

<b>Policy &amp; Procedure Title</b>	Storage and Handling-Storage Unit Requirements	<b>Issuing Date</b>	07/17/2012
<b>Policy &amp; Procedure Number</b>	8	<b>Revision Date</b>	04/01/2017
<b>Policy &amp; Procedure Approval Authority</b>	Dave McConnick		

### Policy & Procedure Summary

There are few immunization issues more important than the appropriate storage and handling of vaccines. The success of efforts against vaccine-preventable diseases is attributable in part to proper storage and handling of vaccines.

Vaccines must be stored properly from the time they are manufactured until they are administered. Proper maintenance of vaccines during transport is known as the cold chain. A proper cold chain is a temperature-controlled supply chain that includes all equipment and procedures used in the transport and storage and handling of vaccines from the time of manufacturer to administration of the vaccine.

Vaccine storage equipment should be selected carefully, used properly, maintained regularly (including professionally serviced when needed), and monitored consistently to ensure the recommended temperatures are maintained.

All enrolled providers must complete the Cold Storage Unit Certification in Vaccine Ordering Management System (VOMS) during the Annual Provider Recertification Process to document which types of storage units are currently being utilized at their clinic(s).

### Policy Statement

This policy defines the minimum standards that must be met and maintained by each provider enrolled in the Indiana State Department of Health (ISDH), Immunization Division for receipt, storage and proper management and handling of publicly funded vaccine.

This policy supersedes all policies previously issued by the Indiana Immunization Division addressing the storage unit requirements for publicly funded vaccine. It replaces the following policy:

Title of Policy: **Refrigeration/Freezer Standards for Vaccine Storage**  
 Policy Number: II-02  
 Creation Date: Feb 18, 2009

Refrigerators and freezers used to store publicly provided vaccines must be capable of reaching and maintaining the required temperatures established by the vaccine manufacturers, the Centers for Disease Control and Prevention (CDC), and the National Institute of Standards and Technology (NIST) standards.

#### *Storage Unit Requirements*

Providers receiving publicly funded vaccine must adhere to all of the following **requirements** for a permanent vaccine storage unit:

- **Beginning January 1, 2015 all newly enrolled providers are required to have Stand-alone units, refrigerators without freezers and/or freezer-only units. This means a self-contained unit that only refrigerates or freezes, is suitable for vaccine storage, and meets all other requirements for vaccine storage. These units can vary in size, from a compact, under-the-counter style to a large, stand-alone, pharmaceutical grade storage unit.**
- **Starting January 1, 2018, all enrolled providers are highly encouraged to use stand-alone units to store publically funded vaccine. However, all providers will be required have stand-alone units by the submission of the 2019 Provider Recertification in order to continue participating in the Indiana VFC or Adult Vaccine Program.**

All providers receiving publicly funded vaccine enrolled prior to January 1<sup>st</sup>, 2015 must adhere to all of the following **requirements** for a permanent vaccine storage unit:

- **As of 3/1/2014, any VFC provider office purchasing or acquiring a new unit which will store VFC vaccines must purchase a stand-alone unit.**
- **ISDH encourages providers enrolled that still use a combination vaccine storage unit to begin budgeting/planning to replace it with stand-alone units. Starting 2019, all VFC and Adult Vaccine providers will be required to have stand-alone storage units to continue participation in the program.**
- Must have separate exterior doors, with separate gaskets, that seal tightly and properly for both the refrigerator and freezer areas.
- Units with a single exterior door and an interior door separating the refrigerator and freezer areas **are not permitted** for vaccine storage at any time.
- Providers with units containing only 1 thermostat control must have a separate stand-alone freezer.
- CDC recommends the use of stand-alone units, refrigerators without freezers and/or freezer-only units. This means a self-contained unit that only refrigerates or freezes and is suitable for vaccine storage. These units can vary in size, from a compact, under-the-counter style to a large, stand-alone, pharmaceutical grade storage unit.
- While the use of stand-alone units is best practice and highly recommended, an alternative to stand-alone units is using only the refrigerator compartment of a combination household refrigerator/freezer unit to store refrigerated vaccines. In this case, the combination household refrigerator/freezer must have separate exterior doors and thermostat controls. A separate stand-alone freezer should then be used to store frozen vaccines, since studies conducted by the National Institute for Standards and Technology (NIST) have demonstrated that the freezer section of combination units is not capable of reliably maintaining appropriate frozen vaccine storage temperatures.

All providers receiving publicly funded vaccine must adhere to all of the following **requirements** for a permanent vaccine storage unit:

- Must be able to maintain the *Temperature Requirements* at all times.
- Refrigerators **must maintain** temperatures between 36°F and 46°F (2°C to 8°C).
- Freezers **must maintain** temperatures +5°F (-15°C) or colder not to exceed -50°C.
- Must be dedicated to the storage of vaccine.
- Food, beverages (including bottled drinking water) or lab specimens may not be stored in the vaccine storage unit.
- If other biologic products must be stored in the same unit than the vaccines, products should be stored on a lower level shelf than vaccines.
- Must be large enough to hold the year's largest vaccine inventory, while still adhering to the requirements for vaccine storage
- No minimum requirement for unit size.
- Must be located in a well-ventilated room with space around the sides and top and at least 4 inches between the unit and a wall for good air circulation.
- Nothing can block the cover of the motor compartment and the unit should be level and stand firmly with at least 1 to 2 inches between the bottom of the unit and the floor.
- Must be plugged directly into wall outlets; **multi-strip outlets should not be used.**
- Must post a sign with wall outlet to alert all staff, janitors and electricians that the unit must not be unplugged.
- Must label the circuit breakers to alert janitors and electricians not to turn off the power to the storage unit.
- Label must contain the circuit number that controls power to the vaccine storage unit and emergency contact information.
- Keep a calibrated, data logger with a Certificate of Traceability and Calibration in each refrigerator and freezer compartment. (Refer to the Storage and Handling-Temperature Requirements policy 9 for full details)

- Must have temperature monitoring completed twice daily and logs maintained for all storage units. These records must be kept on site for a minimum of 3 years. (Refer to the Storage and Handling-Temperature Requirements policy 9 for full details)

The following are recommendations and not required, but strongly encouraged.

- Storage unit should be frost-free or have an automatic defrost cycle (manual defrost refrigerators are **prohibited**).
- Plug guards or safety-lock plugs should be put in place to prevent someone from inadvertently unplugging the unit.
- A temperature alarm system that will alert staff to after-hour temperature excursions, particularly if large vaccine inventories are maintained, may be helpful in assuring a timely response to storage problems.

#### *Temporary Storage Units*

Dormitory-style refrigerator/freezer units are no longer permissible for vaccine storage at any time. The use of these specific refrigerator/freezers is not allowed at any time for Vaccines for Children (VFC) program providers. Please note that there are compact, purpose built storage units for biologics that are not considered to be dormitory-style or bar-style.

If vaccine must be stored temporarily during a clinic day, the storage unit must meet the same requirements as any long term storage unit.

#### *Storage Unit Organization Requirements*

Providers receiving publicly funded vaccine must adhere to all of the following **requirements** for vaccine storage unit organization:

- All vegetable/fruit bins or drawers must be removed from the refrigerator unit.
- Containers of water, labeled “Do NOT Drink,” must be placed in the refrigerator to help stabilize the temperature in the unit. Place these water bottles in the area where there is a greater risk for temperature excursions (for example, top shelf, floor, and in the door racks of refrigerator).
- The water containers may be put in place of the vegetable/fruit bins or drawers, if available.
- Frozen water bottles that are properly conditioned should be stored in the freezer.
- Never store vaccines in the door of the refrigerator or the freezer.
- Water bottles may be placed in the door of the freezer.
- Extra water containers labeled “Do NOT Drink” or similar may be placed in the door of the refrigerator.
- Diluents, that do not contain vaccine antigen, may be placed in the door of the refrigerator.
- Items in door must be placed securely so that they cannot dislodge and prevent the door from closing.
- Caution must be taken to avoid weighing down the doors so much that the seals are compromised when the doors are closed.
- Vaccines or vaccine containers must be placed away from the walls, coils, and vents.
- There must be at least adequate room between the vaccine stacks or containers to provide for good air circulation for even cooling.
- Vaccines must be kept in their original packaging with the lids intact and closed.
- Vaccines must be protected from light at all times.
- Not only live attenuated vaccines, but some inactivated vaccines must be protected from light.
- The vaccine manufacturer’s product information indicates if the vaccine must be protected from light.
- Vaccines must be organized within the unit so that they are the stacked in rows with vaccine of the same type.
- Short dated vaccines must be placed in front of vaccines with a later expiration date.
- Each vaccine and diluent stack or container must be clearly labeled.
- Vaccine purchased with public funds must be labeled and easily differentiated from privately purchased vaccines.

The following are *recommendations* and not required.

- Vaccines should be stored in bins, baskets, or some other type of container that allows for air circulation to organize the vaccines within the storage unit.
- Labels differentiating private vs. public stock may be attached directly to the shelves on which vaccines and diluents are sitting or by placing labels on the containers.
- It may be helpful to use color coding (e.g., one color for pediatric and another for adult) or include the age indications for each vaccine type on the labels.
- Having each vaccine and diluent stock or container labeled helps decrease the chance that someone will inadvertently administer the wrong vaccine or use the wrong diluent to reconstitute a vaccine.
- Vaccines that sound or look alike should not be stored next to each other, e.g. DTaP and Tdap.

#### *Vaccine Storage Troubleshooting*

To maintain the proper temperature ranges, the freezer and refrigerator must be in good working condition and they must have power at all times.

- While it is important to take measures to prevent problems, equally important is taking immediate corrective action when a problem does exist, for example when the storage unit temperature falls outside the recommended range.
- Every clinic should also have an emergency vaccine retrieval and storage plan. The plan should be easily accessible to staff and identify a backup location where the vaccine can be stored.
- It is very important that staff know whom to contact in case of a malfunction or disaster.
- If the problem is short-term (usually 2 hours or less) and depending on outside ambient temperature, the storage unit temperature can probably be maintained with water bottles in the refrigerator and freezer, and by keeping the unit doors closed.
- If there is an extended period of time before the situation can be corrected and there are no other storage units available on site, the vaccine should be moved to the backup storage facility using the guidelines in the *Vaccine Emergency Management Plan*.
- Potential backup locations might include a local hospital, pharmacy, long-term care facility, or the Red Cross.

#### *Diluents*

- Vaccines that must be reconstituted are shipped with diluent specific to that vaccine. Vaccine diluents are not all the same, some contain vaccine antigen.
- As with vaccines, diluents should be stored according to the guidelines in the manufacturer's product information.
- When feasible, diluents that require refrigeration should be stored with their corresponding vaccines.
- Never store any diluent in the freezer because the vials are not designed for freezer storage and could crack.

#### **References & Resources**

Centers for Disease Control and Prevention. (2018) Vaccine Storage and Handling Toolkit, Revised January 2018. <https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf>

Centers for Disease Control and Prevention. (13<sup>th</sup> Edition) Epidemiology & Prevention of Vaccine-Preventable Diseases, Pink Book. Revised 2015. <http://www.cdc.gov/vaccines/pubs/pinkbook/index.html>

Refrigerator/Freezer Temperature Log

#### **Revision History**

07/17/2012, Created  
03/01/2014, Revised  
11/19/2014, Revised  
02/16/2016, Revised  
04/01/2017, Revised