



SC Department of Health and Environmental Control  
Immunization Division

### South Carolina Vaccine Management and Disaster Recovery Plan

**PRACTICE NAME:** \_\_\_\_\_

**PROVIDER PIN:** \_\_\_\_\_

This document provides a template for development of a comprehensive vaccine management plan for protection and maintenance of your practice’s vaccine supply. The Vaccine Management and Disaster Recovery Plan consists of two sections: (1) the Routine Storage and Handling Plan, which covers all aspects of routine vaccine management and (2) the Disaster Recovery Plan, which is used in the event of an emergency situation that may affect the storage and potential viability of your vaccines.

The completed Vaccine Management and Disaster Recovery Plan (VMDR) must be posted on or near the vaccine storage equipment. Ensure that all staff (current and new), including those persons who may be required to transport vaccine in an emergency situation, read the plan and understand it. Also, ensure that janitorial and security staff are aware of the plan and know the procedures to follow for notifying designated personnel about any problems with the vaccine storage equipment.

One staff member must be designated as the primary vaccine coordinator, providing oversight for all vaccine management within the office. At least one back-up vaccine coordinator should be trained to perform the same responsibilities as the primary vaccine coordinator in the event that the primary person is unavailable.

Review and update the contact lists as needed.

The entire plan must be reviewed and updated annually.

Date Reviewed/ Updated

Reviewed By

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## Contact Numbers

**1. Contact information for Vaccine Coordinator:**

Name of Employee	Title of Employee	Work Phone	Home Phone
Primary:			
Back-Up:			

**2. Contact Information for Health Department**

Resources	Name of Employee	Work Phone	Other
SC DHEC (Central Office/ Columbia):		803-898-0460	800-277-4687
SC DHEC (Regional Immunization Program Manager)			

**3. Points of contact for restoring electrical power in the event of a power failure:**

Electrical Power Company	Point of Contact	Work Phone	Emergency Phone

Building Maintenance	Point of Contact	Work Phone	Emergency Phone

**4. Designated company responsible for repair when the compressor or other refrigeration equipment has been destroyed or you need emergency maintenance:**

Name of Repair Company	Point of Contact	Work Phone	Emergency Phone

<b>Part A: Routine Storage and Handling</b>
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**I. Storage:**

The vaccine in this practice is stored according to the following:

1. Stored in a refrigerator that has a separate freezer compartment with separate exterior door or stand alone refrigerator and freezer.
2. Calibrated thermometers (*covered by a Certificate of Traceability and Calibration*) are placed in the center of each vaccine storage unit. A copy of the thermometer certificate must be provided to the Immunization Division.
  - a. In order to maintain accuracy of temperature readings, all calibrated thermometers are recalibrated or replaced, if more cost effective, within the time frame specified by the manufacturer (contact manufacturer for details regarding recalibration).
  - b. The thermometer certificate (initial or recertification) to verify calibration is up-to-date.
  - c. A supply of batteries is maintained for thermometer, if applicable.
  - d. Date the thermometer was initially placed in the unit: \_\_\_\_\_.
  - e. Date the thermometer certification expires: \_\_\_\_\_.
3. The unit is cleaned monthly and defrosted on a routine basis, if applicable. Periodically, the exterior coils are vacuumed to remove dust.
4. To help stabilize the temperatures, ice packs are stored in the bottom and in the door of the freezer and water bottles in the door and bottom of the refrigerator.
5. To prevent accidental power loss, a “Do Not Disconnect” sign is placed on the outlet that the unit is plugged into and on the circuit breaker that supplies power to the storage unit. The plug is secured by using a plug guard.
6. Vaccines are stored in the central area of the unit, away from the walls and floor to allow air circulation. No vaccine is stored in the door or crisper bins.
7. No food or beverages are stored in the same unit where vaccines are stored.
8. Vaccines stored in the refrigerator are: DTaP, Pediarix, Pentacel, Kinrix, HepB, HepA, Hib, IPV, MCV4, MMR, PCV13, Rotavirus, Td, DT, Tdap, HPV, PPSV23, and Flu.
9. Vaccines stored in the freezer are: Varicella, MMRV and Shingles vaccine.
10. The location that diluent is stored: \_\_\_\_\_.
11. Vaccine is kept in the original box until time of use. MMR, MMRV, Varicella, HPV, Rotavirus, TIV\*, and MCV\* vaccines are protected from light by keeping box lids intact and closed. See **Handling Inappropriate Vaccine Storage Conditions (Light and Temperature)**. \*See **Storage and Handling Requirements for Specific Vaccines** for specific brands

12. Refrigerator temperature is maintained at 35 - 46°F (2 - 8°C). Freezer temperature is maintained at -58°F to +5°F. (-50°C to -15°C).
13. Temperatures are checked each morning and each afternoon and are recorded on the Refrigerator/Freezer Temperature Log. The current month's log for each unit is posted on each unit's door. Logs will be retained in a file for 3 years.
  - a. If out-of-range temperatures are found, immediate corrective action will take place.
  - b. Action taken will be documented on the "**Vaccine Storage Action Plan for Temperature Excursions**" section of the Refrigerator/Freezer Temperature Log.

## **II. Handling:**

**The vaccine in this practice is handled according to the following:**

1. Private stock and vaccine ordered through SC DHEC are labeled and stored separately.
2. Vaccines that will expire first are stored in the front of the unit.
3. Vaccines are inventoried monthly.
4. SC DHEC Immunization Division will be notified if vaccine will not be used by the expiration date.

## **III. Ordering and Receiving:**

**The vaccine in this practice will be ordered and received according to the following:**

1. Alert reception staff to be ready to receive vaccine shipment on arrival.
2. Once delivery has arrived, the primary vaccine coordinator or designated backup person will be notified immediately.
3. Upon receiving a vaccine shipment, cold chain temperature monitors will be inspected to assure appropriate temperature has been maintained during shipment.
4. Varicella vaccine is direct shipped from the manufacturer (Merck). It is packed for shipping with 6 frozen gel packs as refrigerant in the shipping containers. The frozen gel packs in the shipping containers are designed to maintain proper temperatures for three days from the shipment date located on the shipping box. **PLEASE NOTE:** If container is received within three days of shipment, immediately open the container and store vaccine in the freezer. If the container is received after the three-day shipping time period, contact the Merck Order Management Center immediately for replacement (**Do NOT use vaccine**).
5. Invoice will be cross-checked with vaccines shipped and vaccines requested. Check shipment for diluent, if applicable, and match dose-for-dose with appropriate vaccine. SC DHEC Immunization Division (803-898-0460) will be notified immediately if there is a discrepancy found or a problem with cold chain while being shipped.

6. Invoice will be retained in a file for 3 years.

#### **IV. Wastage:**

**The vaccine in this practice will be wasted (if appropriate) according to the following:**

1. Expired vaccine will be removed from the storage unit once it has expired.
2. All wasted vaccine (includes spoiled, doses drawn up but not administered, dropped/broken vials, lost vials and expired) will be reported to SC DHEC Immunization Division (800-277-4687 or 803-898-0460).
3. Instructions will be given by SC DHEC for disposal of wasted and expired vaccine.
4. A South Carolina Vaccine Wastage and Return Form will be completed and faxed to SC DHEC Immunization Division at 803-898-0318. This form will be retained for 3 yrs.
5. If instructed to return vaccine to McKesson, a return label will be mailed by SC DHEC or McKesson to the office. The wasted vaccine along with a copy of the wastage report will be packaged properly and sent back to McKesson. Ice packs are not needed.

#### **V. Inappropriate Vaccine Storage Conditions**

1. **Immediate action** will be taken when temperature is out of range.
  - a. If out-of-range temperatures are found, immediate corrective action will take place.
  - b. Action taken will be documented on the “**Vaccine Storage Action Plan for Temperature Excursions**” section of the Refrigerator/Freezer Temperature Log.
2. If **refrigerator** temperature is too warm:
  - a. Immediately label affected vaccines as “Do Not Use” and contact SC DHEC Immunization Division at 800-277-4687 or 803-898-0460 to assess whether vaccine potency could have been affected.
  - b. Do not presume that the vaccine has been compromised.
3. If **refrigerator** temperature is too cold:
  - a. Immediately label affected vaccines as “Do Not Use” and contact SC DHEC Immunization Division at 800-277-4687 or 803-898-0460 to assess whether vaccine potency could have been affected.
  - b. Do not presume that the vaccine has been compromised.
4. If **freezer** temperature is too warm:
  - a. Immediately label affected vaccines as “Do Not Use” and contact SC DHEC Immunization Division at 800-277-4687 or 803-898-0460 to assess whether vaccine potency could have been affected.

- b. Do not presume that the vaccine has been compromised.
5. If MMRV, varicella, or shingles vaccine(s) have been inadvertently placed in the refrigerator:
  - a. Label the affected vaccine(s) as “Do Not Use” and place in the freezer unit.
  - b. Contact SC DHEC Immunization Division at 800-277-4687 or 803-898-0460 to assess whether vaccine potency could have been affected.
  - c. Do not presume that the vaccine has been compromised.
6. If HPV, MMR, MMRV, rotavirus, varicella, TIV\*, and/or MCV\* vaccines have been exposed to light:
  - a. Return the vaccine to a dark environment at the appropriate storage temperature and record the length of time the vaccine may have been exposed.
  - b. Label the affected vaccine(s) as “Do Not Use” and contact SC DHEC Immunization Division at 800-277-4687 or 803-898-0460 to assess whether vaccine potency could have been affected.
  - c. Do not presume that the vaccine has been compromised.
  - d. \*See **Storage and Handling Requirements for Specific Vaccines** for specific brands.
7. Store all potentially compromised vaccines under appropriate conditions in a properly functioning vaccine storage unit until the integrity of the vaccine is determined. If your vaccine storage unit is not maintaining the appropriate storage conditions, **it may be necessary to activate your Disaster Recovery Plan.**

## Part B: Disaster Recovery Plan

### I. General Information

1. Purpose: The purpose of the Disaster Recovery Plan is to offer guidance for protecting your vaccine in the event of a refrigerator or freezer malfunction due to mechanical failure or natural disaster.
2. Location: The completed Disaster Recovery Plan is required to be posted on or near the vaccine storage equipment.
3. Ensure that all staff (current and new) read the plan and understand it. Also ensure that janitorial and security staff are aware of the plan and know the procedures to follow for notifying designated personnel about any problems with the vaccine storage equipment.
4. Review and update the contact lists in the plan quarterly; review and update the entire plan annually.
5. Contact SC DHEC for questions regarding vaccine transportation or stability at 800-277-4687 or 803-898-0460.

## II. Content

### **The Disaster Recovery Plan for this practice contains the following:**

1. Name of person(s) responsible for preparing and transporting vaccine in the event of an emergency, including contact information
2. Location that will receive the vaccine
3. How the receiving location will be notified of transport
4. How to pack vaccine for transport
5. How to document the steps taken when vaccine is involved in a power or equipment failure
6. Identification of an alternative storage facility (i.e. hospital, fire department, etc) with back-up power (generator) where the vaccine can be properly stored and monitored for the interim
7. Provide training for staff regarding the proper way to transport vaccine
8. Ensure the availability of staff to pack and move the vaccine
9. Maintain the appropriate packing materials (coolers, gel packs, etc)
10. Ensure a means of transport for the vaccine to the secure storage facility
11. Fill the empty space in your refrigerator with bottles of water and line the sides and bottom of your freezer with ice packs. In the event that your refrigerator/freezer is out of order, this practice will help maintain the temperature for a longer period of time.

**NOTE: Whenever possible, facilities should suspend vaccination activities BEFORE the onset of emergency conditions to allow sufficient time for packing and transporting vaccine.**

## III. Vaccine Packing

1. Use properly insulated containers to transport the vaccine (shipping containers the vaccines arrived in from the manufacturer, hard-sided plastic insulated containers, or Styrofoam coolers with **at least 2” thick walls**).
2. **Refrigerated vaccines:**
  - a. Pack refrigerated vaccines first, using enough refrigerated/frozen packs to maintain the cold chain. (See Chart of Refrigerated/Frozen Pack Needs for

Different Climates at:

[http://www.aimtoolkit.org/vaccine/vaccine/ChartRefrigr\\_Frozen\\_Pack\\_Needs.pdf](http://www.aimtoolkit.org/vaccine/vaccine/ChartRefrigr_Frozen_Pack_Needs.pdf)

- b. Place an insulating barrier (e.g., bubble wrap, crumpled brown packing paper, Styrofoam peanuts) between the refrigerated/frozen packs and the vaccines to prevent accidental freezing (exposure of these vaccines to freezing temperatures may reduce their potency). MMR is the only exception and may be transported directly on cold packs (*not dry ice*).
- c. Use a properly placed thermometer near the vaccine to assess whether the cold chain has been broken. Layer the container as follows: refrigerated/frozen packs, barrier, vaccine, thermometer or temperature monitor, another layer of barrier, and additional refrigerated/frozen packs.
- d. Attach label to outside of container to clearly identify contents as vaccines.
- e. Document the following information:
  - Time/temperature of refrigerator storage unit temperature at the time the vaccine is removed for transport.
  - Time/temperature of insulated container at end of transport.
  - Time/temperature of refrigerator storage unit at alternate vaccine storage facility upon receipt of vaccine(s).

### 3. Frozen vaccines:

- a. ***Dry ice cannot be used for transport or storage of varicella-containing vaccine.***
- b. If frozen vaccines must be transported, the CDC recommends transport with a **portable freezer** that maintains a temperature between  $-58^{\circ}\text{F}$  and  $+5^{\circ}\text{F}$  ( $-50^{\circ}\text{C}$  and  $-15^{\circ}\text{C}$ ). Any portable freezer used to transport vaccine in a frozen state must be used according to specific manufacturer's instructions for maintaining appropriate freezer temperature during transport. **If transporting frozen vaccine under frozen conditions, the following information must be documented:**
  - Time/temperature of freezer storage unit temperature at the time the vaccine is removed for transport.
  - Time/temperature of insulated container at end of transport.
  - Time/temperature of freezer storage unit at alternate vaccine storage facility upon receipt of vaccine(s).
- c. If varicella-containing vaccine must be transported and a portable freezer unit is not available, the vaccine may be transported under refrigerated conditions for up to 72 continuous hours prior to reconstitution. *Immediately upon arrival at the alternate storage facility, **place the varicella-containing vaccine in the freezer between  $-58^{\circ}\text{F}$  and  $+5^{\circ}\text{F}$  ( $-50^{\circ}\text{C}$  and  $-15^{\circ}\text{C}$ ).** Contact the manufacturer (Merck) for guidance*



*regarding vaccine use and stability. **If transporting frozen vaccine under refrigerated conditions, the following information must be documented:***

- Time/temperature of freezer storage unit temperature at the time the vaccine is removed for transport.
- Time/temperature of insulated container at end of transport.
- Time/temperature of freezer storage unit at alternate vaccine storage facility upon receipt of vaccine(s).
- Recommendation from Merck on stability and use of the vaccine after the transport.

**4. Protocol for transporting vaccine to and from alternate vaccine storage facility (follow pre-arranged plan)**

- a. How to load transportation vehicle. **Transport vaccine in the passenger compartment of the vehicle, NOT in the trunk.**
- b. Routes to take (alternative routes if necessary).
- c. Time enroute.
- d. Ensure vaccine containers are stored properly in the emergency storage facility. (Placed within appropriate storage unit; adequate circulation; functioning temperature monitoring devices, etc.).
- e. **Contact the Immunization Division before transfer of vaccine back to original storage facility and submit completed Vaccine Transfer Form (DHEC 1208) which will be provided by the Immunization Division.**

**IV. Vaccine Storage Facilities**

- 1. Entering vaccine storage facilities: Describe how to enter the building and vaccine storage spaces in an emergency if practice is closed or after hours. Include a floor diagram and locations of the following:

Item	Location(s)
Doors	
Vaccine Storage Unit #1	
Vaccine Storage Unit #2 (if applicable)	
Vaccine Storage Unit #3 (if applicable)	
Flash Lights	
Spare Batteries	
Light Switches	
Keys	

Locks	
Alarms	
Circuit Breakers	
Packing Materials	

2. Alternative storage facility(s) with a back-up generator: Examples of appropriate alternative storage sites include - the local hospital, retirement home, fire station, pharmacy or another practice.

Arrangements must be made to store your vaccine at an alternative storage facility when the following conditions occur:

- a. when severe weather conditions (ie. tornadoes, hurricanes, major ice/snow storms) are predicted
- b. when your vaccine storage equipment cannot be repaired, or when the power cannot be restored before the temperature in your vaccine storage unit rises above the recommended ranges.

Before moving your vaccine, call the alternative storage facility location to ensure their back-up generator is operational, if necessary.

Alternate Facility	Point of Contact	Work Phone	Emergency Phone

**V. Other Useful Information**

		Telephone Number
National Weather Service	www.nsw.noaa.gov	
Vaccine Manufacturers	GlaxoSmithKline	888-825-5249
	MedImmune	877-633-4411
	Merck	800-672-6372
	Novartis	877-683-4732
	Pfizer (formerly Wyeth)	800-438-1985
	Sanofi Pasteur	800-822-2463

## Storage and Handling Requirements for Specific Vaccines

**NOTE:** The following table is accurate as of 7/2011. Refer to the manufacturer's Prescribing Information or call manufacturer for any vaccine in question.

Vaccine/ Biologic	Storage at 35-46°F. (2-8°C.)	Storage at -58°F to +5°F. (-50°C to -15°C)	Protect from light	Diluent required	Shelf life after reconstitution
<b>DTaP</b>	Yes	No—DO NOT FREEZE	No	No	N/A
<b>Tdap</b>	Yes	No—DO NOT FREEZE	No	No	N/A
<b>DTaP-IPV-HepB (Pediarix)</b>	Yes	No—DO NOT FREEZE	No	No	N/A
<b>DTaP-IPV (Kinrix)</b>	Yes	No—DO NOT FREEZE	No	No	N/A
<b>DTaP-IPV/Hib (Pentacel)</b>	Yes	No—DO NOT FREEZE	No	Yes*	30 minutes
<b>Td</b>	Yes	No—DO NOT FREEZE	No	No	N/A
<b>DT</b>	Yes	No—DO NOT FREEZE	No	No	N/A
<b>HPV</b>	Yes	No—DO NOT FREEZE	Yes	No	N/A
<b>IPV</b>	Yes	No—DO NOT FREEZE	No	No	N/A
<b>Hib</b>	Yes	No—DO NOT FREEZE	No	<b>ActHIB--</b> Yes∅ (sanofi pasteur) <b>PedvaxHIB--</b> No	<b>ActHIB--</b> 30 minutes  <b>PedvaxHIB--</b> N/A
<b>MMR</b>	Yes	Yes—lyophilized vaccine may be maintained at freezer temperatures	Yes	Yes∅ (Merck)	After reconstitution, use immediately or store at 35-46°F (2- 8°C.) and protect from light. <i>Discard if not used within 8 hours of reconstitution.</i>
<b>Hep B</b>	Yes	No—DO NOT FREEZE	No	No	N/A
<b>Hep A</b>	Yes	No—DO NOT FREEZE	No	No	N/A
<b>MCV</b>	Yes	No—DO NOT FREEZE	<b>Menactra</b> No <b>Menveo</b> Yes	No	N/A

## Vaccine Management Plan and Disaster Recovery Plan

Vaccine/ Biologic	Storage at 35-46°F. (2-8°C.)	Storage at -58°F to +5°F. (-50°C to -15°C)	Protect from light	Diluent required	Shelf life after reconstitution
PCV	Yes	No—DO NOT FREEZE	No	No	N/A
PPSV	Yes	No—DO NOT FREEZE	No	No	N/A
Varicella	May be transported at refrigerator temp (see temps above) for up to 72 continuous hours prior to reconstitution. <b>Upon arrival at alternate storage facility, place vaccine in freezer and call Merck for guidance regarding stability and use of vaccine. Contact Immunization Division.</b>	Yes	Yes	Yes <sup>∅</sup> (Merck)	Reconstitute just before use. <b>Discard if not used within <u>30 minutes</u> of reconstitution. Do not freeze reconstituted vaccine.</b>
MMRV	May be transported at refrigerator temp (see temps above) for up to 72 continuous hours prior to reconstitution. <b>Upon arrival at alternate storage facility, place vaccine in freezer and call Merck for guidance regarding stability and use of vaccine. Contact Immunization Division.</b>	Yes	Yes	Yes <sup>∅</sup> (Merck)	Reconstitute just before use. <b>Discard if not used within <u>30 minutes</u> of reconstitution. Do not freeze reconstituted vaccine.</b>
Influenza (TIV)	Yes	No—DO NOT FREEZE	<b>Fluzone</b> No <b>Fluvirin</b> Yes <b>Fluarix</b> Yes	No	N/A
Influenza (LAIV)	Yes	No—If inadvertently frozen, vaccine should be immediately moved to the refrigerator and may be used until expiration date.	No	No	N/A
Rotavirus	Yes	No—DO NOT FREEZE	Yes	<b>Rotarix--</b> Yes <sup>∅</sup> (GlaxoSmith Kline) <b>Rotateq--</b> No	<b>Rotarix</b> —Administer within 24 hours of reconstitution. <b>Rotateq</b> —Administer shortly after withdrawal from refrigerator. Do NOT return dosing tube to refrigerator once screw cap has been removed.

\*DTaP-IPV/Hib (Pentacel) is ActHIB (sanofi Pasteur) reconstituted with a DTaP-IPV solution (DTaP-IPV vials and ActHIB vials packaged together). **Do NOT store them separately and do not administer them separately.**

∅Use only the diluent supplied by the manufacturer to reconstitute the vaccine.

Diluent should be stored separately at room temperature (68-77°F, 20-25°C.), or in a refrigerator (35 to 46°F, 2-8°C.). **Do NOT freeze diluents.**

Source: **Manufacturer's Prescribing Information for individual vaccine(s)**

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

South Carolina  
Vaccine Management and Disaster Recovery Plan

Instructions for Completing

**Purpose:**

The purpose of the Vaccine Management and Disaster Recovery Plan is to provide a template for development of a comprehensive vaccine management plan for protection and maintenance of non-VFC Providers' vaccine supply.

**Item-By-Item Instructions:**

1. Provider will enter identifying information.
2. Provider will enter disaster recovery information, as applicable.

**Office Mechanics and Filing:**

1. Upon completion, the provider will retain current version and also post a copy on the vaccine storage unit(s).
2. Plan should be updated as necessary.
3. Form Retention: Contracting Parties under a DHEC Memorandum of Agreement (MOA) for Adult Vaccines: Both Provider and DHEC must retain the original/copy for (6) six years.