

Please return the complete document, and retain a copy for your records.

**New York State Department of Health (NYSDOH) Bureau of Immunization
Vaccine Storage and Handling Plan**

Primary Provider/Practice Name _____ VFC PIN (if renewal) _____

Vaccines need to be properly stored and administered to ensure maximum efficacy and safety. Check “yes” or “no” for each item. Implement changes for items marked “no.”

Personnel:

- Yes No 1. We have designated a primary vaccine coordinator and a back-up coordinator for this office. He/She will be responsible for ensuring that vaccines are handled and stored appropriately, that all necessary documentation is completed and that all staff are properly trained in the handling and storage of vaccines.

Our Vaccines for Children (VFC) coordinator is _____

Our back up coordinator is _____

- Yes No 2. We review this storage and handling plan with all staff annually and with new staff, including temporary staff, when they are hired.

Equipment and Temperature Monitoring:

- Yes No 1. We maintain the refrigerator temperature at 35°F-46°F (2°C-8°C), and we aim for 40°F (5°C).
- Yes No 2. We maintain the freezer temperature at or below +5°F (-15°C).
- Yes No 3. We understand that dormitory style refrigerator/freezer units are never acceptable for storage of any VFC vaccines. Dormitory refrigerators are small single-door combined refrigerator/freezer units.

a. The type of refrigerator we use is (mark all that apply):

- Stand alone, refrigerator (not a dual refrigerator/freezer)
- Stand alone, pharmaceutical-grade refrigerator
- Household type, dual refrigerator freezer
- Only using the refrigerator compartment

b. The type of freezer we use is (mark all that apply):

- Stand alone, freezer (not a dual refrigerator/freezer)
- Stand alone, pharmaceutical-grade freezer
- Household type, dual refrigerator freezer
- Only using the freezer compartment

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Yes No 4. Our refrigerator and freezer each contain a calibrated thermometer that has a Certificate of Traceability and Calibration in accordance with National Institute of Standards and Technology (NIST) standards. Thermometers will be recalibrated at least every two years and a valid certificate will be available for NYSDOH regional representatives to review at the time of a site visit. Thermometers with Certificates of Calibration that do not specify a recalibration date will be recalibrated annually. Thermometer probes are located in the center of the storage compartment. Thermometers are inspected monthly for signs of breakage or wear. Ideally, thermometers will have an alarm or alert system that indicates when the temperature may be out of a preset range.

a. The type of thermometer used for each refrigerator/freezer is:

- Calibrated digital thermometer
- Calibrated digital thermometer built into refrigerator/freezer
- Other calibrated thermometer, please specify: _____

b. Our thermometer is capable of showing the minimum/maximum temperature recorded Yes No

If yes, can the minimum/maximum temperature be cleared? Yes No

c. We use a temperature probe:

- Directly exposed to the air
- In a tube or container holding glass beads
- In a tube or container holding glycol
- In a tube or container holding a biosafe liquid other than glycol

d. Continuous data logger used (not required under NYSDOH VFC guidelines):

- Paper chart recorder (e.g. a circular paper chart that tracks all temperatures)
- Downloadable data logger via a USB connection to computer
- Automatic logging via WiFi connection
- Other
- We do not use a data logger

e. As of January 1, 2015, we keep at least one back up thermometer with a current calibration certificate on hand in case a thermometer in use is no longer working properly or calibration testing of the current equipment is required (CDC Requirement). Yes No

Yes No 5. Our freezers and refrigerators are not connected to an outlet with a ground-fault circuit interrupter (GFCI) or one activated by a wall switch. We have a "Do Not Unplug" sign next to the electrical outlets for the refrigerator and freezer and "Do Not Stop Power" warning label by the circuit breaker for the electrical outlets.

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- Yes No 6. The NYSIIS temperature log or a temperature log book will be used to record refrigerator and freezer temperatures twice a day. Each temperature reading will include the initials of the person taking the temperature along with the time of day. Temperatures will be taken and recorded manually twice daily regardless of whether or not there is a temperature alarm, a chart recorder thermometer, or a digital data logger. Temperatures are measured and recorded at the start and end of each clinic day. Paper temperature logs will be recorded on a temperature log provided by the Immunization Action Coalition (IAC) and will kept for a minimum of three years. IAC logs may be obtained at www.immunize.org.

Procedures for Storing and Handling Vaccines Correctly:

A. When we receive a vaccine shipment:

- Yes No 1. Our office is open at least one day other than Monday to receive vaccine shipments. On this day we are open for at least 4 consecutive hours.
- Yes No 2. We examine shipping container for any evidence of damage during transport.
- Yes No 3. We examine cold-chain monitor cards for any evidence of exposure to out-of-range temperatures.
- Yes No 4. We do not accept shipment if reasonable suspicion exists that the delivered product may have been mishandled.
- Yes No 5. We contact the manufacturer when circumstances raise questions about the efficacy of a delivered vaccine. We follow manufacturers' recommendations.
- Yes No 6. We check expiration date to make sure vaccine has not expired.
- Yes No 7. We place vaccine in an appropriate storage unit immediately.

B. Refrigerator and Freezer Set-Up:

- Yes No 1. We always store vaccines in the appropriate storage unit throughout the office day.
- Yes No 2. We always store vaccines in the center of the storage unit, stacked with air space between the stacks and the sides and back of the unit to allow cold air to circulate around the vaccines.
- Yes No 3. We do not store vaccine on the top shelf of the refrigerator directly under a fan because it could cause the vaccine to freeze.
- Yes No 4. We do not store vaccines on the door or in the vegetable bins as these are areas where the temperature can deviate from the rest of the storage unit (these are good places for water or ice packs to help stabilize temperatures.)
- Yes No 5. We do not store food or drink in a refrigerator or freezer where vaccines are stored.
- Yes No 6. We do not store radioactive materials or lab specimens in a refrigerator where vaccines are stored.
- Yes No 7. We store vaccines in their original packaging in clearly labeled uncovered containers with slotted sides that allow air to circulate.
- Yes No 8. We check vaccine expiration dates and rotate our supply of each type of vaccine so that we use the vaccines that will expire soonest.
- Yes No 9. Our publicly purchased vaccine is labeled and can be distinguished from our private stock.
- Yes No 10. We place filled water bottles in the doors and the bottom of refrigerator and ice packs in a freezer to serve as temperature ballast in the event of a power outage.

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C. Vaccine Administration:

- Yes No 1. We discard reconstituted vaccines not used within the interval allowed on the package insert.
- Yes No 2. We do not open more than one multi-dose vial of a specific vaccine at a time.
- Yes No 3. We use multi-dose vials of vaccine until the expiration date set by the manufacturer.
- Yes No 4. We always contact the appropriate vaccine manufacturer if there is any question about the storage or handling of any vaccine and inform the Bureau of Immunization.

D. Emergency Action:

- Yes No 1. If we identify a temperature that is out of range, we do not use vaccines while determining the cause of an out of range temperature. Vaccines remain in the storage unit or are moved to a properly functioning unit with a sign that says "DO NOT USE."
- a. **For a freezing temperature in a refrigerator unit** (at or below 32°F (0C): we immediately adjust the temperature warmer and contact the VFC program.
 - b. **For a warm temperature in either a refrigerator or freezer** (above 5°F (-15C) in the freezer; above 46°F (8C) in the refrigerator): This may be due to a defrost cycle and we do not adjust the thermostat immediately.
 - a. If the freezer temperature is above 32°F (0C), we immediately contact the VFC Program.
 - b. We identify whether the temperature increase is due to an open door and address the issue.
 - c. We check the position of the probe to ensure that it is not in the back of the unit against the wall or in the door. If the probe is not properly placed, we move it to the center of the unit.
 - d. We recheck temperature in 30-60 minutes. During this time we do not use the vaccine.
 - i. If the temperature is back in range, we note the excursion and potential causes on temperature log.
 - ii. If the temperature is not in range we make an adjustment and contact VFC program staff immediately for further guidance.
- Yes No 2. In case of a power outage, we do not open the freezer or refrigerator door. The exception to this would be to transport the vaccine to a working unit.
- Yes No 3. If a power outage results in freezer and/or refrigerator temperatures going out of the recommended range, we call the vaccine manufacturers for guidance and follow the manufacturers' recommendations. We also report the incident to the NYSDOH Bureau of Immunization as soon as possible.
- Yes No 4. If a power outage is prolonged (more than one hour) we have a written procedure for alternate storage. Our written procedure will be available for a NYSDOH regional representative for review at the time of a site visit. The written procedure will be reviewed and tested with staff once a year.

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Please describe your emergency plan including any alternate site locations, whether you have a generator and who is designated to respond to emergencies:

Ordering Vaccine:

- Yes No 1. We always conduct a physical inventory of our vaccine supply within 14 days of placing an order. Inventory that is entered into the NYSIIS module is physically counted as well.
- Yes No 2. We order VFC vaccine using the NYSIIS vaccine ordering module.
- Yes No 3. We are prepared to order all vaccines needed for the entire month as VFC is unable to accept more than one order per VFC PIN in any calendar month.
- Yes No 4. We document all immunizations using the New York State Immunization Information System (NYSIIS).
- Yes No 5. We call the NYSDOH Bureau of Immunization at 1-800-543-7468 to inform the VFC Program staff of any expired or wasted vaccine. Program staff will guide us on the proper procedure for the return of all publicly purchased, expired or wasted vaccines. They will advise us if revaccination may be necessary.
- Yes No 6. We have a separate procedure for ordering vaccine for our private stock.

Provider Education:

- Yes No 1. Our primary and back up coordinator have participated in the CDC's "You Call the Shots" Vaccines for Children overview webinar.

Date of training for coordinator: _____

Date of training for back up coordinator: _____

- Yes No 2. Our primary and back up coordinator have participated in at least one recorded storage and handling training session. We attended the following training session(s). (Please list date attended for primary and backup.)

Primary Coordinator	Back-up Coordinator	Training Session
_____	_____	NYSDOH Storage and Handling Update
_____	_____	CDC "You Call the Shots" Storage and Handling Module
_____	_____	CDC YouTube video, "Keys to Storing and Handling Your Vaccine Supply"

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We agree to implement the above plan. For any areas marked “no” we will implement needed changes.

Supervising Provider:

Name (Print)	Title (Print)	Email Address (Print)
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Signature	Date
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Primary Coordinator:

Name (Print)	Title (Print)	Email Address (Print)
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Signature	Date
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Back Up Coordinator:

Name (Print)	Title (Print)	Email Address (Print)
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Signature	Date
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