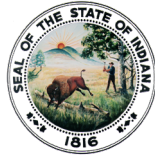


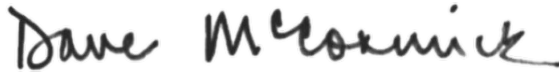


**Indiana
Department
of
Health**



Eric J. Holcomb
Governor

Lindsay M. Weaver, MD, FACEP
State Health Commissioner

<p>Title: Storage and Handling-Storage Unit Requirements</p>	<p>Policy #: IDOH Immunization Division Policy 8</p>
<p>Effective dates: 01-Jan-24 to 31-Dec-24</p>	<p>Approvals:  <hr/> Dave McCormick, Immunization Director July 7, 2024 <hr/> Date</p>

Policy Statement

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.

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

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).

Storage Unit Requirements

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

- Refrigerators **must maintain** temperatures between 36°F and 46°F (2°C to 8°C)
- Freezers **must maintain** temperatures between +5°F and -58°F (-15°C to -50°C)
- As of 2019, all providers must utilize stand-alone refrigerators and stand-alone



- 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 as the vaccines, products should be stored on a lower-level shelf than vaccines
- Must be large enough to hold all the provider's inventory during peak seasons, such as influenza season or back-to-school
- No minimum requirement for unit size
- Must be in a well-ventilated room with space around the sides and top and at least four 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 1-2 inches between the bottom of the unit and the floor
- Must be plugged directly into wall outlets; **extension cords or 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. Emergency contact must have 24-hour access to the building.
- 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 in policy nine for full details.)
- Must have temperature monitoring completed twice daily and logs maintained for all storage units. These records **must be maintained and accessible** for a minimum of three years **for VFC (Vaccine For Children) purposes (can be electronically stored)**. (Refer to the storage and handling-temperature requirements policy nine for full details.)

The following are not required but are 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 permitted for vaccine storage at any time. Dormitory-style refers to a small unit that has one exterior door with a small freezer inside the refrigerator. 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 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
- Never store vaccines in the door of the refrigerator or the freezer
- Water bottles may be placed in the door of the freezer
- Diluents that do not contain vaccine antigen and are packaged separately from the vaccine may be placed in the door of the refrigerator
- Items in the 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
- No two boxes of the same vaccine should be open at the same time
- Vaccines must be always protected from light
- Vaccines must be organized within the unit so that they are 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
- 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 always have power.

- Take 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 management 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 two 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 an extended period of time passes 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
- 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

Centers for Disease Control and Prevention. (2023) Vaccine Storage and Handling Toolkit, Revised January 2023.

<https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf>

Centers for Disease Control and Prevention. (13th Edition) Epidemiology & Prevention of Vaccine-Preventable Diseases, Pink Book. Revised 2021.

<http://www.cdc.gov/vaccines/pubs/pinkbook/index.html>

Forms

Fridge/Freezer Temperature Logs

<https://www.in.gov/health/immunization/files/ISDH-Temperature-Logs-1-31-Fridge-Freezer-with-Min-Max-v-4-15-2018.pdf>

Freezer Temperature Logs

<https://www.in.gov/health/immunization/files/ISDH-Temperature-Logs-1-31-Freezer-with-Min-Max-v-4-15-2018.pdf>

Refrigerator Temperature Logs

<https://www.in.gov/health/immunization/files/ISDH-Temperature-Logs-1-31-Refrigerator-with-Min-Max-v-4-15-2018.pdf>