



**TO:** Regional Directors, Public Health Regions  
Regional Immunization Program Managers, Health Service Regions  
Directors, Local Health Departments  
Immunization Managers, Local Health Departments

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**SUBJECT:** Texas Vaccines for Children (TVFC) Program: Vaccine Storage Equipment

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The Centers for Disease Control and Prevention (CDC) has recently updated the federal Vaccines for Children (VFC) Operations Guide. One section of this manual identifies the requirements of vaccine storage equipment used in all VFC provider sites. Equipment includes thermometers, refrigerators, and freezers. In accordance with these guidelines, the following changes will become effective in the Texas Vaccines for Children (TVFC) program beginning January 1, 2009, and will be reviewed during the annual site visits conducted in 2009.

Providers enrolled in the TVFC will be required to have certified calibrated thermometers in all refrigerators and freezers used for vaccine storage. Use of continuous recording devices, temperature alarm systems, and other equipment will not replace the need to have a certified thermometer in each refrigeration/freezer unit. The Immunization Branch has committed to purchasing initial supplies of certified thermometers, and Health Service Regions (HSR), Local Health Departments (LHD), and staff making site visits will assist with distribution. It is the provider's responsibility to comply with future needs and/or re-calibration of thermometers in order to adhere to the federal guidelines.

Certified thermometers require periodic recalibration to retain the certified status. TVFC guidelines for replacement and/or re-calibration will be determined and communicated prior to January 1, 2009. The certificate accompanying Certified Thermometers should be retained as proof of certification. An informational document on Certified Thermometers is attached as a reference.

The second change in the requirements that will affect some TVFC providers specifies the types and conditions of refrigerators and freezers that are acceptable for vaccine storage. The following four criteria all apply:

All refrigerators and freezers must be able, year round, to maintain the required vaccine storage temperatures of 36-46 degrees Fahrenheit, and 5 degrees or lower Fahrenheit respectively.

The units must be large enough to hold the year's largest inventory.

The units must be dedicated to the storage of vaccines. (Food and beverages must not be stored in vaccine storage units because this practice results in frequent opening of the door and destabilization of the temperatures).

A refrigerator/freezer combination unit must have separate exterior doors for the refrigerator and freezer compartments; or be stand-alone separate refrigerator and freezer units.

Refrigerators with a freezer unit inside (does not have a separate outside door) will not be allowed for the storage of TVFC vaccine, whether or not varicella vaccine is stored. Providers with this type of storage unit will need to upgrade refrigeration/freezer equipment in accordance with the guidelines. According to CDC this type of unit is restricted because the freezer compartment is incapable of maintaining temperatures cold enough to store frozen vaccines (varicella, MMRV, zoster). If attempts are made to cool the freezer compartment to the appropriate temperature, the temperature in the refrigerator compartment will fall below the recommended range, potentially freezing the refrigerated vaccines.

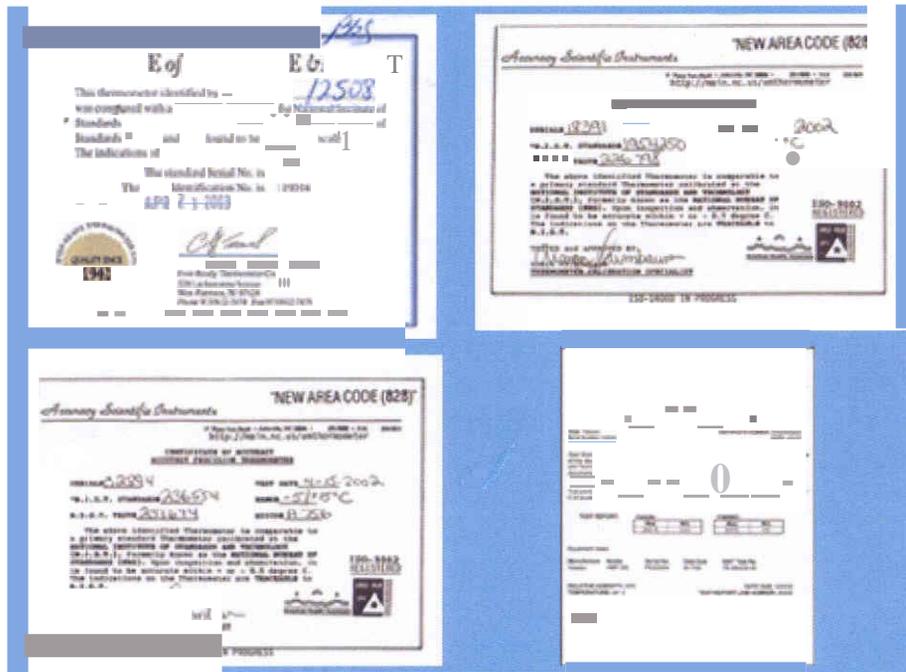
Refrigerators with a freezer unit inside may be used to store a clinic's single-day supply of refrigerated-only vaccines; and these refrigerated vaccines should be returned to the main refrigerator at the end of each clinic day. If refrigerators are used for this purpose, do not place vaccines directly beside or below the freezer compartment, as this may expose vaccines to temperatures below the recommended range. Place cold packs (not frozen packs) or water bottles in this space to provide a temperature buffer. Temperatures must be monitored twice daily as with all vaccine storage units; be sure to place the thermometer on a shelf holding vaccines.

Again these requirements will become effective in January 2009. Providers who have questions regarding these changes may contact their LHD, HSR, or TVFC Consultant.

Attachment: Certified Thermometers document

## Certified Thermometers

Providers enrolled in the Texas Vaccines for Children (TVFC) Program are required to have certified calibrated thermometers in all refrigerators and freezers used for vaccine storage. All thermometers are calibrated during manufacturing, meaning that they are given a temperature scale. Certified calibrated thermometers undergo a second individual calibration against a reference standard from an appropriate agency, such as the National Institute of Standards and Technology (NIST) or a laboratory recognized by NIST. Calibration can be traceable to NIST using American Society for Testing and Materials (ASTM) methods for the calibration process. They are then given a certificate indicating successful completion of this process, which is provided with the instrument when purchased. This certificate is different from the manufacturer's warranty, and should be retained as proof of certification. Certified calibrated thermometers are available through laboratory and scientific supply companies.



Examples of thermometer calibration certificates.

## Thermometer Maintenance and Recertification

Some thermometers require batteries. If you use one of these, have a supply of extra batteries on hand.

Certified calibrated thermometers require periodic recertification and recalibration against reference thermometers in order to remain accurate. Contact the manufacturer for instructions regarding recalibration procedures. When choosing a certified calibrated thermometer, be sure to consider the cost and frequency of required recalibration. Recalibration costs will vary by manufacturer, model, and type of thermometer.

The National Center for Immunization and Respiratory Diseases recommends adhering to the recalibration schedule recommended by the manufacturer. Graphing thermometers, with their moving parts and frequent pen/paper changes, are likely to become less accurate with time; compliance with the manufacturer's recalibration schedule would be optimal. Digital thermometers may also become less accurate with time; however, these are relatively inexpensive, and may be less expensive to replace than to recalibrate. Bottle-type thermometers, which have no mechanical or electronic parts, are most likely to remain accurate for extended periods, and may be less expensive to replace than to recalibrate. However, bottle-type thermometers may be rendered inaccurate if the liquid column separates.

If the certified calibrated thermometer indicates an out-of-range temperature and if it is properly positioned assume it is accurate and take immediate steps to safeguard the vaccine. Once the vaccine is safely stored under proper conditions, the accuracy of the thermometer can be checked. However, always check other causes of inappropriate storage temperatures first.