

VACCINE INCIDENT REPORT and WORKSHEET
Pennsylvania Department of Health
Vaccines for Children Program

PIN # _____

DATE _____

PROVIDER NAME: _____ **PIN #:** _____

DATE/TIME OF INCIDENT: _____ **Phone:** _____

ADDRESS: _____
 _____ (City) (County) (District)

TYPE OF INCIDENT: _____
 (Power outage, equipment failure, failure to properly store, etc.)

REPORTED BY: _____ **REPORTED TO:** _____
 (Include name, title, and work location)

TEMPERATURE DATA:

Date, time and temperature of units prior to the incident:

Refrigerator _____
 Date _____ Time _____ Temperature _____

Min _____ Max _____

Freezer: _____
 Date _____ Time _____ Temperature _____

Min _____ Max _____

Date, time and temperature of units when aware of the incident:

Refrigerator _____
 Date _____ Time _____ Temperature _____

Min _____ Max _____

Freezer: _____
 Date _____ Time _____ Temperature _____

Min _____ Max _____

DESCRIPTION OF INCIDENT (Circle all appropriate responses and/or write a narrative giving details of actions taken; attach additional sheet of paper if needed.)

Out of range temperature in fridge or freezer	Fridge or freezer door not closed
Failure to store properly upon delivery	Power failure due to:
Shipping from distributor error due to:	Storage unit malfunction due to:
Transporting to/from another VFC site	Thermometer malfunction due to:
Damaged shipping container due to:	Storage unit unplugged due to:
No/Non sufficient coolant in shipping container	Other/Additional Information:
Expired	

INCIDENT RESOLUTION (Circle all appropriate responses and/or write a narrative giving details of actions taken after a problem was detected; attach additional sheet of paper if needed.)

Fridge, Freezer, Thermometer repaired replaced Date _____

Notified your VFC Immunization nurse of storage repairs/replacements Date _____

Manufacturers called IMMEDIATELY for all incidents (list their instructions on the "Vaccine Worksheets")

Requested Vaccine Return label from VFC Program (do so if need to return vaccine) Yes _____ No _____

Other/Additional information:

*** Must complete all four pages of worksheet and an additional two pages of Vaccine Return Form if vaccine is wasted.**
 Forms must be completed within 5 Business days. Page 1 of 4

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***MUST DOCUMENT A CORRECTIVE ACTION PLAN** (Write a narrative giving details of actions taken to assure that another preventable loss does not occur in the future; attach additional sheet of paper if needed.)

Staff educated re:

Developed protocol re:

Alternate delivery instructions posted

Emergency instructions reviewed/posted in prominent place

Other:

REQUIRED INFORMATION:

***Must submit** a copy of the temperature log with the incident report.

1. Was it necessary to waste vaccine because of the incident: Yes _____ No _____

If so, also complete the **Vaccine Return and Accountability Forms** and the **Vaccine Worksheets**; be sure to include the manufacturer's instructions and the number of doses wasted, short dated, etc.

2. Were any affected vaccines administered to patients and they now require revaccination:

Yes _____ No _____

If so, how many patients need revaccinated: _____

Patients were notified of need for revaccination Yes _____ No _____

3. Are water bottles stored on the refrigerator floor and crisper bins removed? Yes ___ No ___

4. Are there ice packs stored along the perimeter of the freezer as recommended: Yes ___ No ___

5. Is a dormitory-style storage unit being used to store vaccines (**not permissible**): Yes ___ No ___

6. Type of Storage unit (i.e. Combo unit, medical grade, or stand alone) _____

7. Are there NIST-certified thermometers with current calibration in the middle of each compartment: Yes _____ No _____ Due Date _____

8. Are temperatures being taken twice daily during operating hours: Yes ___ No ___

9. Are any adjustments to the thermometers noted on the temperature logs: Yes ___ No ___

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**CALL EACH MANUFACTURER OF AFFECTED VACCINE(S) AND ASK FOR THE
 VACCINE STABILITY SECTION**

VACCINE	MANUFACTURER	TELEPHONE NUMBER
DT, DTaP (Tripedia), DTaP (Daptacel), DTaP-IPV-Hib (Pentacel) EIPV (Polio), Flu (Fluzone), Hib (ActHib), Meningococcal (MCV4), Td (Decavac), Tdap (Adacel))	sanofi pasteur www.us.aventispasteur.com	1-800-822-2463
Flu (Afluria), Hep A (Vaqta, Hep B (Recombivax), HepB-Hib (Comvax), Hib (PedvaxHib), HPV (Gardasil), MMR , MMRV (ProQuad), Pneumococcal PPV23 (Pneumovax), Rotavirus (RotaTeq), Varicella (Varivax)	Merck www.merck.com	1-800-672-6372
DTaP (Infanrix), DTaPHBIP (Pediarix), DTaP-IPV (Kinrix), Flu (Fluarix), Hep A (Havrix), Hep B PF (Engerix), Hep AB (Twinrix), HPV (Cervarix) Tdap (Boostrix), Rotavirus (Rotarix)	GlaxoSmithKline www.gsk.com/products/vaccines.jsp	1-888-825-5249
PNU13 (Pevnar PCV13)	Pfizer www.pfizer.com	1-800-572-8221
Fluvirin , Meningococcal (Menveo)	Novartis www.novartisvaccines.com	1-800-244-7668
FluMist (LAIV)	MedImmune www.medimmune.com	1-877-358-6478

Sample documentation below

Vaccine Brand Name	Manufacturer	Lot Number	Expiration Date	Number of Doses	Manufacturer's Recommendation
DTaP (Tripedia)	sanofi pasteur (Aventis)	20034	12/1/2012	3	Spoke with Doreen, vaccine ok as long as it didn't freeze. None wasted.
VARICELLA (Varivax)	Merck	1234	12/1/2012	20	Spoke with Tim, must waste all doses. 20 doses wasted.
DTaHBIP (Pediarix)	GSK	64AA	12/1/2012	10	Spoke with Lucy, must use within three months. 10 doses marked with new expiration date.

Please attach additional sheets as needed.

