



**Department  
of Health**

**NYS Vaccines for Children (VFC) Program  
Training Series  
11: Temperature Excursions**

New York State Department of Health  
Bureau of Immunization

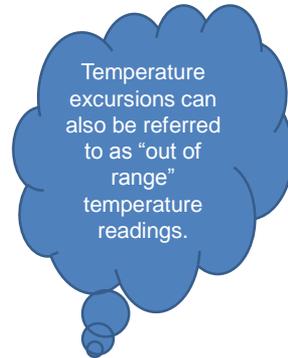
Hello and welcome.

The objective of this training is to provide general guidance to New York State (NYS) Vaccines for Children (VFC) providers on temperature excursions.

Each temperature excursion is a unique event which can be influenced by many different factors. Because of this, it's important to call the NYS VFC Program each time a temperature excursion occurs.

# What Is A Temperature Excursion?

- Temperature Excursion: An event in which vaccine is exposed to temperatures outside of the acceptable range.
  - Acceptable temperature range for refrigerated vaccine is between 36°F and 46°F or between 2° and 8°C. The acceptable temperature range for frozen vaccine is between -58°F and +5°F or between -50°C and -15°C.
- Out of range temperature readings can be current, minimum or maximum temperature readings and can also come from downloaded data logger data.



Whenever vaccine is exposed to temperatures outside of the acceptable range, it's called a temperature excursion, or an "out of range" temperature reading.

- The acceptable temperature range for refrigerated vaccine is between 36 and 46 degrees Fahrenheit (F) or between 2 and 8 degrees Celsius (C).
- The acceptable temperature range for frozen vaccine is between -58 degrees Fahrenheit and +5 degrees Fahrenheit or between -50 degrees Celsius and -15 degrees Celsius.

Remember that this information can also be found on the manufacturer's package inserts included with each vaccine.

Out of range temperature readings can be current, minimum or maximum temperature readings and can also come from downloaded data logger data.

## NYS VFC Program Requirements: Temperature Excursions

1. Report temperature excursions to NYS VFC program within 1 business day (800) 543-1468
  - Record in NYSIIS temperature log
  - Report vaccine lost in NYSIIS
    - Return spoiled vaccine to McKesson, CDC's Centralized Distributor
    - Vaccine lost due to staff negligence or unreported excursions may warrant financial restitution
2. Revaccinate children who were administered non viable vaccine
3. Replace any vaccine storage units that can't maintain acceptable ranges



We'll now talk about the NYS VFC Program requirements related to temperature excursions.

As a general rule, it's always best to take immediate action whenever a temperature excursion occurs. Remember that although you can always contact the NYS VFC Program for guidance anytime a temperature excursion occurs, excursions must be reported to the NYS VFC program within one business day.

Providers must record all out of range temperatures in the New York State Immunization Information System (NYSIIS) temperature log.

Providers are also required to report spoiled vaccine in NYSIIS and return it to McKesson which is the Centers for Disease Control and Prevention or CDC's Centralized Distributor for publicly-funded vaccine.

Excursions caused by staff negligence and any excursions that are not reported may require provider financial restitution.

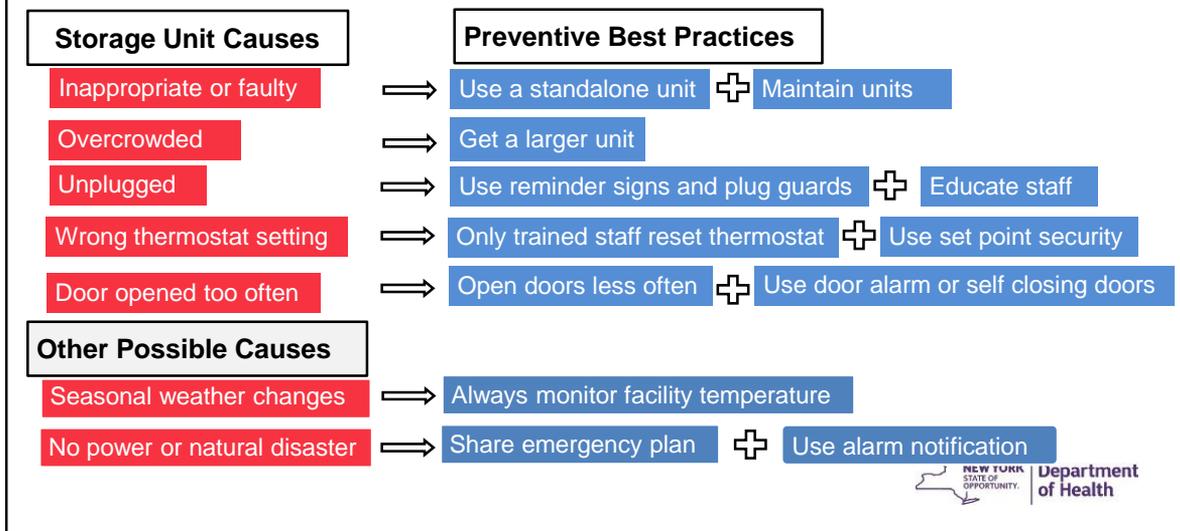
If NYS VFC providers either knowingly or accidentally administer vaccine that was stored out of range and the vaccine is nonviable, they'll be required to revaccinate according to the NYSDOH Bureau of Immunization's clinical recommendations.

The NYS VFC program also requires that VFC providers replace storage units that can't maintain acceptable temperatures, are overcrowded, or otherwise cause vaccine loss.

The next slides give general information on actions to take during different

temperature excursion scenarios.

# Preventing Temperature Excursions



Temperature excursions can occur for a variety of reasons. Here are some possible causes followed by preventive best practices that can be used to reduce the likelihood of a temperature excursion.

- One possible cause is faulty or inappropriate storage unit equipment. To prevent this from happening use standalone refrigerators and freezers only, and be sure to regularly maintain vaccine storage units.
- Another cause of a temperature excursion could be an overstocked or over-packed storage unit. To prevent this from happening make sure that your unit has enough space to store the year's largest inventory, considering school and flu season.
- If a storage unit was accidentally unplugged, this could cause a temperature excursion. Place signs near the outlets where the units are plugged in and on any linked circuit breakers, use plug guards, and be sure to educate staff about not disconnecting power to the units including maintenance and custodial staff.
- To prevent a storage unit thermostat from being incorrectly set, allow only designated staff, such as the vaccine coordinator and backup, to adjust the thermostat. Some storage units come equipped with set point security, in which a key is required to change the thermostat.
- Opening a storage unit door too often or leaving it open could cause temperature excursions. To prevent this from happening, only open storage unit doors when necessary and put a reminder to keep the storage unit door closed on the unit. Some storage units come equipped with door ajar alarms or self-closing doors. If your practice has frequent issues with the door being left open and a large vaccine supply, having a storage unit with this feature may be a worthy investment.
- Also be aware that seasonal temperature variation can inadvertently cause vaccine temperature excursions. Check that the room temperature in your practice is appropriate and adjust the room thermostat as needed.
- Finally, although there's nothing that can be done to prevent power outages or natural disasters, in order to prevent a loss of vaccine during a power outage, have an emergency plan with written procedures that is accessible to all staff. Some continuous temperature monitoring devices come equipped with alarms that will contact staff after hours in the event that an outage or excursion is detected.

# Safeguarding Your Power Supply: Do's and Don'ts

## DO

- Plug vaccine storage unit directly into wall.
- Plug only one unit into an outlet
- Use a plug guard or safety-lock plug
- Label circuit breakers and electrical outlets
- Install a temperature alarm
- Use water bottles in refrigerator and frozen water bottles in freezer
- Perform daily inspection of storage units
- Advise staff (custodial and maintenance) to never disconnect power
- Post warning signs that include emergency contact information

## DON'T

- Plug units into:
  - multi-outlet power strips
  - power outlets with built-in circuit switchers or GFCI's (reset button)
  - power outlets that can be activated by a wall switch



This slide includes recommendations for safeguarding your practice's vaccine storage unit power supply:

- All vaccine storage units should be plugged directly into the wall. If possible, plug only one unit into each outlet and consider using a plug guard or safety-lock plug.
- Label all outlets and circuit breakers with warning signs discouraging a disconnect of power.
- Consider installing a temperature alarm to alert you to temperatures excursions quickly and during off hours.
- Use water bottles in the refrigerator and frozen water bottles in the freezer to help ballast temperatures during power outages.
- Perform a daily inspection of storage units including checking the door seals and the current storage capacity.

As a best practice, educate all staff, including maintenance and custodial staff who may work on weekends or off hours, about never disconnecting the power to the vaccine storage units. Remember to post warning signs that include contact information so that staff will know who to call in the event of an emergency.

In terms of your power supply, it's important not to plug storage units into multi-outlet power strips (also known as surge protectors), power outlets with built-in circuit switches or ground fault circuit interrupter's (GFCI's), which generally have a reset button, or into power outlets that can be activated by a wall switch.

## Temperatures **Warmer** Than 46°F/8°C in Refrigerator\*

Check:

- power supply
- door/door seal
- overcrowding of vaccine
- temperature monitoring device probe
- thermostat setting
- circulation behind the unit, coils
- room temperature
- unit usage



If a refrigerator temperature excursion occurs and temperatures are too warm:

- Check to see whether the unit is still plugged in and connected to a power source. If an outage has occurred, refer to the steps on slide 8 of this training. As a reminder, it helps to label both the wall plug and the circuit breaker to prevent an accidental power disruption.
- Check the unit's door and door seal. If the door was left open, shut the door and recheck the temperatures in one hour.
- Also check the air circulation inside of the unit, making sure the vaccines aren't crowded, and there are no obstructions that could prevent the door from sealing properly. Vaccines and their containers should be stored in the center of the unit at least 2-3 inches away from the walls. If it looks like the unit doesn't have enough space, move some of the vaccine to another unit that can maintain appropriate temperatures and has a temperature monitoring device with a current, valid certificate of calibration testing. If temperatures don't return to normal in the unit which originally held all of the vaccine within 2 hours, it probably isn't large enough. You should then activate your emergency plan, arrange for alternate storage for your vaccine and purchase a larger unit or an additional unit. Remember that only standalone units are allowed for new purchases. To calculate the best storage unit size for your practice, refer to the Storage Unit Purchasing Guidance document. A link is included on the last slide of this training.
- Another area to troubleshoot is the temperature monitoring device probe. Make sure that the probe is connected to the display and that the probe wire hasn't been damaged. If your practice uses a thermal buffering agent, such as glycol, make sure that the probe didn't dislodge from the buffer vial inside of the unit, and that the vial hasn't tipped over. The probe should be positioned centrally in the vial.
- If the temperature hasn't gone back into range within two hours and all other obvious possibilities for the temperature excursion have been exhausted, you can adjust the thermostat to a slightly cooler setting. Keep in mind that some units may not register a thermostat change immediately, so you'll want to monitor closely over the next 24 hours. Don't make any temperature adjustments before leaving for the evening or right before the weekend. Never leave a storage unit unattended if an out of range temperature is observed before closing. Make sure the issue is addressed

- completely and that the temperatures are back in range before leaving the office.
- Look to see that there is enough distance, as specified by the manufacturer, between the storage unit and nearby walls for adequate circulation. Dust and dirt build up on the unit coils and motor can make the unit less efficient. To be safe, check manufacturer instructions before you examine the coils and motor. You may need to unplug the unit first (and store vaccine in another unit that can maintain proper temperature).
  - Know that storage unit temperatures may become elevated right after a new vaccine shipment is loaded into the unit, or during very busy days. Allow the unit time to cool down if temperatures are elevated. If they stay elevated for more than 2 hours and are not declining back into normal range, activate your practice's emergency plan.
  - Increased or decreased unit usage can cause refrigerator temperatures to fluctuate as well. If warmer temperatures are occurring and are sustained, the unit may be experiencing a temporary overload due to increased unit usage. It is important to keep this in mind when evaluating whether to adjust the thermostat.

## Temperatures **Colder** than 36°F/2°C in Refrigerator\*

Check:

- Placement of temperature probe
- Thermostat setting
- Room temperature
- Unit usage/stock



For vaccines stored in refrigerators, temperatures that are colder than 36° F or 2°C are cause for immediate attention. Refrigerated vaccine that is exposed to colder temperatures can lose potency much faster than refrigerated vaccine that is exposed to too warm temperatures.

As already noted, temperature probes that are not properly inserted into their buffers can cause erratic and often incorrect temperature readings, so make sure that the probe tip is in the thermal buffer and that the buffer vial hasn't tipped over. The probe should be centrally placed, close to the vaccine but away from storage unit doors, walls, and vents. It shouldn't be on the top shelf or floor of the storage unit.

Is the thermostat set on a setting that is too cold? If so, make only a small adjustment to a warmer setting. Refer to the product/owner's manual for instructions on operating your unit's thermostat. Remember that units don't always show temperature changes right away, and it's important to make adjustments only when it will be possible to closely monitor the unit for the next 24 hours.

Other factors that can cause abnormal temperatures drops, are colder than normal room temperatures, decreased unit usage, and the amount of stock inside of the unit. Often, more than one factor is a problem. For example, if your office is closed for winter vacation and there has been less storage unit door opening, cooler room temperatures and reduced vaccine stock in the refrigerator, can cause cooler than average temperatures to occur.

## Temperatures **Warmer** than 5°F/-15°C in Freezer\*

### Check:

- Automatic defrost cycle (recheck temperatures in 1 hour)
- Ice buildup (refer to job aid and manually defrost freezer if > 1 inch accumulation)
- Items on previous slide if excursion lasts > 1 hour, or if there is no ice buildup



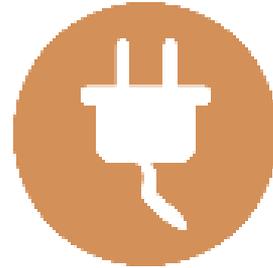
If your freezer unit is warmer than 5°F or -15°C and your unit has automatic defrost, check to see if the unit is going through an automatic defrost cycle, which can cause brief temperature fluctuations. Recheck the storage unit temperature again after 1 hour. Back in range temperatures suggest that the fluctuation resulted from an automatic defrost.

If your freezer is warmer than 5°F or -15°C and your unit does not have automatic defrost, check that there is no ice buildup which could be causing warmer temperatures or preventing the door from closing completely. If ice buildup is greater than 1 inch, you need to manually defrost the freezer or call for service. A separate job aid is available which outlines basic steps for performing manual freezer defrosts.

If the unit does not go back into range after 1 hour, and does not have ice buildup, check the other items mentioned on the previous slide for evaluating refrigerator temperature excursions.

## Power Outages

- **For power outages < 2 hours:**
  - **Do not open storage unit door(s)**
  - Use water bottles to help maintain temperatures
  - Start recording room temperatures as soon as possible
  - Monitor unit temperatures as soon as possible only if you can do so without opening the unit door
  - Also record min/max temps reached during power outage
- **For power outages >2 hours:**
  - **Activate emergency plan**
  - Don't keep vaccines in a nonfunctioning unit for an extended period of time.



For short-term power outages that you anticipate will last less than 2 hours: do not open storage unit doors.

Depending on the room temperature, storage unit temperatures can often be maintained with water bottles in the refrigerator, and frozen water bottles in the freezer.

You'll need to monitor the temperatures regularly during the outage. As soon as possible, start recording the room temperature and monitoring the internal temperature of the storage unit if you can do this without opening the unit doors (otherwise wait until the power outage is over to get the internal storage unit temperature ).

You should also record minimum and maximum temperatures reached during the power outage.

For longer-term power outages lasting more than 2 hours or power outages of uncertain duration:

activate your facility's emergency plan.

Above all, do NOT allow vaccines to remain in a nonfunctioning unit for an extended period of time.

## Temperature Excursions: Next Steps

**If all possible causes of the excursion have been explored and there is no reasonable explanation, the unit probably needs to be serviced or replaced:**

1. Arrange to move vaccine to an acceptable unit with available space:
  - ✓ Can maintain appropriate temperature for at least 5 days
  - ✓ Has temperature monitoring device with valid calibration certificate
2. Contact a repair company
3. Call the NYS VFC Program (1)800-543-7468 (M-F 8 am - 4 pm)
4. Check vaccine viability with the manufacturer.
  - Complete NYSIIS Returns/Wastage Request
5. Note the excursion in the NYSIIS temperature log.



If you have explored all possible causes for a temperature excursion and there is still no reasonable explanation, it's likely that the storage unit needs to be serviced or replaced.

If this is the case, temporarily move vaccine to another storage unit that has adequate space, a temperature monitoring device with a valid calibration certificate, and the capacity to maintain appropriate temperatures for at least 5 days.

If necessary, contact a repair company to determine if the unit can be serviced or if it needs to be replaced.

Call the NYS VFC Program if you haven't done so already. The NYS VFC program can provide additional guidance.

Contact the vaccine manufacturers to determine whether the vaccine is still viable. If the vaccine is no longer viable, document the loss in the NYSIIS returns/wastage module and return any spoiled, unopened vaccine. Note the excursion and potential causes in the NYSIIS Temperature Log.

## Key Messages: Temperature Excursions

- Any temperature reading outside of acceptable ranges is considered a temperature excursion. This includes current temperature and min/max temperature readings. Always contact the NYS VFC Program if you have had or are having a temperature excursion: 1-800-543-7468.
- Excursions can occur for a variety of different reasons. Prevent excursions by plugging storage units directly into wall, using plug guards, labelling all outlets and circuit breakers with warning signs, and purchasing a larger storage unit if the one in use is crowded.
- Exhaust all obvious causes of an excursion before adjusting the thermostat. If an excursion has happened during an automatic freezer defrost, recheck the temperature again in 1 hour.
- Never leave a storage unit unattended if an out of range temperature is observed before the office will be closed. Make sure the issue is addressed completely and that the temperatures are back in range before leaving the office.
- Don't open storage unit doors during a short-term power outage (<2 hours).
- DO NOT allow vaccines to remain in nonfunctioning unit for an extended period of time (2+ hours). Have an emergency plan in place to reference in the event of a power outage or unit failure.



Let's review some key messages from this training.

The first is that any temperature reading outside of acceptable ranges is considered a temperature excursion. This includes current temperature and min/max temperature readings. Always contact the NYS VFC Program if you have had or are having a temperature excursion. The NYS VFC program can give you guidance on next steps.

Secondly, excursions can occur for a variety of different reasons. Try to prevent excursions by doing things like plugging storage units directly into wall, using plug guards, labelling all outlets and circuit breakers with warning signs, and purchasing a larger storage unit if the one your practice has is too crowded.

Check for all possible obvious causes of an excursion before adjusting the thermostat. When making a thermostat adjustment, factor in the room temperature, unit usage and amount of stock. Make small adjustments to thermostat and monitor temperatures closely. If a temperature excursion in a freezer has occurred as a result of an automatic defrost process, recheck the freezer temperature after 1 hour.

Never leave a storage unit unattended if an out of range temperature is observed before the office will be closed. Make sure the issue is addressed completely and that the temperatures are back in range before leaving the office.

During short-term power outages of less than 2 hours, do not open storage unit doors. DO NOT allow vaccines to remain in a nonfunctioning unit for an extended period of time (2+ hours). Have an emergency plan in place to reference in the event of a power outage or unit failure.

# Resources

## **NYS Vaccines for Children (VFC) Program**

Manufacturer Follow Up Information Sheet

[http://www.health.ny.gov/prevention/immunization/vaccines\\_for\\_children/docs/vaccine\\_manufacturer\\_follow-up\\_info\\_sheet.pdf](http://www.health.ny.gov/prevention/immunization/vaccines_for_children/docs/vaccine_manufacturer_follow-up_info_sheet.pdf)

Storage Unit Purchasing Guidance

[https://www.health.ny.gov/prevention/immunization/vaccines\\_for\\_children/storage\\_and\\_handling.htm#vacstorunit](https://www.health.ny.gov/prevention/immunization/vaccines_for_children/storage_and_handling.htm#vacstorunit)

NYSIIS Returns/Wastage Training and Handouts

[https://www.health.ny.gov/prevention/immunization/vaccines\\_for\\_children/ordering\\_and\\_inventory.htm](https://www.health.ny.gov/prevention/immunization/vaccines_for_children/ordering_and_inventory.htm)

Manual Defrost Guidance

[http://www.health.ny.gov/prevention/immunization/vaccines\\_for\\_children/docs/manual\\_defrost\\_guidance.pdf](http://www.health.ny.gov/prevention/immunization/vaccines_for_children/docs/manual_defrost_guidance.pdf)

## **Immunization Action Coalition (IAC)**

Vaccine Storage Troubleshooting Record

<http://www.immunize.org/catg.d/p3041.pdf>



Here is a listing of available resources.

# Additional Training for NYS VFC Providers

**Next: NYS VFC Program Training Series #12: Managing Vaccine Inventory**



There are a number of additional trainings available.  
The next training in this series is #12: Managing Vaccine Inventory.