

# Vaccine Storage and Handling

## INTERIM GUIDANCE

### Introduction

In response to recent scientific studies<sup>1</sup> on equipment used for vaccine storage and a better understanding of best practices for vaccine storage and handling, the Centers for Disease Control and Prevention (CDC) is providing interim guidance on appropriate vaccine storage and handling practices. This guidance is intended for use by all public and private sector providers and, while recognizing that cost may be a barrier, we encourage practices to move toward implementing these recommendations as soon as possible. CDC is currently evaluating the most efficient and cost effective method to phase these recommendations in and more guidance is forthcoming.

With the goal of improving the way providers store and handle vaccines nationwide, several important changes have been made to previous recommendations issued by CDC, including:

1. Use of a biosafe glycol-encased probe or a similar temperature buffered probe rather than measurement of ambient air temperatures, and;
2. Use of digital data loggers with detachable probes that record and store temperature information at frequent programmable intervals for 24 hour temperature monitoring rather than non-continuous temperature monitoring, and;
3. 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 fragile biologics, such as vaccines, and;
4. Discontinuing use of dorm-style or bar-style refrigerator/freezers for ANY vaccine storage, even temporary storage, and;
5. Weekly review of vaccine expiration dates and rotation of vaccine stock.

More detail regarding these changes and the rationale behind them is included below.

*Biosafe Glycol-Encased Probes or Similar Temperature Buffered<sup>1</sup>Probes*

CDC recommends use of a digital thermometer with a biosafe glycol-encased probe or a similar temperature buffered probe that will more closely approximate the measure of liquid temperature. A temperature buffer enables a thermometer probe to more closely match the temperature changes experienced by stored vaccine. Examples of temperature buffers are a probe inserted into a glycol-filled vial or one inserted into glass beads. CDC recommends this type of probe because studies by the National Institutes of Standards and Technology (NIST), U .S. Dept of Commerce <sup>i</sup> conducted in 2009 showed that compared to temperature monitors that measure ambient air temperature, the digital thermometer with glycol-encased probe more accurately reflects the temperature of the vaccine vial and does not register normal air temperature fluctuations which do not significantly impact vaccine temperature. Because the main factor affecting potency of refrigerated vaccines is exposure to freezing temperatures, it is important that glycol-encased or similar temperature buffered probes be placed among the vaccines instead of on a wall, and at least for refrigerated vaccines, in the part of the refrigerator unit where manufacturer recommended vaccine storage temperatures can best be maintained. To ensure validity of temperature measurements, only calibrated thermometers with a certificate of Traceability and Calibration should be used. Calibrated thermometers will continue to be a requirement for providers who receive VFC vaccine.

*Digital Data Loggers for Temperature Monitoring*

In addition to the use of a digital thermometer with a biosafe glycol-encased or similar temperature buffered probe, the thermometer should also be able to provide and store data monitoring information set at programmable intervals in an active display that allows for reading temperatures without opening the unit door. This means that the digital data logging thermometer probe should be able to remain in place and not be disturbed during data reading and recording. A detachable probe facilitates downloading temperature data without removing the probe from the storage unit, and should simplify daily use and minimize operator cause of temperature variability. The digital data logger should also include the following:

- Hi/Lo alarm for out-of-range temperatures;
- Current temperature, as well as minimum and maximum temperatures;
- Reset button ;

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<sup>1</sup> The purpose of a temperature buffer is to slow the response time of the probe to temperature changes so that it matches the temperature changes experienced by the vaccine.

- Low battery indicator;
- Accuracy of +/- 1°F (0.5°C);
- Memory storage of at least 4000 readings, device will not rewrite over old data and stops recording when memory is full;
- User programmable logging interval (or reading rate).

These changes in the use of systems for continuous temperature monitoring mean more accurate and comprehensive monitoring of any temperature excursions to which vaccines may have been exposed, and diminish the need for opening the unit door while conducting this routine monitoring. Finally, it is a requirement for VFC providers and a recommendation for all providers that storage unit temperatures continue to be read and documented twice each workday. It is recommended that minimum/maximum temperatures be checked and documented once per day preferably in the morning. Reviewing the minimum/maximum temperatures helps to ensure that temperature excursions will be identified more quickly and corrections made that can prevent vaccine loss, as well as minimize the inaccuracy of generalizing twice daily measurements.

Stored temperature monitoring data should be downloaded and reviewed at least weekly by providers, both to ensure the timely review of the data and the appropriate response to issues. When the data is downloaded, the data logger should be reset so there is sufficient memory available. The downloaded information should be kept for a minimum of 3 years or according to individual state record retention requirements. These practices ensure that the data logger will continue to function properly with sufficient memory for accurate monitoring and that problems with storage equipment can be identified and corrected early.

#### *Stand-Alone Refrigerator and Stand-Alone Freezer Units*

CDC strongly recommends the use of stand-alone refrigerator and stand-alone freezer units, meaning a self-contained unit that only refrigerates or freezes and is suitable for vaccine storage. These units can vary in size, from a compact, under-the-counter style to a large, stand-alone, pharmaceutical grade storage unit. CDC does not recommend use of dormitory<sup>2</sup> or bar-style refrigerator/freezers for ANY vaccine storage. The use of these specific refrigerator/freezers is not allowed at any time for Vaccines for Children (VFC) program providers.

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<sup>2</sup> Dormitory-style or bar-style refrigerator is defined as a small combination freezer/refrigerator unit that is outfitted with one exterior door and an evaporator plate (cooling coil), which is usually located inside an icemaker compartment (freezer) within 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.

The characteristics of a recommended storage unit include: 1) enough room to store the year's largest inventory without crowding and 2) sufficient room to store water bottles in the refrigerator and frozen coolant packs in the freezer to stabilize the temperature and minimize temperature excursions that can impact vaccine potency. The addition of water bottles (not gel packs) reduces the risk of freezing due to the tremendous latent heat released from water prior to freezing. In addition, frost-free or automatic defrost cycle units are preferred. Because freezing of refrigerated vaccines affects vaccine potency more than other exposure problems, it is especially important that refrigerators be selected and set up in a way that eliminates the chance of freezing vaccine. Use of stand-alone units is a best practice. Studies by NIST<sup>i</sup> show that 1) dormitory-style or bar-style combination units pose a significant risk of freezing vaccine even when used for temporary storage, and 2) the usual house-hold single-condenser combination refrigerator/freezer units are less capable of simultaneously maintaining proper storage temperatures in the refrigerator and freezer compartments. These refrigerators are cooled by venting cold freezer air into the refrigerated section – thus a real risk of freezing vaccine near the cooling vents. An alternative to stand-alone units is to use only the refrigerator compartment of a combination household refrigerator/freezer unit to store refrigerated vaccines and to be very careful not to use the top shelf if the vent from the freezer opens there. A separate stand-alone freezer should then be used to store frozen vaccines; this is because the freezer compartment of a combined house-hold unit should not be used for vaccine storage if the refrigerator unit is being used for that purpose.

#### *Procedures for Efficient Management of Vaccines*

Each provider practice (each location) should have written storage and handling plans, updated annually, both for routine storage and handling of vaccines, and for emergency vaccine retrieval and storage. Plans for routine storage and handling of vaccines should include detailed descriptions of the procedures for: 1) ordering and accepting vaccine deliveries; 2) storing and handling vaccines (e.g., ensuring that refrigerated vaccines are stored between 35°F and 46°F [2°C and 8°C] and frozen vaccines between -58°F and +5°F [-50°C and -15°C]); 3) managing potentially compromised vaccines (i.e., vaccine that has been exposed to temperatures outside of the recommended range defined above); 4) managing vaccine inventory (e.g., checking vaccine and diluent expiration dates weekly and removing expired items from usable stock); and 5) downloading and reviewing electronic monitoring data weekly.

Another necessary component of good practice is ensuring adequately trained vaccination personnel at all levels. This includes personnel that can serve as designated primary and back-up vaccine coordinators, both permanent and temporary staff who are familiar with proper storage and handling policies and procedures, comprehensive storage and handling training for both new staff and maintaining competence of current staff, and accountability checks to ensure protocols are followed. It is also important that a physician partner or member of management is directly involved with the responsible clinical staff – someone with a clear understanding of the vaccine replacement costs of miss-managed refrigerators and vaccine.

Frequently Asked Questions (FAQs) regarding this Interim Guidance are available on our website. The changes summarized in this Interim Guidance will also be reflected in a comprehensive update of CDC's Vaccine Storage and Handling Toolkit (target date for publication Fall 2012). In addition, CDC's posted guidance will continue to be updated as necessary to reflect best practices on vaccine storage and handling. For example, ongoing and planned studies with NIST, U.S. Department of Commerce are being conducted to better understand areas such as optimizing frequency of checking temperature recording by data loggers and packing of vaccine vial boxes for transport.

Thank you and please direct any questions to [NIPINFO@cdc.gov](mailto:NIPINFO@cdc.gov)

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<sup>i</sup> NISTIR 7656 "Thermal Analysis of Refrigeration Systems Used for Vaccine Storage", Michal Chojnacky, Wyatt Miller, Dean Ripple, Gregory Strouse CSTL November 2009  
NISTIR 7753 Michal Chojnacky, Wyatt Miller, Gregory Strouse. Thermal Analysis of Refrigeration Systems Used for Vaccine Storage, PML, September 2010

CENTERS FOR DISEASE CONTROL AND PREVENTION  
Interim Guidelines for Vaccine Storage and Handling  
**Frequently Asked Questions**

1. Is it more harmful for refrigerated vaccine to be too warm or too cold?
2. What temperature is considered an excursion on refrigerated vaccine? Frozen vaccine?
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18. When should I record the min/max temperature? Is this a new requirement?
19. Should I have a back-up temperature probe?

**1. Is it more harmful for refrigerated vaccine to be too warm or too cold?**

While exposure to both warm and cold temperatures can affect the potency of refrigerated vaccine, exposure to freezing temperatures will destroy some refrigerated vaccines. Hepatitis B and DTaP/Td/DT/Tdap vaccines are especially sensitive to freezing temperatures. That is why it is important to regularly monitor the temperature of your vaccines and take quick action when temperature excursions occur. It is also critically important that your vaccine storage equipment meet current recommendations and be able to maintain correct storage temperatures.

**2. What temperature is considered an excursion on refrigerated vaccine? Frozen vaccine?**

Any temperature readings outside the ranges noted in the table below are considered a temperature excursion. If there is a question about whether a vaccine has been exposed to a temperature excursion, label the vaccines “DO NOT USE” and store them under appropriate conditions separate from other vaccines. Then, contact vaccine manufacturer for further guidance. If you are a VFC provider, please contact either the vaccine manufacturer and/or your state or local Immunization Program as directed by the VFC Program in your area.

	Minimum Temperature	Maximum Temperature
Refrigerated vaccines	35° F (2° C)	46°F (8° C)
Frozen Vaccines	-58° F (-50° C)	+5° F (-15° C)

**3. How long does the temperature of the refrigerator have to be out of range to be considered an excursion?**

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. For example, if your temperature probe shows that the temperature of a refrigerated vaccine rose to 48° F (9° C) for 10 minutes in the morning and 5 minutes in the afternoon, the cumulative time out of range was 15 minutes.

Because the characteristics that determine vaccine viability vary for each lot of vaccine, it is important to contact vaccine manufacturer for further guidance to determine whether or not the vaccine can be used.. When contacting the manufacturer and/or state or local immunization program you should be prepared to provide them with data from the temperature logs and/or the digital data logger so that they can offer you the best guidance. If you are a VFC provider, please contact the vaccine manufacturer and/or your state or local Immunization Program as directed by the VFC Program in your area

**4. How do I determine where are the best locations for vaccine storage in a storage unit?**

As a general guide, the best way to store vaccine is:

- in the original packaging
- inside designated storage trays in the center of the unit
- at least 2-3 inches away from the walls, floor and ceiling of the storage compartment

This type of storage provides the most stable temperature environment for vaccine storage.

All refrigerators vary, with warmer and colder storage areas that differ among different types of units. In addition, several factors can affect the temperature where the vaccine is located including seasonal weather affecting room temperature, frequency of opening and closing the unit door and the unit's mechanism for cooling.

For more information, please see the following presentation titled, "Guidelines for Storage and Temperature Monitoring of Refrigerated Vaccines" at <http://www.nist.gov/pml/div685/grp01/upload/Guidelines-for-Storage-and-Temperature-Monitoring-of-Refrigerated-Vaccines.pdf>. See specifically slides # 12-15 for examples of how to set up various types of vaccine storage units.

**5. *What do I do when a temperature alarm goes off repeatedly?***

If the temperature alarm goes off repeatedly, start by conducting basic checks of the refrigerator door, power supply and thermostat setting. If the alarm continues to sound, move vaccines to another refrigerator or freezer that is operating at temperatures appropriate for vaccine storage. A qualified service technician should check your equipment to determine need for repair or replacement.

All practices should have written routine **and** emergency storage and handling plans. The routine vaccine storage and handling plan should include guidance on routine vaccine management process/practices. The emergency vaccine storage and handling plan must include guidance on what to do in the event of refrigerator or freezer malfunctions, power failures, natural disasters, or other emergencies that might compromise vaccine storage conditions.

In any type of power outage follow the below guidance:

- Do not open freezers and refrigerators until power is restored, except to transport vaccine to an alternative storage location
- Monitor and record temperatures and duration of power outage
- Do not discard or administer vaccine until the situation has been discussed with public health authorities and/or the vaccine manufacturers

For information on how to develop written routine and emergency vaccine storage and handling plans, please contact your state or local immunization program for assistance.

**6. *I have a "certified" thermometer that claims to be traceable to the National Institute of Standards and Technology (NIST). What is the difference between a "certified" and a "calibrated" thermometer?***

Calibration is a comparison of measurements from two different devices – one measurement from a device known to be correct and another measurement made in as similar a way as possible with a second device. The "standard" device is the device whose measurement is known to be correct. The device being calibrated is often called the unit under test, or test instrument

There is no official definition of "certified." Often, a certified thermometer has been tested against standards traceable to NIST, but the user is given less information on the certificate than is typical for a calibration report. To be sure that the thermometer is truly traceable, we suggest asking the vendor if the certification followed a documented process, what was the measurement uncertainty, and were the reference standards traceable to an ISO 17025 (International Organization of Standardization) accredited testing laboratory, from NIST, or from another internationally recognized standards agency.

**7. What information should be contained in a certificate of calibration to assure that it meets the VFC requirement?**

There is no VFC standard for what must be contained in a certificate of calibration. The vendor will establish the contents of the certificate of calibration, but at a minimum, NIST recommends that:

- Calibration methods and procedures should be openly documented.
- Uncertainties of calibration should be clearly stated.
- Measurement results should be documented.

In addition, NIST notes:

- Traceability records should not be claimed to be private or proprietary knowledge.
- Laboratory accreditation is not a guarantee of traceability, but accreditation does provide assurance that qualified assessors have looked at a laboratory's traceability procedures.

**8. What is the appropriate action to take if I check the temperature and it is out of range?**

**Immediate action** must be taken to correct improper vaccine storage conditions and this action should be documented.

- Notify the primary or back-up vaccine coordinator (if not available, immediate supervisor) immediately of any temperature excursion.
- 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.
- Note if water bottles were in the refrigerator and/or frozen coolant packs in the freezer at the time of the event.
- Label the vaccines "DO NOT USE" to reduce risk of using vaccines that may have reduced potency because they were stored under inappropriate conditions and **immediately store them under appropriate conditions separate from other vaccine supplies.**
- Contact your immunization program and/or vaccine manufacturer(s) for guidance.
- Do not discard vaccines unless directed to by your immunization program and/or the manufacturer(s).

**9. Can we use a temperature probe in glass beads instead of a temperature probe in glycol?**

CDC recommends a temperature probe in glycol to more accurately reflect the temperature of vaccine in a vial. CDC recognizes that some providers may use a temperature probe in glass beads to approximate the temperature of vaccine in a vial and is currently working with the National Institute of Standards and Technology (NIST) to evaluate a temperature probe in glass beads. Until more data are obtained, temperature probes in a buffer, like glass beads, are allowable. Please note that CDC may revise its recommendations and allowable buffered substitutes at a later date pending the outcome of the NIST evaluation.

**10. Where should the temperature probe in glycol (thermometer) be placed?**

The location of the thermometer should be in proximity to the vaccines being stored. Proper place is very important since it helps the provider to most accurately identify the actual vaccine vial temperatures and to take appropriate corrective actions quickly if necessary.

**11. What thermometer should I use to measure temperature when I conduct a site visit in a provider's office, the provider's probe in glycol or my own thermometer?**

CDC recommends that site visitors use the same type of probe in glycol monitoring device that is recommended for routine use by vaccine providers and is currently reviewing best practices for assessing temperatures readings during VFC compliance site visit.

In the interim CDC recommends that site visitors accept provider readings if the storage unit and the temperature monitoring devices meet **current** CDC guidelines. For those providers who are not using recommended storage, thermometers and monitoring devices, CDC recommends that site visitors bring a backup probe in glycol to each site visit to assess temperature readings.

**12. Are combination household units acceptable for storing vaccines anymore?**

CDC strongly recommends standalone refrigerators and freezers. This recommendation is because:

- Most common household refrigerator/freezers have combined temperature control units that can create cold spots and temperatures fluctuations in the refrigerator portion of the unit
- The risk of freeze-damage to refrigerated vaccines is increased in combination units because air from the freezer is circulated into the refrigerator to cool it. This can freeze temperature-sensitive vaccines.
- The freezer portions of many combination units are not capable of maintaining the correct storage temperature for frozen vaccines

Purchasing new vaccine storage equipment may require planning and existing equipment may need to be used for a certain amount of time until new equipment can be purchased. In this situation, CDC recommends using a combination refrigerator/freezer unit for refrigerated vaccine only and using a separate standalone freezer to store frozen vaccines.

It is important to note that most combination refrigerator/freezers share a single condenser, and freezing air from the freezer compartment is vented into the refrigerator compartment to cool the refrigerator. You should not turn off the freezer portion of the combination unit because it will not maintain the proper temperature for refrigerated vaccines stored in that part of the unit. If you are using the refrigerator portion of the combination unit, it is important that you add water bottles to the refrigerator to absorb cold air blown in from the freezer to reduce the risk of vaccines becoming too cold.

**13. What if I have a refrigerator/freezer combination unit with separate condensers?**

There are some combination refrigerator/freezers that have a separate freezer condenser and separate refrigerator condenser with no air vents connecting the two, and separate digital temp controls for freezer and refrigerator sections. All vaccine storage units must be monitored by a calibrated thermometer and must demonstrate that the unit can reliably maintain appropriate vaccine storage temperatures. Although

these types of “twin cooling” combination units have not been formally evaluated by NIST to determine whether they are acceptable alternatives, for the time being these types of combination units may be used to store vaccines. However, in the future, CDC may revise this exception if this specific type of combination refrigerator/freezer is tested and found to cause an increased risk of potentially freezing refrigerated vaccines.

**14. Can I use the freezer compartments of a combination unit to store frozen vaccines?**

No, frozen vaccine should not be stored in a freezer of a combination unit because NIST has found that household freezers cannot hold proper storage temperatures for frozen vaccine. This applies to both temporary and long term storage of frozen vaccines. A separate standalone freezer should be used to store frozen vaccines. A storage unit that is frost-free or has an automatic defrost cycle is preferred.

**15. Does CDC recommend specific brands of vaccine storage equipment?**

CDC does not recommend specific brands of vaccine storage equipment but based on refrigerator storage equipment testing by NIST, CDC provides guidance on types of storage equipment that provides greater assurance of proper temperatures for vaccine storage.

CDC strongly recommends standalone units (refrigerator or freezer), meaning a self-contained unit that only refrigerates or freezes, and is suitable for vaccine storage. A less optimal but acceptable alternative to standalone units is to use the refrigerator compartment only of a combination refrigerator/freezer unit to store refrigerated vaccines. A separate standalone freezer should be used to store frozen vaccines. A storage unit that is frost-free or has an automatic defrost cycle is preferred.

Another option is to use pharmacy grade or purpose built refrigerators and/or freezers. These are specifically engineered to have even temperatures throughout. Purpose built or pharmacy grade refrigerators can be compact in size, thus making them ideal for small offices.

CDC strongly recommends that you use water bottles throughout the refrigerator storage unit to increase temperature mass and to reduce the risk of freezing temperature sensitive vaccines.

**16. How often should I set the digital data logger to measure temperature?**

CDC’s interim recommendation is to set the digital data logger to measure every 15 minutes. If you wish to set the data logger to measure temperature more frequently or if the manufacturer recommends a more frequent setting, that is acceptable. CDC is currently working with the National Institute of Standards and Technology (NIST) to evaluate the most efficient and effective settings for digital data logger temperature measurements

**17. Why do I need to continue to document temperatures twice daily, if I have a continuous data logger and/or alarm system?**

CDC recommends documenting temperatures twice daily even with a continuous data logger and/or alarm system because twice daily checks will give you a better indication of any problems with your storage unit’s function. This additional safety check ensures that any temperature excursions recorded by the data logger and alarm system are addressed promptly.

**18. When should I record the min/max temperature? Is this a new requirement?**

CDC recommends recording the min/max temperature in the morning at the beginning of the workday. This is a new recommendation for all providers and a new requirement for VFC providers.

**19. Should I have a back-up temperature probe?**

It is always a good idea to have a back-up temperature probe for each vaccine storage unit, in the event that something happens to the primary temperature probe or if the primary probe needs to be sent in to a laboratory for calibration.

If you plan to use a back-up temperature probe, CDC highly recommends that the back-up probe have the same set up (i.e., temperature probe in glycol) rather than purchasing a back-up probe that measures air temperature. In addition, CDC recommends that the back-up probe have a different calibration schedule than the primary probe so that your back-up is available when the primary probe is sent in for calibration.

It is important to note that some state or local VFC programs require VFC providers to have a back-up temperature probe. Please contact your state or local VFC program to inquire about specific requirements.

The Interim Vaccine and Handling Guidance is posted at <http://www.cdc.gov/vaccines/recs/storage/interim.htm>