Vaccine Storage and Handling Toolkit

National Center for Immunization and Respiratory Diseases

Centers for Disease Control and Prevention

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Introduction

Vaccination efforts have been successful in preventing and eradicating vaccine-preventable diseases in part because of proper vaccine storage and handling practices. Failure to adhere to recommended specifications for storage and handling can reduce vaccine potency, resulting in inadequate immune responses in the recipients and inadequate protection against disease. Vaccine quality is the shared responsibility of all parties, from the time vaccine is manufactured until it is administered.

Storage and handling errors result in the loss of millions of dollars worth of vaccine each year in the United States. Vaccine failures caused by administration of reduced potency vaccine can affect a large number of patients, causing embarrassment, expense, and potential liability. Patient confidence in vaccines and in vaccine providers is diminished when repeat vaccinations are required to replace invalid doses administered with reduced-potency vaccines.

Vaccine storage and handling mistakes are easily avoidable. This toolkit will provide you with general guidelines for correct vaccine storage and handling. Specific recommendations for vaccine storage and handling procedures may vary among different state health department immunization programs. This toolkit does not replace these state health department policies but rather is meant to supplement them. Contact the state health department immunization program for details regarding recommended vaccine storage and handling procedures in your state.

This toolkit does not replace state health department policies but rather is meant to supplement them.

Vaccine storage and handling recommendations included in the product package inserts should be followed carefully and will provide you with the most up-to-date information. If you have concerns about vaccine that may not have been stored or handled properly, follow your state health department immunization program policy and contact either the manufacturer's quality control office or the immunization program for guidance.

Cold Chain

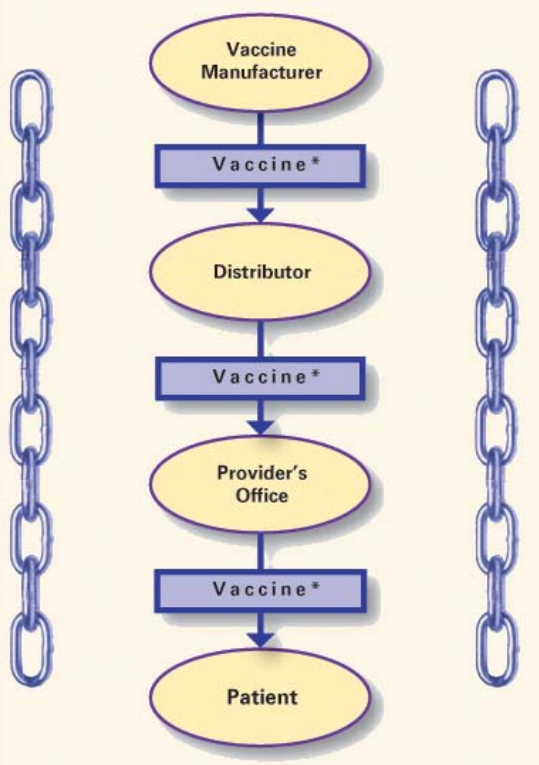
What Is the Cold Chain?

Vaccines must be stored properly from the time they are manufactured until the time they are administered. Excess heat or cold will reduce their potency, increasing the risk that recipients will not be protected against vaccine-preventable diseases. The system used to keep and distribute vaccines in good condition is called the cold chain. The cold chain has three main components: transport and storage equipment, trained personnel, and efficient management procedures. All three elements must combine to ensure safe vaccine transport and storage.

The cold chain begins with the cold storage unit at the vaccine manufacturing plant, extends through the transfer of vaccine to the distributor and then to the provider's office, and ends with the administration of the vaccine to the patient. Proper storage temperatures must be maintained at every link in the chain.

Proper storage temperatures must be maintained at every link in the chain.

The Cold Chain



***Vaccine is transported in a refrigerated or frozen state, as appropriate (refrigerator 35°– 46°F [2°– 8°C]; freezer 5°F [-15°C] or colder), using an insulated container or a refrigerated truck.**

Importance of Maintaining the Cold Chain

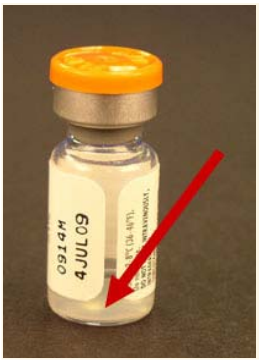
Vaccine Potency

Excessive heat or cold exposure damages vaccine, resulting in loss of potency. Once potency is lost, it can never be restored. Furthermore, each time vaccine is exposed to heat or cold, the loss of potency increases and eventually, if the cold chain is not correctly maintained, all potency will be lost, and the vaccine becomes useless.

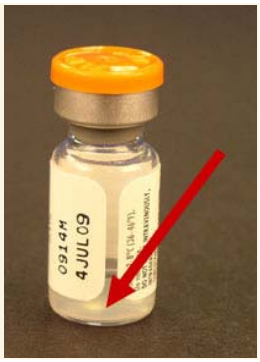
Excessive heat or cold damages vaccines.

Vaccine Appearance After Exposure to Inappropriate Storage Conditions

Some vaccines may show physical evidence of altered potency when exposed to inappropriate storage conditions, such as clumping in the solution that does not go away when the vial is shaken. Other vaccines may look perfectly normal when exposed to inappropriate storage conditions. For example, inactivated vaccines exposed to freezing temperatures (i.e., 32°F [0°C] or colder) may not appear frozen and give no indication of loss of potency. Therefore, visual inspection of vaccines is an unreliable method of assuring potency.



Properly stored vaccine
Full Potency



Improperly stored vaccine
Diminished Potency

Visual inspection of vaccines is an unreliable method of assuring potency

Burden of Cold Chain Failure

An estimated 17% to 37% of providers expose vaccines to improper storage temperatures. Refrigerator temperatures are more commonly kept too cold rather than too warm.[1,2] One study involving site visits showed that 15% of refrigeration units had temperatures of 34°F (1°C) or lower.[2] Out-of-range temperatures require

⚠**immediate action**.

Loss of vaccine potency due to improper storage conditions is a costly mistake. Patients receiving vaccine with decreased potency caused by improper storage conditions may not be fully protected against the vaccine-preventable disease. In the General Recommendations on Immunization, the Advisory Committee on Immunization Practices (ACIP) and the American Academy of Family Physicians (AAFP) state that mishandled vaccine doses should not be counted as valid doses and should be repeated unless serologic testing indicates a response to the vaccine.[3] Recalling patients to repeat vaccine doses because vaccine has been stored improperly can damage public confidence in vaccines and in your practice.

Store each vaccine in its proper location.

Vaccines are also expensive. The vaccines needed for a single infant visit can cost $181 to $281 or more. For toddlers, vaccine costs jump to $198 to $338 or more per child. The vaccines needed for one child at school entry cost $111 to $188 or more.[4] Avoid extra expenses by following procedures to maintain the cold chain.

References

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Centers for Disease Control and Prevention

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Vaccine Storage and Handling Plans

General Recommendations

All healthcare providers who administer vaccines should evaluate their cold chain procedures to ensure that vaccine storage and handling guidelines are being followed. Each office should develop and adhere to a detailed written Routine Vaccine Storage and Handling Plan. This plan should include all aspects of routine vaccine management, from ordering vaccines and controlling inventory to storing vaccines and monitoring storage conditions. A written plan will help vaccine providers stay organized and will provide quality assurance of proper vaccine management.

Develop and adhere to a Routine Vaccine Storage and Handling Plan.

Each office needs an Emergency Vaccine Retrieval and Storage Plan.

In addition, each office should have a detailed written Emergency Vaccine Retrieval and Storage Plan in the event of refrigerator or freezer malfunctions, power failures, natural disasters, or other emergencies that might compromise appropriate vaccine storage conditions. Establishing a set of written plans for both daily and emergency situations helps assure the continued viability of vaccines. These plans should be easily accessible to staff and should be kept near the vaccine storage unit(s).

Many components of the routine and emergency plans will be the same for every practice but some of the details may vary depending on local policies. Consult your agency or local or state health department immunization program, as appropriate for your situation, for any special instructions.

Routine Vaccine Storage and Handling Plan

The information below is provided as a guideline for developing a Routine Vaccine Storage and Handling Plan for the protection and maintenance of your vaccine supply.

Whenever there is a question about the integrity of the vaccine, follow your state health department immunization program policy and contact either the manufacturers quality control office or the immunization program for guidance.

You may also use the Routine Vaccine Storage and Handling Plan Worksheet in the Resources section to help organize your plan. Consult your agency, local health department, or state health department immunization program, as appropriate for your situation, for any special instructions or forms. Whenever there is a question about the integrity of the vaccine, follow your state health department immunization program policy and contact either the manufacturers quality control office or the immunization program for guidance.

Each Routine Vaccine Storage and Handling Plan should include the following information:

- **Up-to-date contact information**
  - For the primary and backup vaccine coordinators who are responsible for routine vaccine storage and handling (see the section on Vaccine Personnel)
  - For the state or local health department immunization program (see State Immunization Program Contact Information in the Resources section)
  - For the manufacturers of the vaccines in your inventory (Manufacturer Quality Control Office Telephone Numbers in the Resources section)
  - For the refrigerator and freezer maintenance and repair company(s)
  - For the vaccine storage unit alarm company (if applicable)
  - For the sources of packing materials and certified calibrated thermometers
- **Descriptions of the roles and responsibilities of the primary and backup vaccine coordinators** (see the section on Vaccine Personnel)
- **Summaries of the storage requirements for each vaccine and diluent in your inventory** (see the sections on Vaccine Storage Practices and Selected Biologicals)
- **Protocols for vaccine storage unit temperature monitoring** (see the section on Temperature Monitoring and Thermometers in the Vaccine Storage Equipment section)
- **Protocols for vaccine storage equipment maintenance** (see the section on Vaccine Storage Equipment)
- **Protocols for the correct placement of vaccine within storage units** (see Vaccine Storage Locations and Positioning in the section on Vaccine Storage Practices)
- **Protocols for responding to vaccine storage and handling problems** (see the section on Storage Troubleshooting)
- **Protocols for vaccine inventory management** (contact your state health department immunization program for details and see the section on Vaccine Inventory Management for general guidelines)
- **Protocols for transporting and receiving vaccine shipments** (contact your state health department immunization program for details and see the section on Vaccine Shipments and Maintaining the Cold Chain During Transport in the Resources section for general guidelines)
- **Policies for preparing vaccine for administration** (see the section on Vaccine Preparation and Disposal)
- **Protocols for proper disposal of vaccines and supplies** (contact your state health department immunization program for details and see the section on Vaccine Preparation and Disposal for general guidelines)
- **Samples of the forms used in your vaccination program** (contact your state health

department immunization program for details and see the Resources section —e.g., temperature logs, stock records, tally sheets)

Keep your Routine Vaccine Storage and Handling Plan in a prominent and easily accessible location near the vaccine storage units. Also establish a checklist of procedures and post it on all vaccine storage units (see Checklist for Safe Vaccine Handling and Storage in the Resources section).

All staff members who administer or handle vaccines in any way should be familiar with the Routine Vaccine Storage and Handling Plan (see Training in the Vaccine Personnel section).

Staff members should be familiar with the Routine Vaccine Storage and Handling Plan.

Emergency Vaccine Retrieval and Storage Plan

General Guidelines

To protect the vaccine inventory and to minimize potential monetary loss, every facility that stores vaccine should have a written Emergency Vaccine Retrieval and Storage Plan. Various situations may compromise vaccine storage conditions, such as equipment failures, power outages, or natural disasters. The Emergency Vaccine Retrieval and Storage Plan should provide up-to-date information regarding procedures to follow to protect and/or retrieve vaccines as quickly as possible when a potentially compromising situation occurs. Post the Emergency Vaccine Retrieval and Storage Plan on or near the vaccine storage equipment. Ensure that all staff (current and new) read the plan and understand it. Also ensure that janitorial and security staff are aware of the plan and know the procedures to follow to notify designated personnel about any problems with the vaccine storage equipment. Review and update the contact lists in the plan quarterly; review and update the entire plan annually.

When state officials, local officials, or providers have reasonable cause to believe that weather conditions, natural disasters, or other emergencies might disrupt power or flood any office where vaccine is stored, emergency procedures should be implemented **in advance of the event**.

Whenever there is a question about the integrity of the vaccine, follow your state health department immunization program policy and contact either the manufacturer's quality control office or the immunization program for guidance.

The information below is provided as a guideline for developing an Emergency Vaccine Retrieval and Storage Plan for the protection of vaccine inventories before and during emergency situations. You may also use the Emergency Vaccine Retrieval and Storage Plan Worksheet and the Emergency Response Worksheet in the Resources section to help organize your response. Consult your agency, local health department, or state health department immunization program, as appropriate for your situation, for any special instructions or forms. Whenever there is a question about the integrity of the vaccine, follow your state health department immunization program policy and contact either the manufacturers quality control office or the immunization program for guidance.

Advance Preparations

Well in advance of any emergency situation you should have the following personnel, equipment, information, and protocols in place:

- **Designated primary and backup vaccine coordinators with emergency contact information.** Record this information in the Emergency Vaccine Retrieval and Storage Plan Worksheet found in the Resources section. In addition to their routine vaccine storage and handling duties (see the section on Vaccine Personnel for details), the primary and backup vaccine coordinators should:
  - Monitor the operation of the vaccine storage equipment and systems;
  - Track inclement weather conditions;
  - Set up and maintain a monitoring/notification system during times of inclement weather or other conditions that might cause a power outage (a continuous-monitoring temperature alarm/notification system should be considered, especially for practices with large inventories);
  - Ensure the appropriate handling of the vaccine during a disaster or power outage;
  - Ensure 24-hour access to the building and vaccine storage unit(s); and
  - Ensure that sufficient fuel is on hand to continuously run the generator for at least 72 hours if the facility has a backup generator.
- **Emergency staff contact list in order of contact preference.** Determine whether all or certain persons on the list should be contacted in the event of a vaccine storage emergency or if the first person reached is sufficient. Include the primary and backup vaccine coordinators on the list. Record the names (in order) and contact information in the Emergency Vaccine Retrieval and Storage Plan Worksheet.
- **Vaccine storage unit specifications.** For each vaccine storage unit in your facility, identify the type of unit (e.g., refrigerator, freezer, combination refrigerator/freezer), the brand name, the model number, and the serial number. Record this information in the Emergency Vaccine Retrieval and Storage Plan Worksheet. These specifications may be useful for the repair company.
- **Alternate vaccine storage facility or facilities.** Establish working agreements with at least one alternate storage facility with a backup generator where vaccine can be appropriately stored and monitored for the interim (e.g., hospital, long-term care facility, state depot, Red Cross, fire station, packing plant). Make advance arrangements with the facility(s) to store your vaccine when weather predictions call for inclement conditions (e.g., tornadoes, hurricanes, ice, severe snowstorms), when your vaccine storage equipment cannot be repaired, or when the power cannot be restored before the vaccine storage unit temperature rises above the recommended range. Record the name of the alternate facility(s), the name of the contact person(s), and the telephone number(s) in the Emergency Vaccine Retrieval and Storage Plan Worksheet.

Establish at least one alternate storage facility where vaccine can be appropriately stored and monitored. This facility should have a backup generator.

- **Written protocols, vehicles, and drivers for transporting vaccine to and from the alternate vaccine storage facility.**
  - If the vaccine can be moved to the alternate facility before the vaccine storage temperature rises above the recommended range, it may be transported in insulated containers or coolers within ordinary vehicles inside the passenger compartment (not in the trunk because temperatures cannot be controlled inside the trunk). Make advance arrangements for a primary and backup vehicle and driver and record the contact information in the Emergency Vaccine Retrieval and Storage Plan Worksheet.

When transporting vaccine in ordinary vehicles use the passenger compartment—not the trunk.

  - If the location is far away or if you have a large quantity of vaccine, consider renting a refrigerated truck to transport the vaccine. In this case, joining with other practices to reduce costs may be advantageous if a refrigerated truck rental is necessary. Make advance arrangements with a local refrigeration company and an alternate and record the contact information in the Emergency Vaccine Retrieval and Storage Plan Worksheet.

A refrigerated truck can be used to transport vaccine.

  - Develop written protocols for transporting vaccine to and from the alternate vaccine storage facility.
    - Establish how to load the vehicle.
    - Have preselected routes to take (and alternate routes if necessary).
    - Determine the estimated time en route.

- **Written instructions for entering your facility and vaccine storage spaces in an emergency if the building is closed or if it is after hours.** These instructions should include the building security/after-hours access procedure, a floor diagram and the locations of the following:
  - Doors
  - Flashlights
  - Spare batteries
  - Light switches
  - Keys
  - Locks
  - Alarms (including instructions for use)
  - Circuit breakers
  - Packing materials
- **Appropriate packing materials to safely transport or temporarily store vaccine.** These materials may include insulated containers, refrigerated/frozen packs, and dry ice (depending on the type of vaccine—see Written protocol for vaccine packing in this section, Maintaining the Cold Chain During Transport in the Resources section, Chart of Refrigerated/Frozen Pack Needs for Different Climates in the Resources section for general guidelines). In situations where an alternate vaccine storage facility with a backup generator cannot be identified within a reasonable distance, maintain the appropriate packing materials to temporarily and safely store vaccine at your facility. Record the names and contact information for sources of these materials in the Emergency Vaccine Retrieval and Storage Plan Worksheet.

Insulated containers.


Refrigerated/frozen packs.


Dry Ice.

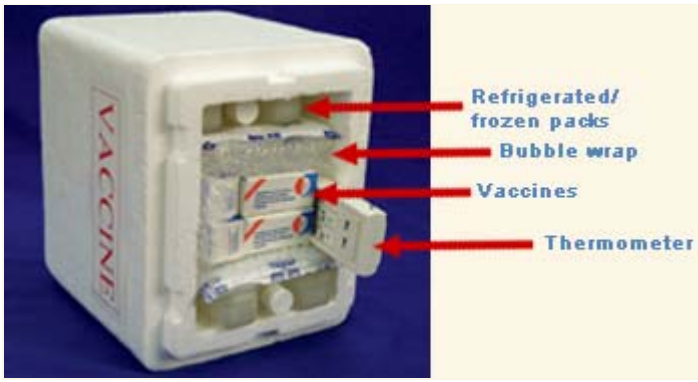
- **Prioritized vaccine packing list.** Make a written list of which vaccines to pack first in an emergency. Contact your state or local health department immunization program for advice on prioritization. If it is not possible to pack and transport all your vaccines, use your prioritized vaccine packing list to determine the types and amounts of vaccine to save.
- **Written protocol for vaccine packing.** Each facility should develop its own standard operating procedures (SOPs) for packing vaccine. These instructions should be readily available for staff unfamiliar with vaccine packing procedures. Key steps that should be reflected in all SOPs are:
  - Open the refrigerator and/or freezer doors only when absolutely necessary and only after you have made all preparations for packing and moving the vaccine to the alternate storage facility.
  - Use properly insulated containers to transport the vaccine. These containers should be validated to ensure that they are capable of maintaining the vaccine at the correct temperatures. You may use the shipping containers the vaccines arrived in from the

manufacturer. Alternatively, you may use hard-sided plastic insulated containers or Styrofoam™ coolers with at least 2-inch thick walls. Thin-walled Styrofoam™ coolers, such as those purchased at grocery stores to hold beverages, are not acceptable.

Refrigerated vaccines:

- Pack the refrigerated vaccines first, using enough refrigerated/frozen packs to maintain the cold chain. The number and placement of refrigerated/frozen packs inside the container will depend on container size and outside temperature. For detailed instructions, see Chart of Refrigerated/Frozen Pack Needs for Different Climates in the Resources section.
- Be sure to place an insulating barrier (e.g., bubble wrap, crumpled brown packing paper, Styrofoam™ peanuts) between the refrigerated/frozen packs and the vaccines to prevent accidental freezing. The contents of the container should be layered as follows: refrigerated/frozen packs, barrier, vaccine, thermometer or temperature monitor, another layer of barrier, and additional refrigerated/frozen packs.
- Use properly placed thermometers near the vaccine to assess whether the cold chain has been broken. The thermometer should be placed next to the vaccine and should not come in contact with the refrigerated/frozen packs.
- Attach labels to the outside of the container to clearly identify the contents as being valuable and fragile vaccines.
- Record vaccine type(s), quantity, date, time, and originating facility on a label on the outside of the container.
- Document the vaccine storage unit temperature at the time the vaccine is removed for transport.

Place bubble wrap, crumpled brown packing paper, or Styrofoam™ peanuts between the refrigerated/frozen packs and the vaccines.



Place the thermometer next to the vaccine but not in contact with the refrigerated/frozen packs.

Attach appropriate labels to the outside of the container.

Frozen vaccines:

- Pack the frozen vaccines last, using a separate insulated container. Remove combined measles, mumps, rubella, and varicella vaccine (MMRV); varicella vaccine; and zoster vaccine from the freezer and pack with dry ice immediately before they are to be transported. At least 6 pounds of dry ice should be used in the container to maintain the vaccines in their frozen state.
- Attach labels to the outside of the container to clearly identify the contents as being valuable and fragile vaccines.
- Record vaccine type(s), quantity, date, time, and originating facility on a label on the outside of the container.
- Document the vaccine storage unit temperature at the time the vaccine is removed for transport.

Use properly insulated containers to transport vaccine.

Dry ice should be used during transport to maintain vaccines in their frozen states.

- **Written protocol for appropriately storing vaccine at the alternate vaccine storage facility.** Combined measles, mumps, rubella, and varicella vaccine (MMRV); varicella vaccine; and zoster vaccine should be stored in the freezer at 5°F (-15°C) or colder. Other vaccines should be stored in the refrigerator at 35° to 46°F (2° to 8°C). There should be adequate cold air circulation around the vaccines. Each alternate vaccine storage unit should have a functioning certified calibrated thermometer in each compartment.

Temperatures inside the storage units should be monitored and recorded at least twice a day for as long as vaccine is stored in this location.	Temperatures inside the storage units should be monitored and recorded at least twice a day for as long as vaccine is stored in this location (see the sections on Vaccine Storage Practices and Temperature Monitoring for further details).

- **Up-to-date list of Manufacturer Quality Control Office Telephone Numbers.** An example may be found in the Resources section.

Emergency Actions

The following emergency procedures should be implemented **in advance of the event** if possible. If you have no warning and the emergency event is already occurring or has already occurred, you should still follow these procedures. Consult your agency, local health department, or state health department immunization program, as appropriate for your situation, for any special instructions. Whenever there is a question about the integrity of the vaccine, follow your state health department immunization program policy and contact either the manufacturers quality control office or the immunization program for guidance.

- **Suspend vaccination activities before the onset of emergency conditions, if possible.** This will allow sufficient time for packing and transporting vaccine.
- **Notify staff at the alternate vaccine storage facility.** Before moving your vaccine, call the alternate storage facility to make them aware of the situation and to ensure that their backup generator is working.
- **Conduct an inventory of the vaccines and record the actions taken.** Use the Emergency Response Worksheet in the Resources section. Also note if water bottles were in the refrigerator and frozen packs in the freezer at the time of this event.
- **Pack and transport the affected vaccines according to your priority list.** (see Written protocol for vaccine packing and Prioritized vaccine packing list in this section).
- **Follow established vaccine transport procedures for moving vaccine.** (see Written protocols, vehicles, and drivers for transporting vaccine to and from the alternate vaccine storage facility in this section).

Vaccine Personnel

Primary Vaccine Coordinator and Backup Vaccine Coordinator

Each practice should designate one staff member to be the primary vaccine coordinator. This person will be responsible for ensuring that all vaccines are handled correctly and that procedures are documented. Proper vaccine storage and handling procedures include but are not limited to the following tasks:

- ordering vaccines;
- overseeing proper receipt and storage of vaccine shipments; and
- at least twice daily temperature monitoring of the refrigerator(s) and freezer(s);
- at least twice daily recording on the temperature logs;
- response to storage temperatures outside the recommended range;
- maintenance of storage and handling equipment and records;
- rotation of vaccine stock so that vaccine closer to its expiration date will be used first;
- monitoring expiration dates on vaccines and ensuring that expired vaccine is not administered to patients;
- overseeing proper vaccine transport.

Each office should also designate a backup vaccine coordinator who is able to perform the same tasks as the primary vaccine coordinator in the event that the primary person is unavailable. Both the primary and backup vaccine coordinators should be fully trained in routine and emergency procedures related to vaccine shipments, storage, handling, transport, and inventory management.

Each practice should designate a Primary Vaccine Coordinator and a Backup Vaccine Coordinator.

Other Staff

Other staff members who handle or administer vaccines should also be familiar with the site's policies and procedures for vaccine storage and handling. This includes staff members, such as receptionists and mail handlers, who accept vaccine shipments. These policies and procedures should be available in writing as a reference for all staff members. Both the Routine Vaccine Storage and Handling Plan and the Emergency Vaccine Retrieval and Storage Plan see section on Storage and Handling Plans) should be easily accessible and should be kept near the vaccine storage units.

Staff who handle or administer vaccines should be familiar with their site's policies and procedures for vaccine storage and handling.

Training

During new staff orientation, all staff who administer vaccines should be trained in proper vaccine storage and handling practices. This toolkit can serve as a training guide. Additional training may be available through your state health department immunization program. Vaccine storage and handling practices should be reviewed annually to update all staff members on the latest policies. Records should be kept of vaccine training sessions and attendees. All staff members responsible for vaccines should understand the importance of cold chain maintenance and the procedures to follow if there is a break in the cold chain. There is no benefit to recording the temperature in a vaccine storage unit if action is not taken when the temperature is outside the recommended range. All staff members should know that any break in the cold chain must be reported immediately to the vaccine coordinator or to the immediate supervisor. The vaccine coordinator and supervisory staff should know that ⚠**immediate action** must be taken to correct inappropriate storage conditions (including both inappropriate light exposure and inappropriate temperature exposure).

Vaccine Storage Equipment

Disclaimer: This chapter will give you details about the requirements and maintenance of each piece of vaccine storage equipment and will provide information about methods and equipment used to protect vaccines against equipment failure. Individual projects and state health department immunization programs may have specific requirements for providers who receive public vaccine. Check with the project/state for more information. The use of trade names and commercial sources in this toolkit is for identification only, and does not imply endorsement by the U.S. Department of Health and Human Services (DHHS), the U.S. Public Health Service (PHS), or the Centers for Disease Control and Prevention (CDC). Photographs from non-Federal organizations found in the toolkit are provided solely as a service to our users. These photographs do not constitute an endorsement of these organizations by CDC or the Federal Government and none should be inferred.

General Requirements

Vaccine storage units must be selected carefully and used properly. Refrigerators without freezers, and stand-alone freezers, may be better at maintaining the required temperatures. However, a combination refrigerator/freezer unit sold for home use is acceptable for vaccine storage if the refrigerator and freezer compartments each have a separate external door.

Combination refrigerator/freezer.

Stand-alone freezer.

Any refrigerator or freezer used for vaccine storage must

- be able to maintain required vaccine storage temperatures year-round
- be large enough to hold the year's largest inventory
- have a certified calibrated thermometer inside each storage compartment
- be dedicated to the storage of vaccines. Food and beverages should **not** be stored in a vaccine storage unit because this practice results in frequent opening of the door and destabilization of the temperature.

Food and beverages should not be stored in a vaccine storage unit.

Backup Equipment

No piece of vaccine storage equipment is infallible. At some point, equipment failure will occur because of a power failure, breakdown, or normal wear and tear. Vaccine security requires that these failures be anticipated and that backup equipment and backup plans be available.

Equipment Logbooks

Consider keeping a logbook for each piece of cold chain storage equipment. This logbook should contain records indicating the serial numbers of each piece of equipment, the date each piece of equipment was installed, the dates of any routine maintenance tasks (such as cleaning), the dates of any repairs or servicing, and the name of the person performing each of these tasks. This logbook is also an ideal place to keep the instructions that came with the equipment.

Refrigerators and Freezers

Equipment Requirements

General Requirements

Vaccines that require storage temperatures between 35° and 46°F (2° and 8°C) may be stored in the refrigerator compartment of a household- or commercial-style refrigerator-freezer unit. Vaccines that require storage temperatures at 5°F (-15°C) or colder may be stored in the freezer compartments of such units. Sites that store large volumes of vaccine might prefer separate refrigerators and freezers since stand-alone refrigerator and freezer units may maintain the required temperatures better. Whatever type of storage unit is used, the refrigerator and freezer compartments must have separate external doors. The storage unit must have enough room to store the year's largest inventory without crowding and to store enough water bottles (in the refrigerator) and frozen packs (in the freezer) to stabilize the temperature. Additionally, the unit must function properly and reliably maintain the appropriate temperatures.

Refrigerator and freezer compartments must have separate external doors.

Dormitory-Style Units

Small single-door (dormitory-style or bar-style) combined refrigerator-freezer units should not be used for permanent vaccine storage. The freezer compartment in this type of unit is incapable of maintaining temperatures cold enough to store MMRV, varicella, and zoster vaccines. 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. However, this type of unit may be adequate for temporarily storing **small quantities** of inactivated vaccines and MMR vaccine in the refrigerator compartment (not the freezer compartment) **if** the refrigerator compartment can maintain temperatures at 35° to 46°F (2° to 8°C). Make sure not to overstock the unit because this will impede cold air circulation and can result in temperature fluctuations that may expose the vaccines to inappropriate temperatures. Refrigerated vaccines stored in a dormitory-style unit should be returned to the main storage unit at the end of the clinic day.

Dormitory-style units may be used only for small quantities of inactivated vaccines and MMR vaccine. Never use these units for MMRV, varicella, or zoster vaccines.

Do not place vaccines directly beside or directly below the freezer compartment in a dormitory-style unit, 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. To reduce the risk of exposing vaccine to freezing temperatures, consider using a compact refrigerator without a freezer compartment.

Frost-Free Versus Manual Defrost Freezers

MMRV, varicella, and zoster vaccines may be stored in either a manual defrost or a frost-free freezer at 5° F (-15° C) or colder.

Varicella, MMRV, and zoster vaccines in the freezer.

Equipment Placement

Good air circulation around the vaccine storage unit is essential for proper heat exchange and cooling functions. The unit should be placed in a well-ventilated room and should have space around the sides and top. If the unit has coils on the back, leave at least 4 inches (10 cm) of space between the grid or coils and the wall. If there are no coils on the back, you should still keep the unit at least 4 inches (10 cm) away from the wall to allow air circulation. Nothing should be blocking the cover of the motor compartment, which is normally located at the back or the side of the unit. Make sure that the unit stands firmly and level and that the wheels or leveling legs are adjusted so that the bottom of the unit sits 1 to 2 inches (2.5 to 5 cm) above the floor.

Keep the unit at least 4 inches (10 cm) away from the wall to allow air circulation.

Recommended Temperature Range

Refrigerator

The refrigerator compartment should maintain temperatures between 35° and 46°F (2° and 8°C). The temperature should never fall below 35°F (2°C) or rise above 46°F (8°C). Therefore, set the temperature mid-range to achieve an average of about 40°F (5°C). This temperature setting will provide the best safety margin.

Freezer

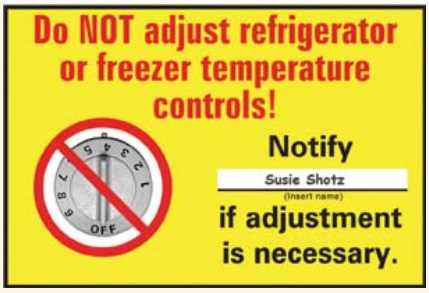
The freezer compartment should maintain an average temperature of 5°F (-15°C) or colder.

Setting and Stabilizing the Temperature

Who Should Adjust the Temperature?

Only the primary or backup vaccine coordinator should adjust the temperature of a vaccine storage unit. Limiting access to the thermostat reduces the risk that the temperatures will be adjusted inappropriately. If the thermostat requires adjustment, alert the vaccine coordinator or immediate supervisor. A warning sign should be posted on the storage unit that says, “Do not adjust refrigerator or freezer temperature controls. Notify (insert name) if adjustments are necessary” see example warning sign in the Resources section).

Only the primary or backup vaccine coordinators should adjust the temperature of a vaccine storage unit.



Only the primary or backup vaccine coordinators should adjust the temperature of a vaccine storage unit.

Thermostats

Refrigerator and freezer thermostats are marked in various ways, depending on the brand. There are a variety of ways to indicate the temperature setting. For example, some have a series of numbers or letters on the control knob. Others may have "MIN," "MED," and "MAX" marked on the knob or a dial ranging from "cold" to "coldest." In general, thermostats do not show temperatures, but rather the levels of coldness. The only way to know the temperature inside the unit is to measure it with a thermometer. In combination refrigerator-freezer units, the thermostat actually controls the volume of cold freezer-temperature air that goes into the refrigerator. Consult the manual that came with the refrigerator for instructions on how to operate the thermostat.

Refrigerator and freezer thermostats.

How to Adjust the Temperature

To adjust the temperature, first be sure the unit is plugged into a power source, then check the temperatures inside the refrigerator and freezer compartments. Next, turn the knob slightly toward a warmer or colder setting as necessary. Adjust the thermostat slowly so as not to exceed the recommended temperature range. Allow the temperature inside the unit to stabilize for **30 minutes** then recheck the temperature. Adjust the thermostat again as necessary. Aim to stabilize the refrigerator temperature around 40°F (5°C). Make sure the temperature does not fall below the lower limit or rise above the upper limit of the recommended refrigerator temperature range of 35° to 46°F (2° to 8°C). Aim to stabilize the freezer temperature at 5°F (-15°C) or colder. If you are using a combined refrigerator-freezer unit, be careful not to lower the freezer temperature so much that the refrigerator temperature falls below the recommended temperature range. Combined refrigerator-freezer units use a cooling system that directs cold air from the freezer compartment into the main refrigerator compartment. This type of unit has two thermostat controls: one controls the freezer temperature and the other controls the volume of freezing air that enters the main refrigerator cabinet. Therefore, use care when adjusting the freezer temperature because this will affect the temperature of the air venting into the refrigerator compartment. Without careful and frequent temperature monitoring inside the refrigerator compartment there is a danger of inappropriately freezing the refrigerated vaccines.

Frequent temperature monitoring of both the freezer and refrigerator compartments throughout the day as well as at the beginning and end of the work day is required whenever thermostats are adjusted. The temperature in a newly installed or newly repaired refrigerator may take 2 to 7 days to stabilize within the recommended range or 35° to 46°F (2° to 8°C). The temperature in a newly installed or newly repaired freezer unit may take 2 to 3 days to stabilize within the recommended range of 5°F (-15°C) or colder. Allow one week of twice daily refrigerator and freezer temperature recordings before using the unit to store vaccines.

Allow 1 week of twice daily refrigerator and freezer temperature recordings before using a newly installed or newly repaired refrigeration unit to store vaccines.

To maintain the cold chain during any period when the refrigerator or freezer is out of service, vaccines should be temporarily stored in an alternate vaccine storage unit until the temperature in the original unit can be stabilized within the recommended range. The alternate unit should be functioning properly and should have sufficient space to properly store the vaccines. Another option is to store the vaccines in an appropriately packed cooler if the storage unit will be out of service for a short time. However, if the refrigerator or freezer cannot be repaired in time to maintain the temperature in the cooler within the recommended range, move the vaccines to an alternate vaccine storage unit. Contact the state health department immunization program for policies regarding vaccine packing and procedures for maintaining the cold chain while the vaccine storage unit is not functioning properly or turned off (see Handling Inappropriate Vaccine Storage Conditions [Light and Temperature] in the Storage Troubleshooting section for details).

When to Adjust the Temperature

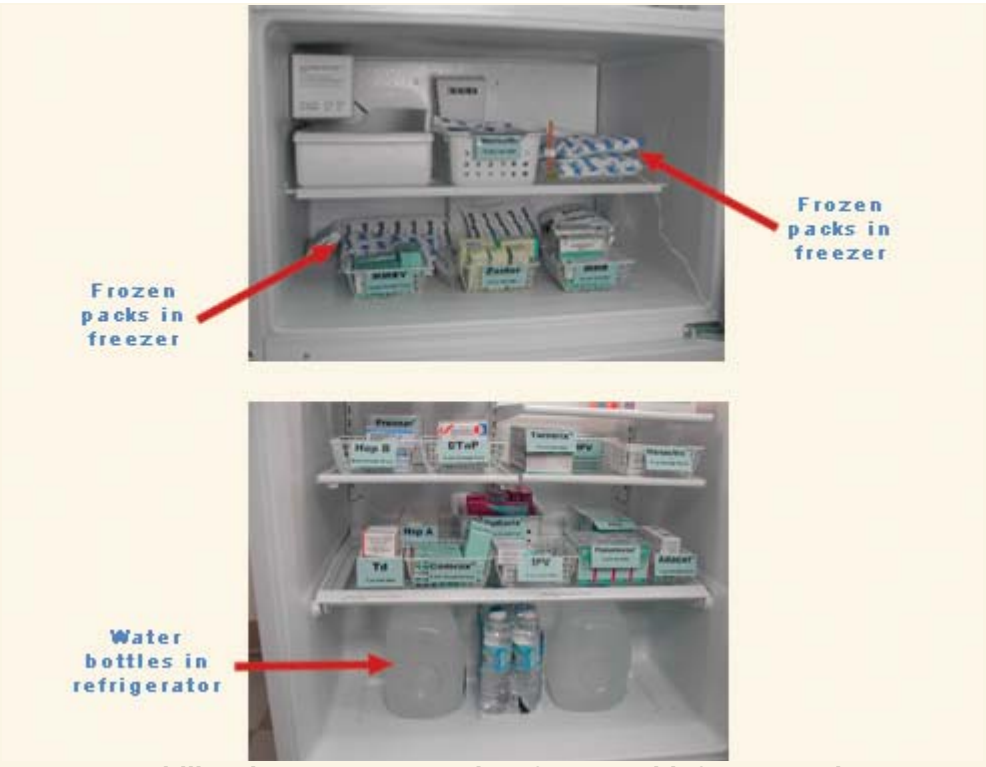
The refrigerator temperature should be adjusted if it is outside the recommended range or if, over time, the temperature appears to be moving toward the upper or lower temperature limit. It is best to set the temperature mid-range to achieve an average of about 40°F (5°C). This temperature setting will provide the best safety margin.

The freezer temperature should be adjusted if it is outside the recommended range or if, over time, the temperature appears to be moving toward the upper temperature limit of 5°F (-15°C).

In some situations, the thermostat may need to be reset in summer and winter, depending on the room temperature. If so, post instructions about this procedure on the vaccine storage unit door and include this information in the Routine Vaccine Storage and Handling Plan (see section on Storage and Handling Plans).

Stabilizing the Temperature with Water Bottles and Frozen Packs

You can help stabilize the temperature in the refrigerator by keeping at least two or three large containers of water inside. Store the water bottles against the inside walls and in the door racks. You can help stabilize the temperature in the freezer by keeping frozen packs or ice trays inside. Store the frozen packs along the walls, back, and bottom of the freezer compartment and inside the racks of the freezer door. Not only will water bottles and frozen packs help maintain an even temperature in the compartments with frequent opening and closing of the doors, they will also help keep the temperatures stable in the event of a power failure.



Stabilize the temperatures in a freezer with frozen packs and in a refrigerator with water bottles.

Opening the Door

Limit the number of times the vaccine storage unit doors are opened and avoid letting the doors stand open unnecessarily. Not only does this affect the temperature in the unit, it also exposes the vaccines to light (which can affect the potency of HPV, MMR, MMRV, rotavirus, varicella, and zoster vaccines). Routinely check the doors throughout the day and at the end of the day to ensure they are tightly closed.

Vegetable Bins

Consider removing the vegetable bins from the refrigerator. Removing the bins not only provides extra space for storing containers of water, but it also removes the temptation to use the bins for storage of food, beverages, or vaccines. Food and beverages should never be stored in a vaccine storage unit. Vaccines should never be stored near the floor of the refrigerator in the vegetable bins because the temperature in this area is different from that in the body of the refrigerator.

Temperature Variations

Temperatures can vary in a vaccine storage unit based on the contents, how often the door is opened, and power interruptions. The only way to be sure the temperature in the storage unit has remained within the recommended range is to frequently monitor and record the temperature using a thermometer.

Equipment Maintenance

General Principles

The most important action to take if the vaccine storage unit is not working properly is to protect the vaccine supply. Activate the Emergency Vaccine Retrieval and Storage Plan (see section on Storage and Handling Plans). Move the vaccine to a properly functioning storage unit with internal temperatures within the recommended ranges.

The most important action to take if the vaccine storage unit is not working properly is to protect the vaccine supply.

After this is accomplished, attempt to find the cause of the problem and correct it (see section on Storage Troubleshooting). Do not allow the vaccine to remain in a nonfunctioning unit for an extended period of time while you attempt to resolve the problem. If you are unsure how long the storage unit will not be functioning properly or you determine that the problem cannot be corrected in time to maintain the internal temperature within the recommended range, activate the Emergency Vaccine Retrieval and Storage Plan (see section on Storage and Handling Plans).

Consider keeping a logbook for each piece of cold chain storage equipment to document routine maintenance tasks and repairs. See Equipment Logbooks in this section for details.

Regular maintenance is required to ensure proper operation, to maintain required temperatures, and to extend the useful life of the appliance. Maintenance tasks can be divided into daily, weekly, monthly, and periodic actions.

Daily Maintenance Tasks

Check the internal temperature

The temperature inside each compartment of the vaccine storage unit must be checked with a certified calibrated thermometer at least twice each day.

The temperature inside each compartment of the vaccine storage unit must be checked with a certified calibrated thermometer at least twice each day, once in the morning when the door is first opened, and once at the end of the clinic day just before the door is closed for the last time. More frequent temperature monitoring is required following thermostat adjustments. The temperatures should be recorded on a temperature log. If the temperature is outside the recommended range, the vaccine coordinator or supervisor should be notified without delay.

⚠**Immediate action** must be taken (see Handling Inappropriate Vaccine Storage Conditions [Light and Temperature] in the Storage Troubleshooting section for details).

Check that the doors are closed

To maintain internal temperatures within the recommended ranges, the vaccine storage unit doors must fit securely and tightly against the unit. The rubber-like seals that run around the inner edges of the doors contain magnets that help hold the doors closed and create tight seals, keeping cold air inside. Check that the doors are properly sealed each time they are closed by giving a gentle tug on the door handles. The doors should also be checked at the end of each clinic day to make sure that they are properly closed and sealed.

Check that doors are properly sealed each time they are closed and at the end of each day.

Weekly Maintenance Tasks

Defrost the freezer (manual defrost units only)

If you have a manual defrost freezer, it is quite normal for ice and frost to accumulate inside the compartment. A thin layer of frost does not affect the cooling performance but a thick layer of frost negatively affects the efficiency of the system.

Check the inside walls of the freezer compartment **weekly**. When frost has accumulated to a thickness of ¼ inch or so, the unit requires defrosting. Remove the vaccines from the freezer compartment (and from the refrigerator compartment of a combined refrigerator-freezer unit) and store them in a functioning unit (see Emergency Vaccine Retrieval and Storage Plan in the section on Storage and Handling Plans). Alternatively, vaccine may be stored in an appropriately packed cooler. Contact the state health department immunization program for policies regarding vaccine packing and procedures for maintaining the cold chain while the storage unit is turned off.

Turn off the power and unplug the unit. Open the freezer door and allow all the frost to melt. Loose ice can be removed by hand, but no sharp tools or sharp instruments should be used to remove the ice. Remove all frozen packs from the freezer. Defrosting time can be reduced by putting a container of warm water (not greater than 122°F [50°C]) inside the compartment.

Once the frost has melted completely, wipe the unit dry and clean thoroughly. This is also a good time to clean the refrigerator compartment. Plug in the unit and ensure that the thermostat is turned to an appropriately cold setting. Wait for each compartment of the unit to reach and stabilize at the proper temperature range then restock each compartment with vaccine. If defrosting is necessary once a month or more frequently, the door may not be sealing properly, the door may have been opened too frequently, or there may be other mechanical problems with the freezer (see Refrigerator and Freezer Door Problems in the Storage Troubleshooting section for details). Consult a technician and monitor temperatures carefully.

Frost-free freezers do not need to be manually defrosted. They have regular defrost cycles three or four times a day when the freezer temperature increases and melts the ice automatically.

Monthly Maintenance Tasks

Clean the coils and motor

Once a month, the vaccine storage unit coils should be examined and cleaned. Dust and dirt build-up affects the transfer of heat from the coils and, therefore, the efficiency of the unit. The coils are located either on the back of the unit or underneath the unit behind the toe kick plate. Unplug the unit and use a soft brush, cloth, or vacuum cleaner with an attachment hose to remove any dirt or dust from the surface of the coils. If the motor is accessible, it should also be cleaned using a soft brush, cloth, or vacuum cleaner with an attachment hose. After cleaning, plug in the unit and document that the power is restored and that the temperature has been maintained. Avoid cleaning the coils and motor at the end of a Friday. Accidentally damaging the coils will cause a problem that may not be detected until the following Monday.

Refrigerator coils.

This process should only take a few minutes; therefore, it is not necessary to transfer the vaccine to another storage unit as long as the doors remain tightly closed for the duration of the procedure. If cleaning will take longer than the expected few minutes, activate the Emergency Vaccine Retrieval and Storage Plan (see section on Storage and Handling Plans) and transfer the vaccine to a backup storage unit.

Clean the refrigerator and freezer compartments

Clean the refrigerator and freezer compartments every month to discourage bacterial and fungal growth. Remove the vaccines from the compartments and store them in a functioning unit (see Emergency Vaccine Retrieval and Storage Plan in the Storage and Handling Plans section for details). Alternatively, vaccine may be stored in an appropriately packed cooler. Contact the state health department immunization program for policies regarding vaccine packing and procedures for maintaining the cold chain while the storage unit is turned off. Unplug the unit or turn off the power and wash all inside surfaces and shelves with warm, slightly soapy water. Dry thoroughly then plug in the unit or turn the thermostat back to an appropriately cold setting. Wait for the unit to reach and stabilize at the proper temperature range and restock each compartment with vaccine.

Check the door seals

Once a month, perhaps while cleaning the vaccine storage unit compartments, check the integrity of the rubber-like door seals. They should not be torn or brittle and there should be no gaps between the seals and the body of the unit when the doors are closed. The doors should open and close properly and fit squarely against the body of the refrigerator. For this to happen, the hinges must be correctly adjusted. If there are any problems with the door seals, see Refrigerator and Freezer Door Problems in the Storage Troubleshooting section for details about troubleshooting. Consult a technician as necessary and monitor temperatures carefully.

Periodic Maintenance Tasks

Clean the drain pan

Frost-free freezers have a drain pan at the bottom of the unit that holds the water that collects after frost melts during the defrost cycle. You do not need to empty the pan because the water will evaporate. However, over time, it may begin to smell and become moldy. You may be able to remove the pan for periodic cleaning by detaching the toe kick plate and sliding the pan out

from the bottom of the unit. It is not necessary to unplug the unit or transfer the vaccine when the drain pan is cleaned.

Thermometers

Certified Calibrated Thermometers

The National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention recommends using only certified calibrated thermometers for measuring vaccine storage unit temperatures.

The National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention recommends using only certified calibrated thermometers for measuring vaccine storage unit temperatures. Thermometers are a requirement for VFC providers.) 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. Certified calibrated thermometers are available through laboratory and scientific supply companies.

Avoid using thermometers that are not certified because they are not certified as accurate and they may not remain accurate with time. A thermometer costing a few dollars is not worth the risk of damaging thousands of dollars worth of vaccine because of inaccurate readings. In the long run, it is better to invest in a more expensive but more reliable certified calibrated thermometer because it is more cost-effective.

Providers enrolled in the Vaccines for Children (VFC) Program are required to have certified calibrated thermometers in all refrigerators and freezers used for vaccine storage. Contact your state or local immunization program for more information.

Examples of thermometer calibration certificates.

Types of Certified Calibrated Thermometers

Overview

The use of trade names and commercial sources in this section is for identification only, and does not imply endorsement by the U.S. Department of Health and Human Services (DHHS), the U.S. Public Health Service (PHS), or the Centers for Disease Control and Prevention (CDC). Individual projects and state health department immunization programs may have specific requirements for providers who receive public vaccine. Check with the project or state health department for more information.

To ensure that refrigerators and freezers are maintaining the proper temperatures for vaccine storage, each compartment should have a certified calibrated thermometer

and the temperature should be checked at least twice each day. Several types of thermometers can be used to monitor the temperatures within vaccine storage units.

Certified Calibrated Thermometers			
	Most information/ Highest cost	**<——————>**	**Least information/ Lowest cost**
Extent of data	**Continuous recording**	**Minimum/maximum temperature reading**	**Single point reading**
Types	**Chart recorders, electronic data loggers**	**Fluid-filled, some digital**	**Fluid-filled, some digital, bi-metal stem**

Any of the various types of thermometers are adequate for monitoring temperatures inside vaccine storage units. However, thermometers that provide continuous recording or

minimum/maximum temperatures are preferred because they are the best indicators of temperature fluctuations outside of the recommended ranges. Out-of-range temperatures require ⚠**immediate action**.

Fluid-Filled Biosafe Liquid Thermometers

Fluid-filled biosafe liquid (bottle) thermometers consist of two parts. The first part is a glass sensing bulb connected to a glass tube with a numbered scale printed along the tube. Inside the tube is a liquid (usually mercury or colored alcohol) that rises and falls as the temperature changes in the immediate area of the sensing bulb. The second part is a bottle containing a biosafe liquid, such as glycol. The glass sensing bulb is immersed in the liquid. The liquid provides a buffer around the sensing bulb so that the reading does not fluctuate when the refrigerator or freezer door is opened or closed. Fluid-filled biosafe liquid thermometers are available in refrigerator models and in freezer models. Care should be taken to obtain a thermometer with the appropriate temperature scale for refrigerator and freezer compartments. Some models may come with a magnet designed to attach the thermometer to the refrigerator or freezer wall. This is not the correct placement for a thermometer used in vaccine storage. Place the thermometer centrally in the compartment, with the vaccine.

Fluid-filled biosafe liquid thermometer.

Fluid-filled biosafe liquid thermometers can be difficult to read. When reading the thermometer, it should be vertical and your eyes should be level with the top of the liquid in the glass tube. The position of the top of the liquid along the scale indicates the temperature. These thermometers only indicate the temperature at the time they are read. They do not indicate temperature changes over time or the minimum/ maximum temperatures achieved. Therefore, temperature fluctuations outside the recommended range might not be detected. Instructions on How to Read a Fluid-Filled Biosafe Liquid Thermometer can be found in the Resources section.

Fluid-filled biosafe liquid thermometers may be rendered inaccurate if the liquid column separates. This may be correctable; consult the manufacturer for detailed instructions for reuniting the liquid column.

Bi-Metal Stem Thermometers

Bi-metal stem thermometers are typically circular in shape with a needle anchored in the center that points to one or two numbered scales (Fahrenheit and/or Celsius) located around the perimeter of the dial. The temperature is indicated by where the needle points on the scale. These thermometers may be difficult to read. When reading the thermometer, it should be vertical and your eyes should be level with the center of the dial. Certified bi-metal stem thermometers are quite accurate, but they only indicate the temperature at the time they are read. They do not indicate the changes in temperature over time or the minimum/maximum temperatures achieved. Therefore, temperature fluctuations outside the recommended range may not be detected.

Bi-metal stem thermometer.

Minimum/Maximum Thermometers

Minimum/maximum thermometers are available in fluid-filled and digital forms. The fluid-filled types may be difficult to read (see How to Read a Liquid Minimum/Maximum Thermometer— Print Version and How to Read a Liquid Minimum/Maximum Thermometer— Animated Version in the Resources section for details). Digital thermometers are easier to read. Minimum/ maximum thermometers show the current temperature and the minimum and maximum temperatures achieved. Temperature fluctuations outside the recommended range can be detected by referring to the minimum and maximum temperature readings.

Minimum/maximum thermometers.

Digital Thermometers

Digital thermometers have a screen in which the temperature is displayed in Fahrenheit and/or Celsius. Some have optional features, including a display of the minimum and maximum temperatures, a temperature alarm that can be set to ring at a specified temperature, and a temperature probe.

Some digital thermometers have two components: a display that mounts to the outside of the unit and a probe on a cord (usually 3 to 10 feet long) that is placed inside the unit. This arrangement allows the temperature to be read without opening the door of the storage unit.

Minimum/maximum digital thermometer.

Digital thermometer with standard probe.

Digital thermometer with biosafe liquid-encased probe.

Some of these thermometers have audible alarms that ring outside the storage unit. However, alarms that ring inside the unit should not be relied upon since they may not be heard.

Probes are available in two forms: a standard probe and a biosafe liquid-encased probe. Probes should be placed in the center of the compartment. Standard probes should be suspended. Digital thermometers are easy to read because they display a number indicating the temperature and do not require interpretation. These thermometers show the current temperature (and the minimum and maximum temperatures achieved if that option is available). Temperature fluctuations outside the recommended range can be detected by referring to the minimum and maximum temperature readings if that option is available.

Chart Recorders

Chart recorders consist of a graph wheel with replaceable graph paper and ink pens. The pens mark the temperature on the graph paper as the wheel turns. Temperatures are recorded

continuously, 24 hours a day. The graph paper has a Fahrenheit or Celsius scale on it and the temperature is read where the ink line falls on the scale. The graph paper must be changed when it completes a full circle, usually weekly. Record the date on the graph paper when it is fitted, and when you remove/change the graph paper. Keep old graphs as a permanent record of the performance of the vaccine storage unit. As with other thermometers, temperature readings should be checked and recorded at least twice each day and monitored to see if the temperatures are out of range.

Some chart recorders may have a digital display showing a current temperature; however, this display may use a different temperature sensor than the recording pen. The reading from the digital display may vary by several degrees from the reading on the graphing wheel. **In a certified chart recorder, the certification applies only to the temperature sensor used by the recording pen.** When checking and recording temperatures, only the reading from the graphing wheel should be recorded.

Some chart recorders have temperature probes. Probes are available in two forms: a standard probe and a biosafe liquid-encased probe. Probes should be placed in the center of the compartment. Standard probes should be suspended.

Chart recorders are more difficult to read than digital thermometers because they require interpretation of the temperature graph (see How to Read a Chart Recorder—Print Version and How to Read a Chart Recorder—Animated Version in the Resources section for details). These are the only thermometers that record the current temperature, the minimum and maximum temperatures, and the continuous changes in temperature through time.

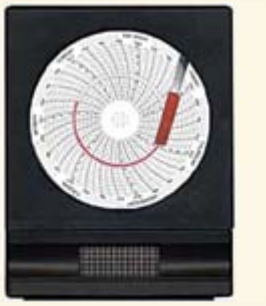
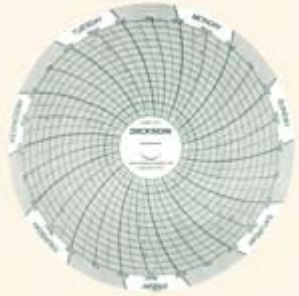
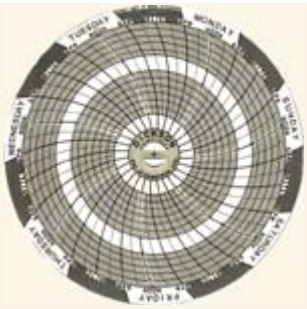


Chart recorder.



Graph paper— two-degree increments.



Graph paper—range.

Temperature fluctuations outside the recommended ranges can be detected by referring to the minimum and maximum temperature readings. Out-of-range temperatures require ⚠**immediate action**.

Digital Data Loggers

Digital data loggers are sometimes used to record temperatures in vaccine storage units. These miniature, battery-operated, electronic devices may be programmed to record temperatures at intervals throughout the day, with the frequency of reading set by the user. Data loggers are capable of recording hundreds or even thousands of individual temperature readings.

Digital data loggers used in vaccine storage are accompanied by special software that is installed in a computer. This software allows the user to set the frequency of the temperature

readings, download data from the device, and calculate temperature averages, minimums, and maximums. In order to review the temperature history, the user must download data from the digital data logger on a regular basis. When digital data loggers are used in vaccine storage, temperatures must still be manually checked and recorded twice a day. A second certified thermometer may be used for these manual temperature checks.

Digital data loggers may have a variety of features in addition to their basic recording function. Some digital data loggers have digital displays showing the current temperature. This display may not use the same temperature sensor as the recorder. Some data loggers may have an audible alarm to alert the user to out-of-range temperature conditions. Other data loggers may have external lights that alert the user to out-of-range temperature events; a green light indicates that temperatures have remained in range and a red light indicates an inappropriate temperature occurred. If a data logger's alarm activates, or a red light is displayed, ⚠ **immediate action** should be taken. Download and review the temperature readings and proceed as noted in Handling Inappropriate Vaccine Storage Conditions (Light and Temperature) in the Storage Troubleshooting section. Digital data loggers may also be used in vaccine transport (see Data Loggers in this section.)

Other Thermometers—NOT RECOMMENDED

Uncertified liquid (mercury or alcohol) thermometers and uncertified dial-type household refrigerator/freezer thermometers should not be used. These thermometers are not accurate enough to risk losing expensive vaccine. **Do not use thermometers that are not certified calibrated thermometers.** Generally, thermometers obtained in hardware and appliance stores are not certified instruments and are designed to monitor temperatures for domestic food storage.

Thermometer Placement

The thermometer should be placed in the center of the compartment away from the coils, walls, floor, and fan in order to obtain a true reading of the temperature. In the refrigerator, the thermometer should be placed on the middle shelf, adjacent to the vaccine, or hanging down from the upper shelf. In the freezer, the thermometer should be suspended from the ceiling of the compartment or placed on a box or some other item so that it is in the middle of the compartment off the floor. If the thermometer indicates a temperature outside the recommended range, check that the thermometer is appropriately situated.

Fluid-filled biosafe liquid thermometer in freezer.

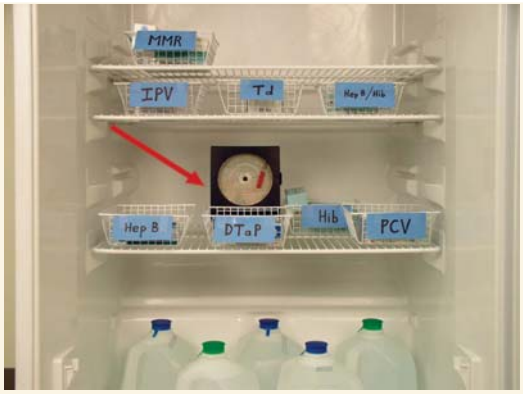


Chart recorder in refrigerator.

Proper placement of thermometers in compartments.

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.	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 (see Handling Inappropriate Vaccine Storage Conditions [Light and Temperature] in the Storage Troubleshooting section for details). 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.

Immunization programs may set their own policies regarding recalibration of thermometers. Please contact your state or local immunization program for more information.

Cold Chain Monitors

General Principles

There are three basic types of cold chain monitors (CCMs): those that indicate whether packages have reached temperatures that are too warm, those that indicate whether packages have reached temperatures that are too cold, and those that continuously record the temperature. These types of monitors are designed to be irreversible indicators of inappropriate temperatures. In general, CCMs are for single use only and should not be re-used. However, some models of digital data loggers may be used more than once.

CCMs are not a substitute for twice-a-day temperature reading and recording. Every vaccine storage unit compartment should have its own certified calibrated thermometer for this purpose. CCMs should only be used to monitor the temperature of vaccine during transport.

Types of Cold Chain Monitors

Heat Indicators

Recommended heat indicators have an activation temperature of 50°F (10°C) and a run out time of 48 hours to 7 days.

Heat indicators, also known as time and temperature indicators (TTIs), are made for single use only. Heat indicators appropriate for vaccine shipping have an activation temperature of 50°F (10°C) and a run out time of 48 hours to 7 days.

A heat indicator releases a colored dye into the windows of the device when the temperature has exceeded the set range (indicated on the device). The dye gradually moves through the windows over time. If the temperature drops below the threshold again, the dye stops moving but does not disappear. Therefore these indicators also show the length of time in hours or days that the temperature has exceeded the desired range. Response cards are used to interpret the time-temperature relationship for each indicator. The heat indicator must be preconditioned **below** its threshold response temperature before use; check manufacturer specifications for the length of conditioning time and the appropriate conditioning temperature.

In general, heat indicators are preconditioned in the refrigerator. This ensures that the dye inside the indicator is in a solid state when the activation tab is pulled. If the dye is not in a solid state, it will start moving down the track of the indicator and through the windows, producing an inaccurate reading. Attach the indicator only to a vaccine vial or box; do not attach it to the transport box. If the surface to which the indicator is attached is at a temperature above the threshold of the indicator, the indicator will activate prematurely. Once the indicator is preconditioned, place it and the vaccine into the environment to be monitored and pull the activation tab. This allows the indicator strip and reservoir pad to come in direct contact with each other and begins the temperature monitoring process.

Freeze Indicators

Freeze indicators appropriate for vaccine shipping have an activation temperature of 32°F (0°C).

Freeze indicators are made for single use only. Unlike heat indicators, freeze indicators do not indicate the length of time vaccine has been exposed to temperatures outside the recommended temperature range. Freeze indicators appropriate for vaccine shipping have an activation temperature of 32°F (0°C). A freeze indicator uses colored liquid to indicate exposure to freezing temperatures. In some models, the freeze indicator has a clear indicator bulb; when the temperature drops below the threshold freezing point, the indicator bulb irreversibly changes color. The indicator

does not require preconditioning and may be attached to any clean dry surface in the environment being monitored. There is no activation tab to pull; the indicator is working at all times.

Other models use a specially designed ampoule filled with dye; when the temperature drops below the freezing threshold, the ampoule will break and release the dye that irreversibly stains the paper behind the ampoule. This type of freeze indicator requires preconditioning in a temperature above the freezing threshold; check manufacturer specifications for the duration of this preconditioning period. Leaving it out at room temperature will meet this requirement. After preconditioning, attach the indicator to any clean dry surface in the environment being monitored. There is no activation tab to pull. To determine if the product has been exposed to freezing temperatures, observe the paper behind the ampoule. If it is stained with color, the product being monitored was exposed. If there is no color, remove the indicator from the surface to which it is attached and vigorously tap the bottom edge of the device three times on a hard surface. If the paper becomes stained, the product being monitored was exposed. Tapping will not cause color staining in an unexposed indicator.

Data Loggers

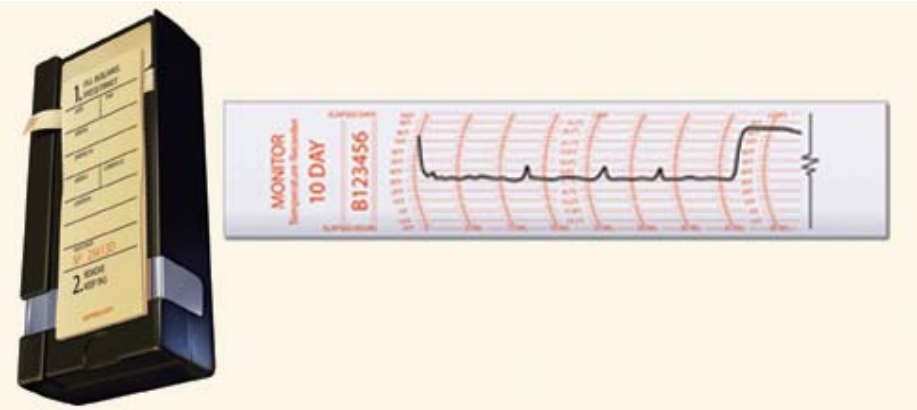
Digital data loggers are miniature, battery-operated, electronic devices that may be programmed to record temperatures at intervals throughout the day. Data loggers are capable of recording hundreds or even thousands of individual temperature readings. They are available in single-use and multi-use models.

Digital data loggers used in vaccine transport have external lights that alert the user to out-of-range temperature events-a green light indicating the cold chain was properly maintained and a red light indicating inappropriate temperature exposure occurred. If a red light is displayed, the vaccine shipment must await approval for use and the device must be sent back to the manufacturer to interpret the temperature data. A special software program must be used to download the temperature data to a computer.

Digital data loggers may also be used in vaccine storage (see Digital Data Loggers in this section.)

Digital data loggers record hundreds or thousands of temperature readings.

Strip monitors are also available. These are battery-powered single-use units that record continuous temperature readings on a paper strip and may be used to monitor vaccine temperatures during transport.



Strip monitors record continuous temperature readings on a paper strip.

Using Cold Chain Monitors

CCMs are primarily used to monitor temperature thresholds when vaccine is shipped by manufacturers, commercial vaccine distributors, and government-managed vaccine depots. When the vaccine arrives at its destination, the CCMs should be checked immediately and the temperature inside the transport unit should be documented. If the CCM has been activated:

- Record the length of time the vaccine may have been exposed to inappropriate temperatures.
- Immediately notify the primary or backup vaccine coordinator. If the primary coordinator or the backup is not available, report the problem to an immediate supervisor.
- Isolate the affected vaccine vials or packages and mark them as “DO NOT USE.” This will reduce the need to revaccinate persons who might be given vaccine that has lost its potency because it was stored under inappropriate conditions.
- Store the potentially compromised vaccines under appropriate conditions in a properly functioning vaccine storage unit until the integrity of the vaccine is determined.
- Finally, contact the vaccine manufacturer and the state health department immunization program for further guidance. **Do not assume** that the exposed vaccine cannot be salvaged.

Vaccine Security

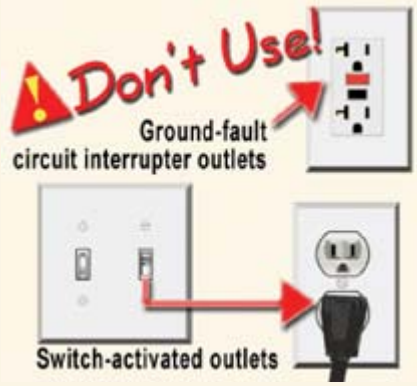
Protecting the Power Supply

To keep the vaccine storage unit temperature within the proper range, the unit must be in good working condition, and it must have power at all times. To prevent problems with the power supply, take the following steps:

- Avoid using power outlets with built-in circuit switches (they have little red reset buttons) and outlets that can be activated by a wall switch. These can be tripped or switched off, resulting in loss of electricity to the storage unit.
- Use a safety-lock plug or an outlet cover to reduce the chance of the unit becoming inadvertently unplugged.
- Post a warning sign at the plug and on the refrigerator or freezer alerting staff, janitors, and

electricians not to unplug the unit.

- Label the fuses and circuit breakers to alert people not to turn off the power to the vaccine storage unit. These labels should include information concerning the immediate steps to take if power is interrupted. When the practice is located in a building owned by a third party and providers do not have access to the circuit breaker, ask the building manager to assist in labeling the appropriate circuit.
- Finally, consider installing a temperature alarm to alert staff to after-hours emergencies, particularly if large vaccine inventories are maintained.



Avoid using power outlets with built-in circuit switches and outlets that can be activated by a wall switch.

Safety-lock plug.

Consider using outlet covers. Post warning signs and labels.

Temperature Alarms

A continuous-monitoring temperature alarm/notification system should be considered, especially for practices with a large inventory, to help prevent substantial financial loss if the temperatures in their storage units exceed the recommended ranges or if the storage units malfunction. These systems help alert staff to after-hours emergencies. Simple systems sound audible alarms when the temperatures inside the storage units exceed the recommended ranges. If feasible, a more sophisticated system that sounds an audible alarm and alerts one or more designated person(s) at a specified phone or pager number is preferable.

Continuous-monitoring temperature alarm/notification systems.

Backup Generators

Facilities storing large vaccine inventories may consider installing backup generators that automatically provide power to the storage units to maintain the recommended storage temperatures in the event of power outages. Backup generators should be tested quarterly and should receive maintenance at least annually (check manufacturer specifications for test procedures and maintenance schedules). Backup generators should be of a sufficient capacity to run continuously for 72 hours if necessary. Plans should be made to ensure that an adequate supply of fuel is on hand.

Backup generators.

Emergency Vaccine Retrieval and Storage Plans

Prepare a written plan of action in the event of refrigerator or freezer malfunctions, power failures, natural disasters, or other emergencies that might compromise proper vaccine storage. See Emergency Vaccine Retrieval and Storage Plan in the Storage and Handling Plans section for more details.

Vaccine Storage Practices

Appropriate Vaccine and Diluent Storage Conditions

Live Vaccines

Live vaccines are sensitive to heat. MMRV, varicella, and zoster vaccines must be stored in a continuously frozen state in a freezer at 5°F (-15°C) or colder until administration. MMRV, varicella, and zoster vaccines deteriorate rapidly after they are removed from the freezer. Measles, mumps, and rubella vaccine (MMR) is routinely stored in the refrigerator, but it also can be stored in the freezer. The National Center for Immunization and Respiratory Diseases recommends keeping MMR in the freezer along with MMRV, if adequate space is available. This may reduce the risk of inadvertent storage of MMRV in the refrigerator. LAIV and rotavirus vaccines are also live virus vaccines, but they should be stored in the refrigerator. Do NOT store these vaccines in the freezer.

Live vaccines are sensitive to heat.

Inactivated Vaccines

Inactivated vaccines are sensitive to both excessive heat and freezing.

Inactivated vaccines are sensitive to both excessive heat and freezing. They should be stored in a refrigerator at 35° to 46°F (2° to 8°C), with a desired average temperature of 40°F (5°C). Exposure to temperatures outside this range results in decreased vaccine potency and increased risk of vaccine-preventable diseases. Inactivated vaccines may tolerate limited exposure to elevated temperatures, but they are cold sensitive and are damaged rapidly by freezing temperatures.

Vaccine Light Sensitivity

HPV, MMR, MMRV, rotavirus, varicella, and zoster vaccines are sensitive to light, which causes loss of potency. These vaccines must be protected from light at all times. Therefore, store these vaccines at the appropriate temperatures in their boxes with the tops on until they are needed.

HPV, MMR, MMRV, rotavirus, varicella, and zoster vaccines are sensitive to light, which causes loss of potency.

Lyophilized (Freeze-Dried) Vaccines and Diluents

MMR, MMRV, varicella, and zoster diluent is packaged separately from the corresponding lyophilized (freeze-dried) vaccine and can be stored at room temperature or in the refrigerator. To conserve space, diluents packaged separately from their vaccines may also be stored in the door of the refrigerator.

- **Diluents packaged separately from their corresponding vaccines can be stored at room temperature or in the refrigerator.**
- **Diluents packaged with their vaccines should be stored in the refrigerator next to their vaccines.**

Diluents packaged with their vaccines (such as ActHIB® and Menomune®) should be stored in the refrigerator next to their vaccines.

Vaccine Storage Locations and Positioning

Freezers

In the freezer, vaccine should be stored in the middle of the compartment, away from the walls, coils, and peripheral areas. Vaccines should not be stored in the freezer door. The temperature in the door is not stable and differs from that in the main compartment. MMRV, varicella, and zoster vaccines may be stored in either a manual defrost or a frost-free freezer at 5° F (-15° C) or colder.

Note
Vaccines should not be stored in freezer door

In the freezer, vaccine should be stored in the middle of the compartment, away from the walls, coils, and peripheral areas.

Refrigerators

In the refrigerator, vaccine should be stored in the middle of the compartment, away from the coils, walls, floor, and cold air vent. The temperature near the floor of the refrigerator is not stable and differs from that in the middle of the compartment. For this reason, vaccine should never be stored in the vegetable bins. Vaccines should not be stored in the refrigerator door. The temperature in the door is not stable and differs from that in the main compartment. In a combination refrigerator-freezer unit, the top shelf of the refrigerator may be colder than the recommended temperature range because of cold air venting on it from the freezer. Refrigerated vaccines should always be stored far enough away from the air venting from the freezer compartment to avoid freezing the vaccines. Ideally, vaccine should be stored on the

middle shelf, away from the cold air vent. However, if vaccine can be situated away from the cold air vent, and the temperature in this area is within the recommended range, vaccine may also be stored on the upper shelf. If the upper shelf must be used for vaccine storage, it would be best to place MMR on this shelf because MMR is not sensitive to freezing temperatures like the other refrigerated vaccines.

Vaccine Spacing

Vaccine should be placed with space between the vaccine and the compartment wall, and with space between each large box, block, or tray of vaccine to allow for cold air circulation around the vaccine. Adequate cold air circulation helps each vaccine to reach a consistent temperature throughout its mass and is necessary for the storage unit to maintain a consistent temperature inside the compartment. Packing any vaccine storage unit too tightly will affect the temperature.

Vaccine Packaging

Vaccine products that have similar packaging should be stored in different locations to avoid confusion and medication errors. For example, if you have pediatric and adult versions of the same vaccine, storing them in different locations lessens the chance that someone will inadvertently choose the wrong vaccine. Likewise, vaccines that have similar sounding names should be stored in different locations. For example, DTaP and Tdap vaccines might be easily confused, as could Hib and hepatitis B vaccines.

Air Vent from Freezer		**Note** **Diluents may be stored in refrigerator door.** **Vaccines should not be stored in refrigerator door.**

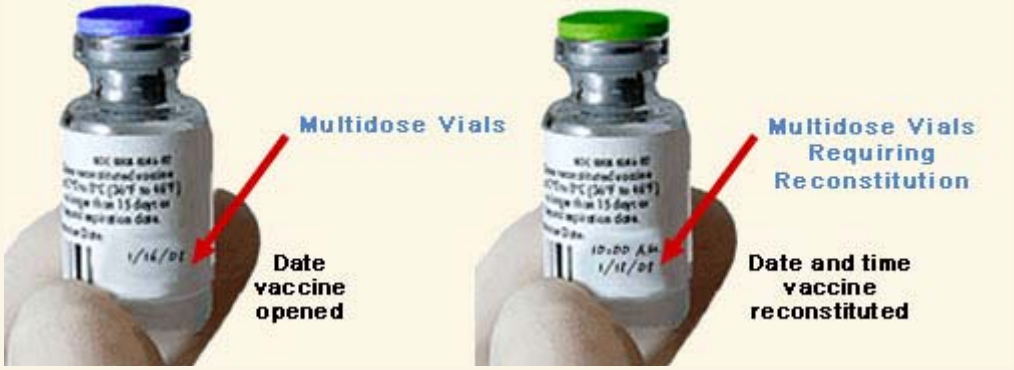
In the refrigerator, vaccine should be stored in the middle of the compartment, away from the walls and coils and off the floor.

Labeling

The location of each specific vaccine inside the storage unit should be clearly labeled. This can be accomplished by attaching labels directly to the shelves on which the vaccines are sitting or by labeling containers in which boxes of the same vaccine type are placed. Storing each vaccine in its own specifically labeled section of the refrigerator or freezer helps decrease the chance that someone will mistakenly administer the wrong type of vaccine.

Attach labels directly to the shelves on which the vaccines are sitting or label trays or containers according to the vaccines they contain.

In addition to labeling the location of vaccines, mark each opened multidose vial with the **date** it was first opened. Mark reconstituted vaccine with the **date and time** it was reconstituted. Dating these vials is important for two reasons. First, some vaccines expire within a certain time after opening or after reconstitution. This may not correspond to the expiration date printed on the vial by the manufacturer. For example, multidose vials of meningococcal vaccine should be discarded if not used within 35 days after reconstitution, even if the expiration date printed on the vial by the manufacturer has not passed. Second, dating opened or reconstituted vials helps manage vaccine inventory by identifying vials that should be used first.



Mark each opened multidose vial with the date it was first opened.
Mark each reconstituted vaccine with the date and time it was reconstituted.

Whenever possible, use all the vaccine in one multidose vial before opening another vial. Similarly, use all the reconstituted vaccine in one vial before reconstituting another vial. This policy helps to reduce vaccine waste.

Diluents should be clearly labeled, whether they are stored at room temperature or in the refrigerator. Label the boxes of corresponding vaccines and diluents from the same manufacturer so that they will be used together. This avoids confusion and helps to ensure that you use only the specific diluent provided by the manufacturer for each type of lyophilized (freeze-dried) vaccine. This is particularly important if you store two or more lyophilized vaccines using different diluents.

Diluents should be clearly labeled, whether they are stored at room temperature or in the refrigerator.

Storage Containers

Vaccine Boxes

To avoid confusion, vaccine boxes should be stored together by type and arranged in rows. Boxes should be stacked according to expiration dates. Vaccines with the shortest expiration dates should be closer to the front of the storage unit compartment for easy access. Store all opened and unopened vials of vaccine in their boxes inside the appropriate storage unit so that their contents and expiration dates are easily identifiable. HPV, MMR, MMRV, rotavirus, varicella, and zoster vaccines should always be stored in their boxes with the lids on to protect them from light. Storing loose vaccine vials outside of their boxes is not recommended. This practice makes inventory management more difficult, makes tracking expiration dates more difficult, predisposes to administration errors when vials are confused, and exposes the vaccines to light.

Store all opened and unopened vials of vaccine in their boxes inside the appropriate storage unit.

Trays and Containers

Trays and containers may be used to organize vaccine boxes. Each tray or container should only store vaccine of the same type. Other medications and biologic products, if they must be stored in the vaccine storage unit, must not be stored on the trays or in the containers to avoid medication errors. Clearly label the tray or container with the name of the vaccine and place vaccine boxes of that type on the tray or in the container inside the refrigerator or freezer. Trays and containers must not be stacked or placed so closely together that air circulation inside the vaccine storage unit compartment is impeded.

Storage of Non-Vaccine Products

Food and Beverages

Never store food or beverages inside the vaccine refrigerator or freezer. This practice results in frequent opening of the storage unit door and greater chance for temperature instability and

excessive exposure to light. It may also result in spills and contamination inside the compartment.

Never store food or beverages inside the vaccine refrigerator or freezer.

Medications and Other Biologic Products

If possible, other medications and other biologic products should not be stored inside the vaccine storage unit. If there is no other choice, these products must be stored below the vaccines on a different shelf. This prevents contamination of the vaccines should the other products spill, and reduces the likelihood of medication errors.

Centers for Disease Control and Prevention

Temperature Monitoring

Checking and Recording Temperatures at Least Twice a Day

The recommended method to ensure that a refrigerator or freezer is maintaining the proper temperature for vaccine storage is to check and record the temperature at least twice a day. This recommendation applies regardless of whether or not there is a temperature alarm, a chart recorder thermometer, or a digital data logger.

Check and record temperatures at least twice a day.

1.	Post a temperature log on the vaccine storage unit door (see Fahrenheit Temperature Log and Celsius Temperature Log in the Resources section).
2.	Read the thermometers in both the refrigerator and freezer at least twice a day: once in the morning when the storage unit door is opened for the first time, and again at the end of the clinic day just before the storage unit door is closed for the last time. (See How to Read a Fluid-Filled Biosafe Liquid Thermometer, How to Read a Liquid Minimum/Maximum Thermometer—Print Version, How to Read a Liquid Minimum/Maximum Thermometer—Animated Version, How to Read a Chart Recorder—Print Version, and How to Read a Chart Recorder—Animated Version in the Resources section for details).
3.	Record the temperatures in both the refrigerator and freezer on the temperature log each time the thermometers are read. Twice daily temperature monitoring and recording is required even if a continuous graphing/recording thermometer or a digital data logger is used.

4.	Record the times the thermometers were read, and have the person reading the thermometer and recording the temperature initial the temperature log.
5.	If a temperature reading is missed, the blank log entry should remain blank. Do not guess what the temperature was.

Do not faithfully record the temperatures on the log and then fail to take action when the temperature in either the refrigerator or freezer is outside the recommended range for vaccine storage. ⚠**Immediate action** must be taken to protect the vaccines. Furthermore, this action should be documented (see Handling Inappropriate Vaccine Storage Conditions [Light and Temperature] in the Storage Troubleshooting section for details).

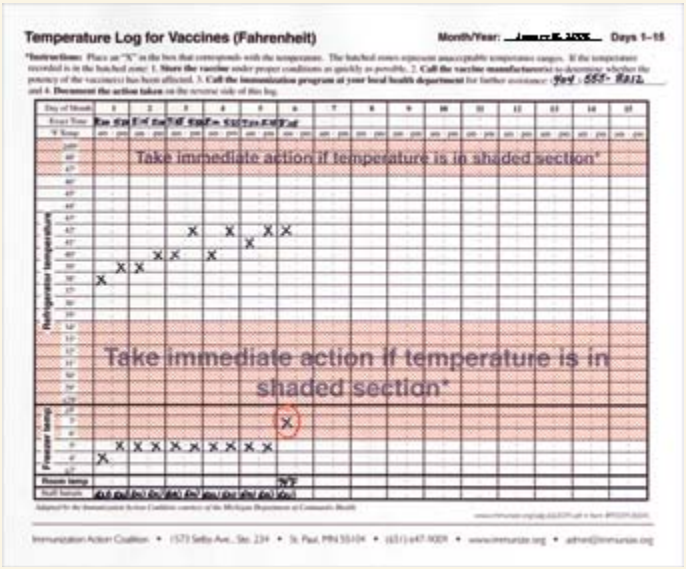
Reviewing Temperature Logs

If other staff are monitoring and recording the temperatures, the primary vaccine coordinator should review the log weekly to ensure proper temperature recording. If the vaccine coordinator is the person monitoring and recording the temperatures, the backup vaccine coordinator should review the log weekly.

The primary vaccine coordinator should review the log weekly to ensure proper temperature recording.

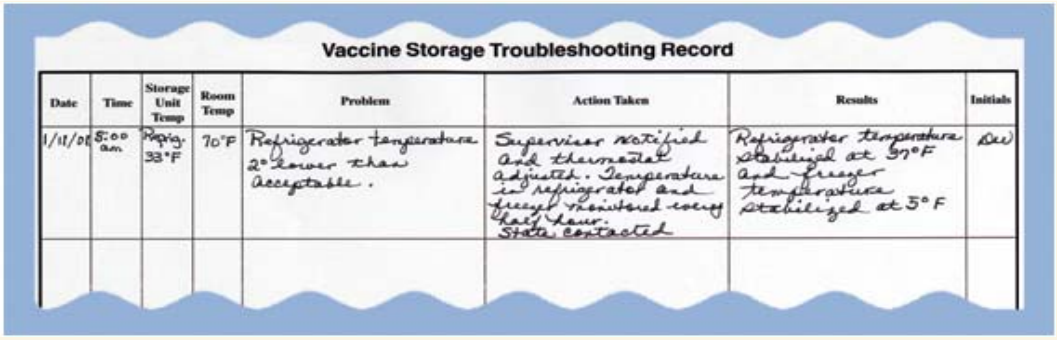
Noting Equipment Failures and Room Temperatures

The date and time of any mechanical malfunction or power outage should be recorded. This information may be recorded on the temperature log or on some other document, for example the Emergency Response Worksheet in the Resources section. As with inappropriate storage temperatures, ⚠**immediate action** must be taken to correct these situations. See Handling Malfunctioning Vaccine Storage Units and Power Outages in the Storage Troubleshooting section for further details.



Front: Temperature Log for Vaccines.

Note: ⚠ Immediate action must be taken to correct improper vaccine storage conditions.



Vaccine Storage Troubleshooting Record

Date	Time	Storage Unit Temp	Room Temp	Problem	Action Taken	Results	Initials
1/11/0[illegible]	5:00 am	Refrig. 33°F	70°F	Refrigerator temperature 2° lower than acceptable.	Supervisor notified and thermostat adjusted. Temperature in refrigerator and freezer rechecked every half hour. State contacted	Refrigerator temperature stabilized at 37°F and freezer temperature stabilized at 3°F	DW

Back: Vaccine Storage Troubleshooting Record.

If a mechanical malfunction or power outage has occurred, the room temperature where the vaccine storage unit is kept should also be recorded. If the cold chain is broken, the room temperature is useful information that will help the vaccine coordinator, the health department officials, and/or the vaccine manufacturer decide how best to handle compromised vaccine. Have a thermometer in the room for measuring the room temperature—a standard household thermometer (the sort you find in a hardware store) is fine for this purpose. **Do not** remove the certified calibrated thermometer from the refrigerator or freezer to measure the room temperature. **Do not** rely on the room thermostat setting.

If a mechanical malfunction or power outage has occurred, the room temperature where the vaccine storage unit is kept should also be recorded.

Maintaining Temperature Logs

Maintain an ongoing file of temperature logs and store completed logs for 3 years (unless state statutes or rules require a longer period). Do not throw away temperature logs before 3 years. As the vaccine storage unit ages, you can track recurring problems or identify how long problems have existed by referring to old temperature logs. If a continuous recording/graphic thermometer is used, the graphs should be kept with the logs for 3 years.

Store completed logs for 3 years (unless state statutes or rules require a longer period).

Using Alarm Systems

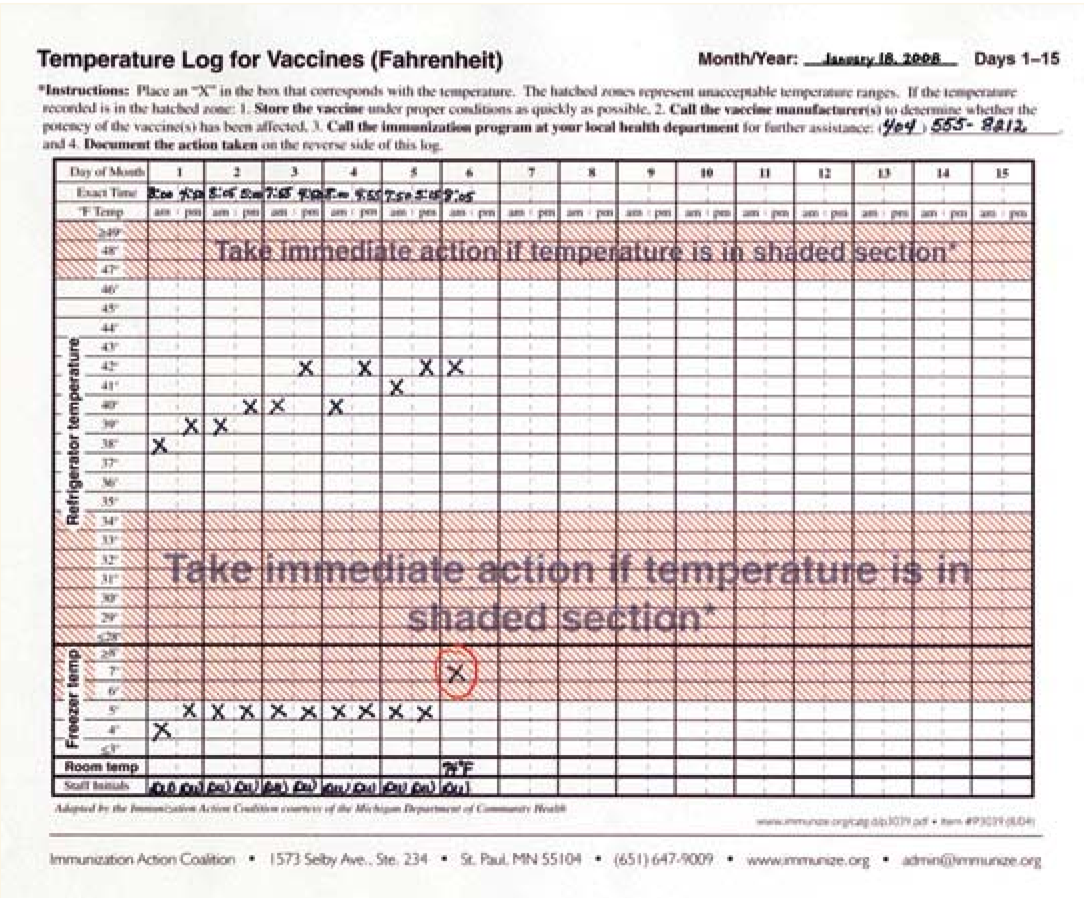
Facilities storing large vaccine inventories may want to consider installing continuous monitoring temperature alarm systems to help prevent substantial financial loss if the temperatures in their storage units exceed the recommended ranges or if the storage units malfunction. See Temperature Alarms in the Vaccine Storage Equipment section for more details. If alarm systems are used, temperatures must still be checked and recorded twice a day.

If alarm systems are used, temperatures must still be checked and recorded twice a day.

Storage Troubleshooting

Handling Inappropriate Vaccine Storage Conditions (Light and Temperature)

Immediate action must be taken to correct improper vaccine storage conditions, including inappropriate exposure to light and inappropriate exposure to storage temperatures outside the recommended ranges.



Temperature Log for Vaccines (Fahrenheit) Month/Year: January 18, 2008 Days 1–15

*Instructions: Place an "X" in the box that corresponds with the temperature. The hatched zones represent unacceptable temperature ranges. If the temperature recorded is in the hatched zone: 1. **Store the vaccine** under proper conditions as quickly as possible. 2. **Call the vaccine manufacturer(s)** to determine whether the potency of the vaccine(s) has been affected. 3. **Call the immunization program at your local health department** for further assistance: (404) 555- 8812, and 4. **Document the action taken** on the reverse side of this log.

Refrigerator temperature — Take immediate action if temperature is in shaded section*

Freezer temp — Room temp — Staff Initials

Adapted by the Immunization Action Coalition courtesy of the Michigan Department of Community Health

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Immediate action must be taken to correct improper vaccine storage conditions.

Furthermore, this action should be documented. In your documentation, state what the problem is, what has been done to protect the vaccines, what has been done to correct the problem, and whether or not the problem has been corrected. You may use the back of the temperature log to record this information. If you become aware of inappropriate vaccine storage conditions, the following steps should be taken:

1. Notify the primary or backup vaccine coordinator immediately of any vaccine storage unit temperatures that are outside the recommended range. If the primary coordinator or the backup person is not available, report the problem to an immediate supervisor.
2. Record the room temperature and the temperature inside the refrigerator and freezer at the time the problem is discovered. Also note the minimum and maximum temperature readings if you have minimum/maximum thermometers in the refrigerator and freezer. Record the length of time the vaccine may have been exposed to inappropriate storage temperatures.

Notify the primary or backup vaccine coordinator immediately of any vaccine storage unit temperatures that are outside the recommended range.

3. Conduct an inventory of the vaccines affected by this event and record the actions taken. Also note if water bottles were in the refrigerator and frozen packs in the freezer at the time of this event. You may use the Emergency Response Worksheet in the Resources section of this toolkit to help organize your response. Consult your agency, local health department, or state health department immunization program, as appropriate for your situation, for any special instructions or forms.
4. Isolate the affected vaccine vials or packages and mark them as "DO NOT USE." This will reduce risk of inadvertently using vaccine that may have lost its potency because it was stored under inappropriate conditions.
5. Store the potentially compromised vaccines under appropriate conditions in a properly functioning vaccine storage unit until the integrity of the vaccine is determined. If your vaccine storage unit is not maintaining the appropriate storage conditions, activate the Emergency Vaccine Retrieval and Storage Plan (see section on Storage and Handling Plans).

Isolate the affected vaccine vials or packages and mark them as "DO NOT USE."

6. Contact the vaccine manufacturer and the state health department immunization program for further guidance. Do not assume that vaccine inappropriately exposed to light or to excessive temperatures cannot be salvaged.
7. Finally, if HPV, MMR, MMRV, rotavirus, varicella, and/or zoster vaccines have been exposed to light, return the vaccine to a dark environment at the appropriate storage temperature and record the length of time the vaccine may have been exposed. Again, contact the vaccine manufacturer and the state health department immunization program for further guidance.

If vaccines have been exposed to inappropriate storage temperatures because of a fault in the refrigerator or freezer, follow the directions above and see Handling Malfunctioning Vaccine Storage Units in this section for further details.

Handling Malfunctioning Vaccine Storage Units

General Instructions

The vaccine storage unit is not working properly if any of the following situations occur:

- The vaccine storage unit is too warm.
- The vaccine storage unit is too cold.
- The vaccine storage unit is too noisy.
- The vaccine storage unit has stopped.

The most important step to take if the vaccine storage unit is not working properly is to protect the vaccine supply. Do not allow the vaccine to remain in a nonfunctioning unit for an extended period of time while you attempt to correct the problem. If at any time you are unsure how long the storage unit will not be functioning properly or you determine that the problem cannot be corrected in time to maintain the internal temperature within the recommended range, activate the Emergency Vaccine Retrieval and Storage Plan (see section on Storage and Handling Plans).

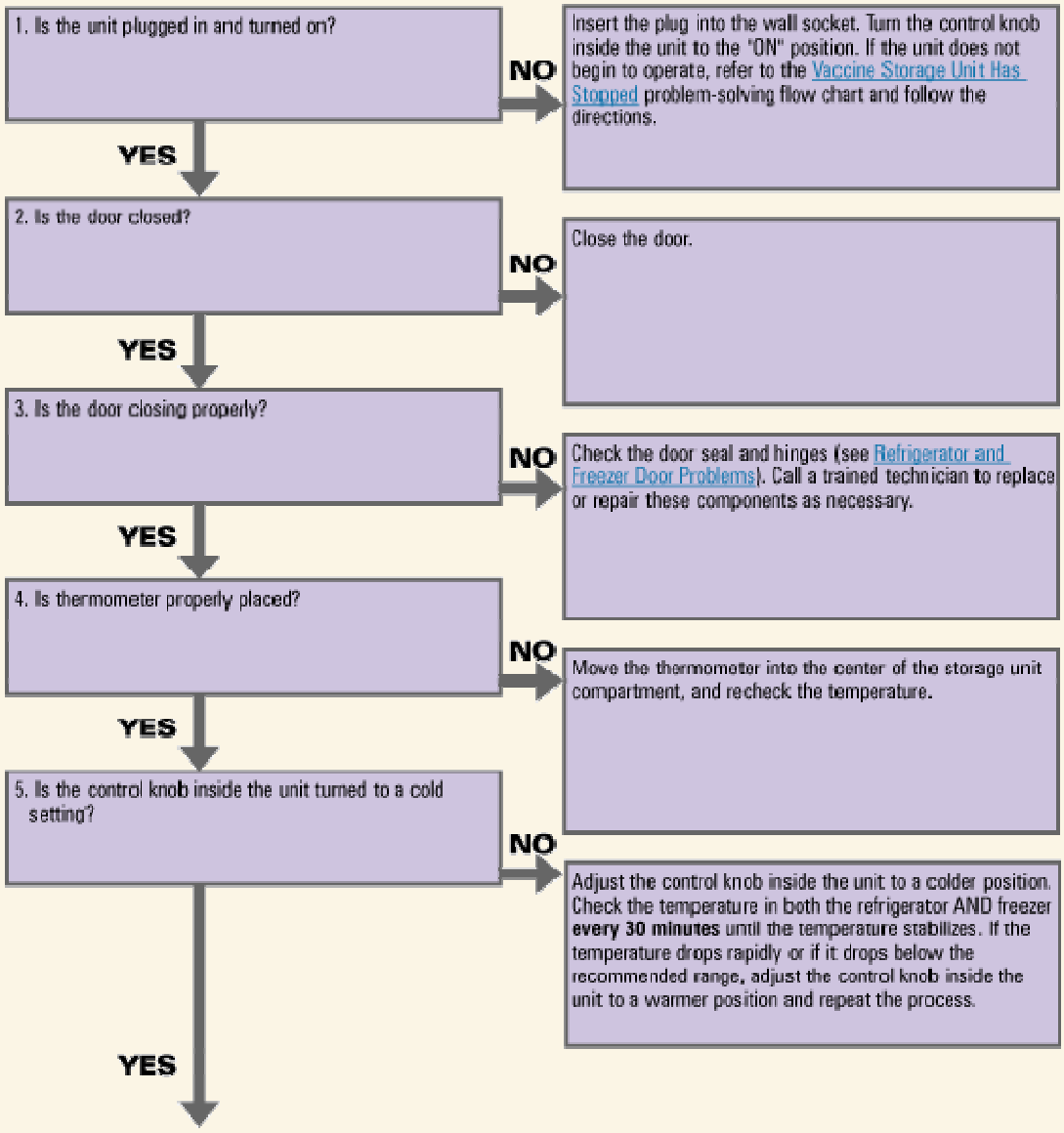
The most important step to take if the vaccine storage unit is not working properly is to protect the vaccine supply.

The problem-solving flow charts provided in this section may be used to identify and correct vaccine storage unit problems. Follow these instructions when using the problem-solving flow charts:

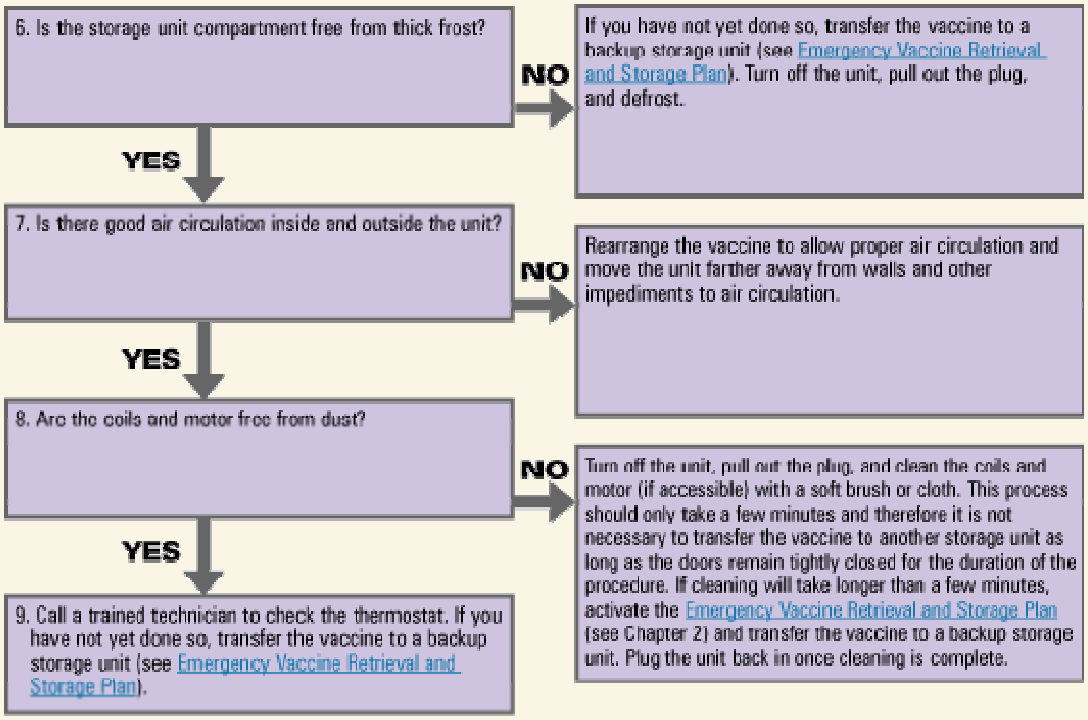
1. Record the room temperature and the temperatures inside the refrigerator and freezer when the problem is discovered. Also conduct an inventory of all vaccines affected by the event (see Handling Inappropriate Vaccine Storage Conditions [Light and Temperature] in this section).
2. Always start with the first problem shown in the problem-solving flow chart.
3. Make sure that a problem does not exist before moving on to the next step.
4. If the storage unit is still not working properly after completing all the steps in the flow chart,
   a. call a technician to examine the faulty equipment; and
   b. if you have not yet done so, transfer the vaccine into another functioning storage unit that has enough space to store the vaccines properly (see Emergency Vaccine Retrieval and Storage Plan in the Storage and Handling Plans section).
5. Record in the vaccine storage unit logbook all the checks you made and the actions taken (see Equipment Logbooks in the Vaccine Storage Equipment section for details). This will help the technician identify the fault with the storage unit.

Vaccine Storage Unit is Too Warm

Warning! Do not allow the vaccine to remain in a nonfunctioning unit for an extended period of time while you attempt to correct the problem. If at any time you are unsure how long the storage unit will not be functioning properly or you determine that the problem cannot be corrected in time to maintain the internal temperature within the recommended range, activate the Emergency Vaccine Retrieval and Storage Plan (see section on Storage and Handling Plans).

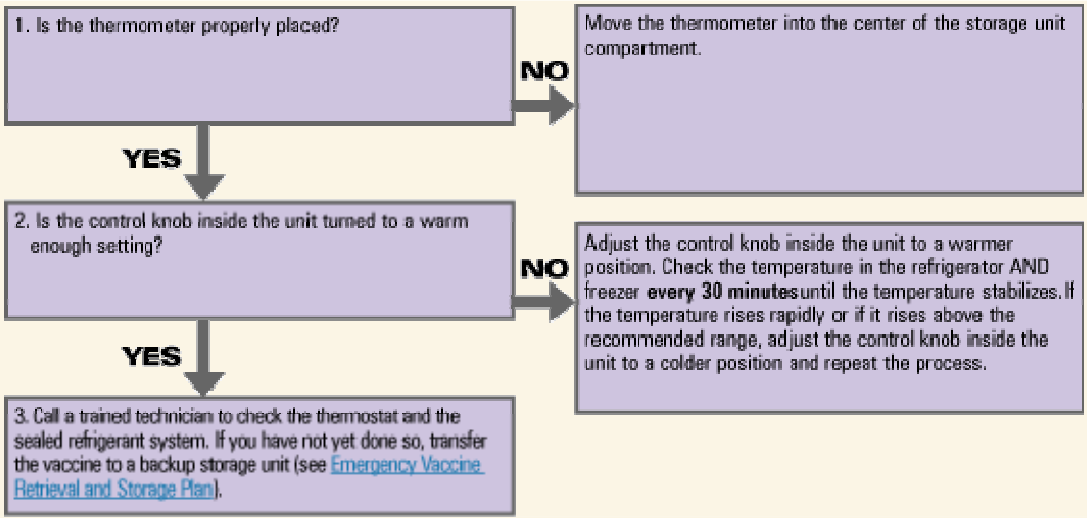


Vaccine Storage Unit is Too Warm cont'd



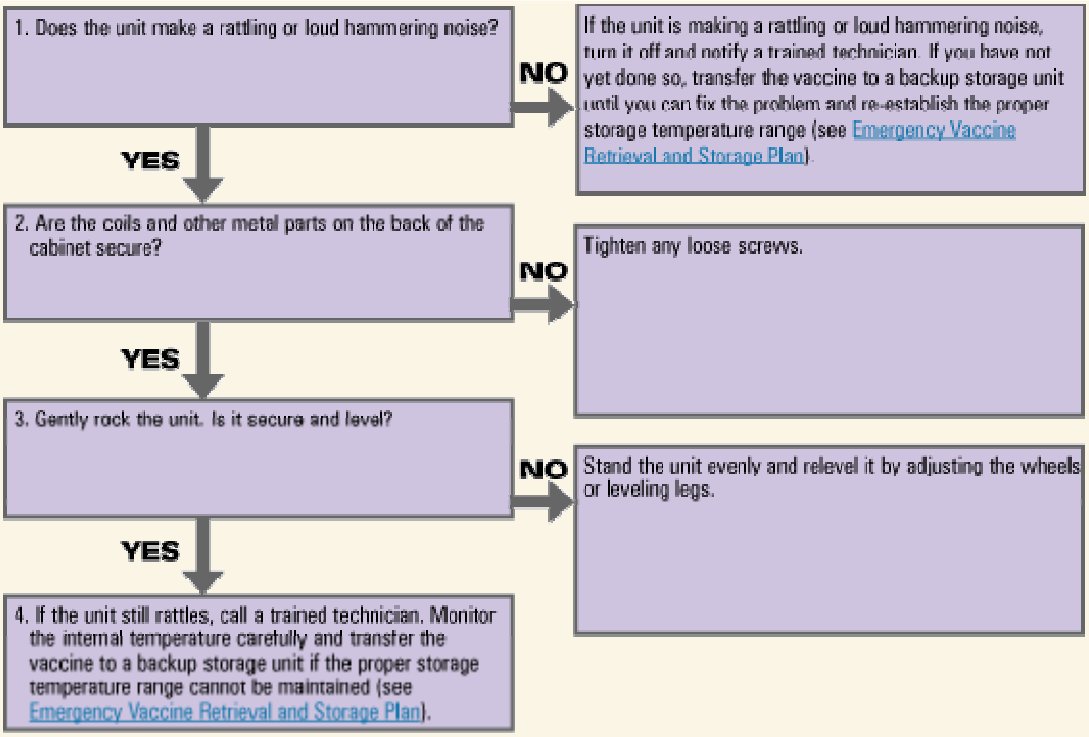
Vaccine Storage Unit is Too Cold

Warning! Do not allow the vaccine to remain in a nonfunctioning unit for an extended period of time while you attempt to correct the problem. If at any time you are unsure how long the storage unit will not be functioning properly or you determine that the problem cannot be corrected in time to maintain the internal temperature within the recommended range, activate the Emergency Vaccine Retrieval and Storage Plan (see section on Storage and Handling Plans).



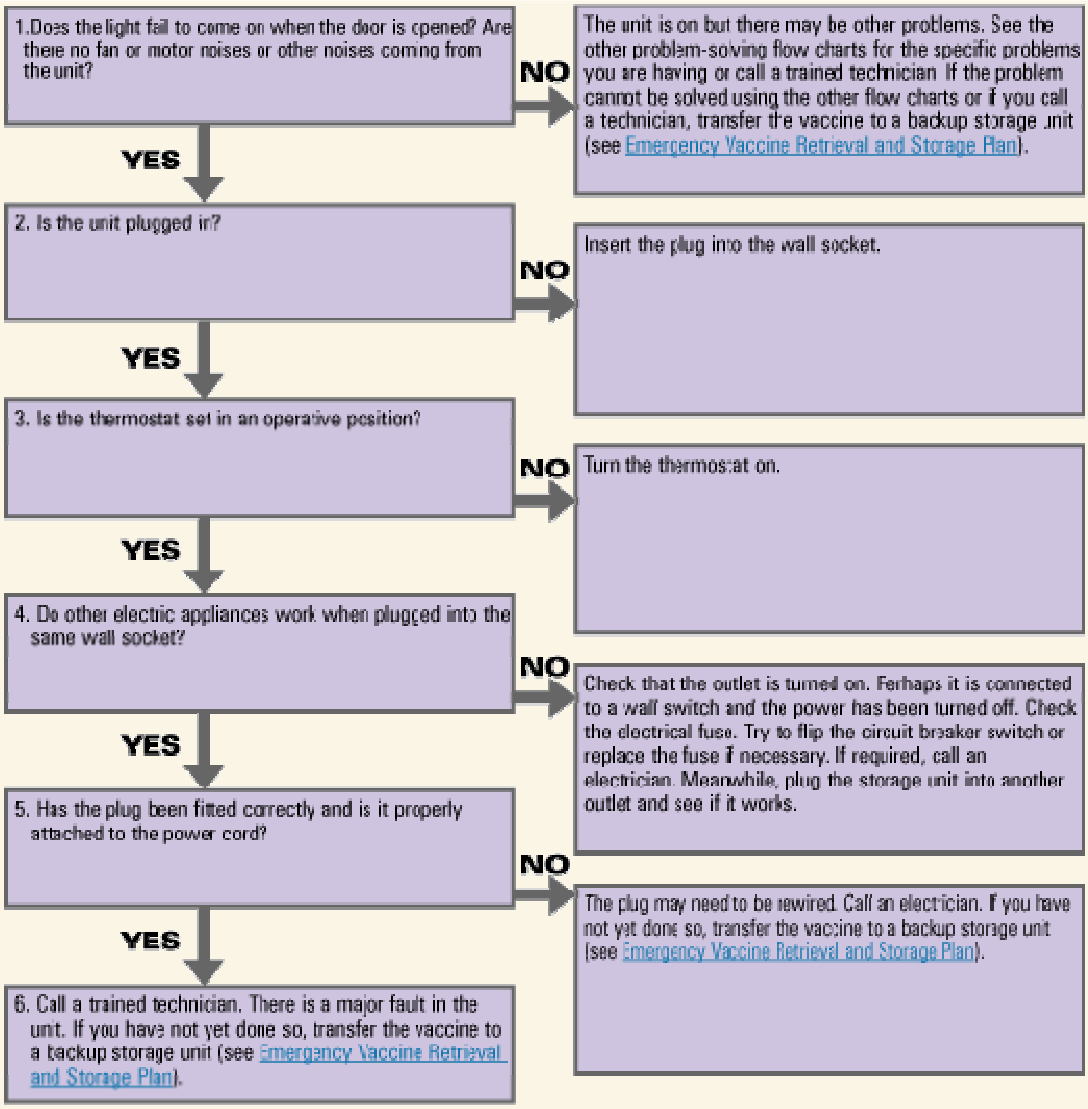
Vaccine Storage Unit is Too Noisy

Warning! Do not allow the vaccine to remain in a nonfunctioning unit for an extended period of time while you attempt to correct the problem. If at any time you are unsure how long the storage unit will not be functioning properly or you determine that the problem cannot be corrected in time to maintain the internal temperature within the recommended range, activate the Emergency Vaccine Retrieval and Storage Plan (see section on Storage and Handling Plans).



Vaccine Storage Unit Has Stopped

Warning! Do not allow the vaccine to remain in a nonfunctioning unit for an extended period of time while you attempt to correct the problem. If at any time you are unsure how long the storage unit will not be functioning properly or you determine that the problem cannot be corrected in time to maintain the internal temperature within the recommended range, activate the Emergency Vaccine Retrieval and Storage Plan (see section on Storage and Handling Plans).



Refrigerator and Freezer Door Problems

Checking the Door Seal

To check that the vaccine storage unit door is sealing properly:

1. Place a thin paper strip against the cabinet front (see Illustration 1).
2. Close the door.
3. Pull the paper strip. If it moves easily or falls away by itself, the door and the rubber-like seal need to be adjusted.
4. Check all the way around the door. Pay particular attention to the corners.

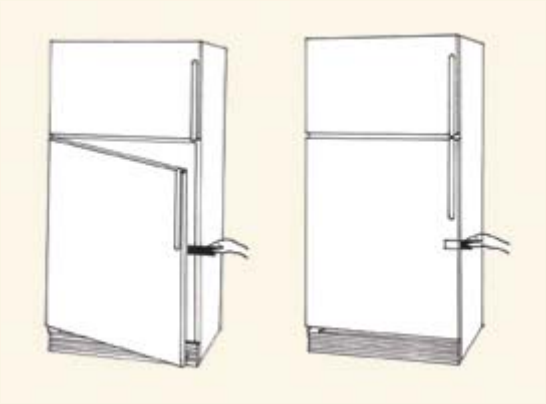


Illustration 1—Checking the door seal.
(Adapted from the *User's Handbook for Compression Refrigerators* WHO/EPI/LOG/84/15)

Adjusting the Door Seal

If you have checked the rubber-like door seal and determined that the door is not closing properly:

1. Loosen the hinge screws on the door slightly and check if the door seals better after the hinges are adjusted (see Illustration 2).
   - **a.** If the seal on the handle side of the door is loose, move the hinges slightly outward.
   - **b.** If the seal on the hinge side of the door is loose, move the hinges slightly inward.
2. If the door seal is loose at the corner, it will need to be replaced. Call a trained technician.

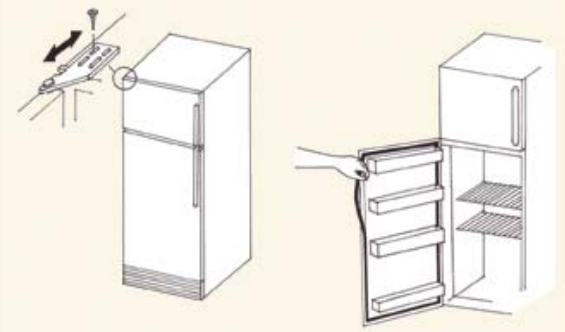


Illustration 2—Adjusting the door seal.
(Adapted from the *User's Handbook for Compression Refrigerators* WHO/EPI/LOG/84/15)

Adjusting Dropped Doors

If the vaccine storage unit door is not level when closed or if it is touching the toe kick plate or another door on the unit, it requires adjustment. Dropped doors can compromise the door seal. To adjust a dropped door:

1.	Loosen the upper hinge screws.	
2.	Make sure the edge of the door is in line with the side of the refrigerator.	
3.	Hold the door in position and tighten the screws.	
	a.	If the lower hinge is worn, the door can be adjusted upward by putting some washers on the hinge. (see Illustration 3)
4.	Check the door seal to be sure it is closing properly and tightly.	
5.	If a dropped door cannot be adjusted, call a trained technician.	

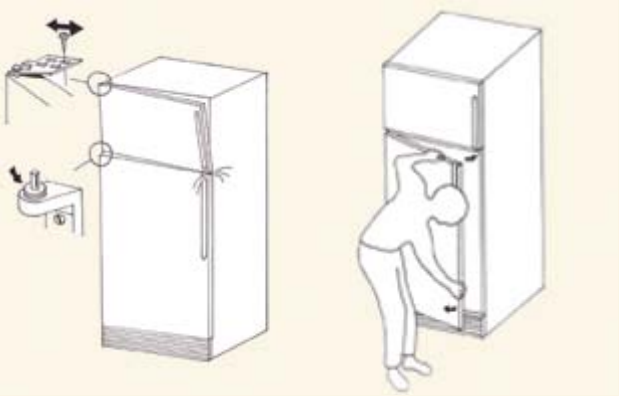


Illustration 3—Adjusting dropped doors.
(Adapted from the *User's Handbook for Compression Refrigerators* WHO/EPI/LOG/84/15)

Thermometer Problems

Checking Thermometer Placement

If the thermometer indicates a temperature outside the recommended range, check that the thermometer is appropriately situated in the center of the storage unit compartment, adjacent to the vaccine. If the thermometer is placed near the coils, walls, floor, or fan, it may indicate colder or warmer temperatures than a thermometer appropriately placed in the center of the compartment where the vaccines should be kept.

Checking If the Thermometer Works

A slight variation in temperature is often seen from one thermometer reading to another, even when the vaccine storage unit thermostat is set at a particular temperature. This is normal. If the thermometer reading does not fluctuate at all over several readings, temporarily remove the thermometer from the storage unit and place it outside the unit at room temperature. Check whether the temperature reading rises. If no change in the temperature reading occurs, the thermometer is faulty and needs to be replaced.

Checking If the Thermometer Is Accurate

If the thermometer appears to be working but there is concern regarding the accuracy of the reading, the standard method of testing the thermometer is to place another certified calibrated thermometer inside the storage unit along with the original one and check the readings on both thermometers.

Power Outages

Advance Preparations

When state officials, local officials, or providers have reasonable cause to believe that a power outage may occur (e.g., adverse weather conditions, natural disasters, or other emergencies that might disrupt power to any office where vaccine is stored) emergency procedures should be implemented **in advance of the event**.

When state officials, local officials, or providers have reasonable cause to believe that a power outage may occur, emergency procedures should be implemented in advance of the event.

Temperature Considerations

Most refrigerated vaccines will remain stable at elevated temperatures for limited periods of time. The vaccines of most concern are MMR, MMRV, varicella, and zoster vaccines, which are more sensitive to elevated temperatures. Whenever a question arises about the integrity of a vaccine, contact the vaccine manufacturer and the state health department immunization program for guidance (see Handling Inappropriate Vaccine Storage Conditions [Light and Temperature] in this section for details).

Power Outage Procedures

The information below is provided as a guideline. You may use the Emergency Response Worksheet in the Resources section of this toolkit to help organize your response. Consult your agency, local health department, or state health department immunization program, as appropriate for your situation, for any special instructions or forms. If there is an ongoing power outage, take the following steps:

1. Do not allow the vaccine to remain in a nonfunctioning unit for an extended period of time. If at any time you are unsure how long the power to the vaccine storage unit will be interrupted or you determine that the power will not be restored in time to maintain the internal temperature within the recommended range, activate the Emergency Vaccine Retrieval and Storage Plan (see section on Storage and Handling Plans) and **disregard** the following steps.
2. If you are **certain** the power will be restored before the vaccine storage unit temperature rises above the recommended range, take the following steps:
    a. Do not open the refrigerator or freezer door until the power is restored.
    b. Continue to monitor the temperatures inside the vaccine storage unit.
        i. Some thermometers allow temperature monitoring without opening the storage unit doors. In this case, record the room temperature and the temperature(s) inside the unit(s) at the time the problem is discovered, as well as the minimum

			and maximum temperatures reached inside the unit(s) during the power outage.
		ii.	If these types of thermometers are not being used, do not open the door(s) to check the temperature(s) during the power outage. Instead, record the room temperature, the duration of the power outage, and the temperature(s) inside the unit(s) as soon as possible after the power is restored. This will provide data on the maximum temperature and maximum duration of exposure to elevated temperatures.
	c.	Record the room temperature and the temperatures inside the vaccine storage units as soon as possible after power has been **restored**. Record the length of time the power has been off and the maximum temperature observed.	
	d.	If the temperature inside the refrigerator has exceeded the recommended range of 35° to 46°F (2° to 8°C) or if the temperature inside the freezer has risen above 5°F (-15°C), record the duration of inappropriate temperature exposure and follow the procedures for Handling Inappropriate Vaccine Storage Conditions [Light and Temperature] in this section.	

The Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration (FDA) offers general guidance concerning the storage and use of temperature-sensitive biological products that have been involved in a temporary electrical power failure or flood conditions (see Emergency Management Internet Resources in the Resources section of this toolkit).

Other Imminent Emergencies

When state officials, local officials, or providers have reasonable cause to believe that weather conditions, natural disasters, or other imminent emergencies might disrupt power or flood any office where vaccine is stored, emergency procedures should be implemented **in advance of the event** (see Emergency Vaccine Retrieval and Storage Plan in the Storage and Handling Plans section).

Selected Biologicals

DT: Diphtheria, Tetanus Toxoids—Pediatric
Td: Tetanus, Diphtheria Toxoids—Adult

Shipping Requirements
Should be shipped in insulated container. Maintain temperature at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.**

Condition upon Arrival
Should not have been frozen or exposed to freezing temperatures. Refrigerate upon arrival.

Storage Requirements
Refrigerate immediately upon arrival. Store at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.**

Shelf Life
Check expiration date on vial or manufacturer-filled syringe.

Instructions for Use
Inspect visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. Shake vial or manufacturer-filled syringe well before use. Discard vaccine if it cannot be resuspended with thorough agitation.

Shelf Life After Opening
Single-Dose Vials: The vaccine should be administered shortly after withdrawal from the vial.
Multidose Vials: Withdraw single dose of vaccine into separate sterile needle and syringe for each immunization. The vaccine should be administered shortly after withdrawal from the vial. Unused portions of multidose vials may be refrigerated at 35° – 46°F (2° – 8°C) and used until expired, if not contaminated or unless otherwise stated in the manufacturer's product information.
Manufacturer-Filled Syringes: The vaccine should be administered shortly after the needle is attached to the syringe.

Special Instructions
Rotate stock so that the earliest dated material is used first.

Note: All vaccine materials should be disposed of using medical waste disposal procedures. Contact the state health department for details.

DTaP: Diphtheria Toxoid, Tetanus Toxoid, Acellular Pertussis Vaccine—Pediatric

DTaP/Hib: Diphtheria Toxoid, Tetanus Toxoid, Acellular Pertussis Vaccine Combined with Haemophilus influenzae type b Conjugate Vaccine*—Pediatric

DTaP/HepB/IPV: Diphtheria Toxoid, Tetanus Toxoid, Acellular Pertussis Vaccine, Hepatitis B Vaccine, Inactivated Polio Vaccine—Pediatric

Tdap: Tetanus Toxoid, Diphtheria Toxoid, Acellular Pertussis Vaccine—Adult

Shipping Requirements

Should be shipped in insulated container. Maintain temperature at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.**

Condition upon Arrival

Should not have been frozen or exposed to freezing temperatures. Refrigerate upon arrival.

If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) then follow your state health department immunization program policy and contact either the Manufacturer's Quality Control office or the immunization program for guidance.

Storage Requirements

Refrigerate immediately upon arrival. Store at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.**

Shelf Life

Check expiration date on vial, container, or manufacturer-filled syringe.

Instructions for Reconstitution* or Use

Shake well before withdrawal and use. Do not use if resuspension does not occur with vigorous shaking.

Shelf Life After Reconstitution* or Opening

Single-Dose Vials: The vaccine should be administered shortly after withdrawal from the vial.

Manufacturer-Filled Syringes: The vaccine should be administered shortly after the needle is attached to the syringe.

Special Instructions

Rotate stock so that the earliest dated material is used first.

Note: All vaccine materials should be disposed of using medical waste disposal procedures. Contact the state health department for details.

* DTaP/Hib (TriHIBit®) is ActHIB® (sanofi pasteur) reconstituted with Tripedia® (sanofi pasteur). Once reconstituted, this combination vaccine must be used within 30 minutes or discarded. The only DTaP vaccine that can be used to reconstitute ActHIB® is Tripedia®. No other brand of DTaP is approved for this use.

Hepatitis Vaccines: Hepatitis A, Hepatitis B, Hepatitis A/B, Hepatitis B/Haemophilus influenzae type b

Shipping Requirements
Should be shipped in insulated container. Maintain temperature at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.**

Condition upon Arrival
Should not have been frozen or exposed to freezing temperatures. Refrigerate upon arrival.
If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) then follow your state health department immunization program policy and contact either the Manufacturer's Quality Control office or the immunization program for guidance.

Storage Requirements
Refrigerate immediately upon arrival. Store at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.**

Shelf Life
Check expiration date on vial or manufacturer-filled syringe.

Instructions for Use
Inspect visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. Shake vial or manufacturer-filled syringe well before use. Discard vaccine if it cannot be resuspended with thorough agitation.

Shelf Life After Opening
Single-Dose Vials: The vaccine should be administered shortly after withdrawal from the vial.
Manufacturer-Filled Syringes: The vaccine should be administered shortly after the needle is attached to the syringe.

Special Instructions
Rotate stock so that the earliest dated material is used first.

Note: All vaccine materials should be disposed of using medical waste disposal procedures. Contact the state health department for details.

Hib: *Haemophilus influenzae* type b Conjugate Vaccine

Shipping Requirements
Should be shipped in insulated container. Maintain temperature at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.**

Condition upon Arrival
Should not have been frozen or exposed to freezing temperatures. Refrigerate upon arrival.
If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) then follow your state health department immunization program policy and contact either the Manufacturer's Quality Control office or the immunization program for guidance.

Storage Requirements
Vaccine: Refrigerate immediately upon arrival. Store at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.**
Diluent: May be refrigerated or stored at room temperature (68° – 77°F [20° – 25°C]). Do not freeze or expose to freezing temperatures.

Shelf Life
Check expiration date on vial or container.

Instructions for Reconstitution* or Use
Inspect visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. Shake vial well before use. Discard vaccine if it cannot be resuspended with thorough agitation.

Shelf Life After Reconstitution* or Opening
Single-Dose Vials: The vaccine should be administered shortly after withdrawal from the vial.

Special Instructions
Rotate stock so that the earliest dated material is used first.

Note: All vaccine materials should be disposed of using medical waste disposal procedures. Contact the state health department for details.

* ActHIB® (sanofi pasteur) reconstituted with 0.4% sodium chloride diluent should be used within 24 hours after reconstitution. If sanofi pasteur DTaP-Tripedia® is used to reconstitute ActHIB®, the TriHibit® vaccine must be used within 30 minutes of reconstitution. Only sanofi pasteur DTaP-Tripedia® or the diluent shipped with the product may be used to reconstitute the sanofi pasteur ActHIB® product. No other brand of DTaP is licensed for use in reconstitution of ActHIB®.

HPV: Human Papillomavirus Vaccine

Shipping Requirements
Should be shipped in insulated container. Maintain temperature at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.**

Condition upon Arrival
Should not have been frozen or exposed to freezing temperatures. Refrigerate upon arrival.
If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) then follow your state health department immunization program policy and contact either the Manufacturer's Quality Control office or the immunization program for guidance.

Storage Requirements
Refrigerate immediately upon arrival. Store at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.** Protect from light at all times.

Shelf Life
Check expiration date on vial or manufacturer-filled syringe.

Instructions for Use
Inspect visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. Shake vial or manufacturer-filled syringe well before use. Discard vaccine if it cannot be resuspended with thorough agitation.

Shelf Life After Opening
Single-Dose Vials: The vaccine should be administered shortly after withdrawal from the vial.
Manufacturer-Filled Syringes: The vaccine should be administered shortly after the needle is attached to the syringe.

Special Instructions
Rotate stock so that the earliest dated material is used first.

Note: All vaccine materials should be disposed of using medical waste disposal procedures. Contact the state health department for details.

IPV: Inactivated Polio Vaccine

Shipping Requirements
Should be shipped in insulated container. Maintain temperature at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.**

Condition upon Arrival
Should not have been frozen or exposed to freezing temperatures. Refrigerate upon arrival.
If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) then follow your state health department immunization program policy and contact either the Manufacturer's Quality Control office or the immunization program for guidance.

Storage Requirements
Refrigerate immediately upon arrival. Store at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.**

Shelf Life
Check expiration date on vial or manufacturer-filled syringe.

Instructions for Use
Inspect visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. Shake vial or manufacturer-filled syringe well before use. Discard vaccine if it cannot be resuspended with thorough agitation.

Shelf Life After Opening
Multidose Vials: Withdraw single dose of vaccine into separate sterile needle and syringe for each immunization. The vaccine should be administered shortly after withdrawal from the vial. Unused portions of multidose vials may be refrigerated at 35° – 46°F (2° – 8°C) and used until expired, if not contaminated or unless otherwise stated in the manufacturer's product information. **Manufacturer-Filled Syringes:** The vaccine should be administered shortly after the needle is attached to the syringe.

Special Instructions
Rotate stock so that the earliest dated material is used first.

Note: All vaccine materials should be disposed of using medical waste disposal procedures. Contact the state health department for details.

TIV: Trivalent Inactivated Influenza Vaccine

Shipping Requirements
Should be shipped in insulated container. Maintain temperature at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.**

Condition upon Arrival
Should not have been frozen or exposed to freezing temperatures. Refrigerate upon arrival.
If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) then follow your state health department immunization program policy and contact either the Manufacturer's Quality Control office or the immunization program for guidance.

Storage Requirements
Refrigerate immediately upon arrival. Store at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.** Protect Fluarix® and FluLaval™ from light at all times by storing in original package.

Shelf Life
Formulated for use during current influenza season. Check expiration date on vial or manufacturer-filled syringe.

Instructions for Use
Inspect visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. Shake vial or manufacturer-filled syringe well before use. Discard vaccine if it cannot be resuspended with thorough agitation.

Shelf Life After Opening
Single-Dose Vials: The vaccine should be administered shortly after withdrawal from the vial.
Multidose Vials: Withdraw single dose of vaccine into separate sterile needle and syringe for each immunization. The vaccine should be administered shortly after withdrawal from the vial. Unused portions of multidose vials may be refrigerated at 35° – 46°F (2° – 8°C) and used until expired, if not contaminated or unless otherwise stated in the manufacturer's product information.
Manufacturer-Filled Syringes: The vaccine should be administered shortly after the needle is attached to the syringe.

Special Instructions
Rotate stock so that the earliest dated material is used first.

Note: All vaccine materials should be disposed of using medical waste disposal procedures. Contact the state health department for details.

LAIV: Live Attenuated Influenza Vaccine

Shipping Requirements
Initially shipped to authorized distributors in the frozen state 5°F (-15°C). Shipped from the distributor to healthcare facilities in the refrigerated state at 35° – 46°F (2° – 8°C).

Condition upon Arrival
Refrigerate upon arrival.
If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) then follow your state health department immunization program policy and contact either the Manufacturer's Quality Control office or the immunization program for guidance.

Storage Requirements
Refrigerate immediately upon arrival. Store at 35° – 46°F (2° – 8°C). **Do not freeze or expose to freezing temperatures**. (If LAIV is inadvertently frozen, the vaccine should be moved immediately to the refrigerator and may be used until the expiration date printed on the package.)

Shelf Life
Formulated for use during current influenza season. Check expiration date on package.

Instructions for Use
LAIV is a colorless to pale yellow liquid and is clear to slightly cloudy; some particulates may be present but do not affect the use of the product. After removal of the sprayer from the refrigerator, remove the rubber tip protector. Follow manufacturer's instructions to deliver ½ dose into one nostril. Then remove the dose-divider clip and deliver the remainder of the dose into the other nostril.

Shelf Life After Opening
Single-Dose Sprayer: The vaccine should be administered shortly after removal from the refrigerator.

Special Instructions
Rotate stock so that the earliest dated material is used first.

Note: All vaccine materials should be disposed of using medical waste disposal procedures. Contact the state health department for details.

MMR: Measles/Mumps/Rubella Vaccine, MR: Measles/Rubella Vaccine, Measles Virus Vaccine, Mumps Virus Vaccine, Rubella Virus Vaccine

Shipping Requirements

Vaccine: Should be shipped in insulated container. Must be shipped with refrigerant. Maintain at 50°F (10°C) or less. If shipped with dry ice, diluent must be shipped separately.
Diluent: May be shipped with vaccine, but do not place in container with dry ice.

Condition upon Arrival

Maintain at 50°F (10° C) or less. If above this temperature, see instructions (*) below. **Do not use warm vaccine.** Refrigerate upon arrival.
If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) then follow your state health department immunization program policy and contact either the Manufacturer's Quality Control office or the immunization program for guidance.

Storage Requirements

Vaccine: Refrigerate immediately upon arrival. Store at 35° to 46°F (2° to 8°C). Protect from light at all times, since such exposure may inactivate the virus.
Diluent: May be refrigerated or stored at room temperature (68° to 77°F [20° to 25°C]). **Do not freeze or expose to freezing temperatures.**
Note: MMR vaccine may be stored in the refrigerator or freezer.

Shelf Life

Check expiration date on vial.

Instructions for Reconstitution and Use

Reconstitute just before use according to the manufacturer's instructions. Use only the diluent supplied to reconstitute the vaccine.

Shelf Life After Reconstitution, Thawing or Opening

Single-Dose Vials: After reconstitution, use immediately or store at 35° – 46°F (2° – 8°C) and protect from light. **Discard if not used within 8 hours of reconstitution.**
Multidose vials: Withdraw single dose of reconstituted vaccine into separate sterile needle and syringe for each immunization. The vaccine dose should be administered shortly after withdrawal from vial. Unused portions of multidose vials may be refrigerated at 35° – 46°F (2° – 8°C), but must be discarded if not used within 8 hours after reconstitution.

Special Instructions

Rotate stock so that the earliest dated material is used first.

Note: All vaccine materials should be disposed of using medical waste disposal procedures. Contact the state health department for details.

MMRV: Measles/Mumps/Rubella/Varicella Vaccine

Shipping Requirements

Vaccine: Should be shipped in insulated container. Must be shipped with dry ice only, at 5°F (-15°C) or colder. Should be delivered within 2 days.
Diluent: May be shipped with vaccine, but do not place in container with dry ice.

Condition upon Arrival

Should be frozen. Vaccine should remain at 4°F (-20°C) or colder until arrival at the healthcare facility. Dry ice should still be present in the shipping container when vaccine is delivered.
If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) then follow your state health department immunization program policy and contact either the Manufacturer's Quality Control office or the immunization program for guidance.

Storage Requirements

Vaccine: Freeze immediately upon arrival. Maintain vaccine in a continuously frozen state at 5°F (-15°C) or colder. **No freeze/thaw cycles are allowed with this vaccine.** Vaccine should only be stored in freezers or refrigerator/freezers with separate doors and compartments. Acceptable storage may be achieved in standard household freezers purchased in the last 10 years, and standard household refrigerator/freezers with a separate, sealed freezer compartment. “Dormitory-style units” are not appropriate for the storage of MMRV vaccine. **Do not store lyophilized vaccine in the refrigerator. If lyophilized vaccine is inadvertently stored in the refrigerator, it should be used within 72 hours. Lyophilized vaccine stored at 35° – 46°F (2° – 8°C) which is not used within 72 hours should be discarded.** Protect the vaccine from light at all times since such exposure may inactivate the vaccine viruses.

In order to maintain temperatures of 5°F (-15°C) or colder, it will be necessary in most refrigerator/ freezer models to turn the temperature dial down to the coldest setting. This may result in the refrigerator compartment temperature being lowered as well. Careful monitoring of the refrigerator temperature will be necessary to avoid freezing killed or inactivated vaccines.
Diluent: May be refrigerated or stored at room temperature (68° to 77°F [20° to 25°C]). **Do not freeze or expose to freezing temperatures.**

Shelf Life

Check expiration date on vial.

Instructions for Reconstitution and Use

Reconstitute just before use according to the manufacturer’s instructions. Use only the diluent supplied to reconstitute the vaccine.

Shelf Life After Reconstitution, Thawing or Opening

Single-Dose Vials: Discard reconstituted vaccine if it is not used **within 30 minutes** of reconstitution. **Do not freeze reconstituted vaccine.**

Special Instructions

If this vaccine is stored at a temperature warmer than 5°F (-15°C), it will result in a loss of potency and a reduced shelf life. If a power outage or some other situation occurs that results in the vaccine storage temperature rising above the recommended temperature, the healthcare provider should contact Merck, the vaccine manufacturer, at 1-800-MERCK-90 for an evaluation of the product potency before using the vaccine.

Note: All vaccine materials should be disposed of using medical waste disposal procedures. Contact the state health department for details.

MCV: Meningococcal Conjugate Vaccine

Shipping Requirements
Should be shipped in insulated container. Maintain temperature at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.**

Condition upon Arrival
Should not have been frozen or exposed to freezing temperatures. Refrigerate upon arrival.
If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) then follow your state health department immunization program policy and contact either the Manufacturer's Quality Control office or the immunization program for guidance.

Storage Requirements
Refrigerate immediately upon arrival. Store at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.**

Shelf Life
Check expiration date on vial or manufacturer-filled syringe.

Instructions for Use
Inspect visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. Shake vial or manufacturer-filled syringe well before use. Discard vaccine if it cannot be resuspended with thorough agitation.

Shelf Life After Opening
Single-Dose Vials: The vaccine should be administered shortly after withdrawal from the vial.
Manufacturer-Filled Syringes: The vaccine should be administered shortly after the needle is attached to the syringe.

Special Instructions
Rotate stock so that the earliest dated material is used first. Vaccine should be injected by the intramuscular route. Do not inject intradermally, subcutaneously, or intravenously.

Note: All vaccine materials should be disposed of using medical waste disposal procedures. Contact the state health department for details.

MPSV: Meningococcal Polysaccharide Vaccine

Shipping Requirements
Should be shipped in insulated container. Maintain temperature at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.**

Condition upon Arrival
Should not have been frozen or exposed to freezing temperatures. Refrigerate upon arrival.
If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) then follow your state health department immunization program policy and contact either the Manufacturer's Quality Control office or the immunization program for guidance.

Storage Requirements
Vaccine: Refrigerate immediately upon arrival. Store at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.**
Diluent: May be refrigerated or stored at room temperature (68° – 77°F [20° – 25°C]). **Do not freeze or expose to freezing temperatures.**

Shelf Life
Check expiration date on vial.

Instructions for Reconstitution and Use
Reconstitute gently. This is a white powder that yields a clear, colorless liquid when reconstituted with 0.6 ml (single-dose vial) or 6 ml (10-dose vial) of sterile distilled water.

Shelf Life After Reconstitution or Opening
Single-Dose Vials: Use **within 30 minutes** of reconstitution.
Multidose Vials: Unused portions of multidose vials may be refrigerated at 35° to 46°F (2° to 8°C) and used up to 35 days after reconstitution.

Special Instructions
Rotate stock so that the earliest dated material is used first.

Note: All vaccine materials should be disposed of using medical waste disposal procedures. Contact the state health department for details.

PCV: Pneumococcal Conjugate Vaccine

Shipping Requirements
Should be shipped in insulated container. Maintain temperature at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.**

Condition upon Arrival
Should not have been frozen or exposed to freezing temperatures. Refrigerate upon arrival.
If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) then follow your state health department immunization program policy and contact either the Manufacturer's Quality Control office or the immunization program for guidance.

Storage Requirements
Refrigerate immediately upon arrival. Store at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.**

Shelf Life
Check expiration date on vial or manufacturer-filled syringe.

Instructions for Use
Inspect visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. Shake vial or manufacturer-filled syringe well before use. Discard vaccine if it cannot be resuspended with thorough agitation.

Shelf Life After Opening
Single-Dose Vials: The vaccine should be administered shortly after withdrawal from the vial.
Manufacturer-Filled Syringes: The vaccine should be administered shortly after the needle is attached to the syringe.

Special Instructions
This vaccine is a suspension containing adjuvant and should not be used if the particles cannot be resuspended after vigorous shaking. Rotate stock so that the earliest dated material is used first.

Note: All vaccine materials should be disposed of using medical waste disposal procedures. Contact the state health department for details.

PPV: Pneumococcal Polysaccharide Vaccine

Shipping Requirements
Should be shipped in insulated container. Maintain temperature at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.**

Condition upon Arrival
Should not have been frozen or exposed to freezing temperatures. Refrigerate upon arrival.
If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) then follow your state health department immunization program policy and contact either the Manufacturer's Quality Control office or the immunization program for guidance.

Storage Requirements
Refrigerate immediately upon arrival. Store at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.**

Shelf Life
Check expiration date on vial.

Instructions for Use
Inspect visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. Shake vial or manufacturer-filled syringe well before use. Discard vaccine if it cannot be resuspended with thorough agitation.

Shelf Life After Opening
Single-Dose Vials: The vaccine should be administered shortly after withdrawal from the vial.
Multidose Vials: Withdraw single dose of vaccine into separate sterile needle and syringe for each immunization. The vaccine should be administered shortly after withdrawal from the vial. Unused portions of multidose vials may be refrigerated at 35° – 46°F (2° – 8°C) and used until expired, if not contaminated or unless otherwise stated in the manufacturer's product information.

Special Instructions
Do not inject intravenously. Intradermal administration may cause severe local reactions and should be avoided. Rotate stock so that the earliest dated material is used first.

Note: All vaccine materials should be disposed of using medical waste disposal procedures. Contact the state health department for details.

Rotavirus Vaccine

Shipping Requirements
Should be shipped in insulated container. Maintain temperature at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.**

Condition upon Arrival
Should not have been frozen or exposed to freezing temperatures. Refrigerate upon arrival.
If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) then follow your state health department immunization program policy and contact either the Manufacturer's Quality Control office or the immunization program for guidance.

Storage Requirements
Refrigerate immediately upon arrival. Store at 35° to 46°F (2° to 8°C). **Do not freeze or expose to freezing temperatures.** Protect from light at all times, since such exposure may inactivate the vaccine viruses.

Shelf Life
Check expiration date on package.

Instructions for Use
Each dose is supplied in a container consisting of a squeezable plastic, latex-free dosing tube with a twist-off cap, allowing for direct oral administration. The dosing tube is contained in a pouch. Remove the dosing tube from the pouch, screw the cap clockwise to puncture the tube, and screw the cap off counter-clockwise so that the liquid can be squeezed from the tube during oral administration of the vaccine.

Shelf Life After Opening
Single-Dose Pouches: The vaccine should be administered shortly after withdrawal from the refrigerator. The dosing tube should not be returned to the refrigerator once the screw cap has been removed.

Special Instructions
Rotate stock so that the earliest dated material is used first.

Note: All vaccine materials should be disposed of using medical waste disposal procedures. Contact the state health department for details.

Varicella (Chickenpox) Vaccine

Shipping Requirements

Vaccine: Use insulated container. Must be shipped with dry ice only, at 5°F (-15°C) or colder. Should be delivered within 2 days.
Diluent: May be shipped with vaccine, but do not place in container with dry ice.

Condition upon Arrival

Should be frozen. Vaccine should remain at 5°F (-15°C) or colder until arrival at the healthcare facility. Dry ice should still be present in the shipping container when vaccine is delivered.
If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) then follow your state health department immunization program policy and contact either the Manufacturer's Quality Control office or the immunization program for guidance.

Storage Requirements

Vaccine: Freeze immediately upon arrival. Maintain vaccine in a continuously frozen state at 5°F (-15°C) or colder. **No freeze/thaw cycles are allowed with this vaccine.** Vaccine should only be stored in freezers or refrigerator/freezers with separate external doors and compartments. Acceptable storage may be achieved in standard household freezers purchased in the last 10 years, and standard household refrigerator/freezers with a separate, sealed freezer compartment. "Dormitory-style" units are not appropriate for the storage of varicella vaccine. **Do not store lyophilized vaccine in the refrigerator. If lyophilized vaccine is inadvertently stored in the refrigerator, it should be used within 72 hours. Lyophilized vaccine stored at 35° – 46°F (2° – 8°C) which is not used within 72 hours, should be discarded.** Protect the vaccine from light at all times since such exposure may inactivate the vaccine virus.

In order to maintain temperatures of 5°F (-15°C) or colder, it will be necessary in most refrigerator/freezer models to turn the temperature dial down to the coldest setting. This may result in the refrigerator compartment temperature being lowered as well. Careful monitoring of the refrigerator temperature will be necessary to avoid freezing killed or inactivated vaccines.
Diluent: May be refrigerated or stored at room temperature (68° to 77°F [20° to 25°C]). **Do not freeze or expose to freezing temperatures.**

Shelf Life

Check expiration date on vial.

Instructions for Reconstitution and Use

Reconstitute just before use according to the manufacturer's instructions. Use only the diluent supplied to reconstitute the vaccine.

Shelf Life After Reconstitution, Thawing or Opening

Single-Dose Vials: Discard reconstituted vaccine if it is not used **within 30 minutes** of reconstitution. **Do not freeze reconstituted vaccine.**

Special Instructions

Rotate stock so that the earliest dated material is used first.
If this vaccine is stored at a temperature warmer than 5°F (-15°C), it will result in a loss of potency and a reduced shelf life. If a power outage or some other situation occurs that results in the vaccine storage temperature rising above the recommended temperature, the healthcare provider should contact Merck, the vaccine manufacturer, at 1-800-9-VARIVAX for a reevaluation of the product potency before using the vaccine.
Note: All vaccine materials should be disposed of using medical waste disposal procedures. Contact the state health department for details.

Zoster (Shingles) Vaccine

Shipping Requirements

Vaccine: Should be shipped in insulated container. Must be shipped with dry ice only, at 5°F (-15°C) or colder. Should be delivered within 2 days.
Diluent: May be shipped with vaccine, but do not place in container with dry ice.

Condition upon Arrival

Should be frozen. Vaccine should remain at 5°F (-15°C) or colder until arrival at the healthcare facility. Dry ice should still be present in the shipping container when vaccine is delivered.
If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) then follow your state health department immunization program policy and contact either the Manufacturer's Quality Control office or the immunization program for guidance.

Storage Requirements

Vaccine: Freeze immediately upon arrival. Maintain vaccine in a continuously frozen state at 5°F (-15°C) or colder. **No freeze/thaw cycles are allowed with this vaccine.**
Vaccine should only be stored in freezers or refrigerator/freezers with separate doors and compartments. Acceptable storage may be achieved in standard household freezers purchased in the last 10 years, and standard household refrigerator/freezers with a separate, sealed freezer compartment. "Dormitory-style units" are not appropriate for the storage of zoster vaccine. **Do not store lyophilized vaccine in the refrigerator.**
Protect the vaccine from light at all times since such exposure may inactivate the vaccine viruses.
In order to maintain temperatures of 5°F (-15°C) or colder, it will be necessary in most refrigerator/freezer models to turn the temperature dial down to the coldest setting. This may result in the refrigerator compartment temperature being lowered as well. Careful monitoring of the refrigerator temperature will be necessary to avoid freezing killed or inactivated vaccines.
Diluent: May be refrigerated or stored at room temperature (68° to 77°F [20° to 25°C]). **Do not freeze or expose to freezing temperatures.**

Shelf Life

Check expiration date on vial.

Instructions for Reconstitution and Use

Reconstitute just before use according to the manufacturer's instructions. Use only the diluent supplied to reconstitute the vaccine.

Shelf Life After Reconstitution, Thawing or Opening

Discard reconstituted vaccine if it is not used within 30 minutes. Do not freeze reconstituted vaccine.

Special Instructions

Rotate stock so that the earliest dated material is used first.
If this vaccine is stored at a temperature warmer than 5°F (-15°C), it will result in a loss of potency and a reduced shelf life. If a power outage or some other situation occurs that results in the vaccine storage temperature rising above the recommended temperature, the healthcare provider should contact Merck, the vaccine manufacturer, at 1-800-MERCK-90 for a reevaluation of the product potency before using the vaccine.

Note: All vaccine materials should be disposed of using medical waste disposal procedures. Contact the state health department for details.

Vaccine Inventory Management

Disclaimer: State or local health department immunization programs may recommend or require different inventory accounting practices and different forms from those described here. The information presented here is meant to provide general guidelines only. Contact the state or local health department immunization program staff for details about inventory accounting practices and follow their recommendations.

Vaccine Access

Limit access to the vaccine supply to authorized personnel only. This will help protect the vaccine supply by avoiding inappropriate removal of vaccine or inappropriate handling of vaccine and vaccine storage units by untrained personnel.

Limit access to the vaccine supply to authorized personnel only.

Expiration Dates

Interpreting Expiration Dates

All vaccines and diluents have expiration dates. The expiration date is the date by which the vaccine or diluent should be used. This date is printed on all vaccine and diluent vials and boxes. Expiration dates vary by the type of vaccine or diluent, and by the lot number. The vaccine or diluent may be used up to and including this date **unless** otherwise stated in the product package insert. Vaccine and diluent should not be used after this date has passed. When the expiration date is marked with only a month and year, the vaccine or diluent may be used up to and including the last day of the month indicated on the vial. Any unused vaccine or diluent should not be used after this month has passed.

Vaccine may be used up to and including the expiration date.

What to Do with Expired and Mishandled Vaccine or Diluent

Expired vaccine and diluent, even if they are only 1 day past the expiration date, should **never** be administered. Likewise, vaccines that have been mishandled and lost their potency because of inappropriate storage conditions should not be administered. If a dose of expired or mishandled vaccine is given by mistake, the dose should not be counted as valid and should be repeated, unless serologic testing indicates that an adequate response to the vaccine has been achieved. Promptly remove expired or mishandled vaccine and diluent from the refrigerator or freezer and dispose of it appropriately. Contact the vaccine supplier, which may be the vaccine manufacturer or the state health department immunization program, for specific policies regarding the disposition of mishandled or expired vaccine. If the expired vaccine is publicly purchased, contact your state health department immunization program for instructions on returning expired vaccine for excise tax credit.

Exceptions to the Expiration Date

The expiration date printed on each vial or box assumes the vaccine has been properly transported and stored at all times and that it has not become contaminated. If vaccine has been inappropriately exposed to excessive heat, cold, or light, its potency may be reduced **before** the expiration date is reached. The only way to determine if proper transport and storage conditions have been maintained is to monitor vaccine and diluent temperatures during every link in the cold chain and to safeguard HPV, MMR, MMRV, rotavirus, varicella, and zoster vaccines from exposure to light. The expiration date printed on each vial or box may also be invalidated after the vial is opened or reconstituted (see Expiration of Different Vaccine Products in this section for details).

Transferring Vaccine or Diluent That Cannot Be Used Before Expiration

If vaccine or diluent is within 120 days of the expiration date, determine whether or not the product can be used within this time period given the volume of patients vaccinated in your practice. If the product cannot be used within this time frame, contact the vaccine supplier, which may be the vaccine manufacturer or the state health department immunization program, for guidance. You may be able to return the vaccine and diluent for credit or you may be able to transfer the product to another facility where it can be used before it expires. If the vaccine is publicly purchased, you may be instructed to return it to the immunization program, or transfer it to another provider. Your state immunization program may recommend a window period different than 120 days for these considerations.

Expiration of Different Vaccine Products

Multidose premixed vaccine vials contain bacteriostatic agents that prevent the growth of bacteria. These vaccines can be used until the date of expiration printed on the vial unless they become contaminated.

Single-dose vials are meant for one-time use only. Once the protective caps on single-dose vials have been unsealed, it may not be possible to determine if the rubber seals have been

punctured. Therefore, do not open single-dose vials until you are ready to use them. To avoid needless waste of vaccine, **always** check the vial before removing the cap to make sure you have the correct vaccine type, and remove the cap only when you are ready to draw up and administer the vaccine. Single-dose vials without their protective caps should be discarded at the end of the clinic day.

Single dose vials are meant for one-time use only.
Once unsealed, discard vial at end of clinic day.

Once lyophilized (freeze-dried) vaccines have been reconstituted, they must be used within a specified time frame or discarded. Consult the product insert for the most up-to-date information about expiration times and dates following reconstitution. MMRV, varicella, and zoster vaccines must be used within 30 minutes of reconstitution and protected from light at all times. TriHIBit® vaccine (DTaP/Hib) and single-dose vials of Menomune® must be used within 30 minutes of reconstitution. MMR must be used within 8 hours of reconstitution and protected from light at all times. ActHIB® vaccine (Hib) must be used within 24 hours of reconstitution. Multidose vials of Menomune® must be used within 35 days of reconstitution. Unused reconstituted vaccines kept beyond these limits should **not** be administered. The best way to avoid such waste is to reconstitute and draw up vaccines immediately before administration (see Expiration of Reconstituted Vaccine in the Vaccine Preparation and Disposal section for details).

Stock Rotation

The vaccine coordinator should ensure that someone rearranges the placement of vaccine and diluent supplies according to the expiration dates on a weekly basis and each time a vaccine shipment arrives. The vials and boxes with the earliest expiration dates should be placed in front of other vials and boxes of the same type with later expiration dates. This practice avoids waste by ensuring that vaccines and diluents with the shortest expiration dates are easily accessible and will be used first, thereby limiting the amount of unused vaccine that has passed its expiration date.

Expired vaccine and diluent should never be administered. Promptly remove expired vaccine from the refrigerator or freezer to avoid accidental use. Vaccine suppliershave different return policies for outdated vaccine. Contact the vaccine manufacturer for advice on returning privately purchased vaccine. Contact the state health

Expired vaccine and diluent should never be administered.

department immunization program for advice on returning publicly purchased vaccine for excise tax credit.

Inventory Accounting

General Recommendations

Inventory accounting is important for vaccine quality management. Proper inventory management means knowing the following:

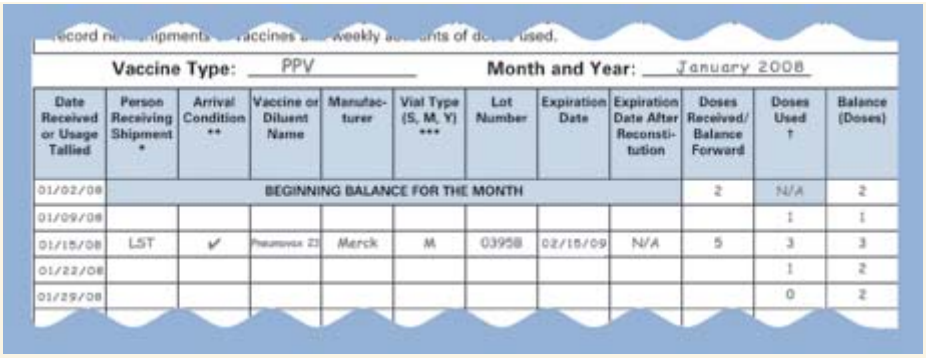
- what quantities of vaccines and diluents have been received;
- what quantities of vaccines and diluents have been administered, wasted, or spoiled;
- which vaccines and diluents are currently in stock;
- which vaccine and diluent vials should be used first;
- which vaccine and diluent vials are expired and must not be administered;
- how many vaccine and diluent vials are in excess supply and may be returned for possible credit; and
- which vaccines and diluents need to be ordered.

Stock Records

Some state or local health department immunization programs have developed stock records or other vaccine inventory protocols and procedures for vaccine providers. Contact program staff for information and follow their recommendations. If stock records **are not** available from the state or local health department immunization program, a Sample Stock Record can be found in the Resources section of this toolkit. This Sample Stock Record shows the components that you may include in your own stock record. A blank version of the Sample Stock Record is also available in the Resources section (see Stock Record).

Maintaining complete and accurate stock records is a critical component of inventory management. The balance of doses remaining in stock as indicated on the stock records should be updated weekly using a tally of doses administered, wasted, spoiled, expired, or transferred that week. A stock record that is not accurate is of no value to the vaccine coordinator and can lead to over- or understocking of supplies and disruption to the immunization program.

Maintaining complete and accurate stock records is a critical component of inventory management.



Vaccine Type: PPV Month and Year: January 2008

Date Received or Usage Tallied	Person Receiving Shipment *	Arrival Condition **	Vaccine or Diluent Name	Manufacturer	Vial Type (S, M, Y) ***	Lot Number	Expiration Date	Expiration Date After Reconstitution	Doses Received/ Balance Forward	Doses Used †	Balance (Doses)
01/02/08	BEGINNING BALANCE FOR THE MONTH								2	N/A	2
01/09/08										1	1
01/15/08	LST	✓	Pneumovax 23	Merck	M	03958	02/15/09	N/A	5	3	3
01/22/08										1	2
01/29/08										0	2

Sample Stock Record.

Stock records may be kept in either computerized or written formats, depending on the setting. Keep separate records for each type of vaccine. For lyophilized (freeze-dried) vaccine that requires reconstitution, record information for diluents on a separate stock record. Quantities of these vaccines and diluents must be equal at all times.

Each stock record should contain the following information:

- the date each vaccine and diluent arrived at the facility;
- the initials of the person who unpacked and checked the vaccine and diluent upon arrival (this person should also record the shipment on the stock record);
- the condition of each vaccine and diluent upon arrival (i.e., did the vaccine arrive in good condition at the proper temperature or was there a reason to question its integrity);
- the name of each vaccine and diluent;
- the manufacturer of each vaccine and diluent;
- the type of container received (i.e., single-dose vial, multidose vial, or manufacturer-filled syringe);
- the lot number(s) (note there may be more than one lot in a shipment— **each lot should be recorded on a separate line on the stock record)**;
- the expiration date(s) for each lot (including the new expiration dates/times for vaccines that have been reconstituted);
- the number of doses received (or the balance of doses carried forward);
- the number of doses used (i.e., administered, wasted, spoiled, expired, or transferred - if vaccine is transferred, note the destination beside the number of doses); and
- the balance remaining (in DOSES) after subtracting the amount used (i.e., administered, wasted, spoiled, expired, or transferred).

If you receive multiple vials of the same vaccine in the same type of container (i.e., single-dose vial, multidose vial, or manufacturer-filled syringe) from the same lot with the same expiration date, these doses may be recorded as one entry on the stock record. Simply indicate the total number of doses of that particular vaccine that were received (regardless of the number of vials or syringes those doses came in). For example, if you receive 10 single-dose vials of the same vaccine meeting the above criteria, these 10 vials can be recorded as a single entry, noting that 10 doses were received.

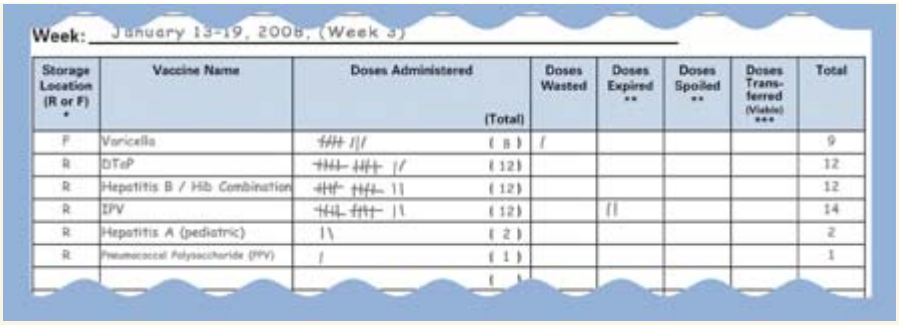
Tally Sheets

Some state or local health department immunization programs have developed tally sheets or other vaccine inventory protocols and procedures for vaccine providers. Contact program staff for information and follow their recommendations. If tally sheets **are not** available from the state or local health department immunization program, a Sample Tally Sheet can be found in the Resources section of this toolkit. This Sample Tally Sheet shows the components that you may include in your own tally sheet. A blank version of the Sample Tally Sheet is also available in the Resources section (see Tally Sheet).

Tally sheets are used to record vaccine doses that were removed from the vaccine storage unit. These include doses that were administered, wasted, spoiled, expired, or transferred.

Tally sheets are used to record vaccine doses that were removed from the vaccine storage unit.

Each time a dose of vaccine is removed, it should be marked on a tally sheet that is placed on the outside of the storage unit door or in some other convenient location. Tick marks can be used to record doses that have been removed from the storage unit. Alternatively, the initials of the person removing the dose may be used.



Week: January 13-19, 2008, (Week 3)

Storage Location (R or F) *	Vaccine Name	Doses Administered (Total)	Doses Wasted	Doses Expired **	Doses Spoiled **	Doses Transferred (Viable) ***	Total
F	Varicella	𝍸 /// (8)	/				9
R	DTaP	𝍸 𝍸 /// (12)					12
R	Hepatitis B / Hib Combination	𝍸 𝍸 // (12)					12
R	IPV	𝍸 𝍸 // (12)		//			14
R	Hepatitis A (pediatric)	// (2)					2
R	Pneumococcal Polysaccharide (PPV)	/ (1)					1
		( )					

Sample Tally Sheet.

These tally sheets can be used to keep stock records updated. For example, place a tally sheet on the storage unit door and record the doses removed from the unit during the week. At the end of the week, the vaccine coordinator or a designated person should add up the number of doses of each vaccine used and update the stock records accordingly to determine the new stock balance at the end of the week. The old tally sheet can then be removed and replaced with a new tally sheet to be used for the following week. Store used tally sheets in a file for future reference.

Recording New Shipments

For details, see Storing and Documenting Vaccine Shipments Upon Arrival in the Vaccine Shipments section.

Recording Administered, Wasted, Spoiled, Expired, and Transferred Doses

Every dose of vaccine and diluent must be accounted for. Contact state or local health department immunization program staff for details about inventory accounting practices and follow their recommendations. The following discussion provides general guidelines only.

Record every dose removed from the vaccine storage unit on the appropriate tally sheet and stock record. Record how many doses were administered, wasted, spoiled, expired, or transferred. At the end of the week, use the tally sheet to update the stock record and calculate the balance of the vaccine and diluent remaining (i.e., the running balance of doses in stock).

While vaccines and diluents remain in storage, expiration dates should be checked weekly and stock should be rotated accordingly (see Expiration Dates and Stock Rotation in this section). Record each time vaccine or diluent doses expire. These records will help you decide how much vaccine to order to minimize waste in the future. Likewise, note each time doses cannot be used because they have been exposed to inappropriate storage conditions or because their vials have been damaged. Subtract these unusable doses from the running balance on the stock record to calculate the new balance of doses. Recording the number of doses that were expired, wasted, or spoiled helps monitor vaccine waste. Contact the state health department

immunization program and the vaccine manufacturer for instructions on how to dispose of these doses. They may have to be discarded but sometimes unused vaccine may be returned for credit.

Some state health department immunization programs accept transfers vaccines with short expiration dates that will expire before they can be used. Occasionally, viable vaccines may also be transferred to other facilities. Contact the state or local health department immunization program for details if such a transfer is required. For each transfer, record the details in the appropriate tally sheet and stock record. Also, record the details of the vaccines and diluents being transferred, a contact name, and a contact telephone number on the delivery note or packing slip which accompanies the shipment. This helps the receiver know exactly what items are being transferred. If vaccine transfer is necessary, contact the state health department immunization program and vaccine manufacturer for information on the process and procedures.

Counting Stock

An actual count of the number of doses of vaccine and diluent in stock is an important component of inventory management and is the responsibility of the vaccine coordinator or designee. Vaccine and diluent doses should be counted at least once a month and before ordering vaccine. This will ensure there are enough supplies to meet the needs of the practice and is useful for checking the accuracy of the running balance of doses in the stock records.

When counting vaccine doses:

- Review the expiration dates of all stock, looking for vaccine with a short expiration date that must be used quickly and for expired vaccine that should not be administered.
- If you have vaccine that will expire within 120 days that cannot be administered during this time period, contact the vaccine supplier, which may be the vaccine manufacturer or the state health department immunization program for further instructions. If the vaccine with a short expiration date is publicly purchased vaccine, in some cases it can be moved to another clinic where it may be used before it expires. Your state immunization program may recommend a window period different than 120 days for these considerations.
- Promptly remove expired vaccine and diluent from the refrigerator or freezer. Contact the vaccine supplier, which may be the vaccine manufacturer or the state health department immunization program, for specific policies regarding the disposition of expired vaccine. If the expired vaccine is publicly purchased, contact your state health department immunization program for instructions on returning expired vaccine for excise tax credit. If expired vaccine cannot be returned, dispose of the vaccine appropriately (see Disposal of Vaccine and Diluent in the Vaccine Preparation and Disposal section for details).
- If the count of vaccine doses is different from the running balance in the stock records, count the stock again and recalculate the running balance to find the error.
- If a discrepancy remains, the stock record is in error and should be corrected. To do this, enter the correct balance from your count on a separate line in the stock record below the old balance. Write a note with your signature beside it to indicate that your count has confirmed the new balance. Use the new corrected balance for all future stock calculations.
- At the end of every month, make a summary of the amount of each vaccine and diluent used during that month and the amount of stock still available at the end of that month. This information is useful for deciding how much vaccine to order and can be used to monitor the seasonality of vaccine use.

- At the end of every year, total the amount of each vaccine and diluent received and the amount used. This information is useful for determining the annual vaccine needs of the practice.

Vaccine Stock Calculations and Vaccine Ordering

In general, there are three main principles to keep in mind when calculating the amount of vaccine supplies needed and when placing vaccine orders:

1. **Order and stock enough vaccine to ensure that there is an adequate supply to meet the needs of the patients.** An adequate supply for most practices would normally be enough vaccine to last 60 days, with a re-ordering threshold of 30 days. Your state health department immunization program may recommend different supply levels, depending on local use.
2. **Do not over order vaccines.** This practice leads to vaccine waste if unused vaccine expires. It also results in unnecessarily large volumes of vaccine being stored, which increases the risk of losing a large quantity of vaccine should there be a storage and handling accident (e.g., mechanical failure of the vaccine storage unit).
3. **Place one large order for all the vaccines required for a specific period of time rather than multiple small orders for individual vaccines.** This reduces the number of vaccine shipments your practice must handle, and also reduces the risk that you will run out of a particular vaccine. If you receive vaccine from the Vaccines for Children (VFC) Program, ordering all vaccines at one time helps the program process orders efficiently.

Contact your state or local health department immunization program for further information about vaccine supply management and ordering. Follow the specific recommendations for your state regarding methods for calculating vaccine supply needs, amounts of vaccine inventory to keep in stock, frequency of ordering, and methods of ordering vaccine. While vaccine orders usually arrive within 1-2 weeks, delays can occur. Avoid placing last minute or rush orders so as to minimize the risk that you will run out of vaccine.

After ordering vaccine, alert office staff that an order has been placed. The primary vaccine coordinator or designated backup person should be notified immediately upon arrival of a vaccine shipment so that the vaccine is stored under appropriate conditions and the cold chain is maintained (see the section on Vaccine Shipments). Vaccine shipments must also be documented in the appropriate stock record.

Vaccine Shipments

Disclaimer: State or local health department immunization programs may recommend or require different vaccine shipment and transport practices from those described here. The information presented here is meant to provide general guidelines only. Contact the state or local health department immunization program for details.

Standard Operating Procedures

Vaccine may be transported by either hand-carrying or shipping to another site. In both cases, the cold chain must be maintained. It is important to establish a routine, systematic process for handling vaccine shipments and vaccine transport. Each facility should develop its own written standard operating procedures (SOPs), covering every aspect of vaccine shipping: receiving, storing, packing, and transportation. Written SOPs are useful for reference, training, and evaluation of staff performing the work and should be included in the Routine Vaccine Storage and Handling Plan (see section on Storage and Handling Plans).

The SOP should specify that the vaccine is attended at all times during transport, that it is promptly placed into appropriate storage units upon arrival, and that it is transported in the minimum needed quantity to avoid unnecessary loss of expensive vaccine.

Without SOPs there can be no assurance that proper procedures will be followed or that problems will be identified, reported, and corrected. You may want to test various materials and packing configurations to find out what works best for your situation before developing your SOPs.

The SOP should specify that the vaccine is:

1.	**Attended at all times during transport.**
2.	**Promptly placed into appropriate storage units upon arrival.**
3.	**Transported in the minimum needed quantity to avoid unnecessary loss of expensive vaccine.**

Receiving and Unpacking Vaccine Shipments

Receiving Vaccine Shipments

Arrange for vaccine deliveries to be made only when the vaccine coordinator or backup person is on duty. All staff members who accept vaccine deliveries must be aware of the importance of maintaining the cold chain and of the need to **immediately notify** the vaccine coordinator or backup person of the arrival of the vaccine shipment so that it can be handled and stored appropriately.

All staff members who accept vaccine deliveries must be aware of the importance of maintaining the cold chain and of the need to immediately notify the vaccine coordinator or backup person upon arrival.

Picking Up Vaccine Shipments

In some states, providers pick up vaccine from public depots and might be required to supply their own coolers for vaccine transport. In this case, the state health department immunization program will provide guidance regarding the appropriate coolers. When picking up vaccine shipments, do not place vaccine in the trunk of the vehicle. The temperature inside the trunk cannot be regulated and could become too hot or too cold for the vaccine. Deliver the vaccine directly to the facility and unpack and store it upon arrival (see Checking the Condition of a Shipment in this section).

When transporting vaccine in ordinary vehicles use the passenger compartment—not the trunk.

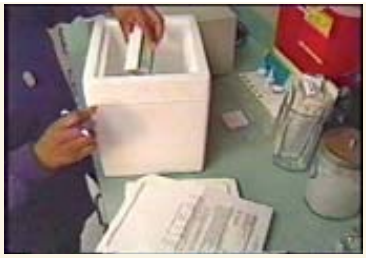
Checking the Condition of a Shipment

When you receive your vaccine shipment, it should be examined immediately.

- Examine the shipping container and its contents for any signs of physical damage.
- Determine if the shipping time was less than 48 hours. If the interval between shipment from the supplier and arrival of the product at the provider's office was more than 48 hours, the vaccine could have been exposed to excessive heat or cold that might have altered its integrity.

Examine the shipping container and its contents for any signs of physical damage.

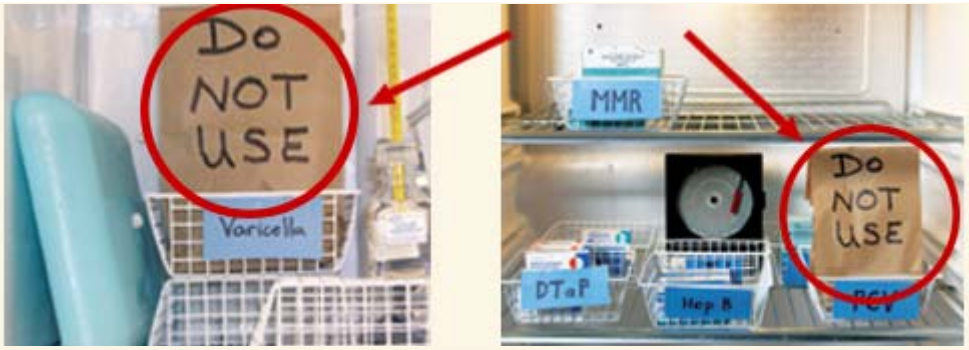
- Crosscheck the contents with the packing slip to be sure they match.
- Check the vaccine expiration dates to ensure that you have not received any vaccine or diluent that is already expired or that has a short expiration date (see Expiration Dates in the Vaccine Inventory Management section for details).
- Check that lyophilized (freeze-dried) vaccine has been shipped with the correct type and quantity of diluent for reconstitution.



Crosscheck the contents with the packing slip to be sure they match.

- Examine the vaccine and diluent for heat or cold damage:
  - Check the cold chain monitor(s) (CCM) to see if the vaccine or diluent has been exposed to temperatures outside the recommended range during transport.
  - Check that inactivated vaccines are cold but not frozen. Refrigerated packs should still be cold. Frozen packs can be melted but the package should still be cold. Vaccines should not be in direct contact with refrigerated/frozen packs. There should be an insulating barrier between the vaccine and the refrigerated/frozen packs, such as crumpled brown packing paper, bubble wrap, or some other barrier.
  - Check that measles/mumps/rubella (MMR) vaccine is cold or frozen.
  - Check that MMRV, varicella, and zoster vaccines are frozen and that dry ice is present in the shipping container. Dry ice must be handled carefully (see Handling Dry Ice in the Resources section for details).
  - Check that diluent is cool or at room temperature. Diluent should not be in direct contact with refrigerated/frozen packs. There should be an insulating barrier between the diluent and the refrigerated/frozen packs, such as crumpled brown packing paper, bubble wrap, or some other barrier. The diluent for varicella vaccine may be shipped with its vaccine but should not be placed in the container with the dry ice.

If there are any discrepancies with the packing slip or concerns about the shipment, immediately notify the primary vaccine coordinator (or the backup person), mark the vaccine and diluent as “DO NOT USE,” and store them in proper conditions apart from other vaccine supplies until the integrity of the vaccine and diluent is determined.



If there are any discrepancies with the packing slip or concerns about the shipment, immediately mark the vaccine and diluent as “DO NOT USE,” and store them in proper conditions.

Contact the vaccine manufacturer and the state health department immunization program for further guidance (see Handling Inappropriate Vaccine Storage Conditions [Light and Temperature] in the Storage Troubleshooting section for details).

Storing and Documenting Vaccine Shipments Upon Arrival

After the vaccine shipment has been checked according to the procedures described in this section (see Checking the Condition of a Shipment), immediately store the vaccine and diluent at the recommended temperatures and record the arrival of each vaccine and diluent noting all the details as outlined in the stock records (see section on Vaccine Inventory Management). Do not leave the shipment unattended. The vaccines inside might warm to inappropriate temperatures and become unusable. All staff who may accept packages for the clinic must be aware that vaccine shipments require ⚠**immediate attention**. Staff who do not routinely handle vaccines but who accept vaccine shipments should alert the primary vaccine coordinator (or the designated backup person) as soon as vaccine shipments arrive so that they may be stored properly.

All staff who may accept packages for the clinic must be aware that vaccine shipments require immediate attention.

Transporting Vaccine to Off-Site Clinics

General Recommendations

The best assurance of vaccine efficacy is to minimize the number of times vaccines are handled and transported. If vaccine transportation to another location is required, it is critical that vaccine potency is protected by maintaining the cold chain at all times.

If vaccine transportation to another location is required, it is critical that vaccine potency is protected by maintaining the cold chain at all times.

When a multidose vial is used, Food and Drug Administration (FDA) regulations require that it be used only by the provider's office where it was first opened. A partially used vial may be transported to or from off-site clinics operated by the same provider as long as the cold chain is properly maintained. However, such a vial may not be transferred to another provider or transported across state lines. While there is no defined limit to the number of times vaccine may be transported to different clinic sites, multiple transport increases the risk that vaccine will be exposed to inappropriate storage conditions.

Transporting Varicella-Containing Vaccines

Varicella-containing vaccines should be transported on dry ice in a frozen state to maintain potency. If these vaccines must be transported to off-site clinics and dry ice is not available, single-antigen varicella vaccine and MMRV may be transported at 35° to 46° F (2° to 8° C); however, this will greatly reduce the shelf life of these vaccines. Single-antigen varicella vaccine and MMRV that are stored at 35° to 46° F (2° to 8° C) must be discarded 72 hours after removal from the freezer. Single-antigen varicella vaccine and MMRV that are removed from the freezer and transported at 35° to 46° F (2° to 8° C) must be labeled with the **date and time** they were removed from the freezer. Only **single-antigen** varicella vaccine and MMRV

may be transported and stored at 35° to 46° F (2° to 8° C). Zoster vaccine must be maintained at +5° F (-15° C) at all times, and must be transported on dry ice. Once removed from the freezer, none of these vaccines may be refrozen. Because of the risk of vaccine wastage, the National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention strongly discourages transport of these vaccines to off-site clinics. Consult your state health department immunization program for advice and details.

Transporting Diluent

Diluent should travel with its corresponding vaccine at all times to ensure that there are always equal numbers of vaccine vials and diluent vials for reconstitution. Additionally, the diluent must always be of the correct type and from the same manufacturer as the vaccine it accompanies.

Diluent should travel with its corresponding vaccine at all times to ensure that there are always equal numbers of vaccine vials and diluent vials for reconstitution.

Diluent may be transported or shipped at room temperature or inside the same insulated cooled container as its corresponding vaccine. If transported inside cooled containers, diluent must not be in direct contact with refrigerated/frozen packs because of the potential for freezing. Refrigerate diluent in advance if it is to be carried in the insulated transport container so that it does not raise the temperature of the refrigerated vaccines.

Diluent for MMR, MMRV, varicella, and zoster vaccines may be transported at room temperature at 68° to 77°F (20° to 25°C), but must never be transported inside a container with dry ice.

Packing Vaccine for Transport to Off-Site Clinics

Different state health department immunization programs may recommend or require different vaccine transport practices and procedures. Contact your state health department immunization program for specific policies regarding vaccine transport, details on how to pack vaccine and diluent for transport, and procedures for maintaining the cold chain in the field.

The following are general guidelines for packing vaccine:

1. Use properly insulated containers to transport vaccine. These containers should be validated to ensure that they are capable of maintaining the vaccine at the correct temperatures. You may use the shipping containers the vaccines arrived in from the manufacturer. Alternatively, you may use hard-sided plastic insulated containers or Styrofoam™ coolers with at least 2-inch thick walls.

Use properly insulated containers to transport vaccine.

Thin-walled Styrofoam™ coolers, such as those purchased at grocery stores to hold beverages, are not acceptable.

Thin-walled Styrofoam™ coolers, such as those purchased at grocery stores to hold beverages, are not acceptable.

2. Pack enough refrigerated/frozen packs to maintain the cold chain. Do not use loose or

	bagged ice. The number and placement of refrigerated/frozen packs inside the container will depend on container size and outside temperature. For detailed instructions, see Chart of Refrigerated/Frozen Pack Needs for Different Climates in the Resources section.
3.	Be sure to place an insulating barrier (e.g., bubble wrap, crumpled brown packing paper, Styrofoam™ peanuts) between the refrigerated/frozen packs and the vaccines to prevent accidental freezing. A layer of toweling is not sufficient as a barrier. The contents of the container should be layered as follows: refrigerated/frozen packs, barrier, vaccine, thermometer, another layer of barrier, and additional refrigerated/frozen packs.
4.	Pack vaccines in their original packaging on top of the barrier. Do not remove vaccine vials from boxes, and do not draw up vaccine in advance.
5.	Use a properly placed thermometer near the vaccine to assess whether the cold chain has been broken. The thermometer should be placed next to the vaccine and should not come in contact with the refrigerated/frozen packs.
6.	Attach labels to the outside of the container to clearly identify the contents as being valuable and fragile vaccines.

Refrigerated/frozen packs.

Place bubble wrap, crumpled brown packing paper, or Styrofoam™ peanuts between the refrigerated/frozen packs and the vaccines.

Place a thermometer next to the vaccine but not in contact with the refrigerated/frozen packs.

Attach appropriate labels to the outside of the container.

7.	Record vaccine type(s), quantity, date, time, and originating facility on a label on the outside of the container.

You may also see Maintaining the Cold Chain During Transport in the Resources section for general guidelines.

Monitoring Temperatures During Off-Site Clinics

If vaccine must be maintained in an insulated cooler during an off-site clinic, keep the cooler closed as much as possible. A thermometer must be kept in the cooler with

If vaccine must be maintained in an insulated cooler during an off-site clinic, keep the cooler closed as much as possible. At a minimum, vaccine temperatures should be checked and recorded hourly.

the vaccines, and temperatures should be checked and recorded periodically to ensure that the cold chain is not broken. The National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention recommends that, at a minimum, vaccine temperatures be checked and recorded **hourly**.

Shipping Vaccine to State Health Departments or Vaccine Manufacturers

Shipping Vaccine with a Short Expiration Date or Other Usable Vaccine

Occasionally, providers may need to return vaccine with a short expiration date or other usable publicly purchased vaccine to the immunization program. Contact the state health department immunization program for detailed instructions on returning these vaccines. Some state health department immunization programs may permit the transfer of vaccine with a short expiration date or other usable vaccine to another provider. Consult your immunization program for specific policies regarding vaccine transfers.

Shipping Unusable Vaccine

Expired vaccine, wasted vaccine, and vaccine that has lost its potency because of inappropriate storage conditions may be returned to the vaccine manufacturer or to the state health department immunization program under certain circumstances. Contact the vaccine supplier, which may be the vaccine manufacturer or the state health department immunization program, for detailed instructions on returning these vaccines. If the vaccines are publicly purchased, contact the state health department immunization program for instructions on returning vaccines for excise tax credit. In general, expired, wasted or mishandled vaccine may be shipped via the U.S. mail or by other available modes of shipment (e.g., UPS™, FedEx®). Do not return loose vials in an envelope. Pack the vials in a box with packing material to avoid breakage.
Returned unusable vaccine is not considered to be hazardous material, so no special warning signs or special handling notices are necessary.

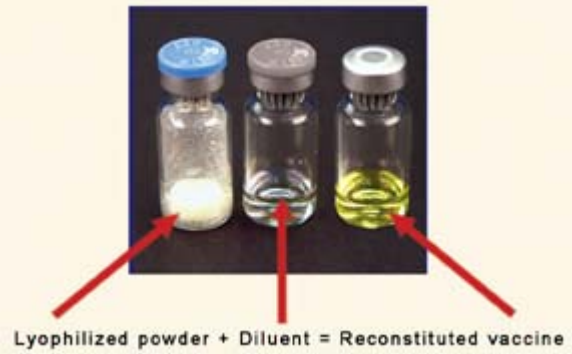
Vaccine Preparation and Disposal

Preparation for Vaccine Administration

Reconstitution

Definitions

Vaccines that come as lyophilized (freeze-dried) powders must be mixed with a liquid (called a diluent) in a process known as "reconstitution" before they can be administered.



Diluents

Diluents vary in their volume. The volume of diluent provided depends on whether a single-dose or multidose vial of vaccine is to be reconstituted. Diluents also vary in their ingredients. Some consist of sterile water only, but others may contain a variety of other substances that can be used to dissolve the lyophilized vaccine into a liquid, stabilize the reconstituted vaccine, and/or maintain the sterility of the reconstituted vaccine. Diluents are specifically designed to meet the volume, pH (acid/alkaline balance), and chemical needs of each vaccine so that optimal immune responses can be achieved. Diluents are **not interchangeable**, unless specified by the manufacturer (e.g., the diluent for MMR, MMRV, varicella, and zoster vaccine). Therefore, use only the specific diluent provided by the manufacturer for each type of vaccine to ensure adequate potency and safety of the resulting mixture. Do not use diluents from other manufacturers.

Use only the specific diluent provided by the manufacturer for each type of vaccine to ensure adequate potency and safety of the resulting mixture.

Instructions for Reconstitution

Refer to the package inserts for instructions on reconstituting specific vaccines.
In general, certain steps should be followed when reconstituting vaccines:

1.	Reconstitute vaccine immediately prior to use.
2.	Do not allow vaccines to sit out and warm up during the reconstitution process. Limit the time live virus vaccines are exposed to light.
3.	Check the diluent label to be sure that the vial contains the correct diluent provided by the manufacturer for that specific vaccine.
4.	Check the diluent label to be sure that the vial contains the correct volume of diluent for reconstitution so that the proper number of doses per vaccine vial is obtained.
5.	Check the labels on both the diluent vial and the lyophilized (freeze-dried) vaccine vial to make sure they have not expired. Do not administer expired vaccine (see Expiration Dates in the Vaccine Inventory Management section for details). Do not use expired diluent.
6.	Remove the protective caps from the diluent and lyophilized vaccine vials and wipe the stoppers with an alcohol swab.
7.	Select a disposable syringe and a needle of the proper length for the vaccine and route of administration. For single-dose reconstituted vials, the needle used for drawing up the diluent is the same needle you will use for vaccine administration. There is no need to change the needle in this case. Only change the needle if it has been damaged or contaminated during the reconstitution and drawing up process. For multidose reconstituted vials, do not use the same needle and syringe to administer multiple vaccine doses. Use a new needle and syringe for each dose of reconstituted vaccine administered.
8.	Insert the needle into the diluent vial and withdraw the entire contents.
9.	Inject all the diluent into the lyophilized vaccine vial and agitate or rotate the vial to ensure thorough mixing (follow the specific instructions given in the package inserts).
10.	Observe the reconstituted vaccine for color and appearance and verify that the appearance matches the description in the package insert. If the lyophilized vaccine cannot be resuspended or if the reconstituted vaccine does not look as it should (e.g., discoloration, extraneous particulate matter), mark the vial as “DO NOT USE” and return it to proper storage conditions. Contact the vaccine manufacturer and the state health department immunization program for further guidance (see Handling Inappropriate Vaccine Storage Conditions [Light and Temperature] in the Storage Troubleshooting section for details). Get another diluent vial and another lyophilized vaccine vial and begin the reconstitution process again.
11.	For multidose vials, record the date and time of reconstitution on the vaccine vial. For single-dose vials, record the date and time of reconstitution on the vaccine vial if it is not administered immediately after reconstitution.
12.	For single-dose vials, withdraw the entire contents of the reconstituted vaccine into the syringe. For multidose vials, withdraw the appropriate volume of vaccine into the syringe. Recheck the vial contents, expiration date, and doctor's order before administering the vaccine.
13.	Administer the vaccine soon after reconstitution to minimize loss of potency. The expiration date and time after reconstitution varies by vaccine. See Expiration of Reconstituted Vaccine in this section for details.

14. After giving the injection to the patient, do not recap the needle. Discard the used needle and syringe using medical waste disposal procedures (see Disposal of Vaccine and Diluent in this section for details).

Expiration of Reconstituted Vaccine

Once lyophilized (freeze-dried) vaccines have been reconstituted, their shelf lives are limited and they must be stored under appropriate temperature and light conditions.

Reconstituted vaccine must be used within a specified time or else be discarded.

Reconstituted vaccine must be used within a specified time or else be discarded. Contact the vaccine supplier, which may be the vaccine manufacturer or the state health department immunization program, for specific policies regarding the disposition of expired vaccine. If the expired vaccine is publicly purchased vaccine, contact your state health department immunization program for instructions on returning expired vaccine for excise tax credit.

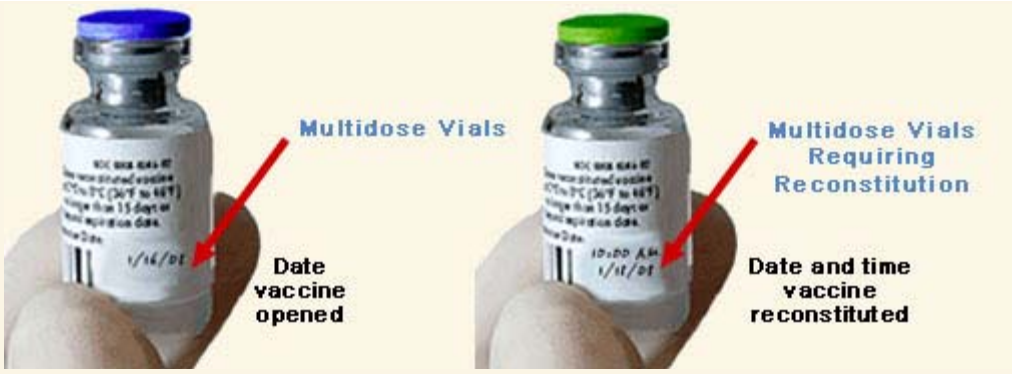
The life of each reconstituted vaccine varies from product to product. Consult the product package insert for the most up-to-date information about expiration dates and times following reconstitution. Unused reconstituted vaccines kept beyond these limits should **not** be administered. The best way to avoid such waste is to reconstitute and draw up vaccines immediately before administration.

Shelf Lives of Reconstituted Vaccines

Vaccine	Expiration After Reconstitution
Varicella vaccine	30 minutes (protect from light)
TriHIBit® vaccine (DTaP/Hib)	30 minutes
Menomune® (single-dose vials)	30 minutes
MMRV vaccine	30 minutes (protect from light)
Zoster vaccine	30 minutes (protect from light)
MMR vaccine	8 hours (protect from light)
ActHIB® vaccine (Hib)	24 hours
Menomune® (multidose vials)	35 days

Dating Vaccine

Mark each opened multidose vial with the **date** it was first opened. Mark reconstituted vaccine with the **date and time** it was reconstituted. Dating these vials is important for two reasons. First, some vaccines expire within a certain time after opening or after reconstitution. This may not correspond to the expiration date printed on the vial by the manufacturer. For example, multidose vials of meningococcal vaccine should be discarded if not used within 35 days after reconstitution, even if the expiration date printed on the vial by the manufacturer has not passed. Second, dating opened or reconstituted vials helps manage vaccine inventory by identifying vials that should be used first.



Mark each opened multidose vial with the date it was first opened.
Mark each reconstituted vaccine with the date and time it was reconstituted.

Whenever possible, use all the vaccine in one multidose vial before opening another vial. Similarly, use all the reconstituted vaccine in one vial before reconstituting another vial. This policy helps to reduce vaccine waste.

Use of Multidose Vials Versus Single-Dose Vials

Multidose vaccine vials contain bacteriostatic agents that prevent the growth of bacteria. Once opened, they can be used until their dates of expiration, unless they become contaminated. All multidose vials must be stored under appropriate temperature and light conditions at all times before and after they have been opened. Single-dose vials are meant for one-time use only.

Once the protective caps have been removed from single-dose vials, it may not be possible to determine if the rubber seals have been punctured. Therefore, do not open single-dose vials until you are ready to use them. To avoid needless wastage of vaccine, **always** check the vial before removing the cap to make sure you have the correct vaccine type, and remove the cap only when you are ready to draw up and administer the vaccine. Single-dose vials must be stored under appropriate temperature and light conditions at all times before and after they have been opened. Contact the vaccine supplier, which may be the vaccine manufacturer or the state health department immunization program, for specific policies regarding the disposition of opened unused single-dose vials. If these vials are publicly purchased vaccine, contact the state health department immunization program for instructions on returning opened unused single-dose vials for excise tax credit.

Single-dose vials are meant for one-time use only.

Prefilling Syringes

Recommendation

The National Center for Immunization and Respiratory Diseases (NCIRD) strongly recommends that providers draw vaccine only at the time of administration.

The National Center for Immunization and Respiratory Diseases (NCIRD), Centers for Disease Control and Prevention strongly recommends that providers draw vaccine only at the time of administration to ensure that the cold chain is maintained and that vaccine is not inappropriately exposed to light. **Do not** predraw doses before they are needed.

Problems Associated with Prefilling Syringes

NCIRD strongly discourages prefilling syringes and has identified the following problems associated with this practice:

- Once vaccine is inside the syringe, it is difficult to tell which vaccine is which; this may lead to **administration errors**.
- Prefilling syringes leads to **vaccine wastage** and increases the risk of vaccine **storage under inappropriate conditions**.
- Most syringes are designed for immediate administration and not for vaccine storage. **Bacterial contamination and growth** can occur in syringes you prefill with vaccines that do not contain bacteriostatic agents, such as the vaccines supplied in single-dose vials.
- No stability data are available for vaccines stored in plastic syringes. Vaccine components may interact with the plastic syringe components with time and thereby **reduce vaccine potency**.
- Finally, prefilling syringes is a violation of medication administration guidelines, which state that an individual should only administer medications he or she has prepared and drawn up. This is a **quality control and patient safety problem** because if you do not draw up the vaccine yourself you cannot be sure of the composition and sterility of the dose you are administering.

Prefilling syringes is generally discouraged.

Influenza Clinics and Prefilling Syringes

The vaccine manufacturers do not recommend that influenza vaccine be predrawn in advance of a large influenza vaccination clinic because there are no data on the stability of vaccine stored in syringes filled by providers. NCIRD also strongly discourages this practice for the reasons noted in the previous section.

Although predrawing vaccine is generally discouraged, **a limited amount** of vaccine may be predrawn in a mass immunization setting **if** the following procedures are followed:

- Only one vaccine type may be administered at the clinic. If more than one vaccine type is to be administered, separate vaccine administration stations must be set up for each vaccine type to prevent medication errors.
- Vaccine should not be drawn up in advance of arriving at the clinic site. Because of the lack of data on the stability of vaccine stored in plastic syringes, the practice of drawing up quantities of vaccine hours or even days before a clinic is **not acceptable**.
- Vaccine should be transported to the clinic site in the manufacturer-supplied packaging.
- Inactivated influenza vaccine must be maintained at 35° to 46°F (2° to 8°C), either inside a refrigerator or inside a properly chilled vaccine transport container. If the vaccine is stored in a transport container, an insulating barrier—such as crumpled paper or bubble wrap—must be placed between the vaccine and the refrigerated/frozen packs. An insulated barrier includes air pockets to help protect the vaccine from exposure to freezing temperatures. A single layer of towel over ice is not adequate protection (contact your state health department immunization program for details and see Maintaining the Cold Chain During Transport in the Resources section for general guidelines).
- Upon arrival at the clinic site, each healthcare worker (HCW) may draw up a **small**

quantity of vaccine to meet the initial needs of the clinic—no more than 1 vial or 10 doses, whichever is greater. This will limit the amount of time the vaccine is held in the syringe before administration and reduce vaccine wastage.

- During the clinic, HCWs should alternate activities. One may stop vaccinating and fill additional syringes as needed; when this HCW resumes vaccinating, the other HCW may stop and draw up additional vaccine as needed. This minimally slows the patient flow, limits the amount of vaccine drawn up at any one time, and conforms to good medication administration practices, in which each HCW administers the vaccine he or she drew up.
- Patient flow should be monitored to avoid drawing up unnecessary doses.
- At the end of the clinic day, any remaining vaccine in syringes should be discarded. Vaccine that has been drawn up and not administered may not be used on subsequent days.

Manufacturer-Supplied Prefilled Glass Syringes

Manufacturer-supplied prefilled glass syringes.

Manufacturer-filled glass syringes are available for a variety of vaccines. NCIRD does not have a preference for specific vaccine brands or product presentations; either vials or manufacturer-filled syringes (when available) are acceptable for use, depending on the preferences of your practice. Manufacturer-filled syringes are an alternative to prefilling syringes yourself. These syringes are prepared under sterile conditions that meet standards for proper handling and storage, and they are individually labeled. They have been specially designed by the manufacturers and thoroughly tested to assure vaccine potency and sterility over prolonged storage times. As long as they are stored under appropriate conditions (temperature and light), they may be kept and used until their dates of expiration unless they become contaminated. When manufacturer-filled glass syringes are not supplied with needles, the needles should be attached just before administration. If a needle is attached to a sealed manufacturer prefilled syringe, the syringe should be used or discarded at the end of the clinic day because the sterile seal has been broken. This does not apply to prefilled syringes prepared by the manufacturer with the needle already attached.

Disposal of Vaccine and Diluent

Unused vaccine and diluent doses may be returnable under certain circumstances. Contact the vaccine supplier, which may be the vaccine manufacturer or the state immunization program, for specific policies regarding the disposition of unopened vials, expired vials, unused doses, doses drawn but not administered, and potentially compromised vaccine due to inappropriate storage conditions. If these vials or doses are publicly purchased, contact the state health department immunization program for instructions on returning doses for excise tax credit.

Contact the state health department for details about medical waste disposal procedures in your area.

The state health department immunization program and the manufacturer may advise you to discard the vials or syringes. This should be done using medical waste disposal

procedures. Contact the state health department for details about medical waste disposal procedures in your area. In general, vaccine and diluent vials, used needles, and used syringes (that may or may not contain vaccine) may be dropped into a sharps container and autoclaved, or disposed of following the procedures for all other biohazard materials. In places where medical waste is buried, soaking the medical waste in a 1:10 dilution of bleach for at least 10 minutes before disposal is advised.

Sharps container.

Vaccine Storage and Handling Toolkit

National Center for Immunization and Respiratory Diseases

Resources

General Vaccine Storage and Handling Guidelines

- Don't Be Guilty of These Errors in Vaccine Storage and Handling (IAC)
- Handle With Care Poster
- Checklist for Safe Vaccine Handling and Storage (IAC)
- Routine Vaccine Storage and Handling Plan Worksheet
- Suggested Supplies Checklist for Adult Immunization Clinic (IAC)
- Suggested Supplies Checklist for Pediatric and Adult Immunization Clinic (IAC)
- CDC Vaccine Price List (VFC)
- Vaccine Storage and Handling FAQs

Multimedia Training Resources

- Top 10 Storage and Handling Errors Video
- How to Protect Your Vaccine Supply Video
- The Cold Chain Challenge Storage and Handling Game

How to Read Thermometers

- How to Read a Fluid-Filled Biosafe Liquid Thermometer
- How to Read a Liquid Minimum/Maximum Thermometer—Print Version
- How to Read a Liquid Minimum/Maximum Thermometer—Animated Version
- How to Read a Chart Recorder—Print Version
- How to Read a Chart Recorder—Animated Version

Logs and Records

- Temperature Log for Vaccines (Fahrenheit) (IAC)
- Temperature Log for Vaccines (Celsius) (IAC)
- Fahrenheit to Celsius and Celsius to Fahrenheit Conversion
- Stock Record (Sample)
- Stock Record
- Tally Sheet (Sample)
- Tally Sheet

Warning Signs (can be printed and reproduced)

- Do Not Adjust Controls (English and Spanish)
- Do Not Unplug Version 1 (English)
- Do Not Unplug Version 1 (Spanish)
- Do Not Unplug Version 2 (English)
- Do Not Unplug Version 2 (Spanish)
- Do Not Unplug Version 3 (English)
- Do Not Unplug Version 3 (Spanish)

Emergency Vaccine Storage and Handling Resources

- Emergency Vaccine Retrieval and Storage Plan Worksheet
- Emergency Response Worksheet (IAC)
- Emergency Management Internet Resources

Routine and Emergency Vaccine Packing and Transport

- Maintaining the Cold Chain During Transport (IAC)
- Chart of Refrigerated/Frozen Pack Needs for Different Climates
- Handling Dry Ice

Contacts

- State Immunization Program Contact Information
- State/Territory VFC Coordinators
- VFC: National VFC Program Consultants by Region
- Manufacturer Quality Control Office Telephone Numbers

Centers for Disease Control and Prevention

PROTECT VACCINE

Handle With Care!

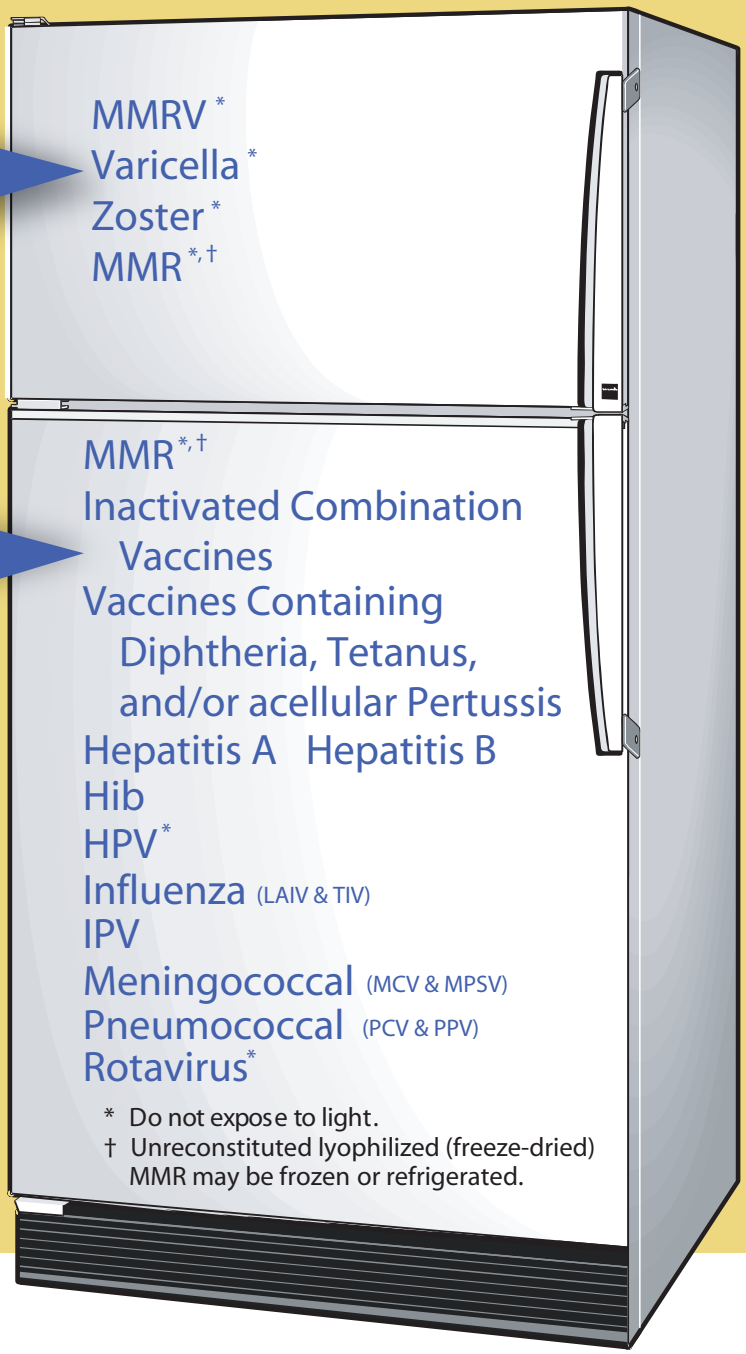
Store in Freezer
5°F (-15°C) or colder

MMRV *
Varicella *
Zoster *
MMR *,†

Store in Refrigerator
35°–46°F (2°–8°C) or colder

MMR *,†
Inactivated Combination Vaccines
Vaccines Containing Diphtheria, Tetanus, and/or acellular Pertussis
Hepatitis A Hepatitis B
Hib
HPV *
Influenza (LAIV & TIV)
IPV
Meningococcal (MCV & MPSV)
Pneumococcal (PCV & PPV)
Rotavirus *

* Do not expose to light.
† Unreconstituted lyophilized (freeze-dried) MMR may be frozen or refrigerated.



Vaccine Storage Rules

- Keep your refrigerator and freezer within the proper temperature ranges.
- Keep your vaccine within the proper temperature ranges.
  - Measure and record refrigerator and freezer temperatures twice daily.
  - Take immediate action if temperatures are out of range.
- Keep HPV, MMR, MMRV, rotavirus, varicella, and zoster vaccines protected from light.
- Keep MMRV, varicella, and zoster vaccines frozen.
- Rotate your vaccine stocks.

PROTECT PATIENTS

Routine Vaccine Storage and Handling Plan Worksheet

Complete the following checklist and forms and store this information in an easily accessible area near the vaccine storage unit. See the section on Vaccine Storage and Handling Plans for details.

Checklist of Resources for the Routine Vaccine Storage and Handling Plan

- ☐ Up-to-date contact information
  - ☐ Primary and backup vaccine coordinators
  - ☐ State or local health department immunization program
  - ☐ Manufacturers of the vaccines in your inventory
  - ☐ Refrigerator and freezer maintenance and repair company(ies)
  - ☐ Vaccine storage unit alarm company (if applicable)
  - ☐ Sources for packing materials and certified calibrated thermometers
- ☐ Descriptions of the roles and responsibilities of the primary and backup vaccine coordinators
- ☐ Summaries of the storage requirements for each vaccine and diluent in your inventory
- ☐ Protocols for vaccine storage unit temperature monitoring
- ☐ Protocols for vaccine storage equipment maintenance
- ☐ Protocols for the correct placement of vaccine(s) within storage units
- ☐ Protocols for responding to vaccine storage and handling problems
- ☐ Protocols for vaccine inventory management
- ☐ Protocols for transporting and receiving vaccine shipments
- ☐ Policies for preparing vaccine for administration
- ☐ Protocols for proper disposal of vaccines and supplies
- ☐ Samples of the forms used in your vaccination program

Vaccine Coordinators

Vaccine Coordinators	Title	Telephone Numbers (home, cell, beeper)
Primary		
Backup		

Resources Contact List

Resources	Contact Person Title	Telephone Numbers (home, cell, beeper)
State Health Department Immunization Program		
Local Health Department Immunization Program		

Emergency Resources	Company Name	Contact Person (title)	Telephone Numbers (home, cell, beeper)
Electric Power Company			
Generator Repair Company (if applicable)			
Generator Fuel Source (if applicable)			
Refrigeration Repair Company			
Temperature Alarm Monitoring Company (if applicable)			
Security or Perimeter Alarm Company (if applicable)			

Emergency Resources	Company Name	Contact Person (title)	Telephone Numbers (home, cell, beeper)
Packing Materials			
Insulated Containers or Coolers			
Insulated Containers or Coolers (alternate)			
Fillers (e.g., crumpled paper, bubble wrap, Styrofoam™ pellets)			
Fillers (alternate)			
Refrigerated/ Frozen Packs			
Refrigerated/ Frozen Packs (alternate)			

Dry Ice Vendor (if inventory includes varicella-containing vaccines)			
Dry Ice Vendor (alternate)			
Certified Calibrated Thermometers			
Certified Calibrated Thermometers (alternate)			

Vaccine Storage and Handling FAQs

Vaccine Potency

What happens to vaccine contents when vaccines are not properly stored (i.e., not refrigerated?)

Excessive heat or cold exposure damages vaccine, resulting in loss of potency. Excessive cold exposure is as bad, if not worse than excessive heat exposure for most vaccines. Once potency is lost, it can never be restored. Furthermore, each time vaccine is exposed to excessive heat or cold, the loss of potency increases and eventually, if the cold chain is not correctly maintained, all potency will be lost, and the vaccine becomes useless. HPV, MMR, MMRV, rotavirus, varicella, and zoster vaccines are sensitive to light, which also causes loss of potency of these particular vaccines. If you have concerns about your vaccine supply, contact the vaccine manufacturer and the state health department immunization program.

How can you determine if vaccine has been out of the safe temperature range long enough to affect its efficacy? Is there a set amount of time that is a guideline for vaccine thresholds?

It depends on the vaccine, the length of time it was outside of recommended storage conditions, and the environment it was in (temperature and light). The National Center for Immunization and Respiratory Diseases (NCIRD), Centers for Disease Control and Prevention recommends that whenever there is any doubt about the integrity of a vaccine it should be clearly marked “Do Not Use” and stored under appropriate conditions in a properly functioning vaccine storage unit until the integrity of the vaccine is determined. . If you have concerns about vaccine that may not have been stored or handled properly, follow your state health department immunization program policy and contact either the manufacturer’s quality control office or the immunization program for guidance. Do not assume that vaccine inappropriately exposed to light or to excessive temperatures cannot be salvaged.

Refrigerator and Freezer Requirements

What are the exact measurements required by the National Center for Immunization and Respiratory Diseases (NCIRD) for a refrigerator to hold vaccines?

NCIRD has never made a recommendation based on size. NCIRD recommends that any refrigerator, freezer, or combined refrigerator/freezer unit used to store vaccine must:

- Be able to maintain required vaccine storage temperatures year-round;
- Be large enough to hold the year’s largest inventory;
- Have a certified calibrated thermometer inside each storage compartment; and
- Be dedicated to the storage of vaccines.

Refrigeration units for vaccine storage are available in various sizes and models, including stand-alone and others models that fit under counters. If an under-counter unit has separate exterior doors for the refrigerator and freezer compartments and can maintain appropriate temperatures in these compartments, both the refrigerator and freezer compartments may be

used for vaccine storage. However, the size of an under-counter unit limits the amount of vaccine that can be stored. Be sure that the capacity is sufficient to store the vaccine supply while still allowing for air circulation within the unit. Avoid overstocking the unit because this impedes air flow and leads to temperature fluctuations that may expose the vaccines to inappropriate temperatures. If you need to store large quantities of vaccine, then additional under-counter units or a full-size unit would be needed.

Small single-door (dormitory-style or bar-style) combined refrigerator/freezer units should not be used for vaccine storage. The freezer compartment in this type of unit is incapable of maintaining temperatures cold enough to store MMRV, varicella, and zoster vaccines. 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. However, this type of unit may be adequate for temporarily storing **small quantities** of inactivated and MMR vaccines in the refrigerator compartment (not the freezer compartment) **if** the refrigerator compartment can maintain temperatures at 35° to 46°F (2° to 8°C). Make sure not to overstock the unit and impede cold air circulation.

Do not place vaccines directly beside or directly below the freezer compartment in a dormitory-style unit, 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. To reduce the risk of exposing vaccine to freezing temperatures, consider using a compact refrigerator without a freezer compartment.

When is a “dormitory-style” refrigerator not adequate for storing vaccines?

NCIRD recommends that dormitory-style refrigerators only be used to store a clinic's single-day supply of **refrigerated** vaccines and these vaccines should be returned to the main refrigerator storage unit at the end of each clinic day. Dormitory-style refrigerators are not adequate for long-term or permanent storage of biological products because they do not maintain appropriate temperatures.

Storage of VFC vaccine in refrigerators that are designed for use in small household spaces such as dorm rooms **are never acceptable for permanent storage of VFC vaccines**. Permanent storage is defined as the vaccine supply is maintained in the unit 24 hours a day/7 days a week.

“Dorm Style” refrigerators are acceptable for short-term storage of select VFC vaccines under **very limited conditions** which are listed below:

1.	The purpose of using these units is for temporary storage when it is not reasonable for the staff administering the vaccine to go to the main storage unit to obtain vaccine for each and every patient.
2.	**The unit is never used for storing varicella-containing vaccines.**
3.	Only small amounts of inactivated vaccines can be maintained in these units. The amount of inactivated vaccines stored in the unit must never exceed the amount used in the clinic in one day.
4.	The vaccine is returned to the main storage unit at the end of each clinic business day and vaccine is never stored in these units overnight or during periods of time when the practice is not open for business.
5.	Each unit has a dedicated certified thermometer in place.

6.	**Temperatures are monitored and documented twice a day on temperature log specifically for that unit.** Appropriate action is immediately taken when the temperatures are outside the appropriate range.
7.	These units must be included and examined during the VFC compliance visit and corrective actions taken and documented by the grantee if any of the above conditions are not met.

We work in a mobile van that has a dorm-like refrigerator for vaccine storage. I have been unable to find a refrigerator and a separate freezer that would meet the vaccine storage temperature requirements. What do you advise?

A dormitory-style refrigerator may be used for temporarily storing small quantities of vaccines (one day's supply) that require only refrigeration if the unit can maintain temperatures at 35° to 46°F (2° to 8°C) **and** if the volume of vaccine stored in the unit is small enough to allow adequate cold air circulation. Zoster vaccine should NOT be stored in the refrigerator. If you store single-antigen varicella vaccine or MMRV in a refrigerator, they **must** be used within 72 hours or discarded and they cannot be refrozen.

Vaccine Storage Locations

I was told that vaccine stored in a refrigerator could not be stored on the top or bottom shelf and the vaccine could only be in the very middle of the shelves. Is this true?

The temperature inside the refrigerator compartment is not consistent throughout. The temperature in the vegetable bins, on the floor, next to the walls, in the door, and near the cold air venting from the freezer may differ significantly from the temperature in the main body of the refrigerator. Ideally, vaccines should be situated on the middle shelves, away from these areas.

Many combined refrigerator/freezer units use a cooling system that directs cold air from the freezer compartment into the main refrigerator compartment through a vent, which is usually located above the top shelf. Refrigerated vaccines should always be stored far enough away from the air venting from the freezer compartment to avoid freezing the vaccines. If the vaccines can be situated away from the cold air vent and the temperature in this area is within the recommended range of 35° to 46°F (2° to 8°C), the vaccines may also be stored on the upper shelf. If the upper shelf must be used for vaccine storage, it would be best to place MMR on this shelf because MMR is not sensitive to freezing temperatures like the other refrigerated vaccines. In addition, top shelves are less affected than lower shelves by the temperature of room air drawn into the refrigerator when the door is opened.

We have a large quantity of vaccines, and space is always an issue. Since we cannot put vaccines in the vegetable bins, can we remove the bins and then put vaccines in that space?

Vaccines should not be stored in the vegetable bins or in the space occupied by the vegetable bins because the temperature near the floor of the refrigerator is not stable and differs from that in the middle of the compartment. It is recommended that you remove the vegetable bins and put bottles of water in that space to help maintain a constant temperature in your refrigerator.

Is it safe to store vaccines and other biologics in the same refrigerator with lab specimens?

If possible, other medications and other biologic products should not be stored inside the vaccine storage unit. If there is no other choice, these products must be stored below the vaccines on a different shelf. This prevents contamination of the vaccines should the other products spill, and reduces the likelihood of medication errors.

What are the guidelines for storing vaccine during off-site clinics?

It does not matter whether the vaccine is being stored at a traditional office or off-site. Vaccines **must** be stored at the temperatures recommended by the manufacturers regardless of where they are. Ideally, vaccines should be stored at the recommended temperatures inside a properly functioning storage unit (e.g., refrigerator, freezer, refrigerator/freezer combination) at the off-site clinic. If such a unit is not available and the vaccine must be maintained in an insulated cooler during the off-site clinic, keep the cooler closed as much as possible. A thermometer must be kept in the cooler with the vaccines, and temperatures should be checked and recorded periodically to ensure that the cold chain is not broken. It is recommended that, at a minimum, vaccine temperatures be checked and recorded **hourly**.

Temperature Monitoring

How often should temperatures be recorded for refrigerator and freezer compartments where vaccines are stored?

Temperatures inside refrigerator and freezer compartments should be measured and recorded at least twice a day; once at the start of the clinic day and a second time before the clinic is closed for the day. Immediate action must be taken if the temperature is outside the recommended range for either compartment.

How long do you need to monitor temperatures after a refrigerator or freezer thermostat is adjusted before you know the temperatures are within the recommended range and you can safely store vaccines in them?

After the thermostat in a working refrigerator or freezer has been adjusted, check the temperature in both the refrigerator **and** freezer (if using a combined unit) **every half hour** until the temperature stabilizes. If the temperature rises or falls rapidly or is outside the recommended range, adjust the thermostat inside the unit and repeat the process. As a general guideline, the National Center for Immunization and Respiratory Diseases (NCIRD) also suggests that you monitor temperatures inside the refrigerator and freezer for a week in any new (or newly repaired) unit before it is used for vaccine storage. This practice allows you to check that the unit is performing well and allows time to make any necessary adjustments before expensive vaccines are put at risk. Of course, twice daily temperature monitoring should be an ongoing practice as well.

Our clinics use a digital thermometer in the refrigerators where vaccines are stored (battery powered and National Institute of Standards and Technology certified). These thermometers also have alarm capability and can show the temperature range since the thermometer was last checked and cleared. Is it still necessary to record temperatures twice a day or will once a day be adequate?

The National Center for Immunization and Respiratory Diseases (NCIRD) still recommends twice daily temperature monitoring and recording. Alarms and continuous recording thermometers add another layer of protection and are a great addition but they are not a substitute for manually checking and recording the temperatures twice daily. Relying solely on alarms can lead to complacency and inappropriate temperatures may not be discovered in a timely manner (e.g., alarm battery failure). Temperatures may be recorded continuously by some thermometers but, unless someone physically checks the recordings twice a day, inappropriate storage temperatures may not be detected and corrected in a timely manner.

Therefore, NCIRD recommends checking and recording the temperatures first thing in the morning to be sure there has not been a problem overnight. Check and record the temperatures at the end of the clinic day to make sure there has not been a problem during the day (which acts as a backup for the alarm in case it is not working or in case no one heard it). This end-of-the-day temperature reading also gives you a reference point should there be a subsequent temperature problem overnight. Recording twice daily temperatures also gives you a record over time of how well your refrigerator and freezer are working so you can spot trends in temperature during the day or overnight. Vaccines are expensive and if they have been damaged because of storage at inappropriate temperatures you may not be protecting your patients. Manually checking and recording the temperatures twice daily takes very little time and is worth the extra effort.

Why is it recommended that we keep temperature logs for 3 years?

By keeping temperature logs for at least 3 years, you can track recurring temperature problems and determine how long they have been happening. This information allows you to better define the time frame in question and take appropriate action. For example, out-of-range temperature problems are sometimes detected after-the-fact. A record review can determine how long temperatures have been out of range, which vaccines may have been compromised, and which vaccine recipients may need to be recalled. Archived temperature logs also show how well the vaccine storage unit is working over time and can be used to determine when a unit may need adjustment, maintenance, or replacement, such as when temperatures are consistently at the limit or sometimes beyond the limit of the recommended temperature range.

Vaccine Expiration

When the expiration date of a vaccine indicates a month and year, does the vaccine expire on the first or last day of the month?

When the expiration date is marked with only a month and year, the vaccine or diluent may be used up to and including the last day of the month indicated on the vial. Any unused vaccine or diluent should not be used after this month has passed.

When a multidose vial is opened and a dose is withdrawn, how long can that vial be retained for use?

Certain vaccines are distributed in multidose vials. When opened, the remaining doses from partially used multidose vials can be administered until the expiration date printed on the vial or vaccine packaging, provided that the vial has been stored correctly and that the vaccine is not visibly contaminated unless otherwise indicated in the manufacturer's package insert.

Some multidose vaccine vials contain lyophilized (freeze-dried) vaccine. Once reconstituted, the life of each vaccine varies from product to product and the new expiration date and time most likely will differ from that printed on the vial of lyophilized vaccine. Consult the package insert for the most up-to-date information about expiration dates and times following reconstitution. Unused reconstituted vaccines kept beyond these limits should not be administered.

Our state supplies us with 2 mL vials of Immune Globulin (Human) USP. Often we only use parts of the vial. I read in the package insert that because the Immune Globulin does not contain a preservative the vial should be entered only once for administration purposes. Do we need to throw away a vial if it is partially used?

Multiple doses may be withdrawn from this vial during that same clinic day because bacterial growth from contamination is unlikely during that short interval. However, this vial must be discarded at the end of the clinic day—it must not be kept overnight for use the next day. This is the same recommendation as that for the use of single-dose vials of vaccine. Single-dose vials with broken seals (either the metal tab or the rubber stopper) should be discarded at the end of the clinic day.

How long is a vaccine dose viable if it has been stored in the refrigerator in a syringe?

There are inadequate data to answer this question. Disposable syringes are meant for administration of immunobiologics not for storage. The National Center for Immunization and Respiratory Diseases (NCIRD) strongly discourages prefilling syringes and has identified the following problems associated with this practice:

- Once vaccine is inside the syringe, it is difficult to tell which vaccine is which; this may lead to **administration errors**.
- Prefilling syringes leads to **vaccine wastage** and increases the risk of vaccine **storage under inappropriate conditions**.
- Most syringes are designed for immediate administration and not for vaccine storage. **Bacterial contamination and growth** can occur in syringes you prefill with vaccines that do not contain bacteriostatic agents, such as the vaccines supplied in single-dose vials.
- No stability data are available for vaccine stored in plastic syringes. Vaccine components may interact with the plastic syringe components with time and thereby **reduce vaccine potency**.
- Finally, prefilling syringes is a violation of medication administration guidelines, which state that an individual should only administer medications s/he has prepared and drawn up. This is a **quality control and patient safety problem** because if you do not draw up the vaccine yourself, you cannot be sure of the composition and sterility of the dose you are administering.

Because of the lack of data concerning the stability and sterility of vaccine stored in syringes prefilled by providers and because of the other reasons just listed, NCIRD recommends that

vaccines drawn into syringes be discarded at the end of the clinic day. This does not apply to manufacturer-supplied prefilled glass syringes.

Vaccine Packing and Transport

In our county we have a number of district offices that are located a significant distance away from the main office where the vaccines are stored. Some offices are as far as 2 hours away from the main office. Nurses in these offices place monthly orders; the orders are filled and the vaccines are transported with ice packs to these offices (not always in a Styrofoam™ container or ice chest). Are guidelines available that outline how the vaccines should be packaged and transported?

Contact the vaccine manufacturer and the state health department immunization program for detailed instructions on packing vaccine for transport. In general, vaccines should be packed and transported in properly insulated containers. You may use the shipping containers the vaccines arrived in from the manufacturer. Alternatively, you may use hardsided plastic insulated coolers or Styrofoam™ coolers with at least 2-inch thick walls. Thinwalled Styrofoam™ coolers, such as those purchased at grocery stores to hold beverages, are not acceptable. Pack the vaccines with an adequate supply of refrigerated/frozen packs. Be sure to place insulating material (e.g., bubble wrap, crumpled paper) between the refrigerated/frozen packs and the vaccine to prevent accidental freezing. Use properly placed thermometers in each container. The thermometers should be placed along side the vaccine and should not be in direct contact with the refrigerated/frozen packs. Frozen vaccines (i.e., varicella-containing vaccines) require dry ice and special procedures for transport. The manufacturers' storage guidelines should be maintained throughout packing and transport and vaccines should be transferred to properly functioning refrigerators/freezers upon arrival.

How to Read a Fluid-Filled Biosafe Liquid Thermometer

How It Works

Fluid-filled biosafe liquid (bottle) thermometers consist of two parts. The first part is a glass sensing bulb connected to a glass tube with a numbered scale printed along the tube. Inside the tube is a liquid (usually mercury or colored alcohol) that rises and falls as the temperature changes in the immediate area of the sensing bulb. The second part is a bottle containing a biosafe liquid, such as glycol. The glass sensing bulb is immersed in the liquid. The liquid provides a buffer around the sensing bulb so that the reading does not fluctuate when the refrigerator or freezer door is opened or closed.

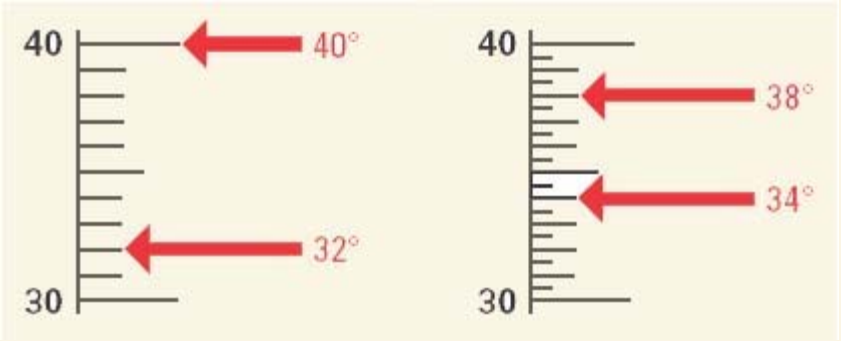
A fluid-filled biosafe liquid thermometer.

How to Read It

1. Examine the scale that is marked on the side. Determine if it is in Fahrenheit or Celsius or both.
2. When reading the temperature, the thermometer should be vertical and your eyes should be level with the top of the liquid in the glass tube. It is preferred that the thermometer is read while still inside the vaccine storage unit. However, if this is not possible, the thermometer may be removed from the unit, read at eye level, and quickly replaced.

Reading a fluid-filled biosafe liquid thermometer.

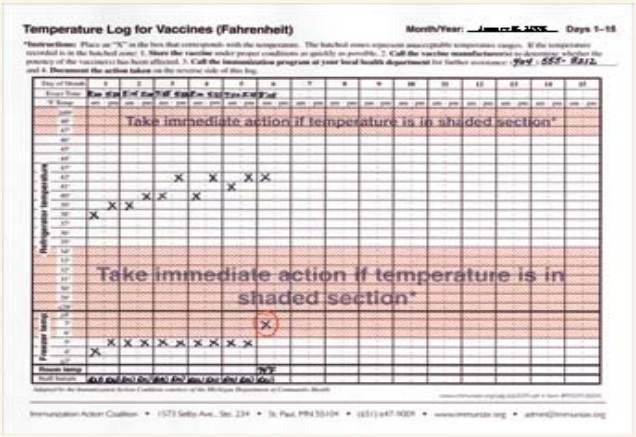
3. The position of the top of the liquid along the scale indicates the temperature. Read the thermometer to the appropriate number of significant digits. Shown below are temperatures indicated on one-degree and half-degree Fahrenheit scales.



One-degree scale (sample readings)

Half-degree scale (sample readings)

4. Record the current temperature on the temperature log. Note any out-of-range temperatures and the action taken on the back of the log.



Front: Temperature Log for Vaccines.

Note: ⚠ Immediate action must be taken to correct improper vaccine storage conditions.

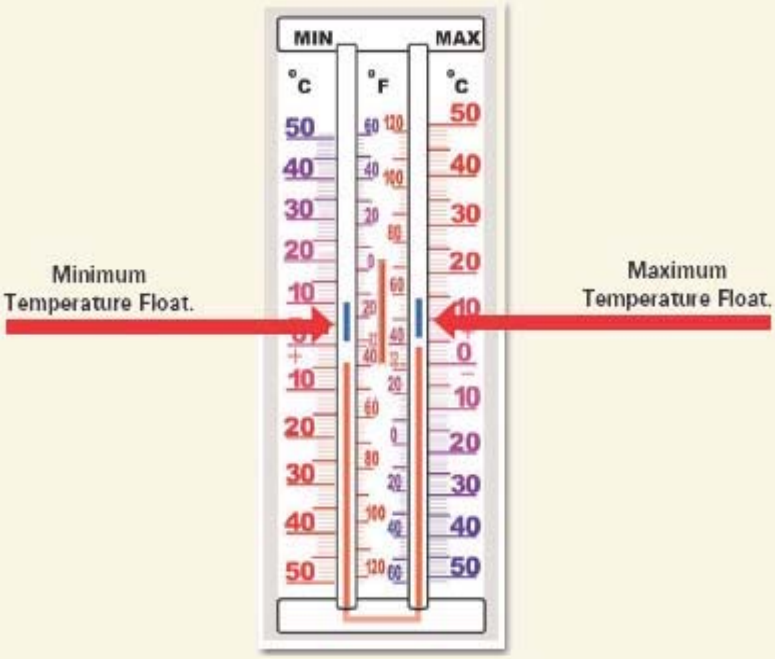
Reverse: Vaccine Storage Troubleshooting Record.

How to Read a Liquid Minimum/Maximum Thermometer

How It Works

Liquid minimum/maximum thermometers consist of 2 interconnected glass columns containing a mercury-free liquid. As the temperature changes, the liquid rises in one column and falls an equal distance in the other column. Each column has one or two numbered scales beside it (Fahrenheit and/or Celsius). These scales run in opposite directions so that the scale beside the “minimum” column is upside down compared to the scale beside the “maximum” column. As the mercury-free liquid rises and falls with the change of temperature, the maximum and minimum temperatures are captured for any given time period by means of two colored floats. The maximum temperature column has a scale indicating warmer temperatures on the top and colder temperatures on the bottom. The minimum temperature scale is upside down, indicating colder temperatures on the top and warmer temperatures on the bottom. Make sure that the liquid minimum/maximum thermometer is reset (see step 7) when it is first placed inside the refrigerator or freezer and following each temperature check.

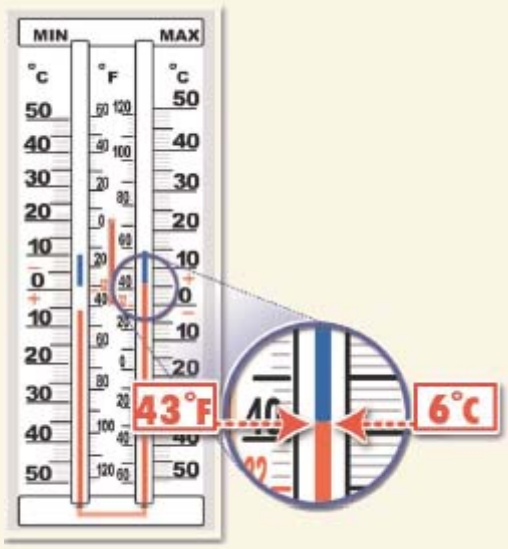
Note The minimum scale is upside-down relative to the maximum scale.



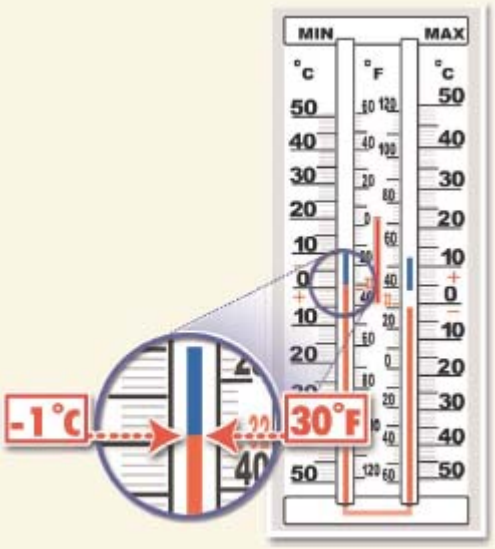
Minimum/maximum thermometer.

How to Read It

1. As the temperature changes, the floats are moved by the liquid columns. The floats “stick” at the highest and lowest temperatures until reset with the reset button.
2. The bottom of the float registers the maximum temperature on the right side and the minimum temperature on the left. Note that the minimum temperature scale is upside down.

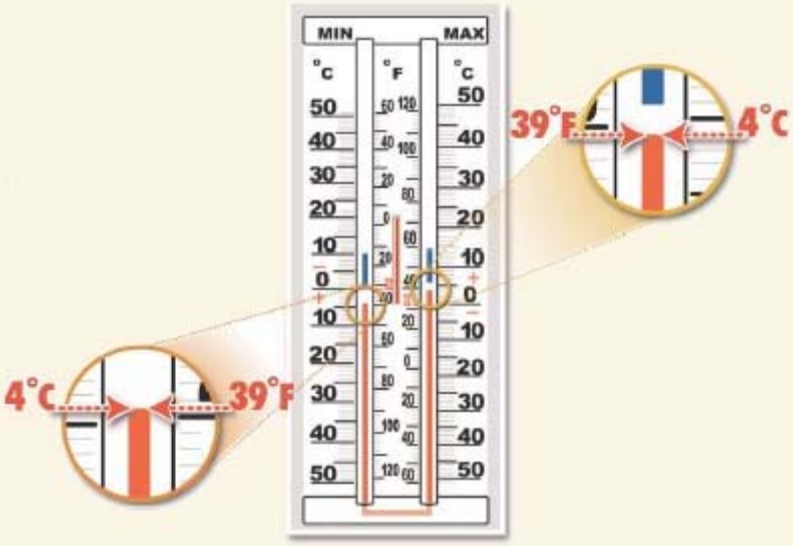


Example of maximum temperature reached: 43°F (6°C).



Example of minimum temperature reached: 30°F (-1°C).

3. The current temperature can be read using either the minimum or maximum column because they should indicate the same temperature.

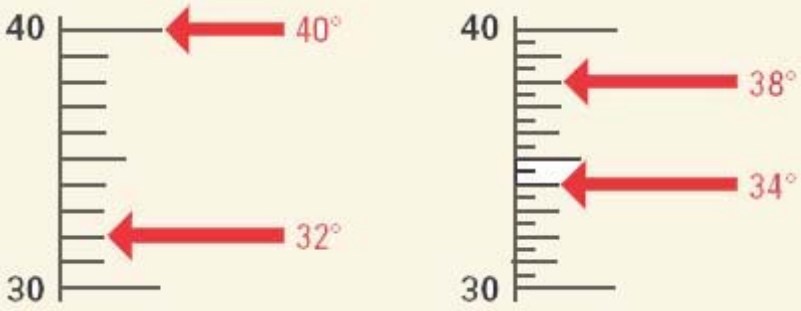


Example of current temperature: 39°F (4°C).

4. When reading the temperature, the thermometer should be vertical and your eyes should be level with the top of the liquid in the glass tube. It is preferred that the thermometer is read while still inside the vaccine storage unit. However, if this is not possible, the thermometer may be removed from the unit, read at eye level, and quickly replaced. Do not touch the liquid column and expose it to body heat because this will cause a falsely elevated temperature reading.

When reading the temperature, the thermometer should be vertical and your eyes should be level with the top of the liquid in the glass tube.

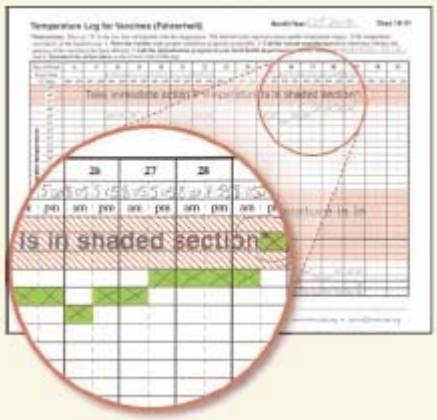
5. Read the thermometer to the appropriate number of significant digits. If there is more than one scale printed on the thermometer, always read the same scale (either °F or °C). Shown below are temperatures indicated on one-degree and half-degree Fahrenheit scales.



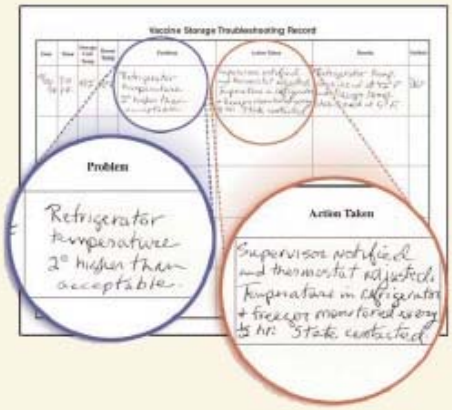
One-degree scale (sample readings). **Half-degree scale (sample readings).**

Note **Read the thermometer to the appropriate number of significant digits.**

6. Record the current temperature on front of the temperature log. Note any out-of-range temperatures and the action taken on the back of the log.

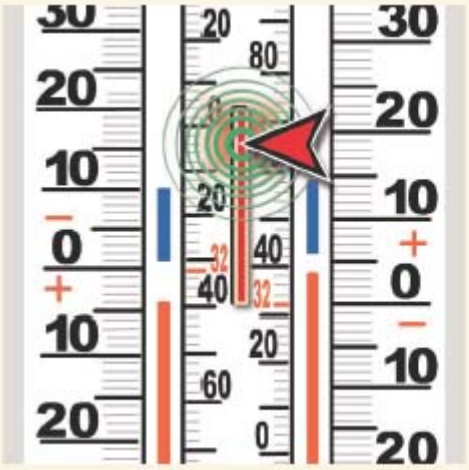


Record the current temperature on front of the temperature log.

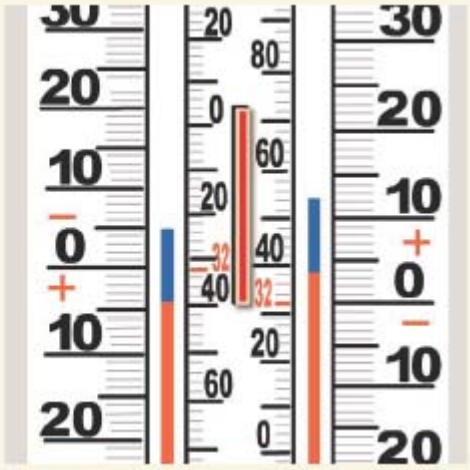


Note any out-of-range temperatures and the action taken on the back of the log.

7. Reset the thermometer only after the current, minimum, and maximum temperatures have been checked. To reset the minimum/maximum thermometer, press the reset button to bring the colored floats to rest on the top of the liquid columns on both the right and left sides. The starting temperature for both floats should be the same.



Press the Reset Button to reset the minimum/maximum thermometer.



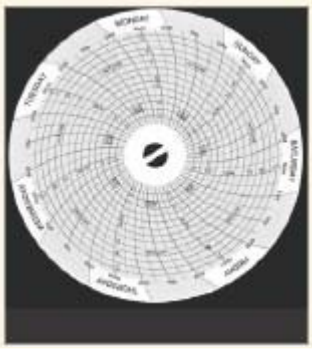
Resetting the thermometer brings the two floats to rest at the current temperature.

How to Read a Chart Recorder

How It Works

Chart recorders consist of a graph wheel with replaceable graph paper and ink pens. The pens mark the temperature on the graph paper as the wheel turns. The current temperature is at the end of the line. Temperatures are recorded continuously, 24 hours a day. The wheels of the most common models used for vaccine temperature monitoring make one full rotation every seven days. The graph paper has Fahrenheit or Celsius scales on it and the temperature is read where the ink line falls on the scale. Follow manufacturer instructions for loading the chart to ensure that the chart references the correct time.

Chart recorder.



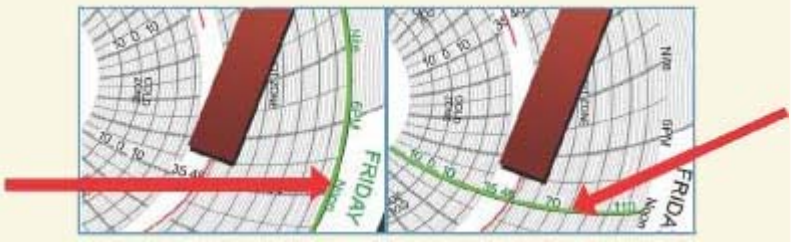
Graph paper—two-degree increments.

Graph paper—range.

How to Read It

1. The graph contains two scales: one along the outer border of the paper that indicates the day of the week and the time; the other radiating from the center of the graph, like the spokes of a wheel, that indicates the temperature. The temperature will either be in Fahrenheit or Celsius.

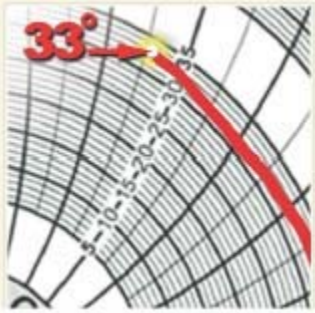
Day and time scale.



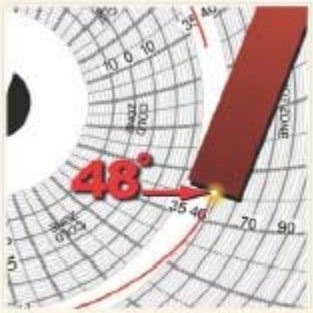
Temperature scale.

Each graph contains two scales.

2. To read the temperature for any point of interest along the recorded ink line, find the nearest graph line that circles the center of the graph. Follow that circular graph line to the temperature scale. The temperature is indicated by where the circular graph line intersects the scale. Temperature scales come in different increments. On some graphs, the circular graph lines represent 1-degree increments on the temperature scale. On other graphs, the circular graph lines represent 2-degree increments.

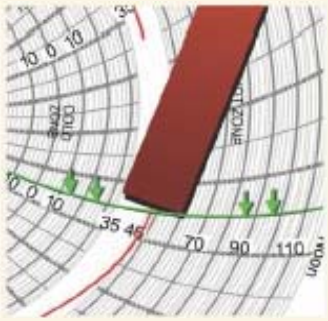


Current temperature is 33°F (end of red line). Each circular graph line represents 1 degree.

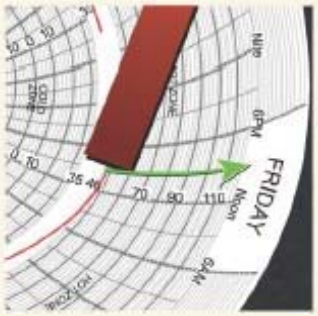


Current temperature is 48°F (end of red line). Each circular graph line represents 2 degrees.

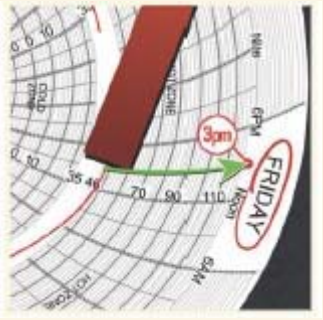
3. To read the day for any point of interest along the recorded ink line, find the nearest curved line flowing from the center of the graph to the outside border. Follow the curved line to the outside border to read the day of the week. Estimate the time of day from the nearest curved line. The curved lines usually progress in 3-hour increments.



Nearest curved line to temperature of interest (current temperature at end of red line).

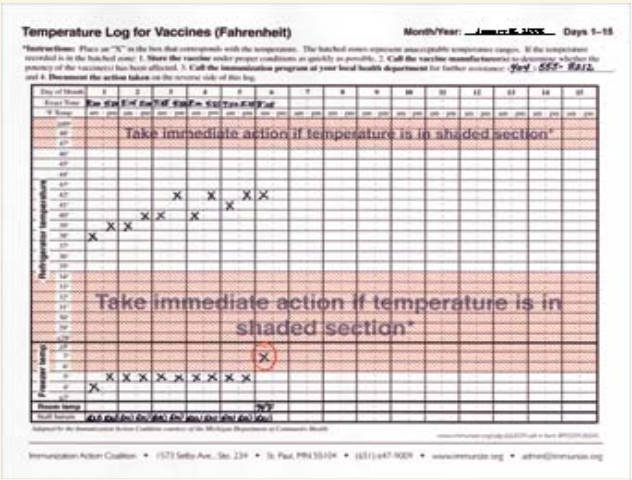


Follow curved line to outside border to reach the day and time scale.



Current temperature falls on the line halfway between the curved lines "Noon" and "6PM" under "FRIDAY", indicating Friday, 3 p.m.

4. Record the current temperature on the temperature log. Note any out-of-range temperatures and the action taken on the back of the log.



Front: Temperature Log for Vaccines.

Note: ⚠ Immediate action must be taken to correct improper vaccine storage conditions.

Reverse: Vaccine Storage Troubleshooting Record.

5. Some charts (such as the one shown here) may have only a white band (without circular graph lines) indicating the recommended temperature range for vaccine storage. In this case, you must still document that the temperatures were checked twice daily and were in range. You may either:

   a. Make a mark in the unshaded area of the temperature log that corresponds to the position of the line on the chart recorder graph (an approximation is acceptable, so long as the recorded temperature is within the recommended range); or

   b. Write "graph in range" or some similar notation in the appropriate column of the temperature log.

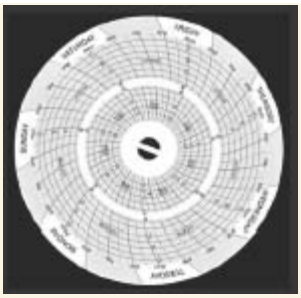


Chart with only a white band (without circular graph lines) indicating the recommended temperature range.

6. All charts from recording thermometers must be kept with the temperature logs for a minimum of 3 years. Charts should always be labeled with the date range before they are place in the chart recorder and when they are removed.

7. Some graphing thermometers have both a recording wheel and a digital temperature display. The reading from the digital display may not be the same as the temperature recorded on the chart. In case of discrepancies, the charted reading on the certified calibrated chart recorder is preferred over the digital reading, which uses a separate, uncertified sensor.

Fahrenheit to Celsius and Celsius to Fahrenheit Conversion

ºF	ºC
-22	-30.0
-21	-29.4
-20	-28.9
-19	-28.3
-18	-27.8
-17	-27.2
-16	-26.7
-15	-26.1
-14	-25.6
-13	-25.0
-12	-24.4
-11	-23.9
-10	-23.3
-9	-22.8
-8	-22.2
-7	-21.7
-6	-21.1
-5	-20.6
-4	-20.0
-3	-19.4
-2	-18.9
-1	-18.3
0	-17.8
1	-17.2
2	-16.7
3	-16.1
4	-15.6
5	-15.0
6	-14.4
7	-13.9
8	-13.3
9	-12.8
10	-12.2
11	-11.7
12	-11.1
13	-10.6
14	-10.0
15	-9.4
16	-8.9
17	-8.3
18	-7.8
19	-7.2
20	-6.7
21	-6.1
22	-5.6
23	-5.0
24	-4.4
25	-3.9
26	-3.3
27	-2.8
28	-2.2
29	-1.7

ºF	ºC
30	-1.1
31	-0.6
32	0.0
33	0.6
34	1.1
35	1.7
36	2.2
37	2.8
38	3.3
39	3.9
40	4.4
41	5.0
42	5.6
43	6.1
44	6.7
45	7.2
46	7.8
47	8.3
48	8.9
49	9.4
50	10.0
51	10.6
52	11.1
53	11.7
54	12.2
55	12.8
56	13.3
57	13.9
58	14.4
59	15.0
60	15.6
61	16.1
62	16.7
63	17.2
64	17.8
65	18.3
66	18.9
67	19.4
68	20.0
69	20.6
70	21.1
71	21.7
72	22.2
73	22.8
74	23.3
75	23.9
76	24.4
77	25.0
78	25.6
79	26.1
80	26.7
81	27.2

ºF	ºC
82	27.8
83	28.3
84	28.9
85	29.4
86	30.0
87	30.6
88	31.1
89	31.7
90	32.2
91	32.8
92	33.3
93	33.9
94	34.4
95	35.0
96	35.6
97	36.1
98	36.7
99	37.2
100	37.8
101	38.3
102	38.9
103	39.4
104	40.0

ºC	ºF
-30	-22.0
-29	-20.2
-28	-18.4
-27	-16.6
-26	-14.8
-25	-13.0
-24	-11.2
-23	-9.4
-22	-7.6
-21	-5.8
-20	-4.0
-19	-2.2
-18	-0.4
-17	1.4
-16	3.2
-15	5.0
-14	6.8
-13	8.6
-12	10.4
-11	12.2
-10	14.0
-9	15.8
-8	17.6
-7	19.4
-6	21.2
-5	23.0
-4	24.8
-3	26.6
-2	28.4
-1	30.2
0	32.0
1	33.8
2	35.6
3	37.4
4	39.2
5	41.0
6	42.8
7	44.6
8	46.4
9	48.2
10	50.0
11	51.8
12	53.6
13	55.4
14	57.2
15	59.0
16	60.8
17	62.6
18	64.4
19	66.2
20	68.0
21	69.8

ºC	ºF
22	71.6
23	73.4
24	75.2
25	77.0
26	78.8
27	80.6
28	82.4
29	84.2
30	86.0
31	87.8
32	89.6
33	91.4
34	93.2
35	95.0
36	96.8
37	98.6
38	100.4
39	102.2
40	104.0

Stock Record (Sample)

Instructions: At the end of each stock record page and at the end of each month, conduct a physical check of the inventory and compare it with the recorded balance, looking for any discrepancies. If the cause of the discrepancy cannot be discovered and corrected, make a note of this. Start a new stock record page by recording the physical count from the previous page. Use the correct physical count for the starting balance. Use the remaining lines to record new shipments of vaccines and weekly accounts of doses used.

Vaccine Type: PPV **Month and Year:** January 2008

Date Received or Usage Tallied	Person Receiving Shipment *	Arrival Condition **	Vaccine or Diluent Name	Manufacturer	Vial Type (S, M, Y) ***	Lot Number	Expiration Date	Expiration Date After Reconstitution	Doses Received/ Balance Forward	Doses Used †	Balance (Doses)
01/2/08	BEGINNING BALANCE FOR THE MONTH								2	N/A	2
01/9/08										1	1
01/15/08	LST	✔	Pneumovax 23	Merck	M	0395B	2/15/09	N/A	5	3	3
01/22/08										1	2
01/29/08										0	2
								Vaccine Totals	7	5	2 ††

* The initials of the person who unpacked and checked the vaccine and/or diluent upon arrival.

** ✔= vaccine arrived in good condition;
X = condition of vaccine questionable and state health department immunization program and vaccine manufacturer contacted. Document details/outcome on reverse side of Stock Record.

*** S = single-dose vial;
M = multidose vial;
Y = manufacturer-filled syringe.

† Includes number of doses administered, wasted, spoiled, expired, or transferred.

†† Enter the sum of "Total Doses Received/Balance Forward" minus "Total Doses Used"

Physical Stock Check (In Doses)	2
Difference ("Balance" minus "Physical Stock Check")	0
Balance Carried Forward (In Doses)	2

Some state or local health department immunization programs have developed their own stock records for vaccine providers. Contact program staff for information. If stock records **are not** available from the state or local health department immunization program, this stock record may be used (see Stock Record in the Resources section for a blank version).

Stock Record

Instructions: At the end of each stock record page and at the end of each month, conduct a physical check of the inventory and compare it with the recorded balance, looking for any discrepancies. If the cause of the discrepancy cannot be discovered and corrected, make a note of this. Start a new stock record page by recording the physical count from the previous page. Use the correct physical count for the starting balance. Use the remaining lines to record new shipments of vaccines and weekly accounts of doses used.

Vaccine Type: _____ **Month and Year:** _____

Date Received or Usage Tallied	Person Receiving Shipment *	Arrival Condition **	Vaccine or Diluent Name	Manufac-turer	Vial Type (S, M, Y) ***	Lot Number	Expiration Date	Expiration Date After Reconsti-tution	Doses Received/ Balance Forward	Doses Used †	Balance (Doses)
	BEGINNING BALANCE FOR THE MONTH									N/A	
								Vaccine Totals			††

* The initials of the person who unpacked and checked the vaccine and/or diluent upon arrival.

** ✔= vaccine arrived in good condition;
X = condition of vaccine questionable and state health department immunization program and vaccine manufacturer contacted. Document details/outcome on reverse side of stock record.

*** S = single-dose vial;
M = multidose vial;
Y = manufacturer-filled syringe.

† Includes number of doses administered, wasted, spoiled, expired, or transferred.

†† Enter the sum of "Total Doses Received/Balance Forward" minus "Total Doses Used"

Physical Stock Check (In Doses)	
Difference ("Balance" minus "Physical Stock Check")	
Balance Carried Forward (In Doses)	

Some state or local health department immunization programs have developed their own stock records for vaccine providers. Contact program staff for information. If stock records are not available from the state or local health department immunization program, this stock record may be used.

Tally Sheet (Sample)

Instructions: Place a copy of this sheet on the door of the refrigerator or freezer in which you store vaccine. Record the week (by date or week number). Write the name of the vaccine and indicate the storage location of each vaccine in the refrigerator (R) or freezer (F). Record a tick mark for each dose of vaccine you remove from the storage unit (i.e., for each dose that is administered, wasted, spoiled, expired, or transferred). At the end of the week, add the tick marks for each vaccine and update the appropriate stock record. Remove the completed tally sheets from the door and store in a file for future reference. Place a new copy of the tally sheet on the storage unit door.

Week: January 13–19, 2008, (Week 3)

Storage Location (R or F) *	Vaccine Name	Doses Administered (Total)	Doses Wasted	Doses Expired **	Doses Spoiled **	Doses Transferred (Viable) ***	Total
F	Varicella	𝍸 || (8)	|				9
R	DTaP	𝍸 𝍸 | (12)					12
R	Hepatitis B / Hib Combination	𝍸 𝍸 || (12)					12
R	IPV	𝍸 𝍸 || (12)		||			14
R	Hepatitis A (pediatric)	|| (2)					2
R	Pneumococcal Polysaccharide (PPV)	| (1)					1
		( )					
		( )					
		( )					
		( )					
		( )					
		( )					
		( )					
		( )					

* R = refrigerator;
F = freezer.

** Some of these nonviable doses should be returned to the state health department immunization program.

*** Viable vaccine doses transferred to the state health department immunization program or another facility.

Some state or local health department immunization programs have developed their own tally sheets for vaccine providers. Contact program staff for information. If tally sheets are not available from the state or local health department immunization program, this tally sheet may be used (see Tally Sheet in the Resources section for a blank version).

Tally Sheet

Instructions: Place a copy of this sheet on the door of the refrigerator or freezer in which you store vaccine. Record the week (by date or week number). Write the name of the vaccine and indicate the storage location of each vaccine in the refrigerator (R) or freezer (F). Record a tick mark for each dose of vaccine you remove from the storage unit (i.e., for each dose that is administered, wasted, spoiled, expired, or transferred). At the end of the week, add the tick marks for each vaccine and update the appropriate stock record. Remove the completed tally sheets from the door and store in a file for future reference. Place a new copy of the tally sheet on the storage unit door.

Week: _____

Storage Location (R or F) *	Vaccine Name	Doses Administered (Total)	Doses Wasted	Doses Expired **	Doses Spoiled **	Doses Transferred (Viable) ***	Total
		( )					
		( )					
		( )					
		( )					
		( )					
		( )					
		( )					
		( )					
		( )					
		( )					
		( )					
		( )					
		( )					
		( )					
		( )					

* R = refrigerator;
F = freezer.

** Some of these nonviable doses should be returned to the state health department immunization program.

*** Viable vaccine doses transferred to the state health department immunization program or another facility.

Some state or local health department immunization programs have developed their own tally sheets for vaccine providers. Contact program staff for information. If tally sheets are not available from the state or local health department immunization program, this tally sheet may be used.

Do NOT adjust refrigerator or freezer temperature contols!

Notify

_____

(Insert name)

if adjustment is necessary.

¡No cambie la temperatura del refrigerador/congelator!

Comuníquese con

_____

(Inserte nombre aquí)

si hay necesidad de cambiar la temperatura

WARNING

Do not unplug the refrigerator/freezer or break circuit. Expensive vaccine in storage.

In event of electrical problem, immediately contact:

WARNING

Do not unplug the refrigerator/freezer or break circuit. Expensive vaccine in storage.

In event of electrical problem, immediately contact:

WARNING

Do not unplug the refrigerator/freezer or break circuit. Expensive vaccine in storage.

In event of electrical problem, immediately contact:

¡AVISO!

No desconecte
el refrigerador/congelador
ni corte el circuito.
¡ Contiene vacunas caras !

Si hay un problema con la electricidad, comuníquese inmediatamente con:

¡AVISO!

No desconecte
el refrigerador/congelador
ni corte el circuito.
¡ Contiene vacunas caras !

Si hay un problema con la electricidad, comuníquese inmediatamente con:

¡AVISO!

No desconecte
el refrigerador/congelador
ni corte el circuito.
¡ Contiene vacunas caras !

Si hay un problema con la electricidad, comuníquese inmediatamente con:


DO NOT UNPLUG!


DO NOT UNPLUG!


DO NOT UNPLUG!

¡No desconecte el refrigerador!

¡No desconecte el refrigerador!

¡No desconecte el refrigerador!

Refrigerator Contains Vaccines!

DO NOT UNPLUG!

Refrigerator Contains Vaccines!

DO NOT UNPLUG!

Refrigerator Contains Vaccines!

DO NOT UNPLUG!

¡El refrigerador contiene vacunas!

¡No desconecte el refrigerador!

¡El refrigerador contiene vacunas!

¡No desconecte el refrigerador!

¡El refrigerador contiene vacunas!

¡No desconecte el refrigerador!

Emergency Vaccine Retrieval and Storage Plan Worksheet

In advance of an emergency, complete the following checklist and forms and store this information in an easily accessible area near the vaccine storage unit. See section on Vaccine Storage and Handling Plans for details.

Checklist of Resources for the Emergency Vaccine Retrieval and Storage Plan

- ☐ Designated primary and backup vaccine coordinators with emergency contact information.
- ☐ Emergency staff contact list in order of contact preference.
- ☐ Vaccine storage unit specifications (type, brand, model number, serial number).
- ☐ Alternate vaccine storage facility or facilities.
- ☐ Written protocols, vehicles, and drivers for transporting vaccine to and from the alternate vaccine storage facility.
- ☐ Written instructions for entering your facility and vaccine storage spaces in an emergency if the building is closed or if it is after hours. These instructions should include the building security/after-hours access procedure, a floor diagram and the locations of the following:
  - ☐ Doors
  - ☐ Flashlights
  - ☐ Spare batteries
  - ☐ Light switches
  - ☐ Keys
  - ☐ Locks
  - ☐ Alarms (including instructions for use)
  - ☐ Circuit breakers
  - ☐ Packing materials
- ☐ Appropriate packing materials to safely transport or temporarily store vaccine.
- ☐ Prioritized vaccine packing list.
- ☐ Written protocol for vaccine packing.
- ☐ Written protocol for appropriately storing vaccine at the alternate storage facility.
- ☐ Up-to-date list of manufacturer quality control office telephone numbers.

Vaccine Coordinators

Vaccine Coordinators	Title	Telephone Numbers (home, cell, beeper)
Primary		
Backup		

Emergency Staff Contact List*

Name	Title	Telephone Numbers (home, cell, beeper)
1.		
2.		
3.		
4.		
5.		
6.		

* List contacts in order of preference. Determine whether all or certain persons on the list should be contacted or if the first person reached is sufficient. Include the primary and backup vaccine coordinators on the list.

Vaccine Storage Unit Specifications

Type of Unit (Refrigerator or Freezer)	Brand	Model Number	Serial Number

Emergency Resources Contact List

Emergency Resources	Contact Person (Title)	Telephone Numbers (home, cell, beeper)
Additional Staff (to move and pack vaccine)		
State Health Department Immunization Program		
Local Health Department Immunization Program		

Emergency Resources	Company Name	Contact Person (title)	Telephone Numbers (home, cell, beeper)
Electric Power Company			
Emergency Generator Repair Company (if applicable)			
Emergency Generator Fuel Source (if applicable)			
Refrigeration Repair Company			
Temperature Alarm Monitoring Company (if applicable)			
Security or Perimeter Alarm Company (if applicable)			
Weather Service			

Emergency Resources	Company Name	Contact Person (title)	Telephone Numbers (home, cell, beeper)
Alternate Vaccine Storage Facility(s)			
Alternate Vaccine Storage Facility (1)			
Alternate Vaccine Storage Facility (2) (if available)			
Alternate Vaccine Storage Facility (3) (if available)			
Alternate Vaccine Storage Facility (4) (if available)			
Transportation to Alternate Vaccine Storage Facility(s)*			
Refrigeration Company			
Refrigeration Company (alternate)			
Private Vehicle	(Not Applicable)		
Private Vehicle (alternate)	(Not Applicable)		
Packing Materials			
Insulated Containers or Coolers			
Insulated Containers or Coolers (alternate)			
Fillers (e.g., crumpled paper, bubble wrap, Styrofoam™ pellets)			
Fillers (alternate)			
Refrigerated/ Frozen Packs			
Refrigerated/ Frozen Packs (alternate)			
Dry Ice Vendor (if inventory includes varicella-containing vaccines)			

Dry Ice Vendor (alternate)			
Certified Calibrated Thermometers			
Certified Calibrated Thermometers (alternate)			

Emergency Management Internet Resources

Three National Oceanic and Atmospheric Administration (NOAA) websites provide up-to-date information on U.S. weather:

http://www.nws.noaa.gov/
http://www.nhc.noaa.gov/
http://www.goes.noaa.gov/

The Federal Emergency Management Agency (FEMA) offers a wide range of information on disaster preparedness:

http://www.fema.gov/index.shtm

The Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration (FDA) offers information concerning the storage and use of temperature-sensitive biological products that have been involved in a temporary electrical power failure or flood conditions:

http://www.fda.gov/cber/weatherimpact.htm

Chart of Refrigerated/Frozen Pack Needs for Different Climates

Outside Temperature	Number of Faces* Covered with Packs	Temperature of Packs	Comment**
Greater than 75°F to 110°F (greater than 24°C to 43°C)	2***	23°F (-5°C)	Up to 48 hours delivery with 10 hours at 110°F (43°C)
32°F to 75°F (0°C to 24°C)	2***	23°F (-5°C)	Up to 48 hours delivery
	4	41°F (+5°C)	Up to 24 hours delivery
Colder than 32°F (°C)	4 to 6****	50°F (+10°C)	About 24 hours exposure to mix of outdoors and heated areas
0°F (-18°C) or colder	6****	68°F (+20°C)	Prolonged, 24 to 48 hours continuous exposure to 0°F (-18°C)

* Faces would include the interior surfaces of the box, including the walls, floor and lid (above the vaccines and insulating material).

** Applies when high quality insulated boxes with walls of 1¾ inches to 2¼ inches expanded polystyrene, 1 inch isocyanurate, or 3 inches polyurethane insulation were used.

*** 3 for the medium-sized box tested by CDC (10x10x7 inches—interior dimensions).

**** Essentially the entire surface area is covered with packs.

Refrigerated/Frozen Packs.

Handling Dry Ice

Dry ice is solid carbon dioxide. It can cause injury if handled improperly. Handling dry ice safely requires following certain precautions:

- Dry ice is extremely cold (-110°F or -79°C). To avoid frostbite, do not touch dry ice with bare skin. Wear goggles, thick gloves, and suitable clothing (e.g., long sleeves) to minimize the risk of skin contact with dry ice.
- Dry ice should only be used in areas with adequate ventilation. Dry ice evaporates to form carbon dioxide gas. This gas can cause respiratory distress and death by suffocation. (See article at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5350a6.htm for additional information.)
  Carbon dioxide gas is heavier than air and can accumulate at floor level or in confined spaces, increasing the risk of suffocation. Early signs include difficulty breathing, or panting. If you experience these signs, immediately move to an open area. Do not enter areas where carbon dioxide gas may have accumulated without first testing for the carbon dioxide and oxygen content. Transport dry ice only in insulated, closed containers to prevent exposure to carbon dioxide gas.

Handle dry ice safely!

- Do not store dry ice in tight containers. Pressure develops as dry ice evaporates, which could burst air-tight containers.
- When handling dry ice, only use equipment designed for low temperatures.
- First aid: In case of frostbite, obtain medical treatment immediately. If carbon dioxide gas is inhaled, remove the exposed person to an area with fresh air. If breathing is difficult, give oxygen if available. Phone 911 for emergency medical assistance if breathing does not become easier. If the person is not breathing, give artificial respiration (e.g., mouth-to-mouth) and phone 911 for emergency medical assistance.
- Disposal: Dry ice can be disposed of by leaving the container open in a well-ventilated area. The dry ice will evaporate to form carbon dioxide gas. Make sure the container is not accessible to children to prevent frostbite.

Wear goggles, thick gloves, and suitable clothing (e.g., long sleeves) to minimize the risk of skin contact with dry ice.

Manufacturer Quality Control Office Telephone Numbers

Manufacturer/Distributor	Telephone Number	Products
sanofi pasteur www.sanofipasteur.us	800-822-2463	DTaP, DTaP-Hib, DT, Td, Tdap, TT, Hib, Influenza (TIV), IPV, MCV, MPSV
Talecris Biotherapeutics www.talecris.com/us	800-520-2807	HBIG, IGIM, RIG, TIG
Centers for Disease Control & Prevention Drug Service www.cdc.gov/ncidod/srp/drugs/drug-service.html	404-639-3670	Distributor for Diphtheria antitoxin
Novartis http://www.novartis-vaccines.com/products/index.shtml	800-244-7668	Influenza (TIV)
GlaxoSmithKline www.gsk.com/	866-475-8222 (customer support) 888-825-5249 (customer support)	DTaP, DTaP-HepB-IPV, Tdap, HepA, HepB, HepA-HepB, Influenza (TIV)
Massachusetts Biological Labs	617-474-3000 617-983-6400	Td, TT, IGIM
MedImmune, Inc. www.medimmune.com	877-358-6478 (LAIV customer support) 877-633-4411 (general customer support)	Influenza (LAIV)
Merck www.merckvaccines.com	800-609-4618 (customer support) 800-672-6372 (customer support)	Hib, Hib-HepB, HepA, HepB, HPV, Measles, Mumps, Rubella, MMR, MMRV, PPV23, Rotavirus, Varicella, Zoster
Nabi Biopharmaceuticals www.nabi.com	800-635-1766	HBIG
Wyeth www.wyeth.com	800-999-9384	Hib, PCV7