



# COVID-19 Vaccine Out-of-Range Temperature Incidents

Report **ALL** out-of-range temperature incidents

An *out-of-range temperature incident*, also called a *temperature excursion* is any temperature outside the recommended range for a vaccine. The TOTAL amount of time a vaccine is stored at an out-of-range temperature affects the viability of the vaccine.

## OUT-OF-RANGE TEMPERATURE:

- When your digital data logger (DDL) alarms/ the display shows an “X” next to the temperature
- When the **refrigerator** thermometer indicates the temperature is **below 36° or above 46° Fahrenheit**
- When the **freezer** temperature is **above 5° Fahrenheit**
- When **Ultra-low** temperature (ULT) is **above -76° Fahrenheit**

## WHAT TO DO (All steps are *required*):

1. **Isolate** the vaccines and **DO NOT USE** until you receive guidance from the Immunization Program.
2. **Label** the vaccines “DO NOT USE” until you have received authorization from the Immunization Program.
3. **Immediately** restart the data logger if it is found not to be recording for any reason.
4. **Upload the data logger files** from all affected units into NMSIIS
5. **Call the Help Desk 833-882-6454** **and** send a notification of the event via email to [covid.vaccines@state.nm.us](mailto:covid.vaccines@state.nm.us)
6. For vaccines stored in a refrigerator or regular freezer ONLY (not ULT freezer) Begin **stabilizing temperatures** in the refrigerator or freezer by slightly turning the thermostat knob. Monitor for 30 minutes; check and record temperature every five minutes until stable. Aim for 40° F in the refrigerator and below 0° F in the freezer.
7. If unable to stabilize temperatures implement your **Emergency Vaccine Management Plan** and **move** the vaccines to another **approved COVID-19 storage unit** with in-range temperatures. **NOTE: If vaccines are moved, a completed Vaccine Transfer Log is REQUIRED and should be submitted to:** [covid.vaccines@state.nm.us](mailto:covid.vaccines@state.nm.us)
8. **Complete** the COVID-19 Troubleshooting Record (TSR).
9. **Contact** the vaccine manufacturers. Every temperature excursion requires contacting the manufacturer for further guidance because the characteristics that determine vaccine viability vary. When you call, be prepared to answer these questions:
  - a. The company may ask to speak to a healthcare professional (i.e., medical assistant, nurse, or pharmacist; not a receptionist, or bookkeeper)
  - b. What was the maximum **and/or** minimum out-of-range temperature?
  - c. What are the names of the vaccines made by this manufacturer that were affected?
  - d. Have these vaccines been exposed to priorexursions?
  - e. Are the products currently stored under recommended temperatures?
  - f. Have any doses of the affected vaccines been administered since the temperature excursion occurred?
10. **EMAIL** the completed COVID-19 TSR to the Immunization Program: [COVID.Vaccines@state.nm.us](mailto:COVID.Vaccines@state.nm.us). In the subject line of the email please include your PIN # and “TSR”
11. **Wait for further instruction from the NM Immunization Program.** Keep the vaccines stored properly but isolated and marked “DO NOT USE”. Do not administer, return, or discard any vaccines unless you are instructed to do so by the Immunization Program. If advised, you will complete a vaccine return in NMSIIS.

Printing this form to complete it is **not** recommended.

Click on “Enable Editing” then use the **Tab** key to move between fields and enter your typed information.

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# COVID-19 Troubleshooting Record (TSR)

**Follow all steps listed under "What To Do" on previous page to ensure the safety of all vaccines. Incomplete or hand-written Troubleshooting Records will be rejected.**

**DO NOT administer, discard, or return any vaccines until instructed to do so by the NM Immunization Program.**

Date TSR Completed:

### Provider Information

Site Name:                      Site PIN#:

TSR prepared by:              Email address:

**Site's Primary COVID-19 vaccine contact** name:                      email:                      cell phone:

**Site's Secondary COVID-19 vaccine contact** name:                      email:                      cell phone:

### Event Details (ALL ARE REQUIRED)

Date range of event: From                      To

Timespan of event: From                      To

**Description and cause:** provide a **detailed** description of the incident, **including the cause** (door left ajar, power outage, etc.):

Refrigerator	Freezer	Ultra-low Transport/storage
<input type="checkbox"/> Event involved refrigerator	<input type="checkbox"/> Event involved freezer	<input type="checkbox"/> Event involved ultra-low transport
*Min. Temp:	*Min. Temp:	*Min. Temp:
*Max. Temp:	*Max. Temp:	*Max. Temp:
<b>*No Temperature Data recorded</b> <input type="checkbox"/>	<b>*No Temperature Data recorded</b> <input type="checkbox"/>	<b>*No Temperature Data recorded</b> <input type="checkbox"/>

\*From data logger files

1. Complete the second page of the COVID-19 Troubleshooting Record
2. Obtain and *attach written advice* from all manufacturers
3. Locate the .pdf version of the temperature log/s from data logger/s involved in the event
4. **Email this completed document, the manufacturer's WRITTEN advice, and your temp logs to [covid.vaccines@state.nm.us](mailto:covid.vaccines@state.nm.us)**

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### Immunization Program Staff Only:

VTrck's Return ID:                      Date Return uploaded:                      By:



# COVID-19 Troubleshooting Record

Pfizer 800-666-7248 option 8 or [CVGovernment@pfizer.com](mailto:CVGovernment@pfizer.com)

Manufacturer Representative:      Date/Time:      Case #

Vaccine Name / NDC	Lot #	# of Doses	Advice Given	Manufacturer's response**
Pfizer COVID-19 / 59267-1000-01				<input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use
				<input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use

## Moderna TBA

Manufacturer Representative:      Date/Time:      Case #

Vaccine Name / NDC	Lot #	# of Doses	Advice Given	Manufacturer's response**
MOD COVID-19 / 80777-0273-10				<input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use
				<input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use

## Hold for future use

Manufacturer Representative:      Date/Time:      Case #

Vaccine Name / NDC	Lot #	# of Doses	Advice Given	Manufacturer's response**
				<input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use

## Hold for future use

Manufacturer Representative:      Date/Time:      Case #

Vaccine Name / NDC	Lot	# of Doses	Advice Given	Manufacturer's response**
				<input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use
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