

Alberta Health Alberta Vaccine Cold Chain Policy

www.health.alberta.ca/professionals/immunization-policy.html

Public Health and Compliance Division

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PART 1

I. Introduction

Alberta Health purchases, stores and distributes provincially funded vaccine from the Provincial Vaccine Depot (PVD) to vaccine depot sites across Alberta referred to as "Alberta Health Services (AHS) Vaccine Depots" 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 refers to the processes and procedures that maintain optimal temperature and light conditions during the transport, storage, and handling of vaccines. The temperature for vaccine storage and handling is +2.0°C to +8.0°C. 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 or 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. As it is not possible to look at a vaccine vial to determine if it has experienced temperature outside the recommended range; 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.

Sites must meet the requirements outlined in the Alberta Vaccine Cold Chain Policy prior to receiving Vaccine and prior to Immunization services being offered.

This policy is based on National Vaccine Storage and Handling Guidelines healthycanadians.gc.ca/publications/healthy-living-vie-saine/vaccine-storage-entreposage-vaccins/index-eng.php as well as vaccine manufacturer recommendations.

II. Definitions

(For the purposes of this document)

Alarmed Temperature Monitoring System	A continuously-monitored alarm system that monitors temperature in Vaccine refrigerators 24 hours a day and seven days a week.
Alberta Health Services (AHS)	The regional health authority established under the <i>Regional Health Authorities Act</i> .
Alberta Health Services Province-wide Immunization (AHS Province-wide Immunization)	Alberta Health Services Province-wide Immunization Program Standards and Quality, Population, Public and Indigenous Health Division. This division of AHS is responsible for immunization program standards and quality within AHS.
Alberta Health Services Vaccine Depots (AHS Vaccine Depots)	AHS sites where Vaccine is shipped to and from the PVD. These sites then distribute the Vaccine to all AHS sites and Community Providers.
Alberta Health Services Sites (AHS Sites)	Sites that report to and are governed by AHS. These include, but are not limited to, Public Health Centres, AHS Workplace Health and Safety, and Acute Care Pharmacy.
Audit	An independent evaluation that will include quantitative and qualitative analysis.
Bar Refrigerator	Small single-door fridge that is non-lab grade and intended for food storage.
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 temperature and light conditions during the transport, storage, and handling of vaccines. This starts at the manufacturer and ends 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	The device that monitors environmental conditions during the transport, storage, and handling of vaccines, from the point of manufacture until such time as the vaccine is administered to a client. They are single use irreversible indicators that show when a temperature excursion has occurred above or below the recommended +2.0°C to +8.0°C. e.g., WarmMark
Community Provider	Community Providers are individuals or group of individuals who receive vaccine from AHS , are authorized to provide immunizations in the community, are not employed directly by AHS, and are compliant with the applicable policies of the Alberta Immunization Policy. Community Providers could include, but are not limited to, physicians, private occupational health services, and post-secondary institutions.
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 exposure to the temperatures lasted. Multiple-use digital data loggers are accompanied by software that is installed in a computer allowing the user to set the frequency of temperature readings, download data from the device, and calculate temperature averages, minimums, maximums, and the time spent at each temperature.
Domestic Refrigerator	Combination refrigerator and freezer units. Also referred to as kitchen-style refrigerators.

Immunizer	A health professional who meets the following requirements and is eligible to administer Vaccine as part of the Alberta Immunization Program: <ul style="list-style-type: none"> • A regulated member of a health profession body under the Health Professions Act or a registered member of a designated health discipline under the Health Disciplines Act; and • Authorized under the respective statute and regulations to administer a vaccine.
Laboratory Refrigerator	Also referred to as pharmacy, purpose-built, laboratory, lab-style or industrial-quality refrigerators.
Manually Recorded	A paper-based temperature log or record keeping system completed manually.
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
Pharmacies	Pharmacies are community pharmacies who receive Vaccine from Alberta Health via wholesale distributors and are not employed by and/or under the governance of AHS. The community pharmacy has signed the Alberta Blue Cross Pharmaceutical Services Provider Agreement and is a proprietorship, partnership, corporation, business organization or other legal entity which is legally authorized by license, permit, registration or other lawful authority to provide pharmaceutical services, and is compliant with the applicable policies of the Alberta Immunization Policy.
Pharmacy Wholesale Distributors (PWD)	Refers to a pharmacy wholesale distributor who has a signed vaccine distribution contract with Alberta Health.
PVD	Provincial Vaccine Depot
Qualified Insulated Container/Package	Purpose-designated container that has been qualified by the manufacturer to transport vaccine. There should be a high degree of assurance that the container will maintain the vaccine at between +2.0°C to +8.0°C.
Staff	All personnel, including both health professional and non-health professional personnel.
Vaccine	Provincially Funded Vaccine
Vaccine Bags	Purpose-designated insulated bags used to transport vaccine.
Vaccine Controller	A staff member who is trained in Vaccine storage and handling protocols, and in procedures for managing cold chain breaks.
Vaccine Suspension	Withholding of provincially funded vaccine by AHS to Community Providers and AHS sites or withholding of provincially funded vaccine by Alberta Health to Pharmacies due to Cold Chain requirements not being met.

III. Purpose

The purpose of the Alberta Vaccine Cold Chain Policy (AVCC Policy) is to define:

- vaccine cold chain practices in Alberta; and,
- the roles and responsibilities of AHS, Community Providers, Alberta Health, and Pharmacies in implementing the AVCC Policy.

IV. Objectives

Objectives of the AVCC Policy are to:

- Protect vaccine safety and efficacy.
- Ensure 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 handlers and providers regarding Vaccine Cold Chain maintenance.

V. 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 regarding distribution and storage and handling of these agents.

VI. Policy Scope

The AVCC Policy applies to all provincially funded vaccines.

The AVCC Policy outlines the accountabilities, roles and responsibilities for immunizers of provincially funded vaccines.

The AVCC Policy sets out requirements for immunizers and distribution of provincially funded vaccine in order to maintain the safety and efficacy of the Vaccine.

PART 2

1. ROLES AND RESPONSIBILITIES

ALL PROVIDERS:

Must comply with the requirements of the AVCC Policy.

Must ensure that staff receive vaccine cold chain orientation or training session.

Must install vaccine storage equipment, temperature monitoring equipment, back-up power and alarms as per AVCC Policy.

AHS

Must designate a senior executive with accountability for the AVCC Policy application.

AHS Province-wide Immunization

Must develop, implement and monitor Vaccine Cold Chain protocols and procedures in accordance with the AVCC Policy including:

- vaccine cold chain standards and management.
- an education component.
- a quality assurance plan for vaccine Cold Chain practices.

Must monitor and report on cold chain breaks as outlined in the AVCC Policy.

May deliver Alberta's Vaccine directly or through another Community Provider in conjunction with Public Health as applicable.

May withhold distribution of Vaccine to AHS sites and Community Providers where there is inadequate vaccine storage, temperature monitoring, or unsatisfactory submission of cold chain break reports until these are corrected and in compliance with the AVCC Policy.

Must provide recommendations on the stability of any Vaccine involved in a Cold Chain Break to all AHS sites and Community Providers, within two business days of the break being reported.

AHS Sites

For specific operational standard see:

www.albertahealthservices.ca/assets/info/hp/cdc/if-hp-cdc-vac-manag-std.pdf.

Community Providers

Must 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.

Must co-operate with AHS for periodic Audits and/or on-site inspections.

New Community Providers must submit a Cold Chain management plan to AHS for review prior to receiving vaccine.

Pharmacies and Pharmacy Wholesale Distributors

Must develop, implement and monitor Vaccine Cold Chain protocols and procedures in accordance with the AVCC Policy including:

- vaccine Cold Chain standards and management.
- an education component.
- a quality assurance plan for vaccine Cold Chain practices.

Pharmacy Wholesale Distributors may deliver Alberta's Vaccine directly to Pharmacies.

Pharmacy Wholesale Distributors must co-operate with Alberta Health for periodic Audits and/or on-site inspections.

Process for Pharmacy audits is through the Alberta College of Pharmacists.

Alberta Health

May deliver Alberta's Vaccine directly to AHS Vaccine Depots and to Pharmacies through Pharmacy Wholesale Distributors.

Must provide recommendations on the stability of any Vaccine involved in a Cold Chain Break to Pharmacists and Pharmacy Wholesale Distributors, within two business days of the break being reported.

May withhold distribution of Vaccine to where there is inadequate vaccine storage, temperature monitoring, or unsatisfactory submission of cold chain break reports until these are corrected and in compliance with the AVCC Policy.

Superseded

2. VACCINE STORAGE AND HANDLING MANAGEMENT

ALL PROVIDERS:

Vaccine Cold Chain Protocols	Each site storing Vaccine must have detailed, written, and easily accessible Vaccine Cold Chain protocols and standards for: <ul style="list-style-type: none"> • Routine day to day operations. • Urgent situations including refrigerator malfunctions, power failures, natural disasters or other emergencies that might compromise Vaccine storage conditions.
Staff Education	All Staff, who handle Vaccine in any way, must be orientated in vaccine storage and handling according to AVCC policy.
Vaccine Controller	<ul style="list-style-type: none"> • Each site where Vaccine is stored must have a designated Vaccine Controller and another Staff member as a back-up. • The designated person is responsible for ensuring vaccines are handled correctly and that procedures are followed and documented.
Vaccine Supply	Sites should maintain no more than a one month supply of Vaccine at any time.
Cold Chain Break	Immediately label and return any Vaccine exposed to a Cold Chain Break to storage between +2.0°C and +8.0°C and report the incident as soon as possible and within one business day of the occurrence.

AHS Sites

Staff Education - Refer to AHS Standard www.albertahealthservices.ca/assets/info/hp/cdc/if-hp-cdc-vac-manag-std.pdf.

Report cold chain breaks to Alberta Health Services zone contact. See Cold Chain Breaks section.

Community Providers

Staff Education - Refer to AHS Standard www.albertahealthservices.ca/assets/info/hp/cdc/if-hp-cdc-vac-manag-std.pdf.

Report cold chain breaks to Alberta Health Services zone contact. See Cold Chain Breaks section.

Pharmacies and Pharmacy Wholesale Distributors

Report cold chain breaks to Alberta Health. See Cold Chain Breaks section.

3. VACCINE STORAGE REQUIREMENTS

ALL PROVIDERS:

Vaccines must remain in the refrigerator, except when being administered (see Cold Chain Maintenance and Vaccine Bags below) or transported (see Vaccine Transport section).

In the case of a power failure, refrigerator failure, or refrigerator maintenance; alternate storage that has the capacity to monitor Cold Chain is acceptable.

Laboratory Grade Refrigerators	<p>Required for Vaccine storage at sites with \$5000 or greater of Vaccine.</p> <p>Advantages:</p> <ul style="list-style-type: none"> • A digital feedback system that ensures narrow tolerances with internal temperatures. • Ongoing air circulation that ensures that the temperature distribution is even. • System for vaccine storage. • 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. • It is built to handle ambient temperature changes.
Domestic Refrigerators	<ul style="list-style-type: none"> • 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 adjustments to store Vaccine. That is, Vaccines should only be stored in certain areas of the refrigerator, depending on the temperature zone. Vaccines should be stored in the middle of the compartment away from the coils, walls, floor, and cold-air vent. Precautions should be taken as temperatures may fluctuate in different compartments of the refrigerator. Vaccines should never be stored in the vegetables bin or doors.
Bar Refrigerator units	Must NOT be used for continuous Vaccine storage (eight hours or longer).
Vaccine Use Only	<ul style="list-style-type: none"> • Refrigerators are "Vaccine Use Only". Do not store other items such as food, beverages, and/or clinical specimens 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.
Refrigerator Maintenance	<ul style="list-style-type: none"> • Refrigerators must have regular maintenance checks (e.g., cleaning coils, checking door seals). • At a minimum, maintenance should be performed annually and records (e.g., a log book) retained for the period of time as determined by records management standards. • Infection Prevention and Control measures should be in place as per current organizational requirements.
Power Supply	<ul style="list-style-type: none"> • All refrigerators must be connected to a dedicated circuit, that is, have nothing else plugged into the circuit. • Steps must be taken to protect the power supply (e.g., safety-lock plug, warning signals, warning signs, labeling fuses and circuit breakers).
Back-up Power	<ul style="list-style-type: none"> • On-site power back-up is required for sites with \$10,000 or greater of Vaccine <p>OR</p> <ul style="list-style-type: none"> • Written agreement with an alternate storage facility with back-up power that can provide storage units to maintain the recommended storage temperatures.

Cold Chain Maintenance	<ul style="list-style-type: none">• Cold Chain must be maintained during clinics when Vaccine is not stored in the refrigerator (e.g., Vaccine Bag).• Appropriately pack Vaccine in Vaccine Bags including a temperature-monitoring device to ensure the Cold Chain is not broken.
Vaccine Bags/Qualified Insulated Container	<ul style="list-style-type: none">• Must be inspected for integrity prior to each use and an appropriate temperature monitoring device must be used to transport Vaccine. If the Vaccine Bag is showing signs of wear due to material break down or damage, it must be replaced.• Must be tested for their ability to maintain a stable temperature between +2.0°C and +8.0°C.• 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.• Infection Prevention and Control measures should be in place as per current organizational requirements.

AHS Sites

For specific operational standard see:

www.albertahealthservices.ca/assets/info/hp/cdc/if-hp-cdc-vac-manag-std.pdf.

Community Providers

For specific operational standard see:

www.albertahealthservices.ca/assets/info/hp/cdc/if-hp-cdc-vac-manag-std.pdf.

4. VACCINE TRANSPORT

ALL PROVIDERS:

Cold Chain must be maintained during transport to another location.

Written protocols	Each site must have written protocols and standards in accordance with the AVCC Policy.
Packing Vaccines	<p>Vaccines must be packed for transport taking into account:</p> <ul style="list-style-type: none"> • Type of transport. • Amount of Vaccine to be transported. • External air temperature. • Length of time the Vaccine will be in a Qualified Insulated Container/Package. <p>Packing configurations will vary on a seasonal basis. It is most important to prevent Vaccines from freezing.</p> <ul style="list-style-type: none"> • If possible do not transport Vaccine if outside temperatures are expected to reach -25.0°C and colder or +25.0°C and warmer unless there is an urgent need for Vaccine delivery.
Container	A Qualified Insulated Container or Vaccine Bag must be used to transport Vaccine.
Temperature Monitoring	An appropriate temperature monitoring device must be used to transport Vaccine.
Receiving Vaccine	<ul style="list-style-type: none"> • When a Vaccine shipment is received, it must be examined and refrigerated immediately. • Check for evidence of physical damage, freezing or excessive heat. • Read and/or stop the recording of the temperature monitoring device upon receipt to determine if it has been activated or alarmed.
Cold Chain Break	In the case of a suspected cold chain failure, see Cold Chain Breaks section.
Staff training	Staff responsible for packing Vaccine for transport must receive appropriate training in accordance with the AVCC.

AHS Sites

Also refer to AHS Standard:

www.albertahealthservices.ca/assets/info/hp/cdc/if-hp-cdc-vac-manag-std.pdf.

Community Providers

Also refer to AHS Standard:

www.albertahealthservices.ca/assets/info/hp/cdc/if-hp-cdc-vac-manag-std.pdf.

5. TEMPERATURE MONITORING

ALL PROVIDERS:

The requirement for all refrigerators where vaccine is stored is monitoring and recording of the minimum, maximum, and current temperature. Then reviewed to determine if any action is needed.

The device needs to clearly show the minimum, maximum, and current temperature.

Temperature Monitoring Devices	<p>The only thermometers and temperature recording devices that are acceptable for monitoring the temperature within Vaccine storage units are:</p> <ul style="list-style-type: none"> • Minimum and Maximum Thermometer. • Data Logger - must function like a min/max device and therefore the minimum, maximum, and current temperatures need to be downloaded twice a day. • Alarmed Temperature Monitoring System - must function like a min/max device and therefore the minimum, maximum, and current temperatures need to be downloaded twice a day. • Chart Recorder in combination with a min/max thermometer Note: Chart recorders can be hard to interpret, inaccurate, and difficult to ascertain minimum and maximum temperatures. In addition, if chart recorders are on the same power supply as the fridge (and do not have back-up power) and the power goes out – there is not enough data to make a decision on vaccine viability. <p>Fluid-filled bio-safe liquid (bottle) thermometers, bi-metal stem thermometers, and household thermometers are NOT acceptable.</p>
Continuous Temperature Recording Devices	<p>Sites where \$5,000 or more of vaccine is stored at any time must have a Continuous Temperature Recording Device. These include:</p> <ul style="list-style-type: none"> • Chart Recorders (in combination with a min/max thermometer) OR • Data Loggers (downloaded twice a day) OR • Alarmed Temperature Monitoring System (downloaded twice a day)
Maintenance	<ul style="list-style-type: none"> • Thermometers should be checked annually to ensure the temperature measurement is accurate. <ul style="list-style-type: none"> ○ Temperature calibration is accurate - within at least $\pm 1.0^{\circ}\text{C}$. This can be done by having the temperature monitoring device calibrated OR The device replaced. ○ Batteries are functioning. ○ Cables or probes are not damaged. • If applicable, there is an adequate supply of graph paper and ink pens for Chart Recorders.
Temperature Recording	<p>At minimum, the temperature must be recorded and reviewed at the beginning and end of each business day for each refrigerator storing Vaccine.</p> <ul style="list-style-type: none"> • The current, minimum, and maximum temperatures need to be recorded. • Minimum/Maximum thermometers need to be reset after recording the temperature. • A stable temperature of $+4.5^{\circ}\text{C}$ to $+5.0^{\circ}\text{C}$ is the optimal temperature for Vaccine storage.
Temperature Logs	<ul style="list-style-type: none"> • All temperature logs that are Manually Recorded must be verified by trained Staff each business day to ensure appropriate vaccine storage temperature. • All Alarmed Temperature Monitoring System logs need to be verified by trained Staff each business day. • Temperature logs and Alarmed Temperature Monitoring System logs must be retained for the period of time as determined by records management standards.
<p>Redundancy is built into temperature monitoring the same way as a back-up power supply – it is there if the system fails.</p>	

6. ALARMS

ALL PROVIDERS:

Alarm Monitoring	<ul style="list-style-type: none">• Sites where \$10,000 or more of vaccine is stored at a time are required to have alarms that are monitored 24 hours a day, seven days a week and the capacity to respond quickly to the alarm.• In the event of an equipment malfunction that occurs outside of regular working hours, an alarm temperature monitoring system can prevent substantial financial losses and help maintain vaccine inventory with current vaccine supply issues.
Alarm Setting	<ul style="list-style-type: none">• Alberta Health recommends alarm settings be programmed to alarm at:<ul style="list-style-type: none">○ Low +3.5°C○ High +6.5°C.• This ensures adequate time for action that may be required to prevent a Cold Chain Break.

7. COLD CHAIN BREAKS

ALL PROVIDERS:

Cold Chain Break Reporting	All known exposures of Vaccine to temperatures outside +2.0°C to +8.0°C or inappropriately exposed to light must be reported.
Isolate Vaccine	<ul style="list-style-type: none"> Affected Vaccines must be isolated and marked as "DO NOT USE" until stability has been assessed. Affected Vaccines must be returned to storage between +2.0°C to +8.0°C as soon as possible following a Cold Chain Break. Affected vaccine must remain in Cold Chain until the stability of the Vaccine has been assessed. Do not assume that Vaccine inappropriately exposed to light or to excessive temperature is not stable.
Exposed to second cold chain break	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 to accurately assess the time out of refrigeration and/or exposure to light.
Stability recommendations	<ul style="list-style-type: none"> Stability recommendations are for a specific incident and must not be applied to other similar exposures since stability information may change. Each separate Cold Chain exposure requires the submission of an individual Cold Chain report.

AHS Province-wide Immunization

Will provide direction on the use of exposed vaccine for AHS sites and Community Providers.

Must investigate all reports of Cold Chain Breaks submitted by AHS sites and Community Providers within two business days of receiving a report and provide recommendations.

Must provide a report separate from the cold chain report to Alberta Health when AHS sites and Community Providers have repeated similar incidents (e.g. human error, refrigerator failures) upon request. The report to include: identifying the root cause of the break(s) and corrective steps that have been taken.

AHS Sites

Vaccine Cold Chain Break Reporting Form can be found on the AHS website (www.albertahealthservices.ca/info/Page10802.aspx).

Refer to AHS Standard: www.albertahealthservices.ca/assets/info/hp/cdc/if-hp-cdc-vac-manag-std.pdf.

Community Providers

Staff who monitor and record Vaccine storage temperatures must report a Cold Chain Break to the designated AHS Vaccine Controller as soon as possible and no longer than one business day after the occurrence.

Vaccine Cold Chain Break Reporting Form can be found on the AHS website (www.albertahealthservices.ca/info/Page10802.aspx).

Non-viable Vaccine must be managed in a manner as determined by AHS. (Discarded at site or returned to the PVD).

Also refer to AHS Standard www.albertahealthservices.ca/assets/info/hp/cdc/if-hp-cdc-vac-manag-std.pdf.

Pharmacies and Pharmacy Wholesale Distributors

Staff who monitor and record Vaccine storage temperatures must report a Cold Chain Break to Alberta Health as soon as possible and no longer than one business day after the occurrence.

Pharmacy Cold Chain Break Reporting Form can be found on the Alberta Health website at:
<https://cfr.forms.gov.ab.ca/form/ah10961.pdf>

Non-viable Vaccine must be discarded according to the pharmacy's standards of practice.

At Alberta Health's request, Pharmacies and Pharmacy Wholesale Distributors with repeated similar incidents (e.g. human error, refrigerator failures), must provide a report separate from the cold chain report to Alberta Health identifying the root cause of the break(s) and corrective steps that have been taken; this report will be required within one month of request from Alberta Health.

Alberta Health

Must investigate all reports of Cold Chain Breaks submitted by Pharmacies and Pharmacy Wholesale Distributors within two business days of receiving a report and provide recommendations.

Review reports requested from AHS and Pharmacy.

8. INFORMATION AND EDUCATION

ALL PROVIDERS

Staff orientation and annual review to include the following elements:

Routine Vaccine Storage and Handling	Routine Vaccine Storage and Handling for day-to-day operations. Includes the use of vaccine bags.
Urgent Vaccine Storage and Handling	Urgent Vaccine storage and handling in the event of refrigerator or freezer malfunctions, power failures, natural disasters, or other emergencies that might compromise vaccine storage conditions.
Management of Inappropriate Vaccine Storage Conditions	Immediate and appropriate action to be taken in the event of a vaccine exposure to temperatures outside the recommended storage conditions.
Routine vaccine storage and handling protocols should include	<ul style="list-style-type: none"> • Importance of cold chain and the implications of cold chain break incidents. • Recommended Vaccine storage and handling practices. • Equipment maintenance and repair procedures. • Appropriate action to be taken in the event of a vaccine exposure. • Contingency plans and ensure that they are in place in the event of premises closure during staff vacation, equipment failure and/or electrical disruptions. • Vaccine storage unit temperature monitoring. • Vaccine storage equipment maintenance. • Placement of vaccine within storage units. • Response to vaccine storage and handling problems, including off-site clinics. • Proper use and packing of vaccine bags/coolers (can be off-site or on-site). • Vaccine inventory management. • Packaging, transporting, and receiving vaccine shipments. • Disposal of vaccines and diluents as directed by jurisdictional policy or guidelines.

AHS Province-wide Immunization

Must provide comprehensive information and education on vaccine cold chain maintenance for AHS Staff.

Must make available educational materials to Community Providers regarding Cold Chain practices, recommended vaccine storage and handling and temperature monitoring equipment.

AHS Sites

Must ensure that all Staff handling vaccines are provided with appropriate training on cold chain maintenance and updated on an annual basis.

Community Providers

Must ensure that all Staff handling vaccines are provided with appropriate training on cold chain maintenance and updated on an annual basis.

Pharmacies and Pharmacy Wholesale Distributors

Must ensure that all staff handling vaccines are provided with appropriate training on cold chain maintenance and updated on an annual basis.

9. QUALITY ASSURANCE

AHS Province-wide Immunization (in conjunction with Public Health where applicable) and Alberta Health:

Vaccine suspension	May withhold distribution of Vaccine to sites where vaccine handling equipment or practice is not in accordance with this policy, until these are corrected.
Audits/Onsite inspections	Periodic Audits and/or onsite on-site inspections may be conducted to assess Cold Chain practices

AHS Province-wide Immunization

May conduct on-site inspections of Community Providers to assess Cold Chain standards.

Must conduct, at minimum, annual on-site inspections of all **AHS depot sites** to assess Cold Chain.

Must provide on-site inspections of **new AHS Public Health sites** prior to distributing and storing Vaccine.

Must review Cold Chain management plans of **new Community Providers** prior to providing them with vaccine.

May withhold distribution of Vaccine to sites where vaccine handling equipment or practice is not in accordance with this policy, until these are compliant with the AVCC Policy.

Must conduct periodic Audits, which may include on-site inspections, as determined by AHS, of AHS sites to assess Cold Chain practices.

Must provide an annual summary report of all cold chain breaks affecting Vaccine to Alberta Health. Annual report to include audits, inspections, any incidents of Vaccine suspensions, and remediation plans if applicable.

Alberta Health

May withhold distribution of Vaccine to Pharmacies and Pharmacy Wholesale Distributors where Vaccine handling equipment or practice is not in accordance with this policy, until these are compliant with the AVCC Policy.

May conduct periodic Audits, which may include on-site inspections as determined by Alberta Health, of Pharmacy Wholesale Distributors sites to assess Cold Chain practices.

Pharmacies

Process for Pharmacy audits is through the Alberta College of Pharmacists.

10. CONTINGENCY PLANNING

ALL PROVIDERS:

Must have established standard operating procedures in the event of a vaccine refrigerator malfunction, power failure, natural disaster, or other emergency that may compromise vaccine storage conditions.

11. VACCINE REPLACEMENT

Immediate Vaccine replacement will be done by the PVD as needed so there is no interruption in immunization services for Albertans.

Alberta Health will determine when and at what level AHS, Community Providers, and Pharmacies/Wholesale Distributors will be required to replace Vaccine lost in a Cold Chain Break.

Those receiving provincially-funded vaccine may be fiscally accountable for all Vaccine discarded due to a Cold Chain Break. Alberta Health will assess accountability of Cold Chain Breaks on a case-by-case basis.

12. AVCC POLICY UPDATES

The AVCC Policy is subject to change and will be reviewed at least every 3 years or as needed. The most recent version may be found at [Alberta Vaccine Cold Chain Policy](#). Questions related to the AVCC Policy may be directed to Alberta Health's Immunization Team at: health.imm@gov.ab.ca

PART 3

Cold Chain Break Reporting Forms

AHS Sites

Vaccine Cold Chain Break Reporting Form can be found on the AHS website
www.albertahealthservices.ca/frm-20322.doc.

Community Providers

Vaccine Cold Chain Break Reporting Form can be found on the AHS website
www.albertahealthservices.ca/frm-20322.doc.

Pharmacies and Pharmacy Wholesale Distributors

Vaccine Cold Chain Break Reporting Form can be found on the Alberta Health website at
cfr.forms.gov.ab.ca/form/ah10961.pdf.

References

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

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