Saskatchewan	**Name of Activity:**	Transportation of Pfizer COVID-19 Vaccine in Ultra-Frozen or Thawed State	
	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:**		**Department:** Population Health Branch
	Document Owner: Vaccine Management Team		**Region/Organization where this Work Standard originated:** Ministry of Health Population Health Branch
	Date Prepared: 2021-01-21	**Last Revision:**	**Date Approved:**

Work Standard Summary: This work standard outlines the guidelines for transportation of the Pfizer COVID-19 vaccine in an ultra-frozen or thawed state, as well as specific vaccine packing considerations.

Essential Tasks:	
1.	**Transportation Recommendations** • Pfizer's recommendation is to administer the vaccine at the initial delivery site with no further distribution due to increased risk to the vaccine. • In exceptional circumstances, Pfizer will allow the vaccine to be transported in either an ultra-frozen or thawed state, subject to additional transport precautions which will be outlined in this work standard. ➢ mRNA vaccines are subject to additional precautions when transported in a thawed state compared to usual vaccines to maintain their stability and integrity, and therefore their effectiveness. The mRNA strands in the vaccine degrade easily and are protected by small spheres of miniature lipids to ensure stability. Once thawed, these spheres can shatter if there is too much impact within the vaccine vial during transportation. • Refer to **Appendix A** for a summary of Pfizer vaccine stability. • For additional information on vaccine storage and handling, refer to: ➢ Ministry of Health's COVID-19 Vaccine Cold Chain Management work standard ➢ Saskatchewan Immunization Manual, Chapter 9: Management of Biological Products https://www.ehealthsask.ca/services/Manuals/Documents/sim-chapter9.pdf
2.	**Prior to Redistributing the Vaccine** • Confirm the number of vaccine doses that are required at the receiving site. ➢ If the receiving site will be storing vaccine in a refrigerator, only the first doses of the vaccine series must be sent. A second delivery will be required for second doses due to limited stability period in a thawed state. • Ensure the receiving site has the appropriate storage equipment, ability, and capacity to store vaccine at the necessary temperature. ➢ If transporting the vaccine in a frozen state, the site requires a temperature monitored freezer or refrigerator.

[1] Transport time is defined as the time the vaccine is physically moving in a vehicle.
[2] Initial distribution route is defined as the first time the vaccine is transported and may include vaccine drop off at multiple sites.

Essential Tasks:	
	➢ If transporting the vaccine in a thawed state, the site requires a temperature monitored refrigerator. ➢ If transporting using dry ice: o Dry ice personal protective equipment and trained staff to handle dry ice is required. o Transportation of dangerous goods certification (HAZMAT Class 9-UN1845) is required when transporting excessive dry ice by aircraft. Consultation with Transport Canada may be needed to help determine if dry ice load is considered excessive. o Transportation of dangerous goods certification is not required when transporting with dry ice by ground as long as the shipment does not include other dangerous goods • Ensure the receiving site has the appropriate Pfizer diluent quantities, ancillary supplies and staff education/information materials to support vaccine storage and administration. **NOTE:** Pfizer education materials and resources are available on their website: https://www.cvdvaccine.ca/ • Ensure each receiving site has patient vaccine handouts including vaccine fact sheets, vaccine screening questions, after care sheets, wallet cards and the I Got My COVID-19 Vaccine stickers. • When transporting in a thawed state, prior to redistribution and accounting for transport time, make sure there will be enough product stability time left for the receiving site to be able to administer the vaccine (maximum five days). See #4. **Example Scenario:** ➢ Vaccine is removed from the ultralow temperature freezer, packed and placed in fridge for 14 hours before transport. ➢ Total courier time between site A and site B is 20 hours (12 hours travel time with eight hour overnight stop) ➢ Total time remaining to administer all vaccine doses= 86 hours (approx. 3.5 days) • Communicate clearly with each receiving site on exact time of vaccine delivery to ensure their readiness.
3.	**Guidelines for Transporting Pfizer Vaccine in an Ultra Frozen State** • Only a full tray of vaccine is permitted to be transported in an ultra-frozen state (i.e. cannot repackage vaccine and transport separate vials). • Transport vaccine between -60° C to -80 ° C. • Vaccine must be shipped in a validated shipping container (i.e. intended to transport ultra-frozen vaccine or drugs). ➢ Shipping containers used may include a portable freezer capable of ultra-frozen temperature, a validated dry ice shipping container, or the Pfizer thermal shipper (Note: Pfizer does not recommend using their thermal shipper for further distribution due to risk of damage or delayed return of the shipper). o If transporting in a container with dry ice, avoid direct contact of paperboard materials with dry ice. Vials should never be in direct contact with dry ice. o Avoid liquid nitrogen as a coolant, which can damage the vials and stoppers. ➢ Condition the shipping container according to manufacturer instructions.

[1] Transport time is defined as the time the vaccine is physically moving in a vehicle.
[2] Initial distribution route is defined as the first time the vaccine is transported and may include vaccine drop off at multiple sites.

Essential Tasks:	
	➢ Maximum transport time is based on the type of shipping container. ➢ Label the shipping container with a cautionary statement pertaining to temperature control (e.g. Freeze Vaccine Immediately on Arrival) and required dry ice labelling, according to transportation of dangerous goods requirements (if applicable). ➢ A data logger is placed at the centre of the shipping container and programmed to alert cold chain excursion warmer than -60° C and warmer than -80° C. **NOTE:** data logger must be compatible for ultra-frozen temperatures and dry ice (if applicable). ➢ Additional vaccine packing information is outlined in #5. • Upon arrival at the destination, keep tray closed and immediately place in a temperature monitored ultralow temperature freezer between -60° C to -80° C or temperature monitored refrigerator between 2° C to 8° C. **NOTE:** Pfizer vaccine is stable for five days (120 hours) in the fridge between 2° C to 8° C. It is important to record the date and time the vaccine is placed in the refrigerator. • Immediately analyze the data logger for cold chain excursion outside of -60° C to -80° C. ➢ If a cold chain excursion occurred, follow the Ministry of Health's COVID-19 Vaccine Cold Chain Work Standard. • Allow vaccine to thaw prior to reconstitution. Follow the thawing instructions outlined in the product monograph.
4.	**Guidelines for Transporting Pfizer Vaccine in a Thawed State** **NOTE:** The five day (120 hour) stability timeline between 2° C to 8° C begins once Pfizer vaccine is removed from the freezer. **DO NOT REFREEZE THAWED VACCINE.** • Either a full tray or separate vials are permitted to be transported in a thawed state. • **Transport thawed vaccine at temperature between 2° C to 8° C.** ➢ Place the vaccine directly from the freezer or refrigerator into a vaccine insulated container/cooler (container/cooler bag typically used to transport vaccine at 2° C to 8° C in current practice may be used. Follow local/organizational work standard for packing vaccine bag). **Record the date and time vaccine is removed from the freezer**. o The container must be able to maintain vaccine between 2° C to 8° C for at least the duration of the intended transport. o A label saying DO NOT REFREEZE or equivalent should be on the transport container. o A label saying FRAGILE-HANDLE WITH CARE or equivalent should be on the transport container. **NOTE:** It is acceptable to transport vaccine while thawing during transport (i.e. when vaccine is placed directly from freezer into container/cooler), however ensure not to refreeze vaccine. ➢ Vials should be stored upright whenever possible. It is understood the vials may roll around the trays when being moved in and out of storage. ➢ Add a temperature monitoring device to the centre of the cooler. ➢ It is strongly recommended to use a data logger for temperature monitoring. Program the device to alert cold chain excursion under 2° C and over 8° C.

[1] Transport time is defined as the time the vaccine is physically moving in a vehicle.
[2] Initial distribution route is defined as the first time the vaccine is transported and may include vaccine drop off at multiple sites.

Essential Tasks:	
	➢ If a data logger is not available, a minimum/maximum thermometer may be used. It is important to manually reset the minimum and maximum temperatures to the current temperature immediately prior to being used for transport. ➢ Use normal practices to maintain the temperature between 2° C and 8° C with temperature monitoring. ➢ Take measures to ensure thawed vaccine does not come into contact with any frozen-packs within the container. ➢ See #5 below for additional vaccine packing information. • **Cumulative transport time[1] must be less than 12 hours**. In addition, the 12 hours is subtracted from the five day (120 hour) stability timeline between 2° C to 8° C. Track and record the total transport time. ➢ Tracking and recording the total transport time is required. Keep the records on file in the event of needing to further transport the vaccine. ○ Utilize a transport time tracking form to document total transport time[1] from the time of pickup of the vaccine until the time of delivery at point of administration site. A sample tracking form is included in **Appendix B**. ○ When additional transportation is required, only transport vaccine that has transportation time tracked and documented. Develop a site process to identify the vials that have been transported and the cumulative transport time. For example, mark the vial label with a red sticker and write the cumulative transport time on the sticker. ➢ Due to the limited stability period and transport time allowed for Pfizer vaccine in a thawed state, **it is recommended to transport Pfizer vaccine in a thawed state less than 100 km or one hour transport time.** • Special precautions must be taken during transport to **prevent excessive movement/"jostling" of the vaccine**. ➢ The vaccine should be handled with care and protected as much as possible from shocks, drops, vibration, etc. ➢ Container must be secured (strapped/braced) when being transported to prevent unnecessary movement. ➢ Travel distance should be as short as possible. ➢ Ground transport should be conducted on paved or smooth gravel/dirt roads. Forest or gravel roads are generally not suitable for transporting this vaccine. • Vials must be transported un-diluted. **Do not transport vials after dilution.** • Upon arrival to destination, immediately place the vaccine in a temperature monitored refrigerator between 2 ° C and 8° C. **DO NOT REFREEZE.** • Immediately analyze the temperature monitoring device for cold chain excursion outside of 2° C to 8°C . If a cold chain excursion occurred, follow the Ministry of Health's COVID-19 Vaccine Cold Chain Work Standard. • If vaccine is to be used immediately following 2° C to 8°C transport, allow vaccine to be at room temperature for 30 minutes prior to diluting to ensure it is fully thawed. For vaccine that was thawed prior to or after transport, refer to product monograph for reconstitution and administration instructions.

[1] Transport time is defined as the time the vaccine is physically moving in a vehicle.
[2] Initial distribution route is defined as the first time the vaccine is transported and may include vaccine drop off at multiple sites.

Essential Tasks:	

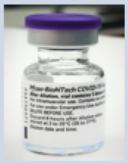
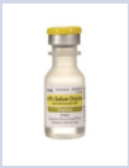
5.	**Vaccine Packing Considerations**
	• Vaccine packing should occur quickly where the vaccines are taken directly from the freezer/fridge and immediately placed into the shipping container/cooler.
	  ➢ **For transport in ultra-frozen state**-full trays that arrive in frozen condition are to be kept closed and should not be at room temperature for longer than five minutes.
	  ➢ **For transport in thawed state**- when packing vaccine at room temperature, when there is a delay and vaccine is exposed to room temperature for longer than five minutes, time should be tracked ensure to stay within the 2-hour allowance for room temperature stability while undiluted.
	• Pick vaccine with the shortest expiry date (if applicable).
	• Fill empty spaces within the shipping container with bubble wrap/paper to prevent shifting in the container/cooler.
	• **For transport in thawed state only**- If vaccine vials are separated from a full tray, refer to #6.

6.	**Packing Vaccines from Original Packaging** • It is a Health Canada requirement that a licensed healthcare professional (e.g., registered pharmacist, registered nurse) oversee the packing of vaccines into new packages (e.g., cardboard boxes, opaque or amber bags) from their original packages (written communication from Health Canada to the Ministry of Health, 2020-11-13). • Vaccine must be placed into a package that will protect the vaccine from light (e.g. opaque or amber bag). • Remove the exact or rounded up vaccines doses from their original package and place them directly into the new package under the required frozen storage conditions. • Remove as much air as possible from the amber bag before sealing it to minimize the possibility of jostling. • Securely seal the new package. • Place a label stating the vaccine name, number of vial/syringe units and corresponding doses, and a reference to the product monograph onto the new packaging. (COVID-19 vaccine specific labels are created by the Ministry of Health and will be posted on the Saskatchewan COVID-19 Immunization Planning Committee SharePoint site). • The package containing the vial(s) should be placed in insulation or bubble wrap or similar padding to protect the product. **NOTE:** Ensure dunnage material (e.g. bubble wrap) is conditioned to 2° C to 8° C prior to placing in container/cooler with vaccine. • The newly prepared package(s) are stored under the required storage conditions until they are ready to be shipped.

[1] Transport time is defined as the time the vaccine is physically moving in a vehicle.

[2] Initial distribution route is defined as the first time the vaccine is transported and may include vaccine drop off at multiple sites.

Appendix A- Stability of Pfizer Vaccine

ULT	2*C to 8*C	Room temperature
 -90*C to -60*C for 30 days (replenish dry ice q 5 days)	 120 hours (5 days)	 Up to 25*C: Must be diluted within 2 hours
 -80*C to -60*C for 6 months	 +  12 **cumulative** hours (comes out of 120 total hours. Risk assumed by redistributor)	 +  2*C to 25*C: Discard unused vaccine within 6 hours after dilution
 -80*C to -60*C: No impact on shelf life (risk assumed by redistributor)		

[1] Transport time is defined as the time the vaccine is physically moving in a vehicle.

[2] Initial distribution route is defined as the first time the vaccine is transported and may include vaccine drop off at multiple sites.

Appendix B- Sample Transport Time Tracking Form

Pfizer COVID-19 Vaccine Transport Time Tracking Form Pick-up Date: Number of Vials: Lot Number(s):		
Transport Start Time[1]	Transport Stop Time[2]	**Cumulative Transport Time**[3]

[1]Document time vehicle begins transport.

[2] Document time vehicle stops at a destination (includes stops to drop off other products, overnight stops, etc.)

[3] Document the total time from transport start time and stop time columns.

[1] Transport time is defined as the time the vaccine is physically moving in a vehicle.

[2] Initial distribution route is defined as the first time the vaccine is transported and may include vaccine drop off at multiple sites.