

## Routine Storage and Handling

### Requirements

- Maintain refrigerated vaccine between 35°F and 46°F (2°C and 8°C).
  - Set refrigerator thermostat at 40°F for the best safety margin
- Maintain frozen vaccine between -58°F and +5°F (-50°C and -15°C).
  - Set freezer thermostat at -5°F for the best safety margin
- Take temperature readings of the vaccine in each storage unit compartment twice a day.
- Record all temperatures on a paper temperature log.
- Paper temperature logs must include the time, date, and signature of the person checking temperatures.
- Keep all temperature logs on file.

### Recommendations

- Providers should take minimum and maximum temperature readings once a day and record them on the temperature log.
- Store vaccine in original packaging.
- Store vaccine in the middle of the unit. Provide space between vaccines and the side/back of the unit.
- Do not store vaccines in the doors, vegetable bins, or floor of the unit.
- Do not store vaccines under or near cooling vents.
- Open one vial or box or a particular vaccine at a time.
- Store vaccine with similar packaging in different locations of the storage unit.
- Limit access to the vaccine supply to authorized personnel only.
- Do not pre-draw vaccine. In the case of a mass vaccination clinic providers may pre-draw 10 doses.

## Provider Staffing and Training

### Requirements

- Have a primary and back-up vaccine coordinator. Notify the immunization program of any staffing changes.
- The primary and back-up vaccine coordinator must receive annual training on vaccine storage and handling. The person with primary responsibility for VFC status screening must receive annual training on the VFC Program. Individuals meet the requirements by doing one of the following:
  - Participating in a VFC Compliance Site Visit.
  - Take the You Call the Shots Vaccine Storage and Handling and VFC Program Requirement trainings.

# Vaccine Management Plans

## Requirements

- Providers must have a vaccine management plan with all the following components:
  - name of current primary and back-up vaccine coordinator
  - storage and handling
  - shipping and receiving
  - ordering
  - inventory control
  - emergency
  - wastage
  - staff training
- The vaccine management plan must include the signature, name and title of the preparer.

# Storage Units and Equipment Maintenance

## Requirements

- No use of dorm style units.
- The storage unit must fit the year's largest inventory without crowding. The storage unit must also have room for water bottles or coolant packs.
- Place "Do Not Unplug" stickers at the electrical outlet and on the circuit breaker.

## Recommendations

- If providers are using combination units, they should replace them with best practice storage units as soon as possible.
- Providers should use the following best practice standards for purchasing storage units:
  - Use a stand-alone refrigerator and a stand-alone freezer
  - Use pharmacy or medical grade units
  - Use frost-free or auto-defrosting units when possible
- Never use the freezer section of a household combination unit.
- Household combination units are not recommended because of their risk for vaccine waste.
- Install locks on the storage units and the electrical plug.
- Do not store food or drink in a vaccine storage unit.
- Place water bottles throughout the storage unit to stabilize the temperatures.
- Provide a source of backup power (generator).
- Have a security system to alert personnel in event of a power outage.
- Test generators quarterly and provide annual maintenance.
- Defrost manual freezers once every 3 to 6 months.
- Clean compressor vents and drain pans every 3 to 6 months to allow the storage unit to run properly.

# Thermometers

## Requirements

- Newly enrolling providers must use data loggers or continuous temperature monitoring systems for vaccine.
- Each storage unit compartment must have a thermometer with a current certificate of calibration. Calibration testing must occur every two years from the date it was calibrated or by the manufacturer's guidelines, whichever comes first.
- Thermometers must be placed in a central location within the storage unit with the vaccines.
- Providers must capture the time and the staff name/initials for each temperature reading.
- An ILAC/MRA accredited lab must perform the calibration testing, or the thermometer must meet ISO/IEC 17025 standards.
  - Valid ILAC/MRA accredited lab certificates must contain:
    - ILAC/MRA signatory body-accredited lab stamp
    - Name of device (optional)
    - Model number
    - Serial number
    - Date of calibration
    - Measurement results indicating whether the unit passed or not
  - Valid Non-ILAC accredited lab certificates must contain:
    - Name of device (optional)
    - Model number
    - Serial number
    - Date of calibration
    - Measurement results indicate whether unit passed or not
    - Measurement results for the device
    - Statement that calibration testing conforms to ISO/IEC 17025
- Providers must have at least one back-up thermometer with a current certificate of calibration on hand.
- Backup thermometers must not be stored in a storage unit.

## Recommendations

- Use a digital data logger with the following features:
  - An alarm for out of range temperatures
  - A digital display with current and min/max temperatures
  - A reset button
  - A low battery indicator
  - An accuracy of +/-1°F (0.5°C)
  - The ability to store 4000 readings without overwriting
  - A user programmable logging interval
- Clinics closed for more than 2 consecutive days should use continuous temperature monitoring equipment.
- Providers should review and record the min/max temperatures at the beginning of each work day.

- All providers must move to data loggers or temperature monitoring systems as soon as possible. This will become a CDC requirement in 2018.

## Inventory Maintenance

### Requirements

- Upon receipt of vaccine:
  1. Open the package immediately.
  2. Check temperature indicators and inspect the vaccine for damage.
  3. Determine the length of time the vaccine was in transit.
  4. Compare vaccine received with the packing list.
  5. Immediately store vaccine at appropriate temperatures.
- Contact McKesson immediately if a vaccine shipment was compromised or there's a problem with the temperature monitors. Contact the manufacturer for direct ship vaccines.
- Providers must notify the LHJ if they have vaccines that are within 90 days of expiration if the provider cannot use the vaccine before it expires.
- Vaccine transfer can only occur after receiving approval from the immunization program.
- For expired, spoiled or wasted vaccine, providers must:
  1. Remove vaccine from the storage unit.
  2. Bag the vaccine and attach a "DO NOT USE" label.
  3. Notify the LHJ
  4. Complete a Vaccine Incident Report.
  5. Return the vaccine within six months.
- If replacement is required, providers must submit receipt of purchase of replacement doses of vaccine within 90 days.
- If vaccine has been exposed to a temperature excursion, providers must:
  1. Store vaccine under appropriate temperatures.
  2. Quarantine the vaccine and attach a "DO NOT USE" label.
  3. Notify the LHJ immediately.
  4. Contact the vaccine manufacturer to determine viability.
  5. Complete a Vaccine Incident Report.
- Rotate vaccine every week or when new shipments arrive. Make sure the shortest dated vaccine is in front.
- Report any expired vaccine and return it within 6 months of the expiration date per LHJ instructions.