Facility Name:	VFC PIN:
Effective Date:	Annual Review Date:
Reviewed By:	

VACCINE STORAGE AND HANDLING PLAN

This document is a vaccine storage and handling plan to safeguard vaccine supplies and respond to improper vaccine storage and handling events.

ROUTINE VACCINE STORAGE AND HANDLING GUIDELINES

1. STORAGE REQUIREMENTS

A. Maintain proper temperatures in the refrigerator, 36.0° through 46.0°F or 2.0° through 8.0°C.

B. Store all varicella-containing vaccine (Varivax, Zoster, ProQuad) at -58.0° through +5.0°F or -50.0° through -15.0°C.

☐ Proper temperatures for refrigerator(s) and freezer(s) are posted on unit(s).

C. Store MMR vaccine in the freezer. Storing MMR vaccine in the freezer with MMRV may help prevent inadvertent storage of MMRV in the refrigerator and may prevent MMR vaccine loss in the event of a temperature excursion. Diluent should NOT be stored in the freezer.

D. A digital data logger should be placed in both the refrigerator and freezer unit. The temperature monitoring device should be certified calibrated with a certificate of traceability and calibration that comes from an ILAC/MRA accredited laboratory or that complies with ISO 17025 specifications.

☐ Digital data logger is in place in each unit (both refrigerator and freezer).

E. A back-up digital data logger with a certificate of traceability and calibration from an ILAC/MRA accredited laboratory or that complies with ISO 17025 specifications is readily available to use if the primary temperature monitoring device breaks.

F. To help stabilize temperatures in the storage units place plastic containers of water in the refrigerator and cold packs in the freezer.

☐ Bulk water/cold packs are present in the unit.

G. Store vaccine on refrigerator shelves in manufacturer packaging in open containers and away from walls and the back of the unit to allow proper air circulation around the vaccine.

☐ Vaccine is stored in center of unit in manufacturer packaging in open containers to allow for air circulation.

H. Vaccine should never be stored in the door of the refrigerator, vegetable containers/bins (crisper) or on the bottom of the refrigerator.

☐ Vaccine is not stored in the door of the unit, crisper, or in the bottom of the unit.

2. EQUIPMENT / SAFEGUARDS

A. Vaccines should be stored in a purpose-built, pharmaceutical/medical grade or household-grade stand-alone or combination unit with enough room to store the largest inventory a provider might have at the busiest point in the year without crowding. These units may vary in size from a compact, under-the-counter style to a large, stand-alone, pharmaceutical grade storage unit.

B. Dorm-style refrigerator/freezers with a cooling plate and an internal door to a freezer compartment are not allowed for the storage of vaccines.

C. If using a combination household refrigerator/freezer unit, only use the refrigerator compartment for storing refrigerated vaccines. A separate standalone freezer is used to store frozen vaccines.

D. Post warning signs on the storage unit and/or on the plug to prevent inadvertent unplugging of the unit.

☐ Warning signs (e.g., Do Not Unplug) are posted on vaccine storage units and on the outlet.

E. Label fuses and circuit breakers to clearly identify power source to the vaccine storage unit.

☐ Fuses and circuit breakers that support vaccine storage units are clearly marked.

F. Do not plug unit into ground fault interrupter (GFI) outlets. When the GFI is tripped the circuit is broken, causing electricity failure to the unit. Do not use an extension cord or power strip to plug in the storage unit.

☐ The vaccine storage unit is not plugged into a GFI outlet, extension cord or power strip.

G. Ensure doors are shut tightly.

☐ Doors close appropriately and are free from defect.

3. TEMPERATURE MONITORING

A. A digital data logger is in place in each unit (both refrigerator and freezer). See 1. D.
   ☐ Digital data logger is in place in each unit (both refrigerator and freezer).

B. A back-up digital data logger is readily available to use if the primary temperature monitoring device breaks. See 1. E.

C. The designated person checks and records min/max refrigerator and freezer temperatures at the start of each work day and records the time and name/initials associated with each temperature reading.

D. The designated person checks and records refrigerator and freezer temperatures twice daily (at the beginning and end of each work day) and records the time and name/initials associated with each temperature reading.

E. Storage temperatures should be recorded on a temperature log and maintained for at least 3 years. This is useful to identify the duration of temperature variations. If a digital data logger has the capability to annotate an electronic temperature check with the time and initials of the person checking the temperature, then it is not necessary to manually log the temperature checks at each temperature check.
   ☐ Refrigerator and freezer min/max temperatures are checked and recorded on a temperature log at the start of each work day along with staff initials and time of reading.
   ☐ Refrigerator and freezer temperatures are checked and recorded on a temperature log twice daily along with staff initials and time of readings. Storage temperature logs are maintained for at least 3 years for each unit either in electronic or paper format (see 3. E. description for electronic storage criteria).

F. If a temperature outside of the recommended range is found, immediate action should be taken to correct the problem as outlined in the standard operating procedures for improper vaccine storage and handling section. Actions taken should be documented on the Vaccine Storage Troubleshooting Record.
   ☐ Clinic staff is trained to take immediate action if temperatures are out of range.

G. The backup person should review the temperature log at least weekly to ensure proper temperature recording and take action if out of range temperatures are found on the logs during review. Digital data logger data should be downloaded, reviewed and printed every 2 weeks.
   ☐ The designated backup person reviews temperature logs at least weekly.

H. Consideration should be given to how power failures or out of range temperature will be identified during non-business hours.

4. VACCINE ORDERING

Health care providers participating in the VFC Program are responsible for ordering and maintaining adequate vaccine inventory for eligible patients to prevent missed opportunities. The Iowa Department of Public Health, Vaccine for Children Program requires VFC providers to place vaccine orders using the Immunization Registry Information System (IRIS). IRIS contains vaccine order functionality which includes recommended order quantities based on ordering patterns and doses administered data. When placing vaccine orders, review recommended order quantities for each vaccine and total amount of vaccine needed including combination and single antigen products.

☐ Review current inventory/expiration dates and consider seasonal events or specialty clinics.
☐ Clinic staff is aware of Economic Order Quantity.
☐ Clinic staff is trained regarding vaccine ordering.
☐ Do not over-order or stockpile vaccine.
☐ Maintain adequate inventory of VFC and private vaccine (if applicable) to eliminate occurrences of borrowing between VFC and private inventories.

5. RECEIVING VACCINE

Develop and post a protocol for accepting vaccine deliveries that indicates who in the practice may accept vaccine shipments to ensure vaccines are stored appropriately and **IMMEDIATELY** after arrival. Train staff how to compare the vaccine received with the vaccine invoice.

Cold and heat indicators should be reviewed immediately to ensure vaccine was maintained at the appropriate temperatures during shipping. Alert the Vaccines for Children (VFC) Program at 1-800-831-6293 if the vaccine is not in proper condition, the number of doses is different than what is on the invoice, or if the lot number is recorded incorrectly on the invoice.

- ☐ Protocol is posted for all staff regarding vaccine deliveries and whom to contact regarding vaccine shipments.
- ☐ Clinic staff ensure vaccine shipments are stored properly immediately upon arrival.
- ☐ Clinic staff is trained how to compare vaccine received to the vaccine invoice and will alert the VFC Program if vaccine doses do not match the invoice or if they are not in proper condition upon arrival.
- ☐ Maintain vaccine packing slips for both VFC and private vaccine inventory for a minimum of three years.

6. VACCINE MANAGEMENT/STOCK ROTATION

Check and rotate your stock monthly or when new vaccine inventory arrives. Ensure vaccine with the most current expiration dates are used first and are in front of vaccines with longer expiration dates.

- ☐ Conduct count of vaccine inventory at least monthly.
- ☐ Rotate vaccine stock regularly; move earliest expiration dates to the front.
- ☐ Check vaccine expiration dates at least monthly.
- ☐ Clinic staff is able to distinguish VFC vaccine from private vaccine.
- ☐ Report VFC vaccine that will not be used and will expire within 2-3 months to the Iowa VFC Program at 1-800-831-6293.

7. STAFFING/TRAINING

Post the Vaccine Storage and Handling Plan on or near the vaccine storage units and ensure all staff are trained regarding the plan. Review current guidelines for handling of individual vaccines that may include special instructions (e.g., protect from light, shelf life after reconstitution). Understand package inserts for new vaccines before using. Additional references include the Centers for Disease Control and Prevention (CDC)'s "You Call the Shots, Vaccine Storage and Handling" available at http://www.cdc.gov/vaccines/ed/youcalltheshots.html

- ☐ Vaccine Storage and Handling plan is posted on or near storage unit.
- ☐ All staff is trained on the plan and training is documented (minimum of annually).
- ☐ Staff is trained on guidelines for handling individual vaccines with special instructions.
- ☐ Staff who administers vaccine have read and understand package inserts prior to administering vaccine.
- ☐ Staff has access to manufacturer's package inserts for each vaccine on hand and the CDC Epidemiology and Prevention of Vaccine Preventable Diseases (Pink book).

8. DESIGNATED PERSON(S)

Designate a primary and a backup person to:

- ☐ Monitor the operation of the vaccine storage units and systems.
- ☐ Set up and maintain a monitoring/notification system during times of inclement weather or other conditions that would create an interruption of power.
- ☐ Ensure the appropriate handling of the vaccine during a disaster or power outage.
- ☐ Ensure access to the building where vaccines are stored 24 hours per day.

Primary Person:	Phone:
Secondary Person:	Phone:
Additional Staff:	Phone:

9. BACK-UP SUPPLIES/FACILITY

It is important to have a back-up plan to appropriately store vaccine. Make formal arrangements (memorandum of understanding) with a backup facility to maintain vaccine if your vaccine storage equipment malfunctions or there is a power outage. Train a designated person and backup person at the facility to accept your vaccine if it must be moved. Before moving your vaccine, call the location to ensure their facility is available to store the vaccine (e.g., not damaged due to storms). If the back-up facility is not available contact the other facilities on your backup facility list.

BACK-UP FACILITIES CONTACT INFORMATION

Name of Facility	Primary/Back-up Contact	Contact Phone Number Work/Home/Cell

EMERGENCY CONTACT LIST

List of emergency phone numbers, companies, and points of contact:

☐ Electric Power Company:
☐ Temperature Alarm Monitoring Company:
☐ Refrigerator Repair Company:
☐ Transportation to Back-up Storage:
☐ Emergency Generator Repair Company:
☐ National Weather Service:

FACILITY FLOOR PLAN

Entering vaccine spaces: Describe, when necessary, how to enter the building and vaccine storage spaces in an emergency if closed or after hours. Include a simple floor diagram (does not need to be a blue print) and the locations of:

☐ Storage units:
☐ Doors:
☐ Flash lights:
☐ Spare batteries:
☐ Light switches:
☐ Keys:
☐ Locks:
☐ Alarms:
☐ Circuit breakers:
☐ Packing materials:

EMERGENCY VACCINE RETRIEVAL AND STORAGE GUIDELINES

1. RESPONSE TO IMPROPER VACCINE STORAGE AND HANDLING

ASSESS THE SITUATION

a. Determine the cause of improper vaccine temperatures (e.g., mechanical failure, power outage, natural disaster, human error).
b. Store the vaccines at appropriate temperatures. Determine if vaccine should be moved and move if appropriate.
c. Record the current temperature of the refrigerator/freezer.
d. Mark the vaccine "Do Not Use" so the potentially compromised vaccines can be easily identified and not used until viability of vaccine is determined.
e. Collect essential data on the Emergency Vaccine Response Worksheet.
f. Call the Iowa Immunization Program (1-800-831-6293).
g. Call all manufacturers of affected vaccine(s).

2. PACK VACCINE

a. Open refrigerated units only when absolutely necessary and only after you have made all preparations for packing and moving the vaccine to alternative storage site.
b. Use hard sided coolers with at least 2 inch walls, or portable refrigeration units, to transport vaccine supply.
c. Pack the refrigerated vaccines first with an adequate supply of cold packs (add packing material so cold packs are not in direct contact with the vaccine). For transport of refrigerated vaccines ice packs should be conditioned by placing them at room temperature for at least 1 hour prior to packing or by running under cold water until freely movable within the packaging.
d. The manufacturer of varicella-containing vaccines, Merck, recommends the vaccines (Varivax, Zoster, ProQuad) **NOT** be transported on dry ice. Use of dry ice may subject the vaccines to temperatures colder than -58.0° F (-50.0° C). Several companies make portable freezer units. **NOTE:** In the event the vaccine must be moved due to emergency situations and a portable freezer unit is not available, Varicella-containing vaccine should be moved in a separate cooler from the refrigerator vaccines. The cooler containing varicella vaccines should be packed with as many ice packs as possible and place a data logger in the cooler. The time and temperature must be monitored and recorded until vaccine is stored under proper conditions in an approved storage unit. Once the vaccine has been stored appropriately the Iowa Immunization Program and the manufacturer must be contacted prior to using the vaccine.
e. Include a data logger with a certificate of calibration with the vaccine in each cooler to monitor the vaccine temperature during transport. It is recommended a digital data logger with a detachable probe in a buffered material be used so temperature readings can be obtained during transport without opening the container.

3. MOVE VACCINE

a. If alternative storage is available within your facility, transfer vaccine to that storage unit. If not, contact your backup facility to notify them of your refrigerator/freezer failure and the need to store vaccine at their location.
b. Prior to transporting vaccine, record the time and the temperature of the refrigerator(s) and freezer(s) units. This will provide data on the maximum temperature and duration of exposure of vaccine to inappropriate temperatures.
c. Conduct an inventory before you transport the vaccine.
d. Transport the vaccine following proper cold chain procedures for storage and handling.
e. Isolate and maintain vaccines at appropriate temperatures and do not administer or discard vaccine until you have contacted the Iowa Immunization Program (1-800-831-6293) for consultation.

4. POST EVENT

Keep exposed vaccine separated from unaffected vaccine and any new vaccine you receive. Maintain vaccines at appropriate temperatures and do not administer or discard any potentially exposed vaccine until you have contacted the Iowa Immunization Program (1-800-831-6293) for consultation.

5. VACCINE WASTAGE

Never assume vaccine is nonviable in the event of a storage problem or handling issue. Contact the Iowa VFC Program immediately (1-800-831-6293) for instructions regarding VFC vaccine. Vaccines determined to be non-viable should be removed from storage units to avoid unintentional use and labeled as "Nonviable Vaccine-Do Not Use". VFC providers using IRIS inventory shall document vaccine loss using appropriate reasons provided in the registry to deduct doses from inventory.

For IRIS non-inventory providers, expired and spoiled vaccine shall be reported on the Nonviable VFC Vaccine Return Form and faxed to the VFC Program at 1-800-831-6292. Expired and wasted vaccines should be returned to McKesson; refer to the VFC Non-viable Vaccine Return Form for instructions.

EMERGENCY VACCINE RESPONSE CONTACT LIST

Post on outside of refrigerator

Vaccine Storage and Handling Staff:

Primary:	Phone:
Secondary:	Phone:
Staff with 24 hour access:	Phone:
Additional Staff:	Phone:

Emergency Contact List:

Backup Storage Facility:	Phone:
Backup Storage Facility:	Phone:
Electric Power Company:	Phone:
Refrigerator Repair Company:	Phone:
Temperature Alarm Monitoring Company:	Phone:
Transportation to Backup Storage:	Phone:
Emergency Generator Repair Company:	Phone:
National Weather Service:	Phone:
Fuel for Generator:	Phone:

Vaccine Storage and Handling Events:

1. Determine the cause of improper vaccine temperatures (e.g., mechanical failure, power outage, natural disaster, human error).
2. Store the vaccines at appropriate temperatures. Determine if vaccine should be moved and move if appropriate.
3. Record the current temperature of the refrigerator/freezer.
4. Mark the vaccine so the potentially compromised vaccines can be easily identified and not used until viability of vaccine is determined.
5. Collect essential data on the Emergency Vaccine Response Worksheet (attach additional copies if necessary).
6. Call the Iowa Immunization Program (1-800-831-6293).
7. Call all manufacturers of affected vaccine(s).

EMERGENCY VACCINE RESPONSE WORKSHEET

Facility Name: _____ VFC PIN: _____

Date of event: _____ Handling Error: _____

Current refrigerator temperature: _____°F/°C Min/Max (Circle) refrigerator temperature reached: _____°F/°C

Current freezer temperature: _____°F/°C Min/Max (Circle) freezer temperature reached: _____°F/°C

Total length of time temperature was outside normal range for refrigerator: _____ or freezer: _____

REFRIGERATOR

Vaccine / Manufacturer	Lot Number	Expiration Date	Number of Doses	Opened Vials	Manufacturer Recommendations

FREEZER

Vaccine / Manufacturer	Lot Number	Expiration Date	Number of Doses	Opened Vials	Manufacturer Recommendations

VACCINE MANUFACTURERS

Vaccine	Manufacturer	Phone
IPV, Daptacel, DT, Td, ActHib, Fluzone, RIG, Imovax, JE-VAX, Menomune, Typhim Vi, YF-VAX, Adacel, Menactra, Pentacel, Decavac, PPD, Quadracel	Sanofi Pasteur	1-800-822-2463
Recombivax HB, MMR, Varivax, PedvaxHIB, Comvax, Pneumovax, Vaqta, RotaTeq, Gardasil, Zostavax, ProQuad	Merck	1-800-672-6372
Infanrix, Pediarix, Engerix B, Havrix, Twinrix, Boostrix, Fluarix, Kinrix, Rotarix, FluLaval, Cervarix, Hiberix, Menhibrix, Bexsero, Menveo, RabAvert , Shingrix	GlaxoSmithKline	1-888-825-5249
Prevnar, Trumenba	Pfizer	1-800-999-9384
Immune Globulin	Talecris	1-800-520-2807
Nabi HB (Hep B Immune Globulin)	Nabi	1-800-458-4244
Synagis, Flumist	MedImmune	1-877-633-4411
Fluvirin, Agriflu, Flucelvax	Novartis	1-800-244-7668
Vivotif	PaxVax	1-800-533-5899
Afluria	CSL Biotherapies	1-888-435-8633

VACCINE STORAGE AND HANDLING TRAINING LOG

Staff	Name of Training	Training Date