Standard on Vaccine Storage and Handling

Section 13:	**Vaccine Storage and Handling**		**Standard #: 13.100**
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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.

Alberta Health Services (AHS) supports the recommendations outlined in the Alberta Health Vaccine Cold Chain Policy April 2017 https://open.alberta.ca/publications/alberta-vaccine-cold-chain-policy

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

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 breaks and the immediate and appropriate action in the event of a cold chain break.

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.

Vaccine Accountability:

- AHS may 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.
- Immediate vaccine replacement will be accommodated so there is no interruption in immunization services.
- Future requirements of provider accountability will include Alberta Health determining when and at what level AHS and community providers will be required to replace vaccine lost in a cold chain break.

An annual cold chain break report will be completed by AHS.

Definitions:

Audit: An independent evaluation that will include quantitative and qualitative analysis.

Biological and/or biological products: Refers to any immunizing agent; including vaccines immunoglobulins and antitoxins.

Cold Chain: Refers to the processes 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 vaccines to the client. The temperature for vaccine storage and handling is +2.0ºC to +8.0ºC.

Cold Chain Break: Occurs when vaccines are exposed to excess light and/or temperatures outside the recommended range.

Cold Chain Monitors: Devices that monitor environmental conditions during the transport, storage and handling of vaccines, from the point of manufacturer until such time as the vaccine is administered to 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., WarmMark

Continuous Temperature Recording Devices: Provide detailed temperature information and indicate the length of time a storage compartment has been operating outside recommended temperature ranges when a cold chain break occurs. Other temperature-monitoring devices should be used for daily temperature monitoring

- **Data Loggers:** Digital data loggers are miniature, battery-powered, stand-alone temperature monitors that record hundreds of temperature readings. These are the ideal temperature monitors because they can indicate **when an adverse temperature exposure occurred and how long the vaccines were exposed to the min/max temperatures**. Data loggers may be single use or multi use. 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.
- **Chart Recorders**: A unit attached to a lab grade refrigerator that contains graphs and pens that record temperatures on paper over time. Graph paper must be changed on a weekly or monthly basis. Recommended for monitoring temperatures of vaccine storage units if access to computer or digital units is not feasible. They are more difficult to read and interpret temperatures than data loggers.

Immunizers: A health professional who meets the following requirements 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 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

Manually Recorded: A paper-based temperature log or record keeping system completed manually

Min/Max Thermometer: Shows the current temperature and the minimum and maximum temperatures that have been reached since the last time the thermometer was reset.

Site Vaccine Coordinator: On site resource person(s) for staff regarding vaccine storage and handling and the liaison between the site, AHS Province-wide Immunization Program and Alberta Health. Each site should have an assigned backup vaccine coordinator.

Vaccine: Provincially funded vaccine.

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: 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 Health Vaccine Cold Chain Policy (April 2017)

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 fridge 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 fridge. • 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 fridges are not acceptable due to temperature instability and must not be used to store vaccines.**	
General storage Requirements	Refrigerators must have the ability to maintain temperatures between +2°C to +8°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.	
	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 for vaccine storage only. Vaccines should not be stored in vegetable bins or side doors of the fridge.	

Equipment	Essential Requirements	AHS Resources:
	Dedicated freezer for frozen vaccines and/or frozen packs.	
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*** *Vaccine Refrigerator Cleaning/Maintenance Log*
	Established maintenance schedule. Refrigerator maintenance must be carried out annually at a minimum and records retained for a period of time as determined by records management.	
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)/backup generators should be considered for all refrigerators. • On-site power back-up is required for sites with $10,000 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.	
Vaccine Bags/Qualified Insulated Container	Must demonstrate the ability to maintain temperature between +2°C to +8°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 break down 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)
Packing materials	Used within insulated containers to maintain temperatures between +2°C to +8°C.	*Vaccine Storage, Handling and Packing*

Equipment	Essential Requirements	AHS Resources:
	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.	*Checklist*
	Refrigerated gel packs: • Must be stored between +2°C to +8°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 2: 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:	*Rationale:*	*AHS Resources*
Temperature monitoring devices	Temperature monitoring devices that provide continuous recording must be used within the refrigerator or freezer storing vaccines. **Minimum/maximum thermometers are a requirement regardless of whether the refrigerator is monitored through an external alarm system, chart recorders and/or data loggers or the refrigerator has a built in minimum/maximum thermometer.**		*Summary of Cold Chain Management Requirements*
	Ensure that the temperature probe or monitoring device is placed in the middle of the fridge. 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.	*Provides a more detailed temperature and may assist in recognizing and responding to temperature changes in a more timely manner*	
Continuous Temperature Recording Devises	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).		

Cold Chain Monitors	A single use irreversible indicator that shows when a temperature excursion has occurred above 8.0°C or below 2.0°C. e.g.,Warmmark	*These devises are primarily used in the transport of vaccine to community providers.*	
Maintenance	Thermometers and monitors should be calibrated within+/− 1.0°C annually.		
	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.		
Temperature alarms	External alarms with 24/7 monitoring must be in place for refrigerator/freezer units where vaccine with a value of $10,000 or more is being stored.	*Can prevent substantial financial losses and help maintain vaccine inventory.*	
	Alarms are to be monitored 24 hours a day, seven days a week and the capacity to respond quickly to the alarm.		
	AH recommends alarm settings of +3.5°C and +6.5°C or +3°C and +7°C.	Alarms should be set at a temperature range to allow adequate response time to prevent a cold chain break.	
Temperature Recording	The current maximum and minimum temperatures from the thermometer are to be manually recorded in °C in a temperature log a minimum of twice a day during regular business hours. This is a requirement regardless of whether the refrigerator is monitored through an external alarm system, chart recorders and/or data loggers. A stable temperature of +4.5°C to +5.0°C is the optimal temperature for Vaccine Storage.	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.	*Temperature Monitoring Log** **temperature monitoring logs must be kept for 5 years. (As per AHS Records Management Standard)*

	Minimum/maximum temperature settings on thermometers must always be **reset** after reading and documentation.	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 Logs	Any Staff member, who has been trained in vaccine storage and handling, is to verify the temperature monitoring logs daily. Site Vaccine Coordinator to audit temperature logs weekly and take appropriate action if discrepancies noted.	To ensure proper temperature recording and to note trends in refrigerator and freezer temperatures	

Section 3: Vaccine Transport

Each site storing vaccine is required to develop, implement and monitor routine vaccine storage and handling protocols. The following table lists key points that are essential to incorporate into site protocols related to the routine duties of receiving, unpacking, monitoring and packing for off-site clinics and / or short transport situations. These protocols should be reviewed and updated annually or sooner if necessary.

Site Duties:	Key Requirements/Actions:	Rationale:	AHS resources
Packing Vaccines	All conditions must be considered when deciding on the amount and types of packing materials. It is most important to prevent vaccine from becoming warm or freezing. If the outside temperature is ≥ +25°C or ≤ -25°C special considerations should be taken when packing vaccines to ensure vaccine is maintained at the appropriate temperatures.	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. At these temperatures there is greater risk of a cold chain break occurring during transport	
	Sites should test and verify their method of packing for each situation (clinic, transport and off-site clinics).	Packing materials and ambient conditions may vary slightly from office to office and season to season and situation to situation.	
	Vaccine package for transport must be clearly identified as containing valuable, fragile and temperature sensitive vaccines.		
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.	Temperature should reflect condition of vaccines.	*Vaccine Storage, Handling and Packing Checklist*

Site Duties:	Key Requirements/Actions:	Rationale:	AHS resources
Vaccine delivery/ Transport	Notification system for estimated time of arrival and mode of transport.	Staff member 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). **Vaccine should never be transported home and stored in a personal home refrigerator.*	To minimize transport time and risk of cold chain break. Check for evidence of physical damage, freezing, or excessive heat.	
	Verify cold chain conditions were maintained during shipment. Read and/or stop the recording of the temperature monitoring device upon receipt to determine if it has been activated or alarmed.	To identify cold chain breaks during shipment.	
	Appropriate organization and placement of new shipments in refrigerator.	Utilize oldest inventory (based on expiry date) first to minimize vaccine storage time.	
Cold Chain Break	If temperature is outside of appropriate range, take immediate action (if indicated move vaccines to another fridge/insulated container). Complete and submit Cold Chain Break Reporting Form if temperature is noted to be outside of recommended range of +2°C to +8°C. *See Section 4: Prevention Strategies for Cold Chain Breaks.*	Vaccines may become ineffective if stored outside recommended range and must not be administered.	*Cold Chain Break Reporting form*

Section 4: Prevention Strategies for Cold Chain Breaks

Each site storing vaccine must have personnel, equipment, information and written protocols in place to predict and/or respond to situations which may compromise vaccine storage conditions. Situations such as (but not limited to) equipment failure, power outages and / or natural disasters can occur unexpectedly. The following table outlines key points in developing a local plan for protecting vaccines from a cold chain break.

Site Duties:	**Key Requirements/Actions:**	**Rationale:**	**AHS Resources**
Advance preparation/early prediction	Twice daily (at minimum) monitoring of temperatures.	Early detection of Cold Chain break safeguards vaccine supply and prevents inadvertent administration of ineffective product.	
	Anticipate potential power outages (monitor for adverse weather conditions, be aware of planned power outages).	Prevention reduces cold chain break opportunities.	
	Enact contingency plan before power outage or severe weather.	Prevention reduces cold chain break opportunities.	*Cold Chain Management Plan*
	Establish routine cleaning/ maintenance schedule.	To recognize & prevent potential equipment failure.	*Routine Cleaning of Vaccine Storage Equipment* ***and*** *Vaccine Refrigerator Cleaning/ Maintenance Log*
Designate key individuals, purchase equipment & negotiate alternate storage sites.	During critical response situations, equipment & written contingency plans must be in place, easily retrievable and quickly activated during emergencies.	Reduce confusion, speed up reaction time & reduce opportunities for cold chain break.	*Cold Chain Management Plan*
Sufficient packing supplies available	Enough packing supplies should be present to move and/or store all vaccines that may be at risk.		

Site Duties:	Key Requirements/Actions:	Rationale:	AHS Resources
Written Cold Chain Management Plan	All individuals and/or services who may respond to refrigerator alarms or power outages should have easy access to directions contained in the site cold chain management plan. Sites where $10,000 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 outline in the Standard • The process involved in transferring vaccine.	Reduce confusion and speed up reaction time.	
Test Written Cold Chain Management Plan	All responders should be familiar with roles, and equipment should be routinely tested to ensure it will function in an emergency.	Identify gaps and fix prior to emergency situation.	

Section 5: Cold Chain Break 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 break is considered to have occurred and must be reported.

Exposure to light, both UV light and fluorescent light can reduce the potency of vaccine. As with exposure to temperatures outside +2.0°C to +8.0°C, the detrimental effects of light exposure on light-sensitive vaccines are cumulative.

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

Site Duties:	**Key Requirements/Actions:**	**Rationale:**	**AHS resources:**
Recognition of cold chain break including vaccine exposed to light	When a cold chain is identified document the current, min and max temperatures. Reset the thermometer and continue with cold chain management processes. Ongoing monitoring and documentation of refrigerator temperatures is required with resetting of thermometer as necessary until the temperature reaches +2°C to +8°C.	These documented temperatures will assist the zone contact in determining the time vaccine was out of cold chain. This process ensures the refrigerator is maintaining temperatures between +2°C to +8°C before vaccine is returned.	*Temperature Monitoring Log* *Cold Chain Break Reporting Form*
Take immediate action	If the current refrigerator is malfunctioning or it has been determined vaccine has been exposed to a possible cold chain break (transportation, left outside the refrigerator etc.) remove vaccines and place in a functioning refrigerator and/or protect from light as soon as possible.	Reduce amount of time in inappropriate storage conditions. Products must remain in cold chain while waiting for recommendations for use.	*Cold Chain Management Plan*
	Quarantine vaccines in a functioning refrigerator and label “DO NOT USE”.	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 break.	
	Notify appropriate Zone contacts immediately.		

Site Duties:	Key Requirements/Actions:	Rationale:	AHS resources:
Report Cold Chain details to Alberta Health Services	Complete Cold Chain Break Report Form. Submit form as per zone process to AHS Coordinator and/or Contact who will then forward to the Centralized Immunization Team for recommendations.	Alberta Health Services, Centralized Immunization Team determines usability of provincially funded vaccines exposed to temperature/light excursions. Each cold chain break is assessed independently. Recommendations for one cold chain break should not be applied to another or subsequent cold chain break.	*Cold Chain Break Reporting Form*
Exposure to two or more cold chain breaks	Vaccine involved in more than one Cold Chain break must be recorded on the report including the dates and locations of the previous breaks.	This allows the accurate assessment of the time out of refrigerator and/or exposure to light.	
Repair cause of cold chain break	Determine source of cold chain/light excursion (e.g. replace thermometer; reset refrigerator temperature, close refrigerator door etc.).	Source of excursion could be numerous.	
Follow-up of cold chain recommendations by Alberta Health Services	Upon request, providers that have repeated cold chain breaks due to similar incidents (i.e. human error, refrigerator failures) or breaks involving large quantities of vaccine will be required to submit a Root Cause Analysis 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.	To prevent future risk of vaccine loss and decreased potency.	

Section 6: Orientation and Continuing Education

Designated Vaccine Coordinators and Zone Vaccine Contacts at sites storing provincially funded vaccine upon appointment or hire must be fully trained in routine and urgent vaccine storage and handling protocols as per AHS Standards and individual Zone Guidelines. The AHS Vaccine Storage and Handling e-Learning Course posted on MyLearningLink and ABSORB Learning Management System has been developed to assist with orientation. The e-Learning Course was designed to provide a wide range of educational material related to this topic; departments and/or programs can review and select the learning modules most appropriate for their teams in order to meet the requirements of the Alberta Vaccine Cold Chain policy.

In addition, all staff members including clinical and non-clinical (e.g., support staff, other programs within each office) staff should 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.

Orientation should be provided upon hire as outlined by each zone as well as an annual review of vaccine storage and handling. Zone orientation should be composed of at minimum the following components based on staff members roles and responsibilities:

- Understand what is cold chain and the implications of cold chain break incidents.
- Recommended vaccine storage and handling practices.
- Understand the concept of heat transfer and the relevance to vaccine storage
- Identify key staff members responsible for vaccine management
- Understand importance of vaccine monitoring and usage of appropriate equipment
- Understand importance of and process for vaccine inventory including ordering, reconciling and receiving products
- Understand the appropriate process for packing the refrigerator/freezer
- Understand how to monitor and interpret refrigerator temperatures
- Understand processes for urgent vaccine storage and handling (e.g., power outage, severe weather)
- Understand what immediate and appropriate action should be taken in the event of a cold chain break
- Understand how to pack a portable insulated container for clinic and/or transport
- Understand the importance of cleaning and maintenance of the vaccine refrigerator/freezer and monitoring equipment and processes for this
- Understand process for appropriate management of expired or cold chain affected vaccines

Section 7: Inventory Management

General Recommendations:

Inventory management is important for vaccine quality management. 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.

The Site Vaccine Coordinator should arrange the vaccine and diluent supplies according to the expiration dates on a weekly basis and each time a vaccine shipment arrives. The vials and boxes with the earliest expiration dates should be placed in front of the other vials and boxes of the same type with later expiration dates. Vaccine that has been involved in a cold chain break and is usable should be placed at the front as well and used first. 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 two to four week's supply of vaccine at any time.
- Current/projected birth 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.

Some biological products require authorized release from Alberta Health (e.g. botulism antitoxin, diphtheria antitoxin). Contact your local Vaccine Depot for details regarding these special situations.

Section 8: Quality Assurance Process for AHS and External Providers

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 Cold Chain Policy (AVCC) requires that AHS and their partners conduct annual and/or periodic audits of all providers of provincially funded vaccine. An Audit Tool has been developed by AHS and the link to this resource can be found in Section 9: Related Resources.

AHS Vaccine Depot Sites:

- AHS must conduct, at minimum, annual on-site inspections of all AHS vaccine depot sites to assess cold chain.

AHS Public Health Sites:

- AHS may withhold 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.
- AHS will conduct periodic audits, which may include on-site inspections to assess cold chain practices.
- AHS must provide on-site inspections of **new** AHS Public Health sites prior to distributing and storing Vaccine.

Other Providers Internal and External to AHS:

- AHS will review cold chain management plans of **new Community Providers** prior to providing them with vaccine.
- AHS may withhold 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.
- AHS will conduct periodic audits, which may include on-site inspections to assess cold chain practices.

AHS Province–Wide Immunization must provide an annual summary report of all cold chain breaks affecting Vaccine to Alberta Health. Annual reports to include audits, inspections, any incidents of Vaccine suspensions, and remediation plans if applicable.

External providers can access the most current AHS Standard on Vaccine Storage and Handling posted on the AHS External website. http://www.albertahealthservices.ca/10802.asp

Section 9: Related Resources

AHS related 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 Break Report form
- Temperature Monitoring Log
- AHS Audit Tool
- AHS Audit Tool Process
- Alberta Health Vaccine Cold Chain Policy (April 2017)
  http://www.health.alberta.ca/documents/AIP-Vaccine-Cold-Chain-Policy-2017.pdf
- 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).

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