There are two distinct processes to follow in the event of a temperature excursion depending on when and where the incident occurs.

SCENARIO 1: Temperature excursion occurs while vaccine is in the custody of the manufacturer, en route to a primary delivery site

When vaccine arrives at a primary site, the temperature monitor provided by the manufacturer is stopped and a report is generated to indicate the temperatures experienced by the vaccine during transit. If this report indicates a break in the cold chain, the following process should be implemented:

1. Quarantine affected vaccine.
2. Receiving site notifies IBCOC_Operations@phsa.ca as soon as possible. If after hours, call 1-250-686-6061, providing as much of the following information as possible:
   - Date of incident
   - Location of incident
   - Number of doses affected
3. Immunize BC Operations Centre notifies the National Operations Centre immediately.
4. Receiving site contacts manufacturer directly:
   - If the incident is outside the hours of: 04:30 - 14:30 PST, Monday-Friday- email the manufacturer instead of calling
   - Copy in the National Operations Centre: PHAC.vaccine.NOC-CNO.vaccin.ASPC@canada.ca
5. Within 24 hours, the incident must be resolved and a report submitted to IBCOC_Operations@phsa.ca with the following information:
   - Date of incident
   - Location of incident
   - Number of doses affected
   - Number of doses wasted
   - Impact on provincial program (e.g. clinic closed early, clinic cancelled)
   - Manufacturer recommendations
6. Upon receipt of this report, the Immunize BC Operations Centre will be responsible to report the incident to the National Operations Centre.

Manufacturer Contact Information

Innomar (Moderna/Janssen):
1-833-847-4270
QA-GMP@innomar-strategies.com

Pfizer:
1-833-829-2684
CanadaCSVaccine@Pfizer.com

Verity Pharma (COVISHIELD/AstraZeneca/):
1-800-977-9778
medinfo.canada@astraZeneca.com

1 Primary site: a site which receives vaccine directly from the manufacturer (i.e. Health Authority site, BCCDC Vaccine Distribution Centre, Pharmacy Distribution Centre)
SCENARIO 2: Temperature excursion occurs while vaccine is in the custody of the health authority or community vaccine provider¹

1. Quarantine affected vaccine and label as “Do Not Use”

2. Receiving site notifies IBCOC_Operations@phsa.ca as soon as possible. Call 1-250-686-6061, if after hours.

3. Cold chain consultation process initiated²

   **Cold chain incident form completed**
   (for cold chain incident form and instructions, see the Vaccine Management webpage)

   🔽

   **Are the vaccines still useable?**

   ▼

   **YES**
   - Remove vaccine from quarantine
   - Label with a red dot and date as being first exposure OR use a number if more than one exposure has occurred.
   - Maintain a history of exposure for any affected vaccines
   - **Use affected vaccines first.**

   ▼

   **NO**
   - Return vaccines to the BCCDC Vaccine Distribution Centre using standard processes for vaccine returns.
   - Ensure wastage is recorded as per provincial procedure (e.g. Panorama).
   - **Do not maintain cold chain.**

4. Within 24 hours, the incident must be resolved and a report submitted to IBCOC_Operations@phsa.ca with the following information:
   - Date of incident
   - Location of incident
   - Situation surrounding incident
     - Excursion temperature(s) and duration(s)
     - Lot number, expiry
     - Detail description of event
   - Recommendations
   - Number of affected doses
   - Number of doses wasted
   - Impact on clinic (e.g. closed early, cancelled, clients redirected to alternate site)

5. Upon receipt of this report, the Immunize BC Operations Centre will be responsible to report the incident to the National Operations Centre.

¹ Health authority or community vaccine provider: vaccine is in the custody of the health authority or community vaccine provider (e.g. health authority storage site, immunization clinic setting, pharmacy, physician office, FNHA)
² Cold chain process consultation: report incident to local public health unit for determination of vaccine use; consultation with BCCDC Vaccine and Pharmacy Services may occur.
## List of Amendments

<table>
<thead>
<tr>
<th>Date</th>
<th>Section</th>
<th>Description</th>
<th>Author</th>
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<tbody>
<tr>
<td>April 28, 2021</td>
<td>Full document</td>
<td>Processes refined to align more closely with standard provincial procedures.</td>
<td>Multiple</td>
</tr>
<tr>
<td>April 29, 2021</td>
<td>Manufacturer Contact Information</td>
<td>Janssen guidance added.</td>
<td>Keren Massey</td>
</tr>
<tr>
<td>April 29, 2021</td>
<td>Scenario 2</td>
<td>Guidance added to confirm requirement to report any vaccine wastage as per provincial procedures in addition to reporting to IBCOC.</td>
<td>Keren Massey</td>
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