

Policy & Procedure Title	Storage and Handling-Temperature Requirements	Issuing Date	07/17/2012
Policy & Procedure Number	9	Revision Date	07/03/2018
Policy & Procedure Approval Authority	Dave McConnick		

Policy & Procedure Summary

There are few immunization issues more important than the appropriate storage and handling of vaccines. The success of efforts against vaccine-preventable diseases is attributable in part to proper storage and handling of vaccines.

Vaccines must be stored properly from the time they are manufactured until they are administered. Proper maintenance of vaccines during transport is known as the cold chain. A proper cold chain is a temperature-controlled supply chain that includes all equipment and procedures used in the transport and storage and handling of vaccines from the time of manufacturer to administration of the vaccine.

Vaccine storage equipment should be selected carefully, used properly, maintained regularly (including professionally serviced when needed), and monitored consistently to ensure the recommended temperatures are maintained.

Policy Statement

This policy supersedes all policies previously issued by the Indiana Immunization Division addressing the storage unit requirements and temperature monitoring for publicly funded vaccine. It replaces the following policy:

Title of Policy: **Refrigeration/Freezer Standards for Vaccine Storage**
 Policy Number: II-02
 Creation Date: Feb 18, 2009

Providers must maintain temperatures for all publicly funded vaccine in accordance with the following requirements:

Temperatures Requirements

Maintaining accurate temperatures are a critical part of ensuring vaccine maintains viability. Vaccines not stored at the proper temperature may not be viable and do not deliver the desired protection from disease. Providers receiving publicly funded vaccine must adhere to all of the following **requirements** for temperatures:

- All inactivated vaccines require refrigerator storage temperatures between 36°F and 46°F (2°C to 8°C), with a desired average temperature of 40°F (5°C).
 - The following live attenuated vaccines must also be kept at refrigerator temperature: influenza (LAIV, FluMist); and rotavirus (RV1, Rotarix and RV5, RotaTeq).
 - Review each manufacturer's instructions in the product information for vaccine specific storage temperatures.
- All varicella-containing vaccines must be stored in a continuously frozen state at the manufacturer recommended freezer temperature (+5°F (-15°C) or colder not to exceed -50°C) until administration. Varicella-containing vaccines (VAR, Varivax; MMRV, ProQuad; ZOS, Zostavax) are sensitive to temperature excursions.
- Varicella-containing vaccines may be transported and stored at refrigerator temperatures, between 36°F and 46°F (2°C to 8°C), for up to 72 continuous hours *prior to reconstitution*. Varicella-containing vaccine stored at refrigerator temperatures must be discarded if it is not used within 72 hours.
 - Discard reconstituted vaccine if it is not used within 30 minutes.
- The use of **dry ice is not allowed**, even for temporary storage. Dry ice may subject varicella-containing vaccine to temperatures colder than -58°F (-50°C).

- If the vaccines must be transported at refrigerated temperatures, follow these steps (Please note: this is considered to be a temperature excursion):
 1. Place a calibrated, glycol-encased, thermometer probe in the container used for transport as close as possible to the vaccines
 2. Place the vaccines in the freezer between -58°F and +5°F (-50°C and -15°C) and label “DO NOT USE” immediately upon arrival at the alternate storage facility. Contact the vaccine manufacturer prior to using varicella vaccine that has experienced the temperature excursion
 3. Document:
 - a. The time the vaccines are removed from the container and placed in the alternate storage unit and the time the vaccines are removed from the storage unit and placed in the container
 - b. The temperature at the beginning, during and end of transport

This policy prohibits providers from refreezing varicella-containing vaccines that are stored at refrigerated temperatures, so please plan accordingly with your vaccine doses.

Do not discard any unused vaccine without first contacting the manufacturer, and the Indiana Immunization Division at (800) 701-0704.

Please refer to the Storage & Handling Transporting Vaccines & Off-site Clinics (policy number 12) for the procedures for maintaining refrigerated temperatures for the varicella-containing vaccines.

Temperature Monitoring Devices

Temperature monitoring devices are a critical part of storage and handling practice. Providers receiving publicly funded vaccine must adhere to all of the following **requirements** for data loggers:

- Must have a certified, calibrated digital data logger in both the refrigerator compartment and the freezer compartment.
 - Must maintain Certificate of Traceability and Calibration for each data logger.
 - This documentation is included with the data logger upon issuance/purchase.
 - Must maintain current certification and calibration of each data logger.
 - Must be a continuous temperature monitoring device such as a data logger
- Pharmaceutical/Purpose Built Storage Units with Built-In Temperature Monitoring OR a dedicated port that dictates placement of the probe.
 - Built in thermometer(s) must be certified and calibrated.
 - Must monitor temperatures in the refrigerator and freezer compartments individually.
 - Must maintain Certificate of Traceability and Calibration for built in thermometer(s).
 - CDC recommends placement of buffered probes in a central location, however placement in other locations may be suitable.

Primary Temperature Monitoring Devices

As of January 1, 2015, The Indiana State Department of Health, Immunization Division requires the use of data loggers. Data loggers collect vaccine storage unit temperature data 24 hours a day, 7 days a week. **After 2017, the Immunization Division will no longer supply data loggers. Providers are expected to use 2017 to prepare and budget for the purchase of a data logger (both primary and back-up data loggers).**

Data loggers allow for improved temperature accountability and will assist in decreasing the amount of wasted VFC vaccine due to unknown storage unit temperatures. Data loggers will also assist providers and ISDH Immunization Division in assuring the storage units in use have stable temperatures and therefore, that viable vaccine is being administered to children. Data loggers are mandatory for any storage unit that contains publicly funded vaccines. Data loggers/continuous monitoring devices are mandatory for temperature monitoring for all storage units that contain publicly funded vaccines.

Indiana State Department of Health Immunization Division requires data loggers to have the following characteristics:

- Alarm for out-of-range temperatures
- Display current, minimum and maximum temperatures
- Low battery indicator
- Accuracy of +/- 1° F (0.5° C)
- Memo stores at least 4,000 readings; device will not write over old data-stops recording when memory is full
- User programmable logging intervals (or reading rate)
- CDC also requires the use of a detachable, buffered probe.

Back-up Temperature Monitoring Devices

Beginning January 1, 2018, providers enrolled in any publicly funded vaccine program must have at least one back-up data logger with a valid and current certificate of calibration readily available to ensure that temperature assessment and recordings can be performed twice a day. If the data logger is unit specific, a back-up data logger will be required for each unit. The data logger must be maintained on-site, unless approval by ISDH has occurred.

ISDH will not supply providers with a back-up data logger. Providers were expected to use 2017 to prepare and budget for the purchase of at least one back-up data logger.

Temperature Monitoring

- Regular temperature monitoring is vital to proper cold chain management.
- Temperatures in both the freezer and refrigerator units should be read twice each day, once in the morning and once before leaving at the end of the workday**. This documentation must include the initials of the person conducting the reading, and the date/time the temperature reading was taken.
- The minimum/maximum temperatures must be checked and documented once per day, preferably in the morning. Reviewing the minimum/maximum temperatures helps to ensure that temperature excursions will be identified more quickly.
- Data loggers must be downloaded and all data saved bi-weekly. Immunization Field Representatives may require temperature downloads from providers at any time, and require providers to send temperature downloads bi-weekly.
- Data loggers must be downloaded and all data saved any time a high or low temperature alarm is activated. Download the data immediately, even if it is not the scheduled download time.
- A temperature log must be posted on the door of the storage unit where the twice daily temperature readings and the minimum and maximum readings are recorded
- Temperature logs must be kept for at least 3 years. As the storage unit ages, recurring temperature variances or problems can be tracked and documented. This data can be important when evaluating the need for a new storage unit or if there is a potential need to recall and revaccinate patients because of improperly stored vaccine.
- Data logger probes should be placed in central area¹ of storage unit.
- Prior to storing vaccines in a unit, the temperature should be allowed to stabilize and then be measured in various locations within the unit to document that a consistent temperature can be maintained. This can detect if there are any particular cold or hot spots where vaccine should not be placed, as well as determining where the most reliable, consistent thermometer reading can be obtained. New units may need 3-5 days of operation to establish a stable operating temperature prior to storing the vaccine in the new unit.

¹ In a pharmaceutical or purpose-built unit (e.g. designed specifically to store vaccines), CDC recommends thermometer placement in a centralized location, but placement in other locations may be suitable because pharmaceutical units maintain more consistent temperatures throughout the unit.

- If at any time it is discovered that stored vaccines have been exposed to temperatures outside the recommended ranges, these vaccines should remain properly stored, but segregated and marked “Do NOT Use” until guidance can be obtained.
- After a temperature excursion, proof of at least 5 days of in-range temperatures need to be provided to ISDH 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.
- Contact the immunization program, vaccine manufacturer(s), or both for guidance.
- Providers will need to conduct a recall to revaccinate patients who receive a dose of non-viable vaccine.

**Providers enrolled in the publicly-funded vaccine program have the option of submitting a proposal to the Director of Field Operations to have temperatures recorded and documented twice daily with an electronic temperature monitoring device. Contact the Immunization Division for more instructions on submitting a proposal.

References & Resources

Centers for Disease Control and Prevention. (2018) Vaccine Storage and Handling Toolkit, Revised January 2018.
<https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf>

Centers for Disease Control and Prevention. (13th Edition) Epidemiology & Prevention of Vaccine-Preventable Diseases, Pink Book. Revised 2015. <http://www.cdc.gov/vaccines/pubs/pinkbook/index.html>

Refrigerator/Freezer Temperature Log

Storage and Handling-Storage Unit Requirement Policy 8

Storage and Handling-Transporting Vaccines & Off-site Clinics Policy 12

Revision History

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03/01/2014, Revised
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