

Vaccine Management Standard Operating Procedure (SOP) Template

Purpose: To ensure the vaccine cold-chain is maintained for optimum potency.

Instructions:

- Review and update document annually, when vaccine management policies change, and when staff with designated vaccine management responsibilities change.
- Post on or near vaccine storage unit(s).
- **All staff handling vaccines including only in emergency settings must read, sign, and adhere to the protocols described in this document.**

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|-----------------------------|-------------------|
| Office/Practice Name | Pin Number |
|-----------------------------|-------------------|

Vaccine Coordinators

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|---|--|--|
| | Primary Vaccine Coordinator | Back-Up (Alternate) Vaccine Coordinator |
| Name | | |
| Phone Number | | |
| Email Address | | |
| Date of VFC Compliance and Vaccine S&H Training | Date: <input type="checkbox"/> in-person <input type="checkbox"/> webinar <input type="checkbox"/> conference | Date: <input type="checkbox"/> in-person <input type="checkbox"/> webinar <input type="checkbox"/> conference |

*Notify the Vaccine Management Unit within 10 days if a new Primary Vaccine Coordinator or Backup is identified.

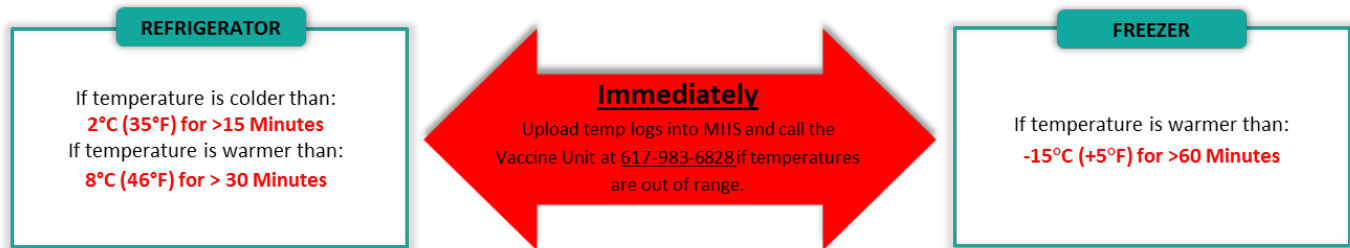
Emergency Vaccine Storage Location

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| Location Name | |
| Location Address | |
| Contact Name: | |
| Contact phone # | |
| Does the vaccine storage location have a pharmaceutical grade refrigerator for storage? | |
| Date of confirmation that location is still available for use as a back-up location: | |

Additional Contact Information (ex. Nurse Coordinator, pharmacist, maintenance, etc.)

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Vaccine Storage & Handling



- Refrigerators/freezers designated for vaccine storage are required to maintain the proper temperature.
- **Pharmaceutical-grade refrigerators are required for refrigerated vaccine storage** for all facilities that administer at least some vaccines to those <19 years of age, excluding sites that only administer flu vaccine. This requirement applies to all state-supplied vaccine storage units.
- **The use of any household combination refrigerator/freezer unit for storage of any vaccines including temporary storage is strictly prohibited.**
- Refrigerated vaccines should be stored within the temperature range of **2° C to 8° C** in a pharmaceutical-grade refrigerator designated for vaccine storage only.
- Varicella and MMRV vaccine must be stored in a stand-alone freezer that maintains a temperature between **-50° C and -15° C**. Store **MMR vaccine in the freezer** to reduce the likelihood of a vaccine loss due to a refrigeration issue.
- Do not store anything on top of the storage unit which could prevent the door from completely closing.
- Rotate stock ensuring that short-dated vaccine is used first.
- Mark or identify inventory to differentiate state-supplied and privately purchased vaccine.
- Place the digital data logger probe in a central area of the refrigerator and freezer unit affixing it to the shelf, adjacent to the vaccine.
- Do not store food or beverages in vaccine storage units.
- **Store vaccines centrally in the refrigerator or freezer**, and away from walls to allow for proper air circulation. There should be sufficient space between rows of vaccine boxes or bins and shelving units to allow proper air circulation. Do not over crowd refrigerators, especially during flu season.
- **Store cold/gel packs in the refrigerator** as part of your emergency preparedness, in case the need arises to transport vaccine during an emergency.
- Stabilize freezer temperatures by placing freezer packs where there is empty space.
- Post a “DO NOT UNPLUG” sign next to the electrical outlet for all vaccine storage units and post a “DO NOT DISCONNECT” sign next to the circuit for any vaccine storage units on the circuit breaker.
- Plug all vaccine storage units directly into a wall outlet. Check with electrician to see if a ‘dedicated line’ is needed for your refrigerator(s).
- Never plug storage units into power strips, surge protectors or use extension cords. Never plug storage units into Ground Fault Circuit Interrupter outlets (GFC), generators or battery pack.
- Vaccine must be moved before servicing or defrosting your storage units, contact the Vaccine Management Unit for guidance

Temperature Monitoring

- All vaccine storage units holding state-supplied vaccines must be monitored by a digital data logger. The digital data logger must have a calibrated glycol-encased probe and be certified by an appropriate agency (e.g. National Institute of Standards and Technology).
- Monitor refrigerator/freezer daily minimum and maximum temperatures and acknowledge twice daily by **pressing the read button on the Fridge Tag 2L data logger**. The read button must be pushed four times in the AM and two times in the PM to fully review and acknowledge all temperatures. Other monitoring systems

must have this capability and will need prior authorization to be used by the MDPH Vaccine Management Unit. A certificate of calibration must be kept on file.

- If your state-supplied data logger is broken, call the Vaccine Management Unit for immediate replacement.

Vaccine Receiving

- Staff receiving shipments (front office, loading dock, reception, etc.) must notify the vaccine coordinators as soon as a vaccine shipment arrives.
- Open shipping container immediately upon arrival. Check the two transit temperature monitors for those shipments sent from McKesson. If temperature monitors indicate a possible temperature deviation, contact McKesson Specialty at (877) 822-7746 and the Vaccine Management Unit by the end of the day.
- For direct ship vaccines from Merck, check the shipment date located on the packing list. Varicella shipments can be sent in a 2-day or 4-day box. MMRV shipments are always shipped in a 24-hour box. Contact Merck Order Management Center by the end of the day of receipt (800-637-8579) and the Vaccine Management Unit if date received is greater than the shipper insert indicates.
- Count vaccines in shipment and compare with packing list and original order to make sure the order and delivery is correct. Check to ensure that expiration dates and lot numbers match. Make sure diluent is also accounted for.
- Ensure that all containers noted on the packing list have been delivered. **Retain packing lists for 3 years.**
- Place vaccine in the refrigerator/freezer designated for vaccine storage immediately after an inventory of the shipment is completed.
- Contact the Vaccine Management Unit immediately for guidance if there are any concerns or inaccuracies with the vaccine order.

Vaccine Transportation Procedures

- Contact the Vaccine Management Unit whenever you are considering transporting state-supplied vaccines outside of your facility to ensure you have the most relevant guidance and advice for your specific situation.
- Obtain and store an adequate number/amount of appropriate packing containers and materials (e.g., frozen and refrigerated gel packs, bubble wrap) needed to pack vaccines for safe transport.
- If a site is transferring all of their vaccine due to a power outage or refrigerator malfunction, they must ensure that the **primary data logger is always kept with state-supplied vaccine.**
 - In cases where you are transporting a smaller amount of vaccine because you are transferring doses to another site, call the Vaccine Management Unit for more guidance.
- Use separate packing containers for refrigerator stored vaccines and freezer stored vaccines. Label outside of packing container 'Must Store in Refrigerator' or 'Must Store in Freezer'.
 - **Refrigerated gel packs** should be placed in the container used to transport refrigerated vaccines. **Separate the vaccine from the cold packs with cardboard and /or bubble wrap. Never place frozen gel packs or ice packs with refrigerated vaccines.**
 - Frozen gel packs should be placed in the container to transport frozen vaccines. **(Dry ice is not recommended for the transport of frozen vaccines. It is too cold.)**
- Place the glycol bottle in each packing container near the vaccine to monitor the temperatures. Ensure that the cord of the glycol bottle is attached to the digital data logger.
- Record the time and temperature when vaccine was removed from the storage units and placed in the containers at the beginning and end of the transport on the *Temperature Troubleshooting log*.
- **Transport of vaccines is considered a temperature excursion**
 - Do not administer the vaccine
 - Upload the temperature log into the MIIS
 - Contact the Vaccine Management Unit with the amount of time that vaccine was out of a refrigerator or freezer and the warmest and coldest temperatures recorded.
- Do not discard vaccine without contacting the Vaccine Management Unit for guidance.

Vaccine Ordering and Inventory Control

- Place vaccine orders through the MIIS Vaccine Management Module and upload the most recent temperature logs for all vaccine storage units within one day of submitting your order.
 - Upload all temperature logs monthly even if you are not placing monthly vaccine orders. Data loggers only hold 56 days of temperatures.
- Complete a physical inventory of all vaccines in the refrigerator(s) and freezer(s), checking expiration dates at least monthly and before placing an order.
- Order when vaccine inventories reach about a 4 week supply.
- Establish a routine to order no more than once per month.
- Contact the Vaccine Management Unit to update any changes in shipping address. Changes to shipping hours or shipping contact can be updated directly in the MIIS. Vaccines will be based on shipping information in the MIIS.
- **Transfer soon to expire vaccines to another pediatric provider 2-3 months prior to expiration. Document all vaccine transfers in the MIIS Transfer Vaccine Module.**

Vaccine Returns

- **Only the Vaccine Management Unit can determine loss of efficacy due to exposure to out of range temperatures.**
- Document all vaccines that cannot be used due to expiration, exposure to unsafe temperatures or vaccines that are wasted/damaged in the *New Order Module* or the *Storage/Handling Problem Module*. Refer to the [Quick Start Guide](#) for instructions.
- Pack vaccine in a box with the return form. A return label will either be e-mailed or UPS will provide a label at time of pick up.
- Do not return broken vials or syringes, opened multi-dose vials or vaccine drawn up into a syringe. Make sure these doses are documented in the MIIS.

Temperatures Out of Range

If there are out of range temperatures, suspend vaccine administration, quarantine vaccine, upload temperature logs and immediately contact the Vaccine Management Unit for guidance.

- **Suspend vaccine administration of state-supplied vaccines in the unit that is experiencing the out of range temperature.**
- **Quarantine vaccines by keeping the vaccines in the proper temperatures and marking them as 'Do Not Use'.**
- Upload temperature logs into the MIIS and select 'Urgent Temperature Log Issue'
- Immediately call the Vaccine Management Unit and report your out of range temperature. Vaccine Management Unit staff will determine if vaccines are viable by contacting vaccine manufacturers.
- Use [Troubleshooting log](#) to document out of range temperatures, contact with the Vaccine Management Unit, and actions taken.
- Remove any vaccine determined by the Vaccine Management Unit to be damaged from the storage unit.
- Please note that out of range temperatures of **any** duration must be reported, even if they do not trigger an alarm.

Power Failure/Refrigerator Failure

- Pack vaccines according to the *Vaccine Transportation Procedures* on page 2 and transport to Emergency Storage location.
- Notify the Vaccine Management Unit as soon as possible. Consult the Vaccine Management Unit before transporting Varicella and MMRV vaccine, if possible.
- Review and update the provider emergency plan on an annual basis.

Documentation

- Enroll annually in the MDPH Immunization Program/Vaccines for Children (VFC) program by completing online enrollment in the *MIIS Provider Enrollment Module*.
- Review and update the SOP annually and when any changes occur.
- Retain a record of vaccines received or transferred, including type of vaccine, manufacturer, lot number, expiration date and number of doses, for a minimum of 3 years. Keep packing slip received in shipments from both McKesson and Merck.
- Maintain temperature logs for a minimum of 3 years. Temperature logs uploaded to the MIIS do not need to be maintained on site. There is no need to retain paper copies if every temperature log for all vaccine storage units is uploaded into the MIIS monthly.
- Offer the appropriate *Vaccine Information Statement (VIS)* with each dose of vaccine administered. Subscribe to the CDC’s e-mail update for VIS at: www.cdc.gov/vaccines/hcp/vis/index.html.
Record vaccine administration information in the patient’s chart including: administration date, type of vaccine, manufacturer, lot number, expiration date, VIS publication date, date VIS is given, name and credentials of person administering the vaccine.
- Report all state-supplied doses administered in the *MIIS Vaccine Management Module* with each vaccine order. Most EHRs are connected so that the dose will decrement from inventory and appear in your usage report as immunizations given.

Staff Training/Provider Education Requirements

- The primary and back-up Vaccine Coordinators must participate in one of the following activities each year. Certificates of completion must be kept on file.
 - VFC compliance site visit with training component (conducted every other year, must be present at site visit and request complete training to receive certificate).
 - In-person presentation (VFC breakout session at MIAP, MDPH Immunization Update Conference, or on-site training by MDPH staff). Certificates will be given after each activity.
 - MDPH on-line webinar trainings.

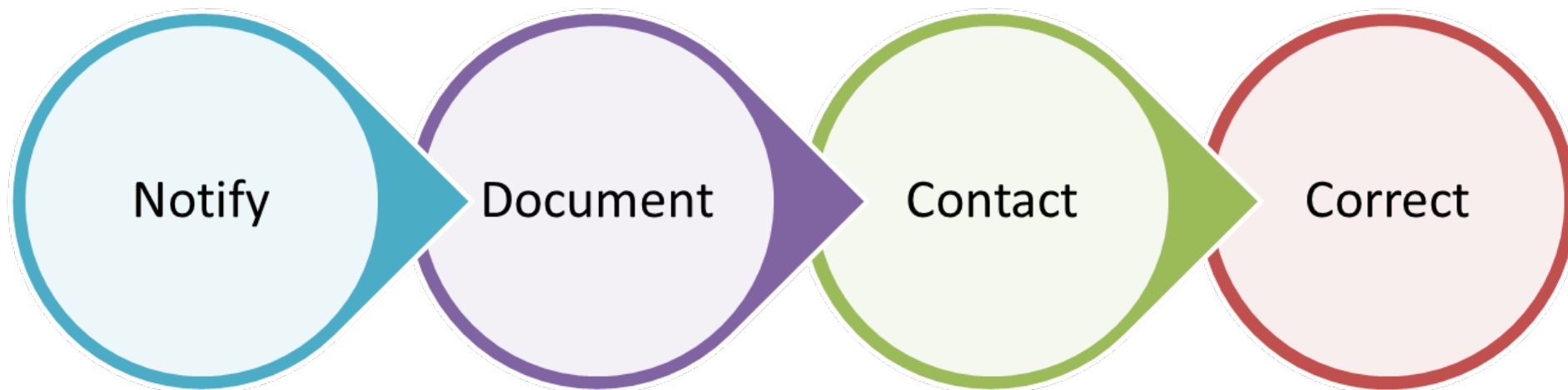
Go to the training page of the MIIS Resource Center, www.contactmiis.info, to view training materials, Quick Reference Guides and Webinars about the MIIS.

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| This SOP was created and completed by: | |
| Name | |
| Title | |
| Date of Completion | |
| Signature | |

| Date | Employee Name | Employee Signature |
|------|---------------|--------------------|
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Handling a Temperature Excursion in Your Vaccine Storage Unit

Any temperature reading outside recommended ranges is considered a temperature excursion. Identify temperature excursions quickly and take immediate action to correct them. This can prevent vaccine waste and the potential need to revaccinate patients.



- Notify the primary/back-up vaccine coordinator immediately or report the problem to a supervisor.
- Notify staff by labeling exposed vaccines, **'DO NOT USE'**, and quarantine them. Do not discard these vaccines and move them into a unit that is operating within the recommended temperature range.

- Upload the temperature log into the MIIS. Choose 'Urgent Temperature Issue' as the reason code.
- Document details of the temperature excursions in the notes section when uploading the log. Include:
 - Date and time
 - Description of the event
 - Length of time vaccine may have been affected
 - Vaccines affected
- Document details in the 'Temperature Troubleshooting Guide'.

- Call the Vaccine Management Unit at 617-983-6824 to discuss the temperature excursion.
- Be prepared to answer questions about what caused the incident and review the temperature log.
- If you are unable to log into the MIIS, contact the MIIS Helpdesk at 617-983-4335.

- If the data logger alarms repeatedly, do not dismiss the alarm until you have determined and addressed the cause.
- Check the basics, including:
 - Power supply
 - Unit door(s)
 - Thermostat setting
 - Ice build-up in freezers
- If you believe the storage unit has failed, inform the Vaccine Management Unit and implement your emergency vaccine SOP.
- **Never allow vaccines to remain in a nonfunctioning unit.**



Massachusetts Department of Public Health
Immunization Division | Vaccine Management Unit

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