

SOUTH CAROLINA ROUTINE and EMERGENCY VACCINE MANAGEMENT PLAN

Worksheet for Key Vaccine Management Information: Keep Near Vaccine Storage Unit(s)

The South Carolina (SC)SCVFC Program requires that each practice develop and maintain a *Routine Vaccine Management Plan.* Properly completing this template will meet the SCVFC Program requirement for participants to have written vaccine management plans. This Plan must be reviewed and updated annually, or when changes to any information within the plan occur.

Staff who are assigned vaccine management responsibilities are to review and sign the signature page at the end of this document annually and when the plan is updated. This Plan will be reviewed by SCVFC Operations Staff and/or Regional Immunization Representatives during new SCVFC program enrollment, routine and drop-in site visits. This plan must be kept near the vaccine storage units, along with your emergency vaccine management plan and storage unit temperature logs.

In addition to the training provided by your Regional Immunization Representatives, practice staff may benefit from online vaccine storage and handling training. SCVFC endorses and recommends the CDC's *You Call the Shots* at http://www.cdc.gov/vaccines/ed/youcalltheshots.htm and CDC's excellent video *Keys to Storing and Handling Your Vaccine Supply* http://www2.cdc.gov/vaccines/ed/youcalltheshots.htm and CDC's excellent video *Keys to Storing and Handling Your Vaccine Supply* http://www2.cdc.gov/vaccines/ed/shvideo/. These sites produce a certificate of completion to print and file. Questions on vaccine storage should be directed to your Regional Immunization Representatives.

Staff Roles & Contact Information

| Office/Clinic Name | |
|--------------------|--|
| SCVFC PIN Number | |
| Address | |

| Role/Responsibility | Name | Title | Phone # | Alt Phone # | Email |
|---|------|-------|---------|-------------|-------|
| Provider of Record (Signatory of SCVFC Provider Enrollment Agreement) | | | | | |
| Primary Vaccine Coordinator | | | | | |
| Back-Up Vaccine Coordinator | | | | | |
| Performs inventory management and reconciliation | | | | | |
| Places vaccine orders | | | | | |
| Receives vaccines | | | | | |
| Stores vaccines upon arrival | | | | | |
| Handles shipping issues | | | | | |
| Handles vaccine returns and transfers | | | | | |
| Other: | | | | | |



Vaccine Storage Units/Locations and Maintenance

| Maintenance/Repair Company | |
|----------------------------|--|
| Company Name | |
| Phone | |

| Unit Type | Location (Room#) | Brand | Model | Type of Service | Date |
|--------------|---------------------|-------|-------|-----------------|------|
| Refrigerator | | | | | |
| Freezer | | | | | |
| Refrigerator | | | | | |
| Freezer | | | | | |
| | | | | | |

Location of Completed Temperature Logs

Data Logger Maintenance

Location of Certificates of Calibration

Location of Back-up Data Loggers

| Data Logger model/serial # | Primary? | Backup? | Battery Replacement Date | Alarm Setting Low | Alarm Setting High | Expiration Date |
|-------------------------------|----------|---------|-----------------------------|----------------------|-----------------------|--------------------|
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Form Certification

| Form Completed By | | |
|-------------------|-----------|--|
| Name | Signature | |
| Title | Date | |



Vaccine Management Personnel

This document highlights key duties of designated vaccine management staff. However, all personnel working with vaccines should be familiar with SCVFC requirements and guidelines.

Provider of Record

- Complies with all federal vaccine management requirements, including key areas outlined in this plan.
- Designates one employee as the practice's Primary Vaccine Coordinator, responsible for vaccine management.
- Designates one employee as the Back-up Vaccine Coordinator responsible for vaccine management when the Primary Vaccine Coordinator is not available.
- Reports staffing changes regarding the Primary Vaccine Coordinator, Back-up Vaccine Coordinator, and Provider of Record (Signatory) to the SCVFC Program by submitting a <u>SIMON Helpdesk</u> Request.
- Meets and documents required orientation and annual training for the practice's vaccine management personnel.
- Ensures that vaccine management personnel are skilled and knowledgeable regarding SCVFC requirements for temperature monitoring and storage equipment.
- Prepare a written plan for vaccine storage and handling during routine, planned office closures (for holidays, vacations, etc.) lasting four consecutive days or longer; submits plan to SCVFC staff for approval as requested.
- Ensures that the practice's vaccine inventory management is consistent with SCVFC Program requirements.
- Ensures that the practice's vaccine storage units meet SCVFC requirements.
- Updates and revises vaccine management plans at least annually and when necessary.
- Reviews SCVFC requirements and management plans with staff at least annually and when necessary.

Primary Vaccine Coordinator

- □ Completes required SCVFC Program trainings.
- Meets responsibilities described in the <u>Vaccine</u> <u>Coordinator job aid</u>.
- Oversees the practice's vaccine management for routine and emergency situations.
- Monitors vaccine storage units.
- Maintains SCVFC-related documentation in an accessible location.

Back-Up Vaccine Coordinator

- □ Completes required SCVFC Program trainings.
- Meets responsibilities described in the <u>Vaccine</u> <u>Coordinator job aid</u> when the Primary Vaccine Coordinator is not available.



Vaccine Storage and Temperature Monitoring Equipment

The Primary Vaccine Coordinator must review and acknowledge the requirements on the following pages by checking all items.

Vaccine Storage Units

Equipment

- The practice uses SCVFC-compliant vaccine storage refrigerator(s) and freezer(s) and maintains recommended temperature ranges:
 - Refrigerator: between 2°C–8°C (36°F-46°F)
 - Freezer: below -15°C (5°F)
- Storage units have adequate capacity to store vaccine supply at all times, including during peak back-to-school and flu season.
- Storage units are routinely cleaned inside, kept dust-free outside, and doors have properseals.
- Keeps maintenance and repair records on file and makes them available to review upon request.

Power Supply

- Each unit is plugged directly into a wall outlet and is not controlled by a light switch, power strips, or surge protectors with an on/off switch.
- Extension cords are never used to connect storage units to an outlet.
- "DO NOT UNPLUG" signs are posted at each outlet and circuit breakers.

Set-up

- Storage units are set up according to SCVFC Program requirements.
- Units are kept away from direct sunlight and away from walls to allow air circulation.
- Vaccine is never stored in the door, drawers, or bins. Unit drawers/deli crispers are removed.
- To stabilize temperatures, water bottles are kept in the refrigerator where vaccines cannot be stored.
 Frozen cold packs are kept in the freezer for similar purpose.
- VFC and State vaccine storage areas/shelves are marked "VFC" and "State" to clearly identify vaccine supplies.
- Privately purchased vaccines are kept separate from SCVFC Program vaccines.
- Vaccines are organized in plastic mesh baskets and clearly labeled by type of vaccine.

- The glycol-encased data logger probe is placed in the center of the unit, near the vaccines.
- □ The data logger's display is securely attached to the outside of the storage unit.
- Vaccines are stored in their original packaging until administered; vaccine supply is 2–3 inches away from walls, air vents, and floor to allow space for air circulation.
- Food, beverages, and laboratory specimens are not stored in the units at any time.
- When medications or biologic media (not inoculated) are stored in the unit, they are placed on the shelves below vaccines.

Temperature Monitoring

Data Loggers

- Each storage unit must have a SCVFC-compliant data logger accurate within +/-1°F.
- Each data logger has a current and valid Certificate of Calibration (also known as a Report of Calibration).
- Each data logger has a biosafe glycol-encased probe placed in the center of the storage unit in close proximity to the vaccine.
- Each data logger has a digital display of current, minimum, and maximum temperatures.
- Probes are NEVER placed in the unit's doors, near or against unit's walls, underneath air vents, or on the unit floor.
- Data logger batteries are replaced every nine months.

Data logger Calibration

- Calibrated digital data loggers are used in all storage units.
- Certificates of Calibration are filed in a readily accessible area, kept for three years, and are presented to SCVFC Immunization program staff for review upon request.
- Data loggers are replaced or recalibrated on or before the expiration date listed on the certificate and/or device.



Safeguarding Vaccines, Handling and Reporting Out-of-Range Temperatures

- When an out-of-range temperature is identified, immediate action is taken to assess the situation and to prevent vaccine spoilage.
- The SCVFC Operations Staff is contacted via SIMON Helpdesk to report the incident, complete and attach the DHEC3266/3265 Vaccine Storage Trouble Shooting Record
- Vaccines in question are bagged and labeled "DO NOT USE" and stored under proper conditions until it is determined if they are viable.
- The practice has an Emergency Vaccine Management Plan to follow in the case of power outage, appliance malfunction, weather conditions, or human error that may affect vaccine viability.
- When it is necessary to transport vaccine to another storage unit or to a predetermined site, the practice always follows SCVFC Program guidelines.
- No vaccine is discarded unless directed to do so by the SCVFC Program.
- Actions are documented on the SCVFC temperature log and other SCVFC forms, as appropriate.

Temperature Monitoring and Documentation

- Reads and records MIN and MAX refrigerator and freezer temperatures at the start of clinic day.
- Verifies that the Data Loggers are ON after checking the min/max temperatures.
- □ The person documenting the storage unit temperature initials the temperature log.
- Temperatures are documented on SCVFC
 Program DHEC3266/3265 temperature logs.
- □ Temperature logs are posted on the storage unit door or nearby in an accessible location.
- The practice maintains completed temperature logs for three years and makes them available for review upon request to SCVFC Representatives.

Inventory Management

- The practice enters inventory into SIMON upon receipt.
- A reconciliation of physical vaccine inventory is conducted at least once a month and before ordering vaccine.
- Vaccine stock is rotated monthly to assure that vaccines with the shortest expiration dates are used first.
- The practice may keep up to two weeks' additional supply to mitigate shortages in the event of shipment delays.
- When diluent is packaged with vaccine, the practice stores them together. When diluent is not packaged with its vaccine, the diluent is clearly labeled and stored where it can be easily identified.
- If vaccine is drawn up and not used*, it is recorded in SIMON and disposed of properly.

Stock Rotation, Returns, and Transfers

- □ The practice organizes vaccines so those with the shortest expiration dates are usedfirst.
- □ The practice returns expired and/or spoiled vaccine to McKesson in a timely manner.
- □ If the practice has vaccine due to expire within three months and it will not be used, it:
 - Notifies the SCVFC Program via <u>SIMON Helpdesk</u> about the vaccine;
 - Identifies SCVFC providers in the area to contact and inquires if they may be able to use the soon-to-expire vaccines.
- If vaccine becomes spoiled or expires, staff remove it immediately from the storage unit, report it, and complete the appropriate documentation in SIMON.
- Vaccine that is spoiled or expired must be reported to the SCVFC Program before a new order can be submitted.
- □ The practice may return spoiled or expired vaccine to McKesson.

*this practice is **strongly** discouraged



- The following vaccine supplies should NOT be returned:
 - Viable vaccine
 - Used syringes with or without needles
 - Syringes with vaccine drawn up and not used
 - Broken or damaged vaccine vials
 - Multi-dose vials that are partially used

Vaccine Ordering

- According to the SCVFC Program, we are (check one):
 - Large-sized provider and receive more than 2,000 vaccine doses/year.
 - ____ Medium-sized provider and receive 500–2,000 vaccine doses/year.
 - Small-sized provider and receive fewer than 500 vaccine doses/year.
- Orders are submitted according to clinic-based eligibility data, vaccine usage, and take into account the inventory in stock.
- The practice does a physical inventory before placing a vaccine order.
- □ A summary of on-hand inventory is included with each order.
- Orders are placed with sufficient inventory on hand to allow time for order processing and vaccine delivery.
- Every SCVFC vaccine dose is accounted for. Sites may be held financially responsible for vaccine doses not accounted for or lost due to negligence.
- The practice verifies its operation hours when placing their order in SIMON before submitting each order. Any changes to the practice's hours are reported with each order to avoid receiving vaccine shipments when the clinic is closed, or the staff is not available.

Receiving and Inspecting Vaccine Shipments

- The practice is familiar with procedures for accepting vaccine shipments as outlined in <u>SIMON</u> <u>-Receive VTrckS Shipments</u>.
- The practice assumes responsibility for all SCVFC vaccine shipped to its site.
- Vaccine shipments are inspected immediately upon arrival to verify that the temperature during transport was within range, and that the vaccines being delivered match those listed on the packing slip.
- □ The practice never rejects vaccine shipments.
- The practice follows the Section 4.4 Receiving VFC Vaccine in the current VFC Provider Handbook.
- Vaccines are immediately stored according to SCVFC requirements.
- Vaccines are accepted into SIMON inventory upon receipt.



Signature Log

By signing, I acknowledge I have reviewed and am familiar with the information in this document.

| Review | |
|----------------------------------|-----------|
| Date | |
| Updates & Comments | |
| Provider of Record name | Signature |
| Primary Vaccine Coordinator name | Signature |
| | |
| Back-up Vaccine Coordinator name | Signature |
| Additional Staff | Signature |

| Review | | |
|----------------------------------|-------|------|
| Date | | |
| Updates & Comments | | |
| Provider of Record name | Signa | ture |
| Primary Vaccine Coordinator name | Signa | ture |
| Back-up Vaccine Coordinator name | Signa | ture |
| Additional Staff | Signa | ture |

| Review | | |
|----------------------------------|-----------|--|
| Date | | |
| Updates & Comments | | |
| Provider of Record name | Signature | |
| Primary Vaccine Coordinator name | Signature | |
| Back-up Vaccine Coordinator name | Signature | |
| Additional Staff | Signature | |



Vaccine Staff Training Log

| Date | Subject of Training | Attendee | Title |
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Worksheet for Emergency Contacts

The South Carolina VFC Program requires that each practice develop and maintain an *Emergency Vaccine Management Plan*. Properly completing this template will meet the VFC Program requirement to have a written plan for vaccine management in an emergency. Plans must be reviewed and updated annually, or when changes to any information within the plan occur.

This *Emergency Vaccine Management Plan* outlines actions staff should take in the event of an emergency that might affect vaccine viability. Examples include unit malfunction, mechanical failure, power outage, natural disaster, or human error. This plan must be kept near the vaccine storage unit.

Staff Roles and Contact Information

| Emergency Contacts | |
|--------------------|--|
| Office/Clinic Name | |
| VFC Pin Number | |
| Address | |

In an emergency, contact the following people in the order listed:

| Role/Responsibility | Name | Phone Number | Alt Phone | Email Address |
|------------------------|------|--------------|-----------|---------------|
| 1. Primary Coordinator | | | | |
| 2. Back-up Coordinator | | | | |
| 3. Additional Contact | | | | |

Useful Emergency Numbers

| Service | Name | Phone # | Alt Phone # | Email Address |
|----------------------------------|---------------------|--------------|-------------|---|
| VFC Regional Imz. Representative | | | | |
| VFC Regional Imz. Representative | | | | |
| VFC/SIMON Helpdesk | VFC Operation Staff | 800-277-4687 | | SIMON Website- SIMON Helpdesk https://www.scdhec.gov/SIMON |
| Utility Company | | | | |
| Building Maintenance | | | | |
| Building Alarm Company | | | | |
| CTM (DDL) Technical Support Line | | | | |
| Refrigerator/Freezer Repair | | | | |
| Generator Repair/ Maintenance | | | | |
| Contact for Vaccine Transport | | | | |
| Other | | | | |



Keep Near Vaccine Storage Unit(s)



Vaccine Storage Unit Information

| Unit Type | Name in SIMON and location of unit | Brand/Model | Serial Number |
|--------------|------------------------------------|-------------|---------------|
| Refrigerator | | | |
| Freezer | | | |
| Freezer | | | |

Attach additional unit information as needed.

| Does the clinic have a generator? | If so, where is it located? |
|-----------------------------------|-----------------------------|
| Yes 🗌 No 🗌 | |

If your clinic does not have a generator, and/or your vaccine storage unit fails, it might be necessary to transport vaccine to alternate storage locations.

| Alternate Vaccine Storage Plans | Site name and address | Site contacts – names and cell phone numbers | Office Phone | Details of plan |
|------------------------------------|---|---|-----------------|-----------------|
| Plan A | | | | |
| Plan B | | | | |
| Plan C | | | | |
| Plan D | Close and seal all vaccine storage units; use large "DO NOT OPEN" signs; record the date and time the units were closed; make sure all data loggers are on and recording. | | | |

Location of emergency packing supplies:

Other Useful Information

Facility Floor Plan: Attach a simple floor diagram identifying the location of doors, light switches, flashlights, spare batteries, keys, locks, vaccine storage units, alarms, circuit breakers, packing materials, etc.

Form Certification

| Form Completed By | | |
|-------------------|-----------|--|
| Name | Signature | |
| Title | Date | |



Emergency Vaccine Management Plan

Use the following guidance for safeguarding vaccines in the event of planned or unplanned power interruptions (e.g., power outages, weather related circumstances, building maintenance/repairs, etc.).

Before an Emergency

- Maintain emergency contact information for key staff responsible for vaccine management.
- Store water bottles in vaccine refrigerators and frozen water bottles in freezers where vaccines cannot be stored. This helps maintain the interior temperature in the event of a power loss.
- Identify alternate vaccine storage location(s), e.g., a local hospital or another VFC provider. Ensure the location has adequate space to accommodate vaccines and their temperature monitoring equipment meets VFC Program requirements.
- Update the necessary contact information for alternate vaccine storage location(s), including the facility name, address, contact person, and telephone number.
- Stock supplies indicated in <u>Transporting</u> <u>Vaccines During and Emergency (CR-011683)</u>
- Label and keep accessible any necessary vaccine packing and transport supplies, copies of vaccine transport job aids, facility floor plans when available, and other related information.
- Be familiar with back-up power sources for commercial/lab/pharmacy grade units.

During an Emergency

- Assess the situation. Do not open the unit.
- Determine the cause of the power failure and estimate the time it will take to restore power.
- Notify the key staff listed on this Emergency Plan as appropriate.
- If the power outage is expected to be short-term, usually restored within 2 hours:
 - Record the time the outage started, the unit temperatures (CURRENT, MIN, MAX) and room temperature.

- Place a "DO NOT OPEN" sign on storage unit(s) to conserve cold air mass.
- If MMR is stored in the refrigerator, move it to the freezer.
- Verify water bottles are distributed throughout the refrigerator.
- Monitor the interior temperature using a data logger until power is restored. Do not open the unit to verify the temperature.
- If the outage is expected to be long term, usually longer than 2 hours, consider moving vaccines to an alternative unit or facility. See details under Vaccine Relocation, below.
- Note: Temperatures in commercial, pharmacy, and lab grade units tend to increase faster during power failures. As a result, clinics using these units need to monitor temperatures more frequently and may need to transport vaccines to an alternate location sooner.

Relocating Vaccine

If a power outage is long-term, is not expected to be restored by the end of the day, or vaccine storage units have reached out-of-range temperatures, prepare to relocate vaccines to the alternate storage location as feasible.

Before transporting vaccines:

- □ Review job aids <u>Transporting Vaccines During and</u> Emergency (CR-011683).
- Contact the alternate storage facility to verify they can accept the vaccines.
- Notify the VFC Program.

If transport or relocation is not feasible, e.g. alternate location not available or unsafe travel conditions:

- Keep units closed and document the temperatures (CURRENT, MIN, MAX).
- Contact the VFC Program.



Packaging and Transporting Vaccines

- Document vaccine storage temperatures before, during and after transport. On a Vaccine Transport Log (DHEC 1208) with a CTM monitoring the system. CTM device must monitor vaccines during transport at all times.
- Prepare cooler(s) following VFC guidelines job aids with <u>Transporting Vaccines During and</u> <u>Emergency (CR-011683)</u>
- Notify the key staff listed on this Emergency Plan as appropriate.
- □ Pack vaccine according to VFC guidelines.
 - Use conditioned frozen water bottles for refrigerated vaccines. Placing refrigerated vaccine directly on frozen packs and packaging it without sufficient insulation may freeze and therefore damage vaccine.
 - Frozen vaccine should only be transported in a frozen vaccine pack-out container. If such a container is not available, leave the frozen vaccines in the freezer and keep the door closed to maintain the temperature.
- Package and prepare diluent.
 - MMR, Varicella and MMR-V diluent can be stored at room temperature or in the refrigerator.
 - Diluents stored in the refrigerator should be transported with refrigerated vaccines.
 - Diluents stored at room temperature should be transported at room temperature.
 - Diluents packaged with their vaccine should be transported with the vaccine.
- Upon arrival at the alternate vaccine storage location, document total vaccine transport time, the temperatures (CURRENT, MIN, MAX) in the transport cooler(s) and the alternate storage unit(s).

After Power Is Restored

- Verify storage units are functioning properly before attempting to move any vaccine.
- □ Follow the same transportation procedures and transfer vaccine back to its original storage unit.
- Vaccine kept at the proper temperature during the power outage, whether transported or not, may be used.
- For any vaccine not stored at the proper temperature:
 - Segregate it in the storage unit.
 - Mark it "DO NOT USE."
 - Contact the VFC Program; be prepared to provide timeframes and temperature information.
- Never return vaccine to the vaccine distributor without VFC Program authorization.



Signature Log

By signing, I acknowledge I have reviewed and am familiar with the information in this document.

| Review | | |
|----------------------------------|-----------|--|
| Date | | |
| Updates and Comments | | |
| Provider of Record name | Signature | |
| Primary Vaccine Coordinator name | Signature | |
| Back-up Vaccine Coordinator name | Signature | |
| Additional Staff | Signature | |

| Review | |
|----------------------------------|-----------|
| Date | |
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| Primary Vaccine Coordinator name | Signature | |
| Back-up Vaccine Coordinator name | Signature | |
| Additional Staff | Signature | |

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

South Carolina Routine and Emergency Vaccine Management Plan

Instructions for Completing

Purpose:

The purpose of the South Carolina Routine and Emergency Vaccine Management Plan (SCREVMP) is to provide a template for development of a comprehensive vaccine management plan for protection and maintenance of your practice's vaccine supply.

Item-By-Item Instructions:

- 1. Provider will enter identifying information.
- 2. Provider will enter Provider PIN number, as applicable.
- 3. Provider review, update and sign this form annually.
- 4. Provider will complete contact information for the facility, alternate facility, and complete all requested information under Routine and Emergency.

Office Mechanics and Filing:

- 1. Upon completion, the provider will retain current version and also post a copy on the vaccine storage unit(s). A copy must be COMPLETED as part of initial enrollment/ annual re-enrollment and provided to the DHEC Division of Immunization upon request.
- 2. SCREVMP should be updated as necessary.
- 3. Previously completed plans should be retained for three (3) years.
- 4. Form Retention:

-VFC & STATE Vaccine providers: retain the original form for (3) three years as required by the Federal Immunization Program.

-DHEC Immunization Program: retain providers' copies for (3) three years as required by the Federal Immunization Program.

-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.

Under Retention schedule 15726 Record Group Number 169 Retention: 3 years, destroy