CENTERS FOR DISEASE CONTROL AND PREVENTION

Interim Guidelines for Vaccine Storage and Handling
Frequently Asked Questions

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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	35º F (2º C)	46ºF (8º C)
Frozen Vaccines	-58º F (-50º C)	+5º F (-15º 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 48º F (9º 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 is 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