

Provider Instructions For Reporting a Temperature Excursion

Immunization providers participating in a publicly-funded immunization program are required to report out of range temperatures, or any instance where vaccines were not stored appropriately, immediately upon discovery to the Immunization Program and follow the guidance below.

1. **Protect the Vaccines and Your Patients**

In all situations, immediately mark the vaccines or the unit “Do Not Use” and take steps to store the vaccines at the appropriate temperature range.

- a. If the unit is currently in-range, put a sign on the storage unit stating, “DO NOT USE UNTIL FURTHER NOTICE”. Vaccine may remain in a stable unit.
- b. If the unit is currently out of range, follow your Emergency Plan.
 - i. Relocate vaccine to a backup unit, or
 - ii. Transport vaccine to your emergency location.

Publicly-supplied vaccine must be monitored using a thermometer with a valid calibration certificate. This includes while stored in a backup or emergency unit and during transport.

2. **Call 307-777-7952 and Notify Wyoming Immunization Program Staff**

Report that you have identified a temperature excursion. You will be forwarded to the Immunization Staff member on call.

- a. Download your data logger file and email the file as an attachment to the staff member.
 - i. The Data logger file(s) should contain no less than 1 week of data. Any additional data will be requested by Immunization staff as needed.
 - ii. Email the file in its original format. Do not convert to a PDF or print and scan.
- b. Based on your temperature data, Immunization staff will determine if a cold chain investigation is necessary.
 - i. If a complete investigation is NOT necessary, make a note on your monthly Temperature Log that includes the date and Immunization staff member you spoke with.
 - ii. **If Immunization Program staff informs you that a cold chain investigation must be completed, proceed with the steps on the following page.**

Cold Chain Investigation

If you are directed by Immunization Program staff to complete a Cold Chain Investigation complete the following activities. Vaccines must continue to be stored appropriately and must not be administered during this time.

1. Get Prepared!

To accurately complete the Incident Report complete the following steps:

- a. Reconcile your publicly-supplied WyIR inventory and your physical count.
 - i. Print your “Reconciliation” screen for your facility’s publicly-supplied vaccine inventory from the Wyoming Immunization Registry (WyIR).
 - ii. Using the print out, physically count the vaccines involved in the incident. Make note of any discrepancies between the WyIR inventory and physical inventory.
 - iii. Adjust the WyIR inventory appropriately.
- b. Temperature Logs
 - i. Scan your current month’s Temperature Log for the unit involved in the incident.

2. Vaccine Cold Chain Incident Report

- a. Providers should download and save the Vaccine Cold Chain Incident Report to their computer prior to entering information.
 - i. The report is located on the VFC/WyVIP Providers, Forms & Reports webpage at www.immunizewyoming.com.
 - ii. Type into the Report. Do not print and handwrite the information.
- b. Complete Page 1 to describe the incident and summarize temperature information.
- c. Complete Page 2 for each vaccine stored in the affected unit(s).
 - i. **Review past Incident Reports to determine whether or not the vaccine involved has experienced a previous temperature excursion as this is relevant in determining current viability. Enter the date of the previous excursion on the form. The manufacturer will also want to know the excursion count and temperature.**
 - ii. If necessary, complete the “Additional Cold Chain Vaccines” document to provide information for additional vaccines that do not fit on Page 2.
- d. All fields must be completed prior to submission to the Immunization Program.

3. Contact the Relevant Vaccine Manufacturers

A licensed healthcare employee from your facility must contact the relevant manufacturers.

- a. Contact information can be found on Page 1 of the Incident Report.
- b. The vaccine manufacturer(s) will need to know the information compiled on Page 1 of the Incident Report.
- c. Providers must document the assigned case number and name of the representative spoken to for each vaccine manufacturer.

- d. Providers must request documentation from each vaccine manufacturer specifying the guidance provided to submit with the Incident Report.

4. **Submit the Vaccine Cold Chain Incident Report and Supporting Documentation**

Providers must email the following information to the Immunization Program.

- a. Completed Vaccine Cold Chain Incident Report (Pages 1 -3)
- b. Temperature Log for current month and affected unit (if applicable)
- c. Written guidance from vaccine manufacturers

5. Incident Conclusion

Publicly-supplied vaccine must not be administered until the incident has been closed by the Immunization Program.

- a. The Incident Report and supporting documentation will be reviewed by Immunization Program staff. If there are any questions or missing documentation you will be contacted immediately.
- b. Any additional recommendations, requirements, or guidance will be added to page 3.
- c. The final Incident Report will be sent back to the provider with guidance on future use of the vaccine.

VFC/WyVIP Program Vaccine Cold Chain Incident Report

***TYPE INTO THIS FORM ONLY-DO NOT PRINT OR HANDWRITE.**

| | | |
|----------------------|--------|---------------|
| Facility Name (PIN): | | Today's Date: |
| Person Completing: | Phone: | Email: |

| PREPARATION CHECKLIST | |
|---|---|
| Vaccines have been marked "Do Not Use" | WyIR inventory and physical inventory has been reconciled |
| Vaccines are being stored at appropriate temperatures | Data logger data has been emailed to Immunization staff |
| Relevant Temperature Log, for affected unit, has been scanned and saved | |

| INCIDENT DESCRIPTION | | | |
|--|----|-------|-----------------------------|
| Date/Time Discovered: Date: | | Time: | By whom? |
| Storage unit(s) involved: (1) | | Type: | Control Type of Combo Unit: |
| (2) | | Type: | |
| CURRENT temperature of unit (1): | °C | Date: | Time: |
| CURRENT temperature of unit (2): | °C | Date: | Time: |
| Current location of vaccines: Primary Unit On-site Backup Emergency Location: | | | |
| Have any of the vaccines involved in the incident been administered since the first identified out of range temperature? | | | |

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| Describe the event. Include details about discovery, reporting, and any action taken: |
| |

| Select the most appropriate cause of this incident (select all that apply): | | |
|---|---------------------------------|--|
| Door Left Open/Ajar | Power Outage/Breaker Tripped | Staff Adjusted Unit Temperature Controls |
| Possible Unit Failure | Vaccine Not Stored Properly | Spoiled During Transport |
| Unit Unplugged | Frequent Access/Busy Clinic Day | Other, Describe Below. |

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| Additional Details for Potential Cause: |
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| OUT OF RANGE TEMPERATURE INFORMATION | | | | |
|--------------------------------------|--------------------|----|--|--------------|
| UNIT 1 | Lowest or Highest: | °C | Accumulative time unit was out of range: | Hrs. Min. |
| UNIT 2 | Lowest or Highest: | °C | Accumulative time unit was out of range: | Hrs. Min. |

| VACCINE MANUFACTURER GUIDANCE | | *Check boxes for each vaccine involved |
|---|--|--|
| Name of Licensed Staff Calling Manufacturer(s): | | Phone: |

| *Do not forget to request documentation from each manufacturer detailing their guidance to submit with the Incident Report. | | | | |
|---|--------------|--------------|------------------|-------------------------------|
| GSK | Merck | Sanofi | Novartis | MedImmune |
| 866-475-8222 x4 | 800-672-6372 | 800-822-2463 | 800-244-7668 x 1 | 877-633-4411 x2 |
| Rep: | | | | |
| Case #: | | | | |
| Boostrix | Infanrix | Comvax | Recombivax | ActHib |
| Cervarix | Kinrix | Gardasil | RotaTeq | Adacel |
| Engerix | Pediarix | MMRII | Vaqta | Daptacel |
| Fluarix | Rotarix | PedvaxHIB | Varivax | Fluzone |
| Havrix | Twinrix | Pneumovax | Zostavax | Tenivac |
| | | ProQuad | | |
| | | | | Fluvirin |
| | | | | Menveo |
| | | | | Pfizer 800-438-1985 |
| | | | | Prevnar 13 |

Vaccine manufactures must be made aware of the time and temperature count of vaccines that were previously involved in an excursion.

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|---|
| Summary of Conversation with Vaccine Manufacturers. |
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INCIDENT OUTCOME

**Completed by Immunization Program Staff*

INCIDENT SUMMARY

Facility Name (PIN):

Outcome Date:

Completed By:

Doses Wasted:

Public Value: \$

Referred to VFC Coordinator?

*Incidents resulting in vaccine waste will be reviewed for replacement per the Vaccine Replacement Policy.

Additional Information:

REQUIRED ACTIVITIES FOR THE PROVIDER

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RECOMMENDATIONS FOR THE PROVIDER