A vaccine storage and handling incident is any event that may compromise vaccine viability.

This document provides guidance on the two most frequent types of vaccine incidents. These incidents are:

- Missing temperature recordings
- Temperature excursions

Relevant Vaccine Management Plans:

All providers are required to have routine and emergency vaccine storage and handling plans. Providers and their staff should review the plans each year and practice for incidents before they occur.

Missing temperature recordings:

The State and Centers for Disease Control and Prevention (CDC) require staff to review storage unit temperatures and record them at least twice a day. This assures vaccines stay at temperature and remain viable. Missing temperature recordings may expose vaccines to out of range temperatures. If recordings are missing, staff may need to:

1. Bag the vaccine.
2. Mark the vaccine with a "Do Not Use" label.
3. Contact the manufacturer.

Providers may have to replace vaccine losses resulting from missing temperature log recordings.

Guidance for Site Visit Reviewers Addressing Missing Temperature Recordings

When data is available from a data logger:

- Review data logger data or reports for the unit. If the data logger has recordings for the missing dates and the temperatures from the data logger are in range, the vaccine is considered viable. The staff should update the missing temperatures on the temperature log using the data logger data. There is no need for further action with the vaccine.
- The provider and their staff must receive education about the importance of recording temperatures twice a day for each vaccine storage unit.

When data is not available from a data logger:

The site visit reviewer should review the temperature logs in the current three month period. The site visit reviewer should assure:

- Trends from previous recordings indicate the storage unit functions properly.
- All recorded temperatures are in range.
- The thermometer in the unit has a current certificate of calibration.
- The temperature reading of the provider thermometer is in range.
- The site visit reviewer's thermometer temperature is in range.

If these criteria are met, there is no need for further action with the vaccine.

If these criteria are not met, the clinic staff must follow the protocol for managing a temperature excursion. The clinic staff must contact the vaccine manufacturer while the site visit reviewer is on site to determine viability of the vaccine. The provider and their staff must receive education about the importance of recording temperatures twice a day for each vaccine storage unit.

Power-outages or temperature excursions:

In the event of a power-outage or temperature excursion:

1. Reference your Vaccine Management Plan.
2. Label the vaccine as "Do Not Use".
3. Keep exposed vaccine separated from new vaccine. Keep all vaccines at the proper temperature.
4. Do not use the affected vaccine until you have consulted with the manufacturer.
5. Record the temperature in the unit right after finding the incident.
6. Leave the unit closed until the incident is over. Do not open units to repeatedly check temperatures, review digital data logger or temperature monitoring system.
7. Record the duration of the out of range temperature exposure. Record the MIN and MAX temperature.
8. Record all related information about the incident. Include the:
    - Time frame
    - Temperature recorded before the incident
    - Current temperature
    - Inventory of vaccines affected by vaccine type and lot number
    - Cause of the incident
9. Contact the vaccine manufacturer for consultation about the viability of the vaccine.
10. Contact DOH (WAChildhoodVaccines@doh.wa.gov) with the results from the manufacturer
11. Complete a Vaccine Incident Report. Update the inventory in the Immunization Information System (IIS).
12. If the storage incident continues, move the vaccine to a different facility. Receiving facilities must have storage units with backup power. Transport the vaccine following proper cold chain procedures. Reference the Packing Vaccines for Transport during Emergencies.
13. Contact a refrigeration service provider if the unit failed.
14. Continue to monitor refrigerator vaccine temperatures until they reach 36 to 45°F (2 to 8°C). Monitor freezer vaccine temperatures until they reach 5°F (-15°C).
15. Do not discard exposed vaccine. Providers must return non-viable state supplied vaccine to McKesson. Contact DOH for assistance with vaccine returns or review the Online Vaccine Returns Quick Reference Guide.

****Manufacturer Quality Control Office Telephone Numbers:**

• GlaxoSmithKline, 866-475-8222 or 888-825-5249, www.gsk.com	• sanofi pasteur, 800-822-2463, www.sanofipasteur.us
• Merck, 800-609-4618 or 800-672-6372, www.merckvaccines.com	• Wyeth, 800-999-9384, www.wyeth.com
• Massachusetts Biological Labs, 617-474-3000 or 617-983-6400	