Hello and welcome.

This training is intended to provide guidance to NYS Vaccines for Children (VFC) providers on purchasing vaccine storage units.
Providers enrolling for the first time in the NYS VFC Program are required to use stand-alone refrigerator and freezer units to store publicly purchased vaccine. Any new unit purchases made by current VFC providers must be standalone units. Standalone units are self-contained units dedicated to a single temperature range, as either a refrigerator OR a freezer.

Providers enrolled and using combination, household-style, or dual zone refrigerator/freezer units prior to January 1, 2015, may continue to use these units as long as they consistently maintain temperatures within acceptable ranges.

Household-style combination units share a single compressor, which means that air is exchanged between the two units. Studies have shown that household units are not effective at maintaining temperatures for vaccine storage, especially when both compartments are used simultaneously.

Combination, self-defrosting refrigerator/freezer units with two separate compressors, two thermostat controls and no air circulating between the two compartments are also allowable for providers who were enrolled in the VFC program and using prior to January 1, 2015.

All providers who are currently enrolled in the VFC program and need to replace failing storage units or make any new purchases of any kind must purchase standalone units.
Vaccine Storage Units: Required Features

- Large enough to hold year’s largest inventory and water bottles without overcrowding (e.g. back to school and flu season)
- Ability to maintain temperatures between acceptable ranges*

In terms of required features of storage units, the units must:

Be large enough to hold the practice’s largest annual inventory and water bottles without overcrowding. Consider back to school and flu season.

The unit also must have the ability to maintain temperatures within acceptable ranges.

The acceptable temperature ranges are between 36° Fahrenheit and 46° Fahrenheit (or between 2°C and 8°C) in the refrigerator and between -58° Fahrenheit and +5° Fahrenheit (or between -50°C and -15°C) in the freezer.
Unacceptable Vaccine Storage Unit Types

• Dormitory-style units
  – small, single-door combination refrigerator/freezer units)
  – incapable of maintaining appropriate temperatures
  – Not allowed by VFC Program

Dormitory-style units are never allowed for the storage of VFC vaccine. A dormitory-style refrigerator/freezer is defined as a small combination refrigerator/freezer unit that is outfitted with one exterior door and an evaporator plate (cooling coil), which is usually located inside an icemaker compartment (freezer) within the refrigerator.

The freezer compartment in this type of unit is incapable of maintaining temperatures cold enough to store frozen vaccine. Additionally, the refrigerated compartment in this type of unit can subject vaccine to freezing temperatures.

These types of units are incapable of storing any vaccine at an appropriate temperature in any part of the unit and are therefore not allowed by the NYS VFC program.
To determine what size vaccine storage unit your practice needs, first determine the maximum number of doses of publicly and privately funded vaccine that will be stored in your refrigerator and freezer, using the formulas in this slide.

You can determine this information from your inventory in the New York State Immunization Information System (NYSIIS), your VFC Provider Profile paperwork and/or the Estimating Patient Population Worksheet included in Training 1 of this series, titled Background and Enrollment.

### Storage Unit Size Assessment: Step 1

<table>
<thead>
<tr>
<th>Refrigerator</th>
<th>Freezer</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Add the number of doses on hand (current inventory)</strong></td>
<td><strong>Add the number of doses on hand (current inventory)</strong></td>
</tr>
<tr>
<td>VFC/CHP/State vaccine</td>
<td>VFC/CHP/State vaccine</td>
</tr>
<tr>
<td>VFC/CHP/State flu vaccine</td>
<td>VFC/CHP/State flu vaccine*</td>
</tr>
<tr>
<td>Private vaccine</td>
<td>Private vaccine</td>
</tr>
<tr>
<td>Private flu vaccine</td>
<td>Private flu vaccine</td>
</tr>
<tr>
<td>Total doses</td>
<td>Total doses</td>
</tr>
<tr>
<td>Total Doses x 1.25 (max inventory)</td>
<td>Total Doses x 1.25 (max inventory)</td>
</tr>
<tr>
<td>Maximum Doses (from line above)</td>
<td>Maximum Doses (from line above)</td>
</tr>
</tbody>
</table>

*No flu vaccine currently stored in freezer*

Formula obtained from the California Department of Public Health's Refrigerator Buying Guide
### Storage Unit Sizes Assessment: Step 2*

<table>
<thead>
<tr>
<th>Volume</th>
<th>Max Doses (Refrigerator)</th>
<th>Minimum Cubic Feet</th>
<th>Types that Meet Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very High</td>
<td>10,000+</td>
<td>Multiple refrigerators needed</td>
<td>Full-size, stand-alone refrigerator units</td>
</tr>
<tr>
<td>High</td>
<td>2,000 – 10,000</td>
<td>May need multiple refrigerators</td>
<td></td>
</tr>
<tr>
<td>Medium – High</td>
<td>1,000 – 2,000</td>
<td>40 cu. ft.</td>
<td></td>
</tr>
<tr>
<td>Medium</td>
<td>901 – 1,000</td>
<td>36 cu. ft.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>701 – 800</td>
<td>17 – 19 cu. ft.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>400 – 700</td>
<td>16.7 cu. ft.</td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td>100 – 399</td>
<td>4.9 – 6.7 cu. ft.</td>
<td>Under-counter, stand-alone refrigerator units</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Volume</th>
<th>Max Doses (Freezer)</th>
<th>Minimum Cubic Feet</th>
<th>Types that Meet Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medium – High</td>
<td>501 – 6,000</td>
<td>7 – 14.9 cu. ft.</td>
<td>Full-size, stand-alone freezer units</td>
</tr>
<tr>
<td>Low</td>
<td>201 – 500</td>
<td>5 – 6.6 cu. ft.</td>
<td>Under-counter, stand-alone freezer units and chest-style freezers</td>
</tr>
<tr>
<td></td>
<td>0 – 200</td>
<td>3.5 – 4.9 cu. ft.</td>
<td>Under-counter, stand-alone freezer units</td>
</tr>
</tbody>
</table>

*Information obtained from the California Department of Public Health’s Refrigerator Buying Guide

Refer to this chart to determine what size/type of storage unit your practice needs based on the volume or maximum doses that were calculated in the previous slide.
Benefits of Using Standalone Units

• Less risk of vaccine loss
  – risk of freezing refrigerated vaccine and/or unintentionally warming frozen vaccine is reduced considerably
• Increased temperature stability
  – reduced fluctuations that can occur due to busy days or large inventory receipt

Why use a standalone unit?

Overall, there is less risk of vaccine loss. Because standalone units are dedicated to maintaining a single temperature range, the risk of freezing refrigerated vaccine and/or unintentionally warming frozen vaccine is reduced considerably.

Another benefit is increased temperature stability. When compared to combination units, standalone units maintain much more consistent temperatures; reducing fluctuations that can occur due to busy days or large inventories being added to the unit.
Standalone Vaccine Storage Units

Standalone units are defined as self-contained units dedicated to a single temperature range, as either a refrigerator OR freezer. Full-size standalone refrigerators and freezers are an appropriate option for medium-to-very-high-volume providers.

Under-counter standalone refrigerators are an acceptable option for low-volume providers. Under-counter standalone freezers can accommodate low to high-volume providers (note that they should have front opening and not top opening doors.

Chest-style standalone freezers can accommodate low to high-volume providers. Chest style freezers typically open from the top of the unit so they cannot be stored under the counter.

Standalone storage units can range in price between $200 to 15,000 per unit, depending on features.
When looking for a storage unit for your vaccine, it is best not to look for labels associated with the value of the product. In other words, a specific grade of unit does not necessarily mean it will meet the needs of your practice.

Different types of grades, from consumer to ‘pharmaceutical’ grade are essentially marketing terms and should not be factored into the decision to purchase a storage unit. Some companies can claim that they offer ‘medical ‘grade’ storage units even if these units are not up to par.
Recommended Features of Standalone Units

- Microprocessor-based temperature control with a digital temperature sensor (thermocouple, Resistance Temperature Detector (RTD), or thermistor)
- Digital temperature display and settings
- Fan-forced air circulation
- Temperature alarms
- Built-in security (i.e. temperature set point security)
- Solid doors
- Automatic or ‘frost free’

When purchasing a standalone unit (either refrigerator or freezer), instead of relying on different marketing terminology, look for these recommended features:

A unit with a microprocessor-based temperature control with a digital temperature sensor (for example, temperature sensor types such as thermocouple, Resistance Temperature Detector (RTD) or thermistor technology).

Another recommended feature of a standalone unit is that it have both a digital temperature display and digital thermostat settings.

Also look for a unit with fan-forced air circulation. This means that fans or multiple cool air vents are present inside the unit to promote temperature uniformity and fast temperature recovery.

It’s beneficial if a unit has built-in temperature alarms to alert your practice to any excursions after hours.

Also look for a unit with built-in security features such as, temperature set point security. Some units offer the ability to have a key-operated master switch that controls the power and/or temperature settings of the unit.

Look for a unit with solid doors, opposed to glass doors, as solid doors provide better temperature maintenance during power outages.

If purchasing a freezer, look for a unit with automatic defrost or a frost-free feature. A unit that is not frost-free will likely need a manual defrost.
### Why go frost-free?

<table>
<thead>
<tr>
<th>Manual Defrost</th>
<th>Automatic Defrost (Frost-free)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Requires back-up unit ($)</td>
<td>• No staff time</td>
</tr>
<tr>
<td>• Can take significant staff time</td>
<td>• Less risk of vaccine being stored under inappropriate conditions</td>
</tr>
<tr>
<td>• Needs to be done regularly and properly</td>
<td></td>
</tr>
</tbody>
</table>

Standalone freezers which require manual defrost (or are not frost-free) are acceptable but are not recommended because of the risks involved with moving vaccines in order to defrost the freezer.

During a manual defrost procedure, vaccines must be moved to a back-up unit that is deemed acceptable for storing of frozen vaccines. This means that providers must essentially have “two” freezers. For low-volume providers, this is an added cost.

The entire process of performing a manual defrost, from start to finish, can take a considerable amount of staff time and may take nurses and office staff away from their main job duties.

If the defrost is not properly done or is not done often enough, the unit may not maintain appropriate temperatures.

A frost-free unit has an automatic defrost cycle which requires no staff time and occurs regularly within the unit to keep ice build-up to a minimum.

Because of this, frost-free units have less risk of vaccine being stored under inappropriate conditions.

Although the price difference between a unit that has automatic defrost and a unit that does not can be significant, the cost is worth it when considering the value of possible vaccine and staff time lost during the procedure.
### Vaccine Storage Units with Built-in or Internal Temperature Monitoring

- Acceptable as long as temperature monitoring:
  1. Meets NYS VFC requirements for data logging and calibration. Refer to separate training or [temperature monitoring device document](#).
  2. Has a display for reading temperatures (preferably located on the outside of the unit).

- If using built-in thermometers and additional type of temperature monitoring, may be slight difference in temperature due to:
  1. Probe type (air vs. thermal buffer)
  2. Probe location (side of wall, back of unit, center)
  3. Temperature sensor type (thermistor, thermocouple)

Some vaccine storage units may come with a calibrated temperature monitoring device that is built into the unit.

These units are considered acceptable as meeting both the storage unit and temperature monitoring device requirement, as long as the temperature monitoring device meets the NYS VFC program’s criteria for data logging and calibration and there is a display for reading temperatures. It is preferable if the display is located on the outside of the unit.

A separate training is available on temperature monitoring device calibration. You can also refer to the temperature monitoring device guidance document by clicking on the link on this slide.

If you decide to purchase units with built-in temperature monitoring and then use data loggers or an additional type of temperature monitoring device to check temperatures, please note that there may be a 1-2 degree difference in temperature between the two devices. This is related to several factors including:

- probe type (air vs. thermal buffer),
- probe location (side wall of unit, back of unit, center), and
- type of temperature sensor used (for example, thermistor vs. thermocouple).

Temperature readings from probes with thermal buffers are more reliable and should override readings from other devices if there are discrepancies.
Household-Style Combination (Dual-zone) Refrigerator/Freezer Units

- Share a single compressor (cold air is exchanged between refrigerator and freezer)
- Not allowed for purchase of new or replacement units or for new VFC program enrollees
  - Providers enrolled and using prior to 1/1/2015 may continue to use as long as functioning properly

Household-Style (or dual-zone) combination refrigerator/freezer units can be defined as combination units that share a single compressor (i.e. air from the freezer flows into the refrigerator to cool the refrigerator section).

As previously mentioned, Household-Style Combination Refrigerator/Freezer Units are not allowed for the purchase of new or replacement units under NYS VFC program policy or for providers enrolling for the first time after January 1, 2015.

Providers enrolled in the VFC Program and using these types of units prior to January 1, 2015 may continue to use these units as long as they function within acceptable temperature ranges. Providers who are not using these units should click on the red arrow at the bottom right corner of this slide to advance to the remainder of the training.
Household-Style Combination (Dual-zone) Refrigerator/Freezer Units

- Single compressor
- Exchange of air from freezer to fridge
  - Difficult to keep both compartments in range simultaneously
  - Adjustment must be made in both units (e.g. freezer colder → refrigerator warmer)
  - Defrost cycles cause excursions
  - Do not use freezer of consumer combination unit
- Units can behave very differently when
  - Full versus empty
  - Busy versus less busy

Household-style combination or dual zone refrigerator/freezer units have a single compressor which means that there is a constant exchange of air from the freezer compartment to the refrigerator compartment. Often times, it is difficult to keep both compartments of the unit in range at the same time.

This is because cold air from the freezer is blown into the refrigerator compartment to cool the refrigerator. This means that anytime the freezer is set to a colder temperature, the refrigerator compartment must be set to a warmer setting to offset the colder temperatures in the freezer. If the refrigerator cannot made warmer, vaccines stored at the very back of the refrigerator or on the top shelf may be exposed to colder temperatures as they sit under the cold air vent.

Household units also have a defrost cycles which occurs regularly to prevent frost build up on the walls of the freezer unit. The compressor turns off, allowing the freezer to warm up briefly. Defrost cycles may cause both your freezer and your refrigerator to exceed the allowable temperature range.

If using a household, combination unit, it's a best practice to use only the refrigerated compartment and use a separate standalone freezer to store your frozen vaccine. Maintaining the balance of temperatures between the two compartments of a household unit can often be an impossible feat and take up quite a bit of staff time.

Additionally, other factors like large vaccine shipments and busy days can quickly change the behavior of the unit resulting in multiple temperature adjustments to try to keep it in range.
NIST Studies of Household Units

- Poor high packing density and poor performance during busy times of year
  - Pockets of warmer and cooler air form which causes drastic temperature differences across refrigerator unit
    - Study showed one thermometer at top wall of refrigerator recording temp of 8.3°C while glycol-filled vial on top refrigerator shelf recorded 1.5°C
- Freezer compartment of household unit
  - Study showed freezer set at maximum setting still unable to maintain suitable frozen vaccine storage temperatures
  - NIST strongly recommends use of separate stand-alone freezer

The National Institute of Standards and Technology (NIST) studies of household (dual-zone) combination units found that especially during times of high packing density (Busiest Times of Year like flu season), freezer compartments of households units set at maximum (coldest) settings can’t maintain suitable frozen vaccine temperatures. There were pockets of warmer and cooler air which caused drastic temperature differences in the unit.

For example, a thermometer placed in the refrigerator on the top wall measured an air temperature of 8.3 degrees Celsius while a glycol encased probe on the top shelf of that same refrigerator recorded a 1.5 degree Celsius temperature.

Additional NIST studies indicated that many household freezers, even when set to coldest setting, are still unable to maintain suitable frozen vaccine storage temperatures.

Due to these studies, NIST strongly recommends the use of separate stand-alone freezers when using a household, combination unit.
These graphs are raw unpublished data taken from a NYS VFC program voluntary pilot project on continuous temperature monitoring which was conducted in 2013. These graphs further complement the NIST Studies that indicate household-style combination units are not suitable for vaccine storage, especially when both compartments are in use simultaneously.

In each of the graphs, the high alarm thresholds are indicated by the red continuous line running along the top of the graph. In the refrigerator graph, the low alarm threshold is indicated by the green continuous line.

The refrigerator temperatures are displayed in the top graph. The stand alone refrigerator, displayed by the orange line, shows very little fluctuation in temperature when compared to combination unit’s fluctuating temperatures, shown in blue. The combination unit refrigerator also drops too cold on occasion, to temperatures below the recommended 36°F Fahrenheit range.

The freezer temperatures are displayed in the bottom graph. As you can see, the freezer temperatures of the combination unit, shown in blue, not only experience a lot of fluctuation but they also frequently rise above the recommended range of 5°F Fahrenheit which is the maximum allowable temperature for frozen vaccine. The stand-alone freezer unit displayed in green, shows very little fluctuation in temperatures, and ALL temperatures were in acceptable range.
This is a combination consumer/household unit showing what happens to the temperature in the refrigerator over 24 hrs. of “normal” use. You will see that while no temperature excursions (which means temperatures above or below the recommended range for a refrigerator) were found, the temperature fluctuates from 37F to over 45F throughout the day. These fluctuations can be caused by the previously mentioned defrost cycles and by frequent opening of the door to the storage unit as we will show in the next slide.
Data from Consumer Combination Unit Refrigerator Over 24 Hours of More Frequent Use

This graph shows what happens to the temperature of the consumer/household refrigerator when the refrigerator door is opened frequently over a 24 hour period. You can see that the temperature reached almost 49 degrees twice during a single day and fluctuated significantly.
Some consumer/household combination units only have a single thermostat. NYS STRONGLY recommends that these units not be used for the storage of vaccines due to their inability to maintain temperatures in both the refrigerator and the freezer at the same time. The two graphs in this slide show refrigerator and freezer temperatures in a combination unit with a single thermostat unit over a 24 hour period.

As you can see the refrigerator temperatures in the top graph are acceptable, but the freezer temperatures in the bottom graph frequently go out of range. If you were to lower the temperature of the freezer, it may result in freezing temperatures in the refrigerator, considering that the average overall temperature for the refrigerator is only around 37° Fahrenheit.
Additional graphs taken from the pilot project show varying freezer temperatures in two different household combination units. As you can see, both have temperature excursions too warm for frozen vaccines.
Best Practice for Household, Combination Units

- Use refrigerated compartment only and separate standalone freezer for frozen vaccine

If existing equipment is a household, combination refrigerator/freezer unit, the CDC and NYS VFC program strongly recommends using only the refrigerator compartment for refrigerated vaccines and a separate standalone freezer for frozen vaccine.
Key Messages: Selecting Vaccine Storage Units

- Standalone units are required for new unit purchases (refrigerator only or freezer only).
- Purchase an adequate size unit. Look for freezer units with automatic defrost.
- If using household, combination unit, use the refrigerator only and a separate standalone freezer for frozen vaccine.
- Do not use combination units with a single thermostat control.
- Never use dorm-style units. **Dorm-style units are not allowed by the NYS VFC program.**
- Contact NYS VFC Program (1-800-543-7468) or email (nyvfc@health.ny.gov) with any questions **before** purchasing a new unit.

The key messages for this training module are:

Standalone refrigerator and freezer units are considered best practice for vaccine storage as they provide the best temperature stability. This is why standalone units are required for all new unit purchases.

Be sure to purchase a unit that is an adequate size. The unit should be large enough to hold your year's largest supply and water bottles. Use the formulas provided in these slides for assistance. If purchasing a freezer, look for a unit with automatic defrost. Frost-free units have less risk of vaccine being stored under inappropriate conditions.

For those providers enrolled and using household combination units prior to January 1, 2015, we strongly recommend using the refrigerated compartment only and a separate standalone freezer for frozen vaccine.

Do not use household style combination units with one thermostat that controls both the refrigerator and freezer.

Never use dorm-style units for the storage of any vaccine. These are not allowed under NYS VFC program policy.

If you are ever unsure that your storage unit purchase will meet our program requirements, contact the NYS VFC program prior to the purchase.
## Resources

**New York State Vaccines for Children (NYS VFC) Program**
Storage Unit Purchasing Guidance

**Centers for Disease Control and Prevention (CDC)**
Vaccine Storage and Handling Toolkit
[http://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf](http://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf)

**American Academy of Pediatrics (AAP)**
Immunization Resources Storage and Handling Series- Refrigerators, Freezers, and Vaccine Storage

Here is a listing of available resources.
Additional Training for NYS VFC Providers

Next:  NYS VFC Program Training Series #7: Setting Up Vaccine Storage Units

There are a number of additional trainings available.

The next training in this series is #7: Setting Up Vaccine Storage Units.