



Montana Immunization Program

Vaccine Storage Unit and Data Logger Requirements

Vaccine Storage Units must be:

- Stable enough to maintain vaccine storage temperatures year-round
- Large enough to hold the year's largest inventory of vaccine
- Equipped with a calibrated, digital data logger¹ for recording temperatures (see requirements below)
- A CDC-recommended appliance type. Either
 - Pharmaceutical-grade² stand-alone³ or combination⁴ units, or
 - Household-grade⁵ stand-alone units, or
 - Household-grade combination units using only the refrigerator section
- **Prohibited** - Dormitory-style storage units⁶ or using the refrigerator and freezer section of a household-grade combination unit.

Providers historically using the refrigerator *and* freezer of a household-grade combination unit can continue to do so as long as the units have been approved by the Immunization Program and reliably hold appropriate vaccine storage temperatures in both chambers.

Storage Unit Data Loggers must:

- Be continuous recording devices that take readings at least every 30 minutes
- Read temperatures from a buffered probe
- Display the current, minimum, and maximum temperatures on the outside of the storage unit
- Generate data that is reviewable, archivable, and able to be sent to the Immunization Program for review
- Alarm to indicate temperatures outside proper vaccine storage temperatures
- Have a current certificate of calibration testing that indicates the testing:
 - Was performed by an ILAC MRA⁷ signatory body, **or**
 - Meets international standards for calibration testing and traceability (e.g., ISO 17025, NIST, ASTM Standard E2877)

And includes the following information:

- Model/Device name or number
- Serial number
- Date of calibration
- Instrument passed test and is in tolerance

¹ A digital, continuous monitoring thermometer

² Designed to store pharmaceuticals in a laboratory or pharmacy setting

³ An appliance that is either a refrigerator or freezer

⁴ An appliance with both a refrigerator and freezer chamber

⁵ Appliances typically found in homes and sold at retail appliance store

⁶ A refrigerator with a small freezer inside the refrigerator chamber and only one external door

⁷ International Laboratory Accreditation Cooperative – Mutual Recognition Arrangement