

INDIANA IMMUNIZATION PROGRAM
STATEMENT OF POLICY
External Policy

Title of Policy: **Refrigeration/Freezer Standards
For Vaccine Storage**

Policy Number:
II-02 (R3-2/2009)

Effective Date: February 18, 2009

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Purpose: 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 Program for receipt, storage and proper management and handling of publicly supplied vaccine.

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 Indiana Immunization Program.

Refer to the *CDC Vaccine Storage and Handling Tool Kit*; <http://www2a.cdc.gov/vaccines/ed/shtoolkit/> for additional guidance on the proper handling and storage of vaccines.

Small single-door (dormitory-style or bar-style) combined refrigerator-freezer units may not be used for permanent vaccine storage. If the refrigerator compartment can maintain proper temperatures, these units may be adequate for temporary storage of small quantities of refrigerated vaccines and MMR vaccine in the refrigerator compartment. MMRV, varicella, and zoster vaccines **may not** be stored in these units at any time. Refrigerated vaccines stored in a dormitory-style unit must be returned to the main storage unit at the end of the clinic day.

Refrigerators and freezers used for permanent storage of publicly provided vaccines must meet the following minimum standards:

- Have separate external doors, with separate gasket door seals for the refrigerator unit and the freezer unit.
- Refrigerators **must maintain** a temperature range from 2°C - 8°C, (35° F - 46° F) year-round.
- Freezers **must maintain** a temperature range of (minus) -15 degrees C, (5 degrees F) or lower year-round.
- Refrigerators and freezers must be dedicated to the storage of vaccines. Food, beverages (including bottled drinking water) or lab specimens may not be stored in the vaccine storage unit. If possible, other medications and biologic products should not be stored inside the vaccine storage unit. If there is no other choice, these products must be stored below the vaccines on a different shelf. This prevents contamination of the vaccines should the other products spill, and reduces the likelihood of medication errors.

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- Refrigerators and freezers must have enough room to store the year's largest anticipated vaccine inventory, while maintaining proper air circulation. Enough space must be maintained between the vaccine and interior refrigerator/freezer walls as well as between the stacked boxes of vaccines to allow for even cold-air circulation.
- Vaccines should not be stored in areas within refrigerator or freezer units that are known to have variable temperatures. Vaccines should not be stored in the refrigerator/freezer doors, vegetable bins, on the bottom of the refrigerator or in air-tight containers or unventilated trays. Vaccines must be kept in their original cardboard boxes with lids intact to protect them from light.
- Refrigerators must also have adequate room to store at least two or three large containers of water labeled, "Not for Consumption". Store water containers against the inside walls, near the bottom of the storage unit, and in the door racks. Removal of vegetable bins from refrigerators will help prevent the storage of vaccine in this area and provide additional space for water container storage. In freezer units, store frozen packs along the walls, in the back and on the bottom of the freezer to help maintain temperature stability resulting from frequent opening and closing of doors, as well as during power or equipment failures.
- Refrigerators and freezers must have thermometers that are certified calibrated, traceable by National Institute of Standards and Technology (NIST) standards, inside each vaccine storage compartment. Thermometers should be placed in the center of the refrigerator/freezer compartment to allow for accurate temperature monitoring. A copy of the current calibration certificate and three (3) years of historical certificates must be kept on file and available for review by ISDH staff.
- Temperature logs must be maintained for both refrigerator and freezer compartments of **all** units used to store vaccine. This includes small refrigerators used to temporarily store vaccine for day-use only. Log entries are required twice-daily during regular business hours. It is recommended that temperatures be checked and recorded first thing when the practice opens and at the end of the day. Written logs must be kept on file for three (3) years and available for review by ISDH staff.
- Approved temperature logs may be downloaded at the CDC Vaccines website:
 - Fahrenheit thermometers <http://immunize.org/catg.d/p3039.pdf>
 - Celsius thermometers <http://immunize.org/news.d/celsius.pdf>Approved temperature logs may also be obtained from the Indiana Immunization Program.

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- Publicly funded vaccine must be designated as separate vaccine stock from privately funded vaccine by the use of stickers/labeling, or a distinct shelf or section of the refrigerator/freezer.
- Signs warning against unplugging or turning off power to vaccine storage units with visible and accessible electrical receptacles must be posted on the wall immediately adjacent to the electric receptacle. Warning signs for non-visible and non-accessible receptacles (e.g., behind the vaccine storage units) must be posted on the storage unit. Warning signs must be clearly visible.
- The use of safety-lock plugs or outlet covers (plug guards) are recommended to reduce the chance of the unit becoming inadvertently unplugged.
- Each circuit breaker/fuse box controlling the electrical power for all refrigerator/freezers containing vaccine must be marked with a sign warning against shutting off the power switch. This warning must be clearly visible to anyone needing to work on the electrical system, in order to prevent the circuit from being inadvertently turned off.
- Approved electric receptacle warning signs may be downloaded from the CDC website at <http://www2a.cdc.gov/vaccines/ed/shtoolkit/pages/resources.htm>.
- Each facility must have written emergency procedures for the proper handling of publicly provided vaccines in the event of power or equipment failure. See *Procedural Guidelines for Emergency Management of Vaccines*, Policy II-02 (R2-7/2006), Attachment A.
- If a temperature is recorded **above** or **below** the recommended range in a vaccine storage unit, do not use the vaccine until the viability of the vaccine has been established by following the steps provided in the *Vaccine Cold Chain Failure Policy, II-09 (2/2009)*.
- During periods of extreme temperatures during winter months, vaccine shipments may be postponed. If forecasted or actual outside temperatures reach 10 degrees F or below for more than two days in any part of Indiana, vaccine shipments may be postponed to that area. Providers will be notified of any shipping delays through Vaccine E-Letters or E-Notices.


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Approved by:  Date: February 18, 2009
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Policy Review Log:

Initials						
Date	2/18/2009					