	Name of Activity: Vaccine Storage and Handling and Cold Chain Break Procedure for COVID-19 Vaccines (Pfizer Comirnaty® XBB.1.5, Moderna Spikevax™ XBB.1.5, and Novavax Nuvaxovid™ original vaccines)		
	Role Performing Activity: Saskatchewan Health Authority, Athabasca Health Authority, Northern Intertribal Health Authority, First Nations and Inuit Health Branch Staff Ministry of Health		
WORK STANDARD	Location: COVID-19 Immunization Manual		Department: Population Health Branch
	Document Owner: Vaccine Management Team		Region/Organization where this Work Standard originated: Ministry of Health Population Health Branch
	Date Prepared: 2020-12-10	Last Revision: 2023-10-04	Date Approved: 2020-12-10

Work Standard Summary: COVID-19 vaccines have very strict storage and handling guidelines. This work standard outlines the storage requirements, the process for identifying and reporting a cold chain break, quarantining the vaccine, and determining the viability of COVID-19 vaccines implicated in a cold chain break. Additional vaccine storage and handling information can be found in the [Saskatchewan Immunization Manual](#), Chapter 9: Management of Biological Products.

See Appendices A & B for Storage and Handling Summary Tables (found on the [COVID-19 Immunization Manual website](#)).

Essential Tasks:	
1.	<p>Arrival of Vaccine from the National Operations Centre or the Manufacturer</p> <p><u>Pfizer BioNTech Comirnaty® COVID-19</u></p> <p>Vaccines will arrive ultra-frozen in thermal containers with dry ice. Follow required Occupational Health and Safety dry ice storage and handling procedures, including proper Personal Protective Equipment (PPE) use and dry ice disposal. Pfizer has dry ice Safety Data Sheets and other dry ice safe handling resources on their website: https://www.cvdvaccine.ca/resources</p> <p>For pediatric vaccine, depending on the order quantity of product, the packaging may contain either a freezer case (white plastic box) or blue foil bag; neither the box nor the bag provide cold chain protection.</p> <p>Additional information on receiving Pfizer Comirnaty® COVID-19 vaccines can be found on their website: https://www.cvdvaccine.ca/</p> <p>Moderna Spikevax™ COVID-19 vaccines will arrive in frozen containers between -50 °C to -15 °C.</p> <p>Novavax Nuvaxovid™ COVID-19 vaccine will arrive in +2 to +8 °C shipping containers.</p> <p>Refer to the Ministry of Health's Procedure for Receiving COVID-19 Vaccines, Diluent, and Dry Ice work standard found on the COVID-19 Immunization Manual website.</p>
2.	<p>Arrival of Vaccine from the Roy Romanow Provincial Lab (RRPL)</p> <p><u>All COVID Vaccines</u></p> <p>Default vaccine transport temperatures from RRPL to vaccine holding points are outlined in the Routine and Urgent COVID-19 Vaccine Requests—via Panorama Inventory Module work standard found on the COVID-19 Immunization Manual website</p>

Essential Tasks:	
	<p><u>Pfizer BioNTech Comirnaty® COVID-19—all formulations</u></p> <p>When vaccine is transported from RRPL to the vaccine holding point in an ultralow temperature (ULT) portable freezer, staff must retrieve the vaccine from the courier truck (the driver cannot bring the freezer into the building). If maintaining cold chain is a concern, staff may consider moving the portable freezer from the courier truck into the facility themselves (use of a hand dolly needed).</p>
3.	<p>Storage of Vaccine</p> <p><u>Pfizer Comirnaty® 12+ XBB.1.5 (0.3ml [30mcg] Gray Cap/Label)) -DO NOT DILUTE</u></p> <p>AND</p> <p><u>Pediatric Pfizer Comirnaty® 5-11 years XBB.1.5 (0.3ml [10mcg] Blue Cap/Label) -DO NOT DILUTE</u></p> <p>AND</p> <p><u>Infant Pediatric Pfizer Comirnaty® 6months-4 years XBB.1.5 (0.2 ml [3 mcg] Maroon Cap/Label)- MUST DILUTE PRIOR TO USE</u></p> <p>Store in an ULT freezer between -90°C to -60°C until the expiry date.</p> <p>Do not store at -25°C to -15°C.</p> <p>If an ULT freezer is not available, the thermal container in which the Pfizer COVID-19 vaccine arrives may be used as temporary storage when consistently replenished to the top of the container with dry ice (refer to the re-icing guidelines packed in the original thermal container for instructions regarding the use of the thermal container for temporary storage).</p> <p>The dry ice must be replenished within 24 hours after delivery and then up to five additional times, five days apart for a total of 30 days.</p> <p>If a ULT freezer is not available, the vaccine can be stored in a temperature monitored refrigerator between +2°C to +8°C for up to 10 weeks prior to first puncture.</p> <p>Do not refreeze thawed vials.</p> <p>During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.</p> <p><u>Moderna Spikevax™ XBB.1.5 (0.1mg/ml Royal Blue Cap/Coral Blue Label)</u></p> <p>Store in a temperature monitored freezer between -50°C to -15°C. Do not store on dry ice.</p> <p>Store in the original carton to protect from light.</p> <p>If a temperature monitored freezer is not available the vaccine can be stored in a temperature monitored refrigerator between +2°C to +8°C for up to 30 days prior to first use.</p> <p>Do not refreeze thawed vials.</p> <p><u>Novavax Nuvaxovid™ Original COVID-19 Vaccine</u></p> <p>Unopened vials (prior to use):</p> <p>Store in a refrigerator between +2°C to +8°C until expiry date.</p> <p>Do not freeze.</p> <p>Protect from light during storage.</p>

Essential Tasks:	
	<p>Opened vials:</p> <p>After first vial puncture, use within 12 hours stored between +2°C to +25 °C.</p> <p>Time out of Refrigeration (ToR) limits for the storage of Novavax Nuvaxovid™ withdrawn into a sterile syringe supports temperature excursions for up to 12 hours at temperatures between +2°C and +25°C.</p> <p>If vaccine is not used within these time periods, it must be discarded. Any discarded vaccine is considered wastage and must be reported to the Ministry of Health using the Product Wastage Report Form</p>
4.	<p>Thawed Vials</p> <p><u>Pfizer Comirnaty® 12+ XBB.1.5 (0.3ml [30mcg] Gray Cap/Label) — DO NOT DILUTE</u></p> <p>AND</p> <p><u>Pediatric Pfizer Comirnaty® 5-11 years XBB.1.5 (0.3ml [10mcg] Blue Cap/Label) -DO NOT DILUTE</u></p> <p>AND</p> <p><u>Infant Pediatric Pfizer Comirnaty® 6 months-4 years XBB.1.5 (0.2 ml [3 mcg] Maroon Cap/Label)-MUST DILUTE PRIOR TO USE</u></p> <p>Prior to use:</p> <ul style="list-style-type: none"> Frozen vials may be thawed and stored in the refrigerator at +2°C to +8°C. <ul style="list-style-type: none"> For Pfizer 12+ and 5-11yr formulations: A carton of 10 vials may take up to 6 hours to thaw in the refrigerator. For Pfizer 6mo-4yr formulation: A carton of 10 vials may take up to 4 hours to thaw in the refrigerator. Before dilution, let each thawed vial stand at room temperature for at least 15 minutes. <p>Do not refreeze thawed vials.</p> <ul style="list-style-type: none"> Mark the date and time on the vials that they were removed from the freezer to the refrigerator. Un-punctured vials may be stored in the refrigerator between +2°C and +8°C for up to 10 weeks. Frozen vials may also be thawed at room temperature (up to +25°C). Mark the date and time on the vials that they were removed from the refrigerator to room temperature. <ul style="list-style-type: none"> Vial(s) take 30 minutes to thaw at room temperature. Un-punctured vials may be stored at room temperature for up to 12 hours prior to use. Vials thawed or held at room temperature may be returned to the refrigerator for storage if necessary, but total time at room temperature must be tracked to ensure the vial stays within the 12 hours at room temperature limit. <p>After first puncture:</p> <ul style="list-style-type: none"> Vials may be stored at +2°C to +25°C. Vials must be discarded 12 hours after first puncture. <p>Thawed vials can be handled in room light conditions.</p>

Essential Tasks:	
	<p>Moderna Spikevax™ XBB.1.5 (0.1mg/ml Royal Blue Cap/Coral Blue Label)</p> <p>Thaw each vial before use:</p> <ul style="list-style-type: none"> Thaw in refrigerated conditions between +2°C to +8°C for 2 hours. Let each vial stand at room temperature for 15 minutes before administering. Alternatively, thaw at room temperature between +15°C to +25°C for 45 minutes. <p>Once thawed, the vaccine may be stored in the refrigerator at +2°C to +8°C for up to 30 days prior to first use.</p> <p>Un-punctured vials may be stored between +8°C and +25°C for up to 24 hours.</p> <p>Track the duration of time the vaccine is stored at over +8°C so the total time does not exceed 24 hours.</p> <p>NOTE: Vaccine not used within this timeline is considered a cold chain excursion and must be reported to the Ministry of Health as outlined in #4 below.</p> <p>Punctured vials:</p> <p>Once the vial has been entered (needle-punctured) it can be stored at room temperature or refrigerated, but must be discarded after 24 hours.</p> <p>The duration of time an un-punctured vial is stored at room temperature is counted against the 24 hour stability period after puncture. After the 24 hour period, punctured vials must be discarded. Any discarded vaccine is considered wastage and must be reported to the Ministry of Health using the Product Wastage Report Form.</p> <p>Do not refreeze thawed vials.</p>
5.	<p>Process for Temperature Excursion</p> <p><u>Pfizer Comirnaty® 12+ XBB.1.5 (3ml [30 mcg] Gray Cap/Label)—DO NOT DILUTE</u></p> <p>AND</p> <p><u>Pediatric Pfizer Comirnaty® 5-11 years XBB.1.5 (0.3ml [10mcg] Blue Cap/Label) -DO NOT DILUTE</u></p> <p>AND</p> <p><u>Infant Pediatric Pfizer Comirnaty® 6months-4 years XBB.1.5 (0.2 ml [3 mcg] Maroon Cap/Label)-MUST DILUTE PRIOR TO USE</u></p> <p>For frozen vaccine:</p> <ul style="list-style-type: none"> A temperature excursion colder than -90°C or warmer than -60°C constitutes a cold chain break. Immediately quarantine the vaccine by labelling it as being involved in a cold chain break and place it away from other vaccine in the freezer. Do not assume the vaccine is to be wasted. <p>For thawed vaccine storage in the fridge:</p> <ul style="list-style-type: none"> A temperature excursion under +2°C or over +8°C constitutes a cold chain break. Immediately quarantine the vaccine in the refrigerator between +2°C and +8°C, label it as being involved in a cold chain break and place it away from other vaccine in the refrigerator. Do not assume the vaccine is to be wasted. <p>For thawed vaccine stored at room temperature:</p> <ul style="list-style-type: none"> Storage longer than 12 hours or over temperature of +25°C constitutes a cold chain break. Immediately quarantine the vaccine in the refrigerator between +2°C and +8°C, label it as being

Essential Tasks:	
	<p>involved in a cold chain break and place it away from other vaccine in the refrigerator. Do not assume the vaccine is to be wasted.</p> <p>Complete a cold chain break report form (Appendix D), print a temperature log reading from the data logger if applicable and fax both to the Ministry of Health at 306-787-3237 immediately.</p> <p>Moderna Spikevax™ XBB.1.5 (0.1mg/ml Royal Blue Cap/Coral Blue Label)</p> <p>For frozen vaccine, a temperature excursion of colder than -50°C or warmer than -15°C, immediately quarantine the vaccine by labelling it as being involved in a cold chain break and placing it away from other vaccine in the freezer. Do not assume the vaccine is to be wasted.</p> <p>For opened or unopened, thawed vaccine, a temperature excursion under +2°C for any length of time or over +8°C for more than 24 hours constitutes a cold chain break. Immediately quarantine the vaccine in the refrigerator, label it as being involved in a cold chain break and place it away from other vaccine in the refrigerator. Do not assume the vaccine is to be wasted.</p> <p>Complete a cold chain break report form (Appendix D), print the temperature log reading from the data logger if applicable and fax to the Ministry of Health at 306-787-3237 immediately.</p> <p>Novavax Nuvaxovid™ Original COVID-19 Vaccine</p> <p>For unopened vials, a temperature excursion under +2°C or over +8°C constitutes a cold chain break. Immediately quarantine the vaccine in the refrigerator, label it as being involved in a cold chain break and place it away from other vaccine in the refrigerator. Do not assume the vaccine is to be wasted.</p> <p>Complete a cold chain break report form (Appendix D), print the temperature log reading from the data logger if applicable and fax to the Ministry of Health at 306-787-3237 immediately.</p>
6.	Upon receiving notification of the cold chain break, the Ministry of Health will contact the manufacturer regarding the stability and viability of the vaccine.
7.	When recommendations are received from the manufacturer, the Ministry of Health will advise regarding viability of the vaccine.

Found on the [COVID-19 Immunization Manual website](#):

- **Appendix A:** XBB.1.5 mRNA COVID-19 Vaccines Storage and Handling Summary Table
- **Appendix B:** Non-mRNA COVID-19 Vaccines Storage and Handling Summary Table



Appendix D- Cold Chain Break Report Form

A fillable PDF is available on the COVID-19 Immunization Manual website:

<https://www.ehealthsask.ca/services/Manuals/Pages/COVID-19.aspx>



For COVID-19 vaccines: fax form to the Ministry of Health at 306-787-3237
For publicly funded vaccines: fax the form to the regional immunization supervisor.
Pharmacists: fax form to the Ministry of Health at 306-787-3237

Complete for all publicly funded products. Do not assume that vaccines must be wasted.

Ensure report is completed in full. If pertinent information is missing, report will be returned for completion.

Section 1

Date of Break: <u>(www-mm-dd)</u>	Date of Report: <u>(www-mm-dd)</u>	Reporter Name: _____
Telephone Number: _____	Fax Number: _____	Reporter Email Address: _____
Organization (SHA Network, FNIJ, AHA, Pharmacy) _____	Location (Community) _____	Facility Name _____
Facility type: <input type="checkbox"/> Public Health <input type="checkbox"/> Pharmacy <input type="checkbox"/> Physician office <input type="checkbox"/> Primary Health Care <input type="checkbox"/> Long-Term Care <input type="checkbox"/> Acute Care <input type="checkbox"/> Employee Health		
Are products Quarantined & Labeled DO NOT USE and stored on cold chain? <input type="checkbox"/> Yes <input type="checkbox"/> No (attach explanation if no)		

Check box for type of break and complete corresponding information:

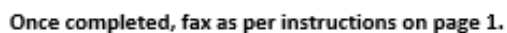
☐ Vaccine left out of fridge/freezer:
☐ in cooler with cold packs ☐ in cooler with no cold packs ☐ in package on counter ☐ out of package on counter
Vaccine returned to storage within required temperature range on: (date) _____ at (time) _____
Maximum length of time outside required temperature range: _____
Room temperature at time of break: _____ °C on (date) _____ at (time) _____

Section 2

☐ Fridge/freezer temperature excursion:
Fridge/freezer temperature when break identified _____ °C on (date) _____ at (time) _____
Max. temp recorded during break interval _____ °C Min. temp recorded during break interval _____ °C
Vaccine returned to storage within required temperature range on (date) _____ at (time) _____
Maximum length of time outside required temperature range: _____
Last fridge temperature record before the break _____ °C on (date) _____ at (time) _____
Room temperature before the break _____ °C on (date) _____ at (time) _____
Is temperature log being submitted? ☐ Yes ☐ No If No, indicate why: _____
Refrigerator/freezer type:
☐ Lab Fridge ☐ Biological Fridge ☐ Domestic Fridge ☐ Bar Fridge ☐ ULT Freezer ☒ Freezer ☐ Thermal Shipper
☐ Other _____
Date last serviced: _____
Thermometer/Monitor Type (Not Brand Name):
☐ Digital Min/Max ☐ Smart Button/Data Logger ☐ Warm/Cold Mark ☐ Chart/Wheel Recorder ☐ Not Monitored
☐ Other _____

Section 3

☐ Break during transportation
Transportation category: ☐ from RRPL to a facility ☐ from a wholesaler to a pharmacy ☐ from a facility to a facility
Vehicle type (e.g. car/courier) _____ Time delivery received: _____ Time when unpacked: _____
Was there a data logger included in the cooler/container? ☐ Yes ☐ No
If yes, is it being sent back to RRPL (or if COVID-19 vaccine, to the manufacturer)? ☐ Yes ☐ No
Was there a warm/cold marker in cooler? ☐ Yes ☐ No If yes, was it activated? ☐ Yes ☐ No Reading: _____
Description of break: _____
Cause of cold chain break:
☐ Human error ☐ Power outage ☐ Backup generator failed ☐ Thermometer malfunction ☐ Refrigerator malfunction
☐ Other: _____
Corrective action details and additional comments: _____
Were any affected products administered to clients? ☐ No ☐ Yes
If yes, indicate the date the local Medical Health Officer was notified: _____
If yes, identify these products with an asterisk* on page 2 or use a separate page if necessary.



Go to <http://www.ehealthsask.ca/services/manuals/Documents/sim-chapter9.pdf> for further instructions.

Ministry of Health reviewer: _____ Date: _____