

Temperature Excursion Incident Checklist

Site name and PIN:

A temperature excursion incident can happen when your continuous temperature monitoring device records a temperature that falls outside the recommended range, even for a short amount of time. This is considered an excursion or out-of-range temperature. Vaccines exposed to out-of-range temperatures may become nonviable (ineffective).

Move vaccine immediately for refrigerated vaccine that is less than 2°C (36°F) and follow action steps below for out-of-range temperatures. Vaccines exposed to freezing temperatures for even a brief time may be nonviable (unusable). **Open multi-dose vials and refrigerated MMR vaccine are especially sensitive to out-of-range temperatures.** Confirm viability with vaccine manufacturer(s) with every excursion even if the temperature stabilized within 30 minutes.

All the following incidents must be reported to the MnVFC program:

- Refrigerated vaccine reached a temperature **less than 2°C (36°F)** for any amount of time.
- The temperature of the fridge or freezer unit was too warm and did not stabilize in the correct range **within 30 minutes**.
- Any out-of-range temperature happened in any unit storing **open multi-dose vials (MDVs) or refrigerated MMR vaccines** for any amount of time.
- Vaccine was stored improperly in a way that led to the vaccine sitting at an out-of-range temperature for 30 minutes or more.

Immediate actions when a temperature excursion incident mishap has occurred

- ☐ Determine the problem. Attempt to fix the cause (e.g., door not shut, unit malfunction, etc.).
- ☐ Adjust the storage unit's temperature, if necessary.

Monitor the temperature

- ☐ Report the excursion to the vaccine coordinator or backup vaccine coordinator, if available.

If the temperature is too warm and doesn't stabilize in the correct range within 30 minutes, follow these action steps:

- ☐ Stop using the vaccine.
- ☐ Mark the vaccine "Do Not Use" and quarantine it until viability is determined.
- ☐ Consult and execute your Emergency Vaccine Management Plan.
- ☐ Move the vaccine to a storage unit that is maintaining the correct temperature.
- ☐ Gather vaccine information, storage unit temperatures, room temperature, and duration of excursion.
- ☐ Determine if any of this vaccine was involved in a previous storage and handling mishap.
- ☐ Call the vaccine manufacturer(s) for stability data to determine viability. Ask to speak to the medical consultant or quality assurance staff. Manufacturer contact information is available at [Immunize.org: Vaccine Manufacturers Contact and Product Information \(www.immunize.org/clinical/external/manufacturers/\)](https://www.immunize.org/vaccine-manufacturers-contact-and-product-information). Gather vaccine information, storage unit temperatures, room temperature, and duration of excursion.
- ☐ Report the temperature excursion to the MnVFC program by completing the [MnVFC and UUAV Vaccine Temperature Excursion Report \(https://redcap.health.state.mn.us/redcap/surveys/?s=7ADPY3EN73A8993T\)](https://redcap.health.state.mn.us/redcap/surveys/?s=7ADPY3EN73A8993T) form. Our staff will follow-up with you on next steps.

Date (mm/dd/yyyy):

Room temperature (if available):

Reason for excursion (if known):

Refrigerator: Between 36°F and 46°F (between 2°C and 8°C)

Refrigerator name/location:

Time out of range:

☐ °F

☐ °C

☐ Too cold

☐ Too warm

Highest or lowest out-of-range temperature:

Vaccines stored in this refrigerator

Vaccine name	Manufacturer	Lot number	Expiration date (mm/dd/yyyy)

Freezer: Between -58°F and +5°F (between -50°C and -15°C)

Freezer name/location:

Time out of range:

☐ °F

☐ °C

☐ Too cold

☐ Too warm

Highest or lowest out-of-range temperature:

Vaccines stored in this freezer

Vaccine name	Manufacturer	Lot number	Expiration date (mm/dd/yyyy)

Vaccine manufacturer recommendation

☐ Vaccine is viable to current expiration date. If only certain vaccines are viable, list them here:

☐ Vaccine is viable to a modified expiration date (write the date on the box).
Note the vaccine name and new expiration date here (mm/dd/yyyy):

☐ Vaccine is nonviable. If only certain vaccines are nonviable, list them here:

Contact the MnVFC program at health.mnvfc@state.mn.us or 651-201-5522 to report the mishap, for instructions on how to return nonviable MnVFC vaccine, and help with patient recall, if applicable. Do not discard or remove vaccine from the storage unit before speaking to MnVFC staff.

If vaccine is determined to be nonviable:

- ☐ Remove nonviable vaccine from the storage unit with the “Do Not Use” marking still in place.
- ☐ Determine if affected vaccine was administered to patients. If so, identify patients to contact for revaccination.
- ☐ Return MDH nonviable vaccine by following instructions in your MnVFC Policies and Procedures Manual in “Manage MnVFC vaccine efficiently.”
- ☐ Return or dispose of privately purchased nonviable vaccine per your site’s policy.