

OFFICE VACCINE MANAGEMENT PLAN *TEMPLATE*

This plan has been developed to assure the proper handling and storage of vaccines administered by this clinic. Vaccines are temperature and light sensitive and must be stored correctly to maintain their effectiveness. The following personnel are responsible for vaccine management:

Vaccine Coordinator _____

Home phone number _____

Cell phone number _____

Back Up Vaccine Coordinator _____

Home phone number _____

Cell phone number _____

VACCINE ORDERING

To request state supplied vaccine, follow instructions in the Vaccines for Children Program Protocol (pages 8-10).

To order privately supplied vaccine, refer to _____.

VACCINE RECEIVING

When vaccine is received by the front desk personnel, the vaccine coordinator or back-up will be notified **immediately**. All staff will be trained in vaccine receipt. The box will be taken to the vaccine storage area and unpacked in the following manner **within 2 hours of receipt**:

REFRIGERATED VACCINE

1. Upon opening the box, verify that the cold chain has been maintained. First, check the temperature indicator to determine if the vaccines were exposed to temperatures above 46°F. Follow the instructions on the card. Second, inspect the temperature indicator for evidence that the vaccines were frozen. Follow the instructions on the card. Examine the shipping container and contents for signs of damage. If damage to the contents or cold chain failure is noted, then call the Nevada State Immunization Program (775-684-5900). Finally, check the interval between shipment from the supplier and arrival of the product at the office. If more than 48 hours has elapsed, call the Nevada State Immunization Program. **The vaccine shipment must be inspected within 2 hours of arrival.** If problems are discovered two hours after arrival of the vaccine, then McKesson is not responsible for replacement of the compromised vaccine.
2. Check the contents of the shipment against the shipping invoice. Compare quantities, lot numbers, and expiration dates carefully. Log in the date, name of the vaccine, lot number, manufacturer, expiration date, arrival condition and quantity received in your log book. Any discrepancies must be reported immediately to the Nevada State Immunization Program (775-684-5900).
3. File the shipping invoice in your Immunization Program binder.
4. Place the new vaccines in the refrigerator with the shortest expiration dates in the front of the pack. Make sure to separate the VFC vaccines from the private supply by _____.

FROZEN VACCINE

1. Upon opening the box, verify that the cold chain has been maintained. A slip inside the box states when the shipment was packed. If more than 48 hours have elapsed since the box was packed, then call the Merck Order Management Center immediately at 1-800-MERCK RX (1-800-637-2579) for replacement instructions and the Nevada State Immunization Program (775-684-5900).
2. Check the contents of the shipment against the shipping invoice. Compare quantities, lot numbers, and expiration dates carefully. Log in the date, name of the vaccine, lot number, manufacturer, expiration date, arrival condition and quantity received in your log book. Any discrepancies must be reported immediately to the Nevada State Immunization Program (775-684-5900).
3. File the shipping invoice in your Immunization Program binder.
4. Place the new vaccines in the freezer with the shortest expiration dates in the front of the pack. Make sure to separate the VFC vaccines from the private supply by _____.

VACCINE STORAGE

Publicly supplied (VFC/317) vaccines will be stored in _____.

Privately purchased vaccines will be stored in _____.

REFRIGERATOR TEMPERATURE must be between 35 -46° F or 2 -8° C. Ideally, the temperature should be maintained around 40° F or 5° C. Temperatures will be checked **twice** a day using the **certified thermometer**. The temperature probe contained in a glycol bottle must be placed in the center of the refrigeration unit and away from the sides and vent. Temperatures will be checked first thing in the morning before patients are seen and recorded with an “X” on the state supplied temperature log. Temperatures will be checked at the end of the day and recorded with an “X” on the state supplied temperature log. The maximum and minimum temperatures will be recorded with an “O” on the state supplied forms in the morning every business day. The maximum and minimum temperature readings will be reset every work day after the temperatures are recorded. **Any temperature that is out of range will prompt immediate intervention.** First, double check the thermometer reading with another certified thermometer. Change the batteries in the certified thermometer if it is not accurate. Check to make sure the refrigerator seals are intact, that the unit is plugged in and the circuit breaker intact. If the unit appears to be functioning normally, then adjust the thermostat and check again in a 1/2 hour. If the unit appears to be failing, then transfer the vaccines to a backup unit. Document all actions taken on the back of the temperature log. Store temperature logs for 3 years in the Immunization Program binder.

Providers with data loggers, substitute the following paragraph for the paragraph above. **Delete this section if the office does not have a data logger.**

REFRIGERATOR TEMPERATURE must be between 35 -46° F or 2 -8° C. Ideally, the temperature should be maintained around 40° F or 5° C. Temperatures will be checked **twice** a day by pushing the review button on the data logger. This will place a mark on the graph that is generated. By pushing the review button, the maximum and minimum temperatures will be reviewed. Make sure that an alarm has not occurred since the last temperature check. If an alarm has occurred, download the data immediately and e-mail the files to NVIZ@health.nv.gov . **Any temperature that is out of range will prompt immediate intervention.** First, check that the battery of the data logger is OK. Change the batteries in the data logger if an “X” appears under the battery icon. Check to make sure the refrigerator seals are intact, that the unit is plugged in and the circuit breaker intact. If the unit appears to be functioning normally, then adjust the thermostat and check again in a 1/2 hour. If the unit appears to be failing, transfer the vaccines to a backup unit. Document all actions taken on the vaccine incident report.

FREEZER TEMPERATURE must be equal to or less than 5° F or -15° C. Temperatures will be checked **twice** a day using the **certified thermometer**. The temperature probe contained in a glycol bottle must be placed in the center of the freezer unit away from the sides and back. Temperatures will be checked first thing in the morning before patients are seen and recorded with an “X” on the state supplied temperature log. Temperatures will be checked at the end of the day and recorded with an “X” on the state supplied temperature log. The **maximum** temperature will be recorded with an “O” every morning on the state supplied temperature log and the maximum temperature reset. **Any temperature that is out of range will prompt immediate intervention.** First, double check the temperature reading with another certified thermometer. Change the batteries in the certified thermometer if it is not accurate. Check to make sure the freezer door seals are intact, the unit is plugged in and the circuit breaker intact. If the unit appears to be functioning normally, then adjust the thermostat and check again in a 1/2 hour. If the unit appears to be failing, then transfer the vaccines to a backup unit. Document all actions taken on the back of the temperature log. Store temperature logs for 3 years in the Immunization Program binder.

Providers with data loggers, substitute the following paragraph for the paragraph above. **Delete this section if the office does not have a data logger.**

FREEZER TEMPERATURE must be equal to or less than 5° F or -15° C. Ideally, the temperature should be maintained around 0° F or -20° C. Temperatures will be checked **twice** a day by pushing the review button on the data logger. This will place a mark on the graph that is generated. By pushing the review button, the maximum and minimum temperatures will be reviewed. Make sure that an alarm has not occurred since the last temperature check. If an alarm has occurred, download the data immediately and e-mail the files to NVIZ@health.nv.gov . **Any temperature that is out of range will prompt immediate intervention.** First, check that the battery of the data logger is OK. Change the batteries in the data logger if an “X” appears under the battery icon. Check to make sure the refrigerator seals are intact, that the unit is plugged in and the circuit breaker intact. If the unit appears to be functioning normally, then adjust the thermostat and check again in a 1/2 hour. If the unit appears to be failing, then transfer the vaccines to a backup unit. Document all actions taken on the vaccine incident report.

When recording the refrigerator and freezer temperatures, also record the room temperatures, the time and initials of the reviewer.

Back up certified calibrated thermometer is located _____.

If the refrigeration or freezer unit malfunctions, call _____ for servicing.

See pages 4 and 5 for instructions on how to proceed when a vaccine incident occurs.

MAINTENANCE OF THE REFRIGERATION UNIT AND FREEZER

1. Clean the unit once a month to discourage bacterial and fungal growth.
2. Defrost the freezer on a routine basis if the unit is not self-defrosting.
3. Place the unit in a well ventilated room with sufficient space (4 inches) around the sides and top for air circulation.
4. **NO FOOD OR BEVERAGES** may be stored in units dedicated to vaccine storage.
5. Periodically vacuum the dust from the exterior coils.

6. Keep ice packs in the freezer and full water jugs in the doors and bottom bins of the refrigerator to help stabilize the temperature.
7. Check the seals around the doors monthly for signs of wear.
8. Place a **“DO NOT UNPLUG”** sticker on or near the outlet that the unit is plugged into and a **“DO NOT DISCONNECT”** sticker on the circuit breaker that supplies power to the vaccine storage unit. These warning signs will prevent housekeeping and maintenance staff from turning off the power supply to the vaccine storage units.
9. Check to make sure the certificate of calibration on the thermometers/data loggers in use has not expired.

VACCINE

1. Store the vaccine in their original boxes. **(Vaccines are light sensitive!)**
2. Privately purchased vaccine is stored_____.
3. State supplied (VFC/317) vaccine is stored_____.
4. Diluent is stored _____ **(never in the freezer!).**
5. Vaccines and diluents with the shortest expiration date are located in the front, to be used first.
6. Open **only one box** of each type of vaccine. Mark it as **“opened”** with a sticker or permanent marker to prevent multiple boxes from being opened!
7. Check expiration dates of vaccine stock weekly. If state supplied vaccine cannot be administered prior to the expiration date, then call the Immunization Program to have the vaccine transferred to another provider at least **3 months** before it expires. **Once vaccine expires, remove it from the vaccine storage unit, mark “DO NOT USE,” and store in a cabinet until it is shipped.** Complete the VTrckS UPS Pickup Request for Expired/Spoiled/Vaccine (See page 12.)
8. Arrange the vaccine stacks in the **center** of the refrigerator or freezer. Do not permit the vaccine boxes to touch the side walls or back of the unit. **DO NOT** store vaccines in the crisper bins, door or under the vent.
9. Indicate on the label of each multi-dose vial the date and time that it was reconstituted or first opened. Refer to the manufacturer’s package insert for the expiration date. Influenza and polio vaccine in multi-dose vials can be used until the expiration date if the vial is not contaminated or exposed to out-of-range temperatures.
10. Physically separate similar packages of vaccine to avoid administration errors. Placing the boxes of vaccine in **labeled bins** may also help prevent administration errors.
11. Store vaccine with space between the boxes to allow air circulation.
12. **NO FOOD OR BEVERAGES** may be stored in units dedicated to vaccine storage.
13. Post a sign on the refrigerator door showing which vaccines should be stored in the refrigerator and which should be stored in the freezer.

PROCEDURES IN THE EVENT OF A POWER FAILURE OR MECHANICAL DIFFICULTY

SHORT TERM POWER OUTAGE

1. Record the time and temperatures of the room, refrigerator, and freezer using **certified** thermometers.
2. If you are sure that the power will only be off for several hours, then tape the freezer and refrigerator doors shut so no one inadvertently opens the doors and allows all the cold air to escape.
3. When the power resumes, record the time and the temperatures in the refrigerator and freezer. If temperatures are out of range, contact the manufacturer for instructions and do not use the vaccine until the manufacturer has been consulted. Notify the Nevada State Health Division, Immunization Program (775-684-5900) if state supplied vaccines were involved.

LONG TERM POWER OUTAGE DUE TO A NATURAL OR MANMADE DISASTER: FACILITY WITH A GENERATOR

1. Record the time and temperatures of the room, refrigerator, and freezer using **certified** thermometers.
2. Make sure that the vaccine storage unit is plugged into an outlet that is supplied power by the generator. Once the generator is supplying power to the storage unit, record the temperatures in the freezer and refrigerator. If the generator is not functioning, then prepare to transfer the vaccine to a functioning unit.

LONG TERM POWER OUTAGE DUE TO A NATURAL OR MANMADE DISASTER: FACILITY WITHOUT A GENERATOR

1. Record the time and temperatures of the room, refrigerator, and freezer using **certified** thermometers.
2. Have the following items available in case of a disaster: flashlight with extra batteries, ice packs, bubble wrap and cardboard, coolers (Styrofoam or hard sided), and cold-weather gloves.
3. Complete the **Vaccine Incident Report**. (Page 10)
4. Place ice packs on the bottom of the cooler/box. Place a layer of bubble wrap and cardboard over top of the ice packs. Fill the cooler/box with **refrigerated** vaccine. Place a thermometer in the middle of the box, surrounded by the vaccine, with the display placed outside the box. Place a layer of bubble wrap and cardboard over top of the vaccine boxes. Place ice packs on top of bubble wrap and cardboard. Secure the lid of the cooler/box and the digital thermometer display.
5. Place freezer packs on the bottom and sides of a cooler. Remove **varicella** vaccine from the freezer and place in the cooler on top of the freezer packs. Surround vaccine with freezer packs. Place a thermometer in the middle of the cooler, surrounded by the vaccine, with the display placed outside the cooler. Secure the lid of the cooler and the digital thermometer display. Alternatively, a VaxiPac or AcuTemp unit can be used to transport frozen vaccine.
6. Transport vaccine immediately. Note the amount of time the vaccine is out of the vaccine storage unit and the temperature and call the manufacturer for instructions if appropriate temperatures are not maintained.
7. Transport the containers of vaccine in the cab of the vehicle – **NOT IN THE TRUNK** – to a vaccine storage unit that has been appropriately monitored. Transport the vaccine to:

Name _____

Address _____

Phone _____

8. Continue to record temperatures twice a day and the maximum/minimum temperatures once daily while the vaccine is in the back up storage unit to assure viability of vaccine.
9. If the vaccines were removed from units with temperatures **above** the permissible range, then call the vaccine manufacturer with the information from the **Vaccine Incident Report**. Manufacturers' numbers are listed on page 11.
 - If the manufacturer determines that the vaccine is still viable and can be used, then mark the vaccine boxes and vials with the new expiration date if one is provided.
 - If the manufacturer determines that the vaccine is spoiled and cannot be used, remove it from the vaccine storage unit and return **all** state supplied vaccine to McKesson. See instructions on page 12.
10. If the vaccines were removed from units with temperatures **below** the permissible range, call the vaccine manufacturer with the information from the **Vaccine Incident Report**.
 - If the manufacturer determines that the vaccine is still viable and can be used, then mark the vaccine boxes and vials with the new expiration date if one is provided.
 - If the manufacturer determines that the vaccine is spoiled and cannot be used, remove it from the vaccine storage unit and return **all** state supplied vaccine to McKesson. See instructions on page 12.

MECHANICAL FAILURE OF THE VACCINE STORAGE UNIT

1. Record the time and temperatures of the room, refrigerator, and freezer using **certified** thermometers.

Pack the vaccine as outlined above in #4 and #5 and transfer the vaccine to another storage unit that has been previously monitored. If the temperatures were out of acceptable range in the primary storage unit, then mark the vaccine **"DO NOT USE"** until the manufacturers are contacted for advice.

 - Alternate storage unit for **refrigerated** vaccines is located at _____.
 - Alternate storage unit for **frozen** vaccines is located at _____.
2. Call _____ to schedule a service call on the vaccine storage unit.
3. Complete the **Vaccine Incident Report**. (Page 10)
4. Continue to record the temperatures twice a day and the maximum/minimum temperatures once daily while the vaccine is in the back up storage unit to assure viability of vaccine.
5. If the vaccines were removed from units with temperatures **above** the permissible range, then call the vaccine manufacturer with the information from the **Vaccine Incident Report**. Manufacturers' numbers are listed on Page 10.
 - If the manufacturer determines that the vaccine is still viable and can be used, mark the vaccine boxes and vials with the new expiration date if one is provided.

- If the manufacturer determines that the vaccine is spoiled and cannot be used, remove vaccine from the storage unit and return **all** state supplied vaccine to McKesson. Follow the instructions on page 12.
6. If the vaccines were removed from units with temperatures **below** the permissible range, call the vaccine manufacturer with the information from the **Vaccine Incident Report**.
 - If the manufacturer determines that the vaccine is still viable and can be used, mark the vaccine boxes and vials with the new expiration date if one is provided.
 - If the manufacturer determines that the vaccine is compromised and cannot be used, remove it from the vaccine storage unit and return all state supplied vaccine to McKesson. See instructions on page 12.
 7. When the storage unit has been repaired, resume checking temperatures twice a day and maximum/minimum temperatures once daily. **Vaccines may be returned to the repaired unit after 5 consecutive days of acceptable temperatures and state immunization program approval.**
 8. If the malfunctioning storage unit cannot be repaired and a new unit is purchased, **acceptable temperatures must be recorded in the new unit for 5 consecutive days and state approval must be obtained before the vaccine can be moved into the new unit.**

VACCINE WASTAGE

1. State supplied vaccine that is drawn up into a syringe but not administered should be discarded into the sharps container. **Wasted doses** should be recorded on the “Vaccine Inventory and Accountability Report” that is submitted to the state at the end of the month.
2. State supplied vaccine that is **spoiled** due to inappropriate storage or shipment should be returned to McKesson. Complete a **Vaccine Incident Report** (page 10) and fax to the Nevada State Immunization Program (775-684-8338). Follow the procedure and forms included on page 12 to have the spoiled vaccine picked up by UPS.
3. State supplied vaccine that is **expired** should be returned to McKesson. Follow the procedure and forms included on page 12 to have the expired vaccine picked up by UPS.
4. **Wastage of vaccine due to expiration can be prevented** by notifying the state when vaccine is 3 months from its expiration date, and will not be administered prior to expiration. The state will make arrangements to have the vaccine picked up and moved to another provider enrolled in the Nevada State Immunization Program.

VACCINE STORAGE AND HANDLING TRAINING FOR STAFF MEMBERS

The office vaccine coordinator and back up vaccine coordinator must be knowledgeable about vaccine storage and handling. Vaccine is very expensive and can be compromised by out of range temperatures and light exposure. **Therefore, the vaccine coordinator and back up vaccine coordinator must read the following:**

1. **Nevada State Immunization Program Protocol** (updated yearly)
2. **The PINK book – Chapter 5 – Vaccine Storage & Handling:**
www.cdc.gov/vaccines/pubs/pinkbook/vac-storage.html
3. **EZIZ Storage and Handling course:** <http://eziz.org/eziz-training/>

4. CDC Vaccine Storage & Handling Toolkit:
www.cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf

5. CDC “You Call the Shots” modules 10 (Storage and Handling) and 16 (VFC Program).
<http://www2a.cdc.gov/nip/isd/ycts/mod1/courses/sh/ce.asp>
<http://www2a.cdc.gov/nip/isd/ycts/mod1/courses/vfc/ce.asp>

This document was created by (print)_____.

Signature_____.

Date_____.



State of Nevada
 Dept of Health and Human Services
 Nevada State Immunization Program
 4150 Technology Way, Suite 210
 Carson City, NV 89706
 Phone: (775) 684-5900 Fax: (775) 684-8338

Vaccine Incident Report

(Print clearly)

Facility Name: _____ PIN # _____

Reported by: _____ Telephone # _____ Date Reported: _____

Current temperature of refrigerator: _____ F or _____ C Max/Min temperature reached: _____ F or _____ C

Current temperature of freezer: _____ F or _____ C Max/Min temperature reached: _____ F or _____ C

Date of incident and refrigerator temperature at time incident discovered: Date: _____ F or _____ C

Date and time of last recorded temp before incident: _____ at _____ am/pm _____ F or _____ C

Amount of time the temperature was outside normal range: Refrigerator _____ Freezer _____

Vaccines were moved to a working refrigerator/freezer post event: Yes No

Description of incident: DO NOT THROW OUT AFFECTED VACCINES- (do not assume vaccines are not viable)

What steps will be taken to prevent this from happening in the future?

Report of viability from manufacturer (required):

Complete section below for all vaccines affected by the event: (use additional page if necessary)

Vaccine Brand Name	Manufacturer	Lot No.	Exp. Date	No. of Doses	Vial Open or Closed	Disposition Per manufacturer i.e.: *wasted, exp date changed, etc

*For wasted vaccine, please complete the "UPS Pickup Request Form for Expired or Spoiled Vaccine"

Contact Information: Selected Vaccine Manufacturers & Distributors Manufacturer/Website	Phone Number	Products
Centers for Disease Control & Prevention www.cdc.gov/ncidod/srp/drugs/drug-service.htm . www.cdc.gov/laboratory/drugservice/index.html	404-639-3670	Distributor for diphtheria antitoxin, VIG, smallpox vaccine
GlaxoSmithKline www.gskvaccines.com	866-475-8222	Infanrix, Kinrix, Pediarix, Havrix, Engerix-B, Twinrix, Hiberix, Cervarix, Fluarix, FluLaval, Rotarix, Boostrix
Massachusetts Biological Labs www.umassmed.edu/massbiolabs/index.aspx	617-474-3000	IGIM, Td, TT
MedImmune, Inc. www.medimmune.com	877-633-4411	FluMist
Merck & Co., Inc. www.merckvaccines.com	800-637-2590	PedvaxHIB, Comvax, Vaqta, Recombivax-HB, Gardasil, M-M-R II, ProQuad, Afluria, Pneumovax 23, RotaTeq, Varivax, Zostavax, Td
Biotest Pharmaceuticals www.biotestpharma.com/products/nabiHB.html	800-458-4244	HBIG
Novartis Vaccines www.novartisvaccines.com/us/index.shtml	877-683-4732	Fluvirin, Agriflu, Menveo, RabAvert (distributor for Ixiaro)
Pfizer (Wyeth Vaccines) www.pfizerpro.com/	800-438-1985	Prevnar 13
sanofi Pasteur www.vaccineshoppe.com	800-822-2463	Daptacel, Tripedia, Pentacel, ActHIB, Fluzone, Menomune, Menactra, IPOL, Imovax, Decavac, Tenuvac, Adacel, Typhim Vi, YF-Vax
Talecris Biotherapeutics www.talecris.com/talecris-biotherapeutics-us-home.htm	800-520-2807	HBIG, IGIM, RIG, TIG



State of Nevada
 Department of Health and Human Services
 Nevada State Immunization Program
 4150 Technology Way, Suite 210 ♦ Carson City, Nevada 89706
 Phone: (775) 684-5900 Fax: (775) 684-8338

VTckS UPS Pickup Request for Expired/Spoiled Vaccine

Date: _____ PIN: _____ Facility Name: _____
 Address: _____ Contact: _____
 Phone: _____ Fax: _____

INSTRUCTIONS: (Applies to **state supplied vaccines ONLY**.) (**DO NOT** discard or return any vaccine to the Immunization Program or local health districts.) (**DO NOT** contact McKesson directly.)

EXPIRED VACCINES

- 1) Complete this form.
- 2) Fax the completed form to (775) 684-8338 (keep a copy for your records.)
- 3) Securely pack the vaccine to be returned with a copy of this form in any available box.
- 4) Expired/Spoiled vaccines do NOT need to be stored in your refrigerator.

VACCINES INCIDENTS

- 1) Complete a Vaccine Incident Report
 - a) **Call the Immunization Program to report any incident of compromised cold chain within 2 hours of discovery** at (775) 684-5900
- 2) Fax the completed form to (775) 684-8338 (keep a copy for your records.)
- 3) If the manufacturer deems any or all of the vaccines are non-viable, follow instructions in the Expired Vaccines section on the left.

Return Reason Codes:

- | | |
|--|--------------------------------|
| 1. Expired | 6. Vaccine spoiled in transit* |
| 2. Natural Disaster/power outage* | 7. Mechanical Failure* |
| 3. Refrigerator temperature too warm* | 8. Other (explain): _____ |
| 4. Refrigerator temperature too cold* | 9. Recall |
| 5. Failure to store properly upon receipt* | 10. Duplicate request |

***indicates Vaccine Incident Report required**

REQUIRED Vaccine Information (Please print clearly -This form must be legible or it will be returned)

Reason Code	NDC NO	# of Doses	VACCINE	Exp. Date

How many boxes for UPS to pick up?