



Wyoming
Department
of Health

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Vaccine Storage and Handling

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Vaccine Storage & Handling

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- Introduction to Vaccine Storage & Handling
- Review of OIG Storage & Handling Audit
- CDC Vaccine Storage & Handling Toolkit
- Temperature Excursions
- CDC Storage & Handling Guideline Recommendations & FAQ's
- Data Loggers
- Storage & Handling Education

Introduction to Vaccine Storage & Handling

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- There are few immunization issues more important than the appropriate storage and handling of vaccines.
- Vaccine storage and handling errors can result in the loss of vaccines worth millions of dollars.



Introduction to Vaccine Storage & Handling

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- Failure to adhere to required protocols for storage and handling can reduce vaccine potency, resulting in inadequate immune responses in patients.
- The success of preventing vaccine-preventable diseases is attributable in part to **proper storage and handling** of vaccines.

Introduction to Vaccine Storage and Handling

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- It is better to not vaccinate than to administer a dose of vaccine that has been **mishandled**.
- Vaccines must be stored properly from the time they are manufactured until they are administered (i.e. proper cold chain).



Review of OIG Storage & Handling Audit

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- **Why the OIG (Office of Inspector General) conducted the study**
 - To assess the vulnerabilities in vaccine management
 - In 2010, approximately 82 million VFC vaccine doses were administered to an estimated 40 million children at a cost of **\$3.6 billion.**



Review of OIG Storage & Handling Audit

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- VFC providers must meet certain requirements for vaccine management, such as:
 - **storing vaccines** within required temperature ranges and **monitoring expiration** dates to ensure that these vaccines provide children with maximum protection.
- These requirements are also intended to decrease VFC program fraud, waste, and abuse.



CDC Vaccine Storage & Handling Toolkit Review

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- **Vaccine Storage & Handling Toolkit**
 - Updated November, 2012
- **The Toolkit is based on the recommendations of the:**
 - Advisory Committee on Immunization Practices (ACIP),
 - The manufacturer's product information
 - Studies from the National Institute for Scientific Technology (NIST).

CDC Vaccine Storage & Handling Toolkit Review

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- **The Toolkit outlines *best practices*, strategies & recommendations on:**
 - Equipment considerations for storage units and thermometers
 - Maintaining the cold chain
 - Routine storage and handling practices
 - Inventory management
 - Emergency procedures for protecting vaccine inventories



CDC Recommendations for Storage & Handling

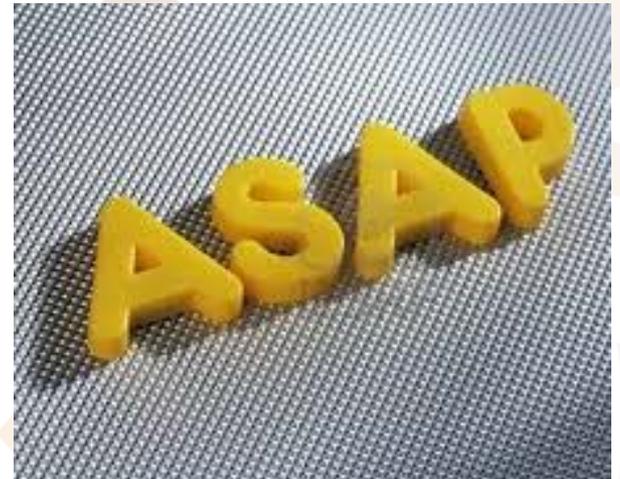
- The Centers for Disease Control and Prevention (CDC) have provided guidance on appropriate vaccine storage and handling practices
 - Based on recent scientific studies on equipment used for vaccine storage and a better understanding of best practices for vaccine storage and handling



CDC Recommendations for Storage & Handling

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- The guidance is intended for use by ***all*** providers and, while recognizing that cost may be a barrier, CDC encourages practices to move toward implementing these recommendations as soon as possible.



CDC Recommendations for Storage & Handling

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- Recommendations for Storage & Handling include:
 - Use of a **biosafe glycol-encased probe** or a similar temperature buffered probe (Example)
 - Use of **digital data loggers with detachable probes** (Example)
 - Use of **stand-alone refrigerator and stand-alone freezer** units suitable for vaccine storage
 - Weekly review of vaccine expiration dates and rotation of vaccine stock.



NEW

CDC Requirement for Storage & Handling

- **REQUIREMENT:** Discontinuing use of dorm-style or bar-style refrigerator/freezers for ANY vaccine storage, even temporary storage.
 - A recent NIST study revealed severe temperature control and stability issues
 - Large spatial temperature gradients, leading to no “safe” place inside to store vaccines.



What kind of refrigerator should I use?

Household, consumer-grade units

Freezerless



Dual-zone



Pharmaceutical-grade units

Under-the-counter



Full-sized



Dual-zone unit is acceptable for refrigerated vaccine storage only – do not use freezer compartment

Vaccine Storage Methods and Locations

DUAL ZONE

NO vials touching glass shelf or directly under cooling vent = 2 to 5 °C colder



No storage in crisper drawers: thermally isolated + floor level runs cold. Remove drawers, fill space with water bottles

PHARMACEUTICAL

Avoid storage on top shelf – near cooling vent. First location to exceed max allowed temp during outages.



Manufacturer recommends no floor storage, but vial TC maintained at 2 to 8 °C throughout testing

FREEZERLESS



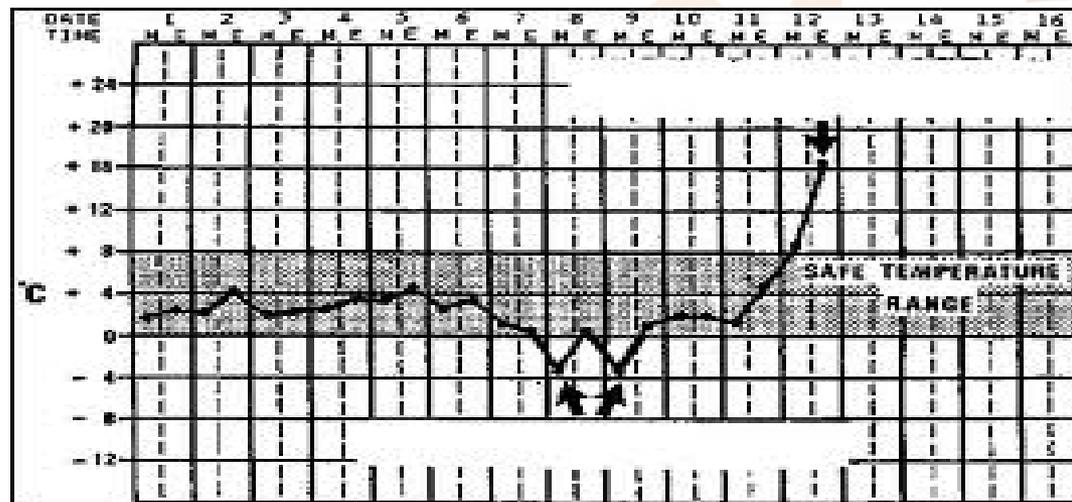
1 to 2 °C colder than main fridge space

Best storage practice – place vaccines in center fridge space, contained in original packaging, inside designated storage trays positioned 2 to 3 in from refrigerator walls

Temperature Excursions

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- An excursion is any temperature outside the recommended temperature range for a vaccine. However, it is the total amount of time, or cumulative time, out of range that affects the viability of a vaccine.



Temperature Excursion, cont.

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- **Take Immediate Action**
 - Immediately store the vaccines under appropriate conditions and label them “DO NOT USE”
 - Document the storage unit and ambient room temperatures and the length of time the vaccines may have been exposed to the inappropriate storage temperatures.
 - Conduct an inventory of the vaccines affected.
 - Contact the Immunization Program for guidance.
 - Do not discard vaccines unless directed to by the Immunization Program.

CDC Interim Storage & Handling Guideline FAQ



- **Why does CDC recommend not using the combination units for storing vaccines?**
 - Most common household units have combined temperature controls that can create cold spots and temperatures fluctuations
 - The freezer portions of many combination units are not capable of maintaining the correct storage temperature for frozen vaccines.
 - If you are currently using a combination storage unit, it is recommended that providers not use the freezer and store their frozen vaccines in a standalone freezer unit.

CDC Interim Storage & Handling Guideline FAQ

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- **Why do I need to continue to document temperatures twice daily, if I have a continuous data logger and/or alarm system?**
 - Twice daily checks give a better indication of any problems with a storage unit's function.
 - This additional safety check ensures that any temperature excursions recorded by the data logger and alarm system are addressed promptly.



CDC Interim Storage & Handling Guideline FAQ

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- **When should I download the data logger information?**
 - Data loggers should be downloaded and reviewed weekly, or
 - Any time there is a temperature excursion
- The Immunization Program does not have information on all data loggers
- Providers should be familiar with their data loggers and review the instructions provided by the manufacturer to ensure they can properly collect and download the data

Recommended Data Logger Features and Specifications

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<p>Detachable temperature probe</p> <ul style="list-style-type: none"> ✓ To be kept in liquid-filled bottle ✓ Cable length > 1 m preferred 	<p>Integrated Liquid Crystal Display (LCD) with minimum:</p> <ul style="list-style-type: none"> ✓ Last measured temp displayed in °C or °F ✓ Hi/Lo alarm status indicator
<p>Continuous temp monitoring</p> <ul style="list-style-type: none"> ✓ At least one reading/15 min 	<p>Alarm capabilities</p> <ul style="list-style-type: none"> ✓ Factory set, end-user adjustable ✓ Alarm activation at 2 °C (low) and 8 °C (high)
<p>Memory storage : 4000 readings</p> <ul style="list-style-type: none"> ✓ ~ 39 days recording at one rdg/15 mins ✓ Device stops recording when memory is full, reset after data download 	<p>Download/ archival software</p> <ul style="list-style-type: none"> ✓ Download data via standard computer ports (e.g., USB) ✓ Graphical presentation of date/time/temperature data ✓ Display alarm configuration details and total time outside high/low thresholds ✓ Data export capability (e.g., csv, Excel, txt)
<p>Operating refrigerator range: -20 °C to 40 °C</p>	<p>Resolution: ± 0.1 °C (the number of digits displayed)</p>
<p>Uncertainty: ± 0.5 °C</p> <ul style="list-style-type: none"> ✓ In the range of -1 °C to 15 °C ✓ Often listed as device “accuracy” 	<p>Battery life: 6 months minimum</p>

Free Storage & Handling Training

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- **“You Call the Shots”**
 - A **free** educational module regarding Storage & Handling from the CDC
 - An interactive, web-based module which provides learning opportunities, self-test practice questions, reference and resource materials, and an extensive glossary.
 - **Free** Continuing education credit is available.
- <http://www2a.cdc.gov/nip/isd/ycts/mod1/courses/sh/ce.asp>
- EZIZ Training Modules: <http://eziz.org/eziz-training>
- Tag Demo



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