vaccine Policy (13.4).*

Completing this temperature log: Check the temperature in the refrigerator of vaccine storage units at least twice each working day. Vaccine must be stored **between 2.0°C and 8.0°C**. Record the minimum and the maximum temperatures for each time frame, the room temperature, the time of the temperature readings, and staff initials. At the end of each month, save and file the completed form (in Alberta, hard copy records must be kept for seven years).

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