# Compliance with CDC Guidelines for Vaccine Storage

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Vaccines require storage within a defined temperature range in order to maintain potency. Some require refrigeration at temperatures between 2 and 8 °C (36 and 46 °F) and some must be kept in a freezer at between -50 and -15 °C (-58 and 5 °F). In 2009 the Centers for Disease Control and Prevention (CDC) issued a vaccine storage requirement to help ensure that Vaccines for Children (VFC) vaccines are properly stored and managed. In 2012 the CDC issued interim guidance and a toolkit for all vaccine storage and handling.[1,2] That guidance and toolkit were based on studies and tests performed for CDC by the National Institute of Standards and Technology (NIST). The CDC toolkit was updated in 2014, in June of 2016 and was last updated in January 2018[3]. The CDC requirements are intended for all public and private sector vaccine providers to prevent inadvertently administering improperly stored vaccines and costly vaccine losses.

The CDC guidelines reinforce several important requirements for vaccine storage and temperature monitoring equipment:

- **Use of stand-alone refrigerator and stand-alone freezer units suitable for vaccine storage rather than combination (refrigerator + freezer) or other units not designed for storing vaccines.**

  Combination refrigerator/freezer units with a single compressor condensing unit are incapable of simultaneously controlling proper storage temperatures in both the refrigerator and freezer compartments. Medical-grade or laboratory-grade refrigerators and freezers are equipped with larger compressors, properly distributed forced air cooling, and sensitive digital temperature controllers in order to maintain the necessary tight temperature range throughout the storage volume required for stand-alone vaccine storage. Automatic defrost cycle units are preferred. CDC also recommends choosing a model with enough storage volume for the year's largest inventory without crowding.

- **Discontinuing use of dorm-style or bar-style refrigerator/freezers for ANY vaccine storage.**

  Dormitory-style or bar-style refrigerators are small combination refrigerator/freezer units with one exterior door and a passive evaporator plate located inside. In performance testing, the dorm-style refrigerator/freezers consistently demonstrated unacceptable temperature control regardless of where the vaccines were located inside the storage cabinet.

- **Use of Temperature Monitoring Devices (TMDs) and more specifically digital data loggers (DDLs) with a current and valid Certificate of Calibration Testing and detachable probes that record and store temperature information at frequent programmable intervals (no less frequently than every 30 minutes) for continuous temperature monitoring.**

  The use of continuous and comprehensive temperature monitoring facilitates identification of temperature excursions, allowing corrections to be made that can help to prevent costly vaccine losses.

  Placement of the active display of the data logger should be outside the refrigerator or freezer so readings can be taken without opening the door. A detachable temperature probe allows downloading temperature data without disturbing the glycol-encased probe inside which should remain in place during data reading and recording.

  CDC specifically recommends that the digital data logger includes the following features:
  - Current and valid Certificate of Calibration Testing
  - Detachable probe in a thermal buffered material (glycol, glass beads, sand, Teflon®)
  - Programmable sampling rate, minimum 1 reading every 30 minutes
  - Hi/Lo temperature alarms
  - Displays current temperature, minimum and maximum temperatures
  - Reset button

- Low battery indicator
- Recommended uncertainly of ± 0.5 °C (±1 °F)
- Memory storage of minimum 4000 readings
- Will not over-write (wrap) data
- Stops recording when memory is full

- **Use of a buffered temperature probe, rather than measurement of the storage volume air temperatures.**

  A buffered temperature probe will more closely represent temperature changes experienced by the stored vaccines. The buffered temperature probe should be securely placed in close proximity among the stored vaccines (e.g. in a tray in the center of the refrigerator/freezer).

  CDC also recommended proportions for the glycol bottle relative to the size of the probe. The diameter of the bottle should be at least 4 x the probe diameter. The probe should be centered in the bottle, immersed in glycol to a depth of 10 x the probe diameter, and 1-2 cm away from the bottom. Probes that are permanently imbedded in a buffer are acceptable as long as the temperature monitoring system for the entire unit can be calibration-tested:[3, p. 17]

  CDC does not recommend the following thermometers for monitoring vaccine temperatures:[3, p. 17]

  - Fluid-filled liquid thermometers
  - Bi-metal stem thermometers
  - Food thermometers
  - Household mercury thermometers
  - Chart recorders
  - Infrared thermometers
  - Thermometers that do not have a current and valid Certificate of Calibration Testing

- **Use only calibrated thermometers with a Certificate of Calibration Testing or Report of Calibration.**

  This has been a requirement for providers who receive VFC vaccines. Calibration of the thermometer must meet one or more of the following:[3, p. 16-17]

  - Tested by a laboratory with accreditation from an International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) signatory body, such as A2LA (American Association for Laboratory Accreditation) or L-A-B (Laboratory Accreditation Bureau)
  - Conforms to ISO-IEC 17025 standards and guarantees a documented chain of traceability
  - Traceable to the standards maintained by the National Institute of Standards and Technology (NIST)
  - Meets specifications and testing requirements for the American Society for Testing and Materials (ASTM) Standard E2877 Tolerance Class F (<± 1 °F or <± 0.5 °C) or better
  - Refers to another acceptable accuracy validation method, such as comparison to other traceable reference standards or tests at thermometric fixed points

  NIST also recommended an inexpensive ice point validation method for routine in-house comparison checks to determine when calibration may actually be required.[5, p.11]

Vaccine storage refrigerators and freezers, whether they are monitored by an external data logger accessory, a centralized temperature monitoring system, or an integral data logger, must meet the aforementioned CDC data logging requirements, features and calibration certification for compliance.

References


1. Vaccine Storage and Handling Interim Guidance; CDC; October 2012
2. Interim Guidelines for Vaccine Storage and Handling, Frequently Asked Questions; CDC; October 2012

3. Vaccine Storage & Handling Toolkit; CDC; January 2018; pp. 14-30
http://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf
4. Guidelines for Storage and Temperature Monitoring of Refrigerated Vaccines; CDC; July 2013
https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html
5. Data Logger Thermometers for Vaccine Temperature Monitoring; NISTIR 7899; November 2012; p.11
http://nvlpubs.nist.gov/nistpubs/ir/2012/NIST.IR.7899.pdf

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