VACCINE STORAGE AND HANDLING PLAN

Vaccine must be properly stored and administered to ensure maximum efficacy and safety. All Vaccines for Children (VFC) sites must attest to their compliance with routine and emergency storage and handling plans.

Newly enrolling providers are required to have standalone refrigerator and freezer units and digital data loggers for every unit storing VFC vaccine. Dormitory style refrigerator/freezer units are never acceptable. For additional guidance, see VFC Program Vaccine Storage and Handling Requirements on pages 14 and 15 of the VFC enrollment packet, and visit: https://www.health.ny.gov/prevention/immunization/vaccines_for_children/storage_and_handling.htm.

PRIMARY VFC REFRIGERATOR UNIT

Unit Location/ID #

Use ○ Primary ○ Backup/Overflow

Refrigerator Grade
○ Commercial ○ Medical/Lab/Pharmaceutical ○ Household/Consumer ○ Other *(Specify)*: _____

Refrigerator Make

Refrigerator Model

Data Logger Model
○ State issued ○ Other *(Specify make and model)*: _____

Data Logger Calibration Expiration Date

ADDITIONAL VFC REFRIGERATOR UNIT

Unit Location/ID #

Use ○ Primary ○ Backup/Overflow

Refrigerator Grade
○ Commercial ○ Medical/Lab/Pharmaceutical ○ Household/Consumer ○ Other *(Specify)*: _____

Refrigerator Make

Refrigerator Model

Data Logger Model
○ State issued ○ Other *(Specify make and model)*: _____

Data Logger Calibration Expiration Date

PRIMARY VFC FREEZER UNIT

Unit Location/ID #

Use ○ Primary ○ Backup/Overflow

Freezer Grade
○ Commercial ○ Medical/Lab/Pharmaceutical ○ Household/Consumer ○ Other *(Specify)*: _____

Freezer Make

Freezer Model

Data Logger Model
○ State issued ○ Other *(Specify make and model)*: _____

Data Logger Calibration Expiration Date

ADDITIONAL VFC FREEZER UNIT

Unit Location/ID #

Use ○ Primary ○ Backup/Overflow

Freezer Grade
○ Commercial ○ Medical/Lab/Pharmaceutical ○ Household/Consumer ○ Other *(Specify)*: _____

Freezer Make

Freezer Model

Data Logger Model
○ State issued ○ Other *(Specify make and model)*: _____

Data Logger Calibration Expiration Date

BACKUP TEMPERATURE MONITORING DEVICE *(required)*

Data Logger Model
○ State issued ○ Other *(Specify make and model)*: _____

Data Logger Calibration Expiration Date

VACCINE PROGRAM STORAGE AND HANDLING REQUIREMENTS

(For additional guidance, visit https://www.health.ny.gov/prevention/immunization/vaccines_for_children)

1. Maintain refrigerator temperatures at 36°F - 46°F (2°C - 8°C), with an optimal temperature of 40°F (5°C).
2. Maintain freezer temperatures at or below +5°F (-15°C).
3. Do not connect vaccine storage units to any outlets with a ground-flow circuit interrupter (GFCI) or an outlet activated by a wall switch. Post "Do Not Unplug" signs next to the electrical outlets for the refrigerator and freezer and "Do Not Stop Power" warning labels by the circuit breaker for the electrical outlets. Instruct all staff and any maintenance and custodial staff to never turn off the power to the vaccine storage units.
4. Maintain a calibrated digital data logger with an alarm or alarm system to indicate when storage units are out of range and a Certificate of Traceability and Calibration in accordance with National Institute of Standards and Technology (NIST) standards in each VFC/VFA refrigerator and freezer.
    - Place data logger probes in the center of the storage compartment.
    - Inspect data loggers monthly for signs of breakage or wear.

    Certificates of Calibration Testing must be current and valid. These should include the model number of the monitoring instrument, as well as the serial number, date of calibration, confirmation of the instrument passing testing, and notice that the instrument's accuracy is within +/-.5°C/1°F.

    As of June 2016, the CDC does not recommend logging temperature with alcohol or mercury thermometers, bi-metal stem temperature monitoring devices, food monitoring equipment, infrared temperature monitoring devices, or non-NIST calibrated devices. Chart recorders are no longer recommended for vaccine temperature logging.

    All temperature monitoring devices must be capable of displaying minimum/maximum* temperatures.

    *Minimum and maximum temperatures are defined as the coldest (minimum) and the warmest (maximum) temperatures recorded in the storage unit since the last time the min/max was cleared.
5. Keep at least one back-up data logger with a current certificate of calibration on hand in case a temperature monitoring device stops working or calibration testing of the current equipment is required.
6. Record temperatures for each VFC/VFA storage unit (refrigerator and freezer) at the beginning each clinic day. Record the minimum and maximum temperatures for each vaccine storage unit daily.

VACCINE STORAGE

1. Store vaccines in appropriate storage units at all times.
2. Store vaccines in the center of the storage unit and maintain space between the vaccine containers and all storage units to allow cold air to circulate around the vaccine.
3. Do not store vaccines on the top shelf of the refrigerator directly under a fan because they may freeze.
4. Monitor expiration dates and rotate vaccine stock to ensure short-dated inventory is used first.
5. Label all publicly-funded vaccine so that it can be distinguished from private stock.
6. Place filled water bottles in storage unit doors and bottoms to help maintain temperatures during potential power outages.
7. Do not keep food, drink, lab specimens, or radioactive materials in a storage unit where vaccines are stored.

8. Store vaccines in their original packaging in clearly labeled, uncovered containers with slotted sides to allow air circulation.
9. Do not store vaccines in storage unit doors or in vegetable bins as these are areas where the temperature can deviate (these are good places for water bottles to help stabilize temperatures).

VACCINE DELIVERIES

1. The practice must be open at least one day other than Monday for 4 or more consecutive hours to receive vaccine shipments.
2. Examine all shipping containers for any evidence of damage during transport.
3. Examine cold-chain monitor cards for any evidence of exposure to out-of-range temperatures.
4. Do not accept shipments if reasonable suspicion exists that the delivered product may have been mishandled.
5. Contact the manufacturer when circumstances raise questions about the efficacy of a delivered vaccine.
6. Check expiration dates to be sure vaccine has not expired.
7. Immediately place vaccine deliveries in an appropriate storage unit.

VACCINE INVENTORY MANAGEMENT

1. Do a physical inventory of all public vaccine supply within 14 days of placing an order and confirm the inventory in NYSIIS.
2. Order at least a month's supply of vaccine but preferably 2 – 3 months' supply using the NYSIIS vaccine ordering module. VFC Program cannot accept greater than one order per PIN# within 30 days.
3. Document all doses administered and VFC recipient eligibility in NYSIIS (Public Health Law Section 2168).
4. Prevent vaccine wastage by ordering accurately and transferring unused vaccine to an alternate facility.
5. Notify the Vaccine Program between 60 – 90 days prior to the expiration date of all unused vaccine excluding flu.
6. Report wasted and returned vaccine in the NYSIIS Returns/Wastage module.

VACCINE ADMINISTRATION

1. Discard reconstituted vaccines if not used within the interval allowed on the package insert.
2. Open only one multi-dose vial of a specific vaccine at a time.
3. Only draw up vaccine immediately before administration.
4. Discard single-dose vials with cap or dust cover removed and any active manufacturer-filled syringes (i.e. syringe cap removed or needle attached) that are not used by the end of the workday.
5. Contact the appropriate vaccine manufacturer and the VFC Program for any storage and handling questions.

VACCINE EMERGENCY PLAN

Instructions: All NYS VFC/VFA practices must either have an internally developed emergency plan or use the NYS Vaccine Program guidance below for any emergency situation which will require emergency transport. Practices using their own vaccine emergency plans must consider the key elements of the vaccine emergency plan below (sections 1 - 4). All practices must complete this emergency plan, those with more detailed plans should maintain them and be prepared to present them to NYS VFC staff upon request.

In the event of emergency, this practice will use *(Select one)*:

Internally developed vaccine emergency plan; a copy of this plan is attached.

NYS vaccine emergency plan outlined below; sections 1 and 2 are filled out.

Failure to adhere to this guidance may result in the practice providing restitution for lost vaccine.

In the event of site power failure, pending natural disaster, or other emergencies which could compromise vaccine viability, vaccines may need to be transported to an alternate location. **In the event of refrigerator or freezer malfunction or failure, vaccine must be relocated to an alternate location or back-up unit.** A Vaccine Tracking Transport Sheet must be completed and emailed (nyvfc@health.ny.gov) or faxed (518-449-6912) to the VFC program. If vaccine temperatures go out of acceptable range for any length of time, the VFC program must be notified at vaccinetempexcursion@health.ny.gov.

SECTION 1: RESPONSIBLE STAFF

The Primary Vaccine Coordinator or the Backup Vaccine Coordinator designated in the Provider Agreement is responsible for making the decision whether vaccine relocation is necessary. These individuals must have after hours office access. The vaccine coordinator or back-up coordinator will be available 24/7 as the point person to contact the emergency relocation site to ensure it is prepared to accept the vaccines. The Primary Vaccine Coordinator and/or Backup Vaccine Coordinator are responsible to pack and relocate the vaccines.

	Full Name	Business Hours Phone Number	Emergency Phone Number
Vaccine Coordinator			
Backup Coordinator			
Additional Staff			

SECTION 2: ALTERNATE SITE OR BACKUP LOCATION

VFC provider sites must have a designated site to transfer all VFC vaccines to in an emergency. The alternate site must have the capacity to store the entire public vaccine inventory. **Residences are not acceptable backup locations.** The designated contact person must have 24/7 access to the alternate location.

Site Location	Full Name of Contact Person	Business Hours Phone Number	Emergency Phone Number

SECTION 3: EMERGENCY PLAN VACCINE PACKING AND TRANSPORT INFORMATION

A. PLAN PACKING MATERIALS

1. Portable vaccine refrigerator and freezer units are the best option for transport.
2. Hard sided coolers or Styrofoam™ vaccine containers are acceptable. Coolers must be large enough to accommodate an average supply of vaccine, including influenza and all required packing materials.
3. Enough conditioned frozen water bottles for two layers inside cooler; 16.9 oz. for medium/large coolers or 8 oz. for small coolers.
4. Cushioned insulating materials, including bubble wrap and packing foam.
5. Corrugated cardboard.
6. Digital data logger (DDL) with buffered probe.
7. Refrigerated/Frozen Vaccine Transport Tracking Sheet.

B. PROCEDURES FOR REFRIGERATED VACCINE

Once it is determined that vaccines must be transported to ensure their viability, the following procedure must be followed to pack refrigerated vaccines:

1. Open affected units only when necessary and only after all preparations for packing and moving vaccine have been made.
2. Condition frozen water bottles by placing in a sink filled with several inches of cool or lukewarm water until a layer of water forms near the surface of the bottles. The ice block spins freely when rotated.
3. Line bottom of the cooler with a single layer of dried, conditioned water bottles.
4. Place one sheet of corrugated cardboard over the water bottles to cover completely.
5. Place a one-inch layer of bubble wrap, packing foam, or Styrofoam™ on top to cover the cardboard completely.
6. Place boxes of vaccine and diluents on top of insulating materials.
7. Place DDL buffered probe in center of the vaccines. Keep DDL display outside cooler until finished packing.
8. Cover vaccine with another inch of insulating material.
9. Place another layer of corrugated cardboard on top of the insulating material.
10. Place another layer of dried, conditioned water bottles on top.
11. Close and secure the lid and attach the DDL display.
12. Document transfer information on Refrigerated/Frozen Vaccine Transport Tracking Sheet and affix to transport container. Temperatures are to be maintained between 36°F and 46°F (2°C and 8°C).

C. PROCEDURES FOR FROZEN VACCINE

1. Follow steps for packing refrigerated vaccines but use FROZEN water bottles (not conditioned).
2. If transporting frozen vaccine in the same container as refrigerated vaccine, pack refrigerated vaccine first and place insulating material around refrigerated vaccine. Place rubber bands around frozen vaccine to aid in identification.
3. Do NOT use frozen vaccine transported at refrigerated temperatures. Contact the manufacturer for guidance on viability.

SECTION 4: EMERGENCY PLAN PROCEDURES FOR TRANSPORTING VACCINE IN AN EMERGENCY

1. Staff responding to vaccine emergency must stay with the vaccine during transport and promptly place in appropriate storage unit(s) upon arrival.
2. If transporting vaccine in a vehicle, use the passenger compartment, never the trunk.
3. Before opening cooler:
    - Record time, temperature of vaccine, and temperature of receiving storage unit on the Refrigerated/Frozen Vaccine Transport Tracking Sheet.
    - Immediately transfer vaccine to alternate storage units.
    - Contact the VFC program (800-543-7468) if vaccine temperatures were out of normal range at any time during the vaccine emergency. Any potentially affected vaccine should be quarantined until viability is determined.

REQUIRED SIGNATURES

We agree to implement the storage and handling plan outlined above and/or attached to this document. In the event of any situation which could potentially compromise the efficacy of VFC vaccine, we will comply with the emergency procedure.

Medical Director or Equivalent *(Print full name)*	
Signature	Date
Primary Vaccine Coordinator *(Print full name)*	
Signature	Date
Backup Vaccine Coordinator *(Print full name)*	
Signature	Date