	<b>Name of Activity:</b> Transportation of Moderna COVID-19 Vaccine in Frozen or Thawed State	
	<b>Role Performing Activity:</b> Saskatchewan Health Authority, Athabasca Health Authority, Northern Intertribal Health Authority, First Nations and Inuit Health Branch Staff Ministry of Health	
<b>WORK STANDARD</b>	<b>Location:</b>	<b>Department:</b> Population Health Branch
	<b>Document Owner:</b> Vaccine Management Team	<b>Region/Organization where this Work Standard originated:</b> Ministry of Health Population Health Branch
	<b>Date Prepared:</b> 2021-01-21	<b>Last Revision:</b>

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

<b>Essential Tasks:</b>	
1.	<p><b>Transportation Recommendations</b></p> <ul style="list-style-type: none"> <li>• Moderna’s recommendation is to transport their COVID-19 mRNA vaccine in a frozen state.</li> <li>• In exceptional circumstances, Moderna has permitted the vaccine to be transported in a thawed state, subject to additional transportation precautions outlined in this work standard.</li> <li>• 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.</li> <li>• Refer to <b>Appendix A</b> for a summary of Moderna vaccine stability.</li> <li>• For additional information on vaccine storage and handling, refer to: <ul style="list-style-type: none"> <li>➤ The Ministry of Health’s COVID-19 Cold Chain Management work standard</li> <li>➤ The <a href="#">Saskatchewan Immunization Manual</a>, Chapter 9: Management of Biological Products</li> <li><a href="https://www.ehealthsask.ca/services/Manuals/Documents/sim-chapter9.pdf">https://www.ehealthsask.ca/services/Manuals/Documents/sim-chapter9.pdf</a></li> </ul> </li> </ul>
2.	<p><b>Prior to Redistributing the Vaccine</b></p> <ul style="list-style-type: none"> <li>• Confirm the number of vaccine doses that are required at the receiving site. <ul style="list-style-type: none"> <li>➤ For receiving sites that will store vaccine in a refrigerator - if delivery includes second doses, ensure all doses are planned to be administered within 30 days (this period begins once vaccine is removed from freezer).</li> </ul> </li> </ul>

<sup>1</sup> Transport time is defined as the time the vaccine is physically moving in a vehicle.

<sup>2</sup> Initial distribution route is defined as the first time the vaccine is transported and may include vaccine drop off at multiple sites.

<b>Essential Tasks:</b>	
	<ul style="list-style-type: none"> <li>• Ensure the receiving site has the appropriate storage equipment, ability, and capacity to store vaccine at the necessary temperature. <ul style="list-style-type: none"> <li>➤ If transporting the vaccine in a frozen state, the site requires a temperature monitored freezer or refrigerator.</li> <li>➤ If transporting the vaccine in a thawed state, the site requires a temperature monitored refrigerator.</li> </ul> </li> <li>• Ensure the receiving site has the appropriate ancillary supplies and education/information materials to support vaccine storage and administration.</li> <li>• 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.</li> <li>• Communicate clearly with each receiving site on exact time of vaccine delivery to ensure their readiness.</li> </ul>
3.	<p><b>Guidelines for Transporting Moderna in a Frozen State</b></p> <ul style="list-style-type: none"> <li>• Transport vaccine between -25°C to -15°C. DO NOT use dry ice.</li> <li>• Vaccine must be shipped in a validated shipping container (i.e. intended to transport frozen vaccine or drugs), such as a Credo-Cube. <ul style="list-style-type: none"> <li>➤ Assemble and condition the shipping container according to manufacturer instructions.</li> <li>➤ Maximum transport time is based on the model and type of shipping container.</li> <li>➤ Label the shipping container with a cautionary statement pertaining to temperature control (e.g. Freeze Vaccine Immediately on Arrival).</li> <li>➤ A data logger is placed at the centre of the shipping container and programmed to alert cold chain excursion colder than -25° C and warmer than -15° C.</li> <li>➤ Additional vaccine packing information is outlined in #6.</li> </ul> </li> <li>• Upon arrival at the destination, the frozen vaccine is immediately placed in a temperature monitored freezer between -25°C to -15°C or in a temperature monitored refrigerator between 2°C to 8°C. <p><b>NOTE:</b> Moderna vaccine is stable for 30 days in the refrigerator between 2°C to 8°C. It is important to record the date and time the vaccine is placed in the refrigerator.</p> </li> <li>• Immediately analyze the data logger for cold chain excursion outside of -25°C to -15°C. <ul style="list-style-type: none"> <li>➤ If a cold chain excursion occurred, follow the Ministry of Health’s COVID-19 Vaccine Cold Chain Work Standard.</li> </ul> </li> <li>• Allow vaccine to thaw prior to administration. Follow the thawing and administration instructions outlined in the <a href="#">product monograph</a>.</li> </ul> <p>Also refer to the following Saskatchewan Health Authority Work Standards:</p> <ul style="list-style-type: none"> <li>• Credo Cube Data Logger- Multiple Shipping Points</li> <li>• Credo Cube Data Logger- Single Ship to Location</li> </ul>
4.	<p><b>Guidelines for Transporting Moderna in a Thawed State</b></p> <p><b>NOTE:</b> The 30-day stability timeline in a thawed state begins once Moderna vaccine is removed from the freezer. <b>DO NOT REFREEZE THAWED VACCINE.</b></p>

<sup>1</sup> Transport time is defined as the time the vaccine is physically moving in a vehicle.

<sup>2</sup> Initial distribution route is defined as the first time the vaccine is transported and may include vaccine drop off at multiple sites.

## Essential Tasks:

- **Transport thawed vaccine at 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.**
    - The container must be able to maintain vaccine between 2° C to 8° C for at least the duration of the intended transport.
    - A label saying DO NOT REFREEZE or equivalent should be on the transport container.
    - 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.
  - Place vials in an upright position.
  - Transport vaccine in the carton/box whenever possible. The carton should be surrounded by dunnage (padding material) inside the container to minimize product/carton movement during transport.
    - If transportation of single or multiple vials (out of the carton/box) must be conducted, refer to #6.
  - 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.
    - 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.
  - DO NOT use DRY ICE (Moderna vaccine should not get colder than -40° C).
  - 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<sup>1</sup> must be less than 12 hours.** In addition, the 12 hours is subtracted from the 30 day stability timeline between 2° C to 8° C.
  - 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<sup>1</sup> from the time of pick-up 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 total transport time on the sticker.

<sup>1</sup> Transport time is defined as the time the vaccine is physically moving in a vehicle.

<sup>2</sup> Initial distribution route is defined as the first time the vaccine is transported and may include vaccine drop off at multiple sites.

<b>Essential Tasks:</b>	
	<ul style="list-style-type: none"> <li>➤ <b>Maximum transport time via aircraft is up to three hours</b> (included within 12-hour cumulative transport time). For example, air transport for three hours allows only nine additional transport hours by ground.</li> <li>• Special precautions must be taken during transport to <b>prevent excessive movement/“jostling” of the vaccine.</b> <ul style="list-style-type: none"> <li>➤ The vaccine should be handled with care and protected as much as possible from shocks, drops, vibration, etc.</li> <li>➤ Container must be secured (strapped/braced) when being transported to prevent unnecessary movement.</li> <li>➤ Travel distance should be as short as possible.</li> <li>➤ Ground transport should be conducted on paved or smooth gravel/dirt roads. Forest or gravel roads are generally not suitable for transporting this vaccine.</li> </ul> </li> <li>• <b>Never transport open (punctured) vials or pre-filled syringes.</b></li> <li>• Upon arrival to destination, immediately place the vaccine in a temperature monitored refrigerator between 2° C and 8° C. <b>DO NOT REFREEZE.</b></li> <li>• Immediately analyze the temperature monitoring device for a cold chain excursion outside of 2° C to 8° C. <ul style="list-style-type: none"> <li>➤ If a cold chain excursion occurred, follow the Ministry of Health’s COVID-19 Vaccine Cold Chain Work Standard.</li> </ul> </li> <li>• Prior to administering, ensure vaccine is fully thawed if vaccine was frozen at the beginning of transport. Follow the thawing and administration instructions outlined in the <a href="#">product monograph</a>.</li> </ul> <p>Refer to <b>Appendix C</b> for specific transportation scenarios provided by Moderna.</p>
5.	<p><b>Vaccine Packing Considerations</b></p> <ul style="list-style-type: none"> <li>• Vaccine packing should occur quickly where the vaccines are taken directly from the freezer/fridge and immediately placed into the shipping container/cooler.</li> <li>• Pick vaccine with the shortest expiry date (if applicable).</li> <li>• If vaccine vials are separated from a full box (10 vials), refer to #6.</li> </ul>
6.	<p><b>Packing Vaccines from Original Packaging</b></p> <ul style="list-style-type: none"> <li>• 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).</li> <li>• Vaccine must be placed into a package that will protect the vaccine from light (e.g. opaque or amber bag).</li> <li>• Remove the exact or rounded up vaccine doses from their original package and place them directly into the new package under the required frozen storage conditions.</li> <li>• Securely seal the new package.</li> <li>• 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</li> </ul>

<sup>1</sup> Transport time is defined as the time the vaccine is physically moving in a vehicle.

<sup>2</sup> Initial distribution route is defined as the first time the vaccine is transported and may include vaccine drop off at multiple sites.

**Essential Tasks:**








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.

**Appendix A - Stability of Moderna Vaccine**

Frozen (-25°C to -15°C)	2°C to 8°C	Room temperature (8°C to 25°C)
 <p>Seven months (or six months frozen + 30 days refrigerated)</p>	 <p>Up to 30 days if intact (not needle punctured)</p>	 <p>Unpunctured, should not exceed 12 hours</p>
 <p>Seven months (or six months frozen + 30 days refrigerated)</p>	 <p>2-8°C</p> <p>+</p>  <p>12 <b>cumulative</b> hours of transport</p>	 <p>Once punctured, vials should be discarded after 6 hours</p>

<sup>1</sup> Transport time is defined as the time the vaccine is physically moving in a vehicle.

<sup>2</sup> 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**

<b>Moderna COVID-19 Vaccine Transport Time Tracking Form</b>		
Pick-up Date:		
Number of Vials:		
Lot Number(s):		
Transport Start Time <sup>1</sup>	Transport Stop Time <sup>2</sup>	Cumulative Transport Time <sup>3</sup>

<sup>1</sup>Document time vehicle begins transport.

<sup>2</sup> Document time vehicle stops at a destination (includes stops to drop off other products, overnight stops, etc.)

<sup>3</sup> Document the total time from transport start time and stop time columns.

<sup>1</sup> Transport time is defined as the time the vaccine is physically moving in a vehicle.

<sup>2</sup> Initial distribution route is defined as the first time the vaccine is transported and may include vaccine drop off at multiple sites.

## **Appendix C- Moderna Transportation in Thawed State - Scenarios**

(excerpt from Memorandum to Health Canada from Moderna)

NOTE: the transport timelines outlined in the scenarios are based on Moderna's current stability data.

### **Scenario 1: Short Duration Transport on a Medical, Commercial or University Campus-Like Setting**

Transport in a qualified container, as defined above, may be carried out using a well-functioning wheeled cart on a relatively smooth pathway. Transport may also be conducted as a hand-carry (walked, no running). Follow the general precautions described above. Such transport may be conducted for up to one (1) hour. If cumulative time for this local transport (walked/pushcart) will exceed one (1) hour, user should transport in frozen state at  $-20^{\circ}\text{C} \pm 5^{\circ}\text{C}$  (i.e.,  $-25^{\circ}$  to  $-15^{\circ}\text{C}$  ( $-13^{\circ}\text{F}$  to  $5^{\circ}\text{F}$ )).

### **Scenario 2: Medium and Long Duration Ground Transport**

Transport in qualified container, as defined above, may be carried out using a car, van, or truck on paved, smooth gravel, or smooth dirt roads, following the general precautions described above. Such transport may be conducted for up to twelve (12) hours.

### **Scenario 3: Medium and Long Duration Ground Plus Air Transport**

Transport in qualified container, as defined above, may be carried out using a combination of ground transportation (car, van, or truck on paved, smooth gravel, or smooth dirt roads) for up to nine (9) hours plus a flight for up to three (3) hours. Total travel should not exceed twelve (12) hours.

<sup>1</sup> Transport time is defined as the time the vaccine is physically moving in a vehicle.

<sup>2</sup> Initial distribution route is defined as the first time the vaccine is transported and may include vaccine drop off at multiple sites.