Vaccine Management Plan

For Illinois Vaccines for Children Program Providers

January 2014
| **PRACTICE NAME:** | |
| **PIN (6 DIGITS):** | |
| **DATE REVIEWED/UPDATED:** | (Review/update at least annually or more often as staff changes) |
| **PERSON PREPARING PLAN:** | |
| **SIGNATURE OF PERSON PREPARING PLAN:** | |
| **Print or Type Name** | **Title** |
| **Signature** | |
| **PRIMARY VACCINE COORDINATOR:** | |
| **BACK-UP VACCINE COORDINATOR 1:** | |
| **BACK-UP VACCINE COORDINATOR 2:** | |
| **PERSON(S) WITH 24-HOUR ACCESS TO BUILDING:** | |
| **Name** | **Phone Number** |
| **Name** | **Phone Number** |
| **Name** | **Phone Number** |
| **Name** | **Phone Number** |
1 DESCRIPTION ........................................................................................................................................... 4
2 PRIMARY AND BACK-UP VACCINE COORDINATORS .................................................................................. 4
  2.1 Responsibilities ......................................................................................................................................... 4
  2.2 Annual Training Requirement .................................................................................................................. 5
3 VACCINE UNIT EQUIPMENT AND MAINTENANCE, TEMPERATURE MONITORING AND STORAGE PRACTICES .................................................................................................................... 5
  3.1 Unit Equipment and Maintenance .............................................................................................................. 5
  3.2 Vaccine Storage Unit Temperature Monitoring ........................................................................................ 7
  3.3 Vaccine Storage Practices ........................................................................................................................ 9
Vaccine Refrigerator Setup .................................................................................................................................. 11
Vaccine Freezer Setup ....................................................................................................................................... 12
4 VACCINE STORAGE AND EMERGENCY RESPONSE PLAN .............................................................................. 12
  4.1 Short-Term Power Outage ........................................................................................................................ 13
  4.2 Long Term Power Outage .......................................................................................................................... 13
  4.3 Vaccine Retrieval and Transfers ............................................................................................................... 13
5 VACCINE ORDERING, ACCOUNTABILITY, INVENTORY, RECEIVING, AND BORROWING ...................... 14
  5.1 Vaccine Ordering, Accountability and Inventory ........................................................................................ 14
  5.2 Vaccine Receiving ........................................................................................................................................ 14
  5.3 VFC Vaccine Borrowing Report ............................................................................................................... 15
6 VACCINE WASTAGE/EXPIRED AND VACCINE TRANSFER PROCEDURES .................................................... 16
  6.1 Vaccine Wastage/Expired Procedures ....................................................................................................... 16
  6.2 Vaccine Transfers ......................................................................................................................................... 16
VACCINE STORAGE AND EMERGENCY RESPONSE PLANS ............................................................................ 17
VFC TRAINING LOG ........................................................................................................................................... 18
VFC EQUIPMENT ROUTINE MAINTENANCE LOG .......................................................................................... 19
VFC RESOURCES ............................................................................................................................................. 20
1 DESCRIPTION

This Vaccine Management Plan template is provided as a guideline for the protection and maintenance of the office’s vaccine supply. The responsibilities listed in this plan are those of the primary and back-up vaccine coordinators.

Office staff who handle or administer vaccines should be familiar with the Vaccine Management Plan, which includes the Vaccine Storage and Emergency Response Plan, and ensuring vaccines are maintained within the required temperature range.

A copy of the Vaccine Storage and Emergency Response Plan must be posted on all refrigerators/freezers used to store vaccines.

The Vaccine Management Plan should be reviewed and updated annually or more often as staff changes.

2 PRIMARY AND BACK-UP VACCINE COORDINATORS

2.1 Responsibilities

Each practice should designate one staff member to be the primary vaccine coordinator and at least one staff member as the back-up vaccine coordinator. These individuals should have 24-hour access to the building where the refrigerator/freezer is located. Responsibilities of the vaccine coordinator include, but not limited to the following:

- Ordering vaccines.
- Overseeing proper receipt and storage of vaccine shipments.
- Monitoring the refrigerator and freezer temperatures twice daily (at the beginning of the day and at the close of business) to maintain the required temperature (refrigerator – between 35°F and 46°F (2°C – 8°C) and freezer between -58°F and +5°F (-50°C and -15°C); adjusting the temperature of the storage unit as necessary to maintain the required temperature; and recording the temperatures on the temperature log (templates available at http://www.idph.state.il.us/about/immunizationvfc.htm), and storing the temperature log sheets for at least three years. Temperatures should be documented in I-CARE on a weekly basis.
- Implementing standard procedures in the event of storage temperatures violations.
- Maintaining storage and handling equipment, including adjusting the temperature of a vaccine storage unit and records.
- Rotating vaccine stock so vaccines closer to their expiration date are used first.
- Monitoring expiration dates, on a regular basis, on vaccines and ensuring expired vaccine(s) is/are not administered to patients. If vaccines are within 90 days of expiration and will not be used, transfer the vaccines to another VFC provider who may be able to use the vaccines. Refer to the Vaccine Transfer Approval Request Form available at http://www.idph.state.il.us/about/immunizationvfc.htm. It is the vaccine coordinator’s responsibility to find another VFC provider willing to accept the vaccine.
- Train staff responsible for administering vaccines on proper storage and handling protocols.
- Ensure new employees receive annual training and understand necessary requirements for documenting, administering, and managing vaccines for optimal effectiveness. Documentation of training must be retained. Documentation may be a certificate of completion or a log sheet with the staff member’s name and date of training.
- VFC coordinators, backup coordinators, and other staff member who will have responsibility for VFC vaccines should complete the Centers for Disease Control and Prevention (CDC) “You Call The Shots – Module 10 – Storage and Handling” online course available at http://www2a.cdc.gov/nip/isd/ycts/mod1/courses/sh/ce.asp to ensure each has received individual training on VFC storage practices.
• Place “DO NOT UNPLUG” stickers next to wall outlets providing power to the refrigerator and freezer and the circuit breakers. For circuit breakers, the number of the circuit that is active for the unit(s) needs to be marked on the posted sticker.

• Instruct maintenance and/or cleaning personnel **not** to unplug the refrigerator/freezer or switch the circuit breaker off. If power needs to be shut off, the primary and/or back-up vaccine coordinator needs to be notified so that actions can be taken to safeguard the vaccines inside of the refrigerator and/or freezer.

### 2.2 Annual Training Requirement

Each VFC vaccine coordinator is required to complete and maintain documentation of receiving annual VFC education on vaccine storage and handling. Education is available through VFC compliance site visits, VFC educational visits, regional VFC trainings offered through Illinois Department of Public Health partners (ICAAP or EverThrive) or through CDC online training, “You Call The Shots – Module 10 – Storage and Handling,” available at [http://www2a.cdc.gov/nip/isd/vcts/mod1/courses/sh/ce.asp](http://www2a.cdc.gov/nip/isd/vcts/mod1/courses/sh/ce.asp). Additional online training will be available soon through the Illinois Chapter of American Academy of Pediatrics at [http://illinoisaap.org/](http://illinoisaap.org/). Document all training you have received on the VFC Training Log in the appendix and retain copies of all certificates of completion or certificates of attendance.

### 3 VACCINE UNIT EQUIPMENT AND MAINTENANCE, TEMPERATURE MONITORING AND STORAGE PRACTICES

#### 3.1 Unit Equipment and Maintenance

The office will ensure it has the appropriate equipment to store vaccine and to maintain proper conditions. The following types of storage units are acceptable:

1. Stand-alone refrigerator.
2. Stand-alone freezer.
3. Combination refrigerator/freezer- using only the refrigerator compartment for vaccine storage.
4. Pharmaceutical/medical/laboratory grade refrigerator.
5. Pharmaceutical/medical/laboratory grade freezer.
6. Compact (under counter) refrigerator.
7. Compact (under counter) freezer.

CDC recommends providers store vaccines in separate, stand-alone refrigerators or freezer units. However, if a combination unit is used, it should have separate controls for the refrigerator and freezer sections.

**As of January 1, 2013, the CDC mandated dormitory-style refrigerators are not allowable to store VFC vaccine at any time.** Dormitory-style refrigerators do not maintain proper temperatures and pose a high risk of freezing vaccine. Any VFC vaccines found to be in dormitory-style refrigerators will be wasted and providers will be expected to replace the wasted VFC vaccine with privately purchased vaccine. See the CDC Storage and Handling Toolkit at [http://www.cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf](http://www.cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf) for additional information.

Any refrigerator or freezer unit used for vaccine storage must be able to maintain vaccine storage temperatures year-round, be large enough to hold the year’s largest inventory, be dedicated only to the storage of vaccines, and must have a certified calibrated thermometer inside each compartment used for storing vaccine.

VFC Providers receive vaccine at no cost to them. However, the vaccines they receive are purchased with millions of taxpayer dollars. To reduce waste and spoilage of expensive vaccines, the VFC program has guidelines for vaccine storage units.
## Equipment Size Recommendations

<table>
<thead>
<tr>
<th>Office Size</th>
<th>Required Equipment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very High Volume</td>
<td>Pharmacy-grade or biologic-grade refrigerator-only units and stand-alone freezer units</td>
</tr>
<tr>
<td>10,000 doses/year</td>
<td></td>
</tr>
<tr>
<td>High Volume</td>
<td>Refrigerator-only (16.7 cubic feet minimum) and stand-alone freezer units</td>
</tr>
<tr>
<td>2,000-10,000 doses/year</td>
<td></td>
</tr>
<tr>
<td>Medium Volume</td>
<td>Refrigerator-only (16.7 cubic feet minimum) and stand-alone freezer units</td>
</tr>
<tr>
<td>500-2,000 doses/year</td>
<td>OR</td>
</tr>
<tr>
<td>Low Volume</td>
<td>Pharmacy-grade or biologic-grade under the counter units</td>
</tr>
<tr>
<td>Less than 500 doses/year</td>
<td></td>
</tr>
</tbody>
</table>

Refrigerator temperatures must be between 35 to 46 F (2 to 8 C). Ideally, the temperatures should be maintained around 40 F (5 C). Freezer temperatures must be less than 5 F (-15 C).

The unit must be placed in a well-ventilated room with sufficient space (at least 4 inches) around the sides and top for air circulation. Ensure the refrigerator/freezer is plugged into an outlet in a protected area where it cannot be accidentally disconnected.

- The use of a “safety-lock plug” or an outlet cover is strongly recommended to reduce the chance of the unit becoming inadvertently unplugged.
- Label the refrigerator, electrical outlets, and circuit breakers on the power circuit with information that clearly identifies the perishable nature of vaccines and the immediate steps to be taken in case there is an interruption of power.
- Place “DO NOT UNPLUG” signs by the electrical outlet for the refrigerator and freezer, and circuit breaker panel to ensure that the power is not turned off.
- Instruct maintenance and/or cleaning personnel not to unplug the refrigerator and freezer or switch off the circuit breaker.
- If the power needs to be shut off for any reason, the primary and/or back-up vaccine coordinator needs to be contacted immediately to ensure the vaccine inside of the refrigerator and/or freezer can be safeguarded.

Regular maintenance is recommended to ensure proper operation, to maintain required temperatures, and to extend the useful life of the appliance. Maintenance of the refrigeration unit and freezer include:

- Cleaning the unit once a month to discourage bacterial and fungal growth.
- Periodically vacuuming the dust from the exterior coils.
- Periodically checking to make sure the seals are intact.
- Checking the inside walls of the freezer compartment weekly for accumulation of frost – defrost if necessary.
- Keeping a logbook (see appendix) to indicate the date(s) of routine maintenance tasks, date(s) of any repairs or servicing, and the name of the person and/or company performing each of these tasks.

It is normal for ice and frost to accumulate inside the freezer and even in refrigerator compartment depending on the type of storage unit. A thin layer of frost does not affect the cooling performance, but a thick layer will affect the unit’s ability to maintain temperature efficiently and will eventually cause unit failure. If defrosting is necessary every month or more frequently, check the seals on the doors or call a technician for necessary maintenance. The following is a suggested procedure for defrosting a manual defrost unit:

1. Check the inside walls of the freezer weekly
   a. When frost has accumulated to a thickness of approximately one cm, the unit requires defrosting.
   b. The more the unit is opened and closed, the quicker frost will build.
   c. Follow the manufacturer’s specific recommendations for defrosting a freezer.
2. Remove all vaccine (from both compartments if using a combination refrigerator/freezer).
3. Place all vaccine in an alternate storage unit(s) that will maintain correct temperatures.
4. Turn off the power to the unit you are defrosting and unplug the unit.
5. Remove all frozen packs (keep frozen if possible).
6. Keep the freezer door open to allow the frost to melt.
7. Remove loose ice by hand to speed the process, but do not use sharp tools.
8. Defrosting time can be reduced by placing a container of warm water (not boiling hot) inside the compartment.
9. Once the frost is melted completely, clean the freezer compartment thoroughly and wipe dry.
10. Clean refrigerator compartment as well.
11. Connect the power, ensure that the thermostat is turned on and set correctly.
12. Wait for temperature to stabilize at the proper range before returning vaccine to defrosted unit. This may take hours or a day depending on the unit, so monitor with a calibrated temperature monitoring device.
13. Monitor and record the temperature frequently (every hour for several hours).
14. Re-stock the unit with vaccine once the temperature is stabilized.
15. Continue to monitor the temperature after the vaccine is returned to the unit.

For more information on vaccine storage and handling, please refer to the CDC Vaccine Storage and Handling Toolkit at http://www.cdc.gov/vaccines/recs/storage/toolkit/.

3.2 Vaccine Storage Unit Temperature Monitoring

The recommended method to ensure a refrigerator or freezer is maintaining the proper temperature for vaccine storage is to check and to record the temperature at least twice a day each workday, with no fewer than three times a week. The office must adhere to the following guidance:

- Each refrigerator and freezer must have a calibrated working thermometer certified in accordance with the National Institute of Standards and Technology (NIST) or a laboratory recognized by NIST, placed in a central area inside each compartment used for storing vaccine.
- CDC recommends providers also have a certified calibrated back-up thermometer in place.
- Calibration testing of thermometers must be performed at least every two years from the last calibration testing date (date certificate issued).

Providers should have a thermometer in each unit, with a back-up thermometer available. CDC recommends use of a digital data logger thermometer with a detachable probe in a buffered material (e.g., glycol) with continuous monitoring capabilities. The temperature should be easily readable from the outside of the unit. Additional recommended features include:

- Alarm for out-of-range temperatures
- Current, minimum and maximum temperatures
- Reset button
- Low battery indicator
- Accuracy of +/- 1 F (0.5 C)
- Memory stores at least 4,000 readings; device will not write over old data and stops recording when memory is full
- User programmable logging interval (or reading rate)

Providers are responsible for maintaining current Certificates of Traceability and Calibration Testing¹. Calibration testing of all thermometers must be performed at least every two years from the last calibration testing date (date certificate issued). Provider must keep the certificate of calibration for each thermometer and back-up thermometer.

As of April 2013, CDC will allow calibration testing and traceability to be performed by a laboratory accredited by an ILAC MRA signatory body OR as an alternative by a laboratory or manufacturer that provides documentation that demonstrates that calibration testing performed meets ISO/IEC 17025 international standards for calibration testing and traceability. Between the two options, CDC recommends that testing be performed by ILAC accredited laboratories. An ILAC MRA accredited laboratory is the easiest way to identify that the instrument has been tested correctly according to international standards.

¹ Certificate of Traceability and Calibration Testing (also known as Report of Calibration) is a certificate that informs the user of a thermometer’s level of accuracy compared to a recognized standard based on testing by the National Institute of Standards and Technology (NIST).
Calibration testing performed by an ILAC accredited laboratory

- ILAC accredited laboratories are (logos are shown below):
  - The American Association for Laboratory Accreditation (A2LA).
  - Laboratory Accreditation Bureau (L-A-B).
  - ANSI-ASQ National Accreditation Board (AClass).
  - International Accreditation Service (IAS).
  - Perry Johnson Laboratory Accreditation, Inc. (PJLA).
  - National Voluntary Laboratory Accreditation Program (NVLAP).

ILAC/MRA Signatory body accredited Laboratory

The following Table lists the accredited laboratories:

<table>
<thead>
<tr>
<th>A2LA</th>
<th>L-A-B</th>
<th>ACLASS</th>
<th>IAS</th>
<th>PJLA</th>
<th>NVLAP</th>
</tr>
</thead>
</table>

- The certificate of calibration must have these items:
  - Name of device (optional)
  - Model number
  - Serial number
  - Date of calibration (report or issue date)
  - Measurement results indicate unit passed test and the documented uncertainty is within suitable limits (recommended uncertainty = +/- 1F or 0.5 C)

Calibration testing not performed by an accredited laboratory:

- These manufacturers or laboratories must provide a Certificate of Traceability or Report of Calibration Test that must include the following elements:
  - Name of device (optional)
  - Model number
  - Serial number
  - Date of calibration (report or issue date)
  - Measurement results indicate unit passed test and the documented uncertainty is within suitable limits (recommended uncertainty = +/- 1F or 0.5 C)
  - Measurement results for the device
  - Statement that calibration testing conforms to ISO 17025

Record the date(s) the certified thermometers were last calibrated and/or purchased. Add additional units as necessary to represent all vaccine storage units. Record and update thermometer and appliance information in I-CARE.

<table>
<thead>
<tr>
<th>Unit</th>
<th>Location of Unit</th>
<th>Date of Calibration</th>
<th>Calibration Due Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Refrigerator #1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Refrigerator #2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Refrigerator #3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Refrigerator #4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Freezer #1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Freezer #2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Freezer #3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Freezer #4</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
To ensure that vaccines are kept at the correct temperatures, vaccines must be stored at a stable cold temperature in the event of a power outage, or if the door is opened frequently. Store large water bottles or jugs against the inside walls and door of the refrigerator. This helps maintain a stable cold temperature in the event of a power outage, or if the door is opened frequently. Never store food, beverages or specimens in the same units as vaccines. This interferes with proper temperature control and may contaminate vaccines. Frequently opening the refrigerator/freezer door can lead to temperature variations, which could affect vaccine efficacy.

Store vaccines that require refrigeration in the middle of the refrigerator compartment away from the coils, walls, floor, and cold air vent. Do not store them in the doors, air-tight containers, or in the vegetable bins. Offices may want to consider removing vegetable bins so staff does not place vaccines inside them.

Keep vaccines in their original packaging with the lids in place until ready for administration and stacked in rows with vaccine of the same type.

Bins, baskets, or some other type of uncovered containers with slotted sides or openings can be used to store the vaccines. There should be space between the vaccine stacks or containers to allow for air circulation around the vaccines. These measures will help to avoid confusion between vaccines, provide for air circulation around and through vaccine stacks for even cooling, and protect vaccines from unnecessary light exposure. Do not overstock the unit because this will impede cold air circulation and can result in temperature fluctuations that may expose the vaccines to inappropriate temperatures.

Store diluents as directed in manufacturer's product information.

Store refrigerated diluents with corresponding vaccine (these diluents may contain vaccine antigen).

Store vaccines that require freezer storage in the middle of the freezer compartment, away from the walls, coils, and peripheral areas.

Develop and maintain complete, accurate and separate records for both VFC and private purchased vaccines. Label “VFC” vaccines and keep separate from the private vaccine supply.

Rotate vaccine stock and diluents on a regular basis by placing vaccines with shorter expiration dates in front of those with longer expiration dates; check expiration dates of the vaccines weekly for short-dated vaccines and diluents.

3.3 Vaccine Storage Practices

To ensure that vaccines are kept at the correct temperatures, refer to the practices listed below and the diagrams:

- Store extra ice packs and/or gel packs along the walls, back, and door of the freezer compartment. This helps keeps a steady temperature during the automatic defrosting cycles and provides additional reserves of cold in the event of a power failure.
- Store large water bottles or jugs against the inside walls and door of the refrigerator. This helps maintain a stable cold temperature in the event of a power outage, or if the door is opened frequently.
- Never store food, beverages or specimens in the same units as vaccines. This interferes with proper temperature control and may contaminate vaccines. Frequently opening the refrigerator/freezer door can lead to temperature variations, which could affect vaccine efficacy.
- Store vaccines that require refrigeration in the middle of the refrigerator compartment away from the coils, walls, floor, and cold air vent. Do not store them in the doors, air-tight containers, or in the vegetable bins. Offices may want to consider removing vegetable bins so staff does not place vaccines inside them.
- Keep vaccines in their original packaging with the lids in place until ready for administration and stacked in rows with vaccine of the same type.
- Bins, baskets, or some other type of uncovered containers with slotted sides or openings can be used to store the vaccines. There should be space between the vaccine stacks or containers to allow for air circulation around the vaccines. These measures will help to avoid confusion between vaccines, provide for air circulation around and through vaccine stacks for even cooling, and protect vaccines from unnecessary light exposure. Do not overstock the unit because this will impede cold air circulation and can result in temperature fluctuations that may expose the vaccines to inappropriate temperatures.
- Store diluents as directed in manufacturer's product information.
- Store refrigerated diluents with corresponding vaccine (these diluents may contain vaccine antigen).
- Store vaccines that require freezer storage in the middle of the freezer compartment, away from the walls, coils, and peripheral areas.
- Develop and maintain complete, accurate and separate records for both VFC and private purchased vaccines. Label “VFC” vaccines and keep separate from the private vaccine supply.
- Rotate vaccine stock and diluents on a regular basis by placing vaccines with shorter expiration dates in front of those with longer expiration dates; check expiration dates of the vaccines weekly for short-dated vaccines and diluents.

Revised 03/14/2014
• Keep vaccines organized. Place opened vials of vaccine in a tray, so that they are readily identifiable. Indicate on the label of each multi-dose vial the date and time it was reconstituted or first opened. Refer to the package insert for expiration date. **Multi-dose vials do not have to be discarded 30 days after opening.**

• Open only one vial, or box, of a particular vaccine at a time to control vaccine usage and allow easier inventory control.

• Store vaccine products that have similar packaging in different locations to avoid confusion and medication errors.

• Post a sign on the refrigerator door showing which vaccines should be stored in the refrigerator and which should be stored in the freezer.
Vaccine Refrigerator Setup

- Always keep vaccine in its original box. Do not open the box until you are ready to use the vaccine.
- Place vaccine boxes in breathable plastic mesh baskets or directly on shelves. Label baskets or shelves by type of vaccine.
- Group vaccines by pediatric, adolescent, and adult types.
- Separate VFC vaccine from privately purchased vaccine and label them clearly.
- Keep baskets 2-3 inches from walls and other baskets.
- Store only vaccine and other medication in vaccine storage units.
- Keep vaccines with shorter expiration dates to front of shelf.
- Keep temperatures between 35°F to 46°F.
- If you have vaccine that will expire in 3 months or less that you will not be able to use, notify the VFC Program.
- No vaccine in drawers or on floor of refrigerator.
- No vaccine in doors.
- No vaccine in solid plastic trays or containers.
- No food in refrigerator.
Vaccine Freeze Setup

4 VACCINE STORAGE AND EMERGENCY RESPONSE PLAN

Refer to the Vaccine Incident Form anytime vaccines are stored outside of the recommended temperature range, such as a result of a power failure, the refrigerator door being left open, temperature was too cold or too warm, refrigerator plug was pulled, or any other situation which would cause improper storage conditions. Immediate action is required when a refrigerator or freezer is not storing vaccines at the appropriate temperature.

The Vaccine Incident Form is available at http://www.idph.state.il.us/about/immunizationvfc.htm. A copy of the Vaccine Incident Form should be posted on all refrigerators/freezers used to store vaccines.
4.1 Short-Term Power Outage

Most refrigerated vaccines are relatively stable at room temperature for limited periods of time. The vaccines of most concern are measles, mumps, and rubella (MMR) and varicella (Varivax), which are sensitive to elevated temperatures. MMR may retain potency at room temperature, depending on the duration of exposure.

- If you are certain the power has or will only be off for a few minutes, tape the freezer door and refrigerator doors shut so no one inadvertently opens the doors and allows cold air to escape. It also helps seal the door in the event the door seal is worn. Record the time.
- When the power is restored, record the time, length of time the power has been off and the maximum temperature inside of the refrigerator and freezer. This will provide data on the maximum temperature and maximum duration of exposure to elevated temperatures. If temperatures are outside of the recommended range, follow the instructions on the Vaccine Incident Form.
- Follow the steps for vaccine incident procedures, as stated on the Vaccine Incident Form available at [http://www.idph.state.il.us/about/immunizationvfc.htm](http://www.idph.state.il.us/about/immunizationvfc.htm).

4.2 Long-Term Power Outage

Situations can arise at inopportune times when power cannot be restored immediately; planning ahead is crucial. Staff must take the following steps:

- Identify a local provider (hospital, medical center, etc.) that has back-up generator abilities that could be used as an alternate vaccine storage location and is willing to take responsibility for your vaccine.
- Before transporting the vaccine, record the room temperature and inside temperature of the refrigerator and freezer and call the alternate storage location to ensure they have power or that their generator is working.
- Transfer the vaccine, following proper “cold chain” procedures, to a functioning unit at one of the previously identified alternate storage locations.
- If you are concerned about the exposure or efficacy of any of your vaccine stock, do not administer the vaccine until you have consulted with the vaccine manufacturer’s quality control office.
- Follow the steps on the Vaccine Incident Form available at [http://www.idph.state.il.us/about/immunizationvfc.htm](http://www.idph.state.il.us/about/immunizationvfc.htm).

4.3 Vaccine Retrieval and Transfers

It is critical to maintain the cold chain when transporting vaccine to and from the alternate vaccine storage facility. To ensure efficacy of biologics, follow the practices listed below:

- **VFC providers must obtain prior approval before transferring any vaccine to another VFC provider. Refer to the Transfer Approval Request at [http://www.idph.state.il.us/about/immunizationvfc.htm](http://www.idph.state.il.us/about/immunizationvfc.htm).**
- Utilize appropriate packing materials to safely transport or temporarily store vaccine.
- Prioritize vaccine packing list, identifying which vaccines to pack first. Pack and transport all vaccine or, if that is not possible, determine the types and amounts to save (e.g., save only the most expensive vaccines to minimize dollar loss or save some portion of all vaccines to ensure a short-term, complete supply for resuming the vaccination schedule). Give the first priority to those vaccines which would be the most expensive to replace.
- Utilize appropriate coolants to ensure biologics are kept at the correct temperature during transport. If vaccines are to be moved, ensure they are packed in an insulated container with cold packs, freezer packs, or dry ice, as appropriate.
- Do not allow vaccines normally kept at refrigerated temperatures to come into direct contact with cold packs straight from the freezer.
- Keep a thermometer in the transport container and note the temperature when you place the vaccine in the alternate storage facility and the time. This will alert staff how long the vaccine was at less than ideal temperature.
- Continue to record the temperature of the vaccine at the alternate storage facility twice a day to assure viability of vaccine.
• The vaccine manufacturer does not recommend transporting varicella-containing vaccines (MMRV, VARIVAX). Providers must receive pre-approval before transporting varicella-containing vaccines. Refer to the transportation guidelines in the Vaccine Transfer Approval Request Form available at [http://www.idph.state.il.us/about/immunizationvfc.htm](http://www.idph.state.il.us/about/immunizationvfc.htm). If these vaccines must be transported, CDC recommends the following transportation guidelines:
  ➢ Transport only in a portable freezer unit that maintains the temperature between -58°F and +5°F (-50°C and -15°C).
  ➢ Use of dry ice is not recommended, even for temporary storage or emergency transport. Dry ice may subject varicella-containing vaccines to temperatures colder than -58°F (-50°C).
  ➢ All requests for varicella transfer will be reviewed on a case-by-case basis to ensure transportation guidelines are followed.

5 VACCINE ORDERING, ACCOUNTABILITY, INVENTORY, RECEIVING, AND BORROWING

5.1 Vaccine Ordering, Accountability and Inventory

• Providers should order vaccine in accordance with actual vaccine need; avoid stockpiling or build-up of more than a three-month supply.
• Providers should maintain enough vaccine inventory to last five weeks, but no more than three months.
• Orders take 1 ½ to three weeks from submission of order to vaccine delivery.
• All vaccine orders are submitted through I-CARE. As of June 1, 2013, faxed or e-mailed orders are no longer accepted.
• Providers must enter the following information to submit an order in I-CARE:
  ➢ Vaccine accountability
  ➢ Temperature logs with temperatures
  ➢ Delivery hours, with at least office hours three days a week
• In 2014, all Illinois VFC providers must provide patient-level data on the administration of VFC vaccines, also referred to as Phase 2 of I-CARE VFC use. This patient-level data can either be manually entered directly into I-CARE or can be electronically transmitted to I-CARE from the provider’s electronic medical record (EMR) system via HL7 messaging. Illinois has established a schedule to transition providers to Phase 2. Providers will be notified when they need to begin to transition and will have 30 days to come into compliance. **VFC providers must be at Phase 2 (patient-level data in I-CARE) no later than May 31, 2014.** VFC providers not in compliance will not be able to continue participating in the VFC program.
• Additional information on ordering through I-CARE is available in I-CARE under “About I-CARE” then going to “How To.”
• Providers may also use the “Contact Us” button in I-CARE and select “VFC” under the category for additional assistance.
• Providers not currently registered for I-CARE may find additional information at [http://www.idph.state.il.us/health/vaccine/icarefs.html](http://www.idph.state.il.us/health/vaccine/icarefs.html).

5.2 Vaccine Receiving

All staff who accepts vaccine deliveries must be instructed on the importance of maintaining the “cold chain.” Vaccines must be stored properly from the time they are manufactured until the time they are administered. Excess heat or cold will reduce their potency and increase the risk that recipients will not be protected.

When the vaccine is received by front desk personnel, the vaccine coordinator or back-up vaccine coordinator must be notified immediately. The box should be taken to the storage area and unpacked in the following manner:

1. **Open the shipping container immediately upon delivery** and examine the contents for signs of physical damage, and temperatures out of range.
a. Check the color of the temperature indicator (McKesson’s MonitorMark or ColdMark Freeze Indicators) enclosed with the vaccine shipment. Vaccines to be refrigerated should be cold, but not frozen.
b. Check the interval between shipment from the supplier and arrival of the product at the office.
   1. If this period is more than 48 hours, the vaccine could have been exposed to excessive heat or cold that might have affected the integrity of the vaccine.
   2. Mark the vaccine as “DO NOT USE” and place it in a specially marked, segregated tray in the refrigerator or freezer. Do not leave the vaccine out and assume it is not viable. It may still be viable.

2. **WITHIN TWO HOURS OF VACCINE DELIVERY:** If any damage, excessive shipping time, cold chain breach has occurred, provider must IMMEDIATELY call the Department’s Immunization Promotional Center (IPC) at 217-786-7500.
   - If the provider does not call the Department within two hours of the vaccine delivery to report discrepancies and/or cold chain issues, this constitutes provider negligence in accordance with the Vaccine Loss and Replacement Protocol due to handling and storage mishaps by provider staff. Shipments that result in vaccine loss negatively impact the Illinois VFC vaccine budget.
   - **When calling McKesson Specialty about a vaccine delivery:** Expect that McKesson Specialty staff will have provider staff report on temperature indicators. If anything is wrong, (cold chain breach indicated), McKesson Specialty staff will advise provider staff to contact the Illinois VFC program, and the providers will be instructed to put the questionable vaccine supply into refrigerator. A questionnaire will be completed with Illinois VFC program and CDC/manufacturer to determine viability. Provider staff should store the vaccine appropriately maintain the shipment packing list. Ensure that temperature logs are maintained for the vaccine in question. Both CDC and McKesson Specialty WILL ask for this paper work.

3. **With each vaccine delivery, check the actual vaccines received against the shipping invoice to verify all vaccines were received.** Compare the original order against what was received. If there is a discrepancy with the order, contact the Illinois VFC program at 217-786-7500 or dph.vaccines@illinois.gov.

4. Make sure diluents that accompany MMR, MMRV, and varicella match the amount of vaccine received.

5. Place the new vaccines into the refrigerator and/or freezer immediately with the shortest expiration dates in the front of the pack. Separate the VFC vaccines from the private supply by tagging the VFC vaccines and placing them in a separate labeled area of the refrigerator and/or freezer. **Vaccines should be kept in their original packaging with the lids in place until ready for administration and stacked in rows with vaccine of the same type.**
   - Store refrigerated diluents with corresponding vaccine (these diluents may contain vaccine antigen).

5.3 **VFC Vaccine Borrowing Report**

VFC enrolled providers are expected to maintain adequate inventories of vaccine for their privately insured and VFC eligible patients. **VFC vaccine cannot be used as a replacement system for a provider’s privately purchased vaccine inventory.** The provider must ensure their VFC vaccine supply is adequate to meet the needs of the provider’s VFC eligible patients.

**As of January 1, 2014, the VFC program will no longer allow the borrowing of VFC vaccine.** The VFC program cannot support a policy that permits borrowing of VFC vaccine for use in non-eligible children. Private vaccine used on VFC patients cannot be paid back using VFC vaccine. Similarly, VFC vaccine cannot be used in non-eligible children and then paid back with private stock. If VFC vaccine is unavailable, the provider should refer the VFC eligible child to a local health department or FQHC for vaccination or reschedule the child.
VACCINE WASTAGE/EXPIRED AND VACCINE TRANSFER PROCEDURES

6.1 Vaccine Wastage/Expired Procedures

The vaccine loss and replacement policy (available at http://www.idph.state.il.us/about/immunizationvfc.htm) is the policy to follow when incidents occur that results in loss of VFC vaccine. **The Illinois VFC program requires providers to replace vaccine that has been wasted due to negligence or failing to correctly store, handle, or transport vaccine.** The action taken by the Illinois VFC program will depend on the category of the vaccine loss. Refer to the vaccine loss and replacement policy that was signed at enrollment, regarding the categories.

Vaccine that has been deemed wasted or unusable should be immediately removed from the vaccine storage unit and labeled as wasted vaccine. The vaccine must be documented in I-CARE as waste or expired vaccine.

**All returns must be completed within six months after the product expiration or waste date.**

1. Record the vaccine as waste or expired in I-CARE. NOTE: McKesson Specialty no longer requires a minimum of doses to be returned, but does require that doses be submitted within six months after the product expiration date.
2. Indicate the reason why the vaccine was wasted in the area provided.
3. Print the completed **Vaccine Waste Packing List for Excise Tax Credit and Disposal** form.
4. Fax a copy of the **Vaccine Waste Packing List for Excise Tax Credit and Disposal** form to the Illinois VFC Immunization Promotional Center (IPC) at 217-786-7506 or e-mail to DPH.Vaccines@illinois.gov.
5. The Illinois VFC program will arrange to have McKesson Specialty MAIL a return label to be to you, so that your office can ship the expired/wasted vaccines back to McKesson Specialty in the vaccine shipping box you maintain.

6.2 Vaccine Transfers

**VFC providers are responsible for finding a VFC home for their short-dated vaccines.** It is the provider’s responsibility to find another VFC provider willing to accept the vaccine. No less than 90 days before the expiration date, contact your local health department or other VFC providers in your area to see if they are willing to accept a transfer. Network with area VFC providers neighbors or consult with IPC staff to identify a possible recipient for surplus vaccine. Use the **Vaccine Transfer Approval Request Form** available at http://www.idph.state.il.us/about/immunizationvfc.htm to request pre-approval for a transfer. **Please allow at least two weeks for pre-approval requests for the Illinois VFC program to review.** The requesting facility must ensure vaccines follow the CDC transporting vaccine guidelines, which are defined in the Vaccine Transfer Approval Request Form.
# VACCINE STORAGE AND EMERGENCY RESPONSE PLANS

*Post on outside of each refrigerator and freezer*

<table>
<thead>
<tr>
<th>Practice Name</th>
<th>PIN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of Person Completing Emergency Response Plan</td>
<td></td>
</tr>
<tr>
<td>Signature of Person Completing Emergency Response Plan</td>
<td>Date Emergency Response Plan Reviewed and Updated</td>
</tr>
<tr>
<td>Primary Person Responsible</td>
<td></td>
</tr>
<tr>
<td>Phone Number (Work and Home/Cell Phone)</td>
<td></td>
</tr>
<tr>
<td>Secondary Person Responsible</td>
<td></td>
</tr>
<tr>
<td>Phone Number (Work and Home/Cell Phone)</td>
<td></td>
</tr>
<tr>
<td>Person with 24-hour Access</td>
<td></td>
</tr>
<tr>
<td>Phone Number (Work and Home/Cell Phone)</td>
<td></td>
</tr>
</tbody>
</table>

Ensure primary and secondary contacts are on a notification list for practice-based power outages.

**For a Power Outage:** If you do not have a generator, identify one location with a generator (hospital, 24-hour store, etc.). Before transporting, call back-up location to ensure their generator is working.

#1. Location and Contact Name ____________________________ Phone __________________

#2. Location and Contact Name ____________________________ Phone __________________

Vaccines must be transported in an insulated cooler with a barrier separating the vaccine from the ice/cold packs. Frozen vaccines should only be transported or shipped in an emergency (see VFC Vaccine Transport Guidelines in the Vaccine Transfer Approval Request Form available at [http://www.idph.state.il.us/about/immunizationvfc.htm](http://www.idph.state.il.us/about/immunizationvfc.htm)). Contact the Illinois Department of Public Health’s VFC program prior to transporting or shipping frozen vaccines. If your emergency back-up location is more than 30 minutes away and you have a large quantity of vaccine, consider renting a refrigerated truck to transport vaccine.

Refrigeration Company ________________ Phone ________________

Utility Company ____________________________ Phone ________________

**OTHER RESOURCES:**
Local Health Department ____________________________

Contact Name ____________________________ Phone ________________

Regional Immunization Representative ____________________________ Phone ________________

---

**PREVENT LOSS FROM EXPIRED VACCINES**

Check and rotate your stock to assure shortest dated vaccine is use first.

If temperature excursions are noted, please refer to the Vaccine Incident Form at [http://www.idph.state.il.us/about/immunizationvfc.htm](http://www.idph.state.il.us/about/immunizationvfc.htm).
All VFC vaccine coordinators are required to complete and maintain documentation of receiving annual VFC education on vaccine storage and handling. Education is available through VFC compliance site visits, VFC educational visits, regional VFC trainings offered through Department partners (ICAAP or EverThrive) or through CDC online training, “You Call The Shots – Module 10 – Storage and Handling,” available at http://www2a.cdc.gov/nip/isld/ycts/mod1/courses/sh/ce.asp. Additional online training will be available soon through the Illinois Chapter of American Academy of Pediatrics at http://illinoisapa.org/. Document all training and retain copies of certificates of completion or certificates of attendance.

<table>
<thead>
<tr>
<th>Date of Training</th>
<th>Vaccine Coordinator Name</th>
<th>Training Attended</th>
<th>Training Provided By</th>
<th>Training Focus</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Keep a **logbook** to indicate the date(s) of routine maintenance tasks, date(s) of any repairs or servicing, and the name of the person and/or company performing each of these tasks.

<table>
<thead>
<tr>
<th>Date</th>
<th>Type of Maintenance (Routine, Service Call)</th>
<th>Person/Company Performing Maintenance</th>
<th>Repair or Service Performed</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
VFC RESOURCES

Illinois Department of Public Health: VFC program forms, policies, and memos:
http://www.idph.state.il.us/about/immunizationvfc.htm

E-mail: DPH.Vaccines@illinois.gov
Telephone: 217-786-7500

Illinois Comprehensive Automated Immunization Registry Exchange (I-CARE):
http://www.idph.state.il.us/health/vaccine/icarefs.html

E-mail: DPH.ICARE@illinois.gov
Telephone: 217-785-1455

Questions about I-CARE receiving data from EMRs, data transfers, or HL7 E-mail:
DPH.HL7ICARE@illinois.gov


Illinois VFC program information, including program forms, policies, and memos are also available at
http://illinoisaap.org/projects/immunizations/vfc/vfc-illinois/

Immunization Action Coalition (IAC): www.immunize.org

Immunization Action Coalition (IAC) E-mail Subscriptions: http://www.immunize.org/subscribe/

Centers for Disease Control and Prevention (CDC): www.cdc.gov/vaccines/

Healthcare Professionals/Providers Vaccine & Immunization Information:
http://www.cdc.gov/vaccines/hcp.htm


Immunization Schedule for Children and Adolescents:
http://www.cdc.gov/vaccines/schedules/index.html

Vaccine Information Statements: http://www.cdc.gov/vaccines/hcp/vis/index.html

Vaccine Administration Protocols: Pink Book, Appendix D at
www.cdc.gov/vaccines/pubs/pinkbook/index.html

Vaccine Adverse Event Reporting System and how to report: http://vaers.hhs.gov/esub/index

Vaccine Contraindications: www.cdc.gov/vaccines/recs/vac-admin/contraindications.htm

Vaccine Storage and Handling Toolkit:
http://www.cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf

You Call The Shots – Module 10 – Storage and Handling Training:
http://www2a.cdc.gov/nip/isd/ycts/mod1/courses/sh/ce.asp