

Indiana Department of Health-Immunization Division

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 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 cold or hot spots where vaccine should not be placed, as well as determining where the most reliable,

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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.

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

07/17/2012, Created
03/01/2014, Revised
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