Standard on Vaccine Storage and Handling

Alberta Health Services
Communicable Disease Control

Section 13	Vaccine Storage and Handling	**Standard # 13.100**	
Created and approved by	Provincial Immunization Program Standards and Quality		
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Preamble

Alberta Health Services (AHS) Provincial Immunization Program Standards and Quality, Provincial Population & Public Health Division provides Public Health and other partners who administer provincially funded vaccines with ongoing and timely information. 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* (Alberta Vaccine Storage and Handling Policy for Provincially Funded Vaccine) and the *Alberta Vaccine Storage and Handling for COVID-19 Vaccine* (Alberta Vaccine Storage and Handling for COVID-19 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 trusts 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.
- 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 understand recommended vaccine storage and handling practices. They must recognize the importance of maintaining proper cold chain, the implications of cold chain excursions and must take the immediate and appropriate action in the event of a cold chain excursion.

Definitions:

AHS Zone Contact	Contact for the zone regarding vaccine storage and handling.
AHS 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.
Alarmed Temperature Monitoring System	A continuously-monitored alarm system that monitors temperature in vaccine refrigerators and freezers 24 hours a day and seven days a week.
Alberta Health Services (AHS)	AHS is the single regional health authority established by the Government of Alberta to deliver health services to Albertans, as per the *Regional Health Authorities Act.*
Alberta Health Services (AHS) Provincial Immunization Program	AHS Provincial Immunization Program Standards and Quality, Provincial, Population and Public Health. This division of AHS is responsible for immunization program standards and quality within AHS. This program also provides follow up and recommendations on the viability of vaccine involved in cold chain excursions for AHS supplied vaccines and biologicals.
Alberta Health Services (AHS) Vaccine Depots	AHS locations that receive vaccine from the provincial vaccine depot and then distribute the vaccine to AHS sites and community providers.
Alberta Health Services (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 includes quantitative and qualitative analysis of an event or situation.
Bar Refrigerator	Small single-door refrigerator that is non-lab grade and intended for food storage only.
Biological and/or biological products	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	The process used to maintain optimal temperature and light conditions during the transport, storage, and handling of vaccines. This starts with the vaccine 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 as specified in the product monograph.
Cold Chain Monitors	The devices that monitor environmental conditions during the transport, storage, and handling of vaccines, from the point of manufacture until 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 temperatures +2°C to +8°C or as specified in the product monograph (for example, TempTale®, TagAlert®).
Community Pharmacies	Receive vaccine from Alberta Health via wholesale distributors and are not employed by and/or are not 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.
Community Provider	Individuals or groups of individuals who are authorized to provide immunizations in the community and are not employed directly by AHS. community providers could include medical clinics, private occupational health services, and post-secondary institutions. Community providers may receive vaccine from AHS or from wholesale distributors contracted by Alberta Health. Some community providers may receive provincially funded vaccine from both AHS and wholesale distributors.
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 refrigerator.
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.
Pharmacy Wholesale Distributors	A pharmacy wholesale distributor who has a signed vaccine distribution contract with Alberta Health.
Phase-Change Material	Substances that absorb and release thermal energy during the process of melting and freezing. This includes gel packs and shipping containers that maintain temperature for longer periods.
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 between +2°C to +8°C or as specified in the product monograph.
Staff	Persons who direct 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.

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 to store provincially funded vaccines will be reviewed by Public Health and approval will be based on ability of the site 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 this Standard including: • Routine day to day operations • Vaccine handling during transport • Urgent situations including refrigerator/freezer malfunctions, power failures, natural disasters or other emergencies that might compromise vaccine storage conditions • 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 this 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 this Standard.
Temperature Monitoring/Alarms See Section 4	Sites must have temperature monitoring equipment and alarms in place as per this Standard.
Vaccine Transportation See Section 5	Sites must have standard operating procedures for vaccine transportation as per this Standard.
Cold Chain Excursions See Section 6	Vaccine involved in a potential cold chain excursion must be immediately labelled “do not use” and returned to storage between +2°C and +8°C or as specified in the product monograph. The cold chain excursion must be reported as soon as possible.
Quality Assurance See Section 7	Sites must have a quality assurance plan for vaccine storage and handling 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 Alberta Vaccine Storage and Handling Policy for Provincially Funded Vaccine. • AHS Provincial 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 Alberta Vaccine Storage and Handling Policy for Provincially Funded Vaccine.

Section 2: Information and Education

Staff members (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
Provide Staff Orientation Upon Hire and Annual Review	• Identify key staff members responsible for vaccine cold chain management • Understand cold chain and the implications of cold chain excursions • Understand importance of equipment maintenance, cleaning and repair procedures • Understand how to monitor and interpret temperature recording devices • Placement of vaccine within storage units • Packing, transporting, and receiving vaccine shipments • Process for vaccine inventory including ordering, reconciling, and receiving products • Understand and undertake immediate and appropriate actions in the event of a cold chain excursion • Understand and carry out proper disposal of vaccines and diluents based on recommendations from AHS zone contact • Understand and undertake 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.

Section 3: Vaccine Storage Requirements

The following chart outlines the key recommendations in choosing basic vaccine storage equipment. Vaccines must remain in the appropriate refrigerator or freezer, except when being prepared, administered or transported.

Note: Store vaccines in their original packaging; the packaging provides protection from light and physical damage.

Equipment	Essential Requirements
Laboratory Grade Ultra Low Temperature Freezers	• Vaccine is to be stored at temperatures in the range from -90°C to -60°C • Must have an alarm setting that provides audible sound in the event that the temperature of the unit deviates beyond the alarm set points or if the door is ajar • Must have adjustable alarm set points/range • Should have adjustable temperature set points or temperature controls • Should have a digital temperature display on front that displays current temperature to 1°C resolution
Laboratory Grade Freezers	• Vaccine is to be stored at temperatures in the range from -25°C to -15°C • Must have an alarm setting that provides audible sound in the event that the temperature of the unit deviates beyond the alarm set points or if the door is ajar • Must have adjustable alarm set points/range • Should have adjustable temperature set points/temperature controls

Equipment	Essential Requirements
	• Should have a digital temperature display on front that displays current temperature to 1°C resolution.

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:
	  ○ A digital feedback system that ensures narrow tolerances with internal temperatures
	  ○ Ability to handle ambient temperature changes
	  ○ Ongoing air circulation that ensures that the temperature distribution is even
	  ○ A set-point temperature kept within the range specified in the product monograph
	  ○ An appropriate temperature recovery system.

Domestic Refrigerators	Domestic refrigerators may be used for storage of vaccine valued at less than $5,000
	• Acceptable domestic combination refrigerator and freezer units **must** have separate external doors for the freezer and refrigerator.
	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 how and where the vaccine is stored :
	  ○ 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 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 hours or longer).**
Vaccine Use Only	• Refrigerators/freezers being used for vaccine 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/ Freezer Cleaning and Maintenance	• Infection prevention and control measures should be in place as per current organizational requirements • Refrigerator/freezer maintenance must be carried out as per manufacturer instructions, at minimum, annually • Maintenance logs must be kept a minimum of 1 year as per AH policy.. or longer as per the organizational requirements.
Power Supply	• Refrigerators/freezers must be connected to a dedicated electrical circuit, that is, have nothing else plugged into the circuit.

Equipment	Essential Requirements
	• Steps should be taken to protect the power supply (for example, safety-lock plug, warning signs, labeling fuses and circuit breaker).
Back-up Power	• 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/freezer (for example, vaccine bag usage in clinic) • Appropriately pack vaccine in vaccine bags including a temperature monitoring device unless using a container with phase-changing material.
Vaccine Bags/Qualified Insulated Containers	• 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 not be used • Must be tested for their ability to maintain a stable temperature between $+2^0$C and $+8^0$C or at temperature specified in product monograph • Vaccine bags must be replaced periodically (for example, every 2 years), due to material break down and decreased effectiveness of ability to maintain temperature • Infection prevention and control measures should be in place as per current organizational requirements.

Section 4: Temperature Monitoring Requirements for Refrigerators and Freezers

The required monitoring and recording for all refrigerators or freezers where vaccine is stored includes the minimum, maximum, and current temperatures. 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
Temperature monitoring devices	The only thermometers and temperature recording devices that are acceptable for monitoring the temperature within vaccine storage units are: • **Minimum/Maximum Thermometer** – must be separate from the refrigerator/freezer (not built into the refrigerator/freezer) • **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 (for example., Sensaphone)** - 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 **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 refrigerator/freezer (and do not have back-up power) and the power goes out – there is not enough data to make a decision on vaccine viability.

Equipment	Site Requirements
	• Fluid-filled bio-safe liquid (bottle) thermometers, bi-metal stem thermometers, and household thermometers are **NOT** acceptable.
Thermometer Placement	• Place the thermometer probe(s) centrally (in the middle of the middle shelf) in the refrigerator or freezer, not at the back, front or at the door • 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.
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)
Cold Chain Monitors	• A single use indicator that shows when a temperature excursion has occurred below +2°C or above +8°C (for example, Endicate®) • These devices are only to be used when transporting vaccine.
Thermometer Maintenance	• Thermometers should be checked annually to ensure the temperature measurement is accurate as follows: o Temperature calibration is accurate - within at least ± 1ºC. This can be done by having the temperature monitoring device calibrated (contact the manufacturer for instruction) OR by replacing the device o Batteries are functioning o Cables or probes are not damaged • If applicable, there is an adequate supply of graph paper and ink pens for chart recorders.
Alarm Monitoring	• Sites where $20,000 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 vaccine and financial loss.
Alarm Setting	• Alarms for fridges and freezers should be set at a temperature range to allow adequate response time to prevent a cold chain excursion • AH and AHS recommend alarm settings of: o +3.5°C and +6.5°C for refrigerator storage between +2°C and +8°C o -15°C for lab grade freezer
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/freezer storing vaccine: • The current, minimum, and maximum temperatures must be recorded • Minimum/maximum thermometers must be reset after recording the temperature • Documentation of temperatures must be consistently recorded from the same device. *Sites using both a minimum/maximum thermometer and a data logger only need to record temperatures twice daily from one of the temperature

Equipment	Site Requirements
	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.
Temperature Logs	• 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 downloaded and verified by trained staff each business day • Temperature logs and alarmed temperature monitoring system logs must be retained for 1 year .

Section 5: Vaccine Transport

Cold chain must be maintained during transport of vaccine to another location.

Site Duties	Key Requirements/Actions
Written Cold Chain Management Plan	Each site must have a written cold chain management plan in accordance with this 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 plans should be reviewed and updated annually or sooner if necessary.
Packing Vaccines	Vaccines must be packed for transport taking into account: • 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 • Packing configurations will vary on a seasonal basis.
Container	A qualified insulated container or vaccine bag must be used to transport vaccine.

Packing Materials	Frozen ice/gel packs:
	• Must be completely frozen prior to use
	• Use of bagged or loose ice is not acceptable
	• Must be conditioned prior to use for transport and/or clinic settings
	  ○ Wait until there is a small amount of liquid water inside the ice packs
	  ○ Shake one of the ice packs every few minutes. The ice is conditioned as soon as it begins to move about slightly inside its container (approximately 15-30 minutes)
	Refrigerated gel packs:
	• Must be stored between +2°C to +8°C prior to use (approximately 24 hours)
	Insulating materials:
	• Used as a barrier to prevent direct contact between biological product and frozen packs
	• Also acts as a filler to prevent shifting of contents during transport.

Site Duties	Key Requirements/Actions
Temperature Monitoring	An appropriate temperature monitoring device must be used to transport vaccine unless using a pre-qualified container with phase-changing technology. Ensure that the temperature monitoring device is placed beside the vaccines.
Receiving Vaccine	• The vaccine shipment must be examined and stored as specified in the product monograph • 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 Excursion	In the case of a suspected cold chain excursion, see *Section 6: Cold Chain Excursion Response.*
Staff Training	Staff responsible for packing vaccine for transport must receive appropriate training in accordance with this Standard.

Section 6: Cold Chain Excursion Response

In the event that vaccines and/or diluent are exposed to inappropriate temperatures 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.

Site Duties	Key Requirements/Actions
Quarantine Vaccine	• Affected vaccines must be isolated and marked as "DO NOT USE" until viability has been assessed • Affected vaccines must be stored under the temperature conditions as specified in the product monograph as soon as possible following a cold chain excursion • Affected vaccine must remain in quarantine until the viability of the vaccine has been assessed.
Exposed to Second Cold Chain Excursion	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 excursion(s), in order to accurately assess the time out of cold chain and/or exposure to light, which can have a cumulative effect on vaccine potency.
Reporting Cold Chain Excursions	AHS Sites • AHS Provincial Immunization Program will provide direction on the reporting of cold chain excursions. • Must report cold chain excursions to AHS Provincial Immunization Program as soon as possible (Vaccine Storage and Handling Home Page). • AHS Provincial Immunization Program must contact the manufacturer of the vaccine to request a viability assessment and determination of all reports of cold chain excursions within 5 business days of receiving a report • AHS Provincial Immunization Program must provide viability determination of any vaccine to AHS sites. Community providers receiving AHS distributed vaccine • AHS Provincial Immunization Program will provide direction on the reporting of cold chain excursions

Site Duties	Key Requirements/Actions
	• Must report cold chain excursions to AHS Provincial Immunization Program as soon as possible (Vaccine Storage and Handling Home Page). • AHS Provincial Immunization Program must contact the manufacturer of the vaccine to request a viability assessment and determination of all reports of cold chain excursions within 5 business days of receiving a report • AHS Provincial Immunization Program must provide viability determination of any vaccine.

Viability Assessment and Determination	• **Affected vaccine must remain in quarantine until the viability of the vaccine has been assessed by AHS Provincial Immunization Program.**
	  ○ Each cold chain excursion is assessed independently
	  ○ Recommendations for one cold chain excursion should not be applied to another or subsequent cold chain excursions
	  ○ AHS Provincial Immunization Program will provide direction on how to handle non-viable vaccine
	  ○ Vaccine that has been involved in a cold chain excursion and is usable should be placed at the front of the refrigerator and used first.

Power Outages	In the event of a power outage, all refrigerator and freezer doors should remain closed until the issue is rectified.
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/freezer temperatures until the current, minimum and maximum temperatures are the appropriate temperature range. • These documented temperatures will assist the AHS Provincial Immunization Program in determining the time vaccine was out of cold chain • Ensure the refrigerator/freezer is maintaining appropriate temperatures before vaccine is returned to the refrigerator/freezer
Follow-up of Cold Chain Excursion Recommendations by AHS	• AHS Provincial Immunization Program 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.

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.

AHS Public Health:

- Must conduct, at minimum, annual on-site inspections of all AHS depot sites to assess cold chain practices
- 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 receiving AHS distributed vaccine prior to providing them with vaccine

- Must conduct periodic audits, which may include on-site inspections, as determined by AHS, of AHS sites to assess cold chain practices
- May conduct on-site inspections of community providers to assess cold chain practices

Vaccine suspension:

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

Section 8: Additional Resources

- Refer to the AHS Vaccine Storage and Handling Home Page for additional resources: AHS Audit Tool
- AHS Audit Tool Process
- Cold Chain Excursion Report Form
- Vaccine Packing Checklist
- Vaccine Refrigerator Maintenance and Cleaning Log
- Vaccine Storage Unit Temperature Record
- Vaccine Storage Unit with Continuous Temperature Recording Device Record

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