VERMONT
DEPARTMENT OF HEALTH

Vaccine Storage and Handling Standard Operating Procedures (SOP)

(Revised January 2023)

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:		
2nd Backup Coordinator (*optional*):		

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	

Additional Information (use as needed)	

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

Contents

Vaccine Storage and Handling SOP

I. Rationale

Providers enrolled in the Vermont Children's Vaccine Program (VCVP), Vermont Adult Vaccine Program (VAVP), or Vermont COVID-19 Vaccination programs 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 2022, the value of vaccine distributed to VCVP and/or VAVP enrolled practices in Vermont was valued at more than $18,500,000.

II. Vaccine Emergency Management

A. Temperature excursions

If you experienced 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. 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 resolves, 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.

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. http://www.cdc.gov/vaccines/recs/storage/downloads/emergency-transport.pdf

III. Roles and Responsibilities

A. Vaccine coordinators

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: https://forms.office.com/g/JsWjfAmEZy

Training: The Primary Vaccine Coordinator and Backup Vaccine Coordinator must complete the following training *annually* if they did not receive a VCVP/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)

Modules: https://www.cdc.gov/vaccines/ed/youcalltheshots.html

Obtaining Certificates of Completion and sending to the Immunization Program: https://www.healthvermont.gov/sites/default/files/documents/pdf/ID_IZ_INFOHCP_S%26H_YCTS%20instructions.pdf

B. Other staff

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.

IV. Storage and Handling-Best Practices

A. Unit approval

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.
- **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 flu 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).
- Freezers in combination units are not recommended and will become not permitted in the coming years.
- Freezers are recommended to be auto-defrosting or self-defrosting.

B. Vaccine storage

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.
- 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.

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)

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. The time needed to transport should be less than 8 hours, and the vaccine should be placed in a stable, monitored storage unit as quickly as possible. Vaccines should only be transported when necessary (in an emergency or to ensure the use of vaccines that are about to expire).

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

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)
- Insulating materials such as corrugated cardboard and bubble wrap (enough for two layers per container)

Follow instructions on packing and transporting refrigerated vaccines at http://www.cdc.gov/vaccines/recs/storage/downloads/emergency-transport.pdf

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

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. If interested in learning more, email AHS.VDHImmunizationProgram@vermont.gov.
- Portable vaccine storage units: Portable units are available to purchase.

Vaccine Carrier Borrowing Program
https://www.healthvermont.gov/sites/default/files/documents/pdf/HS-IZ-Vaccine-Carrier-Program.pdf

Offsite Clinic Guidance:
https://www.healthvermont.gov/sites/default/files/documents/pdf/COVID19-Vaccine-Off-Site-Clinic-Guidance.pdf

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 a non-Senso system (third party or a LogTag Data logger): Min/Max, time, and initials must be documented on paper or through another accessible system.
  - 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).

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).

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

Vaccine Storage and Handling SOP

Permanent Storage Temperatures:

Vaccine stored only in the freezer	Vaccine stored in the freezer *or* refrigerator	Vaccine to stored only in the refrigerator
○ Varicella ○ MMRV	○ MMR (freezer preferred) ○ COVID-19* (Moderna)	○ All other routine vaccines ○ COVID-19* (Pfizer, Novavax)
Diluent	• 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. • Diluents that are packaged separately from their vaccines may be stored at room temperature or in the refrigerator, *not in the freezer.* This includes diluents for MMR, MMR-V, and Varicella.	
COVID*	**Moderna:** Stored in the freezer through expiration, BUD of 30 days in the refrigerator. Do not refreeze. **Pfizer:** Permanent storage is ultra cold, NO FREEZER storage, BUD of 10 weeks in the refrigerator. Do not refreeze. **Novavax:** Permanent storage is in the refrigerator. BUD does not apply.	

Senso Scientific Alarms:

Alarm	Meaning	Conditions	Action Required of Practice During Normal Business Hours	Action Required After Standard Business Hours
Data Alarm	Temperature is out of range.	Alarms when temperatures are out of range for 45 minutes.	• Contact the Immunization Program. • After the issue is resolved, log into the cloud system and confirm the alarm under the Monitoring tab.	• Contact the on-call person for guidance if you need to use the vaccine before the next business day.
Signal Alarm	Internet connection has been lost.	Alarms when Wi-Fi is off for 2 hours. The downloads once the connection is reestablished unless the data logger is reset.	• Wait 60 minutes for the connection to reestablish. If it has been longer than 60 minutes, contact the Immunization Program. • After the issue is resolved, log into the cloud system and confirm the alarm under the Monitoring tab.	• No action is required outside standard hours of operation. • If the network failed to reconnect, contact the Immunization Program the next business day.
Battery Alarm	The batteries are low.	Alarms when batteries need to be replaced.	• Data loggers use four 1.5V AA Lithium Batteries. • If you need help with replacing the batteries, contact the Immunization Program. • Login to the cloud system under the Monitoring tab to confirm an alarm after you replace the batteries.	• No action is required outside standard hours of operation. • Replace the batteries on the next business day.
Audible Alarm	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.			
Do not suspend the alarm notification until the issue is resolved and the Immunization Program provides instructions.				

G. LogTag data loggers – Back-up

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 VCVP/VAVP/COVID 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 installed https://logtagrecorders.com/lta3/download/
- For more information, see the LogTag Data Logger Device User Guide: https://www.healthvermont.gov/sites/default/files/documents/pdf/HS-IZ-TempMonitoring-LogTag-Device-User-Guide.pdf

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.

V. Inventory Management and Ordering Vaccine

A. Avoid administration errors

- Label each basket/tray with the vaccine type. Labels are available for printing at https://www.cdc.gov/vaccines/hcp/admin/storage/guide/vaccine-storage-labels.pdf
- 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 https://vaers.hhs.gov/ 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

- 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.
- The unit is too small if there is not enough space in your refrigerator or freezer to store the vaccine, as described in this document. Request an increased ordering frequency and consider the purchase of a unit that can hold the largest anticipated inventory.

C. VIMS and vaccine ordering

- VIMS is accessed through the Vermont Immunization Registry (IMR) found here: http://www.healthvermont.gov/health-statistics-vital-records/registries/immunization.
  - 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 is available on the Immunization Program website:
  - http://www.healthvermont.gov/sites/default/files/documents/pdf/ID_IZ_vax_ordering_User%20Guide.pdf
- 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.

D. Receipt of vaccine shipments

- Most vaccines are shipped from McKesson Specialty Distribution. Freezer stable vaccines (varicella and MMR-V) are shipped by the manufacturer, Merck. COVID-19 vaccine may come as a transfer from the Vermont Vaccine Depot (see COVID section)
- 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.
- **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 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.

E. Avoiding wastage due to vaccine expiration

- Conduct a weekly check to ensure that vaccine with the earliest expiration date is used first.
- Sixty 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.
- **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

F. Handling expired, spoiled, and wasted vaccine

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 non-COVID 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 listed Primary contact a shipping label.
  - 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.
  - COVID-19 vaccines are not returned regardless of status and should always be documented as 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.

VI. COVID-19 Vaccine Storage and Handling

COVID-19 vaccine storage and handling guidance are changing rapidly. Find these at the manufacturer websites listed below. Always refer to the specific Emergency Use Authorization for storage and handling information.

Refer to the below websites frequently to obtain the most up to date information on available COVID-19 Vaccines:

CDC - U.S. COVID-19 Vaccine Product Information
www.cdc.gov/vaccines/covid-19/info-by-product/index.html

Health Department – Vaccine Information for Health Care Professionals
www.healthvermont.gov/covid-19/health-care-professionals/vaccine-information-health-care-professionals

CDC - Use of COVID-19 Vaccines in the United States
www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

Pfizer-BioNTech

Manufacturer:

- Website: www.cvdvaccine-us.com/
- Expiration Date Look-up Tool: lotexpiry.cvdvaccine.com/

EUAs and FDA:

- EUAs (Fact Sheets) for providers and recipients: www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccines

CDC:

- Pfizer Vaccine At A Glance: www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/vaccine-at-a-glance.pdf
- Pfizer Storage and Handling Summary: www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/storage-summary.pdf
- Pfizer Administration Summary: www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/diluent-poster.pdf

Moderna

Manufacturer:

- Website: eua.modernatx.com/covid19vaccine-eua/providers/
- Expiration Date Look-up Tool: https://modernacovid19global.com/vial-lookup

EUAs and FDA:

- EUAs (Fact Sheets) for providers and recipients: www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccines

CDC:

- Moderna Vaccine At A Glance: www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/vaccine-at-a-glance.pdf
- Moderna Storage and Handling Summary: www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/storage-summary.pdf
- Moderna Administration Summary: www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/prep-and-admin-summary.pdf

Novavax

Manufacturer:

- Website: https://us.novavaxcovidvaccine.com/hcp
- Expiration Date Look-up Tool: https://us.novavaxcovidvaccine.com/hcp

EUAs and FDA:

- EUAs (Fact Sheets) for providers and recipients: https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/novavax-covid-19-vaccine-adjuvanted#additional

CDC:

- Novavax Storage and Handling Summary: www.cdc.gov/vaccines/covid-19/info-by-product/novavax/downloads/novavax-storage-handling-summary.pdf
- Novavax Administration Summary: www.cdc.gov/vaccines/covid-19/info-by-product/novavax/downloads/novavax-prep-admin-summary.pdf

Vaccine Storage and Handling SOP

A. Provider agreement

All providers are required to sign a COVID-19 Vaccination Program Provider Agreement before receipt of this vaccine. As a part of this agreement, providers are required to:

- Store and handle COVID-19 vaccines under proper conditions, including maintaining cold chain conditions and chain of custody at all times in accordance with an EUA or vaccine package insert, manufacturer guidance, and CDC guidance.
- Monitor storage unit temperatures at all times, using equipment and practices that comply with the guidance.
- Comply with Immunization Program guidance for handling temperature excursions (above).
- Monitor and comply with COVID-19 vaccine expiration dates.
- Preserve all records related to COVID-19 vaccine management for a minimum of three years.
- Comply with federal instructions and timelines for disposing of COVID-19 vaccine and diluent, including unused doses.

B. Vaccine deliveries and inventory management

You will manage the state-supplied COVID-19 vaccine in the VIMS system, similar to other vaccines.

There are two types of COVID-19 orders:

- **Direct Ship:** The Health Department prefers to use direct distributor deliveries. With a direct ship, the COVID-19 vaccine ships directly to you, just like routine vaccines. However, there are minimum order limitations. Ancillary supplies arrive in separate packaging within a day or two of the vaccine delivery.
- **Depot Delivery:** The Depot delivers vaccine and ancillary supplies to sites that need less than the minimum order quantities. Deliveries are batched geographically, and the date is confirmed by email. All vaccines coming from the Depot should be ordered by Thursday at 4 pm for delivery the following week and placed in refrigerated temperatures upon delivery unless otherwise stated.

C. Beyond use date (BUD)

The current presentation of COVID-19 vaccines is multi-dose vials with no preservatives. Preservative-free means that the time a vaccine is thawed, brought to room temperature, reconstituted, punctured, or drawn into a syringe will determine its shelf life and viability.

A BUD may not exceed an expiration date.

A vaccine is no longer viable when the BUD or expiration is reached, whichever occurs first

- BUD begins when an mRNA vaccine (Moderna and Pfizer) is removed from permanent storage and put into the refrigerator.
  - **Pfizer BUD:** 10 weeks after removal from ultracold.
  - **Moderna BUD:** 30 days after removal from a standard freezer.
- BUD is not associated with a vaccine lot number and will not be documented in VIMS. The practice is responsible for tracking and documenting a vaccine's BUD.

COVID-19 Vaccine Expiration Date and BUD Guidance
www.healthvermont.gov/sites/default/files/documents/pdf/HS-IZ-COVID19-Expiration-Date-BUD-Guidance.pdf

D. Provider training

All staff members who receive vaccine deliveries and those who handle or administer vaccines should be trained in vaccine-related practices and procedures. Please refer to the Role and Responsibilities section in this document.

COVID-19 vaccine administration is much more complicated than the standard vaccines, and stability storage guidelines may change as more data becomes available. Please refer to the COVID-19 Vaccine Information for Health Care Professionals website below for current guidance and links to recent training sessions and communications from the Immunization Program.

www.healthvermont.gov/covid-19/health-care-professionals/vaccine-information-health-care-professionals

E. Temperature monitoring

Please refer to the above document for general information on the Immunization Program's temperature monitoring systems and reporting requirements. For COVID-19 enrolled providers, a third-party monitoring system may be approved.

- **Refrigerator temperatures** – Between 2 and 8 °C, strive for an average reading of 5 °C.
- **Freezer temperatures** – Between -50 and -15 °C. Once thawed, no COVID vaccine should be refrozen.
- **Ultra Cold temperatures** – Only Pfizer-BioNTech vaccine has ultra-cold temperature requirements between -80 and -60 °C. These temperatures require special monitoring equipment, and the vaccine must be direct ship to a facility from the manufacturer.
- **During transport** – Even when transported short distances, temperature monitoring of COVID-19 vaccine is required. Please refer to Vaccine Transport (transfers) above.
- **During clinics** - Qualified pack-out or portable refrigerators are required during a clinic, with continuous monitoring and hourly documentation. Refer to the Vaccine Carrier Borrowing Program guide for information on loaning an appropriate vaccine carrier through the Immunization Program.

COVID-19 Vaccine Storage and Handling for Off-site Clinics
www.healthvermont.gov/sites/default/files/documents/pdf/COVID19-Vaccine-Off-Site-Clinic-Guidance.pdf

Vaccine Carrier Borrowing Program
www.healthvermont.gov/sites/default/files/documents/pdf/HS-IZ-Vaccine-Carrier-Program.pdf