

COMPROMISED VACCINE HANDLING PROCEDURE

When it is discovered that vaccine has been stored at temperatures out of the acceptable range or compromised due to equipment failure, temperature change/out of range or shipping/handling incidents the Vaccine Coordinator or assistant needs to implement the following:

1. Check to be sure the refrigerator/freezer doors are closed tightly and the equipment is plugged in.
2. **Separate and label compromised vaccine.** Store the vaccines at appropriate temperatures. Make sure the refrigerator/freezer is working properly or move the vaccines to a unit that is.
3. **Do Not Discard the Affected vaccine.** Separate and mark the vaccine **“DO NOT USE”**, so the potentially compromised vaccines can be easily identified.
4. Report any out of range temperatures to supervisor or vaccine coordinator.
 - **DO Not assume the vaccines are viable/non-viable**
5. Fill out the **“Vaccine Incident Report and Return Form”** found in the *Cold Chain Policy* section of your immunization manual.
 - Instructions for the Vaccine Incident Report and Return Form are included in this section also.
6. **NOTIFY TCPHSS Immunization Program Immediately at (360) 867-2534 or 867-2548. Do not leave a message on voice mail, you need to talk directly to an immunization staff person.**
7. Call the manufacturer’s to inquire about compromised vaccine viability.

Toll free numbers for the manufacturers. Current as of March 2010.

GlaxoSmithKline	(866) 475-8222
MedImmune, Inc.	(877) 358-6478
Merck & Co., Inc.	(800) 672-6372
Novartis Vaccines	(800) 244-7668
Sanofi Pasteur	(800) 822-2463
Wyeth Vaccines	(800) 999-9384

8. Call Manufacturer and:

- Ask to speak with someone in the medical department.
- Explain what happened.
- Record the name of the person you spoke with.
- Requests a faxed copy of their instructions.

9. Completes the **“Vaccine Incident Report and Return Form”**.

10. Faxes a copy of the manufacturer’s instructions as well as the DOH **“ Vaccine Incident Report and Return Form”** to (360) 867-2608.
11. Documents compromised vaccine on the **“Required Monthly Vaccine Accountability Report”** under *“Doses Wasted, Expired, Compromised, Etc”*. column.
12. Returns viable vaccine to active inventory after the refrigerator/freezer is replaced, repaired or adjusted and stabilized.
13. Packages and groups all vaccine to be returned.
14. Returns wasted state supplied vaccine to McKesson per DOH **“Vaccine Incident Report Form Instructions and Guidelines”**.
- Includes original return form in the compromised vaccine package returned to McKesson.
 - Faxes copy to WA State Department of Health and Public Health and Social Services Immunization Program and keeps a copy for clinic file.
15. Notifies Supervisor or Vaccine Coordinator if there is a need to consider revaccination of clients who received potentially damaged vaccine.