



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. **Fax** the completed TSR to your Regional Immunization Coordinator and to NM Immunization Program/Santa Fe: 505-827-1064.
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
Seqirus	1-855-358-8966
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: _____

Refrigerator – Storage unit # _____	Freezer - Storage unit # _____
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: Min. Temp _____ Max. Temp _____	If digital data logger used: 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.
Fax this document to 505-827-1064.*

NM Immunization STAFF ONLY:

VTrcKs Return ID: _____ Date Return entered: _____ By: _____

NM Adult Immunization Troubleshooting Record

Please print and attach your on-hand inventory from NMIIS

GlaxoSmithKline		Phone: 1-866-475-8222		Case #:
Manufacturer Representative:			Date/Time:	Case #:
Vaccine Name	# of Doses	Advice Given		
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

Pfizer		Phone: 1-800-358-7443		Case #:
Manufacturer Representative:			Date/Time:	Case #:
Vaccine Name	# of Doses	Advice Given		
Pevnar 13 (PCV13)				<input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use

Seqirus		Phone: 1-855-358-8966		Case #:
Manufacturer Representative:			Date/Time:	Case #:
Vaccine Name	# of Doses	Advice Given		
Flucelvax (Flu)				<input type="checkbox"/> OK to Use / <input type="checkbox"/> Do NOT Use

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

Merck		Phone: 1-800-672-6372		Case #:
Manufacturer Representative:			Date/Time:	Case #:
Vaccine Name	# of Doses	Advice Given		
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
Vaqta (Hep A)				<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

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