VFC Program Updates (San Bernardino County)

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Overview

- VFC Updates
  - VFC Program Overview
  - Vaccine Management plans
  - Digital Data Loggers (DDL’s)
  - Vaccine storage units
  - Emphasis on proper storage and handling and temp monitoring:
  - CAIR-2 Update
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VFC Program Overview
VFC Program Background:

• Created as a direct result of the 1989 – 1991 US measles epidemic
  ✓ which resulted in ~55,000 cases of measles and hundreds of deaths.
  ✓ Over 50% of these children with measles had recently seen a healthcare provider but were not immunized

• August 10th, 1993, congress passed the Omnibus Budget Reconciliation Act (OBRA) creating the Vaccines for Children (VFC) Program,
  ✓ as an “entitlement” (a right granted by law) for eligible children 0-18 yrs of age.

• VFC Program became operational in October 1, 1994
The VFC Program is a federally funded program that provides vaccines at no cost to children because of inability to pay.

CDC buys vaccines at a discount and distributes the vaccine to Public and private VFC providers.

Offers all childhood vaccines recommended by the Advisory Committee on Immunization Practices (ACIP).

The VFC program has:
- contributed directly to a substantial increase in childhood immunization coverage levels
- significant contribution to the elimination of disparities in vaccination coverage among young children.

¹Benefits from Immunization During the Vaccines for Children Program Era — United States, 1994–2013; CDC Morbidity and Mortality Weekly Report (MMWR), April 25, 2014 / 63(16);352-355
VFC Program Funding

• The VFC Program’s is almost $4 billion dollars per year

• California’s VFC Vaccine Budget: ~$500 million per year

• The VFC Program is a highly visible federal program
  ✓ Part of the Federal Program Integrity Initiative which seeks to ensure the integrity of operations in all HHS programs, to reduce the risk of fraud, waste, and abuse
VFC Eligibility

• Who’s eligible to receive VFC vaccine:
  ✓ Children birth through 18 years of age
  ✓ Medicaid eligible. In California, Medi-Cal and/or CHDP
  ✓ Uninsured: A child who has no health insurance coverage (regardless of income)
  ✓ Native American Indian or Alaska Native:
  ✓ Underinsured: Underinsured children are eligible to receive VFC vaccine only through a Federally Qualified Health Center (FQHC) or Rural Health Clinic (RHC)
VFC Eligibility

• A provider must select AND document the eligibility category that will require the least amount of out-of-pocket expenses to the parent/guardian for the child to receive the necessary vaccinations.

• Screening for VFC eligibility must occur with ALL clinic patients 0-18 years of age, prior to vaccine administration, and be documented in the patient’s permanent medical record (paper-based or electronic medical record) at each immunization encounter.

• Documentation of eligibility screening must include the following elements:
  ✓ Date of screening
  ✓ Whether the patient is VFC eligible or not VFC eligible
  ✓ If patient is VFC eligible, eligibility criteria met.
VFC Program Administration Fees

• Providers may charge a vaccine administration fee to non-Medicaid VFC eligible children

• Maximum admin fee is $26.03 per dose in CA

• Vaccine administration cannot be denied to an established patient due to inability to pay the administration fee.
  ✓ The only fee that must be waived is the administration fee. Other visit or office fees may be charged as applicable.

• Administration fees for Medi-Cal patients must be billed to Medi-Cal and NOT to the patient
# California Vaccines for Children (VFC) Program

## 2017 Program Participation Requirements at a Glance

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Summary</th>
<th>Resources/Job Aids</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaccine Management Plan</td>
<td>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. Review and update the plan at least once a year, when VFC Program requirements change, and when staff with designated vaccine management responsibilities change. Ensure all staff with assigned vaccine management responsibilities review, sign, and date the plan annually and whenever the management plan is updated.</td>
<td>Vaccine Management Plan (IMM-1122)</td>
</tr>
<tr>
<td>Key Practice Staff</td>
<td>Designate and maintain key practice staff in the practice’s profile, and report key practice staff changes to the VFC Call Center. There are four required VFC roles: <strong>Provider of Record (POR):</strong> 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. <strong>Provider of Record Designee:</strong> 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. <strong>Vaccine Coordinator:</strong> An on-site employee who is fully trained and responsible for implementing and overseeing the provider’s vaccine management plan.</td>
<td>Vaccine Coordinator Roles &amp; Responsibilities (IMM-968) VFC Key Practice Staff Change Request Form (IMM-1166)</td>
</tr>
</tbody>
</table>
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
• Program Participation Requirements At-A-Glance is an essential for understanding the VFC Program
• Review this document prior to annual recertification
  ✓ Program requirements can be found here
• Can be found on eziz.org
Key Requirements for 2017

• Temperature Monitoring Equipment
  ✓ All VFC providers must have a digital data logger for continuous temperature monitoring for all vaccine storage units by December 2017

• Vaccine Storage Equipment
  ✓ *Household* combination refrigerator/freezers will no longer be allowed for the storage of VFC vaccines, at any time.
Key Requirements for 2017

• Both of these requirements are expansions of current requirement in place for VFC providers.
  ✓ For DDLs: Requirement is expanding to ALL providers
  ✓ For vaccine storage units: The requirement is applicable to a small number of low volume VFC providers grandfathered-in during the 2009 requirement.
VFC Compliance Visits
Site Visits

• Providers agree to participate in VFC Program site visits, including:
  - Scheduled compliance visits, also known as Quality Assurance Reviews (QARs)
  - Unannounced Storage & Handling visits
  - Other visits for educational and programmatic support.

• The goal of unannounced storage and handling visits:
  - To ensure VFC supplied vaccines administered to VFC eligible children are managed and stored according to program requirements.
2017 VFC Compliance Site Visits

- New process – nationwide, all VFC States will be utilizing a standard CDC-generated questionnaire online
- New questionnaire is designed to review compliance with federal VFC Program requirements as delineated in the VFC Provider Agreement.
- Provider of Record or their designee (as listed in 2017 Recertification Agreement) will need to be present at time of visit to sign an “Acknowledgement of Receipt” of the Compliance Visit Follow-Up Plan
Vaccine Management Plans
Vaccine Management Plans

- Should have a one already in place
- Should include practice-specific vaccine management guidelines & protocols
- Have names of staff with temperature monitoring responsibilities
- List of staff who have completed the EZIZ online lessons (for key staff)
- All internal staff are required to know what the plan contains
Vaccine Management Plans

• Review and update the plan at least once a year
  ✓ OR . . . When VFC Program requirements change
  ✓ OR . . . When staff with vaccine management responsibilities change

• All staff with vaccine management responsibilities need to review, sign and date the plan annually, or whenever the plan is updated
New for 2017:

**Vaccine Management Plan**

**KEEP YOUR MANAGEMENT PLAN NEAR THE VACCINE STORAGE UNITS**

The California VFC Program requires each practice to maintain a vaccine management plan for routine and emergency situations. This template includes space for information about the practice such as guidelines, protocols, contact information, and staff training. VFC Field Representatives may ask to review it during compliance and unannounced storage and handling site visits.

Review and update your plan at least once a year, and when VFC Program requirements change and when staff with designated vaccine management responsibilities change. Key practice staff must sign and acknowledge the signature log whenever your plan is revised.

**Section 1: Important Contacts**

**KEY PRACTICE STAFF & ROLES**

<table>
<thead>
<tr>
<th>Office/Practice Name</th>
<th>VFC PIN Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Role</th>
<th>Name</th>
<th>Title</th>
<th>Phone #</th>
<th>Alt Phone #</th>
<th>E-mail</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provider of Record</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Digital Data Loggers
Digital Data Loggers

Digital data loggers
A digital data logger (DDL), also known as a “continuous temperature monitoring device” or just a “data logger,” is an electronic device that reads and records temperatures and then stores them in its internal memory.

Temperatures recorded by a data logger can be viewed on a computer and saved as an electronic or paper file.
Digital Data Loggers

Information from a digital data logger helps clinic staff:

• Know the exact times and for how long vaccines are stored at specific temperatures;
• See how a storage unit’s temperatures increase and decrease during clinic operations;
• Continuously monitor temperatures even when the clinic is closed.
• Prevent unnecessary vaccine losses when excursion time frames cannot be precisely determined.
• Also indicates to the provider that the unit may need to be replaced.
Use of DDL for Temp Monitoring of VFC Supplied Vaccines:

- Beginning in 2014, the VFC program began transitioning the following VFC providers to use DDL for temperature monitoring of any storage unit containing VFC supplied vaccines:
  - New VFC program participants
  - Providers open 2 days per week or less
  - Providers with a vaccine loss as a result of a temperature excursion
  - Providers without a VFC compliant thermometer (primary or back-up)
  - Providers conducting mass vaccination transporting vaccines to mass clinic locations.
New VFC Requirement: Use of DDL for Temperature Monitoring of VFC Supplied Vaccines

- The timing for replacement of thermometers with DDLs during 2017 will be dependent upon certificate of calibration expiration for each of the practice’s thermometers.

  ✓ Replacement of thermometers with DDLs should occur prior to the certificate of calibration expiration for each of the practice’s thermometers.

  ✓ Thermometers with a certification expiration date beyond 2017 must also be replaced.
New VFC Requirement: Use of DDL for Temperature Monitoring of VFC Supplied Vaccines

• Minimum Requirements for DDLs or continuous monitoring systems:

  ✓ Detachable probe in a thermal buffered material
  ✓ A visual or audible alarm for out-of-range temperatures
  ✓ Low-battery indicator
  ✓ Current, minimum, and maximum temperature indicator/display
  ✓ Accuracy of +/-1°F (+/-0.5°C) for both freezer use and refrigerator use
  ✓ Logging interval that can be programmed by the user
  ✓ Memory storage of at least 4,000 readings
  ✓ Have a current and valid certificate of calibration
New VFC Requirement: Use of DDL for Temperature Monitoring of VFC Supplied Vaccines

Monitoring and Recording Temperatures Using DDLs

- Maximum, minimum and current temperatures must be checked twice daily and documented using current VFC Program temperature logs, even if using a continuous temperature recording device or a digital data logger.

- Continuous temperature recording devices, digital data logger, and equipment (e.g., temperature alarm systems) do not eliminate the need for staff intervention and monitoring of vaccine unit temperatures and taking immediate actions when indicated.
New VFC Requirement: Use of DDL for Temperature Monitoring of VFC Supplied Vaccines

Monitoring and Recording Temperatures Using DDLs:

- DDL must be inspected twice daily or sooner if a temperature alarm has been triggered.
- DDL’s should record temperatures at a minimum of 30 min intervals
- Download data a minimum of twice monthly from the data logger
- Data downloads should be downloaded and stored in an electronic filing.
- Files should be easily retrievable and accessible to VFC Field Staff and vaccine management staff.
- Temperature files and VFC Temperature Logs must be kept for 3 years.
New VFC Requirement: Use of DDL for Temperature Monitoring of VFC Supplied Vaccines

- Providers are responsible for training their staff:
  - Training should include:
    - ✔ Reading temperatures (min, max and current)
    - ✔ Hands on training with device
    - ✔ Identifying alarms within the unit
    - ✔ Reading alarm temperatures
    - ✔ Recording temperatures on VFC Program logs
    - ✔ Starting and stopping the unit
    - ✔ Downloading and saving data
    - ✔ Meaning of all display icons
New VFC Requirement: Use of DDL for Temperature Monitoring of VFC Supplied Vaccines

• Staff should also become familiar with the different reports and reporting functionality for the DDL.
Tips for Successful implementation of new VFC DDL Requirement

• Start the process several months in advance of your unit’s certificate of calibration expiration or the VFC Program deadline (whichever comes soonest)
  ✓ It takes time to research units and decide which one your practice will purchase
  ✓ Purchasing requests take some time for most organizations.

• Check with the vendors for availability AND anticipated delivery timelines
Tips for Successful implementation of new VFC DDL Requirement

- Work with your practice’s IT provider
- Once the unit arrives, set time aside to get familiar with the unit, set-up, and testing.
- Keep the vendor customer support phone number available
- Familiarize all staff with the unit,
  - **Practice using the unit** before using it officially to record your unit’s temperatures
- Gather all VFC resources to help you succeed in your transition.
CHANGES IN VFC STORAGE AND HANDLING REQUIREMENTS
Vaccine Storage Equipment: Household combination refrigerator/freezers no longer be allowed

- Household combination refrigerator/freezers will no longer be acceptable for the storage of VFC vaccines
  - Even for low volume provider offices.

- These types of units cannot be used to store VFC-supplied vaccines at any time (permanent or day use).
# Acceptable Vaccine Storage Equipment

<table>
<thead>
<tr>
<th>Acceptable Units</th>
<th>Comments</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmaceutical grade/purpose-built units (stand-alone)</td>
<td>Specifically engineered to maintain consistent temperatures throughout the unit. Purpose-built or pharmacy-grade refrigerators can be compact, making them ideal for small offices.</td>
<td>Best</td>
</tr>
<tr>
<td>Pharmaceutical grade/purpose-built units (combination)</td>
<td>Specifically engineered to maintain consistent temperatures throughout the unit. These units have more than one compressor allowing for better and separate temperature control of the refrigerator and freezer compartments.</td>
<td>Best</td>
</tr>
<tr>
<td>Commercial units* (stand-alone)</td>
<td>Usually intended to store food and beverages and are often larger and more powerful than household units. These units are not specifically designed to store biological materials.</td>
<td>Good</td>
</tr>
<tr>
<td>Household* (stand-alone)</td>
<td>Usually smaller than commercial units and are intended for use in small offices and in homes, typically for food storage. Like commercial units, they are not designed to store biological materials.</td>
<td>OK</td>
</tr>
</tbody>
</table>

*These units may require additional water bottles (refrigerator) or frozen cold packs (freezer) to maintain stable temperatures. Consult your VFC Representative for guidance.

**Stand-alone Refrigerator and Freezer Units**

Stand-alone units are self-contained units dedicated to a single temperature range, as either a refrigerator OR freezer. Stand-alone refrigerator and freezer units are considered best practice for vaccine storage as they provide the best temperature stability.
Purpose-built units: Best Vaccine Storage Equipment

Full-size, Stand-alone Refrigerators and Freezers

Biomedical-grade refrigerators and freezers are considered the best, most secure option for vaccine storage. As with most “gold-standard” products, they require a larger investment and are most often found in health departments, laboratories and hospitals. However, many of the biologic-grade manufacturers also produce refrigerators and freezers in an array of sizes and price points. For example, Sanyo produces very large, vaccine/blood refrigerators (see first picture above) but they also produce more moderately priced under-counter models ideally suited for small clinics.

Full-size, Combined Refrigerator and Freezer

While they look similar to household combination units, biomedical-grade combination units are far superior for vaccine storage in several important ways:

- Separate refrigeration systems for the refrigerator and freezer.
- Improved cabinet insulation to avoid hot and cold spots.
- Built-in, digital temperature display.
- Built to industrial standards and warranted for industrial use.
- Fan-forced air circulation delivers quick temperature recovery.

Biomedical-grade, combination units are ideal for clinics wanting a best practice storage solution in a compact package.

Under-counter Refrigerators and Freezers

Under-counter refrigerators and freezers are an excellent choice for clinics with limited space. Benefits of under-counter units include:

- **Lower risk**: Separate compressors and condensers decrease the risk of a total vaccine loss that might occur in a single combined unit.
- **Flexibility**: Small and easy to relocate, under-counter units can be positioned in multiple ways depending on the need.
- **No cold air vent**: Traditional combined units use a cold air vent to blow frozen air into the refrigerator compartment. Separate units mean separate compressors and no need for cold air venting.
- **Cost effective**: If a clinic is looking to add to its existing refrigerator or freezer capacity, this option allows for the purchase of only what is needed. A single under-counter refrigerator or freezer might negate the need to buy a larger, more expensive replacement unit.
ANNUAL VFC RECERTIFICATION
Annual VFC Recertification

- Recertification response has been slower than in previous years
- Recertification is required annually.
- Access the on-line form from your MyVFCvaccines account.
- Utilize the Recertification Worksheet to help gather this information ahead of time.
- Complete all required EZIZ lessons found on the EZIZ website.
- Annual VFC recertification was due on January 27th, 2017
# 2017 VFC Recertification Worksheet

Use this worksheet to gather information needed ahead of time to complete the online VFC Recertification Form on MyVFCvaccines.org.

**DO NOT SUBMIT THIS WORKSHEET TO THE VFC PROGRAM.**

<table>
<thead>
<tr>
<th>Practice Information/Shipping</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Practice Name</td>
<td>Contact Person</td>
</tr>
<tr>
<td>Practice Information/Shipping Address (No P.O. Box)</td>
<td>County</td>
</tr>
<tr>
<td>Shipping Address, Part 2</td>
<td>City</td>
</tr>
<tr>
<td>Employer Identification Number (EIN)</td>
<td>Phone</td>
</tr>
<tr>
<td>National Provider Identifier (NPI)</td>
<td>CHDP Provider?</td>
</tr>
<tr>
<td>Would you like to be on the VFC online locator?</td>
<td>Yes</td>
</tr>
</tbody>
</table>

**DELIVERY:** Check all days and times you may receive vaccine. If closed during lunch hour, please specify.

- **Tuesday:** From: __________ To: __________ (Closed for lunch from: __________ to: __________)
- **Wednesday:** From: __________ To: __________ (Closed for lunch from: __________ to: __________)
- **Thursday:** From: __________ To: __________ (Closed for lunch from: __________ to: __________)
- **Friday:** From: __________ To: __________ (Closed for lunch from: __________ to: __________)
Consequences for not completing Annual Recertification

• To date, not all providers have completed annual recertification
• May affect a provider’s ability to order vaccine
• No vaccine = not able to vaccinate our kids
COLD CHAIN AND VACCINE MANAGEMENT
What is the ‘Cold Chain’?

- The vaccine cold chain is a temperature-controlled environment used to maintain and distribute vaccines in optimal condition.
- Monitor the temperature of your storage unit(s) regularly to assure that appropriate conditions are maintained.
- Take immediate corrective action when a storage unit temperature is outside the recommended range.
- If you are a VFC provider or have other vaccines purchased with public funds, contact your immunization program.
What is the ‘Cold Chain’?

• Vaccine appearance is NOT a reliable indicator that vaccines have been stored under appropriate conditions.

• Vaccine exposed to inappropriate temperatures that is inadvertently administered generally should be repeated. Contact your immunization program, vaccine manufacturer(s), or both for guidance.
Cold Chain Flow Chart

Manufacturer/Distributor Responsibility

Provider's Responsibility

Vaccine

Manufacturer

Distribution

Arrival at Provider Facility

S & H at Provider Facility

Administration

California Department of Public Health, Immunization Branch
Vaccine Potency

• What affects vaccine potency:
  - Light
  - Heat
  - Cold

• Once potency is lost, it cannot be restored.
• Each time vaccines are exposed to improper conditions, potency is reduced further.
• Eventually, if the cold chain is not properly maintained, potency will be lost, and the vaccines become useless.
Required Vaccine Storage Temperatures

**REFRIGERATOR**
- 35° - 46°F (2° - 8°C)
- Aim for 40°F

**FREEZER**
- Varicella, MMR, MMRV, Zostavax
- + 5°F (-15°C) or colder
- Aim for below 0°F

32°F is freezing
Effect of temperature on vaccines

**INACTIVATED AND TOXOID VACCINES**

- **Too cold (freezing 32°F. or below)**
  - Damage happens quickly
  - **Adjuvanted** – Adjuvants enhance immune response to an antigen.
    - Antigen and adjuvant bond is immediately and irreversibly broken; adjuvant effect is lost.
    - Examples: *Hep A*, *Hep B*, *diphtheria-tetanus-pertussis (DTaP, Tdap)*, *Hib*, *HPV*, *Pneumococcal*
  - Non-adjuvanted (IPV, Flu)- denaturing protein, structural damage

- **Too warm (above 35°- 46°F)**
  - Damage is gradual
  - Vaccine manufacturers have conducted numerous stability studies, but most of the studies only show data to support vaccine viability when stored above the recommended temperature for up to 72 hours

Source: Morbidity and Mortality Weekly Report: *Notice to Readers: Guidelines for Maintaining and Managing the Vaccine Cold Chain*; October 24, 2003 / 52(42);1023-1025
Effect of temperature on vaccines

**LIVE VACCINES**

- **Freezing 5°F. or below**
  - Lyophilized is freeze dried - undiluted,
  - Lyophilized vaccines cannot be damaged by freezing
  - **Caution:** **DO NOT FREEZE DILUENT**

- **Too warm (above 5°F.)**
  - Damage is rapid or “quick”
  - [Varicella](#) – does not tolerate any heat
  - [MMR](#) also heat sensitive (store between - 58°F to 46°F). Although stable in either the refrigerator or freezer, we recommended to store in freezer.
STORE PRODUCT IMMEDIATELY
Please store product according to product package and Prescribing Information.

REPLACEMENT
If received more than 1 day after the shipment date, contact the MERCK Order Management Center immediately for replacement instructions at 1-800-MERCK-RX (1-800-637-2579). Requests for replacement must be received by Merck within 15 days of the original shipment date.

SHIPPING TIME
Proper temperatures will be maintained 1 day from the shipment date shown on the enclosed packing slip.

STORE PRODUCT IMMEDIATELY
Please store product according to product package.

FROZEN PRODUCT
Store between -58°F and 5°F (-50°C to -15°C).

REFRIGERATED PRODUCT
Store between 36°F and 46°F (2°C to 8°C).

REPLACEMENT
If received after the specified date, contact the MERCK Order Management Center immediately for replacement instructions at 1-800-MERCK-RX (1-800-637-2579). Requests for replacement must be received by Merck within 15 days of the original shipment.

STORE PRODUCT IMMEDIATELY
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REFRIGERATED PRODUCT
Store between 36°F and 46°F (2°C to 8°C).

REPLACEMENT
If received after the specified date, contact the MERCK Order Management Center immediately for replacement instructions at 1-800-MERCK-RX (1-800-637-2579). Requests for replacement must be received by Merck within 15 days of the original shipment.

SHIPPING TIME
Proper temperatures will be maintained 2 days from the shipment date shown on the enclosed packing slip.

STORE PRODUCT IMMEDIATELY
Please store product according to product package.

FROZEN PRODUCT
Store between -58°F and 5°F (-50°C to -15°C).

REFRIGERATED PRODUCT
Store between 36°F and 46°F (2°C to 8°C).

REPLACEMENT
If received after the specified date, contact the MERCK Order Management Center immediately for replacement instructions at 1-800-MERCK-RX (1-800-637-2579). Requests for replacement must be received by Merck within 15 days of the original shipment.

SHIPPING TIME
Proper temperatures will be maintained 4 days from the shipment date shown on the enclosed packing slip.
Temperature Monitoring

- Temperatures for each unit must be read and documented *twice each workday*, at the beginning and end of each day.

- Additionally, minimum and maximum temperatures must also be read *and documented* at the beginning of each workday.

- Thermometer temperatures must be cleared after each daily MIN/MAX readings.

- Temperatures must be recorded on VFC-provided temperature logs, even if using a continuous temperature-recording device or digital data logger.
Temperature Monitoring

- Temperature logs must be posted in a visible location.
- Temperature logs must be maintained for three years.
- Temperature logs are available through the VFC Program: [www.eziz.org](http://www.eziz.org)
  - Use these logs to document *Current, Minimum and Maximum readings*
- Temperature logs can also be obtained through the San Bernardino County Immunization Program
VFC Temperature Logs
No change since January 2016
How To Record Refrigerator and Freezer Temperatures °F

If your thermometer looks different, refer to the product guide. For data loggers, refer to additional instructions at EZIZ.org/assets/docs/IMM-1206.pdf.

**Before you start**

Fill out the page header:

- **Month/Year** (Days 1-15)
- Refrigerator Location/ID
- VFC PIN

**January 2016**

**Injection Room**

**01245**

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1. **Record time and your initials next to the day of the month:**
   - **a.m.** temperatures **before** opening the refrigerator or freezer.
   - **p.m.** temperatures about an hour before the office closes to allow time for corrective actions.

<table>
<thead>
<tr>
<th>Day</th>
<th>Time</th>
<th>Initials</th>
<th>Refrigerator</th>
<th>Freezer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>8:00 a.m.</td>
<td>NN</td>
<td>54°F</td>
<td>15°F</td>
</tr>
<tr>
<td></td>
<td>4:00 p.m.</td>
<td>NN</td>
<td>47°F</td>
<td>8°F</td>
</tr>
</tbody>
</table>

**Refrigerator Temperature Log**

**Too Warm!**

- 54°F & warmer
- 53°F
- 52°F
- 51°F
- 50°F
- 49°F
- 48°F
- 47°F
- 46.1°F

**OK**

- 46.0°F
- 45°F
- 44°F
- 43°F
- 42°F

**Too Warm!**

- 16°F & warmer
- 15°F
- 14°F
- 13°F
- 12°F
- 11°F
- 10°F
- 9°F
- 8°F
- 7°F
- 6°F
- 5°F

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California Department of Public Health, Immunization Branch
**NEW:**

Record a check mark if you see or hear an alarm. If the alarm was not triggered, leave blank.

![Image of a temperature monitor with an alarm activated]

**A.** Record **CURRENT**, **MIN**, and **MAX** temperatures neatly, accurately, and in the correct columns.

<table>
<thead>
<tr>
<th>CURRENT</th>
<th>MIN</th>
<th>MAX</th>
</tr>
</thead>
<tbody>
<tr>
<td>37.4</td>
<td>33.0</td>
<td>39.2</td>
</tr>
</tbody>
</table>

Data loggers: If alarm was triggered, record MIN and MAX temperatures from downloaded data.

**B.** Circle **ALL** temperatures that are **TOO WARM** or **TOO COLD**.

- Refer to the colored ranges on the log.
- All temperatures must be in the OK range. If not, there is a problem.

The **MIN** is **TOO COLD** even though **CURRENT** and **MAX** are OK!

CONTINUED ON PAGE 2.
How To Record Refrigerator and Freezer Temperatures °F (contd.)

4. Take action for one of the colored temperature ranges.

MIN & MAX are OK.

A. Press MEMORY CLEAR/RESET buttons on thermometer after every recording.
Confirm MIN and MAX now match the CURRENT temperature.

(Skip this step if your data logger has an automatic reset.)

B. Make sure the refrigerator or freezer door is shut.
Done.
A & B. Same as above.

C. Post sign on refrigerator or freezer. Do not use vaccines unless advised by manufacturers or MyVFCvaccines.

D. Alert your supervisor.

E. NEW:

Report ALL excursions at MyVFCvaccines.org.

- Fill out details about the temperature excursion.
- If you do not have internet access, call the VFC Call Center at 1-877-243-8832.

On-site Supervisor Review

- Review completed logs at the end of each two-week period to make sure all temperatures were properly recorded and excursions circled.
- Print and attach excursion reports for all circled temperatures.
- Certify the log by writing your full name, signature, and the date.
- Record the names and initials for all staff that recorded temperatures on the log.
- Keep temperature logs for 3 years.

If the alarm is triggered before the end of the day, follow steps 1-4 immediately.
CONSEQUENCES OF IMPROPER VACCINE STORAGE
"Storage Errors Cause Thousands to Be Vaccinated Again"

Associated Press (01/21/05)

“... Almost 3,900 people in Tennessee's Jefferson and Fayette counties must receive new vaccinations against influenza, hepatitis B, polio, pertussis, diphtheria, tetanus, and pneumonia after storage errors resulted in ineffective vaccines. East Tennessee regional director for the state Department of Health Dr. Paul Erwin says that the vaccinations were stored below freezing for a period of time when they were not supposed to be stored that way. Erwin notes that the ineffective vaccines are not dangerous, and patients requiring new vaccinations are being notified via certified mail...”
Things to consider...

- How many patients do you immunize each day, week, month, or year?
- What if you had to recall all those patients that were immunized with non-viable vaccines?
- How will you explain to parents why their children must repeat the vaccine doses?
- Will your patients maintain their trust in you that you are providing quality care?
- Consider the costs, staff resources and patient time involved with having to revaccinate
- Avoid a situation like this and **TAKE ACTION RIGHT AWAY** if you notice out-of-range temperatures!
Storage and Handling Problem Protocol

• Notify your facility manager

• New online storage and handling problem reporting system called: S.H.O.T.S.

• Mark the affected vaccines as “DO NOT USE UNTIL FURTHER NOTICE”

• Store the vaccines in a properly working refrigerator or freezer while waiting for resolution

• Do NOT use the vaccine until its efficacy has been determined
CAIR2

Bigger, Better, Faster!

Steven Vantine
Educational Consultant
CA State Department of Public Health
Division Of Communicable Diseases
Immunization Branch

Version: 012417sjv
Agenda

- Software updates
- Training updates
- New timeline
Software Updates
Software Updates:

• All Phase Users:
  – We have good news!
  – Most problems identified in CAIR2 with the ACIP recommendations have been fixed!
  – An update to the software was released on March 20th, 2017
Software Updates:

- The following issues should be resolved:
  - Vaccines Recommended should show accurate dates for routine immunizations (based on the ACIP schedule and doses given).
  - Patients’ Immunization Histories should only mark doses as “NOT VALID” if dates conflict with ACIP recommendations.
  - The Yellow Card should show all valid vaccines.
  - Missing patients and doses have been migrated to CAIR2.
Software Updates:

• We apologize for the difficulties you have faced
• Our medical experts have carefully reviewed the many details of the ACIP schedule and hundreds of test cases have been run to check recommendations for all vaccines.
• We still need your help to further validate the system once the updates go live.
Training Updates
Training Updates:

• All existing active CAIR1 users should have already received training for CAIR2.
• Existing user training ended Friday, April 21st
• New users need to sign-up for trainings being offered in May 2017
• Trainings are filling up fast.
Training Updates:

• New users will need to have their supervisors request an account for them in the “Account Update” when it opens after the launch.
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WHY WE DO WHAT WE DO . . .
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