Questions and Answers from the June 12, 2014 Webinar
Vaccines for Children (VFC) Program
Storage and Handling Update

VFC Vaccine Storage Units

Q1: We have a combination refrigerator/freezer unit but only use the refrigerator portion for vaccines. We do not use the freezer other than to store ice packs. Is this still okay? We have a separate stand-alone small freezer instead.

A1: You may continue to use the refrigerator section of a combination unit as long as the refrigerator is functioning properly and maintains temperatures between 35° Fahrenheit and 46° Fahrenheit (2° to 8° Celsius) and the freezer section is not in use. No vaccines should be stored in the freezer.

Q2: You stated that it was acceptable to use a household combination unit as long as it was functioning properly but the next slide showed a picture of a household combination unit that said freezer use for vaccine storage was not acceptable. Do providers now need to purchase a stand-alone freezer no matter what?

A2: Effective January 1, 2015, all New York State (NYS) VFC providers purchasing new refrigerators or freezers to store VFC vaccine are required to purchase stand-alone storage units. Providers who currently use household combination units may continue to do so as long as those units continue to function properly. The freezer must be able to maintain temperatures at or below 5° Fahrenheit (-15° Celsius) and the refrigerator must be able to maintain temperatures consistently between 35° and 46° Fahrenheit (2° to 8° Celsius).

Q3: Will providers purchasing new units next year be able to purchase "medical" grade combination refrigerator/freezer units?

A3: If you mean a combination self-defrosting unit with two separate compressors, a thermostat control for each compartment, and no circulating air between the freezer and refrigerator compartments, yes, it will be allowed but this type of unit is uncommon. When selecting a storage unit for purchase please ensure the unit specifications meet NYS Department of Health (NYSDOH) VFC Program and the Centers for Disease Control and Prevention (CDC) VFC requirements. Do not rely on terms such as "medical" or marketing statements that indicate the unit is for vaccine storage**;** not all units making these claims meet VFC requirements. CDC recommends stand-alone units that either refrigerate or freeze or pharmaceutical/purpose-built units. These units can vary in size from compact under-the-counter style to large, stand-alone units. For more information regarding purchasing the required storage units for VFC vaccine, please see Q&A8 or contact the NYS Department of Health (NYSDOH) VFC Program at 1-800-KID-SHOT (1-800-543-7468) or email nyvfc@health.state.ny.us.

Q4: If a freezer is self-defrosting, won't the temperature go out of range during the defrost cycle? What should a practice do if the temperature is regularly going out of range for short periods of time due to the defrost cycle?

A4: Data collected from the NYSDOH digital data logger pilot program indicate that the majority of frost-free stand-alone freezers and a minority of household combination unit freezers can maintain temperatures under 5° Fahrenheit (-15° Celsius) during the defrost cycle. However, temperatures do cycle out of range in the majority of household combination units. This is particularly true of household combination units with a single thermostat control. The inability of most household combination units to maintain proper temperatures at all times in both the freezer and refrigerator compartments is what prompted the change in storage unit recommendations. Without the use of a continuous temperature monitor it is impossible to track these deviations in temperature, thus we recommend practices who are concerned about defrost cycles purchase a frost-free, stand-alone freezer.

Q5: Can we use the cool packs/freezer packs that come with vaccine deliveries in lieu of water bottles in refrigerator units to maintain temperature stability?

A5: The NYSDOH VFC Program follows the CDC's best practice for vaccine storage; to place filled water bottles in the refrigerator and frozen coolant packs in the freezer when storing VFC vaccine. The addition of water bottles in the refrigerator (not coolant packs) reduces the risk of freezing due to the significant latent heat released from water prior to freezing.

Q6: Are there any plans for NYSDOH VFC Program to offer grant money to practices for the purchase of stand-alone refrigerators/freezers?

A6: No, the NYSDOH VFC Program does not have funding to offer grants to purchase stand-alone storage units for VFC providers.

Q7: How will NYSDOH enforce the purchase of new units by providers?

A7: NYS VFC providers who are asked to purchase new storage units after January 1, 2015 will be required to send the invoice to NYSDOH VFC Program. If it is found that the new unit does not comply with VFC requirements, the provider will not be able to order vaccine until they can demonstrate that they have obtained a unit that complies with VFC requirements. Providers are encouraged to check with VFC Program staff prior to purchasing a new storage unit if they have questions about whether the unit complies with VFC requirements.

Q8: What is the estimated cost for a stand-alone refrigerator and freezer that meets NYSDOH VFC provider requirements and has the best outcome?

A8: NYSDOH cannot endorse or recommend specific products or brands. The information below is only meant to aid you in your selection of vaccine storage equipment. The terms and conditions related to your purchase are between you and the vendor. Before making your final decision, please contact the manufacturer/vendor for up-to-date pricing and specifications.

Acceptable Vaccine Storage Unit Types

- Stand-alone refrigerator units – **Strongly recommended**
- Stand-alone freezer units – **Strongly recommended**

- Stand-alone, compact, under-the-counter household refrigerator and freezer units are an excellent option for low-volume providers and can cost anywhere from $200 - $600 per unit.
- Stand-alone, "freezerless" commercial refrigerator units are an excellent option for medium to high volume providers and can cost between $500 and $6000.
- Stand-alone, pharmaceutical refrigerator and freezer units are considered the gold standard for vaccine storage as they are the most secure and provide the best temperature stability. These units are an excellent option for medium to very high volume providers and can cost between $3000 and $9000.

- Household combination refrigerator/freezer unit with two doors and two thermostat controls, where only the refrigerator compartment is being used for vaccine storage.
  - Household combination units are an acceptable option for low to medium volume providers and can cost anywhere between $400 and $4000. However, household combination units **may only be used for the storage of refrigerated vaccine**, with the use of a separate stand-alone freezer for frozen vaccine
- Household combination refrigerator/freezer unit with two doors and one thermostat control, where only the refrigerator compartment is being used for vaccine storage
- Commercial combination self-defrosting unit with two separate compressors, a thermostat control for each compartment, and no circulating air between the freezer and refrigerator compartments (these are uncommon).

Note: The refrigerator must be able to maintain temperatures consistently between 35° and 46° Fahrenheit (2° to 8° Celsius). The freezer must be able to maintain temperatures at or below 5° Fahrenheit (-15° Celsius). Both units must be large enough to hold the year's largest inventory without overcrowding (e.g. back to school and flu season).
Never Allowed: Dormitory style (small, single-door combination refrigerator/freezer units).

Biologic Storage Unit Manufacturers

Aegis	http://www.aegisfridge.com/
American Biotech Supply	http://americanbiotechsupply.com/find-a-dealer
Compact Appliance	http://www.compactappliance.com/on/demandware.store/Sites-Appliance-Site/default/Search-Show?q=american+biotech
Fisher Scientific	http://www.fishersci.com/
Follett	http://www.follettice.com
Helmer	http://www.helmerinc.com/
Lab Research Products	http://www.labresprod.com/
Living Direct	http://www.livingdirect.com/on/demandware.store/Sites-LD-Site/default/Search-Show?q=american%20biotech%20supply
Migali Scientific Refrigeration	http://migaliscientific.com/
Sanyo Biomedical	http://us.sanyo.com/biomedical
Sun Frost	http://www.sunfrost.com/
Thermo Scientific	http://www.thermo.com/

For more information, see https://www2.aap.org/immunization/pediatricians/pdf/VaccineStorageRF.pd
http://www.cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf

Calibrating Thermometers

Q9: How can we locate a local/regional vendor who will come on-site to calibrate our temperature monitoring system?

A9: To identify a local vendor to calibrate your temperature monitoring device, contact the distributor or manufacturer of the instrument, one of the following accredited laboratories, or your local NYSDOH Regional Representative. **Note**: Effective January 1, 2015, providers enrolled in the VFC program will also be required to have at least one back-up temperature monitoring device with a current certificate of calibration in case of equipment failure or calibration testing of the current equipment. NYSDOH Vaccine Program recommends the back-up temperature monitoring device be stored outside of the storage unit until needed, and the calibration date for the backup device be different than the one in use.

Accredited Laboratories

The American Association for Laboratory Accreditation (A2LA)	http://www.a2la.org/dirsearchnew/rch.cfm
Laboratory Accreditation Bureau (L-A-B)	http://www.l-a-b.com/content/directory-accredited-labs
ANSI-ASQ National Accreditation Board (ACLASS)	http://www.aclasscorp.com/search-accredited-companies.aspx
International Accreditation Service (IAS)	http://www.iasonline.org/Calibration_Laboratories/CL.html
Perry Johnson Laboratory Accreditation, Inc. (PJLA)	http://www.pjlabs.com/search-accredited-labs

A listing of signatory bodies outside of the U.S. can be found on the ILAC website: **https://www.ilac.org/members_contact_details.html.** This listing of accredited laboratories was taken from the CDC's Vaccine Storage and Handling Toolkit, page 38.

Digital Data Loggers

Q10: Is NYSDOH VFC Program requiring providers to use a digital data logger for monitoring temperatures of VFC vaccine storage units? Or are calibrated thermometers still OK to use?

A10: Digital data loggers are not currently required in NYS, but they are strongly recommended by the CDC. Health care providers enrolled in the NYSDOH VFC Vaccine Program are required to use a calibrated temperature monitoring device with a current Certificate of Traceability and Calibration Testing (also known as Report of Calibration) in each refrigerator or freezer used to store VFC vaccine and to manually document the temperature of the units twice a day.

Q11: Have you changed your policy regarding use of data loggers? Are we still required to keep paper temperature logs or log into the New York State Immunization Information System (NYSIIS) and record what we observed on the thermometer even though we have a digital data logger?

A11: The policy regarding the use of data loggers remains the same; data loggers do not replace the manual twice daily refrigerator and freezer temperature checks and the documentation of the temperatures, date, time, and person checking the temperature on paper (and in the NYSIIS

Temperature Log effective January 1, 2015). The purpose of documenting the twice daily temperatures when a data logger is in use is to ensure someone physically checks the temperature and does not rely on equipment that could possibly malfunction. For more information on thermometer requirements and recommendations, please visit: www.health.ny.gov/prevention/immunization/docs/2013_therm_guide_for_sandh.pdf.

Q12: What is the estimated cost of a data logger that has the best outcome?

A12: Data logger prices can range from $50 to thousands of dollars. These range from data loggers that must be manually connected to a computer to a fully integrated system that monitors temperatures in multiple storage units across multiple office locations. NYSDOH cannot endorse or recommend specific products or brands. The information below is only meant to aid you in your selection of temperature monitoring equipment. The terms and conditions related to your purchase are between you and the vendor. Before making your final decision, please contact the manufacturer/vendor for up-to-date pricing and specifications, including their process for thermometer recalibration. Staff should be properly trained and understand how to set up, read, and analyze temperature data provided by a data logger. CDC's recommendations for data logger functionality include:

- Digital display on outside of storage unit to allow reading temperatures without opening unit door
- A display that shows current temperature, as well as the minimum and maximum temperatures, which indicate the coldest and warmest temperatures recorded since device was reset
- Audible High/Low alarm for out-of-range temperatures (that can be reset)
- Reset button to clear minimum and maximum temperatures when a reading has been taken
- Low battery indicator
- Accuracy of +/- 1° F (+/- 0.5° C)
- Memory storage of at least 4,000 readings; the device should not rewrite over old data and should stop when memory is full
- Detachable probe in a bottle filled with a thermal buffer, like glycol, which more closely reflects vaccine temperatures temperature
- User programmable logging interval or reading rate of 15 minutes or less.

Data Logger Manufacturers and Vendors

Accsense	www.accsense.com/p_p_a102.html
Control Solutions Inc.	www.vfcdataloggers.com
Dickson	www.dicksondata.com/products/find/data-logger
Lascar Electronics	www.lascarelectronics.com/data-logger/
Onset (Hobo)	www.onsetcomp.com/
Temperature@lert	hwww.temperaturealert.com/Temperature-Alarm.aspx
Temperature Guard	http://temperatureguard.com/
T&D Corporation	www.tandd.com/#fragment-1
Tip Temperature Products	www.tiptemp.com

Alarm Phone-Dialer Manufacturers

Dickson	**www.dicksondata.com/**
Sensaphone	**www.sensaphone.com**
Temperature@lert	**www.temperaturealert.com/Temperature-Alarm.aspx**
Temperature Guard	**http://temperatureguard.com/**
United Security Products	**www.unitedsecurity.com/**

For more information, please see http://www2.aap.org/immunization/pediatricians/pdf/DataLoggers.pdf
http://www.cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf

VFC Vaccine Storage Unit Temperatures

Q13: Is there any reason to keep the paper temperature logs if we enter the information on the log in NYSIIS? Also, can the NYSIIS system see this log or do we have to fax to NYSIIS?

A13: All NYS VFC vaccine providers are required to keep a temperature log of their twice daily (when the clinic opens and when the clinic closes for the day) refrigerator and freezer temperatures for a minimum of three (3) years; either electronic or paper, or a combination. If you have entered all temperatures on your paper log in NYSIIS, you do not need to keep the corresponding paper log, and you do not need to fax the log to the NYSDOH. Paper logs for temperatures that were not entered into NYSIIS will need to be kept for the required three year period.

Q14: When can we start entering refrigerator and freezer temperatures into NYSIIS for our VFC vaccine?

A14: You may begin to use NYSIIS for reporting VFC vaccine storage unit temperatures at any time. NYS VFC providers will be required to use NYSIIS for reporting VFC vaccine storage unit temperatures effective January 1, 2015. Two training webinars are available. "Entering VFC Temperature Logs in NYSIIS" and "NYSIIS Temperature Log Reports" can be found on the NYSDOH Immunization Update Webinar Series page located at http://www.health.ny.gov/prevention/immunization/providers/webinar_series.htm

Q15: Am I supposed to be reporting "min" and "max" temperatures in NYSIIS or just the twice-a-day current temperature?

A15: Currently, the NYS VFC Program does not require you to report the minimum and maximum (min/max) temperatures in the NYSIIS Temperature Log. However, the CDC recommends checking the min/max temperatures daily, preferably in the morning, along with the current temperatures and to reset the min/max temperatures after checking them. If you have the capability of checking the min/max temperature it is a good guide to let you know if there are problems in your storage unit outside of your twice daily temperature check. NYS VFC Program recommends checking and resetting min/max temperature twice a day along with the current temperature.

Placement of VFC Vaccine in a Refrigerator

Q16: Is the recommendation for not using the top shelf of the refrigerator just for VFC vaccines or private vaccines as well?

A16: All recommendations made by CDC and NYSDOH Vaccine Program regarding the storage and handling of vaccines are considered best practices for the storage of both your publically and privately purchased vaccines. Vaccine should not be placed directly under cold air vents. Because cold air vents are most commonly found near the top shelf and back of the refrigerator or freezer, it is recommended that vaccines are not placed on the top shelf. In addition, in the event of a power outage, the top shelf becomes warmer first.

Q17: Do VFC vaccines have to be in their own refrigerator or freezer? Or can a provider store vaccine purchased privately in the same storage unit with VFC vaccine as long as they are clearly labeled "VFC" and "Private" and in separate containers?

A17: A provider may store vaccine purchased privately in the same storage unit with VFC vaccine as long as they are clearly labeled "VFC" and "Private" and clearly separate from each other (on separate shelves and in separate baskets).

Preventing Temperature Excursions

Q18: What are your guidelines for how to deal with temperature loss due to having to open the refrigerator to monitor inventory? Presumably, we have to take the vaccine out of the refrigerator, look at expiration dates, and then put them back. If we take the vaccine out of the refrigerator and put on counter, then shut the refrigerator to keep it cold, how long can the vaccine sit on the counter? Should we open and shut the refrigerator multiple times to take out and put back multiple vaccines to check expiration dates?

A18: All NYS VFC Program vaccine providers must have a Vaccine Storage and Handling Plan. The plan includes required storage and handling best practices, however, providers should have an individualized standard operating procedure (SOP) for the activities in the plan. To assist you with creating a SOP for performing your monthly inventory, the California Department of Public Health created a one page guide "How to Do a Physical Inventory" that may be used as a template. To view or download the documents, please visit http://eziz.org/assets/docs/IMM-1090.pdf.

In addition, incorporating the "Vaccine Refrigerator Set-Up," and "Vaccine Freezer Set-Up," one page guides on how to organize your vaccine in the refrigerator and freezer into your SOP should make your monthly inventory procedure more efficient. To view or download the documents, please visit http://eziz.org/assets/docs/IMM-963.pdf and http://eziz.org/assets/docs/IMM-966.pdf.