A. Formulations:
- Monovalent – 30 mcg/0.3 ml - intended population: 12 years of age and older
- Bivalent – 30 mcg/0.3 ml - intended population: 12 years of age and older (booster dose only)

B. Shipping:
- Ideally, vaccine will be shipped frozen between -60°C to -90°C.
- Vaccine may be shipped thawed in unpunctured vials 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.

C. 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 12 months after manufacturing date printed on the vial/carton.
2°C to 8°C Refrigerator (thawed):
- Thawed 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):
- Vials may be stored for up to 24 hours at temperatures up to 25°C, with no more than 12 hours from the time of first puncture. After first puncture the vials should be stored at 2°C to 25°C
- Thawed vials can be handled in room light conditions.

D. Thawing:

Regular Use
- A carton of 10 vials may take up to 6 hours to thaw in the refrigerator (2°C - 8°C)

Immediate Use
- Thaw at room temperature (up to 25°C) for 30 minutes.

Handling Frozen Vials
- Cartons containing 10 vials removed from frozen storage may be at room temperature for up to 5 minutes
- 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.

E. Use
- Vials may be stored for up to 24 hours at temperatures up to 25°C with no more than 12 hours from the time of first puncture.
F. Vaccine Stability

<table>
<thead>
<tr>
<th>ULT</th>
<th>2°C to 8°C</th>
<th>Room temperature</th>
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<tbody>
<tr>
<td>-90°C to -60°C for 30 days (replenish dry ice q 5 days)</td>
<td>10 weeks (70 days)</td>
<td>Vials may be stored for up to 24 hours at temperatures up to 25°C with no more than 12 hours from the time of first puncture</td>
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<tr>
<td>-90°C to -60°C for 12 months from manufacturer date</td>
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<td></td>
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</tbody>
</table>

COVID-19 Pfizer Grey Cap Adult/Adolescent Vaccine Standard Operating Procedures
Current as of Oct 11, 2022
G. Helpful Resources

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 www.cvdvaccine.ca

- Pfizer Product Monograph
- Pfizer COVID Vaccine Resources
- Pfizer Dry Ice Safety Data Sheet
- Pfizer Vaccine Shipping And Handling Guidelines
- Pfizer instructions on dry ice replenishment

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>July 22, 2022</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>
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<tr>
<td>Oct 11, 2022</td>
<td>A</td>
<td>Information added about Bivalent formulation</td>
<td>Calvin Kaila</td>
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