

# Vaccine Storage and Handling Standard Operating Procedures (SOP)

(Revised January 2024)

## *Vermont Immunization Providers*

This Vaccine Storage and Handling SOP is based on the CDC Vaccine Storage and Handling Toolkit and "You Call the Shots" webinars. It provides information for proper management of publicly-funded vaccine. Use of this template assures that vaccine is managed according to VCVP/VAVP and Vermont Immunization Program requirements. Post these guidelines near your storage unit where they can be easily accessed. All office staff should be aware of this plan.

Date SOP Reviewed	Date YCTS: VFC and S&H Reviewed	Name & Credentials



# Vaccine Storage and Handling SOP

Practice Name \_\_\_\_\_

PIN# \_\_\_\_\_

Vaccine Coordinators (see page 3)		
Name	Title (e.g. RN, MA)	Home and/or Cell Phone
Vaccine Coordinator:		
Backup Coordinator:		
2 <sup>nd</sup> Backup Coordinator ( <i>optional</i> ):		

Alternate vaccine storage location (see page 4)	
Location name	
Location address	
Phone	
Primary contact person off-hours	Name: Phone:

Regional Immunization Specialist	
Name	
Phone number	
Email address	

Supplies Needed to Transport Vaccine	
Supplies	Location on Site
Hard sided cooler	
Frozen water bottles	
Cardboard and bubble wrap	
LogTag Data Logger (see page 13)	

# Vaccine Storage and Handling SOP

Person Completing This Form	
Date of completion	
Your Name	
Title	
Your Signature	

## Abbreviations:

ACIP: Advisory Committee on Immunization Practices

BUD: Beyond Use Date

MMR: measles, mumps, and rubella vaccine

MMRV: measles, mumps, rubella, and varicella vaccine

VDH: Vermont Department of Health

VCVP: Vermont Child Vaccine Program

VAVP: Vermont Adult Vaccine Program

VIMS: Vaccine Inventory Management System



To view this document on the web, with a smart phone camera application open, point the lens at the included QR code and click pop-up.

*Thank you to all Health care staff for taking steps to provide safe and effective vaccines to the communities you serve by reviewing this document. The Immunization Program is endlessly impressed with the resourcefulness, creativity, and resilience your offices have shown over the last few challenging years. Don't hesitate to get in touch with our program with anything our team can do to make our partnership more effective.*

# Vaccine Storage and Handling SOP

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# Vaccine Storage and Handling SOP

## I. Rationale

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Providers enrolled in the Vermont Children's Vaccine Program (VCVP) and/or Vermont Adult Vaccine Program (VAVP) are entrusted with publicly funded vaccine and must ensure viability. Vaccine that is not stored under required conditions may be ineffective at producing an immune response. In 2023, the value of vaccine distributed to VCVP and/or VAVP enrolled practices in Vermont was valued at more than \$24,300,000.

## II. Vaccine Emergency Management

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### A. Temperature excursions

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If you experience a temperature excursion, defined as any period outside the recommended temperature range, contact the Immunization Program by phone at 802-863-7638 or email [AHS.VDHImmunizationProgram@vermont.gov](mailto:AHS.VDHImmunizationProgram@vermont.gov). This inbox is monitored during regular business hours (7:45 am - 4:30 pm Monday through Friday) outside [Vermont State Holidays](#).

- Label vaccine "Do Not Use" and await guidance.
- Correct obvious problems. For example, if the door is ajar – close it.
- **Do not move the vaccine without approval.**
- Do not make assumptions about vaccine viability.
- Do not adjust the temperature control, add ice packs, or otherwise attempt to cool a refrigerator.
- Once an issue is resolved, acknowledge the alarm in Senso and note all actions taken.

**After Hours**  
802-863-7240  
Option 2

If it is after hours and you need to use the vaccine before the next business day, dial the above number to reach an on-call staff member. Otherwise, wait until the next business day.

Failure to seek and follow VDH guidance for vaccine storage & handling or transport may result in vaccine loss.

Contact the Immunization Program before maintenance or repair to monitored units

Never transport vaccine unless authorized by Immunization Program Staff.  
Vaccine stored in the freezer is NOT usually transported.

# Vaccine Storage and Handling SOP

## B. Alternate storage location

- Alternate locations are used in the event of a mechanical or power failure and must have a generator.
- **Permission from the Immunization Program is always required before moving state-supplied vaccines, even to your alternate storage location.**

Alternate locations must have a backup generator, be enrolled in the state program, and be monitored with a state-supplied device. This location will likely be either your local hospital (if enrolled) or your Local Health Office.

## C. Emergency plan for a power outage

NEVER move vaccines to a home, another storage unit, or an approved location without permission from the Immunization Program. It is often better to leave the vaccine during a power outage than move it. If the building has lost electrical power, check with the building maintenance or the power company to learn if there is an estimate for the restoration of power.

### ➤ **During a short-term power outage**

- Do not open the refrigerator or freezer door until the power outage is resolved and the temperature inside the unit is within the normal range.
- If the outage occurs during business hours, note the time of the power failure.
- Once power is restored, note the time and monitor temperatures (until it reaches 2 to 8 °C for the refrigerator, -50 to -15 °C for the freezer).
- Determine if the temperature has been out of range; if yes, contact the Immunization Program.

### ➤ **During a long-term power outage**

- Do not open the refrigerator or freezer door unless approval is requested and received to transport vaccines to the backup location.
- If instructed to move your vaccines, contact the receiving location to ensure they have storage. If they do not have power or enough space, contact the Immunization Program for assistance.
- Follow the [CDC instructions for packing and transporting vaccines](#)

Wi-Fi will likely be lost during a power outage, so you are not getting real-time data online. Use [paper temperature logs](#) until the data has been downloaded to the cloud and reviewed.

# Vaccine Storage and Handling SOP

## III. Roles and Responsibilities

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### A. Vaccine coordinators

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Designate a Primary Vaccine Coordinator and at least one Backup Vaccine Coordinator to manage all aspects of state-supplied vaccine, as described in this plan. Both contacts should be knowledgeable about vaccine management and capable of fulfilling all vaccine storage and handling requirements.

**Updating Vaccine Coordinators:** When the Primary Vaccine Coordinator or the Backup is changed, complete the [Contact Update Form](#)

**Training:** The Primary Vaccine Coordinator and Backup Vaccine Coordinator must complete the following training *annually* if they did not receive a VCV/VAVP compliance site visit for the calendar year or if they were not present for the duration of the site visit.

- You Call the Shots: Module 10, Storage and Handling
- You Call the Shots: Module 16, Vaccines for Children Program (VCVP providers only)

Follow these [You Call the Shots](#) to complete the training and obtain the certificate of completion which should be sent to the immunization program.

### B. Other staff

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All staff with vaccine storage and handling responsibility should read and sign (on the cover page) this Vaccine Storage and Handling SOP annually *and* when changes are made to the plan.

**It is the responsibility of the Primary and Backup contacts of the program to disseminate Immunization Program communication and training opportunities to appropriate staff.**

# Vaccine Storage and Handling SOP

## IV. Storage and Handling-Best Practices

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### A. Unit approval

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Prior to storage of vaccine, unit(s) *MUST be inspected by Immunization Program staff and have at least 72 hours of in-range temperatures*, as monitored by a data logger supplied by the Immunization Program.

*The CDC strongly recommends stand-alone refrigerators and freezers.*

#### Refrigerators:

- Refrigerator temperature must be maintained **between 2 °C and 8 °C** (36 °F and 46 °F).
- Only the refrigerated part may store the vaccine if using a combination unit, stand-alone units are preferred.
- **Never Permitted:** Dormitory combination refrigerator/freezer units outfitted with one exterior door and an enclosed freezer compartment.
- The unit should have enough room to accommodate the largest inventory of the year – typically during respiratory virus season (or back-to-school) – without over-crowding.

#### Freezers:

- Freezer temperatures must be maintained **between -50 °C and -15 °C** (-58 °F and +5 °F).
- **Never Permitted:** Freezers in combination units, all freezers should be stand-alone units.
- Freezers are recommended to be auto-defrosting or self-defrosting.

Use this guide when purchasing a unit:  
[Refrigerator and Freezer Guide \(healthvermont.gov\)](https://healthvermont.gov)



# Vaccine Storage and Handling SOP

## B. Vaccine storage

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### Do Not Store Vaccine:

- In any unapproved or unmonitored unit.
- In any unit which also stores food.
- In the door, crisper, or space created by removing the crisper bins.
- On the floor of the unit.
- Near a cooling fan or vent.
- Below other biologicals or medications.

### Storage Best Practice:

- At least 2-3 inches away from the walls, floor, and cooling coils.
- As centrally as possible.
- In original packaging to protect from light
- With airflow between each large package, block, tray, or bin.
- Organize units with labeling (pediatric/adult, private purchase/state supplies) and mesh-sided containers (for airflow)
- Water bottles marked "Do Not Drink" can be placed in the door or on the floor as a thermal buffer. If possible, condition water bottles before adding them.
  - a. Ice packs are not allowed as a thermal buffer and should never be stored in the refrigerator.

**Required:** A "Do Not Disconnect" notice must be posted next to every outlet where a vaccine freezer or refrigerator is plugged in AND on or near the corresponding circuit breaker. **Stickers are available from the Immunization Program upon request.**

## C. Vaccine transport (transfers)

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All vaccine transport must be pre-approved by the Vermont Immunization Program

Transport involves vaccine movement over a short time frame and distance between enrolled providers. This transfer refer not to clinics but moving vaccines from practice to practice to reduce waste or in an emergency. Practices should always be prepared for the need to move vaccines with the below supplies.

Don't forget to transport the corresponding diluent

**Frozen vaccines should never be transported except in an emergency and with prior approval.**

# Vaccine Storage and Handling SOP

Supplies each practice must have on-site to transport vaccines safely:

- Hard-sided or Styrofoam cooler (do not use soft-sided coolers)
- Backup data logger (see section G)
- Frozen water bottles (these need to be conditioned before packing)
  - Icepacks are not appropriate for transport.
- Insulating materials such as corrugated cardboard and bubble wrap (enough for two layers per container)

Follow instructions on [packing and transporting refrigerated vaccines](#)

Instructions for packing/transporting frozen vaccines will be provided during transfer approval from the Vermont Immunization Program.

***Never place vaccine directly on conditioned water bottles***

## D. Offsite clinics

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To ensure vaccine viability, you must select a suitable storage option for offsite clinics and monitor the temperatures continuously with a LogTag data logger. **Hard-sided or Styrofoam coolers are not appropriate storage for offsite clinics.**

**Suitable storage includes:**

- Vaccine carriers with phase change panels: any location planning an offsite clinic may borrow one of these coolers from the Immunization Program. Request at least 10 day business days before your clinic. If interested in learning more, email [AHS.VDHImmunizationProgram@vermont.gov](mailto:AHS.VDHImmunizationProgram@vermont.gov).
- Portable vaccine storage units: Portable units are available to purchase privately.

[Vaccine Carrier Borrowing Program](#)  
[Offsite Clinic Guidance](#)

\* These links can all be found on the [Vaccine Storage and Handling Page](#)

The total time for transport, including the clinic day should never extend past 8 hours. *Example*: Clinic location is 1 hour away the clinic day should last a maximum of 6 hours.

# Vaccine Storage and Handling SOP

## E. Temperature monitoring

- **Thermometers:** Storage unit temperatures must be continuously monitored using data loggers purchased and installed by the Vermont Immunization Program.
- **Placement:** The probe in the glycol bottle must be placed centrally in the storage unit.
- **Calibration:** Vaccine thermometers must have a current certificate of calibration. The Immunization Program is responsible for recalibration services.
- **Malfunction:** If a data logger malfunctions, call the Immunization Program immediately.
- **Monitoring:** At the *start of each clinic day*, document min/max temperatures
  - If using Senso: log into the SensoScientific cloud system, check off each vaccine storage unit, and click "Audit Node." This action time stamps the min/max and "signs" with the associated login account.
  - If using backup LogTag Data logger: Min/Max, time, and initials must be documented on [paper temperature logs](#).
  - The refrigerator temperature must be between **2 and 8 °C** (36 °F - 46 °F). Strive for a reading of 5 °C
  - The freezer temperature must be between **-50 and -15 °C** (-58 °F to 5 °F).

**AUDIT NODES**

Confirm that you have viewed a node's current status.

- 1 Select the "MONITORING" tab in the main menu.
- 2 Mark the checkbox in the rightmost column of the node(s) you want to audit.
- 3 Click the "Audit Node" button at the bottom of the page.

# Vaccine Storage and Handling SOP

## F. SensoScientific – Permanent Storage

The Immunization Program provides Senso Scientific devices for any unit permanently storing state-supplied vaccines. Logins are available to any member of your staff who may be tasked with doing daily temperature audits (see Section E: Monitoring) by emailing the main inbox.

Senso Scientific Login: <https://cloud.sensoscientific.com/>

### Permanent Storage Temperatures:

	Vaccine stored only in the freezer	Vaccine stored in the freezer or refrigerator	Vaccine stored only in the refrigerator
	<ul style="list-style-type: none"> <li>○ Varicella</li> <li>○ MMRV</li> </ul>	<ul style="list-style-type: none"> <li>○ MMR (freezer preferred)</li> <li>○ COVID-19* (Moderna)</li> </ul>	<ul style="list-style-type: none"> <li>○ All other routine vaccines</li> <li>○ COVID-19* (Pfizer, Novavax)</li> </ul>
Diluent	<ul style="list-style-type: none"> <li>• Diluents that are packaged with their vaccines (e.g. ACTHIB, Rotarix) must be stored in the refrigerator and should not be separated from the vaccine with which they are packed.</li> <li>• Diluents that are packaged separately from their vaccines may be stored at room temperature or in the refrigerator, <i>not in the freezer</i>. This includes diluents for MMR, MMR-V, and Varicella.</li> </ul>		

# Vaccine Storage and Handling SOP

## Senso Scientific Alarms:

Alarm	Meaning	Conditions	Action Required of Practice During Normal Business Hours	Action Required After Standard Business Hours
<b>Data Alarm</b>	Temperature is out of range.	Alarms when temperatures are out of range for 45 minutes.	<ul style="list-style-type: none"> <li>• Contact the Immunization Program.</li> <li>• After the issue is resolved, log into the cloud system and confirm the alarm under the Monitoring tab.</li> </ul>	<ul style="list-style-type: none"> <li>• Contact the on-call person for guidance if you need to use the vaccine before the next business day.</li> </ul>
<b>Signal Alarm</b>	Internet connection has been lost.	Alarms when Wi-Fi is off for 2 hours. The data downloads once the connection is reestablished unless the data logger is reset.	<ul style="list-style-type: none"> <li>• Wait 60 minutes for the connection to reestablish. If it has been longer than 60 minutes, contact the Immunization Program.</li> <li>• After the issue is resolved, log into the cloud system and confirm the alarm under the Monitoring tab.</li> </ul>	<ul style="list-style-type: none"> <li>• No action is required outside standard hours of operation.</li> <li>• If the network failed to reconnect, contact the Immunization Program the next business day.</li> </ul>
<b>Battery Alarm</b>	The batteries are low.	Alarms when batteries need to be replaced.	<ul style="list-style-type: none"> <li>• Data loggers use four Energizer 1.5V AA Lithium Batteries.</li> <li>• If you need help with replacing the batteries, contact the Immunization Program.</li> <li>• Login to the cloud system under the Monitoring tab to confirm an alarm after you replace the batteries.</li> </ul>	<ul style="list-style-type: none"> <li>• No action is required outside standard hours of operation.</li> <li>• Replace the batteries on the next business day.</li> </ul>
<b>Audible Alarm</b>	If your audible alarm is enabled, the data logger will sound off for the above noted reasons. Press the middle button to temporarily turn it off or log in to the SensoScientific cloud system to turn it off permanently.			
<b>Do not confirm the alarm until the issue has been resolved or the maximum 3-alarm notification will start again flooding your inbox/call/text with additional notifications.</b>				

# Vaccine Storage and Handling SOP

## LogTag data loggers – Back-up

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Backup LogTag data loggers are required for the following:

- When a Senso device malfunctions
- All vaccine transport
- Offsite vaccination clinics.

The Vermont Immunization Program provides backup data loggers to all VACP/VAVP enrolled practices, and the second page of this document should have the device location documented. For additional data loggers, contact the Immunization Program.

- Ensure at least one computer has the current [logtag software](#) – Cannot be downloaded to an Apple device such as a MacBook.
  - For more information, see the [LogTag Data Logger Device User Guide](#).

### **Backup data logger setup before use:**

1. Condition the glycol bottle to the appropriate temperature by placing it in the fridge/freezer.  
Tip: if space allows, leave the glycol bottle in the fridge, so it is always ready for use.
2. Once in range, you may [package the vaccine according to instructions](#).
3. Transport the vaccine.
4. If the data logger stays in range for the entire length of transport or clinic, no further communication with the program is needed.

If the data logger goes out of range during transport OR it was never able to get into proper range due to time constraints, you **MUST contact the program** and report this as a temperature excursion.

# Vaccine Storage and Handling SOP

## V. Inventory Management and Ordering Vaccine

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### A. Avoid administration errors

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- Label each basket/tray with the vaccine type. [Labels are available for printing.](#)
- Separate and label privately-purchased vaccines vs. state-supplied vaccines.
- Separate and label adult vs. pediatric vaccine.
- If applicable, in the case of some COVID vaccines, mark the appropriate Beyond Use Date (BUD) or expiration date.
- Conduct a weekly inventory to ensure the rotation of vaccines. Short-dated vaccines must be used first, and if unused removed promptly upon expiration.
- Report vaccine administration errors to [VAERS](#) or [MedWatch](#) for Beyfortus that is not co-administered and contact the Immunization Program for further guidance.

**Note:** Although the IPOL vaccine is a multi-dose vial, it should be used through the manufacturer's expiration date printed on the vial, even after puncture.

### B. Vaccine ordering schedule

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- Each practice is assigned an ordering frequency with a 2-week window of time.
- All practices are expected to reconcile their entire inventory monthly. VIMS will send out automated emails if this does not occur.
- If there isn't sufficient space in your refrigerator or freezer to store the vaccine, as outlined in this document, the unit is too small. Ask for more frequent orders and explore acquiring a unit capable of accommodating the largest expected inventory.

# Vaccine Storage and Handling SOP

## C. VIMS and vaccine ordering

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- VIMS is accessed through the [Vermont Immunization Registry \(IMR\)](#).
  - Users who do not have IMR access should contact IMR support at 888-688-4667.
  - Once logged in, Select "Vaccine Inventory Management System (VIMS)" from the left navigation menu.
  - VIMS access is available only to your Primary and Backup contacts.
- A step-by-step [VIMS User Guide](#)
- The Immunization Program reviews all vaccine orders. Should adjustments be necessary, you will be contacted. Use the Practice Comments section of the order to convey reasons for ordering outside of the recommended quantities.
- The View History link can check an order's status and tracking information.

### VIMS Tutorials (Approximately 7 minutes each)

[Adjustment Request \(Vaccine Waste/Return\)](#)

[Inventory Reconciliation Request](#)

[All-Vaccine Order Request](#)

[COVID-only Order Request](#)

## D. Receipt of vaccine shipments

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- Most vaccines are shipped from McKesson Specialty Distribution. Freezer stable vaccines (varicella and MMR-V) are shipped by the manufacturer, Merck. Pfizer Covid products are currently being shipped by Pfizer.
- Upon receipt of **refrigerated** vaccines, check the enclosed temperature monitoring card. If an out-of-range temperature occurred during shipping, mark the vaccine "Do Not Use," store it in the refrigerator, and call or email the Immunization Program for guidance that same day its received for the ordering team to assist.
- **Frozen** vaccines are NOT packed with temperature indicators. Instead, they come with a shipper insert that identifies the allowable shipping time. Check the packing slip's shipping date to determine how long the vaccines were in transit. If the shipment arrives beyond the allowed time, mark the vaccine "Do Not Use", store it in the freezer, then call or email the Immunization Program the same day for the ordering team to assist.



# Vaccine Storage and Handling SOP

- The lid of the box contains diluent. **Remove the diluent before you discard the box.** The diluent can be stored in the refrigerator or at room temperature, but not in the freezer.
- Verify that the packing slip agrees with the content of the shipment. Date and sign the packing slip and **keep it for your records.** Do not fax it to Immunization Program.
  - If the shipment contents and the packing slip do not match, call or email the Immunization Program *the same day* the shipment is delivered.
- Rotate vaccine stock within storage units to ensure that vaccines with the shortest expiration dates are placed in a position to be used first (Always use the First In, First Out Method).

## E. Avoiding wastage due to vaccine expiration

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- Conduct a weekly check to ensure that vaccine with the earliest expiration date is used first.
- 60 to 90 days before expiration, if a vaccine is not likely to be used, contact the Immunization Program for assistance redistributing the vaccine to a practice that can use it. Immunization Program permission is required before moving state-supplied vaccines.
  - a. Reasons why redistribution would not be recommended:
    - i. Contact was made late, and the vaccine are set to expire before a practice would be able to use the vaccine.
    - ii. Transporting the vaccines is more work than the cost of the vaccine.
    - iii. If no local practices use that brand of vaccine or have more than enough supply.
- **Remove** the expired or non-viable vaccine from the storage unit immediately and mark "Do Not Use".

Always maintain the integrity of your vaccine stock by never swapping or borrowing doses between state-supplied and private purchase vaccine

# Vaccine Storage and Handling SOP

## F. Handling expired, spoiled, and wasted vaccine

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All spoiled, expired, or wasted vaccines must be accounted for and reported to the Immunization Program in VIMS. These doses are documented via an Adjust Request with an Adjustment Type of Return or Waste.

- **RETURN:** Non-viable, unopened, and intact state-purchased vaccine vials and syringes should be returned to McKesson for federal excise tax credit.
  - All expired, or spoiled vaccines must be reported in a VIMS Adjust Request. Print the request to use as a packing slip.
  - The Immunization Program will review the request and upon approval, UPS will email the shipping label **only** to the primary vaccine contact.
  - Upon receiving the shipping label, carefully package the vaccine to prevent vial breakage and ship it to McKesson within 1 month of spoilage or expiration. Print your Return Adjustment from VIMS to include as a packing slip.
  
- **WASTE:** Vaccines are considered wasted if opened or damaged and they cannot be administered to patients. These vaccines may not be returned and should be discarded as medical waste.
  - Reasons for waste include: being drawn into a syringe but not administered, opened in error, error in reconstitution, vaccine whose sterility has been compromised by the vial being dropped or broken, or open multi-dose vials that have expired.
  - All wasted vaccines must be reported in a VIMS Adjust Request.
  - Dispose of a wasted vaccine on-site in a sharps container.

The Immunization Program appreciates and values the many significant contributions of Vermont provider offices in ordering, storing, handling, and administering immunizations to children, adolescents, and adults.