Vaccine Storage & Handling TOOLKIT

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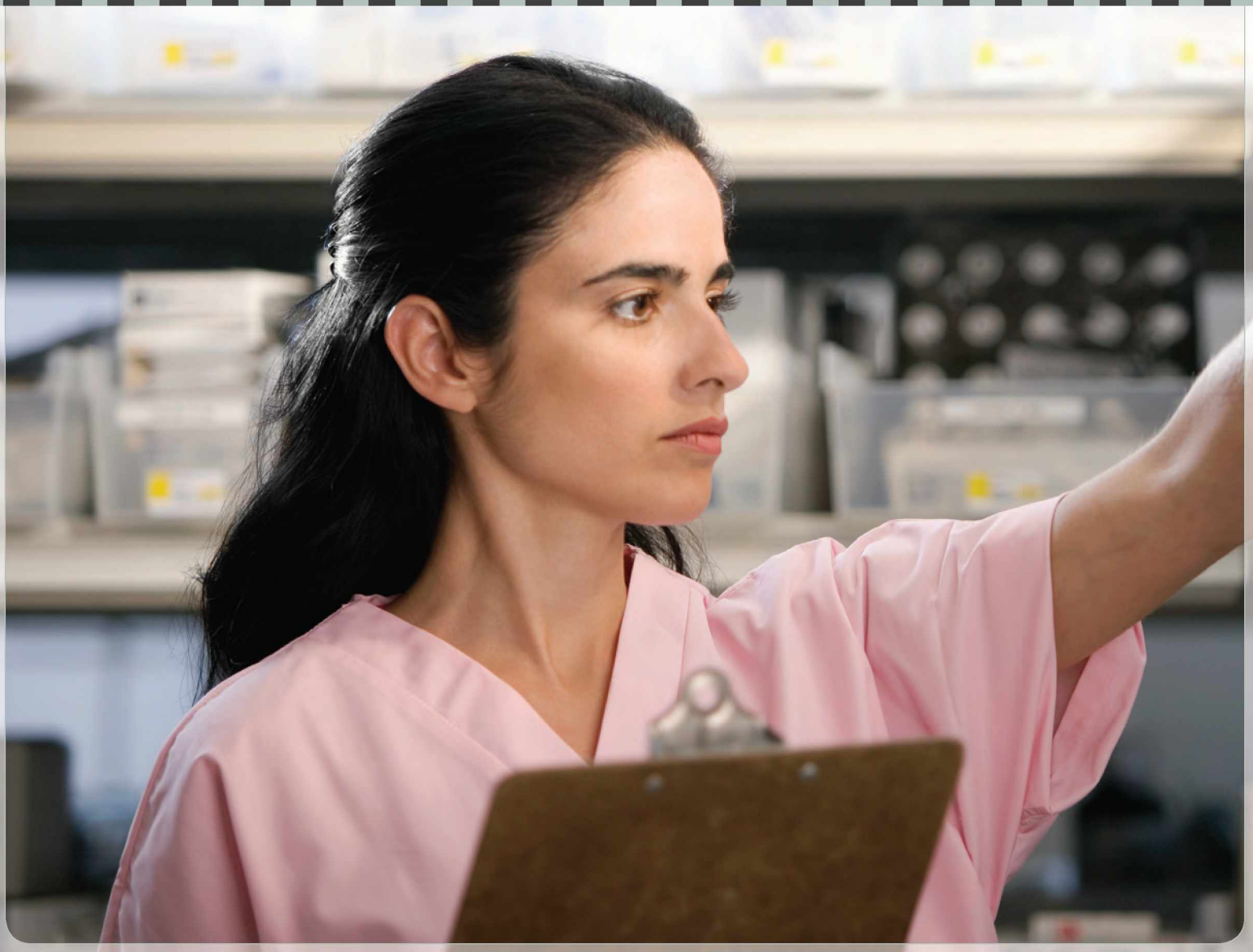

Centers for Disease Control and Prevention
National Center for Immunization and Respiratory Diseases

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Vaccine Storage and Handling

Background

In response to recent scientific studies on equipment used for vaccine storage and a better understanding of best practices for storage and handling, the Centers for Disease Control and Prevention (CDC) is providing updated guidance on appropriate vaccine storage and handling practices. This guidance is intended as the approved standard of care for all public and private sector providers. While recognizing that cost may be a barrier, we encourage practices to move toward implementing these recommendations as soon as possible. CDC is currently evaluating the most efficient and cost-effective method to phase in these recommendations.

The Value of Vaccine Storage and Handling Best Practices

Vaccine storage and handling errors can result in the loss of vaccines worth millions of dollars. The administration of mishandled vaccine can affect a large number of patients. Failure to adhere to required protocols for storage and handling can reduce vaccine potency, resulting in inadequate immune responses in patients, as well as inadequate protection against disease. Vaccine quality is the shared responsibility of all parties, from manufacturing until administration. Patient confidence in vaccines and their providers is diminished when repeat vaccinations are required to replace invalid doses administered with potentially reduced-potency vaccines.

Vaccine Storage and Handling Protocols

This toolkit provides guidance for immunization programs to use when updating their policies, procedures, and guidance.

State/Local health department immunization programs (herein referred to as "immunization program[s]") throughout the United States have been successful in preventing and eradicating vaccine-preventable diseases in part because of proper vaccine storage and handling practices. Immunization programs and practices should have written protocols for routine vaccine storage and handling, as well as for emergency procedures. This toolkit provides guidance for immunization programs to use when updating their policies, procedures, and guidance. Storage and handling plans that include step-by-step protocols should be easily accessible in every facility that provides

immunizations (see routine and emergency plans in the Storage and Handling Plans section).

Avoiding Mistakes

Vaccine storage and handling mistakes are easily avoidable. This toolkit will provide you with specific guidelines that will help curtail those mistakes. Specific guidelines for vaccine storage and handling procedures should not vary among immunization programs. This toolkit replaces the previously published toolkit and should be used by all immunization programs to update their policies and procedures with recommendations for storage and handling best practices. For further advice contact your immunization program at this link: http://www.cdc.gov/vaccines/spec-grps/prog-mgrs/grantee-imz-websites.htm.

Manufacturer Protocols

Manufacturer protocols, found in the manufacturer's product information and package inserts, should be referred to for specific and detailed information about storage and handling of specific vaccines. If you have concerns about vaccines and/or diluents that may have been compromised (exposed to inappropriate conditions/ temperatures or handled improperly), label them "DO NOT USE" and store them under appropriate conditions separate from other vaccine supplies. If vaccines and/or diluents are expired (see Expiration Dates in the Vaccine Inventory Management section), immediately remove them from the storage unit. Then, for compromised or expired vaccines and/or diluents, contact your immunization program and/or vaccine manufacturer(s) for guidance.

If you have concerns about vaccines and/or diluents that may have been compromised (exposed to inappropriate conditions/ temperatures or handled improperly), label them "DO NOT USE" and store them under appropriate conditions separate from other vaccine supplies. If vaccines and/or diluents are expired (see Expiration Dates in the Vaccine Inventory Management section), immediately remove them from the storage unit. Then, for compromised or expired vaccines and/or diluents, contact your immunization program and/ or vaccine manufacturer(s) for guidance.

What is the Vaccine Cold Chain?

Vaccines must be stored appropriately from the time they are manufactured until the time they are administered to a patient. Excessive heat or cold can reduce vaccine potency, increasing the risk that recipients will not be protected against vaccine-preventable diseases. A temperature-controlled environment used to maintain and distribute vaccines in optimal condition is called the vaccine cold chain. The vaccine cold chain relies on three main elements:

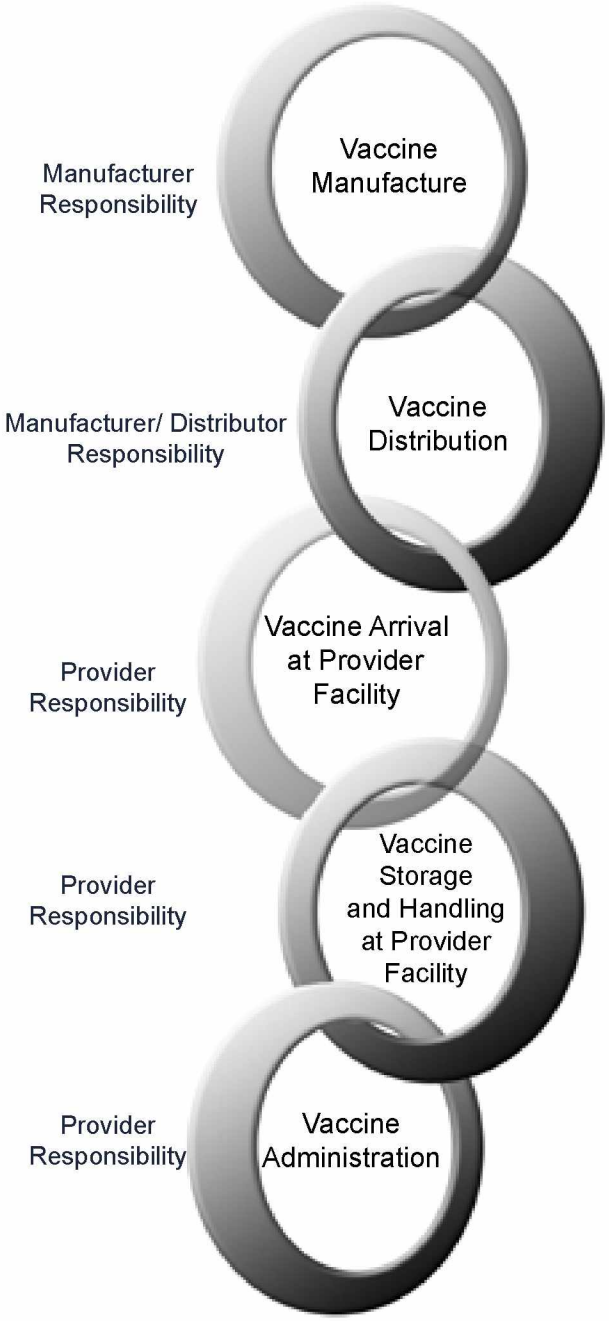
- Effectively trained personnel;
- Appropriate transportation and storage equipment, and;
- Efficient management procedures.

All three elements must stay consistent to ensure vaccines are transported and stored appropriately.

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

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

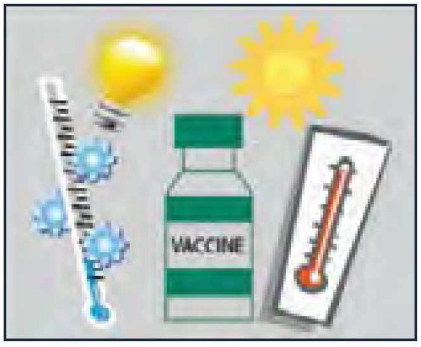
The Vaccine Cold Chain



Vaccine should always be transported in a refrigerated or frozen state. Refer to manufacturer protocols for each vaccine. Transport should include use of an insulated container or refrigerated truck. Appropriate temperatures are: Refrigerator between 35°F and 46°F [2°C and 8°C]
Freezer between -58°F and +5°F [-50°C and -15°C]

Importance of Maintaining the Vaccine Cold Chain

Vaccine Potency



Excessive heat or cold exposure can damage vaccines, resulting in reduced potency. Once potency is lost, it cannot be restored. Each time vaccines are exposed to excessive heat or cold, reduced potency increases. Eventually, if the vaccine cold chain is not properly maintained, all potency will be lost, and the vaccines become useless.

While exposure to both warm and cold temperatures can affect the potency of refrigerated vaccines, a single exposure to freezing temperatures will destroy some refrigerated vaccines. HepB and DTaP/DT/Tdap/Td vaccines are especially sensitive to freezing temperatures. That is why it is important to regularly monitor the temperature of your vaccines and take immediate corrective action when a storage unit temperature reading is outside the recommended range (temperature excursion).

Vaccine Appearance after Exposure to Inappropriate Storage Conditions

Some vaccines may show physical evidence that potency has been reduced when exposed to inappropriate storage conditions. This may appear 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 (see photos below). 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 reduced or lost potency. Therefore, visual inspection of vaccines must be considered unreliable when assuring vaccine was stored under appropriate conditions.

Properly stored vaccine
Full potency

Improperly stored vaccine
Diminished potency

Visual inspection of vaccines is an unreliable method of assuring vaccine was stored under appropriate conditions.

Burden of Vaccine Cold Chain Failure

Out-of-range temperatures (temperature excursions) can be caused by inadequate temperature monitoring, unreliable equipment, and inappropriate use of small dormitory-style refrigerator/freezer units (see Dormitory-Style Units in the on Vaccine Storage Equipment section).[1,2,3] Temperature excursions require ⚠**immediate corrective action.**

Reduced vaccine potency due to inappropriate storage conditions can be costly. Patients who receive vaccine with reduced potency caused by inappropriate storage conditions may not be fully protected against vaccine-preventable diseases. In the *General Recommendations on Immunization*, the Advisory Committee on Immunization Practices (ACIP) recommends "vaccine exposed to inappropriate temperatures that is inadvertently administered generally should be repeated."[4] Providers should contact their state/local health department immunization program, vaccine manufacturer(s), or both for

Store in Refrigerator
Between 35°F and 46°F (2°C and 8°C)

MMR*†
HepA HepB HepA-HepB
Hib* Hib-HepB
Human papillomavirus (HPV2 and HPV4*)
Influenza (LAIV and IIV*)
IPV
Meningococcal-Containing
(Hib-MenCY* MCV4* and MPSV4)
Pneumococcal (PCV13 and PPSV23)
Rotavirus* (RV1 and RV5)
Diphtheria toxoid-, Tetanus toxoid-,
and Pertussis-Containing
(DT, DTaP, DTaP-HepB-IPV, DTaP-IPV,
DTaP-IPV/Hib, Tdap, Td, TT)

Store in Freezer
Between -58°F and +5°F (-50°C and -15°C)

VAR*
HZV*
MMRV*
MMR*†

*Protect from light the following vaccines: Varivax, Zostavax, ProQuad, M-M-R II, Hiberix, Gardasil, Afluria, Fluarix, FluLaval, Fluvirin, MenHibrix, Menveo, Rotarix, and RotaTeq.

†Unreconstituted lyophilized (freeze-dried) MMR may be frozen or refrigerated.

guidance. Recalling patients to repeat vaccine doses should be considered. Vaccine recalls due to inappropriate storage can mean extra doses for patients, increased costs for providers, and damage to public confidence in vaccines. They can also be a liability for a provider's practice. Patients who refuse revaccination can remain unprotected from serious, vaccine-preventable diseases.

Vaccines are very expensive. The costs associated with loss and replacement vaccines, and resources necessary to conduct a recall of patients, can be significant.5,6 Avoid these extra expenses by following the guidance in this toolkit to maintain the vaccine cold chain.

References

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3. Bell KN, Hogue CJR, Manning C, Kendal AP. Risk factors for improper vaccine storage and handling in private provider offices. Pediatrics 2001;107(6):1–5.
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General Recommendations

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

All healthcare providers who administer vaccines should evaluate their vaccine cold chain procedures to ensure that vaccine storage and handling best practices are being followed. Each provider practice (each facility) should develop and adhere to a detailed written Routine Vaccine Storage and Handling Plan that is updated annually. This plan should include all aspects of routine vaccine management, from ordering vaccines and managing inventory to storing vaccines and monitoring storage conditions. A written plan will help vaccine providers stay organized, serve as a reference and training tool, and provide quality assurance of proper vaccine management.

In addition, each facility should have a detailed written Emergency Vaccine Retrieval and Storage Plan in the event of refrigerator and/or freezer malfunctions, power failures, natural disasters, or other emergencies that might compromise appropriate vaccine storage conditions. The emergency plan should also be reviewed and updated annually. 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).

Each office needs an Emergency Vaccine Retrieval and Storage Plan.

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

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. You may also use the Routine Vaccine Storage and Handling Plan Worksheet in the Resources section to help organize your plan. Consult your agency or immunization program, as appropriate for your situation, for any special instructions or forms. Whenever there is a question about whether vaccines and/or diluents may have been compromised (exposed to inappropriate conditions/temperatures or handled improperly), label them "DO NOT USE" and store them under appropriate conditions separate from other vaccine supplies. If vaccines and/or diluents are expired (see Expiration Dates in the Vaccine Inventory Management section), immediately remove them from the storage unit. Then, for compromised or expired vaccines and/or diluents, contact your immunization program and/or vaccine manufacturer(s) for guidance.

Whenever there is a question about whether vaccines and/or diluents may have been compromised (exposed to inappropriate conditions/temperatures or handled improperly), label them "DO NOT USE" and store them under appropriate conditions separate from other vaccine supplies. If vaccines and/or diluents are expired (see Expiration Dates in the Vaccine Inventory Management section), immediately remove them from the storage unit. Then, for compromised or expired vaccines and/or diluents, contact your immunization program and/or vaccine manufacturer(s) for guidance.

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

- Up-to-date contact information for the:
  - Primary and alternate vaccine coordinators who are responsible for routine vaccine storage and handling (see the Vaccine Personnel section);
  - Immunization program (see State Immunization Program Websites on the CDC Vaccine website);
  - Manufacturers of the vaccines in your inventory (see Manufacturer Contact Information in the Resources section);
  - Refrigerator and freezer maintenance and repair company(ies);
  - Utility/power company;
  - Vaccine storage unit alarm company (if applicable);
  - Sources of packing materials and calibrated thermometers.

- Descriptions of the roles and responsibilities of the primary and alternate vaccine coordinators (see the Vaccine Personnel section).
- Policy on education and training for facility staff. 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).
- Protocols for ordering and accepting vaccine deliveries (see Vaccine Stock Calculations and Ordering in the Vaccine Inventory Management section and Receiving and Unpacking Vaccine Shipments in the Vaccine Shipments section).
- Summaries of the storage requirements for each vaccine and diluent in your inventory (see CDC's Vaccine Storage and Handling Guide).
- Protocols for vaccine storage unit temperature monitoring including downloading and reviewing electronic monitoring data weekly (see Temperature Monitoring and Thermometers in the Vaccine Storage Equipment section).
- Protocols for vaccine storage equipment maintenance (see the Vaccine Storage Equipment section).
- Protocols for the correct placement of vaccines within storage units (see Vaccine and Diluent Storage Locations and Positioning in the Vaccine Storage Practices section).
- Protocols for responding to vaccine storage and handling problems such as, potentially compromised vaccines (i.e., vaccine that has been exposed to temperatures outside of the recommended range) (see the Storage Troubleshooting section).
- Protocols for vaccine inventory management, such as checking vaccine and diluent expiration dates weekly and removing expired items from usable stock (contact your immunization program for details and see the Vaccine Inventory Management section for general guidelines).
- Protocols for transporting and receiving vaccine shipments (contact your immunization program for details and see the Vaccine Transport section).
- Protocols for handling vaccine prior to administration (see the Vaccine Preparation and Disposal section).
- Protocols for proper disposal of vaccines and supplies (contact your immunization program for details and see the Vaccine Preparation and Disposal section for general guidelines).

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

- Samples of the forms used in your vaccination program (contact your immunization program for details). Additional resources are available in the Resources section and from the Immunization Action Coalition [IAC] Clinic Resources.

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

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. If a problem is short term (usually 2 hours or less) and depending on ambient room temperature, the storage temperature can probably be maintained with the water containers in the refrigerator, with frozen coolant packs in the freezer, and by keeping the storage unit door(s) closed.

Vaccine manufacturers do not generally recommend or provide guidance for transport of vaccines. However, in certain circumstances (e.g., emergencies, power outages), vaccine may need to be transported to another facility. If there is an extended period of time before the situation can be corrected and there are no other storage units available on site, the vaccines should be moved to a back-up storage facility using the guidelines in the emergency 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, new, and temporary) 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 or power outages. Review and update the contact lists in the plan at least quarterly; review and update the entire plan at least annually.

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

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 in the Resources section and IAC's *Emergency response worksheet* (see Immunization Action Coalition [IAC] Clinic Resources) to help organize your response. Consult your agency or immunization program, as appropriate for your situation, for any special instructions or forms. If you have concerns about vaccines and/or diluents that may have been compromised (exposed to inappropriate conditions/temperatures or handled improperly), label them "DO NOT USE" and store them under appropriate conditions separate from other vaccine supplies. Then contact your immunization program and/or vaccine manufacturer(s) for guidance.

If you have concerns about vaccines and/or diluents that may have been compromised (exposed to inappropriate conditions/ temperatures or handled improperly), label them "DO NOT USE" and store them under appropriate conditions separate from other vaccine supplies. Then contact your immunization program and/ or vaccine manufacturer(s) for guidance.

Advance Preparations

Well in advance of any emergency situation, you should have the following personnel, equipment, information, and protocols in place. Record this information in the Emergency Vaccine Retrieval and Storage Plan Worksheet found in the Resources section.

- **Designated primary and alternate vaccine coordinators with emergency contact information.** In addition to their routine vaccine storage and handling duties (see the Vaccine Personnel section for details), the primary and alternate 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 facilities with large inventories);
  - Post emergency contact information on circuit breaker(s) or electrical panel;

  - Ensure the appropriate handling of vaccine during a disaster or power outage;
  - Ensure 24-hour access to the building and vaccine storage unit(s);
  - Ensure that sufficient fuel is on hand to continuously run the generator for at least 72 hours if the facility has a back-up 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 alternate vaccine coordinators on the list. Record the names (in order) and contact information. Assure that contact information is kept up to date.
- **Vaccine storage unit specifications.** For each vaccine storage unit in your facility, identify the type of unit (e.g., stand-alone refrigerator), the brand name, the model number, and the serial number. 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 back-up generator where vaccines can be appropriately stored and monitored for the interim (e.g., hospital, long-term care facility, state depot, Red Cross, fire station, packing plant, commercial pharmacy). Make advance arrangements with the facility(ies) to store your vaccines 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(ies), the name of the contact person(s), and the telephone number(s). Instructions for 24-hour access should also be included.

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

- **Written protocols, vehicles, and drivers for transporting vaccines to and from the alternate vaccine storage facility.**
  - If the vaccines must be moved to an alternate facility, they may be transported in portable actively or passively cooled refrigerator or freezer units or hard-sided insulated containers. The vaccines may be transported within non-commercial vehicles inside the passenger compartment (not in the trunk because temperatures cannot be controlled inside the trunk). Make advance arrangements for primary and back-up vehicles and drivers and record the contact information.

When transporting vaccines in non-commercial vehicles use the passenger compartment—not the trunk.

  - If the location is far away or if you have a large quantity of vaccines, consider renting a refrigerated truck to transport the vaccines. In this case, joining with other facilities to reduce costs may be advantageous. Make advance arrangements with a local refrigeration company and an alternate and record the contact information.
  - Check with your immunization program for guidance and resources on emergency transport of vaccines.
  - Develop written protocols for transporting vaccines to and from the alternate vaccine storage facility:
    - Establish how to load the vehicle;
    - Have pre-selected routes to take (and alternate routes if necessary);
    - Determine the estimated time en route.

A refrigerated truck can be used to transport vaccines.

- **Written instructions for entering your facility and vaccine storage spaces in an emergency if the building is closed.** These instructions should include the building security/after-hours access procedure, a floor diagram, and the locations of the following:
  - Alarms (including instructions for use)
  - Doors
  - Flashlights
  - Spare batteries
  - Light switches
  - Keys
  - Locks
  - Circuit breakers
  - Packing materials
- **Appropriate packing materials to safely transport or temporarily store vaccine.** Vaccine manufacturers do not recommend reuse of shipping materials, including coolant packs and shipping containers, to further transport vaccine products. Improper repackaging using these materials and improper transportation could negatively impact the vaccine.

  Appropriate materials may include portable actively or passively cooled refrigerator/freezer units, hard-sided insulated containers, "conditioned" coolant packs that are cold or frozen (depending on the type of vaccine), and a calibrated thermometer for each container (see Packing Vaccines and Diluents for Transport in the Vaccine Transport section). There should be an adequate supply of packing materials/containers on hand for the facility's largest annual inventory. In situations where an alternate vaccine storage facility with a back-up generator cannot be identified within a reasonable distance, maintain the appropriate packing materials to store vaccines temporarily and safely at your facility. Record the names and contact information for sources of these materials.
- **Written protocol for vaccine packing.** Each facility should develop its own standard operating procedures (SOPs) for packing vaccines. 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 vaccines to an alternate storage facility.
  - Use proper packing materials and procedures for refrigerated and frozen vaccines (see Packing Vaccines and Diluents for Transport in the Vaccine Transport section for general guidelines).

Emergency Procedures

No piece of vaccine storage equipment is infallible, and there is always potential for vaccine storage equipment failure. At some point, equipment failure will occur related to a power failure, breakdown, or normal wear and tear. Part of a provider's responsibility for proper vaccine storage is preparing for equipment failure by having back-up equipment and back-up plans available.

Power Outages

The information below is provided as a guideline. You may use the Emergency Vaccine Retrieval and Storage Plan Worksheet in the Resources section of this toolkit to help organize your response. Consult your agency or 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 vaccines to remain in a nonfunctioning unit for an extended period of time. If at any time you are unsure how long the power interruption will last, or you determine that the power will not be restored in time to maintain internal temperatures within the recommended ranges, activate the Emergency Vaccine Retrieval and Storage Plan (see the Storage and Handling Plans section) and disregard the following steps.
2. If you are certain the power will be restored before the temperature in each storage unit rises above the recommended range, take the following steps:
    a. Do not open a storage unit door until the power is restored.
    b. Continue to monitor the temperature inside each storage unit.
        i. Some thermometers allow temperature monitoring without opening the storage unit door. In this case, record the ambient room temperature and the temperature(s) inside the unit at the time the problem is discovered, as well as the minimum and maximum temperature reached inside the unit during the power outage.
        ii. If this type of thermometer is not being used, do not open a storage unit door to check the temperature during the power outage. Document the ambient room temperature and the temperature inside each storage unit as soon as possible after power has been restored. If you have a digital data logger, document the length of time the power has been off and the minimum and maximum temperature observed within the storage unit.
    c. At the time power is restored, if the temperature inside the refrigerator is not between 35°F and 46°F (2°C and 8°C) or if the temperature inside

the freezer is not between -58°F and +5°F (-50°C and -15°C), document the duration of inappropriate temperature exposure and follow the procedures for Handling Inappropriate Vaccine Storage Conditions (Light and Temperature) in the Storage Troubleshooting 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).

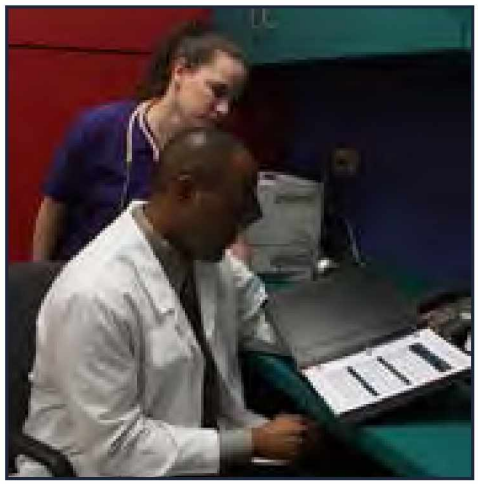
The following emergency procedures should be implemented in advance of an event, if possible. If you have no warning and the emergency event is already occurring or has already occurred, you should still follow these procedures. Consult your agency or immunization program, as appropriate for your situation, for any special instructions. If you have concerns about vaccines and/or diluents that may have been compromised (exposed to inappropriate conditions/temperatures or handled improperly), label them "DO NOT USE" and store them under appropriate conditions separate from other vaccine supplies. Then contact your immunization program and/or vaccine manufacturer(s) for guidance.

Suspend vaccination activities before the onset of emergency conditions, if possible. This will allow sufficient time for packing and transporting vaccines.

- **Notify staff at the alternate vaccine storage facility.** Before moving your vaccines, contact the alternate storage facility to make them aware of the situation and to ensure that their back-up generator is working.
- **Conduct an inventory of the vaccines and record the actions taken.** Use the Emergency Vaccine Retrieval and Storage Plan Worksheet in the Resources section. Also note if frozen coolant packs were in the freezer and water bottles were in the refrigerator at the time of this event.
- **Pack and transport the affected vaccines** (see Written Protocol for Vaccine Packing in this section).
- **Follow established vaccine transport procedures for moving vaccines** (see Written Protocols, Vehicles, and Drivers for Transporting Vaccines to and from the Alternate Vaccine Storage Facility in this section).
- **Check vaccine temperature upon arrival at the alternate facility and ensure immediate storage at manufacturer-recommended temperature.**

Primary Vaccine Coordinator and Alternate Vaccine Coordinator

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



Each practice should designate a Primary Vaccine Coordinator and at least one Alternate Vaccine Coordinator.

- Ordering vaccines;
- Overseeing proper receipt and storage of vaccine shipments;
- Organizing vaccines within the storage unit(s);
- Reading and documenting storage unit temperatures a minimum of twice each workday;
- Reading and documenting storage unit minimum/maximum temperatures once per workday, preferably in the morning;
- Downloading and reviewing stored temperature monitoring data at least weekly;
- Inspecting storage unit(s) daily;
- Rotating stock so that vaccine closest to its expiration date will be used first;
- Monitoring expiration dates and ensuring that expired vaccine is promptly removed from the storage unit(s) and not administered to patients;
- Responding to possible temperature excursions;
- Overseeing proper vaccine transport;
- Maintaining all appropriate vaccine storage and handling documentation, including temperature excursion responses;
- Maintaining storage equipment and records, including Vaccines for Children (VFC) program documentation in participating facilities;
- Ensuring that designated staff is adequately trained.

Each office should also designate at least one alternate vaccine coordinator who can assume these same responsibilities in the absence of the primary vaccine coordinator. The primary and alternate vaccine coordinators should be fully trained regarding routine and emergency policies and procedures related to vaccine shipments, storage, handling, transport, and inventory management. It is also important that a physician partner or member of management is directly involved with the responsible clinical staff—someone with a clear understanding of the

vaccine replacement costs and clinical implications of mismanaged storage units and vaccines.

It is also important that a physician partner or member of management is directly involved with the responsible clinical staff—someone with a clear understanding of the vaccine replacement costs and clinical implications of mismanaged storage units and vaccines.

Other Staff

All staff members who handle or administer vaccines should be familiar with the storage and handling policies and procedures at their facility.

All staff members who handle or administer vaccines should be familiar with the storage and handling policies and procedures at their facility. This includes not only those who administer vaccines, but also anyone who delivers or accepts shipments or who may have access to the unit(s) where vaccines are stored. Both the Routine Vaccine Storage and Handling Plan and the Emergency Vaccine Retrieval and Storage Plan (see the Storage and Handling Plans section) should be easily accessible and should be kept near the vaccine storage unit(s).

Training

Staff who handle and administer vaccines should receive comprehensive training regarding storage and handling policies and procedures. This training should be integrated into new staff orientation. In addition, training should occur whenever recommendations are updated and when new vaccines are added to the facility's inventory to maintain staff competency. Accountability checks should be put in place to ensure policies and procedures are followed.

This toolkit can serve as a reference guide in conjunction with other resources on the CDC Storage and Handling web page. Additional resources or training may be available through your state or local health department immunization program.

All staff, including new and temporary, should understand the importance of vaccine cold chain maintenance and the procedures to follow if there is a break in the cold chain. For example, there is no benefit to recording the temperature in a storage unit if corrective action is not taken when vaccine is exposed to temperatures outside the

recommended range. All staff members should know any break in the vaccine cold chain must be reported immediately to the vaccine coordinator or to the immediate supervisor. The vaccine coordinator and supervisory staff should take ⚠ **immediate action** to correct inappropriate storage conditions (including both inappropriate light and temperature exposures).

Disclaimer: This section provides guidance on vaccine storage equipment, including storage recommendations, equipment maintenance, and methods and devices used to protect vaccines against equipment failure. Individual projects and state/local health department immunization programs may have specific requirements for providers who receive Vaccines for Children (VFC) vaccines or other vaccines purchased with public funds. Consult your immunization program 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 Recommendations

Think of your vaccine storage equipment as an insurance policy to protect patients' health and safeguards your facility against costly vaccine replacement, inadvertent administration of compromised vaccine, and other potential consequences (e.g., the costs of revaccination and loss of patient confidence in your practice). Reliable, properly maintained equipment is critical to the vaccine cold chain.

Equipment Logbook

Consider keeping a logbook with information on each piece of vaccine storage equipment. Logbook records should include the following information for each piece of equipment:

- Serial numbers;
- Date of installation;
- Dates of routine maintenance;
- Dates of repairs or servicing;
- Names of the company(ies) and people performing each of these tasks.

This logbook is an ideal place to keep manuals or instructions related to the equipment.

Vaccine Storage Equipment Recommendations

While CDC does not recommend specific brands of vaccine storage units, CDC does provide guidance on types of storage units that offer greater assurance of proper temperatures for vaccine storage based on equipment testing by the National Institute of Standards and Technology (NIST).

Vaccine storage units must be selected carefully and used properly. Refrigerators and freezers are available in different grades (household, commercial, and pharmaceutical) and types (stand-alone, combination).

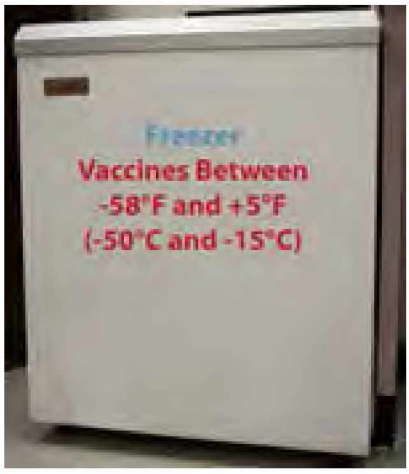
CDC recommends stand-alone units, meaning self-contained units that only refrigerate or freeze, and are suitable for vaccine storage. These units can vary in size, from compact, under-the-counter style to large, stand-alone, pharmaceutical grade units.

A NIST study, conducted in 2009, demonstrated that these units maintain the required temperatures better than combination refrigerator/freezer units.[1] CDC has received multiple reports of incidences where refrigerated vaccines have been compromised by exposure to freezing temperatures in a combination unit. Use of stand-alone units is a best practice.

Stand-alone refrigerator

Vaccines that require storage temperatures between 35°F and 46°F (2°C and 8°C) should be stored in a stand-alone refrigerator unit. Because freezing of refrigerated vaccines affects vaccine potency more than other exposure problems, it is especially important that refrigerators be selected and set up in a way that eliminates the chance of freezing vaccine (see Refrigerators in the Vaccine Storage Practices section).

A separate stand-alone freezer should be used to store frozen vaccines that require storage temperatures between -58°F and +5°F (-50°C and -15°C). A storage unit that is frost-free or has an automatic defrost cycle is preferred. Frozen vaccines should not be stored in the freezer compartment of a combination unit because NIST has found that household freezers cannot hold proper storage temperatures for frozen vaccines. This applies to both temporary and long-term storage of frozen vaccines.



Stand-alone freezer

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

The refrigerator and freezer units must:

- Have enough room to store the year's largest inventory without crowding;
- Have enough room to store water bottles (in the refrigerator) and frozen coolant packs (in the freezer) to stabilize the temperatures and minimize temperature excursions that can impact vaccine potency. The addition of water bottles in the refrigerator (not coolant packs) reduces the risk of freezing due to the tremendous latent heat released from water prior to freezing;
- Have a calibrated thermometer inside each storage unit;
- Reliably maintain the appropriate vaccine storage temperatures year-round;
- 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.

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

Combination refrigerator/freeze

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

It is important to note that most combination refrigerator/freezers share a single condenser, and freezing air from the freezer compartment is vented into the refrigerator compartment to cool the refrigerator. Be very careful not to use the top shelf if the vent from the freezer opens there. You should not turn off the freezer portion of the combination unit because it will not maintain the proper temperature

for refrigerated vaccines stored in that part of the unit. If you are using the refrigerator portion of the combination unit, it is important that you add water bottles to the refrigerator to absorb cold air blown in from the freezer to reduce the risk of vaccines becoming too cold.

Water bottles added to the refrigerator to absorb cold air blown in from the freezer to reduce the risk of vaccines becoming too cold

There are some combination refrigerator/freezers that have a separate freezer condenser and separate refrigerator condenser with no air vents connecting the two, and separate digital temperature controls for freezer and refrigerator sections. Although these types of "twin cooling" combination units have not been formally evaluated by NIST to determine whether they are acceptable alternatives, for the time being these types of combination units may be used to store vaccines. However, in the future, CDC may revise this exception if this specific type of combination refrigerator/freezer is tested and found to cause an increased risk of potentially freezing refrigerated vaccines. All vaccine storage units must be monitored by a calibrated thermometer and must demonstrate that the unit can reliably maintain appropriate vaccine storage temperatures.

Dormitory-Style Units

CDC does not recommend storage of any vaccine in a dormitory-style (or bar-style) combined refrigerator/freezer unit under any circumstances. A dormitory-style refrigerator is defined as a small combination refrigerator/freezer unit that is outfitted with one exterior door and an evaporator plate (cooling coil), which is usually located inside an icemaker compartment (freezer) within the refrigerator. The 2009 NIST research concluded that "the dorm-style refrigerator is NOT recommended for vaccine storage under any circumstance." In performance testing, the dormitory-style refrigerator demonstrated consistently unacceptable performance, regardless of where the vaccine was placed inside the unit. This type of unit exhibited severe temperature control and stability issues. Large spatial temperature gradients confirmed that there is no "good" vaccine storage area in this style unit.[1] Dormitory-style (or bar-style) units pose a significant risk of freezing vaccine even when used for temporary storage. Please note that the use of dormitory-style units for storage of VFC vaccines or other vaccines purchased with public funds is prohibited. There

are compact, purpose-built storage units for biologics that are not considered to be dormitory-style or bar-style.

Dormitory-style (or bar-style) combined refrigerator/freezer units should NOT be used for any storage of any vaccine.

Dormitory-style (or bar-style) units pose a significant risk of freezing vaccine even when used for temporary storage.

Storage Unit Placement

Good air circulation around the vaccine storage unit is essential for appropriate 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, there should be at least 4 to 6 inches (10 to 15 cm) of space between the grid or coils and the wall. If there are no coils on the back, there should still be at least 4 to 6 inches (10 to 15 cm) of clearance between the unit and the wall to allow air circulation. Check the owner's manual to verify minimum spacing for the unit. 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 firm and level and that the wheels or leveling legs are adjusted so that the bottom of the unit is 1 to 2 inches (2.5 to 5 cm) above the floor. Refer to the equipment owner's manual provided by the manufacturer for additional guidance on placement.

There should be at least 4 to 6 inches (10 to 15 cm) of clearance between the unit and the wall to allow air circulation.

Required Temperature Ranges for Storage Units

Refrigerator

The refrigerator should maintain temperatures between 35°F and 46°F (2°C and 8°C). The temperature should never fall below 35°F (2°C) or rise above 46°F (8°C). 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 should maintain temperatures between -58°F and +5°F (-50°C and -15°C).

Setting and Stabilizing the Temperatures in Storage Units

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." Consult the owner's manual for instructions on how to operate the thermostat.

Refrigerator unit thermostat

Freezer unit thermostat

In general, thermostats do not show temperatures, but rather the levels of coldness. The only way to know what the temperature is where the vaccine is stored is to measure it with a calibrated thermometer. Continue monitoring the temperature of the unit using a calibrated thermometer to assure that the vaccines are not exposed to inappropriate temperatures.

Adjusting the Storage Unit Temperatures

Only the primary or alternate vaccine coordinator should adjust the temperature of a vaccine storage unit. 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). Limiting

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

access to the thermostat reduces the risk that the temperatures will be adjusted inappropriately. In some situations, the thermostat may need to be reset in summer and winter, depending on the ambient room temperature. If the thermostat requires adjustment, alert the vaccine coordinator or immediate supervisor.

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

Use caution in adjusting a thermostat. Normal defrost cycles and busy workdays can lead to slight temperature variations that are not necessarily indicative of inappropriate vaccine temperatures. First, be sure the unit is plugged into a power source. Then check the temperatures inside the refrigerator and/or freezer unit(s). Next, data from continuous data loggers should be checked to verify that a temperature reset is appropriate.

To adjust the temperature and avoid exceeding the required temperature range, turn the thermostat knob slowly, making small adjustments toward a warmer or colder setting as necessary. 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 unit temperature around 40°F (5°C). Make sure the temperature remains between 35°F and 46°F (2° C and 8°C). Aim to stabilize the freezer unit temperature between -58°F and +5°F (-50°C and -15°C).

If you are using the refrigerator compartment of a combination unit to store refrigerated vaccine, note that this type of unit has 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 compartment. 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 risk of freezing the refrigerated vaccines. It is for this reason that it is recommended to only use the refrigerator compartment of a combination unit for vaccine storage. Vaccine storage in the freezer compartment should be avoided.

Frequent temperature monitoring of both the freezer and refrigerator units throughout the day, at the beginning and end of each workday, and whenever

thermostats are adjusted is required. It may take 2 to 7 days to stabilize the temperature between 35°F and 46°F (2°C and 8°C) in a newly installed or repaired refrigerator. Likewise, it may take 2 to 3 days to stabilize the temperature between -58°F and +5°F (-50°C and -15°C) in a newly installed or repaired freezer. Allow one week of twice daily refrigerator and freezer temperature recordings, including minimum/maximum temperatures daily (preferably in the morning) to make sure temperatures are within the appropriate ranges before using the units to store vaccines.

Allow one week of twice daily refrigerator and freezer temperature recordings, including minimum/maximum temperatures daily (preferably in the morning) to make sure temperatures are within the appropriate ranges before using the units to store vaccines.

Vaccine should never be stored in a unit that cannot maintain the required temperature range. Identify an alternate unit to temporarily store the vaccine. It should be able to maintain the appropriate temperature range and have sufficient space to store the vaccines.

Stabilizing the Temperatures with Water Bottles and Frozen Coolant Packs

You can help stabilize the temperature in the refrigerator by keeping at least two or three large containers of water inside. Store water bottles labeled "Do NOT drink" against the inside walls and in the door racks. You can help stabilize the temperature in the freezer by keeping frozen coolant packs inside. Store the frozen coolant packs along the walls, back, and bottom of the freezer and inside the racks of the freezer door. Frozen coolant packs in the freezer door and water containers in the refrigerator door should be placed securely so they cannot dislodge and prevent unit doors from closing. In addition, caution must be taken to avoid weighing down a door so much that the seal is compromised when the door is closed. Not only will water bottles and frozen coolant packs help maintain even

Stabilize the temperature in a freezer with frozen coolant packs.

Stabilize the temperature in a refrigerator with water bottles labeled "Do NOT drink."

temperatures in the storage unit with frequent opening and closing of the doors, they will also help to keep the temperatures stable in the event of a power failure.

Opening the Door

Limit the number of times the vaccine storage unit door is opened and avoid letting the door stand open unnecessarily. Not only does this affect the temperature in the unit, it also exposes the vaccines to light, which can reduce the potency of some vaccines (see CDC's Vaccine Storage and Handling Guide for vaccine-specific recommendations). Routinely check the refrigerator and freezer doors throughout the day and at the end of each workday to ensure they are tightly closed.

Deli, Fruit, and Vegetable Drawers

Remove any deli, fruit, and vegetable drawers from the refrigerator. Removing the drawers not only provides extra space for storing containers of water, but it also removes the temptation to use the drawers for storage of food, beverages, or vaccines. Food and beverages should not be stored in a vaccine storage unit. Vaccines should not be stored near the floor or in the deli, fruit, or vegetable drawers because the temperature in these areas is different from that in the body of the refrigerator. For more information on best storage practices for refrigerated vaccines, see NIST Guidance on Storage of Refrigerated Vaccine in the Resources section.

Vaccines and diluent should not be stored near the floor or in the deli, fruit, or vegetable drawers because the temperature in these areas 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 a storage unit has remained within the appropriate range is to frequently read and document the temperature using a calibrated thermometer.

Storage Unit Maintenance

General Principles

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

The most important action to take if vaccine storage units are not working properly is to protect the vaccine supply. If the problem is short term (usually 2 hours or less) and depending on ambient room temperature, the temperatures in the storage units can probably be maintained with water containers in the refrigerator, with frozen coolant packs in the freezer, and by keeping the unit doors closed. If there is an extended period of time before the situation can be corrected and there are no other storage units available on site, the vaccines should be moved to the back-up storage facility using the guidelines in the Emergency Vaccine Retrieval and Storage Plan (see the Storage and Handling Plans section). After this is accomplished, attempt to find the cause of the problem and correct it (see the Storage Troubleshooting section). Do NOT allow vaccines to remain in nonfunctioning units for an extended period of time while you attempt to resolve a problem.

Keep a logbook for each piece of vaccine cold chain storage equipment to document routine maintenance tasks and repairs. See Equipment Logbook 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 appliances. Maintenance tasks can be divided into daily, monthly, and periodic actions.

Daily Maintenance Tasks

Read and document the internal temperature.

- It is a requirement for VFC providers (and a recommendation for all providers) that storage unit temperatures be read using a calibrated thermometer and

documented twice each workday; once in the morning and once before leaving at the end of the workday, and;

- While not a requirement, it is highly recommended that minimum/maximum temperatures be read and documented once per day, preferably in the morning. Reviewing the minimum/maximum temperatures helps to ensure that temperature excursions will be identified more quickly and corrections made that can prevent vaccine loss, as well as minimize the inaccuracy of generalizing twice daily measurements.

The temperature readings should be documented on a temperature log. The temperature log should be posted on the door of the storage unit. If a temperature is outside the recommended range, the vaccine coordinator or supervisor should be notified without delay. **Immediate corrective action** must be taken (see Handling Inappropriate Vaccine Storage Conditions (Light and Temperature) in the Storage Troubleshooting section). More frequent temperature readings may be necessary and are required following thermostat adjustments. Ensure that the temperature in each unit has stabilized before leaving for the day.

Check that each unit door is closed.

To maintain the internal temperature within the recommended range, the vaccine storage unit door must fit securely and tightly against the unit. The rubber-like seal that runs around the inner edges of the door contains magnets that help hold the door closed and create a tight seal, keeping cold air inside. Check that the door is properly sealed each time it is closed by giving a gentle tug on the door handle. The door should also be checked at the end of each workday to make sure it is tightly closed and sealed.

Monthly Maintenance Tasks

Clean the coils and motor.

At least once each month, the coils and motor of each storage unit should be examined and cleaned (check manufacturer specifications for cleaning and maintenance schedules). Dust and dirt build-up affect 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

Refrigerator Coils

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 the workday. Accidentally damaging the coils will cause a problem that may not be detected until the following workday.

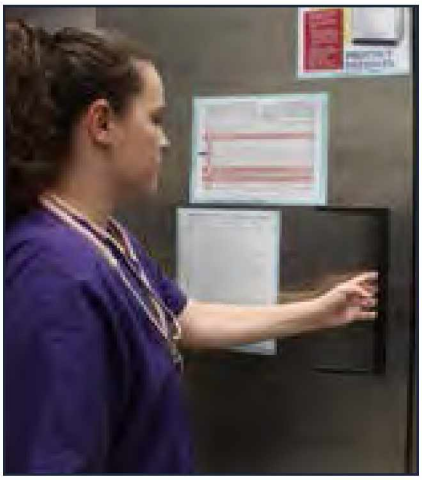
This process should only take a few minutes; therefore, it is not necessary to transfer vaccines to another storage unit as long as the door remains tightly closed for the duration of the procedure. If cleaning will take longer than the expected few minutes, activate the Emergency Vaccine Retrieval and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

Clean the refrigerator and freezer units.

Clean the refrigerator and freezer units every month to discourage bacterial and fungal growth. Remove vaccines from the unit and store them in another functioning unit (see Emergency Vaccine Retrieval and Storage Plan in the Storage and Handling Plans section for details). Alternatively, vaccines may be stored temporarily in appropriately packed coolers. Consult your immunization program (or other agency), herein referred to as the "immunization program," as appropriate for your situation, for policies regarding vaccine packing and procedures for maintaining the vaccine cold chain. 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 before restocking with vaccine.

Check the door seal.

Once a month, perhaps while cleaning each storage unit, check the integrity of the rubber-like door seal on each unit. The seal should not be torn or brittle and there should be no gaps between the seal and the body of the unit when the door is closed. The door should open and close properly and fit squarely against the body of the storage unit. For this to happen, the hinges must be correctly adjusted. If there are any problems with a door seal, see Assessing the Storage Unit Door Seal in the Storage Troubleshooting section. Consult a trained repair technician as necessary and monitor temperatures carefully.



Check that each storage unit door is properly sealed every time it is closed and at the end of each workday.

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

General Recommendations

Thermometers are a critical part of good storage and handling practice. A storage unit is only as effective as the temperature monitoring system inside. Accurate temperature history that reflects actual vaccine temperatures is imperative to effective vaccine management. Every freezer and refrigerator unit used to store vaccine should have a calibrated thermometer. For more information on best storage practices for refrigerated vaccines, see NIST Guidance on Storage of Refrigerated Vaccine in the Resources section.

Immunization programs are often excellent resources for information on thermometers. Providers who receive VFC vaccines or other vaccines purchased with public funds should consult their immunization program regarding recommendations or requirements for thermometers.

Calibrated Thermometers

For measuring vaccine storage unit temperatures, CDC recommends using only calibrated thermometers with a Certificate of Traceability and Calibration Testing (also known as Report of Calibration). This certificate informs the user of a thermometer's level of accuracy compared to a recognized standard.

CDC recommends using only calibrated thermometers with a Certificate of Traceability and Calibration Testing (also known as Report of Calibration). Calibrated thermometers are a requirement for providers who receive VFC vaccines or other vaccines purchased with public funds.

Thermometer calibration must be tested annually or according to the manufacturer's recommendation by a laboratory with accreditation from an International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) signatory body. Laboratories that have attained this accreditation meet the requirements for traceability. Providers are responsible for maintaining certificates of calibration (see box below for links to lists of accredited testing laboratories). Calibrated thermometers are a requirement for providers who receive VFC vaccines or other vaccines purchased with public funds.

Follow links for listings of accredited laboratories:
The American Association for Laboratory Accreditation (A2LA)
http://www.a2la.org/dirsearchnew/newsearch.cfm
Laboratory Accreditation Bureau (L-A-B)
http://www.l-a-b.com/content/directory-accredited-labs
ANSI-ASQ National Accreditation Board (ACLASS)
http://www.aclasscorp.com/search-accredited-companies.aspx
International Accreditation Service (IAS)
http://www.iasonline.org/Calibration_Laboratories/CL.html
Perry Johnson Laboratory Accreditation, Inc.(PJLA)
http://www.pjlabs.com/search-accredited-labs
A listing of signatory bodies outside of the U.S. can be found on the ILAC website:
https://www.ilac.org/members_contact_details.html

Because all thermometers are calibrated as part of the manufacturing process, this recommendation refers to a second calibration process that occurs after manufacturing but before marketing, and is documented with a certificate that comes with the product. When choosing a thermometer, look for high accuracy, +/-1°F (+/-.5°C). This information should be contained in the Certificate of Traceability and Calibration Testing (also known as a Report of Calibration).

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

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

In addition, NIST notes:

- Traceability records should not be claimed to be private or proprietary knowledge.

- Laboratory accreditation is not a guarantee of traceability, but accreditation does provide assurance that qualified assessors have looked at a laboratory's traceability procedures.

All thermometers experience "drift" over time that affects their accuracy. When the Certificate of Traceability and Calibration Testing (also known as a Report of Calibration) expires, CDC recommends one of the following:

- Have the accuracy of your thermometer tested by an accredited laboratory
- Purchase a new thermometer with a Certificate of Traceability and Calibration Testing (also known as a Report of Calibration)
- Contact your immunization program for resources on checking the accuracy of your thermometer

UNITED STATES DEPARTMENT OF COMMERCE
National Institute of Standards and Technology

REPORT OF CALIBRATION

Fixed Point | Temperature | Expanded Uncertainty

Ar TP
Hg TP
H2O TP
Sn FP
Zn FP
Al FP

Coefficients for Zero-Power Resistance Calibration | Coefficients for Self-Heating Calibration

Dean C. Ripple
Leader, Thermometry Group
Process Measurements Division

September 14, 2007

Example of Thermometer Certificate of Traceability and Calibration Testing (also known as a Report of Calibration). This could be a multiple page document.

If calibration testing indicates that your thermometer is no longer accurate within, +/-1°F (+/-.5°C) then your thermometer should be replaced. Adjustments to correct the accuracy of the thermometer are not recommended.

If a thermometer is dropped or hit against the side of the storage unit, CDC recommends that at minimum, the thermometer be checked for accuracy against a known calibrated thermometer. Mishandling a thermometer can affect its accuracy. If there is any uncertainty about a thermometer's accuracy, it should be sent for calibration testing or a new thermometer should be obtained.

Some thermometers require batteries. If you use one of these, have a supply of extra batteries on hand. If you change a battery (this does not include an alarm battery) in a thermometer, it is recommended that the thermometer undergo calibration testing through an accredited laboratory as described above.

Refer to manufacturer guidelines for specific information on calibration testing. Calibration testing schedules vary, but the generally agreed upon industry standard is for annual testing. For many types of thermometers, purchasing a replacement thermometer may be less expensive than calibration testing.

Immunization programs are often excellent resources for information on calibrated thermometers. Providers who receive VFC vaccines or other vaccines purchased with public funds should consult their immunization program regarding the required timeframe for thermometer recalibration.

A thermometer costing a few dollars is not worth the risk of damaging thousands of dollars worth of vaccines because of inaccurate readings. In the long run, it is better to invest in a better-quality, more reliable calibrated thermometer because it is more cost-effective than replacing vaccine.

If a properly positioned calibrated thermometer indicates an out-of-range temperature, take immediate steps to safeguard the vaccines (see Handling Inappropriate Vaccine Storage Conditions (Light and Temperature) in the Storage Troubleshooting section). Once the vaccines are safely stored under appropriate conditions, the cause of the problem can be determined (see Storage Troubleshooting section) and corrected.

Types of Thermometers

To ensure that refrigerators and freezers are maintaining the appropriate temperatures for vaccine storage, each unit should have a calibrated thermometer. Temperatures for each unit should be read and documented a minimum of twice each workday, including recording the minimum and maximum temperatures once each day. The temperature data, regardless of whether using paper or downloaded files, should be kept in a safe, retrievable place for at least 3 years. Several types of thermometers can be used to monitor the temperatures within vaccine storage units.

Before purchasing any temperature monitoring equipment, check with your immunization program for resources and information on thermometers acceptable for vaccine storage use.

CDC recommends thermometers with the following characteristics:

1. Provide continuous monitoring information with an active display.
2. Be a digital thermometer with a probe in a glycol-filled bottle.
3. Include an alarm for out- of- range temperatures.
4. Have a reset button if using a data logger with a min/max display.
5. Be capable of showing current temperature as well as minimum and maximum temperatures.
6. Be within +/-.5°C accuracy (+/-1°F).
7. Have a low battery indicator.

Based on studies of thermometers conducted by NIST in 2009, CDC recommends using a digital thermometer with a detachable probe that is kept in a glycol-filled bottle. A detachable probe facilitates downloading temperature data without removing the probe from the storage unit. NIST studies demonstrated that these probes in glycol-filled bottles can more closely approximate the vaccine vial temperature when placed in the same area where the vaccine is stored.[1]

Temperature Probes

CDC recommends thermometers that employ temperature probes. Probes are available in two forms: a standard probe that will measure air temperature and a biosafe glycol-encased probe (i.e., probe suspended in glycol) that will measure liquid temperature. Glycol-encased probes can provide a more accurate reading of actual vaccine temperature and are therefore recommended by CDC. Standard probes that measure air can be easily affected by short fluctuations in air temperature in the unit such as cycling and frequent opening and closing of the unit doors during busy workdays.

CDC recommends that temperature data, regardless of whether using paper or downloaded files, should be kept in a safe, retrievable place for at least 3 years.

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

CDC recommends using temperature monitoring devices that allow for the main device to remain outside of the storage unit as this allows for reading temperatures without opening the unit door. The main device is attached to the internal temperature probe through a narrow cable (usually 1 to 3 meters long) with the probe placed in glycol and positioned near the vaccine. To download data, the main unit can be easily disconnected from the cable, leaving the probe inside the storage unit.

Main monitor is outside storage unit

Probe in glycol bottle inside unit is attached by cable to main monitor

Probe in glycol bottle is placed in proximity to vaccines

CDC recommends having a back-up temperature probe for each vaccine storage unit, in the event that something happens to the primary temperature probe or if the primary probe needs to be sent to a laboratory for calibration. The back-up probe should have the same set up as the primary set up (i.e., temperature probe in glycol). In addition, CDC recommends that the back-up probe have a different calibration schedule than the primary probe so that your back-up is available when the primary probe is sent for calibration.

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

Recommended Temperature Monitoring Devices for Vaccine Storage Units

CDC recommends using a continuous temperature monitoring device for each storage unit that provides a digital display of the internal storage unit temperature including min/max temperatures and current temperature. These types of

thermometers are preferred as they can provide an indication of the length of time a storage unit has been operating outside the recommended vaccine storage temperature range, whenever a temperature excursion occurs. Continuous monitoring refers to the thermometer's ability to track and record temperatures over time. Unlike a simple min/max thermometer, which provides only information about the warmest and coldest temperature that was reached; the continuous monitoring device provides detailed information on all temperatures recorded at preset intervals. There is a variety of devices available ranging from inexpensive small data loggers to more technologically advanced systems that can be monitored on site or remotely monitored; summarizes information; provides cumulative time and temperature data; provides graphical depictions of data; employs wireless capability and functionality; and has different types of alarms including visible or audible. Contact your immunization program for resources and information on thermometers acceptable for vaccine storage units.

CDC recommends using a continuous temperature monitoring device for each storage unit that provides a digital display of the internal storage unit temperature including min/max temperatures and current temperature.

Digital Data Loggers

CDC recommends using digital data loggers for continuous temperature monitoring in vaccine storage units. These miniature electronic devices may be programmed to record temperatures at intervals throughout the day, with the frequency of reading set by the user. Digital data logger thermometers are capable of recording hundreds or even thousands of individual temperature readings.

Digital data loggers come in many shapes, sizes and styles and are typically battery operated. They are often simple to use and have a number of beneficial features. Choose a model that is capable of displaying the current temperature, as well as the minimum and maximum temperatures. Some models have an alarm that can be set to ring at a specified temperature. An alarm that rings outside the storage unit is preferable as it is readily noticed and can be responded to quickly. Digital units

work by storing continuous temperature data in the device's memory. This stored data can then be downloaded into a computer for review and archive.

Digital data logger thermometers used for vaccine storage are accompanied by special software that is installed on 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. To review the temperature history, the user must download data from the digital data logger thermometer on a regular basis. Even if you do not have a computer to download data to, these devices are still helpful in monitoring temperatures twice daily, as well as providing minimum and maximum temperatures since the last reading. When digital data logger thermometers are used in vaccine storage, CDC recommends that temperatures displayed on the unit are still read and documented a minimum of twice each workday, as well as the minimum and maximum temperatures since the last reading, to determine if temperatures are out of range.

Digital data logger thermometers have a variety of features in addition to their basic recording function. All contain a probe that is used to detect temperature readings. As stated previously, CDC recommends the use of glycol-encased probes, rather than air probes, because they provide a more accurate reading of actual vaccine temperature. Some digital data logger thermometers have digital displays showing the current and min/max temperatures in the storage unit, as well as current ambient air temperature outside the storage unit. This display may not use the same temperature sensor as the recorder. Some data logger thermometers have an audible alarm to alert the user to out-of-range temperature conditions. Other data logger thermometers 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 thermometer's visual or audible alarm activates with the minimum or maximum temperature out of range, CDC recommends that **immediate corrective 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.

If a data logger thermometer's visual or audible alarm activates with the minimum or maximum temperature out of range, CDC recommends that immediate corrective 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.

In addition, the digital data logger should have the following:

- Hi/Lo alarm for out-of-range temperatures;
- Current temperature, as well as minimum and maximum temperatures;
- Reset button ;
- Low battery indicator;
- Accuracy of +/- 1°F (0.5°C);
- Memory storage of at least 4000 readings, device will not rewrite over old data and stops recording when memory is full;
- User programmable logging interval (or reading rate).

Thermometers that are Not Recommended

Fluid-filled biosafe liquid thermometers, bi-metal stem thermometers, food thermometers and household mercury thermometers are NOT recommended for monitoring temperatures. These thermometers can have significant limitations in vaccine temperature monitoring. They can be difficult to read and only indicate the temperature at the precise time they are read. Therefore, temperature fluctuations outside the recommended range may not be detected.

Chart recorders are more difficult to read than digital thermometers because they require interpretation of the temperature graph. In addition, the chart paper must be changed when it is filled and there is insufficient room to record readings. Failure to change the chart paper will result in unusable temperature data. If a facility does not have access to a computer, however this paper based logger may be the only other choice for continuous temperature monitoring.

The recent increase in popularity of infrared thermometers (IR thermometers) has raised questions about the value of these devices in monitoring vaccine storage temperatures. An IR thermometer is a thermometer that detects the infrared radiation emitted by an object in order to determine its temperature. These thermometers are sometimes called laser thermometers or non-contact

thermometers because they can measure temperature from a distance. A NIST review of IR thermometers demonstrated that these devices are not reliable or accurate for assessment of vaccine storage temperatures.

Do not use thermometers that are not calibrated. Generally, thermometers obtained in hardware and appliance stores are not calibrated instruments and are designed to monitor temperatures for domestic food storage. These thermometers are not accurate enough and can pose a significant risk to losing expensive vaccine.

CDC does not recommend the following thermometers for monitoring vaccine temperatures:

- Fluid-filled biosafe liquid thermometers
- Bi-metal stem thermometers,
- Food thermometers,
- Household mercury thermometers,
- Chart recorders,
- Infrared thermometers, and
- Thermometers that are not calibrated

Thermometer Placement

Thermometer placement within the unit is just as important as thermometer selection. Prior to storing vaccines in a unit, determine where the most reliable and consistent temperature readings are. The thermometer should be in proximity to the vaccines being stored. Refer to Vaccine and Diluent Storage Locations and Positioning in the Vaccine Storage Practices section to help determine where the vaccine and the thermometer should be placed. Thermometers should not be placed in the doors, near or against the walls, close to vents, or on the floor of the unit. A thermometer can inadvertently be displaced during a busy workday. Ensure appropriate placement of the thermometer in each unit with daily inspection of each storage unit.

A thermometer can inadvertently be displaced during a busy workday. Ensure appropriate placement of the thermometer in each unit with daily inspection of each storage unit. Proper placement is very important since it helps the provider to most accurately identify the actual vaccine vial temperature and to take immediate corrective action if necessary.

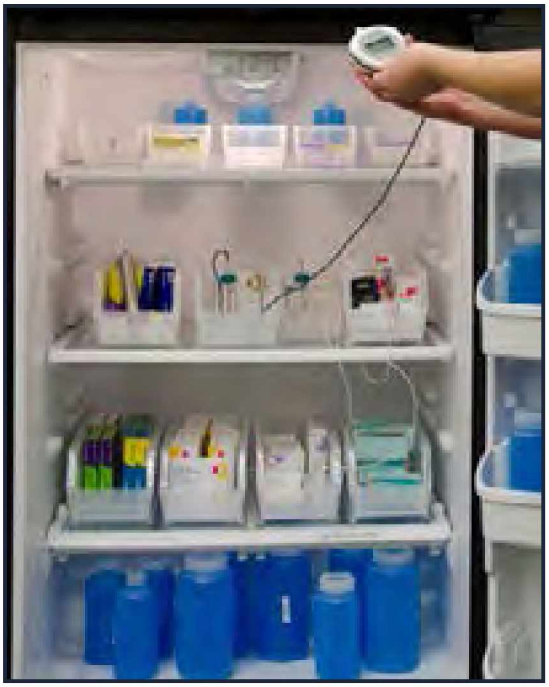
Based on studies of thermometers conducted by NIST in 2009, CDC recommends using a digital thermometer with a detachable probe that is kept in a glycol-

filled bottle. The NIST studies demonstrated that these probes can most closely approximate the actual vaccine vial temperatures when placed in the same area where the vaccine is stored.[1]

Air temperature within a refrigerator, particularly the refrigerator compartment of a standard combination household unit, can fluctuate with the defrost cycles of the unit, opening and closing the door frequently, air circulation patterns, etc. The measurements provided by the ambient air thermometer could lead someone to interpret changes in air temperature to mean that the vaccine temperature is out of range.

However, vaccines are more thermostable than air because they are fluid-filled and thus have a larger thermal mass. Some thermometers, particularly those that measure air temperature, are more sensitive to temperature fluctuations than the fluid-filled vaccine vials, which have a larger thermal mass.

Recent studies of vaccine storage equipment conducted by NIST found that the "actual vial temperatures were not greatly affected by the defrost cycle, but that some of the other thermometers (particularly those measuring air) indicated significant temperature increases." According to NIST, some thermometers are more sensitive to temperature fluctuations than the fluid-filled vaccine vials. If a staff member were to read one of these thermometers during a refrigerator's standard defrost cycle, which produces a brief air temperature spike, he or she might determine that the vaccines had exceeded the allowed temperature limit. During testing conducted by NIST and published in 2009, it was found that actual vial temperatures were not greatly affected by the defrost cycle, but that some of the other thermometers indicated significant temperature increases. Some of the thermometers that were "attached to walls or hanging in the air recorded dramatic temperature spikes followed by a significant drop well below the 2°C limit."[1]



Digital thermometer with probe in glycol-filled bottle

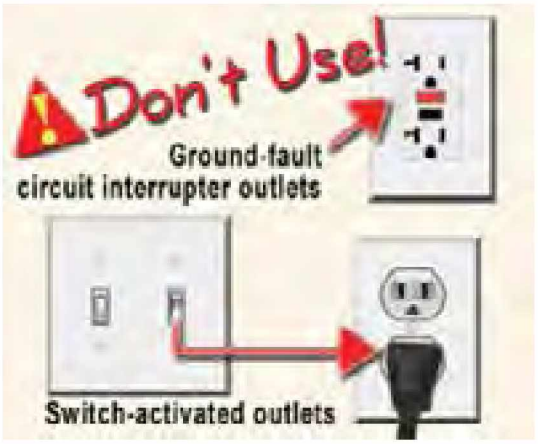
Vaccine Security

Protecting the Power Supply

To keep a storage unit temperature within the appropriate 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), outlets that can be activated by a wall switch, or power strips. 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 a unit becoming inadvertently unplugged.
- Post a warning sign at the plug and on the refrigerator and freezer units alerting staff, janitors, electricians, or any workers not to unplug the units.
- Label the fuses and circuit breakers to alert people not to turn off the power to the storage units. 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.

- Consider installing a temperature alarm to alert staff to after-hours temperature excursions, 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 may be considered, especially for practices with a large vaccine 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 temperature excursions. 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.

These systems are not fool proof. Large vaccine losses and the need to revaccinate have occurred despite using alarmed, continuous monitoring systems. Issues around untrained personnel who do not know how to read the monitor, unexpected events, poor monitoring and response procedures, equipment failure, and improper maintenance have all been implicated in these vaccine storage events.

CDC continues to recommend that at a minimum vaccine storage unit temperatures be read manually and documented twice daily, including minimum/maximum temperatures daily (preferably in the morning), regardless of whether there is a temperature alarm or where the readout occurs. This provides assurance that the equipment is working correctly and if an alarm system should fail or a response process is not correctly followed, the issue will be identified quickly. ⚠ **Immediate corrective action** can then be taken that may save vaccines. Providers who receive VFC vaccines or other vaccines purchased with public funds should contact their immunization program for further guidance.

Continuous-monitoring temperature alarm/notification systems

Back-up Generators

Facilities storing large vaccine inventories should consider installing back-up generators that automatically provide power to the storage units to maintain the recommended storage temperatures in the event of power outages. Back-up generators should be tested quarterly and should receive maintenance at least annually (check manufacturer specifications for test procedures and maintenance schedules). Back-up 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.

Back-up generators

1. **Chojnacky, M. J.; Miller, W. W.; Ripple, D. C.; Strouse, G. F.; Thermal Analysis of Refrigeration Systems Used for Vaccine Storage**; November 02, 2009; http://www.nist.gov/manuscript-publication-search.cfm?pub_id=904574.

Appropriate Vaccine and Diluent Storage Conditions

Vaccines Stored in a Freezer

Varicella-containing vaccines (MMRV, VAR, and HZV) must be stored in a freezer between -58°F and +5°F (-50°C and -15°C) until reconstitution and administration. These vaccines can deteriorate rapidly after they are removed from the freezer. Measles, mumps, and rubella vaccine (MMR) can be stored in a refrigerator or in a freezer. Storing MMR in a freezer can free up space in the refrigerator. In addition, storing MMR in a freezer can decrease confusion when storing both MMR and MMRV. MMRV must be stored in a freezer.

Vaccines Stored in a Refrigerator

All other routinely recommended vaccines should be stored in a refrigerator between 35°F and 46°F (2°C and 8°C), with a desired average temperature of 40°F (5°C). Exposure to temperatures outside this range may result in reduced vaccine potency and increased risk of vaccine-preventable diseases.

Vaccine Light Sensitivity

Vaccines should be kept in their original packaging with the lids in place until ready for administration to protect them from sunlight and fluorescent light.

Several vaccines must be protected from light. Vaccines should be kept in their original packaging with the lids in place until ready for administration to protect them from sunlight and fluorescent light. Storing vaccines outside of their packaging leads to administration errors when staff is confused about vaccines, and makes managing inventory and tracking expiration dates more difficult.

Lyophilized (Freeze-Dried) Vaccines and Diluents

MMR, MMRV, VAR, and HZV diluent is packaged separately from the corresponding lyophilized (freeze-dried) vaccine and can be stored at room temperature or in the refrigerator. Diluents packaged separately from their corresponding vaccines may be stored at room temperature (as long as they do not contain any antigen) or in the refrigerator. Diluents that contain antigen or that are packaged with their vaccines

(e.g., DTaP-IPV/Hib and MCV4 [Menveo]) should be stored in the refrigerator next to their corresponding vaccines. Never store any diluents in the freezer.

- **Diluents packaged separately from their corresponding vaccines may be stored at room temperature (as long as they do not contain any antigen) or in the refrigerator.**
- **Diluents that contain antigen or that are packaged with their vaccines (e.g., DTaP-IPV/Hib and MCV4 [Menveo]) should be stored in the refrigerator next to their corresponding vaccines.**

Vaccine and Diluent Storage Locations and Positioning

Best and worst locations for vaccine storage can vary with different types of refrigerators and freezers. A best practice is to place vaccine in the central area of the storage space and keep vaccines in their original packaging inside storage trays positioned 2 to 3 inches away from storage unit walls.

Freezers

Vaccines should be stored away from the walls and vents in the part of the freezer best able to maintain the required temperature range (between -58°F and +5°F (-50°C and -15°C). Vaccines should not be stored in the freezer door. The temperature in the door is not stable and differs from that inside the unit. Frozen coolant packs can be stored in the freezer door.

Note: Frozen coolant packs can be stored in the freezer door..

Refrigerators

In the refrigerator, vaccines should be placed away from the walls, floor, and vents in the part of the unit best able to maintain the required temperature between 35°F and 46°F (2°C and 8°C). Vaccines should not be stored in the deli, fruit, and vegetable drawers, in the door, or on the floor of the unit. The temperature and/or air flow in these areas may not be stable and may expose vaccines to inappropriate storage temperatures. If the refrigerator of a combination unit is used, the top shelf of the refrigerator compartment may be colder than the recommended temperature range because of cold air venting on it from the freezer compartment. If the top shelf of the refrigerator must be used to store vaccine, place water bottles in the vaccine bins closest to the vent and only store vaccine that is not sensitive to the coldest temperatures (e.g., MMR).

The freezer compartment should not be used and the thermostat should be adjusted to avoid temperatures below 35°F (2°C). Refrigerated vaccines should always be stored far enough away from the air vent to avoid freezing the vaccines. Freezing destroys many vaccines quickly, so care should be taken to avoid freezing the vaccines.

Air vents and water bottles

Water bottles on unit floor

Water bottles in unit door

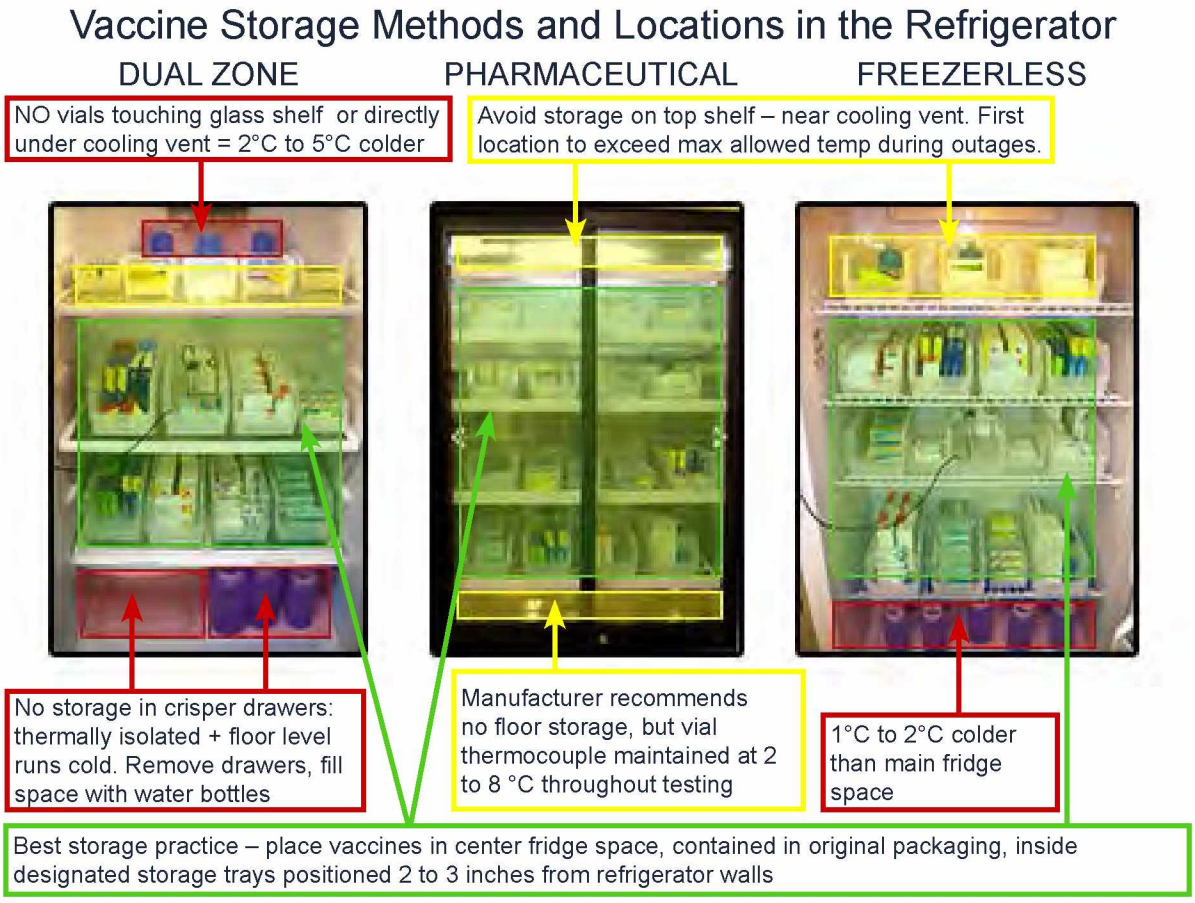
Vaccine Spacing

To allow for cold air circulation around the vaccines, there should be space between the vaccines and the storage unit walls and between each large package, block, tray, or bin of vaccines. Adequate cold air circulation helps each vaccine reach a consistent temperature throughout its mass, and is necessary for the storage unit to maintain a consistent temperature. Packing any vaccine storage unit too tightly can negatively affect the temperature.

Vaccine Packaging

Vaccine products that have similar packaging should be stored in different locations within the storage unit 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. Label pediatric and adult versions of the same vaccine clearly to avoid confusion. For example, DTaP and Tdap vaccines might be easily confused, as might Hib and HepB vaccines.

Removing vaccines from their original packaging and repackaging them (e.g., brown plastic bag) is not recommended. Separating vaccines from their original packaging can increase the risks for storage, handling, and administration errors. Manufacturer product information could be misplaced and repackaged vaccines may not be labeled appropriately or easy to read.



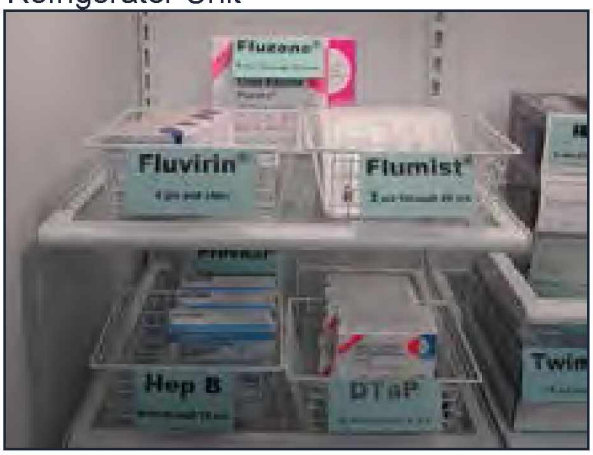
Best and worst locations for vaccine storage can vary with different types of refrigerators and freezers. A best practice is to place vaccine in the central area of the storage space and keep vaccines in their original packaging inside storage trays positioned 2 to 3 inches away from storage unit walls.

Labeling

The location of each specific vaccine type inside the storage unit should be clearly labeled. This can be accomplished by attaching labels directly to the shelves on which the vaccines are placed or by labeling containers in which packages of the same vaccine type are placed. Storing each vaccine type in its own specifically-labeled section of the refrigerator or freezer helps decrease the chance that someone will inadvertently administer the wrong vaccine. Label pediatric and adult versions of the same vaccine clearly to avoid confusion (see CDC's Vaccine Labels for Storage Unit).

Freezer Unit

Refrigerator Unit



Attach labels directly to the shelves on which the vaccines are placed, 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 (beyond use date [BUD]). The BUD varies among vaccines (see CDC's Vaccine Storage and Handling Guide for specific vaccine product information). This may not correspond to the expiration date printed on the vial by the manufacturer. For example, multidose vials of MPSV4 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 strategy helps to reduce vaccine waste.

Diluents should be stored according to the manufacturers' instructions. Diluents should be clearly labeled, whether they are stored at room temperature or in the refrigerator. Label the packages 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. See the Immunization Action Coalition's Vaccines with Diluents: How to Use Them in the Resources section for details.

Diluents packaged separately from their corresponding vaccines may be stored at room temperature (as long as they do not contain any antigen) or in the refrigerator.

Storage Containers

Vaccine and Diluent Packages

To avoid confusion, vaccine and diluent packages should be stored together by type and arranged in rows. Vaccines and diluents should be stacked according to expiration dates. Vaccines and diluents with the shortest expiration dates should be closer to the front of the storage unit for easy access. Store all opened and unopened vaccines and diluents in their original packaging inside the appropriate storage unit so that the contents and expiration dates

Store all opened and unopened vaccines and diluents in their original packaging inside the appropriate storage unit.

are easily identifiable. Storing loose vaccine and diluent vials outside of their packaging is not recommended. This practice makes managing inventory and tracking expiration dates more difficult, increases administration errors when staff is confused about vials, and exposes the vaccines to light. Some diluents can be stored at room temperature (if they do not contain any antigen), separate from their corresponding vaccines. In this case, always assure that the correct diluent is used with the correct vaccine.

Trays and Containers

Trays and uncovered containers may be used to organize vaccine and diluent packages. Each tray or uncovered container should only contain vaccine or diluent of the same type. If other medications and biologic products must be stored in the vaccine storage unit, they must not be stored on the trays or in the containers with vaccine or diluent. This practice helps avoid medication errors. Clearly label the tray or container with the name of the vaccine or diluent, and place packages of that type on the tray or in the container inside the appropriate storage unit. Trays and containers must not be stacked or placed so closely together that air circulation inside the storage unit is impeded.

Storage of Non-Vaccine Products

Food and Beverages

Never store food or beverages inside a 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 unit. Some facilities provide a separate, well marked refrigerator for employee food and beverages. As an added precaution, some facilities store a back-up probe in glycol or other similar buffered temperature probe in the employee refrigerator, in the event that something goes wrong with the primary temperature probe.

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

Medications and Other Biologic Products

If possible, other medications and biologic products should not be stored inside the vaccine storage unit. If there is no other choice, these products should 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.

Reading and Documenting Temperatures

CDC recommends the routine vaccine storage and handling plan include reading and documenting storage unit temperatures a minimum of twice each workday, as well as the minimum/maximum temperatures daily (preferably in the morning). This best practice recommendation can prevent inadvertent loss of vaccine and the potential need for revaccination by assuring that temperature excursions are identified quickly so that **immediate corrective action** can be taken. This also provides an opportunity to visually inspect the storage unit, reorganize any vaccines that are inadvertently misplaced, and remove any expired vaccines.

This best practice recommendation applies to all vaccine storage units, regardless of whether or not there is a temperature alarm, a digital data logger thermometer, or a chart recorder thermometer. These readings will provide a better indication of any problems with the storage unit's function.

CDC recommends the use of a continuous monitoring device/digital data logger to record and store temperature information at frequent programmable intervals for 24-hour temperature monitoring. The digital data logger should be connected to a detachable thermometer probe encased in a biosafe glycol-filled vial. The data logger's active digital display should be attached to the outside of the storage unit to allow reading temperatures without opening the unit door. This allows the thermometer probe to remain in place and not be disturbed during data reading and recording.

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

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

Best practices include:

1. Post a temperature log or other appropriate recording document on each storage unit door.
2. Read the thermometers in both the refrigerator and freezer units a minimum of twice each workday, at least once in the morning and once before leaving at the end of the workday.
3. Read the minimum/maximum temperatures in both the refrigerator and freezer units a minimum of once each workday, preferably in the morning.
4. Document the readings in both the refrigerator and freezer units on temperature logs each time the thermometers are read.
5. Record the times of the thermometer readings and the initials of the person who took the readings.
6. If a temperature reading is missed, the log entry should remain blank.
7. Download and review stored continuous monitoring data at least weekly.

Any temperature readings outside the recommended ranges (Refrigerator – between 35°F [2°C] and 46°F [8°C]; Freezer – between -58°F [-50°C] and +5°F [-15°C]) is a temperature excursion. However, it is the total amount of time, or cumulative time, out of range that affects the viability of vaccine. For example, if your temperature probe shows that the temperature of a refrigerated vaccine rose to 48°F (9°C) for 10 minutes in the morning and 5 minutes in the afternoon, the cumulative time out of range was 15 minutes.

If, at any time, appropriate vaccine storage temperatures are in question, it is important to contact the vaccine manufacturer for further guidance to determine whether or not the vaccine can be used because the characteristics that determine vaccine viability vary for each lot of vaccine. If you are a VFC provider, please contact the vaccine manufacturer and/or your state/local health department immunization program as directed by the VFC program in your area. When contacting the manufacturer or immunization program, you should be prepared to provide them with data from the temperature logs and/or the digital data logger so they can offer you the best guidance (see Temperature Excursion Checklist in the Resources section).

Reviewing Temperature Recording Data

If other staff are monitoring and documenting the temperatures, the primary vaccine coordinator should review the temperature recording data weekly to ensure appropriate temperature documentation. If the vaccine coordinator is the person monitoring and documenting the temperatures, the alternate vaccine coordinator should review the data weekly.

The primary vaccine coordinator should review the logs weekly to ensure appropriate temperature documentation.

Noting Equipment Failures and Room Temperatures

The date and time of any mechanical malfunction or power outage should be documented. This information may be documented on the temperature log or on some other document (for example, the Emergency Vaccine Retrieval and Storage Plan Worksheet in the Resources section). As with inappropriate storage temperatures, immediate corrective action must be taken to correct these situations (see Handling Malfunctioning Vaccine Storage Units in the Storage Troubleshooting section and Power Outages in the Storage and Handling Plans section).

If a mechanical malfunction or power outage has occurred, the temperature within the affected storage unit(s) and the ambient room temperature where the vaccine storage unit(s) is kept should be documented.

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

Maintaining Data from Temperature Logs and Continuous Monitoring Device

Maintain an ongoing file of temperature logs and continuous recording thermometer graph or digital data logger information for each storage unit. Keep this data for 3 years or according to individual state record retention requirements. Do not discard temperature logs before 3 years. As a vaccine storage unit ages, you can track recurring problems or identify how long problems have existed by referring to this data.

Maintain an ongoing file of temperature logs and continuous recording thermometer graph or digital data logger information for each storage unit. Keep this data for 3 years or according to individual state record retention requirements.

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 fall outside the recommended ranges (see Temperature Alarms in the Vaccine Storage Equipment section). If alarm systems are used, temperatures should still be read and documented twice daily, including minimum/maximum temperatures daily (preferably in the morning).

If alarm systems are used, temperatures should still be read and documented twice daily, including minimum/maximum temperatures daily (preferably in the morning).

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 exposure to storage temperatures outside the recommended ranges. This action should be documented and should include:

- Date and time of occurrence;
- Ambient room and storage unit temperatures;
- Description of the problem;
- Action taken;
- Outcome; and
- Initials of the person documenting the incident.

You may use the back of the temperature log to document this information.

If you become aware of inappropriate vaccine storage conditions (light and/or temperature), the following steps should be taken:

1. Notify the primary or alternate vaccine coordinator immediately of any vaccine storage unit temperature that is outside the recommended range (temperature excursion). If the primary coordinator or alternate coordinator is not available, report the problem to an immediate supervisor.
2. Document the ambient room temperature and the temperature inside the affected storage unit(s) at the time the problem is discovered. Also note minimum and maximum temperature readings in the unit(s).
3. Document the length of time the vaccines may have been exposed to inappropriate storage temperatures or inappropriate light exposure. The temperature information should be available to download from a digital data logger.
4. Conduct an inventory of the vaccines affected by this event and document the actions taken.

Notify the primary or alternate vaccine coordinator immediately of any vaccine storage unit temperature that is outside the recommended range.

5. Note if water bottles were in the refrigerator and frozen coolant packs in the freezer at the time of the event.
6. Label the vaccines "DO NOT USE." A clearly labeled paper bag can be used for this purpose. This will reduce risk of inadvertently using vaccines that may have reduced potency because they were stored under inappropriate conditions.
7. Immediately store the vaccines under appropriate conditions separate from other vaccine supplies. If your vaccine storage unit(s) is not maintaining the appropriate storage conditions, activate the Emergency Vaccine Retrieval and Storage Plan (see Storage and Handling Plans).
8. Contact the vaccine manufacturer for further guidance. If you are a VFC provider, please contact the vaccine manufacturer and/or your state/local health department immunization program as directed by the VFC program in your area.
9. Do not discard vaccines unless directed to by your immunization program and/or the manufacturer(s).

You may use the Emergency Vaccine Retrieval and Storage Plan Worksheet in the Resources section to help organize your response. Consult your immunization program (or other agency), as appropriate for your situation, for any special instructions or forms.

If vaccines have been exposed to inappropriate storage temperatures because of a refrigerator or freezer malfunction, follow the directions above and refer to the troubleshooting flow charts and instructions below.

Handling Malfunctioning Vaccine Storage Units

General Instructions

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

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

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

The most important step to take if a vaccine storage unit is not working properly is to protect the vaccine supply. Do not allow the vaccines to remain in a nonfunctioning

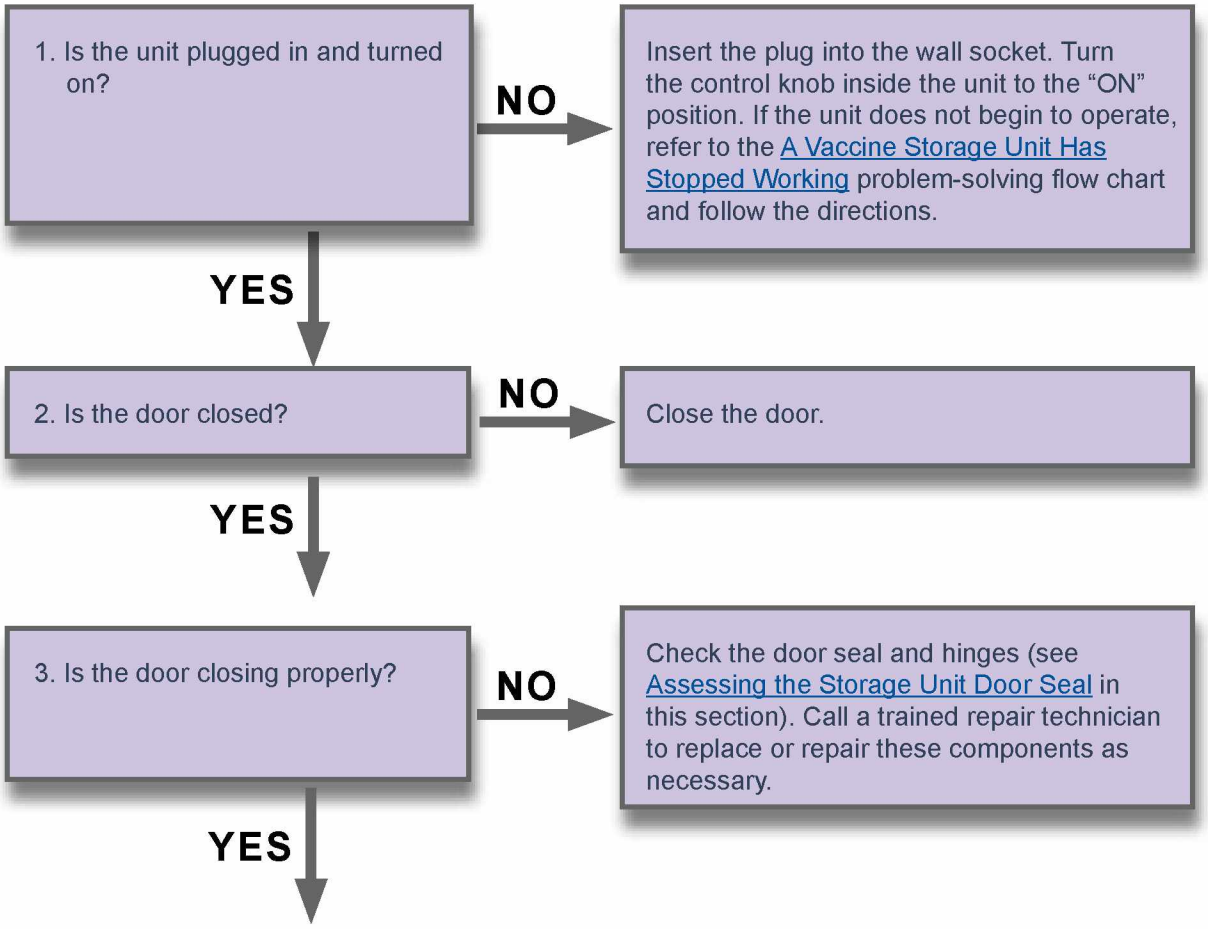
unit for an extended period of time (in general, more than 2 hours) while you attempt to correct the problem. If at any time you are unsure how long a storage unit will not be functioning properly or you determine that the problem cannot be corrected in time to maintain the internal temperature within the recommended range, activate the Emergency Vaccine Retrieval and Storage Plan (see the Storage and Handling Plans section).

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:

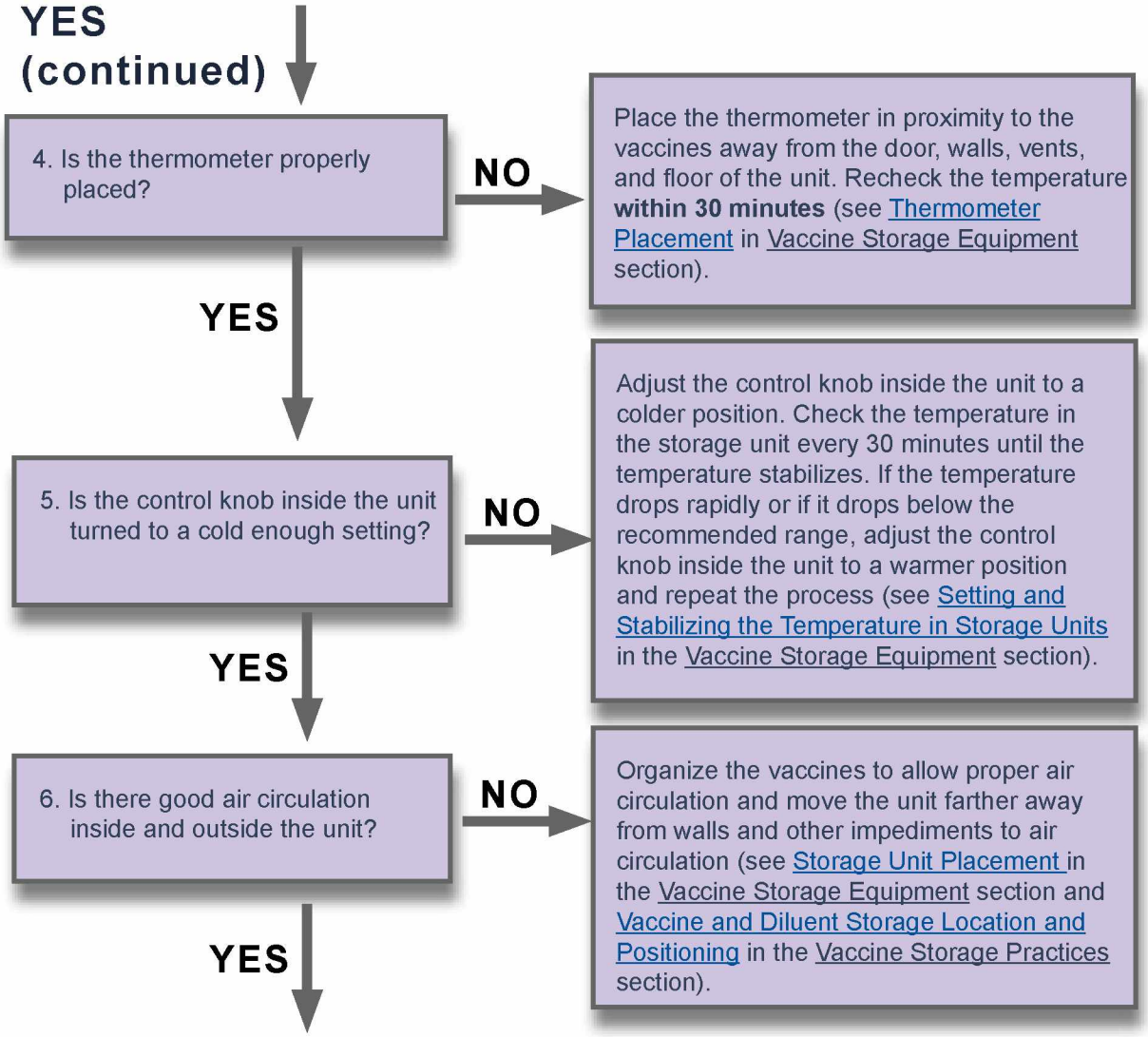
1. Document the ambient room temperature and the temperature inside the affected unit when the problem is discovered. Also conduct an inventory of all vaccines affected by the event (see Handling Inappropriate Vaccine Storage Conditions (Light and Temperature) in this section).
2. Always start with the 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 a storage unit is still not working properly after completing all the steps in the flow chart:
   a. Call a trained repair technician to examine the faulty equipment.
   b. If you have not yet done so, transfer the vaccines to 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. Document in the vaccine storage unit logbook all the checks you made and the actions taken (see Equipment Logbook in the Vaccine Storage Equipment section). This will help the technician identify the problem with a storage unit.
6. Refer to the Equipment User's Guide for instructions on handling malfunctions in a storage unit.

A Vaccine Storage Unit is Too Warm

Warning ⚠ immediate corrective action must be taken. Do NOT allow the vaccines 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 a 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 the Storage and Handling Plans section).



A Vaccine Storage Unit is Too Warm (continued)



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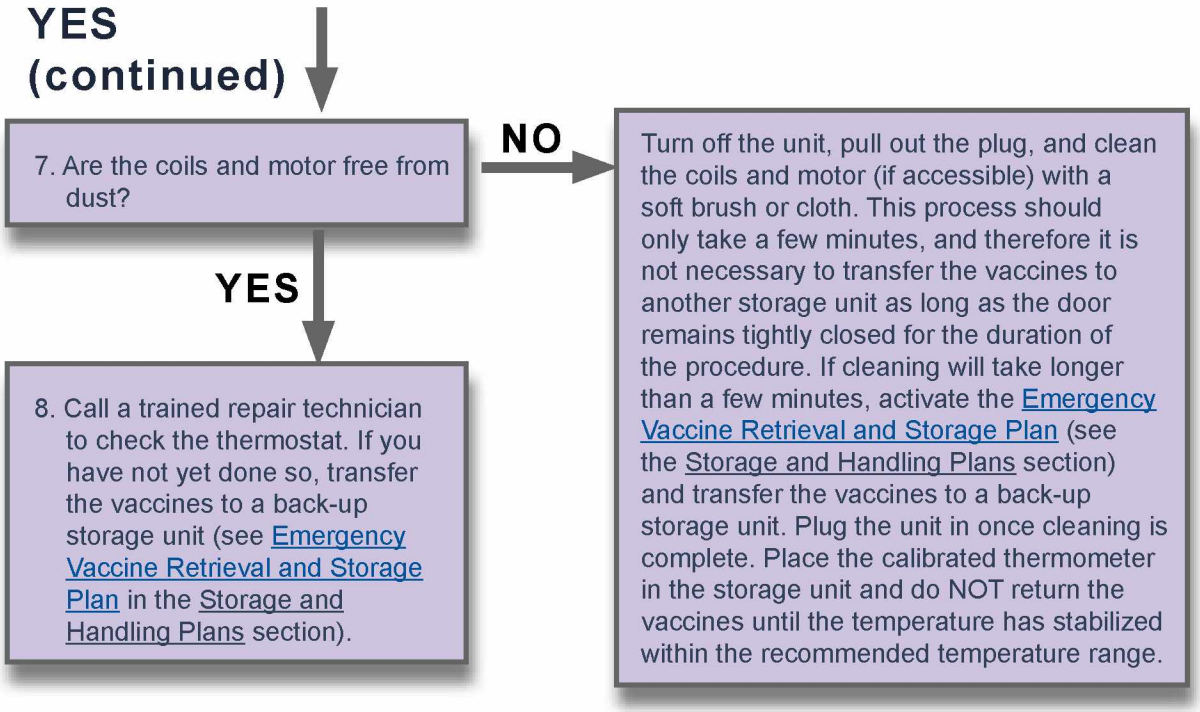
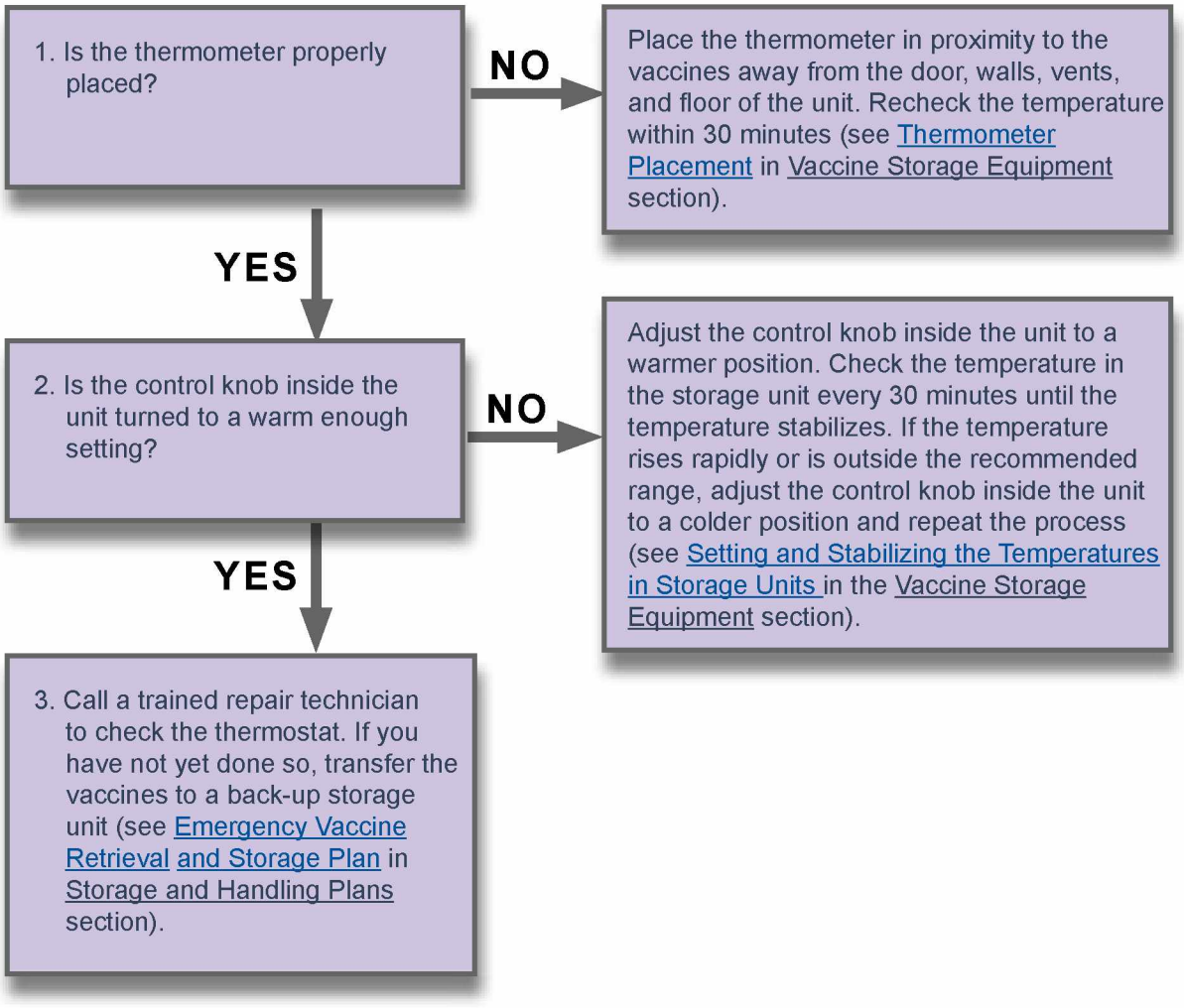


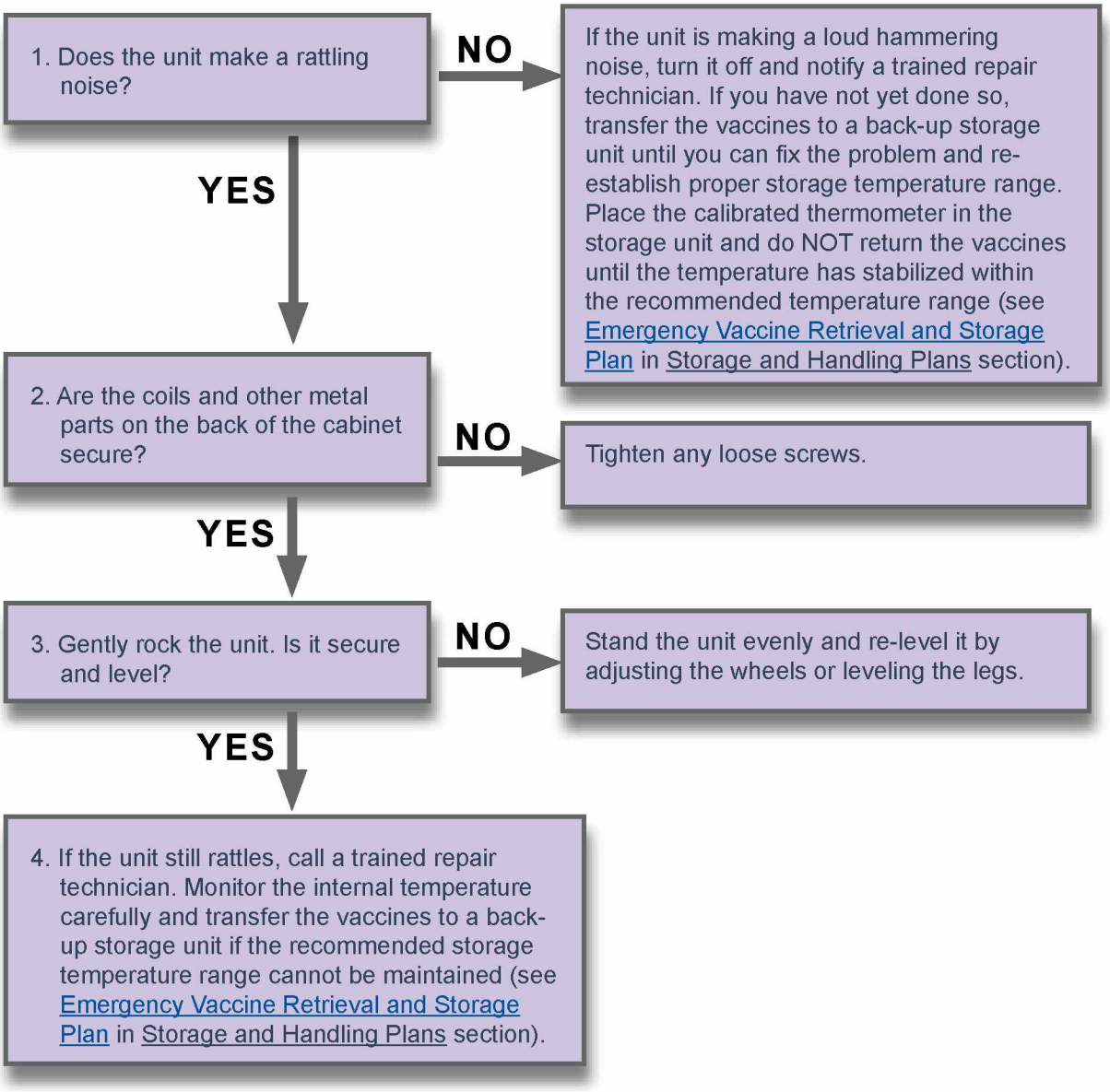
A Vaccine Storage Unit is Too Cold

Warning ⚠ immediate corrective action must be taken. Do NOT allow the vaccines 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 a 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 the Storage and Handling Plans section).



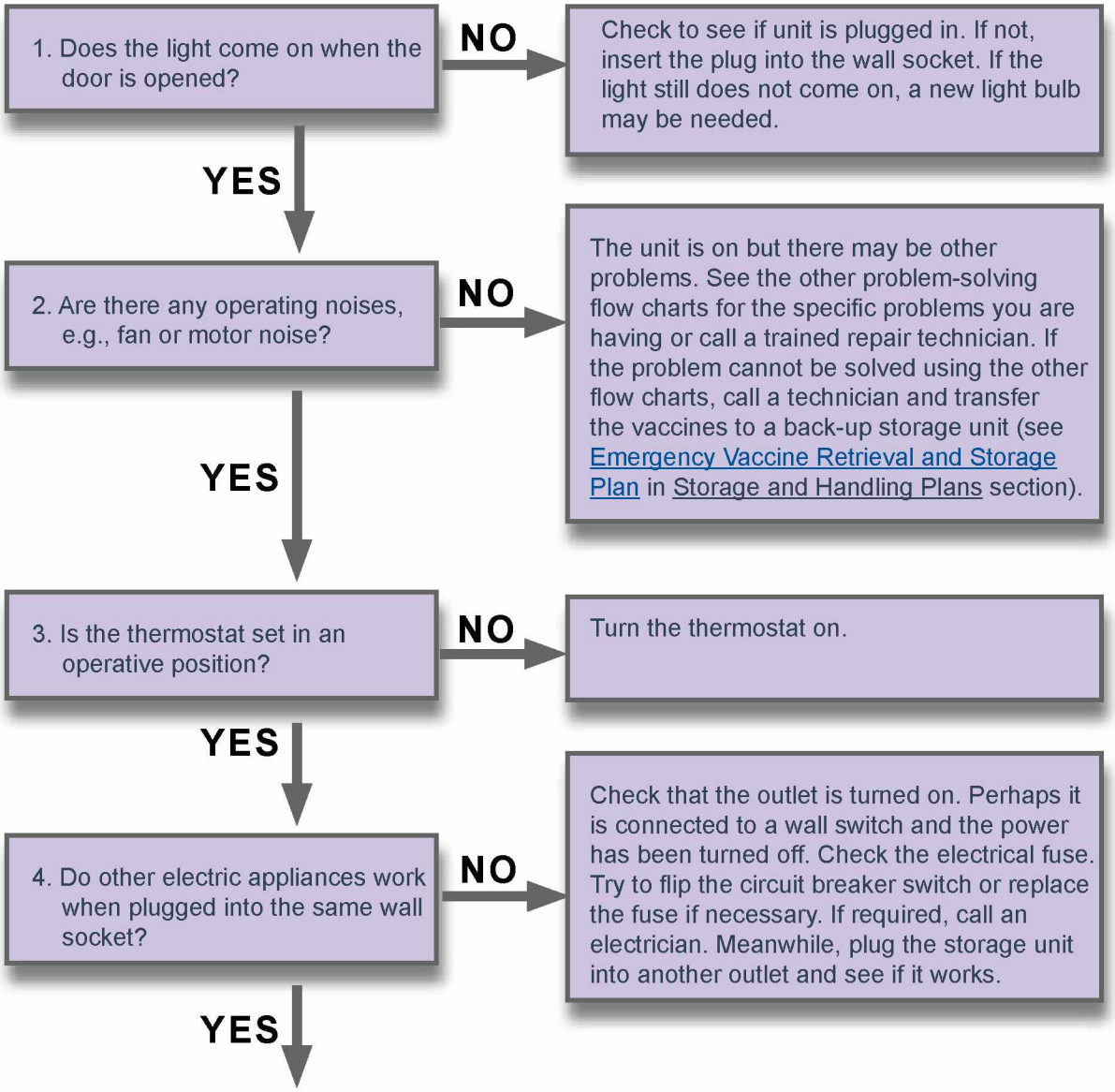
A Vaccine Storage Unit is Too Noisy

Warning ⚠ immediate corrective action must be taken. Do NOT allow the vaccines 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 a 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 the Storage and Handling Plans section).

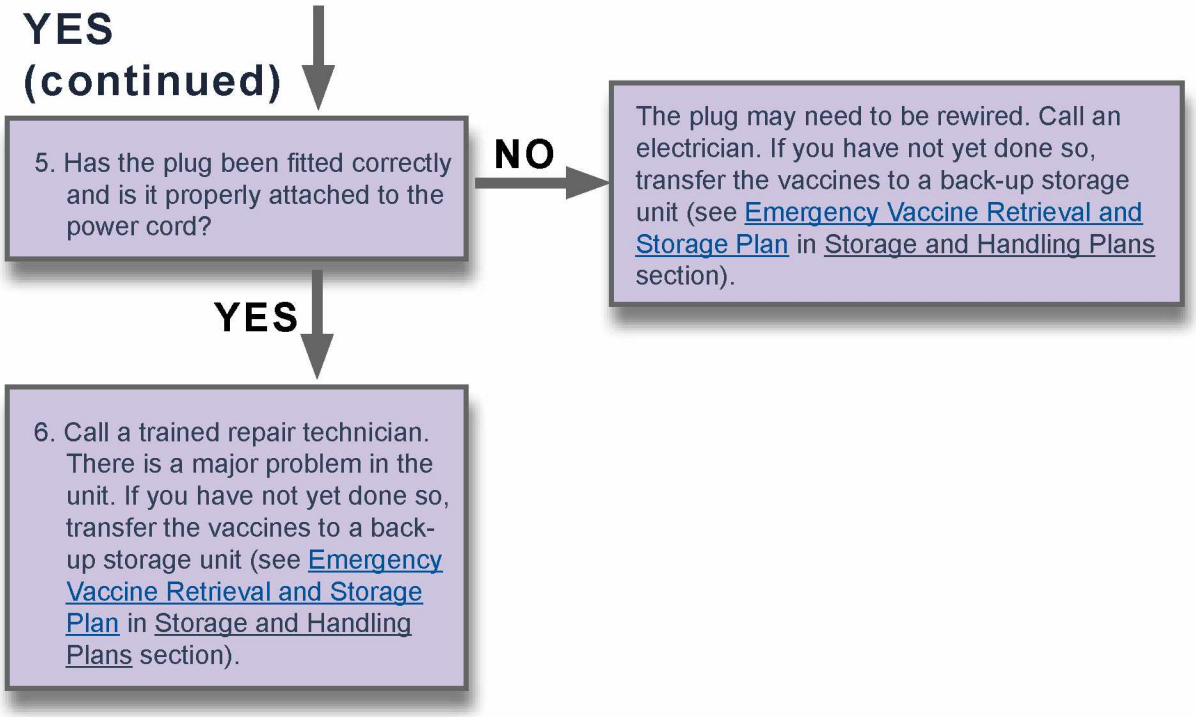


A Vaccine Storage Unit has Stopped Working

Warning ⚠ immediate corrective action must be taken. Do NOT allow the vaccines 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 a 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 the Storage and Handling Plans section).



A Vaccine Storage Unit has Stopped Working (continued)



Assessing the Storage Unit 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.
5. Based on this assessment, if a problem with the door seal or hinges is suspected, contact a trained repair technician.

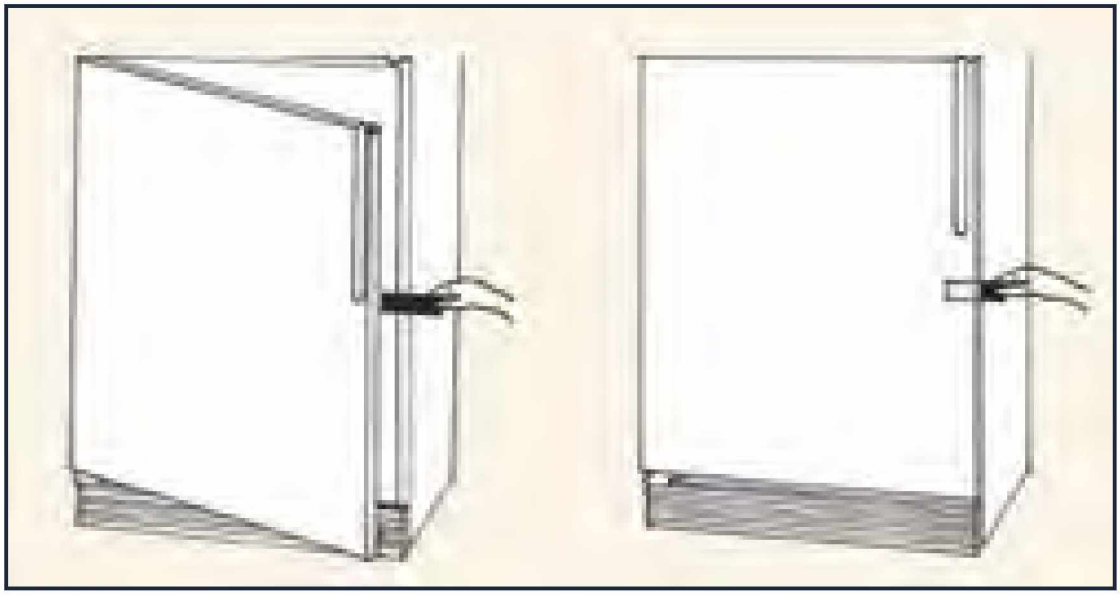


Illustration 1—Checking the door seal
(Adapted from the User's Handbook for Compression Refrigerators WHO/EPI/LOG/84/15)

Thermometer Problems

Checking Thermometer Placement

If the thermometer indicates a temperature outside the recommended range, check that the thermometer is appropriately placed. The location of the thermometer should be in proximity to the vaccines being stored. If the thermometer is placed near the walls, floor, or vent, it may indicate colder or warmer temperatures than a thermometer appropriately placed. Proper placement is very important since it helps

the provider to most accurately identify the actual vial temperatures and to take immediate corrective action if necessary.

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 Repeated Alarm Alerts

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

Vaccine Access

Only authorized personnel should have access to the vaccine supply. This will help protect the vaccine supply by avoiding inappropriate removal of vaccines or inappropriate handling of vaccines and vaccine storage units by untrained personnel.

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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 packages. 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 manufacturer's product information. 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. Any unused vaccine or diluent should NOT be used after this month has passed.

Vaccine Expiration Date
08/16/13
Note: Use through
August 16, 2013.
DO NOT use on or after
August 17, 2013.

Vaccine Expiration Date
08/13
Note: Use through
August 31, 2013.
DO NOT use on or after
September 1, 2013.

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

Some vaccines expire within a certain time after opening or after reconstitution (beyond use date [BUD]). The BUD is the date or time after which the vaccine should NOT be used. This is determined from the date or time the manufacturer-filled syringe is activated, the vial is entered, or the vaccine is reconstituted. The BUD may be different than the expiration date. The BUD varies among vaccines (see CDC's Vaccine Storage and Handling Guide for specific vaccine product information).

What to Do with Expired and Mishandled Vaccines and Diluents

Expired vaccines and diluents should **NEVER** be administered, even if it is only 1 day past the expiration date. **Expired vaccines and diluents should be removed IMMEDIATELY from the vaccine storage unit(s)**.

If a dose of expired vaccine is inadvertently administered, the dose generally should not be counted as valid and should be repeated. Inactivated vaccines should be repeated as soon as possible. Live vaccines should be repeated after a 28-day interval from the invalid dose.

As a general rule, vaccines that have been mishandled or stored at inappropriate temperatures should not be administered. Vaccine exposed to inappropriate temperatures that has been inadvertently administered generally should be repeated. In these situations, clinicians should consult with the vaccine manufacturer(s) and/or the state/local health department immunization program for guidance.

Contact your immunization program, vaccine supplier, or vaccine manufacturer(s), as appropriate for your situation, for specific policies regarding the disposition of expired or mishandled vaccines. If the expired or mishandled vaccines were VFC vaccines or other vaccines purchased with public funds, contact your immunization program for guidance.

Exceptions to the Expiration Date

The expiration date printed on each vial or package is based on the assumption that 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 vaccine cold chain. The expiration date printed on each vial or package may also change once the vial is opened or reconstituted (see Expiration of Different Vaccine Presentations in this section).

Transferring Vaccines and Diluents that Cannot Be Used Before Expiration

The vaccine cold chain must be carefully maintained, especially during transport. If transport of vaccine is necessary, consult the vaccine manufacturer(s) and/or your immunization program for guidance (see Transporting Vaccines in an Emergency or to Off-Site Facilities in the Vaccine Shipments section for details).

Expiration of Different Vaccine Presentations

Multidose pre-mixed vaccine vials contain bacteriostatic agents that prevent the growth of bacteria. These vaccines may be used until the expiration date printed on the vial unless they become contaminated, in which case the vaccine should be removed from the storage unit.

Single-dose vials and manufacturer-filled syringes are meant for one-time use only. They do not contain bacteriostatic agents that prevent bacterial growth. Once the protective cap on a single-dose vial has been removed, it may not be possible to determine if the rubber seal has been punctured. Therefore, do not open a single-dose vial until it is time to use it. To avoid needless waste of vaccine, always check the vial before removing the cap to make sure the correct vaccine has been selected, and remove the cap only when it is time to draw up and administer the vaccine. Once a manufacturer-filled syringe is activated (i.e., syringe cap removed or needle attached) the sterile seal is broken and the vaccine should be administered. An unused single-dose vial without the protective cap or an activated manufacturer-filled syringe should be discarded at the end of the workday.

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

Once a lyophilized (freeze-dried) vaccine has been reconstituted, it must be used within a specified time frame or discarded. Consult the manufacturer's product information (package insert) for the most up-to-date information about expiration times and dates following reconstitution. (See vaccine-specific "Beyond Use Date Shelf Life after Opening" in CDC's Vaccine Storage and Handling Guide. Unused reconstituted vaccine kept beyond this limit should NOT be administered. The best way to avoid waste is to reconstitute and draw up vaccine immediately before administration (see Immunization Action Coalition's Vaccines with Diluents: How to Use Them in the Resources section).

Vaccine Stock Rotation

When new shipments arrive, vaccines should be unpacked immediately. The local practice vaccine coordinator should ensure that someone checks and rearranges the placement of vaccine and diluent supplies in the storage unit according to the expiration dates on a weekly basis and each time a vaccine shipment arrives. The vials and packages with the earliest expiration dates should be placed in front of other vials and packages of the same type of vaccine 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 the expiration date. Expired vaccines and diluents should **NEVER** be administered. **IMMEDIATELY** remove expired vaccines and diluents from the storage unit(s) to avoid the risk of inadvertent use.

Expired vaccines and diluents should NEVER be administered. IMMEDIATELY remove expired vaccines and diluents from the storage unit(s) to avoid the risk of inadvertent use.

Vaccine Inventory Accounting

General Recommendations

Vaccine inventory accounting is important for efficient vaccine management. Proper vaccine inventory management means knowing the following:

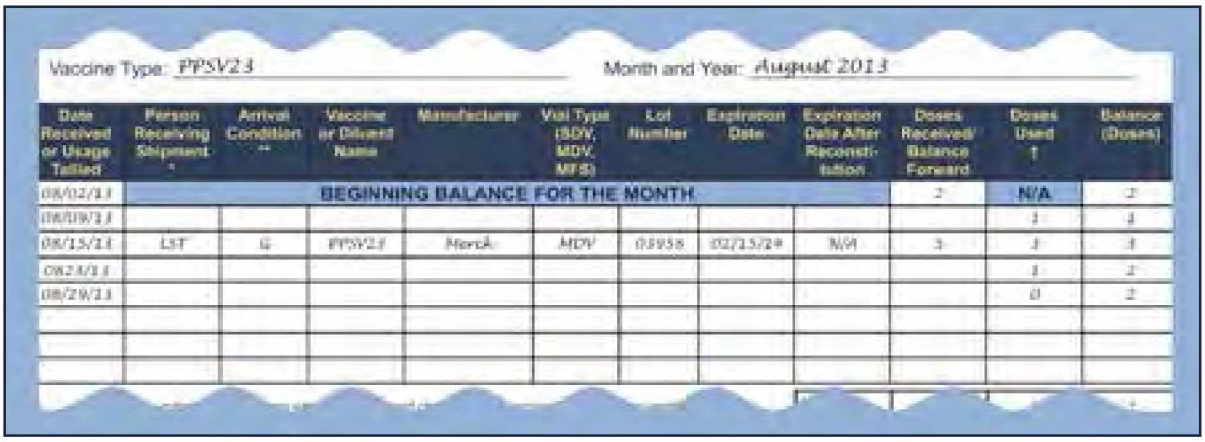
- The quantities of vaccines and diluents that have been received;
- The quantities of vaccines and diluents that have been administered, wasted, or spoiled;
- Which vaccines and diluents are currently in stock;
- Which vaccines and diluents should be used first;

- Which vaccines and diluents are expired and must be removed from inventory;
- Which vaccines and diluents need to be ordered.

Vaccine Stock Records

Some immunization programs have developed vaccine stock records or other vaccine inventory protocols and procedures. Contact your immunization program for information about vaccine stock records and follow their recommendations. If stock records are not available from your immunization program, a Sample Stock Record is available in the Resources section of this toolkit. This Sample Stock Record includes the components that should be on a vaccine stock record. There is also a blank version of the Stock Record available in the Resources section.

Maintaining complete and accurate vaccine stock records is a critical component of vaccine inventory management. All vaccine doses removed from the unit should be recorded on the vaccine stock record and totaled by vaccine type. Tally sheets can assist the vaccine coordinator in completing a vaccine stock record (see Tally Sheets in this section). Vaccine stock records should be completed weekly. The balance of doses remaining in stock is indicated on the vaccine stock record using a tally of doses administered, wasted, spoiled, expired, or transferred during that week. A vaccine stock record that is not accurate is of no value to the vaccine coordinator, and can lead to over- or-under-stocking of vaccines and disruption to your immunization program.



Vaccine Type: PPSV23 Month and Year: August 2013

Date Received or Usage Tallied	Person Receiving Shipment *	Arrival Condition **	Vaccine or Diluent Name	Manufacturer	Vial Type (SDV, MDV, MFS)	Lot Number	Expiration Date	Expiration Date After Reconstitution	Doses Received/ Balance Forward	Doses Used †	Balance (Doses)
08/02/13	BEGINNING BALANCE FOR THE MONTH								2	N/A	2
08/09/13										1	1
08/15/13	LST	G	PPSV23	Merck	MDV	01958	02/15/24	N/A	5	3	3
08/23/13										1	2
08/29/13										0	2

Sample Stock Record

Vaccine stock records may be kept in either computerized or written formats. One of the benefits of participation in an immunization information system (IIS) is the ability

to manage vaccine inventory electronically. Keep separate records for each type of vaccine. For lyophilized (freeze-dried) vaccines that require reconstitution, document information for diluents on a separate vaccine stock record. Quantities of these vaccines and diluents should be equal at all times.

Each vaccine stock record should contain the following information:

- Date each vaccine and diluent arrived at the facility;
- Initials of the person who unpacked the vaccines and diluents upon arrival (this person should document the shipment on the vaccine stock record);
- Condition of each vaccine and diluent upon arrival (i.e., did the vaccine arrive in good condition at the proper temperature or is there concern that the vaccine may be compromised);
- Vaccine cold chain monitor readings and actions taken if monitor was triggered indicating exposure to inappropriate temperatures (see Checking the Condition of a Shipment in the Vaccine Shipments section);
- Name of each vaccine and diluent;
- Name of manufacturer of each vaccine and diluent;
- Type of vaccine presentation (i.e., single-dose vial, multidose vial, or manufacturer-filled syringe);
- Lot number(s) (note there may be more than one lot in a shipment— **each lot should be documented separately**);
- Expiration date(s) for each lot (including the new expiration dates/times based on beyond use date (BUD) guidance in the manufacturers' product information);
- Number of doses received (or the balance of doses carried forward);
- Number of doses used (i.e., administered, wasted, compromised, expired, or transferred – if vaccine is transferred, note the destination beside the number of doses);
- Balance remaining (in DOSES) after subtracting the amount used (i.e., administered, wasted, compromised, expired, or transferred).

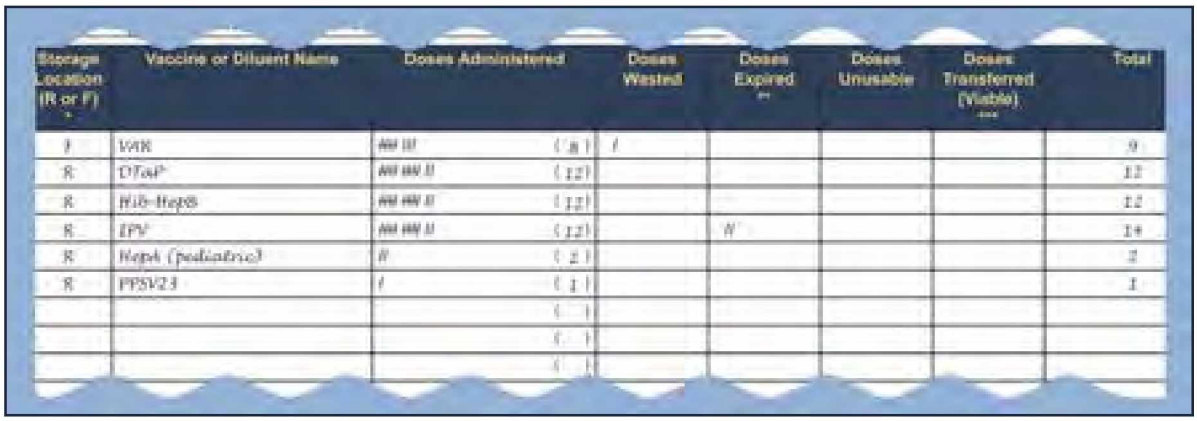
If you receive multiple doses of the same vaccine in the same presentation (i.e., single-dose vial, multidose vial, or manufacturer-filled syringe) from the same lot with the same expiration date, these doses may be documented as one entry on the vaccine stock record. Simply indicate the total number of doses received of that particular presentation (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 documented as a single entry, noting that 10 doses were received.

Tally Sheets

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

Some immunization programs have developed tally sheets or other vaccine inventory protocols and procedures (e.g., vaccine inventory management within electronic immunization information systems). Contact your immunization program for information and follow their recommendations. If there is no mechanism to document vaccine doses removed from inventory available from your immunization program, a Sample Tally Sheet is available in the Resources section. This Sample Tally Sheet includes the components that should be on a tally sheet. A blank version of the Tally Sheet is also available in the Resources section.

Tally sheets are used to document vaccine doses that were removed from the vaccine storage unit. These include doses that were administered, wasted, compromised, expired, or transferred. Each time a dose of vaccine is removed, it should be documented 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 document doses that have been removed from the storage unit, as well as the initials of the person removing the dose.



Storage Location (R or F)	Vaccine or Diluent Name	Doses Administered	Doses Wasted	Doses Expired	Doses Unusable	Doses Transferred (Viable)	Total
R	VAR	||| (8)	/				9
R	DTaP	||| ||| (12)					12
R	Hib-HepB	||| ||| (12)					12
R	IPV	||| ||| (12)		N			14
R	HepA (pediatric)	//	(2)				2
R	PPSV23	/	(1)				1
			( )				
			( )				
			( )				

Sample Tally Sheet

Tally sheets can be used to keep vaccine stock records updated. For example, place a tally sheet on the storage unit door and document 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 vaccine stock record accordingly to determine the new vaccine stock

balance. The old tally sheet should then be removed and replaced with a new tally sheet to be used for the following week. Store and maintain used tally sheets in a file for future reference.

Documenting New Vaccine Shipments

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

Documenting Administered, Wasted, Compromised, Expired, and Transferred Doses

Efficient vaccine inventory management includes an accounting of every dose of vaccine and diluent. Contact your immunization program for details about inventory accounting practices. The following discussion provides general guidelines only.

Document every dose removed from the vaccine storage unit. Document how many doses were administered, wasted, compromised, expired, or transferred. At the end of the week, the vaccine stock record should be updated to determine the amount of vaccine and diluent in inventory.

While vaccines and diluents remain in storage, expiration dates should be checked a minimum of weekly and stock should be rotated accordingly (see Expiration Dates and Vaccine Stock Rotation in this section). Immediately remove expired vaccines and diluents from the storage unit. Document 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 vaccine doses cannot be used because they have been exposed to inappropriate storage conditions or because the vials have been damaged. Once confirmed unusable by your immunization program or the manufacturer(s), immediately remove these vaccines from the storage unit. Subtract these unusable doses from the running balance on the vaccine stock record to calculate the new balance of doses. Documenting the number of vaccine doses that were expired, wasted, or compromised helps monitor vaccine waste. Contact your immunization program for instructions on how to dispose of these doses. They may have to be discarded, but sometimes unused vaccines may be returned for credit.

Sometimes vaccine manufacturers and/or immunization programs accept transfer of vaccines with short expiration dates that will expire before they can be used. Contact the vaccine manufacturer(s) and/or your immunization program for details

if such a transfer is required. For each transfer, document the details on the appropriate tally sheet and vaccine stock record. Also, document the details of the vaccines and diluents being transferred, a contact name, and a contact telephone number on the delivery note or packing slip that accompanies the shipment. This helps the recipient of the shipment know exactly what items are being transferred. It is also a good idea to include copies of the temperature logs that document the temperatures under which the vaccines and diluents have been stored.

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 vaccine doses to meet the needs of the facility, and is useful for checking the accuracy of the running balance of doses in the vaccine stock record. The number of vaccine doses in the storage unit and number of vaccine doses reflected on the vaccine stock records should match. Counting storage unit doses and conducting a monthly vaccine inventory helps providers maintain an adequate stock, helps to prevent under- or over-stocking, and provides guidance for ordering based on doses previously used.

When counting vaccine doses:

- Review the expiration dates of all stock, looking for vaccines with short expiration dates that must be used quickly and for expired vaccines that should NOT be administered.
- Promptly remove expired vaccines and diluents from the refrigerator and freezer units. Contact your immunization program and/or manufacturer(s) for specific policies regarding the disposition of expired vaccines. If the expired vaccines are VFC vaccines or other vaccines purchased with public funds, contact your immunization program for instructions on returning them. If expired vaccines cannot be returned, dispose of them appropriately (see Disposal of Vaccines and Diluents in the Vaccine Preparation and Disposal section).
- 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 vaccine 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. If there are inventory discrepancies of VFC vaccines or other vaccines purchased with public funds, contact your immunization program for guidance.

- 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 facility.

Vaccine Stock Calculations and 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 vaccines to ensure there is an adequate supply to meet the needs of the patients.** Vaccines and presentations ordered should be appropriate for the ages and types of patients the facility serves. An adequate supply for most facilities would normally be enough vaccines to last 60 days, with a re-ordering threshold of 30 days.
2. **Order smaller quantities to help prevent over-ordering and the subsequent risk of expired, wasted vaccines.**
3. **Do not over-order vaccines.** This practice leads to vaccine waste if unused vaccines expire. 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 incident (e.g., mechanical failure of the vaccine storage unit).

While vaccine orders usually arrive within 1–2 weeks, delays can occur. Avoid placing last-minute or rush orders to minimize the risk that you will run out of vaccines.

After ordering vaccines, alert your office staff that an order has been placed. The primary vaccine coordinator or designee should be notified immediately upon arrival of a vaccine shipment to ensure the vaccines are stored under appropriate conditions and the vaccine cold chain is maintained (see the Vaccine Shipments section).

Standard Operating Procedures

It is important to establish routine, systematic procedures for handling vaccine shipments.

It is important to establish routine, systematic procedures for handling vaccine shipments. Each facility should develop its own written standard operating procedures (SOPs). 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 the Storage and Handling Plans section). Without SOPs, there can be no assurance that proper procedures will be followed or that problems will be identified, reported, and corrected.

Receiving and Unpacking Vaccine Shipments

Receiving Vaccine Shipments

Arrange for vaccine deliveries to be made only when the vaccine coordinator or alternate coordinator is on duty. Consider holidays, vacations, staff schedules, and changes in hours of operation when designating vaccine delivery date and time. All staff members (including non-medical staff, e.g., receptionists and other front desk personnel) who accept vaccine deliveries must be aware of the importance of maintaining the vaccine cold chain and the need to ⚠ **immediately notify** the vaccine coordinator or alternate coordinator of the arrival of the vaccine shipment so that it can be handled and stored appropriately.

In some instances, providers may need to pick up vaccine from another facility. Coordinate with the other facility to ensure that proper procedures are followed for maintaining the vaccine cold chain. Consult your state or local immunization program.

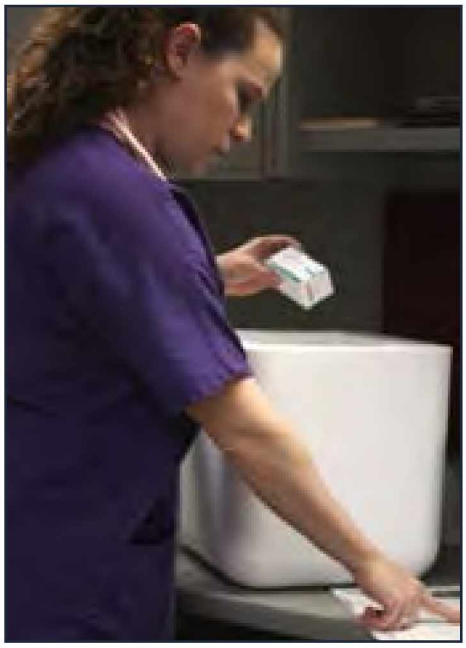
All staff members who accept vaccine deliveries must be aware of the importance of maintaining the cold chain and the need to immediately notify the vaccine coordinator or alternate coordinator upon arrival.

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 (3 days for varicella-containing vaccines). If the interval between shipment from the supplier and arrival of the product at the facility was more than these time frames, the vaccines could have been exposed to excessive heat or cold that may have altered their integrity.
- Cross-check the contents with the packing slip to be sure they match.
- Check the vaccine expiration dates to ensure that you have not received any vaccines or diluents that have already expired or will expire soon (see Expiration Dates in the Vaccine Inventory Management section).
- Check that lyophilized (freeze-dried) vaccines have been shipped with the correct type and quantity of diluents for reconstitution.
- Examine the vaccines and diluents for heat or cold damage:
  - Check the vaccine cold chain monitor(s) (CCM), if present, to determine if the vaccines or diluents have been exposed to temperatures outside the recommended range(s) during transport. Vaccines that require reconstitution and their corresponding diluents will arrive in the same shipping container. For varicella-containing vaccines, the diluents should be in a separate compartment.
  - Check that the vaccines were packed properly. There should be an insulating barrier (such as bubble wrap, Styrofoam pellets, or some other barrier) between the vaccines and the refrigerated or frozen coolant packs.

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



Cross-check the contents with the packing slip to be sure they match.

If there are any discrepancies with the packing slip or concerns about the shipment, immediately notify the primary vaccine coordinator (or the alternate coordinator). Label the vaccines "DO NOT USE" and store the vaccines under appropriate conditions separate from other vaccine supplies. Then contact your immunization program and/or vaccine manufacturer(s) for guidance.

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 vaccines and diluents at the recommended temperatures and record the arrival of each vaccine and diluent, noting all the details as outlined in the Vaccine Stock Records (see the Vaccine Inventory Management section). Do not leave the shipment unattended. The vaccines inside might warm to inappropriate temperatures and become unusable. All staff who accept packages for the facility 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 alternate coordinator) as soon as vaccine shipments arrive so that they can be stored properly.

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

Transporting Vaccine in an Emergency or to Off-Site Facilities

General Recommendations

Vaccine manufacturers do not generally recommend or provide guidance for transport of vaccines. If vaccines must be transported during an emergency or to an off-site facility, it is critical that vaccine potency is protected by maintaining the vaccine cold chain at all times. If at all possible, have vaccines delivered directly to an off-site facility. The number of times vaccines are handled and transported should be kept to a minimum. Each transport increases the risk that vaccines will be exposed to inappropriate storage conditions. If you cannot ensure that the vaccines are transported under proper conditions to maintain the vaccine cold chain, then do NOT transport vaccines unless it is an emergency.

If you cannot ensure that the vaccines are transported under proper conditions to maintain the vaccine cold chain, then do NOT transport vaccines unless it is an emergency.

If vaccines must be transported to an off-site facility, the amount of vaccines transported should be limited to the amount needed for that workday to avoid potential loss of expensive vaccines. Providers should contact manufacturer(s) and/or the state/local health department immunization program for guidance specific to their area.

The facility SOP should specify that the vaccines are:

- Attended at all times during transport;
- Not placed in the trunk of the vehicle;
- Delivered directly to the facility;
- Promptly unpacked and placed into appropriate storage units upon arrival (see Checking the Condition of a Shipment in the Vaccine Shipments section).

When transporting vaccines in a non-commercial vehicle, use the passenger compartment—not the trunk.

Multidose Vials

When a multidose vial is used, Food and Drug Administration (FDA) regulations require that it only be used in the facility where it was first opened. Only if absolutely necessary, a partially used vial may be transported to or from an off-site facility operated by the same provider, as long as the vaccine cold chain is properly maintained. However, a partially used vial may not be transferred to another provider or transported across state lines.

Transporting Varicella-Containing Vaccines

The vaccine manufacturer does not recommend transporting varicella-containing vaccines (MMRV, VAR, HZV). If these vaccines must be transported (e.g., during an emergency), CDC recommends transport in a portable freezer unit that maintains the temperature between -58°F and +5°F (-50°C and -15°C). Portable freezers may be available for rent in some places. If varicella-containing vaccines must be transported and a portable freezer unit is not available, **do NOT use dry ice**.

Varicella-containing vaccines may be transported at refrigerator temperature between 36°F and 46°F (2°C and 8°C) for up to 72 continuous hours prior to reconstitution (see Varicella-Containing Vaccines in CDC's Vaccine Storage and Handling Guide). If varicella-containing vaccines must be transported at refrigerator temperature, follow these steps:

1. Place a calibrated thermometer (preferably with a biosafe glycol-encased thermometer probe) in the container used for transport as close as possible to the vaccines.
2. Record:
   a. The time the vaccines are removed from the storage unit and placed in the container;
   b. The temperature during transport;
   c. The time and temperature at the beginning and end of transport.
3. According to the vaccine manufacturer, **immediately** upon arrival at the alternate storage facility:
   a. **Place the vaccines in the freezer between -58°F and +5°F (-50°C and -15°C) and label "DO NOT USE."** Any stand-alone freezer that reliably maintains a temperature between -58°F and +5°F (-50°C and -15°C) is acceptable for storage of varicella-containing vaccines.
   b. Document the time the vaccines are removed from the container and placed in the alternate storage unit.

c. Note that this is considered a temperature excursion, **so contact the manufacturer at 1-800-637-2590 for further guidance**.

4. Do not discard vaccines without contacting the manufacturer and/or your immunization program for guidance.

Use of dry ice is not recommended, even for temporary storage or emergency transport. Dry ice may subject varicella-containing vaccines to temperatures colder than -58°F (-50°C).

Packing Vaccines and Diluents for Transport

There are many variables to consider when transporting any vaccine (e.g., the time of year and ambient temperature, the amount of vaccine, the shipping container, etc.) Your immunization program may have specific guidance regarding vaccine transport, details on how to pack vaccine and diluent, and procedures for maintaining the vaccine cold chain based on these variables. Here is some general guidance.

Refrigerated vaccines

- Pack refrigerated vaccines before packing frozen vaccines as indicated here: CDC recommends transport with a portable refrigerator unit. If this type of unit is not available, a hard-sided insulated cooler with at least 2-inch walls may be used if it can maintain the recommended temperature range (between 35°F and 46°F [2°C and 8°C]).
- Place a layer (at least 2 inches) of "conditioned" coolant packs in the transport container first. Coolant packs that are frozen must be "conditioned" by leaving them at room temperature for 1 to 2 hours until the edges have defrosted and the packs look like they've been "sweating." Frozen coolant packs that are not "conditioned" can freeze vaccine.

CDC recommends transport with a portable refrigerator unit.

Refrigerated/frozen coolant packs

CDC recommends transport with a portable refrigerator unit. If this type of unit is not available, a hard-sided insulated cooler with at least 2-inch walls may be used if it can maintain the recommended temperature range (between 35°F and 46°F [2°C and 8°C]).

- Place an insulating barrier layer on top of the coolant packs, (e.g., bubble wrap or Styrofoam pellets).

Place bubble wrap or Styrofoam pellets between the refrigerated or frozen coolant packs and the vaccines.

- Place a calibrated thermometer (preferably with a biosafe glycol-encased thermometer probe) on top of the barrier next to the vaccines.
- Stack the vaccines on top of the barrier and thermometer, ensuring that the vaccines do not touch the coolant packs.
- Place another insulating barrier layer on top of the vaccines.
- Place another layer of "conditioned" coolant packs on top of the insulating barrier layer, ensuring there is no direct contact between the coolant packs and the vaccines.
- Place a final insulating barrier layer (at least 2 inches) on top of the coolant packs along with an inventory list of the vaccines in the container.

Attach appropriate labels to the outside of the container.

Frozen vaccines

- If frozen vaccines must be transported, CDC recommends transport with a portable freezer that maintains a temperature between -58°F and +5°F (-50°C and -15°C). Portable freezers may be available for rent in some areas.
- Use the same packing layers as noted above.
- The coolant packs should be frozen. Do NOT use dry ice.
- In addition, according to the manufacturer's product information, MMRV, VAR, and HZV may be stored at refrigerator temperature (between 35°F and 46°F [2°C and 8°C]) for up to 72 continuous hours prior to reconstitution. If

CDC recommends transport with a portable freezer unit.

transporting frozen vaccines under refrigerated conditions, see Transporting Varicella-Containing Vaccines in this section.

- If frozen vaccines are to be transported at refrigerated temperature, refrigerated and frozen vaccines can be transported together in the same container as long as there is adequate space.
- Frozen vaccines should be separated from refrigerated vaccines. This can be accomplished by placing rubber bands around the separate vaccines.
- Insulating material (e.g., bubble wrap) should be placed around the refrigerated vaccines to protect them from being exposed to freezing temperatures.
- Contact the vaccine manufacturer (1-800-637-2590) immediately upon arrival at the alternate storage facility for further guidance.
- Do NOT discard the vaccines without contacting the manufacturer or your immunization program for guidance.

Diluents

- Diluents should be transported with their corresponding vaccines to ensure that there are always equal numbers of vaccine vials and diluent vials for reconstitution. Diluents that do not contain antigen can be transported at room temperature or at refrigerator temperature. Diluents that contain antigen (e.g., DTaP-IPV diluent used with Hib lyophilized vaccine) should be transported with their corresponding vaccines at refrigerator temperature. NEVER transport any diluents at freezer temperature because the vials could crack, or in some cases, the diluents may contain vaccine antigen. Place an insulating barrier between the diluents and coolant packs because of the potential for freezing.

Diluents should be transported with their corresponding vaccines to ensure that there are always equal numbers of vaccine vials and diluent vials for reconstitution.

- If any diluents that have been stored at room temperature are to be transported in the container with refrigerated vaccines, refrigerate the diluents in advance so they will not increase the temperature in the shipping container.

Monitoring Temperatures at Off-Site Facilities

Vaccines should be placed in an appropriate storage unit(s) at the recommended temperature range(s) immediately upon arrival at the alternate facility. Place a calibrated thermometer(s) in the storage unit(s) with the vaccines. CDC does not

recommend keeping vaccines in a transport container(s) unless it is a portable refrigerator or freezer unit. If vaccines must be kept in a transport container(s) during an off-site clinic:

- The container(s) should remain closed as much as possible.
- Only the amount of vaccine needed at one time should be removed for preparation and administration.
- The calibrated thermometer(s) (preferably with a biosafe glycol-encased thermometer probe) should be placed as close as possible to the vaccines.
- The temperature(s) inside the container(s) should be read and documented at least hourly.

Vaccines should be placed in an appropriate storage unit(s) at the recommended temperature range(s) immediately upon arrival at the alternate facility. Place a calibrated thermometer(s) in the storage unit(s) with the vaccines.

If you have concerns about vaccines or diluents that may have been compromised (exposed to inappropriate conditions/temperatures or handled improperly), label them "DO NOT USE" and store them under appropriate conditions separate from other vaccine supplies. Then contact your immunization program and/or vaccine manufacturer(s) for guidance. Do not discard the vaccines or diluents unless directed to by your immunization program and/or the manufacturer(s).

Preparation for Vaccine Administration

Reconstitution

Lyophilized (Freeze-Dried) Vaccines

A lyophilized (freeze-dried) vaccine may be a powder or a pellet that must be mixed with a liquid (called a diluent) in a process known as "reconstitution" before it can be administered.

Lyophilized powder + Diluent = Reconstituted vaccine

Diluents

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

A diluent is a liquid that is mixed with a lyophilized powder or pellet in order to reconstitute the vaccine into a liquid form for administration. Diluents vary in volume and composition. They are specifically designed to meet the volume, pH (acid/alkaline balance), and chemical needs of each vaccine so the optimal immune response can be achieved. Some diluents contain antigen (e.g., DTaP-IPV). Diluents are **NOT interchangeable** unless specified by the manufacturer (e.g., the diluent for MMR, MMRV, VAR, and HZV). Therefore, use only the specific diluent provided by the manufacturer for that vaccine to ensure adequate potency and safety of the resulting mixture. Do NOT use a diluent from another manufacturer. If a vaccine must be reconstituted with sterile water or saline, use only the diluent supplied by the manufacturer for that vaccine. NEVER use a stock vial of sterile water or normal saline to reconstitute vaccines.

A vaccine inadvertently reconstituted with the wrong diluent should NOT be administered. If such a vaccine has already been administered, contact your state/ local health department immunization program, the vaccine manufacturer, or CDC for guidance. A vaccine reconstituted with the wrong diluent and inadvertently administered should generally be repeated.

Instructions for Reconstitution

Refer to the product information 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 a vaccine to sit out and warm up during the reconstitution process. Limit the time a vaccine is 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.
   - Volume of diluent (e.g., MPSV4 single-dose diluent vial contains 0.6 mL., whereas the multidose diluent vial contains 6 mL.).
4. Check the expiration dates on both diluent and vaccine vials to make sure neither has expired. NEVER administer expired diluent or vaccine (see Expiration Dates in the Vaccine Inventory Management section).
5. Remove the protective caps from the diluent and vaccine vials. Clean the stoppers with sterile alcohol swabs because the protective caps function as a dust covers and do not ensure the sterility of the rubber diaphragms.
6. Select a disposable syringe and needle length appropriate for the route of administration and the patient being vaccinated. For a single-dose vial, the same needle can be used to draw up the diluent, reconstitute the vaccine, and administer the dose. There is no need to change the needle unless it has been damaged or contaminated during the reconstitution and drawing up process. For a multidose reconstituted vial, 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.
7. Insert the needle into the diluent vial and withdraw the entire contents.
8. Inject all the diluent into the vaccine vial and agitate or rotate the vial to ensure thorough mixing (follow the specific instructions provided in the product information).
9. Observe the reconstituted vaccine for color and appearance. If the reconstituted vaccine cannot be suspended or does not look as described in the product information (e.g., discoloration, extraneous particulate matter), label the vial "DO NOT USE" and store it under appropriate conditions separate from other vaccine supplies. Then contact your immunization

program and/or vaccine manufacturer for guidance. Replace the diluent and vaccine vials and begin the reconstitution process again.

10. For multidose vials, mark the date and time of reconstitution on the vaccine vial. For single-dose vials, mark the date and time of reconstitution on the vaccine vial if it is not administered immediately after reconstitution.
11. 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, route, dosage, and provider's/standing order before administering the vaccine.
12. Label the syringe with the type of vaccine. Many vaccines are the same dosage (volume) and look similar once in the syringe. Labeling the syringe with the vaccine prevents confusion when multiple injections are being administered. It is important to know which vaccine is being administered when choosing the correct route and site.
13. Administer the vaccine soon after reconstitution to minimize the risk of reduced potency. Expiration date and time after reconstitution varies by vaccine. See Unused Reconstituted Vaccine in this section.
14. After administering the injection to the patient, do NOT recap the needle. Discard the used needle and syringe using medical waste disposal procedures (see Disposal of Vaccines and Diluents in this section).

Unused Reconstituted Vaccine

Once a lyophilized (freeze-dried) vaccine has been reconstituted, its shelf life is limited and varies by product.

Once a lyophilized (freeze-dried) vaccine has been reconstituted, its shelf life is limited and varies by product. See the Immunization Action Coalition's Vaccines with Diluents: How to Use Them in the Resources section for details. Reconstituted vaccine must be stored under appropriate conditions and used within a specified time. Do NOT administer a reconstituted vaccine that has exceeded this time frame. Contact your immunization program for guidance on disposition of unused reconstituted vaccine. The best way to avoid waste is to reconstitute and draw up a vaccine immediately before administration.

Dating a Multidose Vial

Mark each multidose vial with the **date** it was first opened (i.e., when the protective cap is removed). Dating vials is important for two reasons. First, some vaccines expire within a certain time after opening. This may not correspond to the expiration date printed on the vial by the manufacturer. For example, multidose vials of

FluLaval influenza vaccine should be discarded if not used within 28 days after opening, even if the expiration date printed on the vial by the manufacturer has not passed. Second, dating opened vials helps manage vaccine inventory by identifying vials that should be used first. Whenever possible, use all the vaccine in one multidose vial before opening another vial. This policy helps to reduce vaccine waste. However, do NOT use partial doses from two or more vials to obtain a full dose of vaccine.

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

Use of Multidose Vials versus Single-Dose Vials

Multidose vials contain bacteriostatic agents that prevent the growth of bacteria. Once opened, they can be used through their expiration dates, unless contaminated or the product information specifies a time frame for use after opening that is different than the expiration date on the label. All multidose vials must be stored under appropriate conditions at all times before and after they have been opened.

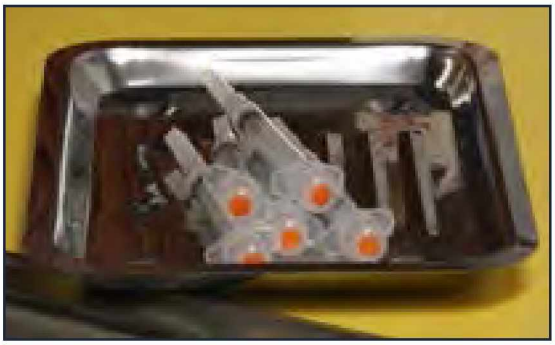
Once the protective cap is removed from a single-dose vial, it should be used by the end of the workday. Do not open a single-dose vial until ready to use it. To avoid needless waste of vaccine, **always** check the vial to make sure the correct vaccine has been selected. Remove the cap only when ready to draw up and administer the vaccine. Contact your immunization program for guidance on disposition of uncapped, unused single-dose vaccine vials.

Single-dose vials are meant for one-time use only and do not contain bacteriostatic agents.

Predrawing Vaccines

CDC recommends that providers draw up vaccines only at the time of administration.

CDC recommends that providers draw up vaccines only at the time of administration. **Do NOT** predraw doses before they are needed.



CDC discourages predrawing vaccines.

Problems Associated with Predrawing Vaccines

CDC discourages predrawing vaccines and has identified the following problems associated with this practice:

- Once vaccines are inside syringes, it is difficult to tell them apart; this has led to **administration errors**.
- Predrawing vaccines leads to **vaccine waste** 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 with predrawn vaccine that do not contain bacteriostatic agents.
- No stability data are available for vaccines stored in plastic syringes. Vaccine components may interact with the polymers in plastic syringes over time potentially **reducing vaccine potency**.
- An individual should only administer a vaccine he or she has prepared and drawn up. If a vaccine is drawn up by one person and then administered by a different person, the person administering the vaccine cannot be sure of the composition and sterility of the dose. This is a **quality control and patient safety issue and a best practice standard of medication administration**.

Influenza Clinics and Predrawing Vaccines

Vaccine manufacturers do not recommend that influenza vaccines be predrawn in advance of a large influenza vaccination clinic because there are no data on the stability of vaccines stored in syringes that have been filled by providers. CDC discourages this practice for the reasons noted in the previous section. As an alternative to predrawing vaccines, CDC recommends using manufacturer-filled syringes for large immunization events such as community influenza clinics. These syringes are designed for both storage and administration.

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

- Only one type of vaccine may be administered at the clinic. If more than one vaccine type is to be administered, separate vaccine administration stations should be set up for each vaccine type to prevent medication errors.
- Vaccines should NOT be drawn up in advance of arriving at the clinic site. Because of the lack of data on the stability of vaccines stored in plastic syringes, the practice of drawing up doses of vaccine hours or even days before a clinic is **NOT acceptable**.
- At the clinic site, healthcare personnel (HCP) may each draw up a **small** number of vaccine doses—no more than 1 multidose vial or 10 doses, whichever is greater. This will limit the amount of time the vaccine is held in the syringes before administration and reduce vaccine waste.
- During the clinic, HCP should alternate drawing up and administering vaccines. This practice has minimal impact on patient flow, limits the amount of vaccine doses drawn up at any one time, and conforms to best medication administration practices, in which each person administers the vaccine dose he or she draws up.
- Patient flow should be monitored to avoid drawing up unnecessary doses.
- At the end of the workday, any remaining vaccine in provider predrawn syringes should be discarded. Vaccine doses that have been drawn up and not administered should NOT be used on subsequent days.

Manufacturer-Filled Syringes

Manufacturer-filled syringes are available for a variety of vaccines. CDC 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 the facility. Manufacturer-filled syringes are recommended instead of predrawing vaccine. Manufacturer-filled syringes are labeled and prepared under sterile conditions that meet standards for proper storage and handling.

Manufacturer-filled syringes

They have been designed and tested to assure vaccine potency and sterility over prolonged storage times. As long as they are stored under appropriate conditions, manufacturer-filled syringes may be kept and used until their expiration dates unless

contaminated. Activate (remove needle guard or attach needle) manufacturer-filled syringes just prior to administration. Unused activated manufacturer-filled syringes should be discarded at the end of the workday.

Disposal of Vaccines and Diluents

Unused vaccine and diluent doses may be returnable under certain circumstances. Contact the vaccine manufacturer(s) or your immunization program for specific policies regarding the disposition of unopened vials, expired vials, unused doses, and potentially compromised vaccine due to inappropriate storage conditions. Doses of vaccine predrawn by a provider should NOT be returned. These doses should be discarded.

When advised to discard vials or syringes, use medical waste disposal procedures. Contact your immunization program for details about medical waste disposal procedures in your area.

Contact your immunization program for details about medical waste disposal procedures in your area.

General Vaccine Storage and Handling Guidelines

Handle with Care Poster

Routine Vaccine Storage and Handling Plan Worksheet

NIST Guidance on Storage of Refrigerated Vaccine

CDC Vaccine Price List

Temperature Conversion Tables

Fahrenheit to Celsius and Celsius to Fahrenheit Conversion

Temperature Excursion Checklist

Temperature Excursion Checklist

Vaccine Inventory Records

Sample Stock Record

Stock Record

Sample Tally Sheet

Tally Sheet

Warning Signs (can be printed and reproduced)

Do Not Adjust Refrigerator Controls (English)

Do Not Adjust Refrigerator Controls (Spanish)

Do Not Adjust Freezer Controls (English)

Do Not Adjust Freezer Controls (Spanish)

Warning! Do Not Unplug Refrigerator (English)

Warning Signs (cont'd)

Warning! Do Not Unplug Refrigerator (Spanish)

Warning! Do Not Unplug Freezer (English)

Warning! Do Not Unplug Freezer (Spanish)

Do Not Unplug Refrigerator (English)

Do Not Unplug Refrigerator (Spanish)

Do Not Unplug Freezer (English)

Do Not Unplug Freezer (Spanish)

Shipping Labels (can be printed and reproduced)

Vaccine Labels for Storage Unit

Refrigerate Upon Arrival

Freeze Upon Arrival

Open Immediately: Refrigerate Upon Receipt

Open Immediately: Freeze Upon Receipt

Refrigerate—Do Not Freeze

Freeze—Do Not Refrigerate

Fragile: Handle with Care

Fragile

Perishable—Rush

Emergency Vaccine Storage and Handling Resources

Emergency Vaccine Retrieval and Storage Plan Worksheet

Emergency Management Internet Resources

Other Sources for Storage and Handling Information

Immunization Action Coalition Clinic Resources

Immunization Action Coalition – Vaccines with Diluents: How to Use Them

Immunization Action Coalition "Ask the Experts"

State Immunization Program Websites

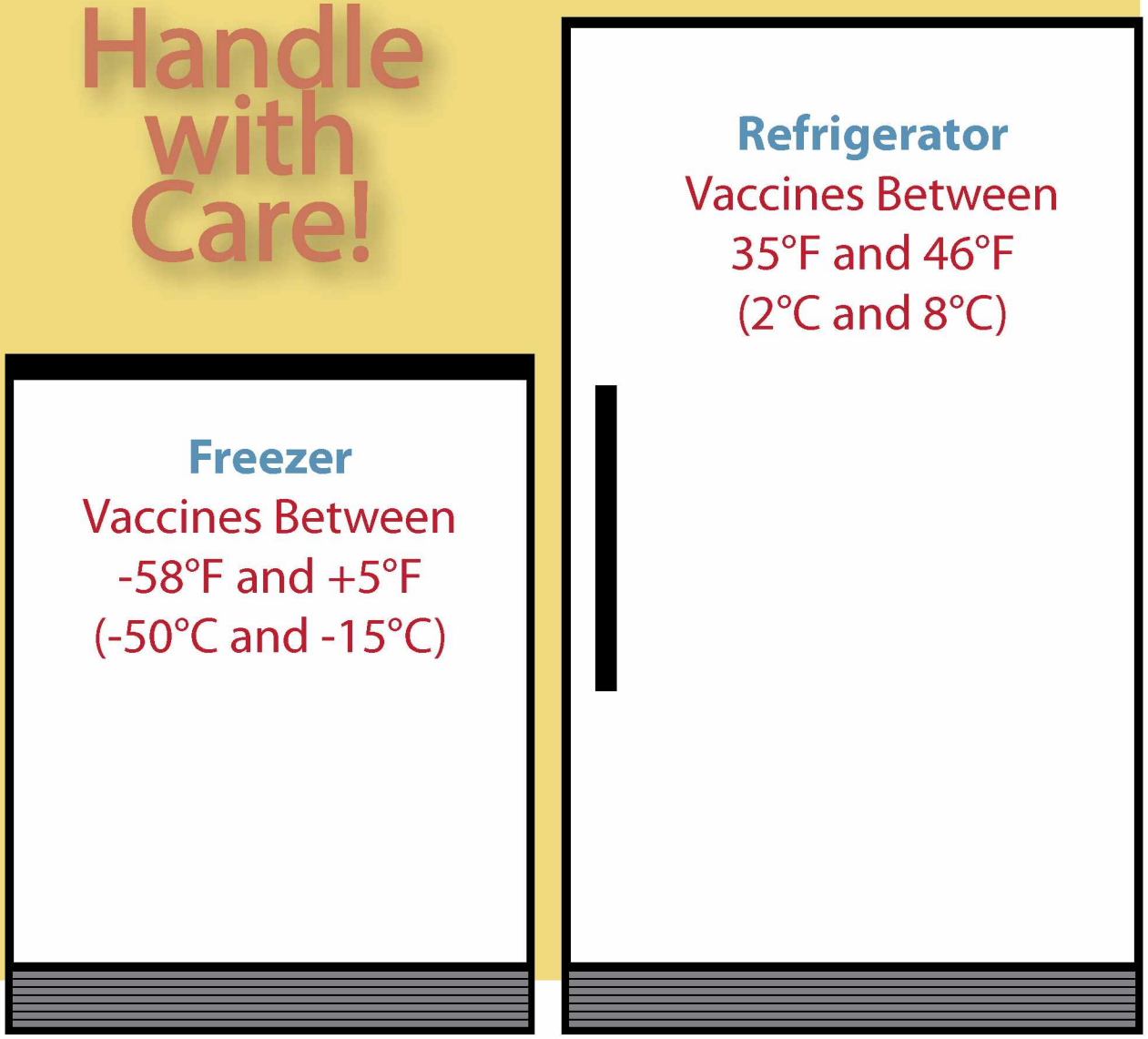
Manufacturer/Distributor Contact Information

PROTECT YOUR VACCINE
PROTECT YOUR PATIENTS

Handle with Care!

Vaccine Storage Rules

- Keep your refrigerator and freezer within the appropriate temperature ranges.
- Keep your vaccine within the appropriate temperature ranges.
- Read and document refrigerator and freezer temperatures twice each workday and min/max temperatures daily.
- Take immediate action if temperatures are out of range.
- Keep vaccines in their original packages.
- Many vaccines should be protected from light (consult manufacturer's product information).
- Keep MMRV, VAR, and HZV vaccines frozen.
- Rotate your vaccine stocks.



Handle with Care Poster

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

Checklist of Resources for the Routine Vaccine Storage and Handling Plan

- ☐ Up-to-date contact information
  - Primary and alternate vaccine coordinators
  - Local and state health department immunization program
  - Manufacturers of the vaccines in your inventory
  - Refrigerator and freezer maintenance and repair companies
  - Vaccine storage unit alarm company (if applicable)
  - Sources for packing materials and calibrated thermometers
- ☐ Descriptions of the roles and responsibilities of the primary and alternate vaccine coordinators
- ☐ Policy on education and training for facility staff
- ☐ Summaries of the storage requirements for each type of 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 vaccines within storage units
- ☐ Protocols for responding to vaccine storage and handling problems
- ☐ Protocols for vaccine inventory management
- ☐ Protocols for receiving vaccine shipments
- ☐ Protocols for transporting vaccines
- ☐ Protocols for handling vaccine prior to administration
- ☐ Protocols for proper disposal of vaccines and supplies
- ☐ Samples of the forms used in your vaccination program

Vaccine Coordinators			
Vaccine Coordinators	**Name/Title**	**Telephone Numbers (home, cell, pager)**	**E-mail Address**
Primary			
Alternate			

Resources Contact List			
Resources	**Contact Person Name/Title**	**Telephone Numbers (home, cell, pager)**	**E-mail Address**
Local Health Department Immunization Program			
State Health Department Immunization Program			
Additional Resources	**Company Name Contact Person Name/Title**	**Telephone Numbers (home, cell, pager)**	**E-mail Address**
Electric Power Company			
Generator Repair Company (if applicable)			
Refrigerator Repair Company			
Freezer Repair Company			
Temperature Alarm Monitoring Company (if applicable)			
Security or Perimeter Alarm Company (if applicable)			

Emergency Resources	Company Name Contact Person Name/Title	Telephone Numbers (home, cell, pager)	E-mail Address
Packing Materials			
Portable refrigerator/ freezer units			
Insulated Containers			
Insulated Containers (alternate)			
Fillers (e.g., bubble wrap, Styrofoam pellets)			
Fillers (alternate)			
Coolant Packs			
Coolant Packs (alternate)			
Calibrated Thermometers			
Calibrated Thermometers (alternate)			

Fahrenheit to Celsius and Celsius to Fahrenheit Conversion

°F	°C	°F	°C	°F	°C
-22	-30.0	37	2.8	96	35.6
-21	-29.4	38	3.3	97	36.1
-20	-28.9	39	3.9	98	36.7
-19	-28.3	40	4.4	99	37.2
-18	-27.8	41	5.0	100	37.8
-17	-27.2	42	5.6	101	38.3
-16	-26.7	43	6.1	102	38.9
-15	-26.1	44	6.7	103	39.4
-14	-25.6	45	7.2	104	40.0
-13	-25.0	46	7.8		
-12	-24.4	47	8.3		
-11	-23.9	48	8.9		
-10	-23.3	49	9.4		
-9	-22.8	50	10.0		
-8	-22.2	51	10.6		
-7	-21.7	52	11.1		
-6	-21.1	53	11.7		
-5	-20.6	54	12.2		
-4	-20.0	55	12.8		
-3	-19.4	56	13.3		
-2	-18.9	57	13.9		
-1	-18.3	58	14.4		
0	-17.8	59	15.0		
1	-17.2	60	15.6		
2	-16.7	61	16.1		
3	-16.1	62	16.7		
4	-15.6	63	17.2		
5	-15.0	64	17.8		
6	-14.4	65	18.3		
7	-13.9	66	18.9		
8	-13.3	67	19.4		
9	-12.8	68	20.0		
10	-12.2	69	20.6		
11	-11.7	70	21.1		
12	-11.1	71	21.7		
13	-10.6	72	22.2		
14	-10.0	73	22.8		
15	-9.4	74	23.3		
16	-8.9	75	23.9		
17	-8.3	76	24.4		
18	-7.8	77	25.0		
19	-7.2	78	25.6		
20	-6.7	79	26.1		
21	-6.1	80	26.7		
22	-5.6	81	27.2		
23	-5.0	82	27.8		
24	-4.4	83	28.3		
25	-3.9	84	28.9		
26	-3.3	85	29.4		
27	-2.8	86	30.0		
28	-2.2	87	30.6		
29	-1.7	88	31.1		
30	-1.1	89	31.7		
31	-0.6	90	32.2		
32	0.0	91	32.8		
33	0.6	92	33.3		
34	1.1	93	33.9		
35	1.7	94	34.4		
36	2.2	95	35.0		

°C	°F	°C	°F
-30	-22.0	29	84.2
-29	-20.2	30	86.0
-28	-18.4	31	87.8
-27	-16.6	32	89.6
-26	-14.8	33	91.4
-25	-13.0	34	93.2
-24	-11.2	35	95.0
-23	-9.4	36	96.8
-22	-7.6	37	98.6
-21	-5.8	38	100.4
-20	-4.0	39	102.2
-19	-2.2	40	104.0
-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		
22	71.6		
23	73.4		
24	75.2		
25	77.0		
26	78.8		
27	80.6		
28	82.4		

1. **Checklist for general power loss**

   - ☐ Contact utility company
   - ☐ Determine if time to restoration is acceptable
   - ☐ Activate alternate generator if available

2. **Checklist for presumed storage unit malfunction**
   DISPOSITION OF STORAGE UNIT
   If Unit is too warm, too cold, too noisy, or stopped:

   - ☐ Check circuit breakers
   - ☐ Unit plugged in
   - ☐ Door closed
   - ☐ Door seal adequate
   - ☐ Assess location of thermometers for temperature reading
   - ☐ Record all temperatures
   - ☐ Space between vaccine for air to circulate
   - ☐ Coils free of dust
   - ☐ Temperature adjusted gradually if not set correctly - (need to re-check temperatures and record every 30 minutes)
   - ☐ Unit secured and level (if unit is noisy)
   - ☐ Screws tightened (if unit is noisy)
   - ☐ Technician called

3. **Disposition of vaccine (if power not restored or if temperature does not begin to recover)**

   - ☐ Vaccine marked “do not use” (Refrigerated Vaccines First)
   - ☐ Check temperature of alternative storage unit
   - ☐ Vaccine moved to alternate storage unit (Refrigerated Vaccines First)
   - ☐ Use data collection tool to record temperature excursion
   - ☐ State Immunization Program contacted
   - ☐ Manufacturer contacted
   - ☐ Resume use of vaccines determined to be usable and returned to unit
   - ☐ Determine disposition of vaccine that is compromised:
     - ☐ Publicly purchased vaccine (provided through the Vaccines for Children Program) prepared for return to McKesson.
     - ☐ Privately purchased vaccine should be disposed of in consultation with the manufacturer or its representative. Replacement plans will vary.
     - ☐ If insured against losses of this type, contact insurance representative.

Stock Record

Instructions: 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 a discrepancy cannot be determined and corrected, make a note of this. Start a new stock record page by recording the physical count of the previous page. Use the correct physical count for the starting balance. Use the remaining lines to record new shipments of vaccines/diluents and weekly accounts of doses used.

Vaccine Type: PPSV23 Month and Year: August 2013

Date Received or Usage Tallied	Person Receiving Shipment *	Arrival Condition **	Vaccine or Diluent Name	Manufacturer	Vial Type (SDV, MDV, MFS)	Lot Number	Expiration Date	Expiration Date After Reconsti-tution	Doses Received/ Balance Forward	Doses Used †	Balance (Doses)
08/02/13	BEGINNING BALANCE FOR THE MONTH								2	N/A	2
08/09/13										1	1
08/15/13	LST	G	PPSV23	Merck	MDV	03958	02/15/14	N/A	5	3	3
0823/13										1	2
08/29/13										0	2

* The initials of the person who unpacked and checked the vaccines/diluents upon arrival

** G = vaccines/diluents arrived in good condition
? = condition of vaccines/diluents questionable and state and local health department immunization program and vaccine manufacturer(s) contacted. Document details/outcome on reverse side of stock record.

*** SDV = Single-dose vial
MDV = Multidose vial
MFS = Manufacture-filled syringe

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

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

Vaccine Totals	7	5	2 ††

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 immunization providers. Contact program staff for information. If stock records are not available from your state or local health department or an Immunization Information System (IIS), this stock record may be used.

Sample Stock Record

Stock Record

Instructions: 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 a discrepancy cannot be determined and corrected, make a note of this. Start a new stock record page by recording the physical count of the previous page. Use the correct physical count for the starting balance. Use the remaining lines to record new shipments of vaccines/diluents 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	Manufacturer	Vial Type (SDV, MDV, MFS)	Lot Number	Expiration Date	Expiration Date After Reconsti-tution	Doses Received/ Balance Forward	Doses Used †	Balance (Doses)
	BEGINNING BALANCE FOR THE MONTH									N/A	

* The initials of the person who unpacked and checked the vaccines/diluents upon arrival

** G = vaccines/diluents arrived in good condition
? = condition of vaccines/diluents questionable and state and local health department immunization program and vaccine manufacturer(s) contacted. Document details/outcome on reverse side of stock record.

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

Vaccine Totals			††

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 immunization providers. Contact program staff for information. If stock records are not available from your state or local health department or an Immunization Information System (IIS), this stock record may be used.

Tally Sheet

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

Week: August 19-23, 2013 (Week 3)

Storage Location (R or F) *	Vaccine or Diluent Name	Doses Administered	Doses Wasted	Doses Expired **	Doses Unusable	Doses Transferred (Viable) ***	Total
F	VAR	~~HH~~ III (8)	I				9
R	DTaP	~~HH HH~~ II (12)					12
R	Hib-HepB	~~HH HH~~ II (12)					12
R	IPV	~~HH HH~~ II (12)		II			14
R	HepA (pediatric)	II (2)					2
R	PPSV23	I (1)					1
		( )					
		( )					
		( )					
		( )					
		( )					
		( )					
		( )					
		( )					

* R = Refrigerator
F = Freezer

** Some non-viable doses (VFC vaccines or other vaccines purchased with public funds) may need to be returned to your state or local health department immunization program.

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

Some state or local health department immunization programs have developed their own tally sheets for immunization providers. Contact program staff for information. If tally sheets are not available from your state or local health department immunization program or an Immunization Information System (IIS), this tally sheet may be used.

Sample Tally Sheet

Tally Sheet

Instructions: Place a copy of this sheet on the door of the refrigerator and freezer units in which you store vaccines. Record the week (by date or week number). Write the names of the vaccines/diluents and indicate the storage location of each vaccine/diluent in the refrigerator (R) or freezer (F). Record a tick mark for each dose of vaccine/diluent you remove from a storage unit (i.e., for each dose that is administered, wasted, unusable, expired, or transferred). At the end of the week, add the tick marks for each vaccine/diluent and update the appropriate stock record. Remove the completed tally sheet from each storage unit 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 or Diluent Name	Doses Administered	Doses Wasted	Doses Expired **	Doses Unusable	Doses Transferred (Viable) ***	Total

* R = Refrigerator
F = Freezer

** Some non-viable doses (VFC vaccines or other vaccines purchased with public funds) may need to be returned to your state or local health department immunization program.

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

Some state or local health department immunization programs have developed their own tally sheets for immunization providers. Contact program staff for information. If tally sheets are not available from your state or local health department immunization program or an Immunization Information System (IIS), this tally sheet may be used.

Do Not Adjust Refrigerator Controls (English)

Do Not Adjust Refrigerator Controls (Spanish)

Do Not Adjust Freezer Controls (English)

Do Not Adjust Freezer Controls (Spanish)

Warning! Do Not Unplug Refrigerator (English)

Warning! Do Not Unplug Refrigerator (Spanish)

Warning! Do Not Unplug Freezer (English)

Warning! Do Not Unplug Freezer (Spanish)

Do Not Unplug Refrigerator (English)

Do Not Unplug Refrigerator (Spanish)

Do Not Unplug Freezer (English)

Do Not Unplug Freezer (Spanish)

Refrigerate Upon Arrival

Freeze Upon Arrival

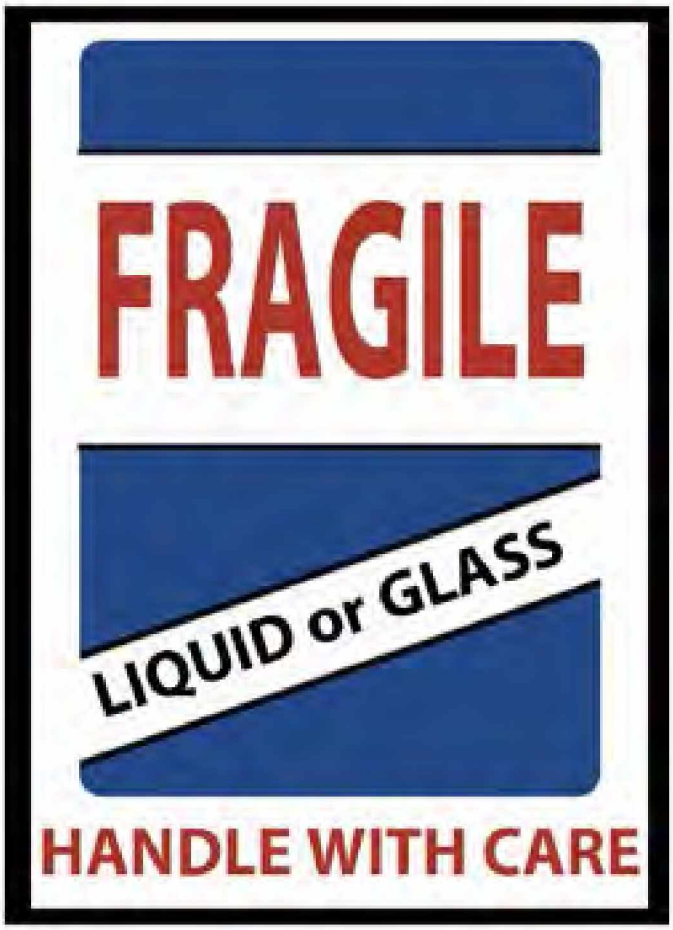
Open Immediately: Refrigerate Upon Receipt

Open Immediately: Freeze Upon Receipt

Refrigerate—Do Not Freeze

Freeze—Do Not Refrigerate

Fragile: Handle with Care



Fragile

Perishable—Rush

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

Checklist of Resources for the Emergency Vaccine Retrieval and Storage Plan

- ☐ Designated primary and alternate vaccine coordinators with emergency contact information.
- ☐ Emergency staff contact list in order of contact preference.
- ☐ Specifications of vaccine storage unit (type, brand, model number, serial number).
- ☐ Alternate vaccine storage facility(ies).
- ☐ Written protocols, vehicles, and drivers for transporting vaccines to and from the alternate vaccine storage facility(ies).
- ☐ Written instructions for entering your facility and vaccine storage areas in an emergency in the event the building is closed. These instructions should include the building security/after-hours access procedure, a floor diagram, and the locations of the following:
  Alarms (including instructions for use)
  Doors
  Flashlights
  Spare batteries
  Light switches
  Keys
  Locks
  Circuit breakers
  Packing materials
- ☐ Appropriate packing materials to safely transport or temporarily store vaccines.
- ☐ Written protocol for vaccine packing refrigerated vaccines.
- ☐ Written protocol for vaccine packing frozen vaccines.
- ☐ Written protocol for vaccine transport
- ☐ Written protocol for appropriately storing vaccines at the alternate storage facility.
- ☐ Up-to-date list of Manufacturers' Telephone Numbers.

Vaccine Coordinators			
Vaccine Coordinators	**Name/Title**	**Telephone Numbers (home, cell, pager)**	**E-mail Address**
Primary			
Alternate			

Emergency Staff Contact List*			
Name	**Title**	**Telephone Numbers (home, cell, pager)**	**E-mail Address**
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 alternate 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 Name/Title**	**Telephone Numbers (home, cell, pager)**	**E-mail Address**
Additional Staff (to move and pack vaccine)			
State Health Department Immunization Program			
Local Health Department Immunization Program			
Electric Power Company			
Emergency Generator Repair Company (if applicable)			
Emergency Generator Fuel Source (if applicable)			
Refrigerator Unit Repair Company			
Freezer Unit Repair Company			
Temperature Alarm Monitoring Company (if applicable)			
Security or Perimeter Alarm Company (if applicable)			
Weather Service			

Emergency Resources Company Name/Address	Contact Person Name/Title	Telephone Numbers (home, cell, pager)	E-mail Address
Alternate Vaccine Storage Facility(ies)			
1.			
2.			
3.			
4.			
Emergency Resources Name/Address	**Contact Person Name/Title**	**Telephone Numbers (home, cell, pager)**	**E-mail Address**
Transportation to Alternate Vaccine Storage Facility(ies)*			
Refrigeration Company			
Refrigeration Company (alternate)			
Private Vehicle			
Private Vehicle (alternate)			

Emergency Resources Company Name/Address	Contact Person Name/Title	Telephone Numbers (home, cell, pager)	E-mail Address
Packing Materials			
Insulated Containers			
Insulated Containers (alternate)			
Fillers (e.g., bubble wrap, Styrofoam pellets)			
Fillers (alternate)			
Coolant Packs			
Coolant Packs (alternate)			
Calibrated Thermometers			
Calibrated Thermometers (alternate)			

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/BiologicsBloodVaccines/SafetyAvailability/ProductSecurity/ucm147243.htm

Manufacturer / Distributor Websites	Telephone Number/E-mail	Products
Centers for Disease Control and Prevention www.cdc.gov/ncidod/srp/drugs/drug-service.html http://www.cdc.gov/laboratory/drugservice/index.html	404-639-3670/ drugservice@cdc.gov	Distributor for diphtheria antitoxin, VIG, smallpox vaccine
GlaxoSmithKline (GSK) http://www.gskvaccines.com/	866-475-8222	DTaP, DTaP-HepB-IPV, DTaP-IPV, HepA, HepB, HepA-HepB, Hib, Hib-MenCY, HPV2, IIV, RV1, Tdap
Massachusetts Biological Labs http://www.umassmed.edu/massbiolabs/index.aspx	800-457-4626	IGIM, Td
MedImmune http://www.medimmune.com/	877-633-4411 medinfo@medimmune.com	LAIV
Merck & Co., Inc https://www.merckvaccines.com/	800-637-2590	HepA, HepB, Hib, Hib-HepB, HPV4, HZV, IIV, MMR, MMRV, PPSV23, RV5, VAR
Biotest Pharmaceuticals http://www.biotestpharma.com/products/nabiHB.html	800-458-4244	HBIG
Novartis http://www.novartisvaccines.com/us/index.shtml	877-683-4732 Vaccineinfo.us@novartis.com	IIV, MCV4
Pfizer/Wyeth http://pfizerpro.com/	800-438-1985	PCV13
Sanofi Pasteur https://www.vaccineshoppe.com/	800-822-2463	DT, DTaP, DTaP-IPV/Hib, Hib, IIV, IPV, MCV4, MPSV4, Rabies, RIG, Td, Tdap, TT
Grifols Biotherapeutics http://www.biotestpharma.com/index.php?submenu=NabiHB&src=gendocs&ref=NabiHB&category=NabiHB	800-520-2807 grifols@medcomsol.com	HBIG, IGIM, RIG, TIG