Shipping:
- Ideally, vaccine will be shipped frozen between -60°C to -90°C.
- Vaccine may be shipped thawed at 2°C to 8°C.
- Single-dose preloaded syringes may be transported in exceptional circumstances.
- Vials should be upright during transport, and tightly packed to reduce jostling of the vials.
- Validated containers must be used for transport.
- Temperature must be monitored continuously during transportation and documented.

B. Storage:
-60°C to -90°C, Ultra-Low Temperature (ULT) Shipper (frozen):
  - Carton may arrive packaged in thermal packing designed for temporary storage. The shipper can be used for temporary frozen storage for up to 30 days.
  - If using the Pfizer-provided shipper upon receipt and after opening, dry ice should be replenished within 24 hours (maximum of 20-23 kg of dry ice pellets; recommended sizes: 9-16 mm). If transferring into a provincially/federally provided shipper, follow guidelines for dry ice replenishment to prepare shipper to store the vaccine.
  - With every re-icing, shipper can maintain ULT storage for 5 days with 2 openings per day of 3 minutes or less, i.e. dry ice must be replenished every five days. **NOTE:** Additional openings of shipper will require more frequent dry ice replenishment (see resource link below).
  - Temperature monitoring must be continually conducted while vaccine is stored in thermal shipper.

-60°C to -90°C, Ultra-Low Temperature (ULT) Freezer (frozen):
  - Can be stored at ULT for 6 months after manufacturing date printed on the vial/carton.

2°C to 8°C Refrigerator (thawed):
  - Thawed and undiluted vaccine can be stored for up to 10 weeks (70 days).
  - Once placed in 2°C to 8°C environment, the carton should be updated with the expiry information.

2°C to 25°C Room Temperature (thawed):
  - Undiluted vials may be stored at room temperature for a total of 12 hours.
  - Thawed vials can be handled in room light conditions.
C. Thawing:

Regular Use
- A carton of 10 vials may take up to 4 hours to thaw.
- Product needs to reach room temperature prior to dilution.¹

Immediate Use
- Thaw at room temperature (up to 25°C) for 30 minutes.
- Product needs to reach room temperature before dilution.¹

Handling Frozen Vials
- Cartons containing 10 vials removed from frozen storage may be at room temperature for up to 5 minutes.
- If at room temperature for close to, but not over 5 (full carton) minutes, place back in ULT freezer for 2 hours before they can be removed again.
- If carton is at room temperature for over 5 minutes, consider it to be thawing and do not place back in freezer. Vials must be stored and moved into a refrigerated (2°C-8°C) container.
- Individual vials removed from a carton and left at room temperature should not be returned to frozen or refrigerated storage and must be thawed for use.

Thawed vaccine cannot be refrozen.

D. Use
- Vaccine must be diluted within 12 total hours at room temperature.
- Vaccine must be used within 12 hours of dilution.
- Vials and cartons may state that vials be discarded 6 hours after dilution. This information is incorrect, and has been updated to 12 hours.

¹ It is not required that the vaccine reach room temperature prior to dilution, however the vaccine must be fully thawed.
E. Vaccine Stability

<table>
<thead>
<tr>
<th>ULT</th>
<th>2°C to 8°C</th>
<th>Room temperature</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Freezer] -90°C to -60°C for 30 days (replenish dry ice q 5 days)</td>
<td>![Refrigerator] 10 weeks (70 days)</td>
<td>![Vials] Up to 25°C: Must be diluted within 12 hours</td>
</tr>
<tr>
<td>![Freezer] -90°C to -60°C for 6 months from manufacturer date</td>
<td>2°C to 25°C: Discard unused vaccine within 12 hours after dilution</td>
<td></td>
</tr>
</tbody>
</table>

**Note:** Total amount of time at room temperature is up to 24 hours (12 hours max undiluted + 12 hours max diluted).
F. Helpful Resources

<table>
<thead>
<tr>
<th>While specific links have been identified below, it is highly recommended that health authorities and sites familiarize themselves with the resources provided by Pfizer at <a href="http://www.cvdvaccine.ca">www.cvdvaccine.ca</a></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Pfizer Product Monograph</td>
</tr>
<tr>
<td>• Pfizer COVID Vaccine Resources</td>
</tr>
<tr>
<td>• Pfizer Dry Ice Safety Data Sheet</td>
</tr>
<tr>
<td>• Pfizer Vaccine Shipping And Handling Guidelines</td>
</tr>
<tr>
<td>• Pfizer instructions on dry ice replenishment</td>
</tr>
</tbody>
</table>

Any questions or requests for revision of this document should be sent to IBCOC_Operations@phsa.ca
## List of Amendments

<table>
<thead>
<tr>
<th>Date</th>
<th>Section</th>
<th>Description</th>
<th>Author</th>
</tr>
</thead>
<tbody>
<tr>
<td>November 24, 2021</td>
<td>A, B, C, D, E, F</td>
<td>SOP developed based on product monograph and information provided by Pfizer</td>
<td>Calvin Kaila</td>
</tr>
<tr>
<td>November 26, 2021</td>
<td>A</td>
<td>Added hyperlink to preloaded syringes</td>
<td>Calvin Kaila</td>
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