MDHHS Guidance for Responding to Vaccine Storage Unit Temperature Excursions

Important reminders regarding temperature excursions:

- ANY out-of-range temperature is considered an excursion and requires immediate action
- Providers are responsible to follow up on excursions, and Vaccines for Children (VFC) providers must notify their Local Health Department (LHD)
- If you are not confident in identifying or responding to an excursion, contact your LHD for assistance
- Do not use vaccine exposed to out-of-range temperatures until you have received guidance from the vaccine manufacturer and documented that guidance, or the LHD advises you to do so
- Each event is unique; the manufacturer recommendations during an excursion are based on existing stability data and cannot be applied to future events that seem to be similar
 - Therefore, all excursions require appropriate notification and follow up to ensure vaccine viability determinations are made

If any temperature is out of range, follow these steps: Identify and Notify

- 1. Stop vaccinating with any vaccine that may have experienced an excursion
- 2. Notify other staff by placing exposed vaccine in a separate paper bag within the unit and label "DO NOT USE;" remember, do not discard vaccine(s)
- 3. Notify your clinic's Primary/Backup Vaccine Coordinator and/or supervisor
- 4. Implement immediate corrective action (shut door if left open, resupply power, etc.)

Download and Evaluate Details of Event

- 5. Download the data logger and review all the data; prepare this information to share with each vaccine manufacturer and the LHD (the manufacturer will utilize the data and look at the cumulative exposure time/temperatures when determining vaccine stability)
- 6. Document all details of the event; VFC providers must notify their LHD and provide temperature excursion data if VFC stock is involved
- 7. If unit is not stabilizing, implement Emergency Plan for transport to backup location/unit. Utilize CDC's guidance when packing for emergency transport, and always transport with data loggers.
 - Ensure appropriate transport; see MDHHS Guidance on Vaccine Transport.
 - For packing refrigerated vaccine in an emergency, see CDC Guidance on Packing Vaccines for Transport During Emergencies.
 - Print and utilize <u>Transport Temperature Logs</u>.

Contact Manufacturers and LHD

- 8. Contact every vaccine manufacturer for each vaccine in question to obtain a decision on vaccine stability (the vaccine manufacturers will request excursion temperatures/time/vaccines, etc.)
- 9. Contact the LHD and provide all documentation, including manufacturer reports—details for vaccine losses can be reviewed in the Michigan Department of Health and Human Services (MDHHS) VFC Loss Policy at www.michigan.gov/vfc

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Manufacturer Contact Information:

• Dynavax: 1-844-375-4728

• GlaxoSmithKline: 1-888-825-5249 or

www.gskusmedicalaffairs.com

• MedImmune: 1-877-633-4411

• Merck: 1-800-672-6372

Pfizer: 1-800-438-1985

 Sanofi Pasteur: 1-800-822-2463 or www.sanofiusmedicalinformation.com

Segirus: 1-855-358-8966

Digital Data Logger Reminders:

Check device calibration, and see if it may be due for recalibration or replacement

- Keep extra batteries on hand, and have a backup digital data logger available in case of malfunction or need of calibration
- All data logger requirements are outlined at <u>www.michigan.gov/vfc</u> under "Temperature Monitoring"

Refer to These Resources for More Information:

- CDC Storage and Handling Toolkit: www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html
- MDHHS guidance for storage and handling can be found at: <u>www.michigan.gov/vaccinequicklooks</u>
- MDHHS VFC Resource Guide: www.michigan.gov/vfc
- Your Local Health Department VFC Contact