



## Out-of-Range Temperature Incidents

An *out-of-range temperature incident*, also called a *temperature excursion*, refers to any storage 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 temperatures can occur under various circumstances: when a package is left unopened, when vaccine is unrefrigerated upon arrival, when a vial is left on the counter after a dose has been drawn, or when a power outage or other incident causes the refrigerator or freezer to fail.

### OUT-OF-RANGE TEMPERATURE:

- When your digital data logger (DDL) alarms and/or its 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**.

### WHAT TO DO:

1. **Isolate** the vaccines and **DO NOT USE** until you receive guidance from the NM Immunization Program.
2. **Label** the vaccines “DO NOT USE” until the issue is resolved.
3. **Contact** your Regional Immunization Coordinator. If you cannot reach your Regional Immunization Coordinator (contact info. on Temp. Log), leave a message and then call the Health Educator at 505-827-2415.
4. Begin **stabilizing temperatures** in the refrigerator or freezer by turning the thermostat knob slightly. 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.
5. If unable to stabilize temperatures implement your **Emergency Vaccine Management Plan** and **move** the vaccines to a unit with in-range temperatures.
6. **Complete** the NM Adult Troubleshooting Record (TSR).
7. **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 (or minimum) out-of-range temperature?
  - c. What is the worst-case scenario length of time that temperatures were out of range?
  - d. What are the names of the vaccines made by this manufacturer that were affected?
  - e. Have these vaccines been exposed to prior excursions?
  - f. Are the products currently stored under recommended temperatures?
  - g. Have any doses of the affected vaccines been administered since the temperature excursion occurred?
8. Email the form to: **Adult.Vaccines@doh.nm.gov**
9. Wait for instructions from the NM Immunization Program. Do not return or discard any vaccines unless instructed to do so by NM Immunization Program. If necessary, you will complete a vaccine return in NMSIIS.

| Vaccine Manufacturers’ Quality Control Phone Numbers |                |
|------------------------------------------------------|----------------|
| GlaxoSmithKline                                      | 1-866-475-8222 |
| Merck                                                | 1-800-672-6372 |
| Pfizer                                               | 1-800-358-7443 |
| Sanofi Pasteur                                       | 1-800-822-2463 |
| Dynavax                                              | 1-844-889-8753 |

## NM Adult Immunization Troubleshooting Record

**Follow all steps listed under "What to do" on previous page to ensure the safety of all vaccines.  
Do NOT discard or return any vaccines until instructed to do so by the NM Immunization Program.**

Date Submitted \_\_\_\_\_

Provider Site Name \_\_\_\_\_

Record prepared by: \_\_\_\_\_ Email address \_\_\_\_\_

Site's Primary Vaccine Coordinator (if different from Preparer): \_\_\_\_\_

**Date** or date range of event: \_\_\_\_\_

**Time** or timespan of event: \_\_\_\_\_

| <b>Refrigerator – Storage unit # _____</b>                                |                          |     |                          | <b>Freezer - Storage unit # _____</b>                                    |                                     |                          |     |                          |    |
|---------------------------------------------------------------------------|--------------------------|-----|--------------------------|--------------------------------------------------------------------------|-------------------------------------|--------------------------|-----|--------------------------|----|
| Event involved refrigerator (check one):                                  | <input type="checkbox"/> | yes | <input type="checkbox"/> | no                                                                       | Event involved freezer (check one): | <input type="checkbox"/> | yes | <input type="checkbox"/> | no |
| Temperature:                                                              |                          |     |                          | Temperature:                                                             |                                     |                          |     |                          |    |
| If digital data logger used:<br>Min. Temp                      Max. Temp  |                          |     |                          | If digital data logger used:<br>Min. Temp                      Max. Temp |                                     |                          |     |                          |    |
| If DDL used, upload data logger files into NMSIIS to obtain temperatures. |                          |     |                          |                                                                          |                                     |                          |     |                          |    |

**Describe the incident and indicate how long the temperature was out of range.**

*Please obtain manufacturer advice and complete the second page of the Troubleshooting Record.*

**NM Immunization STAFF ONLY:**

VTckS Return ID: \_\_\_\_\_ Date Return entered: \_\_\_\_\_ By: \_\_\_\_\_

# NM Adult Immunization Troubleshooting Record

*Please print and attach your on-hand inventory from NMIS*

|                                     |                   |                              |                   |                                                                          |
|-------------------------------------|-------------------|------------------------------|-------------------|--------------------------------------------------------------------------|
| <b>GlaxoSmithKline</b>              |                   | <b>Phone: 1-866-475-8222</b> |                   |                                                                          |
| <b>Manufacturer Representative:</b> |                   |                              | <b>Date/Time:</b> | <b>Case #:</b>                                                           |
| <b>Vaccine Name</b>                 | <b># of Doses</b> | <b>Advice Given</b>          |                   |                                                                          |
| Engerix-B (Hep B-alum)              |                   |                              |                   | <input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use |
| Fluarix (Flu)                       |                   |                              |                   | <input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use |
| Havrix (Hep A)                      |                   |                              |                   | <input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use |
| Shingrix (Shingles)                 |                   |                              |                   | <input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use |
| Twinrix (Hep A/B)                   |                   |                              |                   | <input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use |
| Other:                              |                   |                              |                   | <input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use |

|                                     |                   |                              |                   |                                                                          |
|-------------------------------------|-------------------|------------------------------|-------------------|--------------------------------------------------------------------------|
| <b>Pfizer</b>                       |                   | <b>Phone: 1-800-358-7443</b> |                   |                                                                          |
| <b>Manufacturer Representative:</b> |                   |                              | <b>Date/Time:</b> | <b>Case #:</b>                                                           |
| <b>Vaccine Name</b>                 | <b># of Doses</b> | <b>Advice Given</b>          |                   |                                                                          |
| Prenar 20 (PCV20)                   |                   |                              |                   | <input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use |

|                                     |                   |                              |                   |                                                                          |
|-------------------------------------|-------------------|------------------------------|-------------------|--------------------------------------------------------------------------|
| <b>Sanofi Pasteur</b>               |                   | <b>Phone: 1-800-822-2463</b> |                   |                                                                          |
| <b>Manufacturer Representative:</b> |                   |                              | <b>Date/Time:</b> | <b>Case #:</b>                                                           |
| <b>Vaccine Name</b>                 | <b># of Doses</b> | <b>Advice Given</b>          |                   |                                                                          |
| Adacel (Tdap)                       |                   |                              |                   | <input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use |

|                                     |                   |                              |                   |                                                                          |
|-------------------------------------|-------------------|------------------------------|-------------------|--------------------------------------------------------------------------|
| <b>Merck</b>                        |                   | <b>Phone: 1-800-672-6372</b> |                   |                                                                          |
| <b>Manufacturer Representative:</b> |                   |                              | <b>Date/Time:</b> | <b>Case #:</b>                                                           |
| <b>Vaccine Name</b>                 | <b># of Doses</b> | <b>Advice Given</b>          |                   |                                                                          |
| Gardasil9 (HPV)                     |                   |                              |                   | <input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use |
| MMR-II (MMR)                        |                   |                              |                   | <input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use |
| Pneumovax (PPSV23)                  |                   |                              |                   | <input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use |
| Varivax (Varicella)                 |                   |                              |                   | <input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use |
| Zostavax (Shingles)                 |                   |                              |                   | <input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use |
| PCV15 (Vaxneuvance)                 |                   |                              |                   | <input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use |

|                                     |                   |                              |                   |                                                                          |
|-------------------------------------|-------------------|------------------------------|-------------------|--------------------------------------------------------------------------|
| <b>Dynavax</b>                      |                   | <b>Phone: 1-844-889-8753</b> |                   |                                                                          |
| <b>Manufacturer Representative:</b> |                   |                              | <b>Date/Time:</b> | <b>Case #:</b>                                                           |
| <b>Vaccine Name</b>                 | <b># of Doses</b> | <b>Advice Given</b>          |                   |                                                                          |
| Heplisav-B (HepB adjuvanted)        |                   |                              |                   | <input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use |