

# **Vaccine Management Plan Template**

#### KEEP THIS MANAGEMENT PLAN NEAR VACCINE STORAGE UNITS

The New Jersey Vaccine-Preventable Diseases and Immunization Program (VPDP) requires Vaccines for Children (VFC) and 317 Adult Program providers to maintain a vaccine management plan for routine and emergency situations. This document is a template for information. It includes guidelines, protocols, contact information, and staff training. At a minimum, all identified information in this template must be in your final plan.

Review and update the plan at least once a year, when program requirements change, and when staff with designated vaccine management responsibilities change. Key practice staff must sign and acknowledge the signature log annually and whenever the plan is revised.

NJ Immunization Program Field Representatives will ask to review this plan during routine and unannounced site visits.

# **Section 1**: Provider Information

Each facility must designate a primary and backup vaccine coordinator responsible for the vaccine management plan and for maintaining program compliance. Any personnel changes to the Medical Director, primary vaccine coordinator, or backup vaccine coordinator will need to be communicated by email to <a href="VFC@doh.nj.gov">VFC@doh.nj.gov</a>

Facility Name:	
Facility Address:	
Facility Phone Number:	PIN:

Role	Name	Title	Contact Information Phone and Email (Required for Medical Director, Primary and Backup Coordinators)
Medical Director			
Primary Vaccine Coordinator			
Backup Vaccine Coordinator			

Staff must sign and date the Acknowledgement and Signature Log at the end of this document to confirm that they understand and agree to the duties assigned to them.

# Section 2: Routine and Emergency Contacts

Fill in chart below with contact information and add any additional helpful contacts.

Service	Company Name	Contact Information: Name, Phone Number, and email
Electric Company		
Building Maintenance		
Building Alarm Company		
Generator Company		
Storage Unit Alarm Company		
Digital Data Logger Company (Technical Support)		
NJ VFC Support		609-826-4862 <u>VFC@doh.nj.gov</u>
NJIIS Support		<u>Submit a Request</u> – njiis.nj.gov

# **Section 3**: Vaccine Storage Units

All primary and backup vaccine storage units must meet the storage and temperature monitoring requirements outlined in the New Jersey VFC/317 Provider Manual and <a href="CDC Storage & Handling Toolkit">CDC Storage & Handling Toolkit</a> to ensure the proper storage and handling of vaccines.

Unit	Location (Room #)	Brand and Model	Туре	Notes
Refrigerator			☐ Household combination	
☐ Primary			☐ Household standalone	
☐ Backup			☐ Purpose built	
			[pharmaceutical/scientific]	
			☐ Vending/doorless	
Refrigerator			☐ Household combination	
☐ Primary			☐ Household standalone	
☐ Backup			☐ Purpose built	
			[pharmaceutical/scientific]	
			☐ Vending/doorless	
Freezer			☐ Household standalone	
☐ Primary			☐ Purpose built	
☐ Backup			[pharmaceutical/scientific]	
, 			☐ Vending/doorless	
Freezer			$\square$ Household standalone	
$\square$ Primary			☐ Purpose built	
☐ Backup			[pharmaceutical/scientific]	
			☐ Vending/doorless	
ULT			☐ Purpose built	
□ Primary			[pharmaceutical/scientific]	
□ Backup			☐ Vending/doorless	
ULT			☐ Purpose built	
☐ Primary			[pharmaceutical/scientific]	
☐ Backup			☐ Vending/doorless	
Other			☐ Household combination	
List:			☐ Household standalone	
			☐ Purpose built	
			[pharmaceutical/scientific]	
			☐ Vending/doorless	

Note: Backup units must meet the same criteria as primary storage units. Refer to the CDC's <u>Storage & Handling Toolkit</u> for full guidelines and recommendations.

# **Section 4: Temperature Monitoring**

This section contains information that will be helpful when providers need to quickly identify where temperature monitoring information or equipment is located, and to have all Digital Data Logger (DDL) information in a central location. Complete information in this section to assist with temperature monitoring and documentation.

Information	Location
Completed Paper Temperature Logs	
DDL Download File Path	
Records of Certificates of Calibration	
Storage of Backup Data Loggers	
Other	

# **Digital Data Logger Information**

	Brand and Model	Serial number	Number of Probes	High/Low Alarm Settings	Calibration Date	Calibration Expiration Date	Battery Replacement Date
DDL 1  Primary  Backup			□ 1 □ 2	High: Low:			
DDL 2  Primary  Backup			□ 1 □ 2	High:			
DDL 3  □ Primary  □ Backup			□ 1 □ 2	High:			
DDL 4  □ Primary  □ Backup			□ 1 □ 2	High:			
DDL 5  □ Primary □ Backup			□ 1 □ 2	High:			
DDL 6  Primary Backup			□ 1 □ 2	High: Low:			

**TEMPERATURE EXCURSION:** If you experience a temperature excursion, notify the New Jersey Immunization Program via email at VFC@doh.nj.gov within one business day. Be sure to include your VFC/317 PIN # in the subject line.

After Hours Temperature Excursion Procedures
List steps that will be taken when a temperature excursion is identified after-hours. Include staff that will receive an alarm notification, if applicable, and what next steps are.
Section 5: Timeline for Routine Storage and Handling Activities
This section outlines a suggested timeline for storage and handling activities. Include facility specific information as needed.
INITIAL ACTIONS AND EQUIPMENT SETUP
☐ Review requirements in the VFC/317 Provider Agreement, NJ VFC/317 Provider Manual, and CDC
Storage and Handling Toolkit. Ensure pertinent staff are trained on program requirements.
Use or purchase vaccine storage units that meet <u>CDC requirements</u> .
Do not store vaccines in storage units until temperatures are stable for at least 2 consecutive days. It
may take 2-7 days for temperatures to stabilize.
Note: vaccines should never be stored in the freezer portion of a household combination unit or
dormitory-style unit, even temporarily.  Configure all vaccine storage units to meet <a href="CDC requirements">CDC requirements</a> .
Use or purchase digital data logger (DDL) temperature monitoring devices that meet CDC requirements.
A DDL is required for each permanent and temporary storage unit.
☐ Ensure DDL alarms are set correctly to alarm <i>before</i> a temperature excursion would occur, so you can
correct the issue before the vaccines are exposed to an out-of-range temperature (for example set
minimum at 2.5°C and maximum at 7.5°C, so you can take action to keep the refrigerator in 2-8°C
range). Set DDL to record at least every 30 minutes and ensure a backup DDL is available.
Post <u>vaccine temperature logs</u> on storage unit doors or nearby in an accessible location.
DAILY TASKS

- Read and record MIN and MAX temperatures in all vaccine storage units. Note: this is required in addition to having a working DDL in the units.
  - $\circ\quad$  Log temperatures on paper temperature log or directly into NJIIS.

Reset your DDL's minimum/maximum temperatures after recording the day's temperatures.
 Note: not all DDLs require a daily reset – check your DDL's specifications.

Task	Staff Member Responsible
Read and record CURRENT, MIN, and MAX temperatures in all vaccine	
storage units twice a day	

#### **WEEKLY TASKS**

• Download and analyze DDL data files at the end of every week to look for temperature trends that might indicate performance issues with vaccine storage units.

Task	Staff Member Responsible
Download and analyze DDL data files at the end of every week	

#### **BI-WEEKLY TASKS**

- Update NJIIS temperature logs on the 1<sup>st</sup> and 15<sup>th</sup> of each month if min/max temperatures are not entered directly into NJIIS daily.
  - The min/max temperatures entered into NJIIS must be the same temperatures recorded on your paper logs.

Task	Staff Member Responsible
Update NJIIS temperature logs	

#### **MONTHLY TASKS**

- Conduct a careful and accurate physical vaccine inventory review by comparing inventory in NJIIS to the physical count of vaccines in storage units.
- Review vaccine expirations dates, and transfer vaccines that will expire within three to six months.
   Contact VFC@doh.nj.gov for assistance identifying a provider for transfer.

Task	Staff Member Responsible
Conduct physical vaccine inventory review	
Review vaccine expiration dates and transfer, if needed	

#### **ANNUAL TASKS**

- Review and update the routine and emergency information in the Vaccine Management Plan. Ensure all staff are trained on the plan.
- Complete VFC/317 re-enrollment in NJIIS.
- Complete annual Primary and Backup Vaccine Coordinator education training.
- Prepare for and support site visits from the New Jersey VFC program.

Task	Staff Member Responsible
Update Vaccine Management Plan	

#### **OTHER RESPONSIBILITIES - AS NEEDED**

#### **Routine Vaccine Orders**

- Review on-hand vaccine inventory.
- Determine total doses administered since previous order.
- Update and reconcile NJIIS inventory to account for any transferred, returned, spoiled, wasted, or expired vaccine.
- Only order vaccines that are needed to avoid overstocking.
- Transfer vaccines that are nearing expiration (3-6 months).
- Submit routine vaccine orders according to assigned order frequency.

#### **Vaccine Deliveries**

- Open package and inspect for out-of-range temperatures and excess shipping times.
- Check package contents, packing slip, and approved order for discrepancies.
- Store vaccines in areas designated for VFC/317 vaccines with the earliest expiration dates in the front of the vaccine storage unit.
- Report issues immediately to <a href="VFC@doh.nj.gov">VFC@doh.nj.gov</a>

# **Receiving Vaccines**

- The Primary or Backup Coordinator should be present or ensure that a trained staff member is available to receive vaccine delivery.
- Open package and inspect for damage, out-of-range temperatures, and excess shipping times. Take
  pictures of any concerning findings. Report any issues immediately to <u>VFC@doh.nj.gov</u>
- Compare the vaccines received with the vaccines that appear on the packing list. Take pictures to
  document any discrepancies noted. Ensure vaccines are placed in the proper storage units based on
  manufacturer recommendations.
- Store vaccines in areas designated for VFC/317 vaccines, rotate vaccines if needed so that the earliest expiration dates are in the front of the vaccine storage unit.
- Claim shipment in NJIIS.

### **Routine Maintenance**

- Establish a regular routine for cleaning vaccine storage units, and de-icing units if needed.
- Replace batteries in temperature monitoring devices according to manufacturer's directions.

Service vaccine storage units and DDLs as recommended by the manufacturers.

## **Reporting Temperature Excursions**

- Post "Do No Use Vaccines" sign and alert the supervisor.
- Download and review the DDL temperature data files.
- Complete the Temperature Excursion Viability Assessment.
- Report excursion to <u>VFC@doh.nj.gov</u> and work with the New Jersey immunization program for resolution. Include the DDL file, completed TEVA form, and your VFC/317 PIN in the email.

# **Returning Vaccines**

- Request labels from <u>VFC@doh.nj.gov</u> and return nonviable vaccines to McKesson within six months of expiration or spoilage.
  - o Ensure facility's email address is updated in NJIIS to receive the label.
- Update NJIIS records to account for the returned vaccines.

### **Disposal of Wasted Vaccines**

- Properly dispose of wasted vaccines.
- Report wasted vaccines in NJIIS to maintain and accurate inventory.

# **Section 6**: Vaccine Management Emergency Plan

In the event of an emergency, such as mechanical failure, power outage, natural disaster, or human error, notify <a href="VFC@doh.nj.gov">VFC@doh.nj.gov</a>. Include the Vaccine Coordinators identified above along with any other pertinent staff members at the provider's office.

the pro	ovider somice.
Does t	he facility have a generator?
	Yes, specify location:
	No Note: If there is no generator, and/or the vaccine storage unit fails, it might be necessary to transport vaccines to an alternate storage location (e.g., a local hospital or another VFC/317 provider). Identify an alternate location(s, that has vaccine storage units and temperature monitoring devices that meet VFC/317 program requirements.

Alternate Vaccine Storage Facility	Address	Phone Numbers (Daytime and 24-Hour Contact)	Contact Name and Email

## **Transport Requirements:**

For safe transport and storage of vaccines, proper supplies are essential. Transport packing methods differ between 1) emergency transport and 2) planned transport such as for off-site clinics, satellite facilities, or relocation of stock. In either case, a portable refrigerator/freezer or qualified container and pack out are always the preferred method.

ed co	transport requires either portable vaccine storage ontainers and pack-outs, or the conditioned water l	bottle transport system.			
	step-by-step guidance on packing a cooler for emethod, see CDC's Packing for Emergency Transport.	ergencies using the cond	ditioned water bottle		
priat	e materials include:				
	□ Portable vaccine refrigerator/freezer units				
	Hard-sided insulated containers or Styrofoam  Coolant materials: frozen 16.9-or 8-ounce water bottles that can be conditioned or 4°C to 5°C  Insulating materials such as bubble wrap or corrugated cardboard – enough to form two layers per container				
	A DDL with current Certificate of Calibration for ea	ach container			
	Printed out guidance on Packing for Emergency Ti	ransport			
	Printed out transport temperature log and pen fo	r temperature documer	itation before, during,		
	and after transport				
	T	<b></b>	Discount of the second		
	Transport Method	Emergency Transport	Planned Transport		
	Portable Vaccine Storage Unit	Yes	Yes		
	Qualified Container and Packout	Yes	Yes		
	Conditioned Water Bottle Transport System	Yes	No		
	Manufacturer's Shipping Container	Yes (last resort only)	No		
	Food/Beverage Coolers	No	No		
Do n	Manufacturer's Shipping Container	Yes (last resort only)	No		

#### **EMERGENCY PLAN TASKS**

#### **BEFORE AN EMERGENCY**

Proper preparation for emergency situations is essential for protecting the viability of vaccines. Use the following checklist to help ensure practices are ready for planned or unexpected situations that might impact vaccines.

## **Step Description**

- 1. Maintain current emergency contact information for key practice staff.
- 2. Maintain current contact information for alternate vaccine storage location(s), including the facility name, address, and telephone number.
- 3. Be familiar with backup power sources for commercial- and pharmacy-grade units.
- 4. Stock vaccine packing and transport supplies, including a hard-sided cooler, and bubble wrap. Maintain the coolant material in a conditioned state.
- 5. Keep copies of the <u>CDC Transport Temperature Log</u> and floor plans (when available) for easy access during a vaccine-related emergency.
- 6. Review (at least annually) the steps that key practice staff must take to protect vaccines during short- or long-term outages.

#### **DURING AN EMERGENCY**

Follow these instructions during vaccine-related emergencies in compliance with VFC/317 Program requirements and best practices.

# Step Description

- 1. Call the power company to determine the length of the power outage.
- 2. Do not open unit and place a "DO NOT OPEN" sign on vaccine storage unit(s) and leave door(s) shut to conserve cold air.
- 3. Notify the emergency contacts listed in this plan.
- 4. Note the time the outage started and storage unit temperatures (CURRENT, MIN and MAX).
- 5. Assess the situation to determine the cause of the power failure and estimate the time it will take to restore power.
- 6. If the outage is expected to be longer than two hours\*:
  - ☐ Contact the alternate storage facility to verify they can accept the vaccines.
  - ☐ If vaccines will be relocated, refer to Transporting Vaccines in the NJ VFC/317 Provider Manual and CDC Storage and Handling Kit, Section 6: Vaccine Transport, for instructions.
  - If transport or relocation are not feasible (the alternate location is not available or travel conditions are unsafe), keep vaccine storage units closed.
- 7. Monitor vaccine storage unit temperatures until power is restored.
- 8. Once power has been restored, follow the steps listed in "After an Emergency".
- 9. Notify <u>VFC@doh.nj.gov</u> to report that the outage occurred and whether the vaccines were transported to an offsite location or what steps were taken if they could not be transported.

<sup>\*</sup> **Note:** Temperatures in commercial-, pharmacy-, and biologic-grade units tend to increase faster during power failures. As a result, practices using these storage units need to monitor temperatures more frequently and may need to transport vaccines to an alternate location sooner than two hours.

#### **AFTER AN EMERGENCY**

Follow these step-by-step instructions after vaccine-related emergencies in compliance with VFC/317 program requirements and best practices.

Step	Description	
1.	Verify storage units are functioning properly.	
2.	If vaccine storage units are outside the required temperatures ranges, note the time that power was restored an storage unit temperatures (CURRENT, MIN and MAX).	
3.	If vaccines were transported due to the emergency:  — Follow the same transportation procedures to transfer vaccine back to its original storage unit.	
4.	If vaccines were maintained at required temperatures:  Remove the "DO NOT OPEN" sign from storage unit(s).  Notify Vaccine Coordinator that vaccines may be used.	
5.	If vaccines were exposed to out-of-range temperatures:  ☐ Label affected vaccines "Do Not Use".  ☐ Document and report the excursion following NJ VFC/317 procedures.	

# Section 7: Training and Annual Review Documentation

All staff with vaccine-related responsibilities should have annual training regarding vaccine management best practices. On a yearly basis, staff should review and complete the required education and trainings listed below and sign and date this page once their training/review is complete.

# **Required Education and Training**

Responsibility	Name	Training Title  Examples: You Call the Shots,  Understanding VFC and 317	Date and Signature
*Training recommended, but optional, for Medical Director only.			
Primary Vaccine Coordinator			
Backup Vaccine Coordinator			

# Section 8: Vaccine Management Plan Annual Signature Log

Sign and date one signature block each year and when the provider's office updates practice-specific information. By signing, staff acknowledge they have reviewed and are familiar with all the information in the document.

Date:	
Updates and Comments:	
Medical Director	Signature
Primary Vaccine Coordinator	Signature
Backup Vaccine Coordinator	Signature
Additional Staff	Signature
Additional Staff	Signature
Additional Staff	Signature
Date:	
Updates and Comments:	
Medical Director	Signature
Primary Vaccine Coordinator	Signature
Backup Vaccine Coordinator	Signature
Additional Staff	Signature
Additional Staff	Signature
Additional Staff	Signature