

NEVADA STATE IMMUNIZATION PROGRAM VACCINE STORAGE UNIT PROTOCOL

Vaccine Storage and Handling Guidelines:

Vaccine storage units must be selected carefully and used properly. Stand-alone refrigerators and freezers are the only units proven to consistently maintain required temperature ranges for safe vaccine storage. However, a combination refrigerator/freezer unit with two doors and two thermostat controls is acceptable for vaccine storage if only the refrigerator compartment is being used to store vaccine. Combination units do not maintain consistent in-range temperatures for the freezer compartment. The Centers for Disease Control and Prevention (CDC) recommends that any refrigerator or freezer being used for vaccine storage must:

- 1. Be able to maintain required vaccine storage temperatures year-round;
- 2. Be large enough to hold the year's largest inventory (think back to school and flu season);
- 3. Be monitored using an unexpired, calibrated digital data logger thermometer; and
- 4. Be dedicated to the storage of vaccines or other biologics. No food or beverages should be stored in a vaccine storage unit.

General Requirements:

Vaccines that require storage temperatures between 35° and 46°F (2° and 8°C) must be stored in the refrigerator compartment of a household- or commercial-style refrigeration unit. Vaccines that require storage temperatures of 5°F (-15°C) or colder must be stored in a stand-alone freezer. Frozen vaccines include MMR-V (Proquad), Varivax and Zostavax. It is recommended that provider offices use separate units for vaccine storage, because stand-alone refrigerators and freezers maintain the required temperatures better than home-style combination units. Whatever type of storage unit is used, the refrigerator and freezer compartments must have separate external doors and separate thermostat controls. The storage unit must have enough room to store the year's largest vaccine order without crowding and without the vaccines touching the back or sides of the unit's interior. It is recommended to store full water bottles in the refrigerator and frozen ice packs in the freezer to help stabilize the temperature and assist in keeping the compartments cold in cases of a power outage.

Reminder: Vaccines are not to be stored in the door of a unit nor in the crisper drawers.

For more information on vaccine storage go to: www.cdc.gov/vaccines/recs/storage/default.htm

<u>Unacceptable Vaccine Storage Units:</u>

The following units are unacceptable for vaccine storage, even temporarily, <u>no</u> exceptions:







- "Dorm-style" units provide poor temperature control and often freeze vaccines that require refrigeration, resulting in immediate and irreversible damage. "Dorm-style" units are defined as small refrigerator/freezer combination units with a single external door and an evaporator plate or cooling coil that forms a small freezer compartment within the unit or is pulled across the internal back wall of the unit.
- Manual defrost (or cyclic defrost) refrigerators have significant temperature variations, often freezing and damaging vaccines. These units often have exposed cooling plates, coils or vertical plates in the interior back wall of the refrigerator. These may be covered with visible frost or ice.
- Convertible refrigerator-only units that have an internal switch to convert the "refrigerator-only" unit to a "freezer-only" unit.
- Any refrigeration/freezer unit that is over 10 years old.
- Small apartment size (4ft or below) units.

Dorm-Style Units: Small, single-door combined refrigerator/freezer units **should not** be used for any vaccine storage, even temporary. The freezer compartment in this type of unit is incapable of maintaining temperatures cold enough to store frozen vaccines. If attempts are made to cool the freezer to the appropriate temperature, then the temperature in the refrigerator will fall below the recommended range, potentially freezing the refrigerated vaccines.

Acceptable Vaccine Storage Units:

The following types of units are accepted by the Nevada State Immunization Program:

- Stand-alone refrigerator unit(s) recommended type
- Stand-alone freezer unit(s) recommended type
- Combination refrigerator/freezer unit with two doors and two thermostat controls, where only the refrigerator compartment is being used for vaccine storage.
- 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.

Option 1: Stand-Alone, Under-the-Counter Refrigerator and Freezer Units







Stand-alone, under-the-counter refrigerators and freezers are excellent choices for vaccine storage. Under-the-counter refrigerators and freezers are stand-alone units that allow for the separate storage of frozen and refrigerated vaccines. Stand-alone refrigeration units must also be self-defrosting and it is recommended that stand-alone freezer units be self-defrosting.

The benefits of using stand-alone units for vaccine storage include:

- Lower risk of catastrophic inventory loss. Separate compressors and condensers decrease the risk of total vaccine loss that might occur in a combination style unit.
- **Temperature stability.** Because these units are only required to hold a single set temperature, they are not constantly re-adjusting and circulating cold air between the refrigerator and freezer compartments.
- No risk of accidentally freezing refrigerated vaccine. Combined units often use a
 cold air vent from the freezer to regulate temperatures in the refrigerator
 compartment. This freezing air blows down on the top shelf of the refrigerator and
 can quickly freeze any vaccines stored underneath.

Providers have many options for finding affordable, office-appropriate stand-alone units. **Stand-alone units can be under-the-counter size as discussed here or full-size.**Office Managers can shop local home improvement stores (Home Depot, Lowes) or go for lab/pharmaceutical grade units (Panasonic, Amer Biotech Supply, GemRef):

- o http://www.homedepot.com/ search within appliances
- o http://www.lowes.com/ search within appliances
- o http://www.panasonic.com/business/healthcare/biomedical/vaccine/?_kk=5ce24da0-8f0d-46d9-a4fc-9e7e44de6fe5&_kt=16601245831
- o http://www.americanbiotechsupply.com/Products/Refrigerators/Pharmacy-Vaccine-Basic.aspx
- o http://www.gemref.com/vaccine_refrigerators_freezers.php

Option 2: Home-Style, Combination Refrigerator/Freezer Units

These types of units are most often found in home and appliance stores. Higher-end models are sometimes referred to as "commercial-grade" and are most often used in the food service industry. While not ideal for vaccine storage, many immunization clinics use this type of unit due to its affordability. However, beginning in 2013 all Vaccines for Children providers in Nevada will be required to purchase a stand-alone freezer for storage of frozen vaccines. It is important for providers to choose an appropriate household model for storage of refrigerated vaccines. The unit must incorporate the characteristics detailed in the next paragraph.

Essential features for a combination unit:

- Refrigerator and freezer compartments must have separate external doors;
- Refrigerator and freezer compartments must each have a dedicated thermostat control:
- The shelves should be adjustable; and
- There should be enough room to store vaccine on the middle shelves (away from cool air vents).

Recommended features for a combination unit:

- Outside door locks (manufacturer installed only);
- Separate compressor units for each compartment;
- Automatic condensate removal, no drain lines:
- Forced air circulation;
- Door alarm if left open or ajar; and
- Battery back-up (in cases of power failure).

Risk of freezing vaccine – Never store freeze-sensitive vaccines near the cold air vent in the refrigerator compartment; cold air from the freezer will often blow down on the vaccine and freeze it, resulting in irreparable damage and wasted vaccine.

Single thermostat units – Home-style, combination refrigerators with a single thermostat are <u>strongly discouraged</u>. This type of unit is only acceptable if storing vaccine in refrigerator compartment only. A single thermostat makes it difficult to maintain recommended temperatures in both compartments. **If you are thinking of purchasing a new unit** – **do not purchase a single thermostat unit!!**

Option 3: Stand-Alone, Laboratory Grade Refrigerator and Freezer Units

Stand-alone, laboratory grade refrigerators and freezers are considered the gold standard for dedicated vaccine storage; they are considered the most secure. As with most "gold-standard" products, they carry a hefty price tag and are usually reserved for health departments, laboratories and hospitals. However, many manufacturers also produce an array of refrigerators and freezers that may meet your clinic's vaccine storage needs. Be aware that units with glass-front doors do not maintain cold temperatures during power outages as well as units with solid doors.







PREPARING A NEW UNIT FOR VACCINE STORAGE

Before placing vaccines in a new unit, follow these simple steps to ensure success:

- Plug the vaccine storage unit directly into a wall or floor outlet. Never use surge protectors or extension cords!
- If using a combination unit: remove the crisper drawers or fill them with full bottles of water.
- Carefully label the areas where you will be storing vaccine. Identify where publicly supplied vaccine will be stored versus where privately purchased vaccine will be stored.
- Place digital unexpired, calibrated thermometers (in glycol-enclosed bottles) in the center of the unit. Any thermometer being used, including built-in thermometers in pharmacy or lab-grade units, must have a certificate of calibration proving it has been calibrated to NIST or ASTM standards.
- Set the refrigerator temperature to stay steady around 40°F. Freezer units should be 5°F (-15°C) or colder at all times.
- Monitor the temperature of the new unit twice daily for <u>five business days</u> before placing vaccines within. Vaccines should be temporarily stored in an appropriate, alternate unit until the temperature in the new unit is stable within the recommended range for at least <u>five business days</u>.
- Installation of pharmacy or laboratory grade units should be completed by a refrigeration specialist. They will level the unit, identify the coldest and warmest zones, determine when the unit is ready for use, and provide staff training.

Manufacturers to Consider*

- Kelvinator (used throughout the food service industry) www.kelvinator.com/
- Summit Appliance www.summitappliance.com/
- Sanyo BioMedical http://us.sanyo.com/Biomedical
- Marvel Scientific <u>www.marvelscientific.com/</u>
- Lab Research Products <u>www.labresprod.com/</u>
- Panasonic www.panasonic.com/business/healthcare/biomedical/vaccine/
- American Biotech Supply www.americanbiotechsupply.com/Products/Refrigerators
- Gem www.gemref.com/vaccine_refrigerators_freezers.php

Additional Resources

- CDC's Vaccine Storage and Handling Website www.cdc.gov/vaccines/recs/storage/default.htm
- Shepler Refrigeration <u>www.sheplerrefrigeration.com/</u>
- PMC Scientific <u>www.pmcscientific.com/</u>
- Dickson (temperature monitoring) www.dicksondata.com/
- LogTag Recorders (temperature monitoring) www.logtagrecorders.com/

^{*}The Nevada State Immunization Program does not endorse any specific product or manufacturer. This list is provided for informational purposes only. Providers and their staff should do their own research and choose a product that best fits the needs of the office.

Optional Equipment

Alarmed phone dialers: This type of equipment is designed to call a pre-determined list of phone numbers when the attached probe records a temperature outside of the range set by the user. They are sold by several manufacturers with varied models, styles and prices. Alarmed phone dialers are especially useful in geographical areas that experience frequent power outages. Below are some suppliers of alarmed phone dialers.

- Sensaphone www.sensaphone.com/
- Dickson www.dicksondata.com/
- United Security Products <u>www.unitedsecurity.com/</u>

Storage unit power back-up: Disruption in power supply is one of the most frequent causes of costly vaccine loss. It doesn't take long for a refrigerator and freezer to begin to warm once the power has been cut. With this in mind, a clinic may want to consider adding a secondary source of power in cases of emergency. If the clinic already has a back-up system (e.g., a generator), then it is highly recommended that the vaccine storage unit be placed on that emergency power circuit as well.



For those clinics without one, a small back-up generator might be a great option for an extra layer of protection. Backup generators should have sufficient capacity to run continuously for 72 hours, if necessary. Plans should be made to ensure that an adequate supply of fuel is on hand.

Some examples include:

- Generac Power Systems 8kW Air-Cooled Standby Generator http://www.generac.com/Residential/GuardianSeries/8kW/
- Winco Generators www.usa-emergencygenerator.com/winco/index.html