Standard on Vaccine Storage and Handling

Section 13:	**Vaccine Storage and Handling**		**Standard #: 13.100**
Created by:	Province-wide Immunization Program, Standards and Quality		
Approved by:	Province-wide Immunization Program, Standards and Quality		
Approval Date:	June 1, 2015	**Revised:**	August 1, 2019

Preamble

Alberta Health Services (AHS) Province-wide Immunization Program Standards and Quality, Population, Public and Indigenous Health Division provides Public Health and other partners who administer provincially funded vaccines with ongoing and timely information relating to province-wide immunization program standards and quality. These standards are based on currently available evidence based information, Alberta Health policy, and provincial and national guidelines. Immunizers must be knowledgeable about the specific vaccines they administer.

Background

Immunizing agents are sensitive biological products that may become less effective or destroyed when exposed to temperatures outside the recommended range and/or inappropriate exposure to light. Loss of potency is dependent on the nature of the product, the temperature reached, and the duration of exposure. Any loss of vaccine potency is permanent and irreversible. Damage from successive exposures to adverse conditions is cumulative. 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.

The AHS Vaccine Storage and Handling Standard is provided under the authority of the *Public Health Act Immunization Regulation* Part 3 – Maintenance of Vaccine Viability which outlines the requirements for the storage, handling and transportation of vaccines.

AHS supports the recommendations outlined in the *Alberta Vaccine Storage and Handling Policy for Provincially Funded Vaccine Health Vaccine Cold Chain Policy December 17, 2018* https://open.alberta.ca/publications/alberta-vaccine-storage-and-handling-policy-for-provincially-funded-vaccine.

Protection of biological potency and stability is important because:

- Vaccine ineffectiveness or vaccine failure could result in re-emergence or reoccurrence of vaccine preventable disease,
- The public trust health professionals to ensure effective products are being administered,
- Wastage of vaccines leads to increased costs and possible vaccine shortages.

Purpose

The purpose of this standard is to outline key components necessary in development, maintenance and revision of operational guidelines that support proper storage and handling of vaccines at the recommended temperature range.

Applicability

This standard applies to:

- AHS staff who administer and/or handle provincially funded vaccine and AHS Public Health cost recovery vaccine.
- External providers to whom AHS supplies provincially funded vaccine.

AHS non Public Health staff and external providers, providing non-provincially funded vaccine should reference the Public Health Act, Immunization Regulation for further information.

Competency

All staff involved with immunization programs must have an understanding of recommended vaccine storage and handling practices. They must recognize the importance of maintaining proper cold chain, the implications of cold chain excursion and the immediate and appropriate action in the event of a cold chain excursion.

In November 2008 the Public Health Agency of Canada published the Immunization Competencies for Health Professionals with a goal of promoting safe and competent practices for immunization providers. The following competency outlined in that document is applicable to this standard:

- Storage and Handling of Immunizing Agents – Implements Canadian guidelines when storing, handling, or transporting vaccines.

Definitions:	
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 *Regional Health Authorities Act.*
Alberta Health Services Province-wide Immunization (AHS Province-wide Immunization)	AHS 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 locations that receive vaccine from the Provincial Vaccine Depot and then distributes the vaccine to 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 refrigerator that is non-lab grade and intended for food storage.

Biological and/or biological products	Refers to any immunizing agent; including vaccines immunoglobulins and antitoxins.
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 Excursion	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 +2.0ºC to +8.0ºC. (e.g., TagAlert®).
Community Provider	Community Providers are individuals or group of individuals who receive vaccine from AHS, are authorized to provide immunizations in the community and are not employed directly by AHS. Community Providers could include; physicians, private occupational health services, and post-secondary institutions.
Continuous Temperature Recording Devices	An electronic device that measures temperatures and records the results. This includes Chart Recorders and Data Loggers.
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 on 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 practitioner who meets the following requirement and is eligible to administer vaccine as part of the Alberta Immunization Program: • A regulated member of a health profession body under the *Health Professions Act* and *Government Organization Act* authorized to administer a vaccine.
Laboratory Grade 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/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.
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 +2.0ºC to +8.0ºC.
Staff	Persons who direct the storage/ or who have employment duties respecting the storage, handling and transportation of vaccine.
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, handling and transportation protocols, and in procedures for managing cold chain excursions. Each site should have an assigned backup vaccine controller.
Vaccine Suspension	Withholding of provincially funded vaccine due to cold chain requirements not being met.
Zone Contact	Resource person for the Zone regarding vaccine storage and handling and the liaison between the Zone, AHS Province-wide Immunization Program and Alberta Health.
Zone Vaccine Depot Staff	In Alberta there are several centralized AHS vaccine depot sites. Staff members in these sites are responsible for the day to day maintenance, ordering and transportation of vaccines to outlying offices within their designated areas. These staff are responsible for placing orders with the Alberta Health Provincial Vaccine Depot or vaccine manufacturers.

Section 1: Roles and Responsibilities for Vaccine Storage, Handling and Transportation

All providers must comply with the requirements of the Standard.	
Vaccine Storage and Handling Approvals	All requests received to store Provincially Funded Vaccines will be reviewed by the AHS Zone Contact and approval will be based on ability to meet Vaccine Storage and Handling requirements.
Vaccine Cold Chain Protocols	Each site storing vaccine must have detailed, written, and easily accessible vaccine cold chain standard operating procedures in accordance with the Standard including: • Routine day to day operations; • Vaccine handling during transport; • Urgent situations including refrigerator malfunctions, power

	failures, natural disasters or other emergencies that might compromise vaccine storage conditions; and • Quality assurance plan.
Staff Education See Section 2	All staff, who handle vaccine in any way, must be orientated in vaccine storage, handling, and transportation according to the Standard.
Vaccine Controller	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 and stored correctly and that procedures are followed and documented.
Vaccine Storage Requirements See Section 3	Sites must have vaccine storage equipment and back-up power, if applicable, in place as per the Standard.
Temperature Monitoring/Alarms See Section 4	Sites must have temperature monitoring equipment and alarms in place as per the Standard.
Vaccine Transportation See Section 5	Sites must have standard operating procedures for vaccine transportation as per the Policy.
Cold Chain Excursions See Section 6	Staff who handle vaccine must immediately label and return any vaccine exposed to a cold chain excursion to storage between +2.0°C and +8.0°C and report the incident.
Quality Assurance See Section 7	Sites must have a quality assurance plan for vaccine storage and handling (cold chain) practices.
Vaccine Supply	Sites should maintain no more than a one month supply of vaccine at any time.
Vaccine Distribution	• Sites that have been given the authority to further distribute vaccine within their facility/program assume accountability to ensure the sites they are distributing to are compliant with all aspects of vaccine storage, handling and transportation as per the policy. • AHS Province-wide Immunization Program may withhold distribution of vaccine to AHS sites and Community Providers where there is inadequate vaccine storage, temperature monitoring, or unsatisfactory cold chain excursion reporting until these are corrected and in compliance with the Policy.

Section 2: Information and Education

Any staff member (clinical and non-clinical) must be familiar with all aspects of routine and urgent vaccine storage and handling protocols as per AHS Standards and individual Zone Guidelines based on their roles and responsibilities to ensure cold chain is maintained at all times.

Site Duties	Key Requirements/Actions	AHS Resources
Provide Staff Orientation Upon Hire and Annual Review	• Understand cold chain and the implications of cold chain excursions. • Identify key staff members responsible for vaccine management. • Recommended vaccine storage and handling practices. • Understand importance of equipment maintenance, cleaning and repair procedures. • Understand process for urgent vaccine storage and handling in the event of power outages, office closures and severe weather conditions. • Understand how to monitor and interpret refrigerator temperatures. • Placement of vaccine within storage units. • Packaging, transporting, and receiving vaccine shipments. • Process for vaccine inventory including ordering, reconciling and receiving products. • Understand what immediate and appropriate action should be taken in the event of a cold chain excursion. • Understand proper disposal of vaccines and diluents based on recommendations from Zone Contact.	*AHS Vaccine Storage and Handling eLearning Course posted on MyLearningLink and ABSORB Learning Management System* *AHS Vaccine Storage and Handling webpage*

Section 3: Vaccine Storage Requirements

The following chart outlines the key recommendations in choosing basic vaccine storage equipment. Vaccines must remain in the refrigerator, except when being administered or transported. These recommendations are in alignment with the Alberta Vaccine Storage and Handling Policy for Provincially Funded Vaccine (December 17, 2018).

Equipment	Essential Requirements	AHS Resources

Laboratory Grade Refrigerators	• Sites where $5,000 or greater of vaccine is stored at any time are required to have a laboratory grade refrigerator.
	• Advantages of a lab grade refrigerator include:
	  ○ Ability to handle ambient temperature changes.
	  ○ Ongoing air circulation that ensures that the temperature distribution is even.
	  ○ Temperature recovery system is appropriate.
		Summary of Cold Chain Management Requirements

Domestic Refrigerators	Domestic Refrigerators may be used for storage of vaccine less than $5000.00. • Acceptable domestic combination refrigerator and freezer units **must** have separate external doors for the freezer and refrigerator.	*Summary of Cold Chain Management Requirements*

Equipment	Essential Requirements	AHS Resources
	• Manual and cyclic defrost refrigerators should not be used due to the significant temperature variations and the risk of vaccine freezing. • Some domestic frost free refrigerators can be used but may require adjustments to store vaccine. That is vaccine should only be stored in certain areas of the refrigerator, depending on the temperature zone. Vaccine 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. Vaccine should never be stored in the vegetable bins or doors.	
Bar refrigerator Units	**Bar refrigerators are not acceptable due to temperature instability and must not be used for continuous vaccine storage (eight or more hours).**	*Summary of Cold Chain Management Requirements*
General storage Requirements	Refrigerators must have the ability to maintain temperatures between +2.0°C to +8.0°C. The recommended refrigerator temperature is +4.5°C to +5.0° C. Ensure vaccines are stored in their original packaging until they are needed.	*Summary of Cold Chain Management Requirements*
	Leave at least 10cm of space (or as recommended by the manufacturer) between the back of the refrigerator and the wall. If the refrigerator has coils on the back, measure 10cm from the coils to the wall.	
	Dedicated freezer for frozen vaccines and/or frozen packs.	
Vaccine Use Only	• 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. • Vaccines should not be stored in vegetable bins or side doors of the refrigerators.	*Summary of Cold Chain Management Requirements*
Refrigerator Cleaning and Maintenance	Infection Prevention and Control Measures should be in place as per current organizational requirements.	*Routine Cleaning of Vaccine Storage Equipment **and***

Equipment	Essential Requirements	AHS Resources
	Refrigerator maintenance (cleaning coils, checking door seals) must be carried out, at minimum, annually.	*Vaccine Refrigerator Cleaning/Maintenance Log** * *Maintenance Logs must be kept for 5 years. (As per AHS Records Management Policy)*
Power Supply	Refrigerators and freezers must be connected to a dedicated electrical circuit that is not used for other appliances. Steps should be taken to protect the power supply (e.g. safety-lock plug, warning signs, labeling fuses and circuit breaker).	
Back-up Power	Uninterrupted power sources (UPS)/back-up generators should be considered for all refrigerators. • On-site power back-up is required for sites with $20,000 or greater of Vaccine OR • 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	• Cold chain must be maintained when vaccine is not stored in the refrigerator (e.g. vaccine bag usage in clinic). • Appropriately pack vaccine in vaccine bags including a temperature monitoring device.	*Vaccine Storage, Handling and Packing Checklist*
Vaccine Bags/Qualified Insulated Container	Must demonstrate the ability to maintain temperature between +2.0°C to +8.0°C for the desired length of time.	*Vaccine Storage, Handling and Packing Checklist*
	For use when vaccines are outside the refrigerator or freezer (such as transport or clinic).	
	Must be large enough to store vaccines and packing materials, internal and external surfaces must be intact, strong, durable and the lid must be tight fitting.	
	Must be inspected for integrity prior to each use. If the vaccine bag is showing signs of wear due to material breakdown or damage, it must be replaced.	
	Infection Prevention and Control measures should be in place as per current organizational requirements.	*Refer to Infection Prevention and Control standards or protocols (e.g., for AHS, AHS Infection Prevention and Control Manual)*

Equipment	Essential Requirements	AHS Resources
Packing Materials	Cold chain must be maintained when vaccine is not stored in the refrigerator (e.g., vaccine bag usage in clinic). Appropriately pack vaccine in vaccine bags including a temperature-monitoring device unless using a container with phase-changing material to ensure the cold chain is not broken.	*Vaccine Storage, Handling and Packing Checklist*
	Frozen ice/gel packs: • Must be stored in freezer a minimum of 24 hours and completely frozen prior to use. • Use of bagged or loose ice is not acceptable.	
	Refrigerated gel packs: • Must be stored between +2.0°C to +8.0°C. • Must be stored in refrigerator a minimum of 24 hours prior to use.	
	Insulating materials: • Used as a barrier to prevent direct contact between biological and frozen packs. • Also acts as a filler to prevent shifting of contents during transport.	

Section 4: Temperature Monitoring Requirements

The requirement for all refrigerators where vaccine is stored is monitoring and recording of the minimum, maximum, and current temperature. These temperatures must be routinely reviewed to determine if any action is required. Redundancy is built into temperature monitoring the same way as back-up power supply – it is there if the system fails.

Equipment	Site Requirements	AHS Resources
Temperature monitoring devices	The only thermometers and temperature recording devices that are acceptable for monitoring the temperature within vaccine storage units are: • **Minimum and Maximum Thermometer** – must be separate from the refrigerator (not built into the refrigerator). Recommendation: Minimum/Maximum thermometers that have the capacity to provide a more detailed temperature reading to the tenth degree (i.e., 2.3°C) is preferred. • **Data Logger** - must function like a minimum/maximum device and therefore the minimum, maximum, and current temperatures need to be downloaded twice a day.* • **Alarmed Temperature Monitoring System** - must function like a minimum/maximum device and therefore the minimum, maximum, and current temperatures need to be downloaded twice a day. • **Chart Recorder – must be used in combination with a minimum/maximum thermometer**	*Summary of Cold Chain Management Requirements*

	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. • Fluid-filled bio-safe liquid (bottle) thermometers, bi-metal stem thermometers, and household thermometers are **NOT** acceptable. *Sites using both a minimum/maximum thermometer and a data logger only need to record temperatures twice daily from one of the temperature monitoring devices. Documentation of temperatures must be consistently recorded from the same device. In the event of a cold chain excursion the device with continuous temperature monitoring capabilities will be referred to.	
Thermometer Placement	Ensure that the temperature probe or monitoring device is placed in the middle of the refrigerator away from coils walls, door, floor and fan. Monitor portion should be easily accessible, preferably mounted on the outside of the vaccine storage unit to minimize the number of times the door to the unit is opened. When using units with probes, the probes should be suspended in the center of the compartment or placed in a diluent or vaccine box. It is important to ensure that airflow around the sensor is not blocked.	
Continuous Temperature Recording Devices	Sites where $5,000 or more of vaccine is stored at any time must have "continuous temperature recording devices". • Data Loggers (downloaded twice a day); OR • Alarmed Temperature Monitoring System (downloaded twice a day); OR • Chart Recorders (in combination with a minimum/maximum 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.	
Cold Chain Monitors	A single use irreversible indicator that shows when a temperature excursion has occurred below +2.0°C or above +8.0°C. (e.g., TagAlert®). These devices can be used in the transport of vaccine only. They should not be utilized for temperature monitoring in refrigerators.	

Thermometer Maintenance	Thermometers and monitors should be calibrated within+/− 1.0°C annually by contacting the manufacturer or by replacing the device.	*Routine Cleaning of Vaccine Storage Equipment and Vaccine Refrigerator Cleaning/ Maintenance Log**
	All thermometers must be inspected 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.	* *Maintenance Logs must be kept for 5 years. (As per AHS Records Management Policy)*
Temperature alarms	External alarms with 24/7 monitoring must be in place for refrigerator/freezer units where vaccine with a value of $20,000 or more is being stored.	
	Alarms are to be monitored 24 hours a day, seven days a week and the capacity to respond quickly to the alarm. *An Alarm Temperature Monitoring System can prevent substantial financial losses and help maintain vaccine inventory.*	
	AH and AHS recommends alarm settings of +3.5°C and +6.5°C NOTE: Alarms should be set at a temperature range to allow adequate response time to prevent a cold chain excursion.	
Temperature Recording	At **minimum**, the temperature must be recorded and reviewed at the beginning and end of each business day (separated by at least 8 hours) for each refrigerator storing vaccine. This allows for early detection of a cold chain excursion, safeguarding vaccine supply and preventing inadvertent administration of unviable product. • The current, minimum, and maximum temperatures need to be recorded; and minimum/maximum thermometers need to be reset after recording the temperature. If not reset, future readings are meaningless as the thermometer is not giving “true” readings of what has occurred within the documented time frames. Temperature fluctuations outside the recommended range can be detected by monitoring the minimum and maximum readings. If alarms or chart recorders fail, we have no way of determining when they failed without twice a day minimum/ maximum temperature monitoring. A stable temperature of +4.5°C to +5.0°C is the optimal temperature for Vaccine Storage.	*Temperature Monitoring Log** **Temperature Monitoring Logs must be kept for 5 years. (As per AHS Records Management Policy)*
Temperature Logs	Any Staff member, who has been trained in vaccine storage and handling, is to verify the temperature monitoring logs daily to ensure proper temperature recording and to note trends in refrigerator temperatures. Retain this record for 5 years.	*Temperature Monitoring Log**

	Site Vaccine Controller to audit temperature logs weekly and take appropriate action if discrepancies noted.	**Temperature Monitoring Logs must be kept for 5 years. (As per AHS Records Management Policy)*

Section 5: Vaccine Transport

Cold chain must be maintained during transport to another location.

Site Duties	Key Requirements/Actions	AHS Resources
Written Protocols	Each site must have a written Cold Chain Management Plan in accordance with the Standard, which must include providing instructions to the person(s) who has duties in the transportation of the vaccine to ensure that the temperature conditions are maintained. These protocols should be reviewed and updated annually or sooner if necessary.	*Cold Chain Management Plan Form*
Packing Vaccines	Vaccines must be packed for transport taking into account: • Type of transport; • Amount of vaccine to be transported; • External air temperature; and • Length of time the vaccine will be in a Qualified Insulated Container/Package. There is no set method for every packing scenario. Ambient temperature, distance and time in transit or storage and the amount of vaccines packed all influence packing decisions. Vaccine package for transport must be clearly identified as containing valuable, fragile and temperature sensitive vaccines.	*Vaccine Storage, Handling and Packing Checklist*
Container	A Qualified Insulated Container or Vaccine Bag must be used to transport vaccine	*See section: Vaccine Storage Requirements*
Temperature Monitoring	An appropriate temperature monitoring device must be used to transport vaccine. Ensure that the temperature probe or monitoring device is placed beside the vaccines. See Temperature Monitoring for requirements of monitoring and recording temperatures.	*Vaccine Storage, Handling and Packing Checklist*
Vaccine Delivery/ Transport	Notification system for estimated time of arrival and mode of transport to ensure a staff member is available to receive and unpack vaccines.	*Vaccine Storage, Handling and Packing Checklist*
Receiving Vaccine	Vaccines should be examined and placed in appropriate* storage immediately upon receipt (refrigerator) to minimize transport time and risk of a cold chain excursion.	

Site Duties	Key Requirements/Actions	AHS Resources
	**Vaccine should never be transported home and stored in a personal home refrigerator.*	
	Verify cold chain conditions were maintained during shipment. 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.	
	Appropriate organization and placement of new shipments in refrigerator. Utilize oldest inventory (based on expiry date) first to minimize vaccine storage time.	
Cold Chain Excursion	In the case of a suspected cold chain excursion, *see Section 6: Cold Chain Excursion Response.*	*Cold Chain Excursion Reporting Form*
Staff Training	Staff responsible for packing vaccine for transport must receive appropriate training in accordance with the Standard.	*Vaccine Storage and Handling Modules*

Section 6: Cold Chain Excursion Response

In the event that vaccines are exposed to inappropriate temperatures outside +2.0°C to +8.0°C or have been exposed to direct sunlight and/or fluorescent lighting, a cold chain excursion is considered to have occurred and must be reported.

All sites storing publicly funded vaccine must develop protocols to identify and respond to cold chain excursions. The following table outlines key development points in site response protocols:

Site Duties	Key Requirements/Actions	AHS Resources
Quarantine Vaccine	Remove vaccines, label “DO NOT USE” and place in an appropriate refrigerator and/or protect from light as soon as possible. This reduces risk of inadvertent administration of ineffective vaccine to the public. Some vaccines may be useable depending on the severity and length of the cold chain excursion.	
Exposure to Two Or More Cold Chain Excursions	When vaccines are involved in more than one cold chain excursion, the cold chain excursion report must include the dates and locations of the previous cold chain excursions. This allows the accurate assessment of the time out of the refrigerator and/or exposure to light, which can have a cumulative effect on vaccine potency.	

Site Duties	Key Requirements/Actions	AHS Resources
Temperature Monitoring During Cold Chain Excursion	When a cold chain excursion is identified document the current, minimum and maximum temperatures. Reset the thermometer and continue with ongoing monitoring and documentation of refrigerator temperatures until the current, minimum and maximum temperatures are between +2.0°C to +8.0°C. These documented temperatures will assist the Zone Contact in determining the time vaccine was out of cold chain. Ensure the refrigerator is maintaining temperatures between +2.0°C to +8.0°C before vaccine is returned to the refrigerator.	*Temperature Monitoring Log** **temperature monitoring logs must be kept for 5 years. (As per AHS Records Management Standard)*
Reporting Cold Chain Excursions	Notify appropriate Zone Contacts immediately. Complete and submit Cold Chain Excursion Report Form as per Zone process. This record must be retained for at least seven years.	*Cold Chain Excursion Reporting Form*
Viability Assessment and Determination.	**Affected vaccine must remain in quarantine until the viability of the vaccine has been assessed by your Zone Contact.** Each cold chain excursion is assessed independently. Recommendations for one cold chain excursion should not be applied to another or subsequent cold chain excursions. The Zone Contact will provide direction of how to handle non-viable vaccine. In the event that non-viable vaccine was administered to client(s), the client(s) will be notified by a health practitioner at the site within 5 days and appropriate follow up provided as per Zone Contact recommendation. Vaccine that has been involved in a cold chain excursion and is usable should be placed at the front as well and used first.	
Follow-up of Cold Chain Excursion Recommendations by AHS	AHS Zone Contact will provide written recommendations, including a vaccine viability report to be reviewed and implemented by AHS and community providers. Providers that have repeated or larger quantity cold chain excursions will be required to submit a Root Cause Analysis to prevent future risk of vaccine loss and decreased potency.	
Contingency Planning	Each site storing vaccine must have a written Cold Chain Management Plan that must include designated individuals, equipment, information and alternate storage sites in place to help predict and/or respond to situations which may compromise vaccine storage conditions.	Cold Chain Management Plan Form

Site Duties	Key Requirements/Actions	AHS Resources
	Situations such as (but not limited to) equipment failure, power outages and / or natural disasters can occur unexpectedly. During critical response situations, written contingency plans must be in place, easily retrievable and quickly activated during emergencies to reduce confusion, speed up reaction time & reduce opportunities for cold chain excursions. Enough packing supplies should be present to move and/or store all vaccines that may be at risk. Sites where $20,000 or greater of vaccine is stored at any time without backup power must have a written agreement with another facility that has backup power and equipment to store vaccine This agreement must include: • Term of the agreement • Name of the alternate site • Physical address of alternate site • Contact person and phone number • After hours contact(s) name and phone number • A statement that the alternate site has the capacity to store the vaccines and they have appropriate temperature monitoring equipment, alarms and backup power as outlined in the Standard	

Section 7: Quality Assurance

Each zone is responsible for working with the partners they provide provincially funded vaccines to in order to ensure they are aware of the AHS Standard on Vaccine Storage and Handling and are following the practices outlined in this standard.

The Alberta Vaccine Storage and Handling Policy for Provincially Funded Vaccine requires that AHS conduct periodic audits. AHS requires all sites that store vaccine to conduct self-audits annually. AHS will conduct annual, random audits of at minimum 10% of AHS non Public Health and / or non AHS Partners providing provincially funded vaccines. This may include on-site inspection to assess cold chain practices.

AHS Province-wide and Zone Public Health:

Vaccine suspension:

- May withhold distribution of vaccine to sites where vaccine handling equipment or practices is not in accordance with the standard, until these are corrected.

Audits/Onsite inspections:

- Must conduct, at minimum, annual audits, which may include on-site inspections, of all AHS Public Health sites including Vaccine Depots to assess cold chain practices.
- AHS must provide on-site inspections of **new** AHS Public Health sites prior to distributing and storing Vaccine.
- AHS Province-wide/Public Health Zone Contact will provide a written summary and recommendations report after Audit review complete.

Cold Chain Management Plan:

- Each site that stores vaccine must have a Cold Chain Management Plan in place in the event of a cold chain excursion so all staff involved are aware of site response protocols.
- Information required to be included in a Cold Chain Management Plan can be found at: http://www.albertahealthservices.ca/frm-20595.docx
- Must review and update Cold Chain Management Plan on an annual basis.
- AHS must review cold chain management plans of new Community Providers prior to providing them with vaccine.

AHS Vaccine Depots:

Audits/Onsite inspections:

- Must conduct, at minimum, annual audits to assess cold chain practices.

Cold Chain Management Plan:

- Each site that stores vaccine must have a Cold Chain Management Plan in place in the event of a cold chain excursion so all staff involved are aware of site response protocols.
- Information required to be included in a Cold Chain Management Plan can be found at: http://www.albertahealthservices.ca/frm-20595.docx
- Must review and update Cold Chain Management Plan on an annual basis.

Other Providers:

Self-Audits/Onsite Inspections:

- All sites that store vaccine must conduct self-audits annually.
- AHS Zone Contact will conduct annual random audits of at minimum10% of AHS non Public Health and / or non AHS Partners providing provincially funded vaccines. If selected for a random audit providers will be required to provide documentation of annual self-audits.
- AHS Zone Contact may conduct onsite inspections to assess cold chain practices.

Cold Chain Management Plan:

- Each site that stores vaccine must have a Cold Chain Management Plan in place in the event of a cold chain excursion so all staff involved are aware of site response protocols.
- Information required to be included in a Cold Chain Management Plan can be found at: http://www.albertahealthservices.ca/frm-20595.docx
- Must review and update Cold Chain Management Plan on an annual basis.

Section 8: Inventory Management

Inventory management is important for vaccine quality management.

General Recommendations	Proper inventory management means knowing the following: • Quantities of vaccines and diluents that have been received, • Quantities of vaccines and diluents that have been administered, wasted or spoiled, • Vaccines and diluents, and the quantities that are currently in stock and are available for administration, • Vaccines and diluents, and the quantities that are currently in quarantine awaiting follow up directions, • Vaccines and diluents vials that should be used up first, • Vaccines and diluents vials that are expired and that must not be administered, • Vaccine and diluents that need to be ordered.
Fridge Organization	• Vaccine and diluent supplies should be organized with the earliest expiration dates placed in front of the other vials with later expiration dates on a weekly basis and each time a vaccine shipment arrives. • This practice avoids waste by ensuring that short-dated or cold chain affected vaccine and diluent are easily accessible and will be used first, thereby limiting the amount of unused vaccine that has passed its expiration date. • Contact your local Vaccine Depot for instructions on how to return expired vaccines.
Vaccine Inventory Calculations and Vaccine Ordering Process	Vaccine Depots and each sub-office should determine and subsequently review on a regular basis their vaccine supply needs considering the following: • Sites should maintain no more than one month's supply of vaccine at any time. • Current/projected cohorts (i.e. the number of births in the community or the number of students in school based program), • Scheduled clinics during the next order cycle, • Seasonal/program surges (influenza clinics, school based programs, etc.), • Near expiring vaccines, • Routine vaccine delivery schedules, • Small buffer to accommodate any unexpected increased demand, • All vaccine should be kept in its original packaging. When there is a program change, base order will need to be adjusted. Consider quantity on hand when ordering: base order minus quantity of the vaccine on hand = amount to order.

Section 9: Additional Resources

AHS additional resources:

- Summary of Cold Chain Management Requirements
- Routine Cleaning of Vaccine Storage Equipment
- Vaccine Refrigerator Cleaning/Maintenance Log
- Written Contingency Plan Vaccine Storage, Handling and Packing Checklist
- Cold Chain Excursion Report form
- Vaccine Refrigerator Temperature Record
- AHS Audit Tool
- AHS Audit Tool Process
- Alberta Vaccine Storage and Handling Policy for Provincially Funded Vaccine (December 17, 2018)
- https://open.alberta.ca/publications/alberta-vaccine-storage-and-handling-policy-for-provincially-funded-vaccine
- AHS Standard on Vaccine Storage and Handling has adopted the National Vaccine Storage and Handling Guidelines developed by the Public Health Agency of Canada. To view, see link below:

  Public Health Agency of Canada: National Vaccine Storage and Handling Guidelines for Immunization Providers (2015).

References:

1. Alberta Health. *Alberta Vaccine Storage and Handling Policy for Provincially Funded Vaccine* (2018). Retrieved from https://open.alberta.ca/publications/alberta-vaccine-storage-and-handling-policy-for-provincially-funded-vaccine
2. BC Centre for Disease Control. *Cold Chain Information*. Retrieved July 5 2016 from http://www.bccdc.ca/health-professionals/clinical-resources/immunization/vaccine-management
3. Centers for Disease Control and *Prevention. (2012, May*). *Epidemiology and Prevention of Vaccine-Preventable Diseases 12th Edition Second Printing (The Pink Book: Course Textbook). Retrieved June 25, 2014 from* http://www.cdc.gov/vaccines/pubs/pinkbook/index.html
4. Government of Saskatchewan. *Saskatchewan Immunization Manual*. Saskatchewan Ministry of Health. Retrieved June 25, 2014 from http://www.ehealthsask.ca/services/manuals/Pages/SIM.aspx
5. Manitoba Ministry of Health. *Cold Chain Resources. Manitoba* Health, Public Health, Communicable Disease Control. Retrieved June 25, 2014 from http://www.gov.mb.ca/health/publichealth/cdc/coldchain.html
6. Public Health Agency of Canada. *National Vaccine Storage and Handling Guidelines for Immunization Providers (2015)* Retrieved July 5 2016 from

   http://healthycanadians.gc.ca/publications/healthy-living-vie-saine/vaccine-storage-entreposage-vaccins/index-eng.php