Temperature Monitoring (revised 6/14/2019)

Device Requirements:

All VFC providers are required to have data loggers in all vaccine storage units. Alarm systems are highly recommended.

1. Use of a calibrated data logger with a current Certificate of Traceability and Calibration Testing (also known as Report of Calibration) is required in all vaccine storage units that store VFC vaccine.
    a. Certification usually lasts 1-2 years from the calibration date.
    b. Advice on recalibration schedules will vary but the generally agreed upon industry standard is an annual (yearly) re-calibration schedule. If a manufacturer recommends a different schedule you should follow that schedule; however, CDC requires that calibration certificates not exceed two years.
    c. When purchasing data loggers consider the cost of recalibration as well as purchase price. Periodic replacement may be more cost-effective than recalibration.

2. The calibration certificate must contain:
    a. Model/device name or number
    b. Serial number
    c. Date of calibration (report or issue date)
    d. Confirmation that the instrument passed testing (or instrument in tolerance)
    e. VFC Optional Element: Recommended uncertainty =+/- 0.5°C

3. Digital data loggers must have the following capabilities for continuous temperature monitoring and recording:
    a. Alarm for out-of-range temperatures
    b. Current, minimum and maximum temperatures
    c. Low battery indicator
    d. Accuracy of +/- 1°F (0.5°C)
    e. Memory stores at least 4,000 readings; device will not write over old data – stops recording when memory is full
    f. User programmable logging interval (or reading rate); CDC recommends a temperature recording interval of one reading at least every 30 minutes.
    g. Detachable probe in bottle filled with a thermal buffer.

    Providers are responsible for maintaining valid certificates of calibration for all data loggers. Download and review data from data loggers weekly. Save the actual data files, not just the graphs. Install new batteries at least every six months on all data loggers.

4. CDC recommends that data loggers utilize a probe that is immersed or inserted in: 1), a vial filled with liquid (e.g. glycol, ethanol, glycerin) or a loose media (e.g. sand, glass beads) or 2), a solid block of material (e.g. Teflon®, aluminum). The probe must be placed in a central area of the storage unit with the vaccines. The ONLY allowable exemption to the thermometer placement requirement is for providers who have pharmaceutical storage units (built for vaccine storage) that have either (1) a built-in thermometer (in 2017, this thermometer must be a data logger) OR (2) a dedicated port for the probe that dictates the placement of the probe. Keep in mind that glycol or liquid probes take longer to adjust to the unit temperature so be sure to check frequently until stable.

5. Providers are required to have a backup data logger on hand for use if the current data logger is no longer working appropriately or calibration testing of the current equipment is required. Make sure your backup thermometer can be set up in an emergency (i.e., power outage). Probes for backup thermometers must be kept in a refrigerator or freezer so that they will be pre-conditioned in case of emergency use. If only one back up thermometer is available, the probe must be stored in a refrigerator.

   The reason a backup data logger is required is to prevent or limit the amount of time required to have a temperature monitoring device/mechanism in place to prevent loss of temperature data. Providers should maintain the backup on-site. If a backup thermometer is not physically on-site there must be a plan for how the backup thermometer will be accessed if needed. It must be accessible 24 hours per day and no further than 30 minutes from the site. Plans for accessing a backup thermometer must be approved by the LHD/MDHHS to ensure the plan is reasonable and feasible. The details of the approved plan must be included in the provider's routine vaccine management plan.

Temperature Monitoring Documentation

REQUIRED VFC REFRIGERATOR TEMPERATURES:
36.0 F - 46.0 F (2.0 C – 8.0 C)
Aim for a mid-range temperature of 41.0F (5.0 C)

REQUIRED VFC FREEZER TEMPERATURES:
-58.0 F to +5.0 F (-50.0 C to -15.0 C)

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1. The following information must be documented on a temperature log posted on each refrigerator and freezer unit:
   a. time and temperature readings
   b. initials of the person documenting these readings

   MDHHS temperature logs are available at www.michigan.gov/vfc

   Providers may use temperature logs similar to those supplied through the MDHHS VFC Program or another form that has been approved by your LHD.

2. Assess and record **twice** daily temperatures, including **min/max** once daily. Temperatures must be assessed using a certified calibrated data logger; Document *exact* temperatures and assess if within range. Required temperature checks include:
   a. When clinic opens (AM temps)
      1. Current temp
         AND
      2. Min/max temp
   b. 30-60 minutes before leaving for the day (PM temps)
      1. Current temp

   CDC requires reviewing and recording **minimum and maximum** temperature readings at the beginning of each workday. This helps ensure temperature excursions are identified quickly and corrections made to prevent vaccine loss. Daily MIN/MAX recordings are required for all VFC providers. Staff should be trained on how to properly record MIN/MAX.

3. Out-of-range temperatures (current, min, or max) are considered temperature excursions and require immediate action. All out-of-range temperatures must be documented on temperature logs and must be reported to your LHD immediately. Do not round temperatures to determine if an excursion was or was not a valid excursion: Due to

differences among manufacturer stability reports regarding rounding (or lack of rounding), do not apply rounding rules without first contacting the applicable vaccine manufacturer to obtain their guidance. Additional excursion steps are as follows:

- Vaccine manufacturer(s) must be contacted for decisions on viability before administering vaccine exposed to out-of-range temperatures. The provider must stop vaccination from the unit in question while verifying if the vaccine is viable. Reports can then be provided to the LHD and further guidance obtained. Refer to your Emergency Response Plan document for manufacturer contact information and to implement further emergency actions if necessary. Detailed documentation of all actions taken as a result of out-of-range temperatures is required. If any vaccine loss is incurred, refer to the MDHHS VFC Vaccine Loss Policy.
- For guidance on fluctuations in temperature related to auto defrost cycles, see Frost-Free Defrost Cycle Guidance at the end of this section.

4. Temperature logs and associated documentation must be retained and available in the agency for at least three years.

5. Submit temperature logs to the Local Health Department monthly and with orders.

Electronic or Wireless Monitoring Systems

Wireless or electronic continuous temperature monitoring systems allow a clinic to monitor refrigerator and freezer temperatures in real-time on a remotely connected PC (and in some cases, via internal network or intranet). Wireless systems are best suited for clinics with multiple refrigerators and freezers and the need to remotely monitor and graph temperatures. These systems alert staff to a temperature excursion in real time via cell phone, pager or e-mail. Please note: a wireless system does not preclude you from continuing to check your temperatures twice a day.

1. Wireless or electronic monitoring systems must:
    a. Have a current and valid certificate of calibration
    b. Continuously assess and record temperature readings
    c. Be alarmed and the alarm is set for the appropriate temperature range for the storage unit
        i. 36.0-46.0º Fahrenheit (2.0-8.0º Celsius) for refrigerators
        ii. Maximum of 5.0 º Fahrenheit (-15.0º Celsius) for freezers
    d. Provide daily data on temperatures in readable and interpretable printed form upon request
    e. Record the time and date of assessment of twice daily temperature readings, including morning min/max. These temperature assessments must include name/initials of person assessing temperatures as well as the time of assessment. If not included in the electronic form, then temperature readings must be printed twice daily and these details added to the printout. Electronic records and/or paper printouts must be maintained on file by the provider for at least three years.
    f. Have calibration certificates for all probes used in all units

2. Providers who utilize electronic or wireless temperature monitoring systems must have specific protocols and systems for:
    a. Training provider staff on proper use and interpretation of data using a continuous temperature monitoring and recording device
    b. Monitoring temperatures, ensuring that the temperatures are assessed and recorded twice daily, including AM min/max; AM assessment includes current

temperature and AM min/max (when the clinic opens), and the PM assessment includes current temperature (30-60 minutes before leaving for the day). All temperature assessments must also include the exact time and the name/initials of the person assessing temperatures.

   c. Manually monitoring temperature when the continuous temperature monitoring and recording system is not working
   d. Testing alarm function on a monthly basis
3. When submitting temperature reports for vaccine orders, electronic reports must be:
   a. a readable and interpretable format listing the required daily temperature documentation outlined above

Temperature Monitoring Alarm Systems

A temperature monitoring alarm system will alert when the temperature goes out of the set range, however, it does not provide a permanent record of the temperature so it cannot replace the required use of a data logger. CDC and MDHHS recommend that a continuous-temperature monitoring alarm notification system be in place in **conjunction** with data loggers. Alarm systems are required for LHDs.

1. Alarm system limits should be set at 36.0 – 46.0º F (2.0 - 8.0º C) for the refrigerator and a maximum of 5.0º F (-15.0º C) for freezer.

2. Alarm system must be co-located in the center of the storage unit with vaccines and the certified, calibrated thermometer probe.

3. If an alarm system is in place, it must be calibrated to the certified thermometer at least weekly to ensure the two devices function compatibly and accurately. It is best to check the calibration of the alarm system with the thermometer after the unit has been closed for an extended period of time.

4. Occasional slight discrepancies in temperatures may occur during calibration checks due to the data logger capturing temperatures at specific intervals (e.g., every 30 minutes.) If the discrepancy is more than 3.0º F (1.5º C) from the reading on the certified thermometer, make adjustments and document in detail all actions taken.

5. An alarm system should be tested at least once a month to assure it is working correctly. Expose the probe to temperatures out of range and verify call out is working and numbers are accurate for staff assigned to respond.

Monitoring Private Stock Refrigerator/Freezer Units

If a provider is borrowing vaccine and they store their private stock vaccine in separate vaccine storage units, their private stock vaccine storage units must comply with all VFC requirements (use of calibrated data loggers, temperature checked twice a day and documented on a temperature log, etc.) and must be inspected at the time of a VFC compliance visit. We need to ensure that vaccine replaced to the VFC program from private stock has been stored appropriately and is viable for use in VFC patients.

Frost-Free Automatic Defrost Cycle Guidance

Providers utilizing a frost-free freezer may experience regular defrost cycles which cause a brief temperature fluctuation. All out of range temperatures require data review, and the following guidance may be utilized to evaluate if a defrost fluctuation is considered supported or

unsupported. Supported cycles do not require standard excursion follow-through if all criteria are met. They do, however, require documentation of details provided to the LHD. Unsupported cycles require standard excursion follow-through (stop vaccination, contact manufacturers and LHD, etc.).

This guidance is **only applicable to automatic defrost cycles of frost-free freezers** (Not manual defrost or household units). For temperatures briefly out of range on automatic defrost freezers, providers must download and review data to evaluate the cycle as follows:

Supported: A defrost cycle is considered supported if **all the following criteria are met**:

- The maximum temperature reached during cycle does not exceed 0C/32F.
- The number of defrost cycles within 1 day does not exceed 4 cycles.
- Each defrost cycle does not exceed 60 minutes.
- Temperatures must be documented as assessed, with notes added to temperature logs (or separate page) for LHD review.
    - Notes should indicate “defrost: max temp reached, length of time” (If notes are not included, VFC orders may be delayed)
- LHD may request graphs/data to support provider assessment of defrost cycles

Unsupported: A defrost cycle is unsupported if it **does not meet all above criteria.**

- Unsupported cycles require follow through according to standard excursion measures and emergency response plan.
    - Provider must contact manufacturer, and all documents, including follow-up, must be provided to the LHD immediately following the excursion. Do not use vaccine until LHD has provided guidance.
- Unsupported cycles should be investigated for cause: consider having unit serviced or replaced, water bottles added or removed, etc.