## 2019 VFC Program Updates

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## Overview

#### VFC Updates

- ✓ Vaccine Management Plans
- ✓ Staff Training Requirements
- ✓ Digital Data Loggers
- ✓ Temperature monitoring
- ✓ Program Integrity
- ✓ Afternoon TEAch



## Disclosures

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## VFC Program Requirements



#### 2019 Program Participation Requirements at a Glance

Requirement	Summary	Resources/Job Aids
Vaccine Management Plan	Maintain a current and completed vaccine management plan (for routine and emergency situations) that includes practice-specific, vaccine-management guidelines and protocols, names of staff with temperature monitoring responsibilities, and completion dates of required EZIZ lessons for key practice staff.	EZIZ VFC Program Requirements lesson
UPDATED!	Review and update the plan at least annually, when VFC Program requirements change, and when staff with designated vaccine-management responsibilities change.	Vaccine Management Plan (IMM-1122)
	Designate a staff member responsible for updating the practice's management plan, and execute planned actions in emergency situations. Conduct vaccine management drills to maintain competency and readiness for emergency procedures, such as vaccine transport.	Provider Operations Manual (IMM-1248) Chapter 3
	Ensure staff with assigned vaccine-management responsibilities review, sign, and date the vaccine management plan annually and each time it is updated.	
	Keep the vaccine management plan in a location easily accessible by staff, ideally near the vaccine storage units.	
Key Practice Staff	Designate and maintain key practice staff in the practice's profile, and report key practice staff changes immediately on the online form on MyVFCVaccines. Changes to the Provider or Provider of Record Designee cannot be made online, and a Key Practice Staff Change Request form needs to be completed and submitted to the VFC Program.	Vaccine Coordinator Roles & Responsibilities (IMM-968)
	Add new key practice staff to the practice's vaccine management plan; ensure required EZIZ lessons are taken.	VFC Key Practice Staff Change Request Form (IMM-1166)
	There are four required VFC roles:	Provider Operations Manual
	Provider of Record (POR): The physician-in-chief, medical director, or equivalent role that signs and agrees to the terms of the VFC "Provider Agreement" and the California VFC Program "Provider Agreement Addendum" and is ultimately accountable for the practice's compliance. Must be a licensed MD, DO, NP, PA, pharmacist, or a Certified Nurse Midwife with prescription-writing privileges in California.	(IMM-1248) Chapter One, Program Requirements
	<b>Provider of Record Designee:</b> The on-site person designated by the Provider of Record to sign VFC documents on his/her behalf and to assume responsibility for VFC matters in his/her absence.	
	Vaccine Coordinator: An on-site employee who is fully trained and responsible for implementing and overseeing the provider's vaccine management plan.	
	<b>Backup Vaccine Coordinator:</b> An on-site employee fully trained in the practice's vaccine management activities and fulfills the responsibilities of the Vaccine Coordinator in his/her absence.	
	Immunization Champion (optional): A staff member who goes above and beyond their normal duties to promote immunizations to patients and in the community.	

California Department of Public Health, Immunization Branch

IMM-1240 (12/2018)



#### VFC Program Requirements

- Reviewed and update by the California VFC program on annual basis
- Providers are responsible for reviewing program materials that come out during the year
- Providers are required to update their internal policies/protocols to reflect those changes
- Review this document prior to annual recertification
  - ✓ Program requirements can be found here
- Can be found on eziz.org

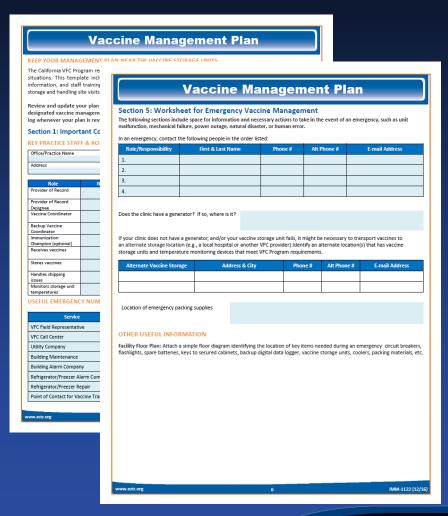


# Vaccine Management Plans



#### Written Vaccine Management Plan

- All facilities storing and administering vaccines should have them
  - ✓ These plans are a requirement for participation in the VFC Program
- Vaccine Management Plan (2 parts)
  - ✓ Routine include all aspects of vaccine management, from ordering, storage conditions to temperature monitoring.
  - ✓ Emergency Outline steps and key contacts in case of an emergency, such as a planed or unplanned power loss.





### Vaccine Management Plans

- Should have a one already in place
- Should include practice-specific vaccine management guidelines & protocols
- Review and update at least once per year or as needed
- Have names of staff with temperature monitoring responsibilities
- List of staff who have completed the EZIZ online lessons (for key staff)
- Ensure all staff with assigned vaccine management duties review, sign and date the plan annually
- All internal staff are required to know what the plan contains



## Vaccine Management Plans

- Major changes from 2018:
  - ✓ Designate a staff member responsible for updating the practice's management plan and execute planned actions in emergency situations
  - ✓ Keep the vaccine management plan in a location easily accessible by staff
    - Ideally near the vaccine storage units



## Staff Training Requirements



#### Skilled and Properly Trained Staff:

- Designate a primary and a back-up vaccine coordinator (VC)
  - ✓ Oversee storage and handling activities within the clinic
  - ✓ A description of the vaccine coordinator's role is included in this job aid
  - ✓ BOTH VCs must be equally trained
- The provider of record should be directly involved in overseeing vaccine management activities in the clinic
  - ✓ Financial implications of vaccine replacement cost AND clinical implications of mishandling of vaccines

#### **Vaccine Coordinator**

#### The Role of the Vaccine Coordinator

Vaccines are expensive and sensitive to temperature. Careful vaccine management is essential to protecting your vaccine supply.

VFC requires providers to designate a fully trained Vaccine Coordinator and a Backup Vaccine Coordinator to implement routine and emergency vaccine management plans. Their names and contact information must be reported to the VFC Program through MyVFCVaccines.org. In many practices, the Vaccine Coordinator is a medical assistant. In other practices, the Vaccine Coordinator is an LVN, RN, office manager, or other staff person.



#### Responsibilities of the Vaccine Coordinator

The Vaccine Coordinator's responsibilities vary depending on the amount of vaccine the practice gives and practice protocols. In some practices, the Vaccine Coordinator is responsible for all vaccine management activities, including training other (especially new) staff. In other practices, a different person may have one or more vaccine management responsibilities, such as ordering vaccines. Below is a list of essential responsibilities.

#### Receiving vaccines

- · Be present when vaccine is delivered and immediately process it into inventory.
- · Ensure that acceptable temperature ranges have been maintained.

#### Storing vaccines

- Rotate the vaccine inventory so that vaccines with shorter expiration dates are used first.
- Ensure that there are no expired vaccines in the refrigerator or freezer.
- Keep VFC vaccine separate from private vaccine stock.

   Parameters of a private vaccine stock.
- Perform routine cleaning on vaccine storage units.

#### Monitoring vaccine temperatures

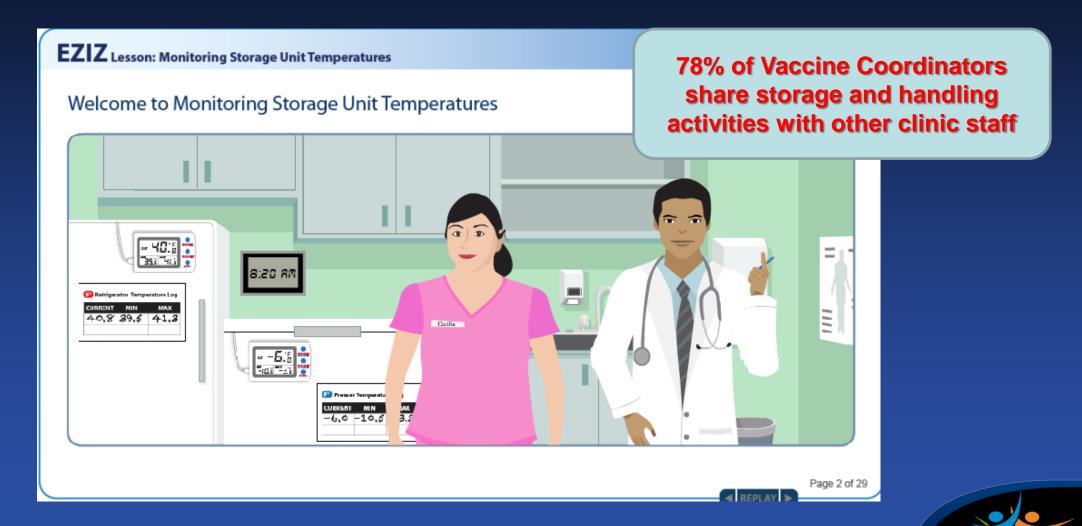
- Use a certified calibrated thermometer to review refrigerator and freezer temperatures.
- Record minimum, current, and maximum temperatures on a VFC-supplied log twice a day.
- Take immediate action if temperatures are outside acceptable ranges
   Implement the emergency vaccine management plan, if necessary.
- Review vaccine temperature logs weekly.
- Retain temperature logs for three years.

#### Ordering vaccine

- Perform a physical inventory of all vaccines in stock.
- Account for doses of returned or transferred vaccines since the last order.
- Complete and submit the VFC vaccine order at MyVFCVaccines.org.



## Temperature Monitoring Lesson Required for key practice staff AND clinic staff responsible for temperature monitoring



### Required EZIZ Lessons for Key Practice Staff

Legend:√= Required Lesson						
		Start Date	Vaccine Coordinator	Backup Vaccine Coordinator	Provider of Record	Provider of Record Designee
	VFC Program Requirements *	Recertification Launch	✓	✓	✓	✓
Lessons	Storing Vaccines*	Recertification Launch	✓	✓	✓	✓
	Monitoring Storage Unit Temperatures*	Recertification Launch	✓	✓	✓	✓
	Conducting a Vaccine Inventory *	Recertification Launch	✓	✓	Encouraged	Encouraged
ew & wledge	Provider Operations Manual (NEW)	Recertification Launch	✓	✓	✓	✓
Revi	Vaccine Management Plan (Updated)	Recertification Launch	✓	✓	✓	✓

<sup>\*</sup>Test-out option available



## Digital Data Logger Requirement



## Digital Data Loggers



Digital data loggers



#### VFC Requirement: Use of DDL for Temperature Monitoring of VFC Supplied Vaccines- Summary

All staff, including supervisors and new employees, must be properly trained on temperature monitoring including proper use of the practice's DDL and the required corrective action for out-of-range temperatures:

- Equip all refrigerators and freezers (primary and back-up) storing VFC-supllied vaccines with VFC-compliant DDL.
- Ensure each device has a current certificate of calibration
- Configure key settings for primary and back-up DDL's including device name, high and low temperature alarm limits and a 30 minute logging interval
- Keep on hand at least one back-up DDL (battery operated) for emergency vaccine transport.
- Store the back-up DDL's buffered probe in the vaccine refrigerator and it's display in a cabinet
  - ✓ Document the device's location on the practice's vaccine management plan.



## VFC Requirement: Use of DDL for Temperature Monitoring of VFC Supplied Vaccines- Summary

- Calibrate primary and back-up devices annually, or every other year when the manufacturer's recommend a period longer than two years
- Keep certificates of calibration on file and make them available to the VFC program upon request
- If any data logger or probe is damaged, replace the entire device



## VFC Requirement: Use of DDL for Temperature Monitoring of VFC Supplied Vaccines

#### Minimum required features for your DDL:

- Detachable temperature probe immersed in buffered material
- Programmable logging interval
- Digital display with current, MIN, and MAX temperatures
- Accuracy of +/-1.0°F (+/-0.5°C) for refrigerator and freezer
- Visual or audible alarm for out-of-range temp
- Low battery indicator
- Memory storage of at least 4,000 readings
- Current and valid certificate of calibration



http://eziz.org/assets/docs/IMM-1236.pdf

## Data Loggers Job Aids



#### **Data Logger Setup & Use**

#### **Preparing New Data Loggers for Use**

Refer to your device's product guide or video to learn how to use your data logger. Please call your vendor's support contact number for all questions regarding setup, functionality, or configuration.

#### **Set Up and Get Familiar with Functions**

- Determine what you will need to set up and prepare your data logger to monitor temperatures.
- Install software and configure the device as needed. For some data loggers, data download may require setup of a cloud account or purchase of a flash drive.
- Locate the vendor's support contact number in case you need to reach them during the software installation or device setup.
- 2. Get familiar with your data logger.
- Make sure you can find CURRENT, MIN, and MAX readings. Some devices display all of these readings on the main digital display.
   For others, you may have to access menus by toggling buttons such as REVIEW, START, and DISPLAY on the device.
- Determine how your device will communicate temperature alarms. Some data loggers may display a red light or icon/symbol on the digital display. Wi-Fi-enabled devices may issue text messages or email alerts wirelessly.
- Locate the necessary steps to download temperature data files.
- Determine if your device must be stopped before downloading data files to prevent recording room temperatures.
- Determine if your device must be unplugged from the probe to download data files. Probe must remain in storage unit at all times.
- Locate the necessary steps to resume temperature recording after data downloads.
- Determine how your device must be stored.
   You may have to plug the data logger back into the probe and press the START button.
- Determine if your device must be reset manually after recording temperatures. Data loggers may reset either manually or automatically.

- Get familiar with your downloaded temperature data files including summary data.
  - Make sure you can locate key temperature excursion details. Look for excursion time/ date, MIN/MAX temperatures, and total time above/below alert limits.
- Locate the summary data. Most devices generate a one-page summary of excursion details that you'll need when reporting temperature excursions to VFC.
- Set up an electronic filing system for saving your downloaded temperature data files to your computer.
- Create separate folders for each storage unit by location. For example, Injection\_Room\_ Unit 01.
- Store your data logger's Certificate of Calibration in a safe accessible location.

#### Configure Settings

Settings may be programmed on the data logger or using the software installed on the computer depending on your device.

- Set the temperature scale to Fahrenheit or Celsius.
- Set the recording intervals to 15 minutes (if not already pre-configured).
- Set the LO/HI temperature alarm limits for refrigerators and freezers:

Settings	Refrigerator	Freezer
LO	34.9°F (1.9°C)	-58.1°F (-50.1°C)
HI	46.1°F (8.1°C)	5.1°F (-14.9°C)
HI	46.1°F (8.1°C)	5.1°F (-14.9°C)

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California Department of Public Health, Immunization Branch, Vaccines for Children (VFC) Program

EZIZ.org

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IMM-1206 (12/15)

## Temperature Monitoring



#### Temperature Monitoring:

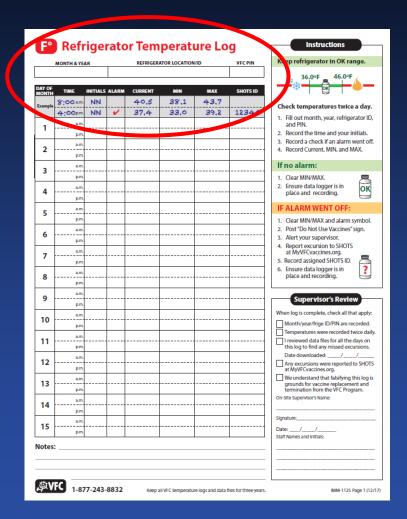
- Ensure vaccine storage unit temperatures are recorded on current VFC temperature logs.
- Monitor and record current, minimum and maximum temperatures in vaccine refrigerators and freezers twice each day,
- Any VFC-approved mass vaccination clinic must monitor and record temperatures every hour and attach data logger download summary report to the transport log.
- Download and analyze temperature data files (feature of digital data loggers) at the end of every two-week

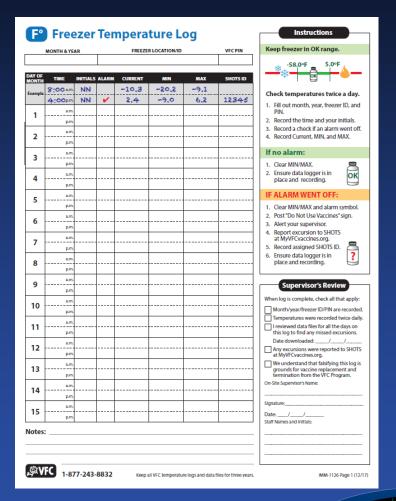


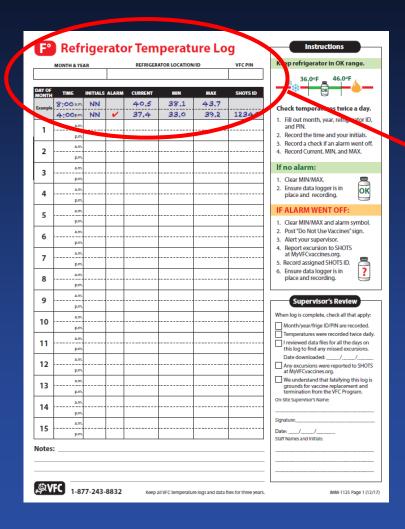
#### Temperature Monitoring:

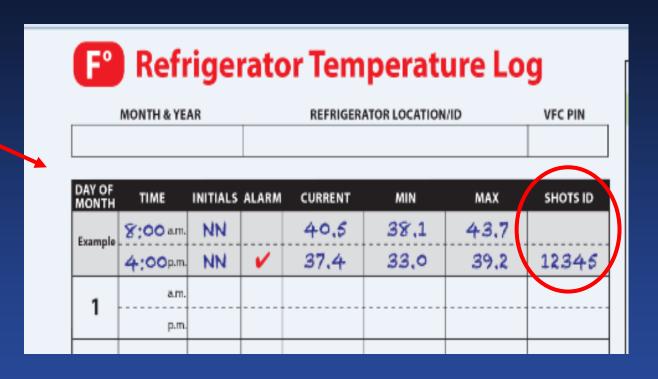
- Acknowledge that if temperatures are not monitored and documented, if temperature logs are missing, or if temperature logs are falsified, all affected vaccines will be automatically deemed non-viable and considered a negligent vaccine loss.
- Ensure VFC temperature logs are legible and completed accurately, and in ink.
- Immediately cross out, correct, and initial neatly any inadvertent documentation error.
- Ensure the supervisor certifies and signs that temperatures were recorded twice daily,
- Acknowledge that temperature logs missing during a VFC site visit but found at a later date will not be accepted.



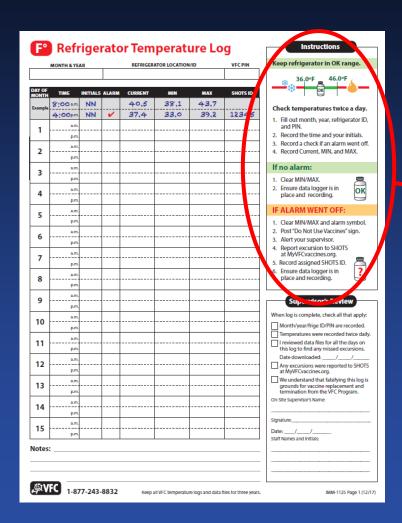


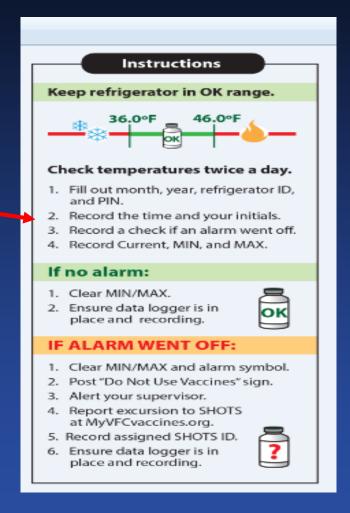




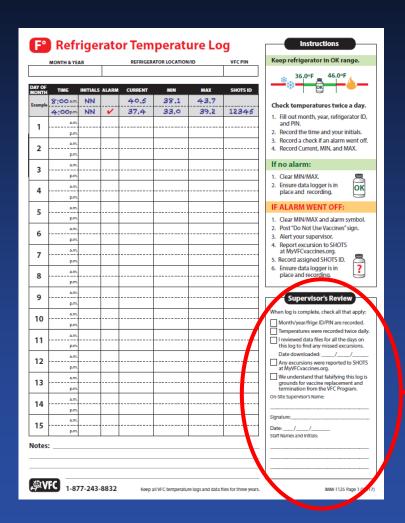










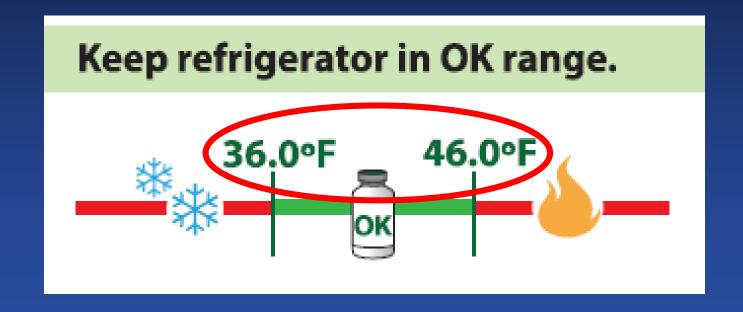


	Supervisor's Review
	When log is complete, check all that apply:
	Month/year/frige ID/PIN are recorded.  Temperatures were recorded twice daily.  I reviewed data files for all the days on this log to find any missed excursions.  Date downloaded:/  Any excursions were reported to SHOTS at MyVFCvaccines.org.  We understand that falsifying this log is grounds for vaccine replacement and termination from the VFC Program.  On-Site Supervisor's Name:
	Signature:  Date:/  Staff Names and Initials:
s.	IMM-1125 Page 1 (12/17)



#### Temperature Monitoring Changes:

 As of January 1<sup>st</sup>, 2018, the new acceptable temperature for refrigerated vaccines is 36° - 46° Fahrenheit





## Vaccine Storage Units



### Acceptable Vaccine Refrigerators

TABLE 2.	Vaccine	refrigerators	by practice	volume
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Grade (Type) Rating	Description	Practice Volume
Pharmacy- or biologic-grade (any) Best	Purpose-built to maintain consistent temperatures for storage of vaccines or biologics. Come in stand-alone and combination units.	Very high (required Others: preferred
Compact pharmacy- or biologic-grade (stand-alone) Best	These under-the-counter storage units are suitable for smaller practices with limited space.	Low, Medium, High
Commercial units (stand-alone) Good	Intended to store food and beverages in commercial settings. They are often larger and more powerful than household units but are not designed to store biologics and might experience temperature fluctuations.	Low, Medium, High
Household (stand-alone) Discouraged	Intended for use in homes and offices— typically for food storage. Like commercial units, they are not designed to store biologics and experience frequent temperature fluctuations.	Low, Medium, High











### Acceptable Vaccine Freezers

TABLE 3. Vaccine freezers by practice volume				
Grade (Type) Rating	Description	Practice Volume		
Pharmacy- or biologic-grade (stand-alone) Good	Specifically designed to maintain consistent temperatures for storage of vaccines or biologics.	Any practice		
Pharmacy- or biologic-grade (combination) Good	These storage units have more than one compressor allowing for better and separate temperature control of the refrigerator and freezer compartments.	Any practice		
Commercial units (stand-alone) Good	Intended to store food and beverages in commercial settings. They are often larger and more powerful than household units but not designed to store biologics and experience some temperature fluctuations.	Any practice		
Household (stand-alone) <i>Good</i>	Intended for use in homes and offices— typically for food storage. Like commercial units, they are not designed to store biologics and experience frequent temperature fluctuations.	Any practice		



#### **Acceptable Storage Units**

Stand-alone. These types are self-contained units designed as either refrigerator-only or freezer-only and range in size from compact, under-the-counter styles to very large pharmaceutical-grade units.



FIGURE 3.3. Stand-alone refrigerators.



FIGURE 3.4. Stand-alone upright and chest freezers.

Combination. These types have a rerigerator and freezer with separate exterior doors.



FIGURE 3.5. Combination purpose-built unit.

#### **Key Terms:**

- Purpose-built. These grades are specifically designed to maintain consistent temperatures for storage of vaccines or biologics. They might be designed for pharmacy, biologic, or laboratory environments.
- Commercial. These grades are intended to store food and beverages in commercial settings. They are often larger and more powerful than household units but are not designed to store biologics. They experience some temperature fluctuations.
- *Household.* These grades are intended for food storage—typically in homes and offices.



## Vaccine Storage



### Vaccine Storage Requirements

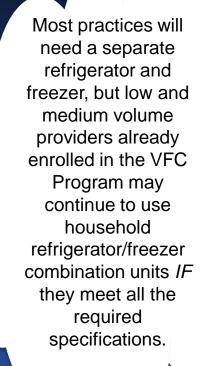
#### REQUIRED SPECIFICATIONS

#### All refrigerator units must:

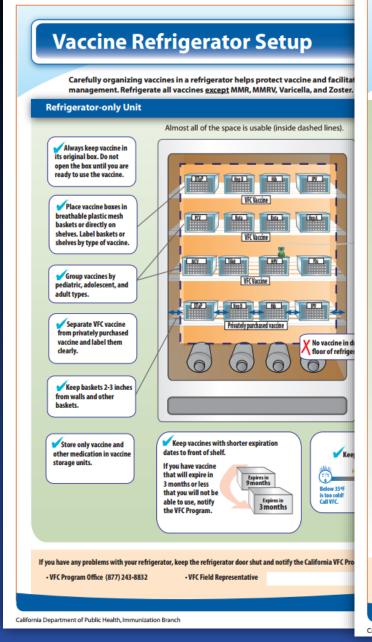
- Maintain required vaccine storage temperatures (35°F 46°F) year-round.
- Be automatic defrost (frost-free) and free of any frost, ice, water or coolant leaks. Manual defrost (cyclic defrost) refrigerators with visible cooling plates/ coiling in the internal back wall are not acceptable.
- Provide enough space to store the largest number of doses expected at one time (including influenza season), allowing for vaccine storage at least 2-3 inches away from walls, floor, and other boxes, and away from cold air vents.
- Be reliable (with a quiet compressor) and has not needed frequent repairs.
   Replacement should be considered for household refrigerator/freezer combination units over 10 years old.
- Have doors that seal tightly and close properly
- Have separate temperature controls for refrigerator and freezer for combination units.
- Not have convertible features that switch to an all-freezer unit.
- Have a working thermometer placed centrally in the unit. Thermometers must be certified
  in accordance with National Institute of Standards and Technology (NIST).
- Be used only for vaccine storage. In limited circumstance, and as space allows, other medications may be stored in the same units.

#### All Freezer units must:

- Maintain required vaccine storage temperatures (5°F or below) year-round.
- Provide enough space to store vaccines along with sufficient frozen cold packs.
- Have an automatic defroster. (Manual defrosters are acceptable only if the office has an alternate place to store vaccines when defrosting the unit.)







#### **Vaccine Freezer Setup**

Storing Vaccines

Carefully organizing vaccines in a freezer helps protect vaccine and facilitates vaccine inventory management. Freeze MMR, MMRV, Varicella, and Zoster vaccines.

Place vaccine in breathable plastic mesh baskets and clearly label baskets by type of vaccine.

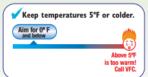
Separate the VFC vaccine supply from privately purchased vaccine.

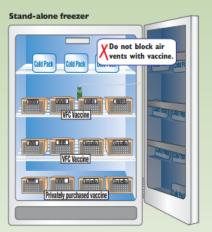
Keep vaccines with shorter expiration dates to front of shelf.

If you have vaccine that will expire in 3 months or less that you will not be able to use, notify the VFC Program.

Expires in 9 months

Expires in 3 months







If you have any problems with your freezer, keep the freezer door shut and notify the California VFC Program.

• VFC Program Office (877) 243-8832

VFC Field Representative

eziz.org

California Department of Public Health, Immunization Branch

IMM-966 (LI/I3)



#### Best practices for vaccine storage

- Store only vaccine in CDC/VFC Approved vaccine storage units.
- Separate the VFC vaccine supply from privately purchased vaccine.
- Place vaccine in breathable plastic mesh baskets and clearly label baskets by type of vaccine.
- Keep vaccines 2-3 inches from walls of the storage unit.
- Rotate vaccines (those expiring first should be placed in front)
- Transfer short-dated vaccine
- Place thermometer probe towards the center of the vaccine storage unit



# ACIP Recommendations and Standards



## **ACIP Recommendations & Standards**

- The VFC Program entitles eligible children to all vaccines recommended by ACIP.
- As a VFC Program participant, your practice is also required that VFCeligible children have access to ACIP-recommended vaccines not routinely administered, and make them available when indicated or requested.
  - ✓ i.e. Meningococcal Group B (Men B)
  - ✓ i.e. Pneumococcal polysaccharide (PPSV23)



# Vaccine Administration



### Vaccine Administration

- Administer all ACIP-recommended vaccines, in-house
- Ensure that VFC-eligible children have access to non-routine, ACIPrecommended vaccines when indicated or requested
- Administer all VFC-supplied vaccines at the approved location for the VFC PIN
  - ✓ Administration of doses away from the approved location is NOT routinely allowed.
- Report clinically significant adverse events to the Vaccine Adverse Events Reporting System (VAERS)
- Report vaccine administration errors (i.e. incorrect doses, wrong or expired vaccines)to the national Vaccine Errors Reporting Program (VERP)



### Vaccine Administration

- Acknowledge and follow VFC Program and manufacturer guidance, including revaccinations, if non-viable vaccines have been administered to patients.
- Document all VFC vaccine doses administered using the VFC Daily Usage Log, Flu Usage Log, an immunization registry, or electronic or paper form.
- Acknowledge that revaccination is recommended if non-viable vaccines have been administered to patients.



# Program Integrity



# **Program Integrity**

- Clinic staff will conduct themselves in an ethical, professional, and respectful manner in all interactions with VFC Program staff.
- Never alter, or falsify immunization or VFC Program-related records
- It is a VFC Program requirement to maintain records for a period of three years



# **Educational Opportunity**











## Afternoon TEAch

- Began in 2018
- Webinar-based educational opportunity
- Topics range from VFC Program requirements to current ACIP recommendations
- Will be broadcast approximately every 2 3 months



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