

## 2024 Vaccine Management Standard Operating Procedure (SOP)

**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.**

Office/Practice Name	Pin Number

**Medical Director:**

Name (First & Last)	
Credentials	
Email Address	
Signature	

**Vaccine Coordinators:**

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

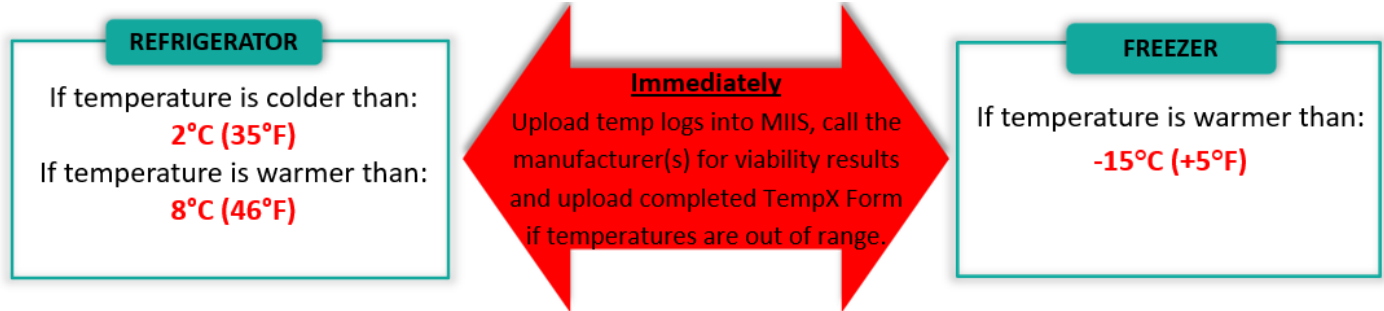
\*Notify the Vaccine Management Unit within 10 days if a new Primary Vaccine Coordinator, Backup, or Medical Director is identified.

**Emergency Vaccine Storage Location:**

Location Name	
Location Address	
Contact Name:	
Contact phone #	
Does the vaccine storage location have a pharmaceutical grade or purpose-built 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.)


## Vaccine Storage & Handling



### Storage Unit Requirements:

- **Pharmaceutical-grade or purpose-built refrigerators are required** for storage of refrigerated state-supplied vaccines. **Stand alone freezer units (pharmaceutical-grade or purpose-built not required) are required** for storage of frozen state-supplied vaccines. All storage units are required to maintain proper temperatures.
- The use of any household combination refrigerator/freezer unit or dormitory style unit for storage of any vaccines including temporary storage is strictly prohibited.

List your site's active vaccine storage units that hold state-supplied vaccines in the table below. If you require additional space, utilize Exhibit A at the bottom of this document. *Whenever a new vaccine storage unit is posted, sites must complete and submit the [Vaccine Storage Unit Checklist](#) to the Vaccine Management Unit.*

<u>Storage Unit Name</u>	<u>Storage Unit Type</u>	<u>Storage Unit Make</u>	<u>Storage Unit Model #</u>
Red Station Fridge	Refrigerator	ABS	XYZ12345

### Vaccine Storage:

- Refrigerated vaccines should be stored within the temperature range of **2° C to 8° C** in a pharmaceutical-grade or purpose-built refrigerator designated for vaccine storage only.
- Varicella, MMRV and Moderna COVID-19 vaccine must be stored in a stand-alone freezer that maintains a temperature between **-50° C and -15° C**. Store **Merck MMR vaccine in the freezer** to reduce the likelihood of a vaccine loss due to a refrigeration issue.
- Rotate stock ensuring that short-dated and soon to expire vaccine is used first.
- Mark or identify inventory to differentiate state-supplied versus privately purchased vaccine.
- Follow the below guidance when packing a vaccine storage unit:
  - Do not store anything on top of the storage unit which could prevent the door from completely closing.
  - 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 non-frozen water bottles in the refrigerator to stabilize temperatures.**
  - **Store frozen water bottles in the freezer** as part of your emergency preparedness in case of transport and to stabilize temperatures.

### Storage Unit Power Requirements:

- Post a “DO NOT UNPLUG” sign next to the electrical outlet for all vaccine storage units and post a “DO NOT DISCONNECT” label 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 an electrician to see if a ‘dedicated line’ is needed for your refrigerator(s).
- Never plug storage units into power strips, surge protectors, extension cords, Ground Fault Circuit Interrupter outlets (GFC), generators or battery packs.
- Vaccine must be moved to a backup unit before servicing or defrosting your storage units. ALWAYS contact the Vaccine Management Unit before moving vaccines.

### 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. If utilizing a state-supplied **Fridge Tag 2L data logger, the minimum and maximum temperatures can be acknowledged by pressing the read button.** The read button must be pushed four times in the AM and two times in the PM to fully review and acknowledge all temperatures. If utilizing a state-supplied **Site-L data logger, the minimum and maximum temperatures can be acknowledged by creating a note in the SmartView system** temperature graph.
- Other monitoring systems must have the capability of acknowledging minimum and maximum temperatures and will need prior authorization from the MDPH Vaccine Management Unit before use. 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.

*List your site’s active primary data logger devices that monitor state-supplied vaccines in the table below. If you require additional space, utilize Exhibit B at the bottom of this document.*

<u>Data Logger Model</u>	<u>Storage Unit Attached To</u>	<u>Calibration Expiration Date</u>
<i>Berlinger Fridge Tag 2L</i>	<i>Red Station Fridge</i>	<i>09/01/2025</i>

### Vaccine Receiving

- Staff receiving shipments (front office, loading dock, reception, etc.) must notify the vaccine coordinators as soon as a vaccine shipment arrives. **Contact the Vaccine Management Unit immediately for guidance if there are any concerns or inaccuracies with the vaccine order shipment.**
- Open shipping container immediately upon arrival. Check the two transit temperature monitors for shipments sent from McKesson. If temperature monitors indicate a possible temperature excursion, **contact** the Vaccine Management Unit at (617) 983-6828 immediately.
- 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 the 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 are 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.

*Describe the process for how state-supplied vaccines are received by your site.*

- 1. Who is responsible for receiving vaccine shipments?*
- 2. Who is responsible for unpacking and reviewing vaccine shipments?*
- 3. How does your site ensure that vaccine inventory is rotated once a new shipment is received?*

### 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. Providers must follow the [2024 Vaccine Transport SOP](#) when transporting state supplied vaccines. Sites must retain an adequate number/amount of appropriate packing containers and materials (e.g., frozen water bottles, bubble wrap, cardboard) 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 the state-supplied vaccine**.
  - If only moving a smaller amount of state-supplied vaccine, a **backup** DDL must be used for the transport of the vaccines.
- 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'.
  - **Conditioned water bottles** should be placed in the container used to transport refrigerated vaccines when following the [CDC Packing for Emergency Transport guide](#). **Separate the vaccine from the conditioned water bottles with cardboard and bubble wrap. Never place frozen gel packs or ice packs with refrigerated vaccines.**
  - Frozen water bottles 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 transport cooler near the vaccine to monitor the temperatures. Ensure that the cord of the glycol bottle is attached to the digital data logger, so that temperatures are recorded.
- **Transport of vaccines is considered a temperature excursion:**
  - Record the time the vaccines were placed in the transport cooler and the time when the vaccines were removed from the transport cooler, so that temperatures during transport can be easily reviewed.
  - Do not administer the vaccine until viability is confirmed. If temperatures fall out-of-range during transit, please complete the [Temperature Excursion Reporting Form](#).
  - Upload the temperature log into MIIS to document temperatures during transit.
- **Never 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.
  - Sites utilizing the Fridge Tag 2L data loggers should upload temperature logs for vaccine storage units containing state-supplied vaccines monthly (regardless of if an order is being placed), as the Fridge Tag 2L device can only store 56 days of temperatures at a time.

- Complete a physical inventory count of all vaccines in the refrigerator(s) and freezer(s), checking expiration dates at least monthly and before placing an order.
- Vaccine orders may take up to 2 weeks to arrive at your site once the order is processed and approved by the Vaccine Management Unit.
- Contact the Vaccine Management Unit to update any changes in shipping address. Changes to shipping hours or shipping contact can be updated directly in MIIS. Vaccine shipments will be sent based on shipping information in MIIS.
- **Transfer soon to expire vaccines to another pediatric provider 3 months prior to expiration. Document all vaccine transfers in the MIIS Transfer Vaccine Module. If unable to locate a practice within the first two weeks of attempting to move the vaccines, contact the Vaccine Management Unit for assistance at 617-983-6828.**

*Describe your internal process for determining your site's vaccine needs when placing an order:*

1. *Outside of the pre-filled recommendation counts provided in MIIS, how does your site determine your upcoming vaccine needs?*
2. *How are the staff members responsible for placing the vaccine order informed of any upcoming changes with your site (i.e. providers leaving, upcoming clinics, back to school seasons, etc.)*

#### **Vaccine Returns**

- **Only the vaccine manufacturer can determine loss of efficacy due to exposure to out-of-range temperatures.**
- Document all vaccines that cannot be used due to expiration/spoilage, 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 enclosed. A return label will either be emailed or UPS will provide a label at the time of pick up (depending on the option selected when submitting the storage and handling issue).
- 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 MIIS as wasted.

#### **Temperatures Out of Range**

In the event of a temperature excursion, sites must follow the steps detailed below:

- Please note that **out-of-range temperatures of any duration must be reported**, even if they do not trigger an alarm on the data logger device.
- **Immediately suspend vaccine administration of state-supplied vaccines stored in the unit** that is experiencing the out-of-range temperature until vaccine viability is determined by the vaccine manufacturer.
- **Quarantine vaccines by keeping the vaccines in the proper temperatures and marking them as 'Do Not Use'.**
- Upload temperature logs into MIIS and select 'Urgent Temperature Issue'.
- Complete the [Temperature Excursion Reporting Form](#) and follow-up with the vaccine manufacturers for viability determinations for the impacted doses. Upload the completed Temperature Excursion Reporting Form into MIIS as an 'Urgent Temperature Issue'.
- The Vaccine Management Unit will review the completed Temperature Excursion Reporting Form and provide necessary guidance and follow-up action items for your site to complete.

### Power Failure/Refrigerator Failure

- Notify the Vaccine Management Unit as soon as possible. Always consult the Vaccine Management Unit before transporting any state-supplied vaccine, if possible.
- **If the power failure is less than 3 hours, keep all vaccines in the appropriate unit(s)** with the door closed.
- **In the event of power failure with a duration over 3 hours, please transport vaccines** according to the **CDC Packing for Emergency Transport guidelines** and transport to your Emergency Vaccine Storage Location.

*Describe your site's emergency plan regarding state-supplied vaccines below:*

### 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 all SOPs annually and when any changes in procedure or staff 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 slips received in shipments from both McKesson and Merck.
- Maintain temperature logs for a minimum of 3 years. Temperature logs uploaded to 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 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](http://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 the 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 online Storage and Handling webinar training.

Go to the training page of the MIIS Resource Center, [www.contactmiis.info](http://www.contactmiis.info), to view training materials, Quick Reference Guides and Webinars about MIIS.

For any clinical questions you can contact the Immunization Nurse at (617) 983-6800

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

***Please Note: All staff who are involved in the vaccine transport process for your site must review and sign this SOP. At a minimum, both Vaccine Coordinators and the Medical Director must sign this SOP.***

Date	Employee Name	Employee Signature

## Exhibit A

<u>Storage Unit Name</u>	<u>Storage Unit Type</u>	<u>Storage Unit Make</u>	<u>Storage Unit Model #</u>
<i>Red Station Fridge</i>	<i>Refrigerator</i>	<i>ABS</i>	<i>XYZ12345</i>

## Exhibit B

<u>Data Logger Model</u>	<u>Storage Unit Attached To</u>	<u>Calibration Expiration Date</u>
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