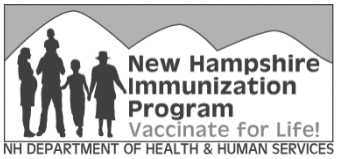


Vaccine Management for COVID-19 Vaccination Sites and Clinics

COVID-19 Vaccination Sites and Clinics must comply with CDC COVID-19 Vaccination Program Provider Agreement Requirement #7

Organization must comply with CDC requirements for COVID-19 vaccine management. Those requirements include the following:

a) Storage and Handling: Organization must store and handle COVID-19 vaccine under proper conditions, including maintaining cold chain conditions and chain of custody at all times in accordance with the manufacturer's package insert and CDC guidance in CDC's *Vaccine Storage and Handling Toolkit*, which will be updated to include specific information related to COVID-19 vaccine;

b) Temperature Monitoring: Organization must monitor vaccine storage unit temperatures at all times using equipment and practices that comply with guidance in CDC's *Vaccine Storage and Handling Toolkit*;

c) Cold Chain Incident Reporting: Organization must comply with each relevant jurisdiction's immunization program guidance for dealing with temperature excursions;

d) Organization must monitor and comply with COVID-19 vaccine expiration dates; and

e) Organization must preserve all records related to COVID-19 vaccine management for a minimum of 3 years, or longer if required by state, local, or territorial law.

Emergency Use Authorization Storage and Handling Information

Specific, detailed storage and handling protocols for individual vaccines are provided in manufacturer package inserts for vaccines licensed by the Food and Drug Administration (FDA). However, because COVID-19 vaccines may initially be authorized for use under an EUA, COVID-19 vaccination providers should refer to the EUA Fact Sheet for Healthcare Providers and manufacturer information for detailed storage and handling information for each vaccine.

Vaccine Cold Chain

A cold chain is a temperature-controlled supply chain that includes all vaccine-related equipment and procedures. It begins with vaccine manufacturing and ends with vaccine administration. Vaccines must be stored properly from the time they are manufactured until they are administered. Potency is reduced every time a vaccine is exposed to an improper condition. This includes overexposure to heat, cold, or light at any step in the cold chain. Once lost, potency cannot be restored.

An effective cold chain relies on three main elements:

- A well-trained staff
- Reliable storage and temperature monitoring equipment
- Accurate vaccine inventory management

COVID-19 Vaccine Storage and Handling Information

updated 3/9/21

	Pfizer	Moderna	Janssen
	MUST be mixed with diluent	**Do NOT mix with diluent**	**Do NOT mix with diluent**
NDC	59267-1000-02	80777-0273-99	59676-0580-05
Presentation	6-dose multidose vial *(as of 2/16/21)*	10-dose multidose vial	5-dose multidose vial
Vaccination Schedule	2-dose series	2-dose series	single dose
	0.3mL each dose	0.5mL each dose	0.5mL each dose
	separated by at least 3 weeks/21 days	separated by at least 4 weeks/28 days	N/A
ULT Storage	-80°C to -60°C up to 6 months. Can be transported at -25°C to -15°C and returned to ULT storage **one time** only.	N/A	N/A
Frozen Vaccine Storage	-25°C to -15°C for up to two weeks (including transport time)	-25°C to -15°C	No frozen storage
Refrigerated Storage and Expiration	2°C to 8°C	2°C to 8°C	2°C to 8°C
	5 days/120 hours	30 days	up to 3 months
	Do not refreeze	Do not refreeze	Do not freeze
Room Temp Stability and Expiration	**Diluted** vaccine can be kept between 2°C to 25°C (35°F to 77°F) and administer within 6 hours.	8°C to 25°C (46°F to 77°F) for cumulative time of 12 hours for unpunctured vials.	9°C to 25°C (47°F to 77°F) for up to 12 hours for unpunctured vials.
	Undiluted vials may be stored at room temperature 8°C to 25°C (46°F to 77°F) for 2 hours		
Storage after first dose is withdrawn	Any mixed vaccine that has not been administered within 6 hours should be returned to NHIP.	2°C to 25°C (35°F to 77°F) for 6 hours. Wastage should be returned to NHIP.	2°C to 25°C (35°F to 77°F) for 6 hours. Wastage should be returned to NHIP.

Data Logger Requirements

All providers participating in the NH COVID-19 Vaccination program are required to use a continuous temperature monitoring device (data logger) in each vaccine storage unit including emergency transport of vaccine.

As of January 1, 2018 CDC requires back-up thermometers to be data loggers. Each provider must have one *available* in the event that something happens to the primary device. It is recommended that the back-up device be on site but, if not, one must be available to monitor the storage unit within an hour. Each of these devices must have a current and valid certificate of calibration.

Data-loggers must meet or exceed the CDC specifications below:

- ✓ **Detachable Bio safe glycol-probe** or similar buffered solution, that remains in the refrigerator or freezer.
- ✓ **Continuous Monitoring**. The ability to record and save temperature information 24 hours a day. Measures at least one reading every 15 minutes.
- ✓ **A digital display on the outside of the unit**.
- ✓ **The ability to display the minimum and maximum temperatures** between readings.
- ✓ **A Hi/Lo alarm**, audible or visual for out- of- range temperatures.
- ✓ **The ability to download and transmit** temperature information by email or fax.
- ✓ **Low battery indicator**.
- ✓ **A current certificate of calibration** that is traceable to the National Institute of the Standards and Technology (NIST).
- ✓ **Accuracy of +/- 1ºF (0.5ºC).** This information should be contained in the Certificate of Traceability and Testing (also known as the Report of Calibration). A copy of this certificate should be readily available for any NHIP staff during a site visit.

Data loggers must always be used when transporting vaccine. Refer to packing vaccine during emergencies when transporting off site.

Certificate of Calibration must be issued either by an ILAC-accredited laboratory or, if not ILAC-accredited, certificate must contain measurement results and a statement indicating that it meets ISO 17025 standards. All certificates must contain:

- ✓ name of device (optional),
- ✓ model number,
- ✓ serial number, and
- ✓ date of calibration.

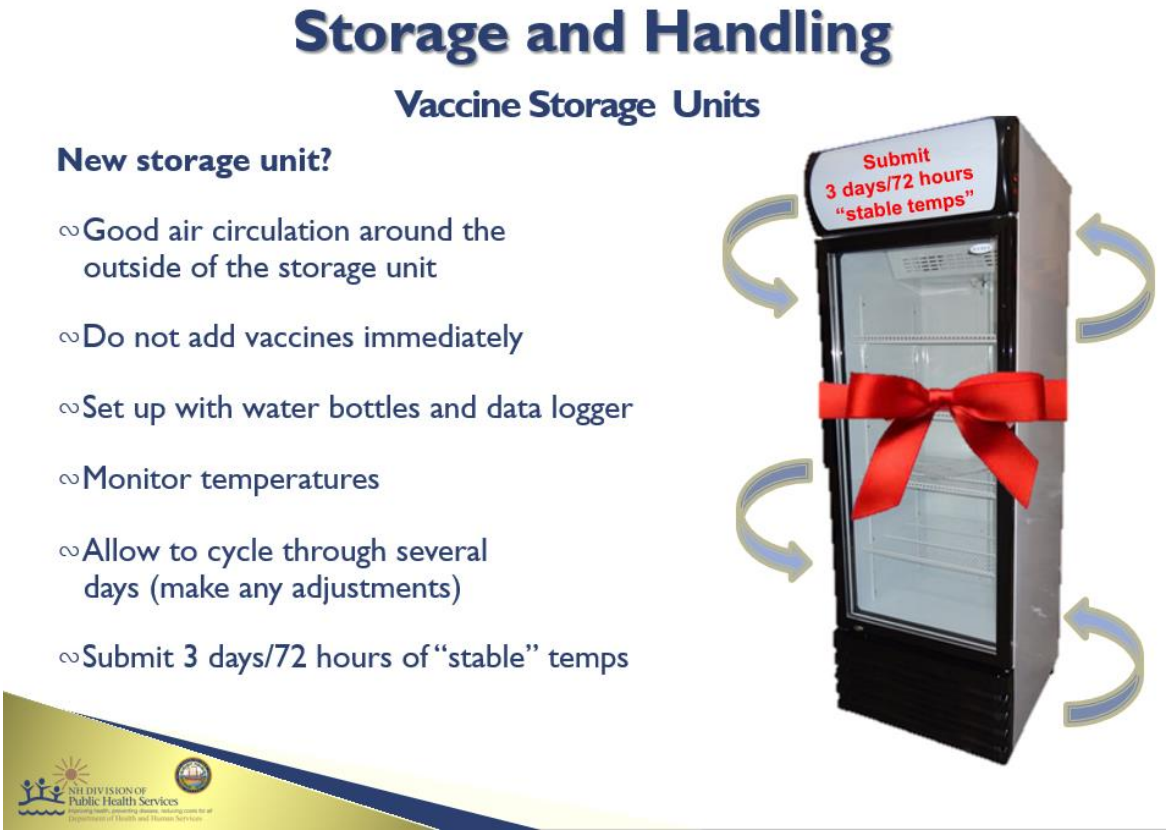
A certificate of calibration is generally valid for 2 years from calibration date, *unless specified on the certificate.*

**** BE ALERT FOR CERTIFICATE EXPIRATION DATE(S)! ****

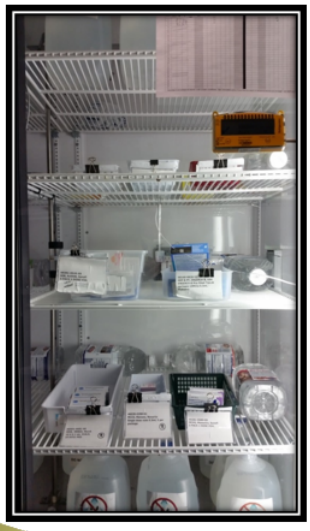
Storage Units

All new vaccine storage units must be monitored with a 24/7 monitoring device before any federal or state supplied vaccine may be moved into it. The only exception would be in an emergency when immediate storage is needed due to unit failure or unexpected power outage.

1. Monitor the new unit. Check the min and max at the beginning and end of every day and adjust the temperature accordingly to reach the optimal temperature between 3-5℃ continuously.
2. After 3 days of stable temperatures in the new unit, download the report.
3. Document on the report the date the device began recording data in the new unit.
4. Submit the report to NHIP by scan/email or fax.
5. Contact NHIP by phone for confirmation and approval to move vaccines into new unit.



Setting up Your Vaccine Storage Units



✓Wire shelving best for air circulation

✓ ✓ Vaccine in open/ventilated baskets not touching unit walls

✓ Do not store in drawers, on floor or door of unit

✓ Baskets clearly labeled

✓ Separate state supplied vaccine from private

✓ Keep vaccines in original boxes

✓ Earliest expiration to the front of the shelf

✓ Water bottles throughout the unit and on doors if equipped

✓ Glycol bottle in **center** of unit

X NO food/drink

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Setting up Your Vaccine Storage Units (outside)

Outlet visible ---
directly above/beside outlet.
Outlet hidden ---
on front storage unit

Added safety

out of range temperatures

Added safety

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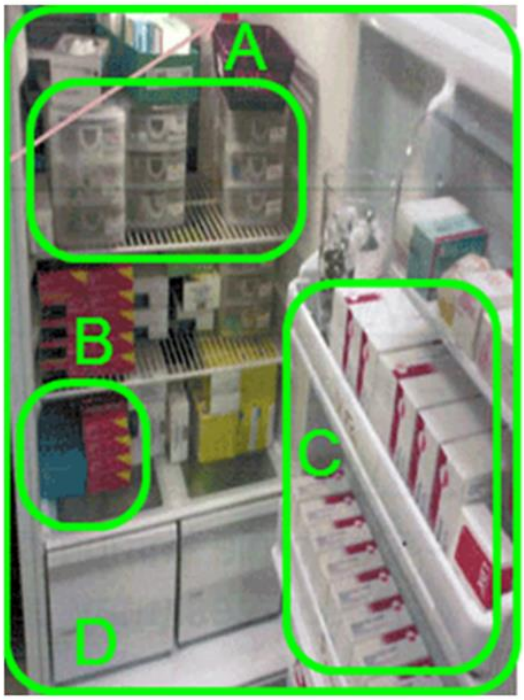
A. Solid storage bins-do not provide good air flow
B. Vaccines touching unit walls
C. Vaccines stored on unit door
D. Remove drawers-prevents storing of vaccine of food & drink
E. Unit is too full



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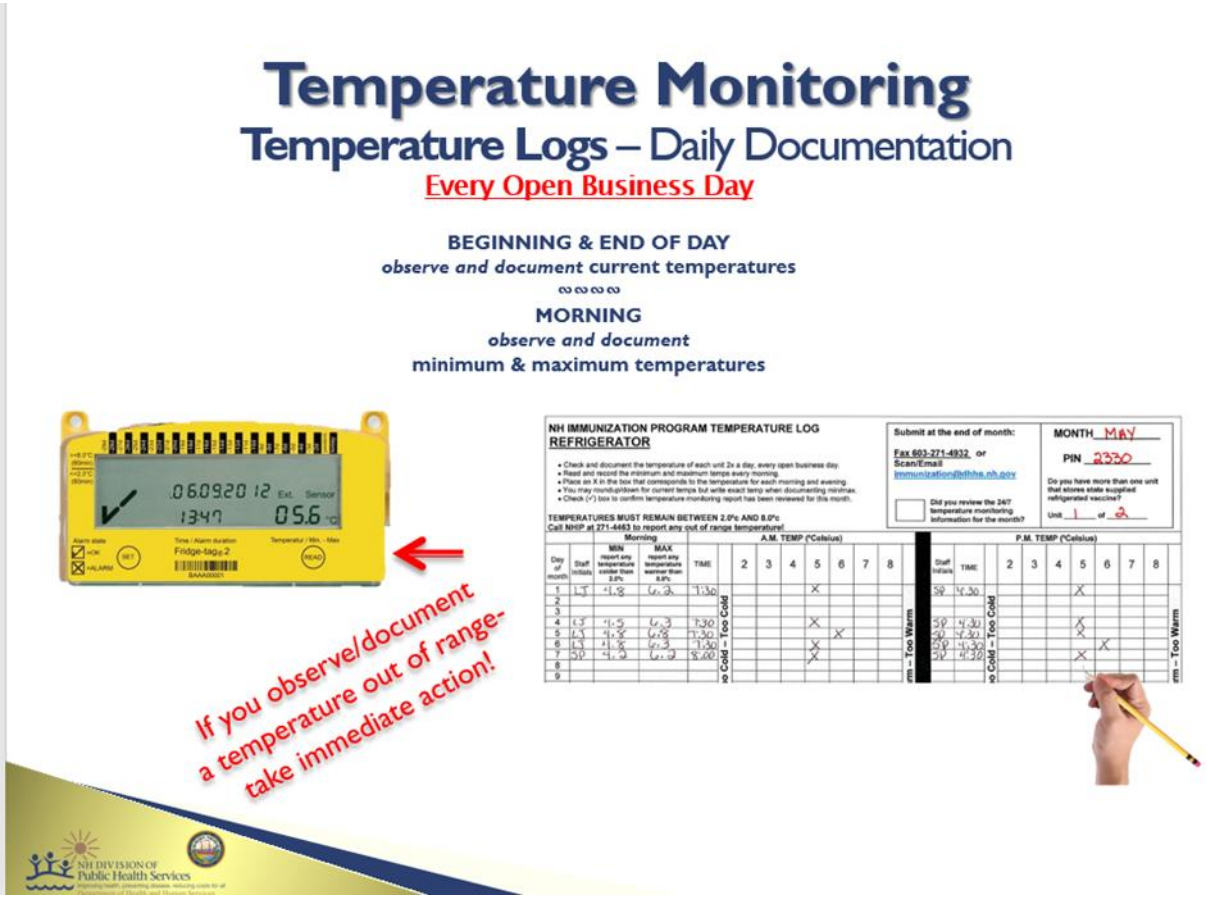
Temperature Monitoring

Call NHIP at 271-4463 to report any out of range temperature and follow all Cold Chain Incident Reporting Procedures ASAP!

All COVID-19 Fixed Vaccination Sites are required to use a continuous temperature monitoring device (data logger) in each vaccine storage unit including emergency transport of vaccine. Each fixed site will record the following every day they are open on the 2021 NHIP Monthly Temperature Log:

- Use the NHIP 2021 Monthly Refrigerator Temperature Log to check and record the temperatures of each storage unit 2x a day, every open business day.
- Read and record the minimum and maximum temps every morning.
- Place an X in the box that corresponds to the temperature for each morning and evening. You may roundup/down for current temps but write exact temp when documenting min/max.
- Check (☑) box to confirm temperature monitoring report has been reviewed for this month.



Temperature Monitoring

Temperature Logs - Submitted end of every month

Scan/email (preferred): immunization@dhhs.nh.gov or Fax: 603-271-4932

Be sure all required documentation is completed

NH IMMUNIZATION PROGRAM TEMPERATURE LOG
REFRIGERATOR

- Check and document the temperature of each unit 2x a day, every open business day.
- Read and record the minimum and maximum temps every morning.
- Place an X in the box that corresponds to the temperature for each morning and evening.
- You may roundup/down for current temps but write exact temp when documenting min/max.
- Check (✓) box to confirm temperature monitoring report has been reviewed for this month.

TEMPERATURES MUST REMAIN BETWEEN 2.0°c AND 8.0°c
Call NHIP at 271-4463 to report any out of range temperature!

Submit at the end of month:
Fax 603-271-4932 or
Scan/Email
immunization@dhhs.nh.gov

✓ Did you review the 24/7 temperature monitoring information for the month?

MONTH January
PIN 1234
Do you have more than one unit that stores state supplied refrigerated vaccine?
Unit 1 of 3

	Morning			A.M. TEMP (°Celsius)								P.M. TEMP (°Celsius)								
Day of month	Staff Initials	MIN report any temperature colder than 2.0°c	MAX report any temperature warmer than 8.0°c	TIME		2	3	4	5	6	7	8	Staff Initials	TIME	2	3	4	5	6	7	8
1	LJ	4.8	6.2	7:30					X				SP	4:30				X			
2	LJ	4.7	6.3	7:30					X												

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Temperature Excursions

Call NHIP at 271-4463 to report any out of range temperature and follow all Cold Chain Incident Reporting Procedures ASAP!

Any temperature reading outside the range recommended by the manufacturer is considered a temperature excursion and requires immediate action. To determine whether a vaccine is likely to still be viable, COVID-19 vaccine manufacturers will analyze information about the magnitude of the temperature excursion, including the total amount of time that temperatures were out of range.

Report any incident in which your COVID-19 vaccine has been exposed to temperatures that may affect the safety and viability of your vaccine. To report, follow all procedures listed on the COVID-19 Vaccine Cold Chain Incident Report immediately and complete all information accurately.

1. **Quarantine vaccine** - do not administer until confirmation of viability has been determined
2. Download continuous temperature monitoring information report and review as soon as the out of range temperature is discovered.
3. Call NHIP for guidance. (If after hours, enact your emergency plan for temporary storage)
4. Complete all the information on the COVID-19 Vaccine Cold Chain Incident Report and call manufacturers.
5. If vaccine has been deemed non-viable by the manufacturer, you must return the vaccine to NHIP. Vaccine should still be packed up using proper vaccine transport procedures despite being deemed compromised.
6. Scan/email the COVID-19 Vaccine Cold Chain Incident Report and your data logger temperature monitoring report(s) to immunization@dhhs.nh.gov or fax to 603-271-3850.

Vaccine Transport

MAINTAIN THE "COLD-CHAIN" WHEN MOVING VACCINES!

It is critical that vaccine potency is protected by maintaining the cold chain at all times during relocation and transport. The following procedures should be followed if vaccines need to be transported due to a power failure, short expiration date, or other reasons that require proper packing procedures of vaccine. If relocating large quantities of vaccine due to impending storm or power/unit failure, be sure to document the inventory prior to transfer and upon its return once the emergency scenario has been resolved. To avoid false out of range data or unnecessary alarm triggers- the buffered probe/glycol bottle should be kept in proper storage unit so it "conditioned" for use.

Preparing for Transport

- The following materials are needed and should be always readily available:
  - ✓ Proper insulated container (e.g. the containers that arrive from NHIP deliveries, hard sided insulated containers or styrofoam cooler with at least 2-inch thick walls)
  - ✓ Frozen water bottles (properly conditioned before use for refrigerated vaccine)
  - ✓ Several chux, bubble wrap or other insulator to place as a barrier between water bottles and vaccine. Sheet of cardboard also helps keep contents stable
  - ✓ A continuous temperature monitoring device (data logger)

AVOID FREEZING REFRIGERATED VACCINE DURING TRANSPORT WITH CONDITIONED WATER BOTTLES

"Conditioning" means warming frozen water bottles until the frost on the outside turns to droplets of water and you can see a small amount of water on the inside of the bottle where the solid ice has begun to melt.

Conditioning Frozen Water Bottles

- **Leave them out on the counter for 25-30 minutes** (process time is dependent on room temperature)
  OR
- **Place frozen bottles in a sink filled with several inches of lukewarm water** (process time is dependent on water temperature)
  OR
- **Place under running tap water** (process time is dependent on water temperature)

Once you see ice and water coexisting in the bottle, you know that the bottle is exactly 0°C and no colder! The bottle is properly conditioned if the ice block inside moves when rotated in your hand. Follow proper packing procedures and your vaccine should be safe from freezing during transport.

Refrigerated Vaccine

- Place *conditioned* water bottles in the bottom of the insulated container
- Place a layer of insulator on top of the water bottles so the vaccines do not directly touch them (to prevent freezing)
- Place vaccines on top of insulator
- Insert data logger near the center of the vaccines, never in direct contact with water bottles
- Add another layer of insulator over the vaccines
- Add another layer of *conditioned* water bottles
- Add chain of custody slip

- Secure the lid of the insulated container, attach data logger to outside and seal with strapping tape.
- Clearly label the outside of the container "**Vaccine – Refrigerate Immediately**"
- Upon arrival at destination-read min/max and record current temperature of data logger. If the temperature rises above 8°c or below 2°c, place vaccine in proper storage unit and contact NHIP

<u>Follow exact procedures when transporting back to original site</u>
If vaccine is transferred for reasons other than emergency, and will become the permanent inventory of another practice, the transfer must be reported to NHIP (to update the NHIIS) and updated in any required inventory systems used during the time of transfer (Vaccine Finder, VAMS, etc.).

Expired Vaccine

Determining when a vaccine or diluent expires is a critical step in proper storage and handling. Expired vaccines and diluents should be removed immediately from storage units to avoid inadvertently administering them. All expired, open or broken vials and vaccine pre-drawn by fixed sites should be returned to NHIP. To help COVID-19 fixed sites track expiration dates and beyond use dates (BUDs), use the COVID-19 Vaccine Expiration Date Tracking Tool released by the CDC.

COVID-19 Vaccine Expiration Date Tracking Tool

Use this tracking tool to record updated expiration dates for COVID-19 vaccine as additional stability data are available from the manufacturer. When the current expiration date gets close, contact the manufacturer before discarding vaccine. Document the current date, the vaccine lot number, and the updated expiration date in the appropriate columns, including the information source and the name of the person completing this form. Keep this document for 3 years or longer if required by your jurisdiction..

Product name: _____ **Manufacturer:** _____ **Original Expiration Date:** _____

Expiration date info is available at (include all available information from manufacturer; website, app, phone number.)

Date	Lot Number	Updated Expiration Date	Info Source	Name
Example: 09/01/2020	ABC123DEF456	06/30/2021	☒ Website ☐ Barcode	Susie Smith RN

12/12/2020 CS321629-D

Failure to store/handle vaccines properly

- May reduce potency, resulting in inadequate immune responses in patients and poor protection against disease

- May cause patients to lose confidence in vaccines and their providers when revaccination is necessary

- May result in significant financial loss if the vaccine(s) cannot be used and/or provider is asked to replace

Its better to not vaccinate that to administer a dose of vaccine that has been mishandled and not stored properly

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