Indiana Department of Health-Immunization Division

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Policy & Procedure Title	Storage and Handling-Temperature Requirements	**Issuing Date**	07/17/2012
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Policy & Procedure Approval Authority	Dave McCormick		

Policy Statement

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.

Maintaining accurate temperatures is a critical part of ensuring vaccine viability. Vaccines not stored at the proper temperature may not be viable and will not deliver desired protection from disease.

Temperatures Requirements

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 of between +5°F and -58°F (-15°C to -50°C) until administration. Varicella-containing vaccines (VAR, Varivax; MMRV, ProQuad; ZOS, Zostavax) are sensitive to temperature excursions.

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 temperature monitoring device in both the refrigerator and the freezer.
    - Must maintain Certificate of Traceability and Calibration for each data logger.
        - This documentation is included with the data logger upon purchase.
    - Must maintain current certification and calibration of each temperature monitoring device.
    - Must be a continuous temperature monitoring device such as a digital data logger
- For 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. Check with the storage unit manufacturer for more information.

Primary Temperature Monitoring Devices

Data loggers allow for improved temperature accountability and will assist in decreasing the amount of wasted VFC vaccine. 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/continuous monitoring devices are mandatory for all storage units that contains publicly funded vaccines.

If the provider has a 24/7 offsite-monitored device that does not have a display, the battery-operated backup data logger should also be on the unit. If power is lost, the 24/7 offsite-monitored device will go off-line and will be unable to monitor temps.

Indiana 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)
- Stores at least 4,000 readings; device will not write over old data, but stops recording when memory is full
- User programmable logging intervals (or reading rate)
    - Must be programmed to measure and record temperatures at least every 30 minutes
- 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.

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. Data logger reports must be sent to the Ordering and Accountability Specialist monthly. The Immunization Division may require temperature downloads from providers at any time.
- Data loggers must be immediately downloaded and all data saved any time a high or low temperature alarm is activated.
- 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 area[1] 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 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 and units that have been moved will need five days of operation to establish a stable operating temperature prior to storing the vaccine in the unit.

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[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. Check with your storage unit manufacturer for more information.

**Providers enrolled in the publicly-funded vaccine program have the option of submitting a proposal to the Quality Assurance Coordinator 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.

- 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 needs 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.
- 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.

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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