Policy & Procedure Title	Storage and Handling-Cold Chain Failure	**Issuing Date**	07/17/2012
Policy & Procedure Number	11	**Revision Date**	02/05/2020
Policy & Procedure Approval Authority	Dave McCormick		

Policy Statement

Vaccines must be stored properly from the time they are manufactured, throughout the delivery process, until the time they are administered. Failure to maintain the cold chain of vaccines due to shipping delays, power outages, equipment failure and human error may cause vaccines to become ineffective**.**

If any vaccine is determined to have been exposed to temperatures outside the established temperature ranges for storage and handling requirements, steps must be **immediately** taken to ensure the viability of all vaccine. The following procedures and corrective actions should be followed to resolve vaccine cold-chain failures:

- Notify the primary or backup VFC coordinator
- Label the affected vaccines *Do Not Use.* Do not discard these vaccines
- Document the details of the excursion
    - Date and time
    - Storage unit temperature and room temperature during the event
    - Length of time the unit was out of range
    - Any problems with the storage unit/vaccines before the event
    - Any other relevant information
- Contact your Regional Quality Assurance Specialist or the IDOH Immunization Division
- Contact the vaccine manufacturers to check on the viability of the vaccines
    - Be prepared to give them all documentation, including data logger data
- Address the root cause of the temperature excursion
    - Check power supply, unit doors, thermostat settings, placement of the glycol probe
    - If the storage unit has failed, implement the emergency vaccine SOP found in the Vaccine Management plan. Never allow vaccines to remain in a non-functioning unit

  Providers must receive a case number before they can resume using the affected vaccines. If the manufacturers are closed (i.e. for the holidays) vaccines cannot be used until a case number is obtained.

- Providers should report all incidents of vaccine cold-chain failure, within 24 hours, to the Immunization Division (800)-701-0704.
    - *If the cold-chain failure occurred during shipping, the provider must report the incident to the Immunization Division within two hours of delivery.*
- For all vaccines determined to be non-viable by the vaccine manufacturers, the provider must report the wastage in VOMS and request a shipping label.

After an unexplained temperature excursion, causing vaccine loss, proof of at least 5 days of in-range temperatures need to be provided to IDOH to establish that the unit is stable and operating properly. A root

cause analysis (RCA) to find out why the excursion occurred is also required. Additional days in-range reports may be required depending upon the reason for the temperature excursion.

Providers should never discard or return any vaccine unless they are instructed to do so by the vaccine manufacturer or Immunization Division.

The Immunization Division has developed a Refrigerator/Freezer Temperature Log to assist providers in tracking storage unit temperatures in order to determine if there has been a temperature excursion. By using this visual temperature log, providers can easily track storage unit temperatures in either Celsius (C°) or Fahrenheit (F°).

The temperature log directs providers to record problems on the reverse side of the log. Providers should document all actions taken and outcomes if temperatures are recorded above or below the required temperature range.

The log also provides the Vaccine Manufacturer contact information to assist providers if calls must be made to the manufacturer to determine vaccine viability.

References & Resources

Refrigerator/Freezer Temperature Log
https://www.in.gov/isdh/files/ISDH%20Temperature%20Logs%201-31%20Fridge-Freezer%20with%20Min-Max%20(v%204-15-2018).pdf

Revision History
07/17/2012, Created
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