Vaccine Storage & Handling Toolkit

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U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

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Description of Icons

This list shows the symbols you will see throughout the toolkit:

Icon	Description
	CDC recommendation that applies to anyone who handles and stores vaccine. It is particularly relevant to VFC providers or other health care providers who receive vaccines purchased with public funds.
	Best practice
	Take immediate action!

Print warning! A printed version of this toolkit may not be the most up-to-date version. Always refer to the online version **www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf** to verify you have the most current information.

Where to Find Additional CDC Vaccine Storage and Handling Information

- Vaccine storage and handling home page: **www.cdc.gov/vaccines/recs/storage/default.htm** (sign up for notifications about updates)
- Educational webinars and netconferences for health care providers: **www.cdc.gov/vaccines/ed/courses.html**
- Contact information for state/local immunization programs: **www.cdc.gov/vaccines/imz-managers/awardee-imz-websites.html**
- E-mail specific questions to CDC: **NIPInfo@cdc.gov**

Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Recommendations and Reports / Vol. 60 / No. 2
January 28, 2011

General Recommendations on Immunization
Recommendations of the Advisory Committee on Immunization Practices (ACIP)

Continuing Education Examination available at http://www.cdc.gov/mmwr/cme/conted.html

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

The Centers for Disease Control and Prevention (CDC) Vaccine Storage and Handling Toolkit (referred to throughout this document as "the toolkit") brings together best practices from **Advisory Committee on Immunization Practices (ACIP) recommendations***, product information from vaccine manufacturers, and scientific studies. Implementing these best practices and recommendations will help protect your patients, safeguard your vaccine supply, and avoid the unnecessary costs of revaccination and replacing expensive vaccines.

Proper vaccine storage and handling has been an important factor in preventing and eradicating many common vaccine-preventable diseases. Yet, each year, storage and handling errors result in revaccination of many patients and significant financial loss due to wasted vaccine. Failure to store and handle vaccines properly can reduce vaccine **potency**, resulting in inadequate immune responses in patients and poor protection against disease. Patients can lose confidence in vaccines and providers if they have to be revaccinated because the vaccines they received may have been compromised.

This toolkit provides information and resources to assist you in properly storing and handling your vaccine supply, including information on:

- Storage and temperature monitoring equipment and setup
- Vaccine organization and storage
- Vaccine temperature and storage equipment monitoring
- Vaccine inventory management, transport, and preparation
- Emergency storage, handling, and transport
- Vaccine storage and handling standard operating procedure development

This toolkit reflects an adjustment in CDC's guidance on the Fahrenheit temperature range for storing refrigerated vaccines. The new recommended Fahrenheit temperature range is between 36° F and 46°F (previously between 35° F and 46° F). The Celsius temperature range (between 2° C and 8° C) remains unchanged, as stated in all manufacturer package inserts for routinely recommended vaccines.

Important Notes

If you are a Vaccines for Children (VFC) provider or receive other vaccines purchased with public funds, you should consult with your state or local immunization program (referred to throughout this document as "**immunization program**")* to ensure you are meeting all mandatory storage and handling requirements for your state, since there may be requirements that are specific or tailored to your jurisdiction. This toolkit provides general background information for many of the VFC storage and handling requirements and illustrates best practices essential to safeguarding public vaccine supply that can ultimately protect individuals from vaccine-preventable diseases.

For specific, detailed storage and handling protocols for individual vaccines, always refer to the manufacturers' product information and **package inserts***, or contact the manufacturer directly.

*ACIP Recommendations: **www.cdc.gov/mmwr/preview/mmwrhtml/rr6002a1.htm?**
Immunization programs: **www.cdc.gov/vaccines/imz-managers/awardee-imz-websites.html**
Manufacturers' package inserts: **www.immunize.org/packageinserts/**

Disclaimer: This document provides best practices and CDC recommendations on storage, handling and transport of vaccines and diluents. 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 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.

The vaccine cold chain is a temperature-controlled environment used to maintain and distribute vaccines in optimal condition. The cold chain begins with the cold storage unit at the manufacturing plant, extends through transport of vaccines to the distributor and delivery to and storage at the provider facility, and ends with administration of vaccine to the patient. Appropriate storage and handling conditions must be maintained at every link in the cold chain.

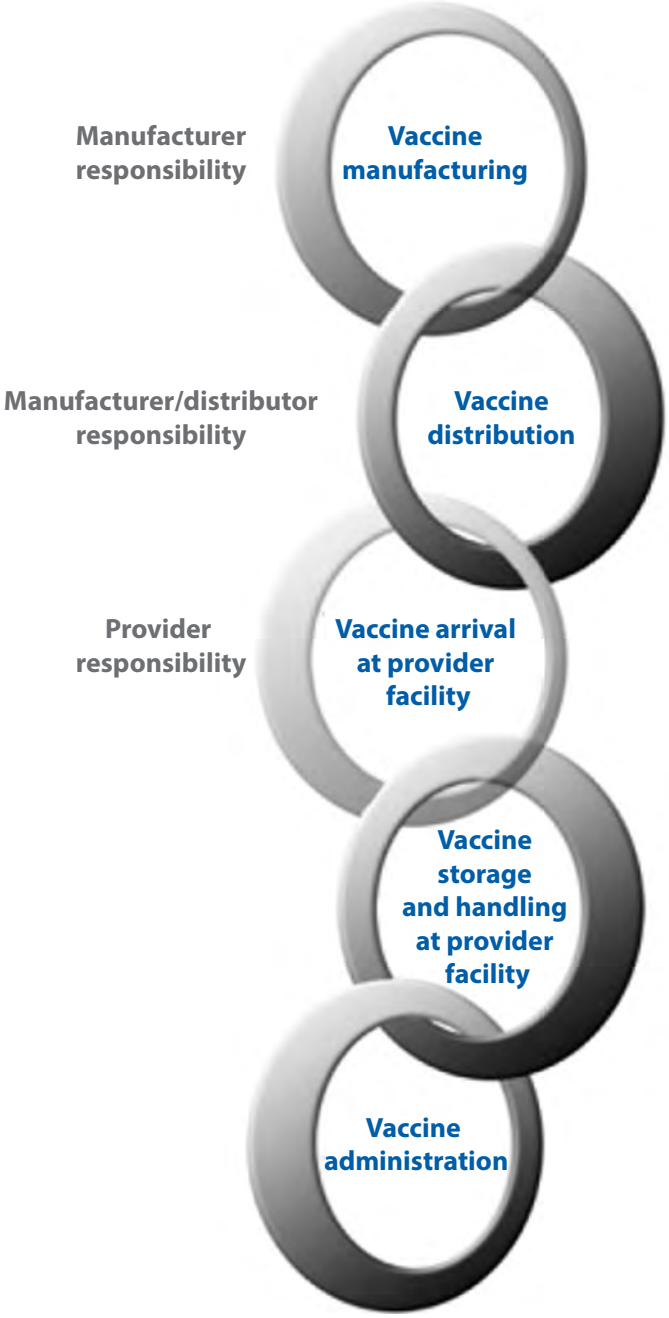
When the Cold Chain Fails

Too much exposure to heat, cold, or light at any step in the cold chain can damage vaccines, resulting in loss of vaccine potency. Once lost, potency cannot be restored. Each time vaccines are exposed to improper conditions, potency is reduced further. Eventually, **if the cold chain is not properly maintained, potency will be lost completely, and vaccines will be useless.**

While exposure to any inappropriate conditions can affect potency of refrigerated vaccines, a single exposure to freezing temperatures (0° C [32° F] or colder) will destroy some. Liquid vaccines that contain an aluminum adjuvant can permanently lose potency when exposed to freezing temperatures.

Vaccine appearance is not a reliable indicator that vaccines have been stored in appropriate conditions. For example, inactivated vaccines, even when exposed to freezing temperatures, may not appear frozen, giving no indication of reduced or lost potency.

Cold chain flow chart



Results of a cold chain failure can be costly.[1,2,3] ACIP's General Recommendations on Immunization state, "Vaccine exposed to inappropriate temperatures that is inadvertently administered generally should be repeated."[4] Inappropriate storage can mean extra doses for patients, increased costs for providers, and damage to public confidence in vaccines. More importantly, patients who refuse revaccination can remain unprotected from serious, vaccine-preventable diseases.

Properly stored vaccine
Full potency

Can you spot the difference?

Improperly stored vaccine
Diminished potency

Vaccine appearance is NOT a reliable indicator that vaccines have been stored in appropriate conditions.

Elements for an Effective and Reliable Cold Chain

An effective cold chain relies on three main elements:

- A well-trained staff
- Reliable storage and temperature monitoring equipment
- Accurate vaccine inventory management

These are the three main concepts upon which this toolkit is organized.

1. Department of Health and Human Services, Office of Inspector General.Vaccines for Children Program: Vulnerabilities in Vaccine Management, June 2012, **oig.hhs.gov/oei/reports/oei-04-10-00430.asp**.
2. Gazmararian JA, Oster NV, Green DC, Schuessler L, Howell K, et al.Vaccine storage practices in primary care physician offices: assessment and intervention.Am J Prev Med 2002;23(4):246–53.
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.
4. Centers for Disease Control and Prevention.General Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practices and the American Academy of Family Physicians.MMWR 2011;60(No.RR-2):17–19. Available from URL: **www.cdc.gov/mmwr/preview/mmwrhtml/rr6002a1.htm**.

Vaccine storage and handling practices are only as effective and successful as the staff that implements them. A well-trained staff, familiar with key storage and handling principles, is critical to ensuring the potency of your vaccine supply and the safety of your patients. Knowledgeable staff can also save your practice significant costs of wasted vaccine and prevent loss of credibility among patients who must be revaccinated due to a storage and handling error.

Staff Training

All staff members who receive deliveries and/or handle or administer vaccines should be familiar with storage and handling policies and procedures at your facility. Keep **standard operating procedures** (SOPs) for storage and handling near storage units and make sure staff knows where to find them.

CDC recommends that storage and handling training should be done:

- As part of new employee orientation
- Annually as a refresher for all staff involved in immunization activities
- Whenever new vaccines are added to inventory
- Whenever recommendations are updated

It is recommended that you record names of trainings, dates, and participants. If you are a VFC provider, this is required. Contact your **immunization program*** for any additional state requirements if you are a VFC provider or have other vaccines purchased with public funds.

CDC offers an online training module, "**You Call the Shots: Vaccine Storage and Handling**,"* and many **immunization programs*** and professional organizations also offer training resources for vaccine storage and handling.

Designate a person to be the primary vaccine coordinator for your facility.
Appoint a second staff member to serve as an alternate in the absence of the primary coordinator.

*Immunization programs: **www.cdc.gov/vaccines/imz-managers/awardee-imz-websites.html**
You Call the Shots: Vaccine Storage and Handling module: **www2a.cdc.gov/nip/isd/ycts/mod1/courses/sh/ce.asp**

Vaccine Coordinator

Designate a person to be the primary vaccine coordinator for your facility. This person will be responsible for ensuring all vaccines are stored and handled correctly. Appoint a second staff member to serve as an alternate in the absence of the primary coordinator (this is particularly important in case of after-hour emergencies). Both coordinators should be fully trained in routine and emergency policies and procedures.

Coordinator responsibilities include:

- Ordering vaccines
- Overseeing proper receipt and storage of vaccine deliveries
- Documenting vaccine inventory information
- Organizing vaccines within storage units
- Setting up temperature monitoring devices
- Reading and recording storage unit temperatures a minimum of 2 times each workday
- Reading and recording **minimum/maximum temperatures** from a digital data logger 1 time each workday, preferably each morning
- Reviewing and analyzing temperature data at least weekly for any shifts in temperature trends
- Rotating stock at least weekly so vaccines with the earliest expiration dates are used first
- Removing expired vaccine from storage units
- Responding to out-of-range temperatures (temperature excursion)
- Maintaining all documentation, such as inventory and temperature logs
- Ensuring staff is properly trained
- Monitoring operation of storage equipment and systems
- Overseeing proper vaccine transport (when necessary)
- Overseeing emergency preparations
  - Tracking inclement weather conditions†
  - Ensuring appropriate handling of vaccines during a disaster or power outage‡

†The National Oceanic and Atmospheric Administration (NOAA) provides up-to-date information on U.S. weather conditions:
www.weather.gov/
www.goes.noaa.gov/

‡The Federal Emergency Management Agency (FEMA) offers a wide range of information on disaster preparedness:
www.fema.gov/
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:
www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ProductSecurity/ucm147243.htm

Proper Vaccine Storage Temperatures

Refrigerated vaccines should be stored at temperatures between 2° C and 8° C (36° F and 46° F). The thermostat should be set at midrange to achieve a temperature of about 5° C (40° F), which will decrease the likelihood of **temperature excursions**.

Vaccines stored in the freezer should maintain temperatures between -50° C and -15° C (-58° F and +5° F). The thermostat should be at the factory-set or midpoint temperature setting to assure appropriate frozen storage temperatures.

This toolkit reflects an adjustment in CDC's guidance on the Fahrenheit temperature range for storing refrigerated vaccines. The new recommended Fahrenheit temperature range is between 36° F and 46° F (previously between 35° F and 46° F). The Celsius temperature range (between 2° C and 8° C) remains unchanged, as stated in all manufacturer package inserts for routinely recommended vaccines.

Think of your storage and monitoring equipment as an insurance policy to protect your patients from inadvertent administration of compromised vaccine, and your facility against costs of revaccination, replacement of expensive vaccines, and loss of patient confidence in your practice. For the best protection, your facility needs appropriate equipment that is set up correctly and maintained and repaired as needed.

To fully ensure the safety of vaccines, the following equipment is recommended:

- Stand-alone refrigerator(s) with enough space to accommodate your maximum inventory without crowding
- Stand-alone freezer(s) with enough space to accommodate your maximum inventory without crowding
- Digital data logger (DDL) with a current and valid Certificate of **Calibration** Testing (also known as a Report of Calibration) for each unit and at least one backup in case of a broken or malfunctioning device.

Stand-alone freezer

Stand-alone refrigerator

Transport situations also require special equipment, such as **emergency transport** containers and additional digital data loggers for each container (if there are more containers than storage units).

Storage Units (Refrigerators and Freezers)

Refrigerators and freezers typically used for vaccine storage are available in different grades (household and purpose-built) and types (stand-alone and combination refrigerator/freezer).

Purpose-built units are sometimes referred to as "pharmaceutical grade" and are designed specifically for storage of biologics. These units often have:

- Microprocessor-based temperature control with a digital temperature sensor (thermocouple, resistance temperature detector [RTD], or thermistor)
- **Fan-forced air circulation**, with powerful fans or multiple cool air vents inside the unit that promote uniform temperature and fast temperature recovery

Household combination refrigerator/freezer

CDC makes the following recommendations for vaccine storage units:

- Use purpose-built units designed to either refrigerate or freeze (can be compact, under-the counter-style or large units).
- If a purpose-built unit is not available, use a stand-alone household unit.
- If you must use a household-grade combination refrigerator/freezer unit, only use the refrigerator compartment for storing vaccines. These units have cold spots and temperature fluctuations, and air circulating from the freezer could expose refrigerated vaccines to freezing temperatures. Use a separate stand-alone freezer to store frozen vaccines.
- **Do not store any vaccine in a dormitory-style or bar-style combined refrigerator/freezer unit under any circumstances**. These units have a single exterior door and an evaporator plate/cooling coil, usually located in

Do not store any vaccine in a dormitory-style or bar-style combined refrigerator/freezer unit under any circumstances.

an icemaker/freezer compartment. These units have been shown to pose a significant risk of freezing vaccines, even when used for temporary storage. (Note: Not all small storage units are dormitory- or bar-style units. Compact purpose-built units for biologics can be used to store vaccines.)

- Make sure the storage unit has enough space to store the largest inventory you might have at the busiest point in the year (e.g., flu season) without crowding.
- Remove any deli, fruit, and vegetable drawers from refrigerator units. This provides extra space for **water bottles to help maintain stable temperatures** and prevents use of the drawers for storing food, beverages, or vaccines.
- Use safeguards to ensure the doors of the unit remain closed (for example, self-closing door hinges, door alarms, door locks, etc.).

Temperature Monitoring Equipment (Digital Data Loggers)

Digital data loggers

An accurate temperature history that reflects actual vaccine temperatures is critical for protecting your vaccines. Every vaccine storage unit must have a temperature monitoring device, and investing in reliable devices is less expensive than replacing vaccines wasted due to inaccurate temperature readings.

CDC recommends the use of a continuous monitoring and recording digital data logger (DDL) with a current and valid Certificate of Calibration Testing (also known as a Report of Calibration), set at a minimum recording interval of at least every 30 minutes. Unlike a simple minimum/maximum thermometer, which only shows the warmest and coldest temperatures reached in a unit, continuous monitoring and recording DDLs provide detailed information on all temperatures recorded at preset intervals. Many DDLs use a **buffered temperature probe**, which is the most accurate way to measure actual vaccine temperatures. Temperatures measured by a buffered probe match vaccine temperatures more closely than those measured by standard thermometers, which tend instead to reflect air temperature. DDLs provide the most accurate storage unit temperature information, including details on how long a unit has been operating outside the recommended temperature range (referred to as a temperature excursion).

Your facility should have a DDL for:

- Each vaccine storage unit
- Each emergency transport unit (this is particularly important if there are more transport units than storage units)
- At least one backup DDL in case a primary device malfunctions or is out for calibration testing (make sure the backup device has a different calibration testing schedule than the primary device so it is available when the primary device is being tested)

CDC recommends DDLs with the following characteristics:

- Detachable probe in a thermal buffered material (e.g., glycol, glass beads, sand, Teflon®)[†]
- Alarm for out-of-range temperatures
- Low-battery indicator[‡]
- Current, minimum, and maximum temperature indicator[§]
- Recommended **uncertainty** of +/-0.5° C (+/-1° F)
- Logging interval (or reading rate) that can be programmed by the user

Temperature data from a DDL can be downloaded to a computer using special software or retrieved from a website. The software or website may also allow you to set the frequency of temperature readings. Reviewing DDL data is critical for vaccine safety, so it is important to decide whether independent software or a website program will work best for your facility.

CDC recommends that a DDL's current and valid Certificate of Calibration Testing (Report of Calibration) should include:

- Model/device name or number
- Serial number
- Date of calibration (report or issue date)
- Confirmation that the instrument passed testing (or instrument in **tolerance**)
- Recommended uncertainty of +/-0.5° C (+/-1° F) or less

If you need to determine if a Certificate of Calibration Testing or Report of Calibration was issued by an appropriate entity, check to see if the certificate indicates one or more of the following items about calibration testing:

- Conforms to International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) 17025 international standards for calibration testing and **traceability**
- Performed by a laboratory accredited by International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) signatory body
  - A list of ILAC/MRA signatories may be found at **ILAC.org/ILAC-MRA-and-signatories/**

- Traceable to the standards maintained by the National Institute of Standards and Technology (NIST)
- Meets specifications and testing requirements for the American Society for Testing and Materials (ASTM) Standard E2877 Tolerance Class F (< +/-.5° C or < +/-1° F) or better
- Refers to another acceptable accuracy validation method, such as comparison to other traceable reference standards or tests at thermometric fixed points

Certain types of temperature monitoring devices have significant limitations and should not be used to measure temperatures in a vaccine storage unit. These devices can be difficult to read and, because they only show the temperature at the exact time they are read, may fail to detect temperatures outside the recommended range.

Specifically, CDC does not recommend the following temperature monitoring devices:

- Alcohol or mercury thermometers, even if placed in a fluid-filled biosafe liquid vial
- Bi-metal stem temperature monitoring devices
- Food temperature monitoring devices
- Chart recorders
- Infrared temperature monitoring devices
- Temperature monitoring devices that do not have a current and valid Certificate of Calibration Testing

CDC does NOT recommend these temperature monitoring devices

Devices sold in hardware and appliance stores are generally designed to monitor temperatures for household food storage. They are not calibrated and not accurate enough to ensure vaccines are stored within the correct temperature range. Using these devices can pose a significant risk of damaging expensive vaccines.

†Probes that are permanently imbedded in a buffer are acceptable as long as the temperature monitoring system for the entire unit can be calibration-tested.
‡Since these devices are typically battery-operated, have a supply of extra batteries on hand.
§Battery changes may affect temperature accuracy and may warrant checking against a known calibrated temperature device. Check with the device's manufacturer for specific information on battery changes.

Storage Unit Setup

Storage Unit Placement

Good air circulation around the outside of the storage unit is important. Place storage units in a well-ventilated room, leaving space between the unit, ceiling, and any wall. Nothing should block the cover of the motor compartment. The unit should be firm and level, with the bottom of the unit above the floor. Make sure the unit door opens and closes smoothly and fits squarely against the body of the unit. Studies find that most units work best when placed in an area with standard indoor room temperatures, usually considered to be between 20° C and 25° C (68° F and 77° F). Check the manufacturer-supplied owner's manual for additional guidance on placement and spacing.

Power Supply

Take the following precautions to protect the storage unit's power supply:

- Plug in only one storage unit per electrical outlet to avoid creating a fire hazard or triggering a safety switch that would turn off power.
- Use a safety-lock plug or an outlet cover to prevent the unit from being unplugged.
- Post "DO NOT UNPLUG" warning signs at outlets and on storage units to alert staff, custodians, electricians, and other workers not to unplug units.
- Label fuses and circuit breakers to alert people not to turn off power to storage units. Labels should include immediate steps to take if power is interrupted. If your building is owned by a third party and you do not have access to circuit breakers, work with your building manager.

Avoid using power outlets that can be tripped or switched off, including:

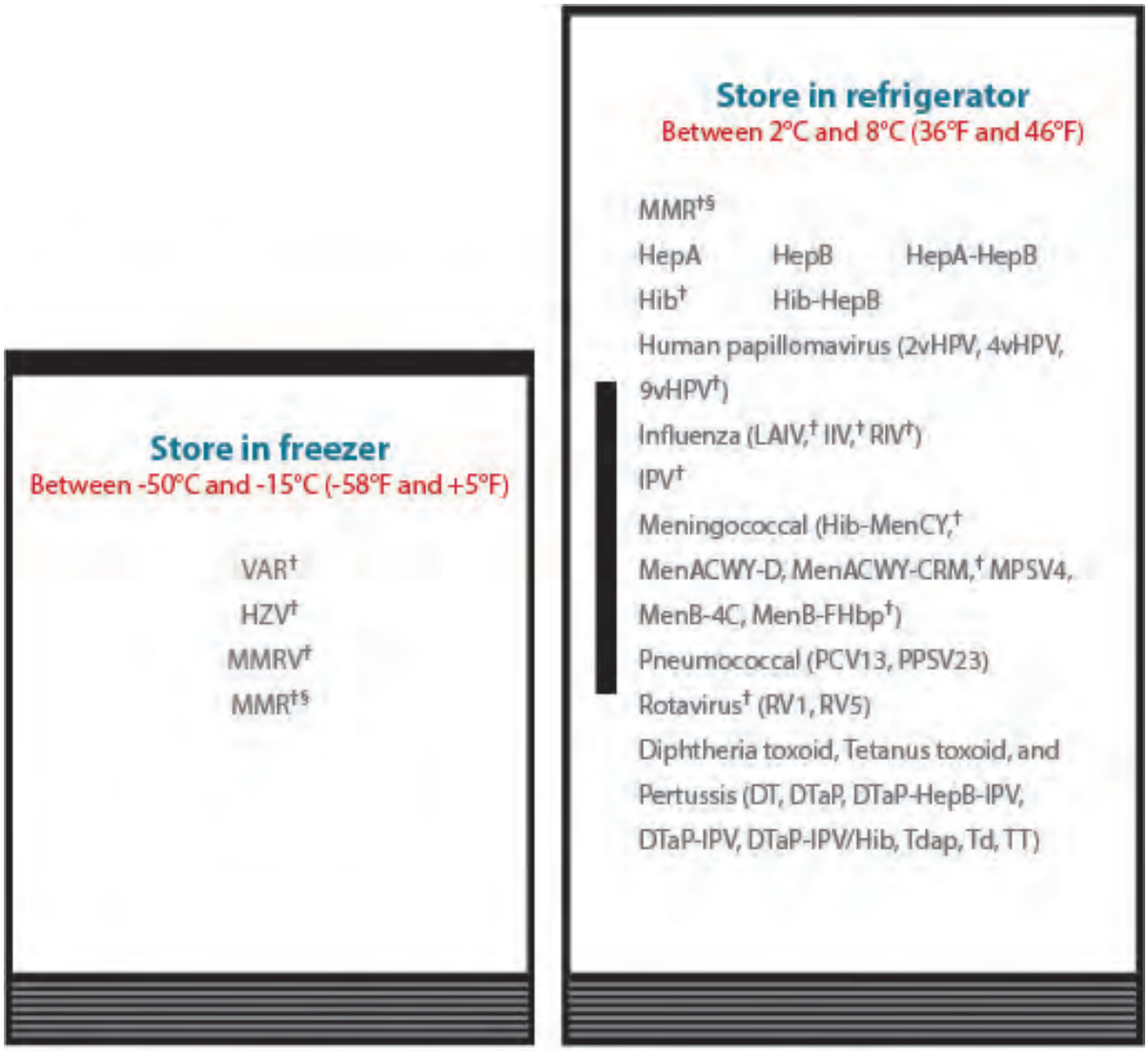
- Built-in circuit switches (may have reset buttons)
- Outlets that can be activated by a wall switch
- Multi-outlet power strips

If the entire storage unit is impacted by out-of-range temperatures because of a power outage or unit malfunction, refer to your facility's emergency storage and handling SOPs.

Temperature Ranges

Refrigerators should maintain temperatures between 2° C and 8° C (36° F and 46° F).† The thermostat should be set at midrange to achieve a temperature of about 5° C (40° F), which will decrease the likelihood of temperature excursions.

Freezers should maintain temperatures between -50° C and -15° C (-58° F and +5° F). The thermostat should be set at the factory-set or midpoint temperature to assure appropriate frozen storage temperatures.



†Protect the following vaccines from light: Varivax, Zostavax, ProQuad, M-M-R II, Hiberix, Gardasil, Gardasil 9, Afluria, FLUAD, Fluarix, Flublok, Flucelvax, FluLaval, Fluvirin, FluMist, IPOL, MenHibrix, Menveo, Bexsero, Rotarix, and RotaTeq.

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

Consult the owner's manual for instructions on how to operate the thermostat. Thermostats are marked in various ways, and in general, show levels of coldness rather than temperatures. The only way to know the temperature where vaccines are stored is to measure and monitor it with a continuous monitoring and recording **digital data logger** (DDL). Each unit should have its own temperature monitoring device.

[†]This toolkit reflects an adjustment in CDC's guidance on the Fahrenheit temperature range for storing refrigerated vaccines. The new recommended Fahrenheit temperature range is between 36° F and 46° F (previously between 35° F and 46° F). The Celsius temperature range (between 2° C and 8° C) remains unchanged, as stated in all manufacturer package inserts for routinely recommended vaccines.

Stabilizing Temperatures in New and Repaired Units

It may take 2 to 7 days to stabilize the temperature in a newly installed or repaired refrigerator or 2 to 3 days for a freezer. Before using a unit to store vaccines, **check and record temperatures a minimum of 2 times each workday for 2 to 7 days**.

If you are using a household combination refrigerator/freezer, do not use the freezer compartment to store vaccines. To maintain proper temperatures in the refrigerator, leave the freezer on at the factory-set or midpoint temperature setting. **Water bottles should also be placed in the refrigerator** to help maintain the correct temperature range and reduce the risk of freezing vaccines.

Organizing and Storing Vaccine in Storage Units

Following recommended guidelines and best practices for placement of vaccines in a storage unit will help to prevent conditions that could reduce vaccine potency or cause vaccine failure.

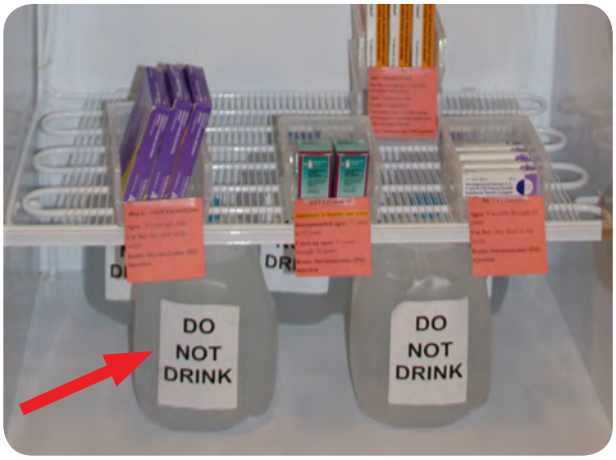
Always refer to manufacturers' product information/package inserts for the most up-to-date storage and handling recommendations for specific vaccines and diluents.

Storing Vaccine in a Refrigerated Unit

All vaccines except varicella-containing vaccines (varicella, zoster, and MMRV) should be stored in a refrigerator between 2° C and 8° C (36° F and 46° F), with a desired target temperature of 5° C (40° F). Measles, mumps, and rubella (MMR) vaccine may be stored in either a refrigerator or freezer. Some diluents must be refrigerated, while others may be stored in the refrigerator or at room temperature (no warmer than 25° C [77° F]).[†]

Best practices for storing vaccine and diluent in a refrigerated unit include:

- **Always store vaccines in their original packaging with lids closed until ready for administration.** This protects them from light and provides additional thermal protection/stability. **Never store loose vials or manufacturer-filled syringes outside of their packaging**. This increases the risk of administration errors, exposes vaccine to light, and makes it more difficult to track expiration dates and manage inventory.
- **Place water bottles on the top shelf and floor and in the door racks.**[‡§] Putting water bottles in the unit can help maintain stable temperatures caused by frequently opening and closing unit doors or a power failure. It can also prevent vaccines from being stored in areas where there is a greater risk of out-of-range temperatures (such as the top shelf, floor, and door). Place water bottles carefully so they cannot dislodge, preventing the door from closing securely or weighing the door down so the seals are not tight. Label all water bottles, "DO NOT DRINK."
- **Whenever possible, store diluent with the corresponding refrigerated vaccine:**
  - Diluents for Pentacel (DTaP-IPV/Hib) and Menveo (meningococcal conjugate vaccine) contain antigen and must be stored with their corresponding (freeze-dried) vaccine.
  - Some diluents can be stored at room temperature (no warmer than 25° C [77° F]).

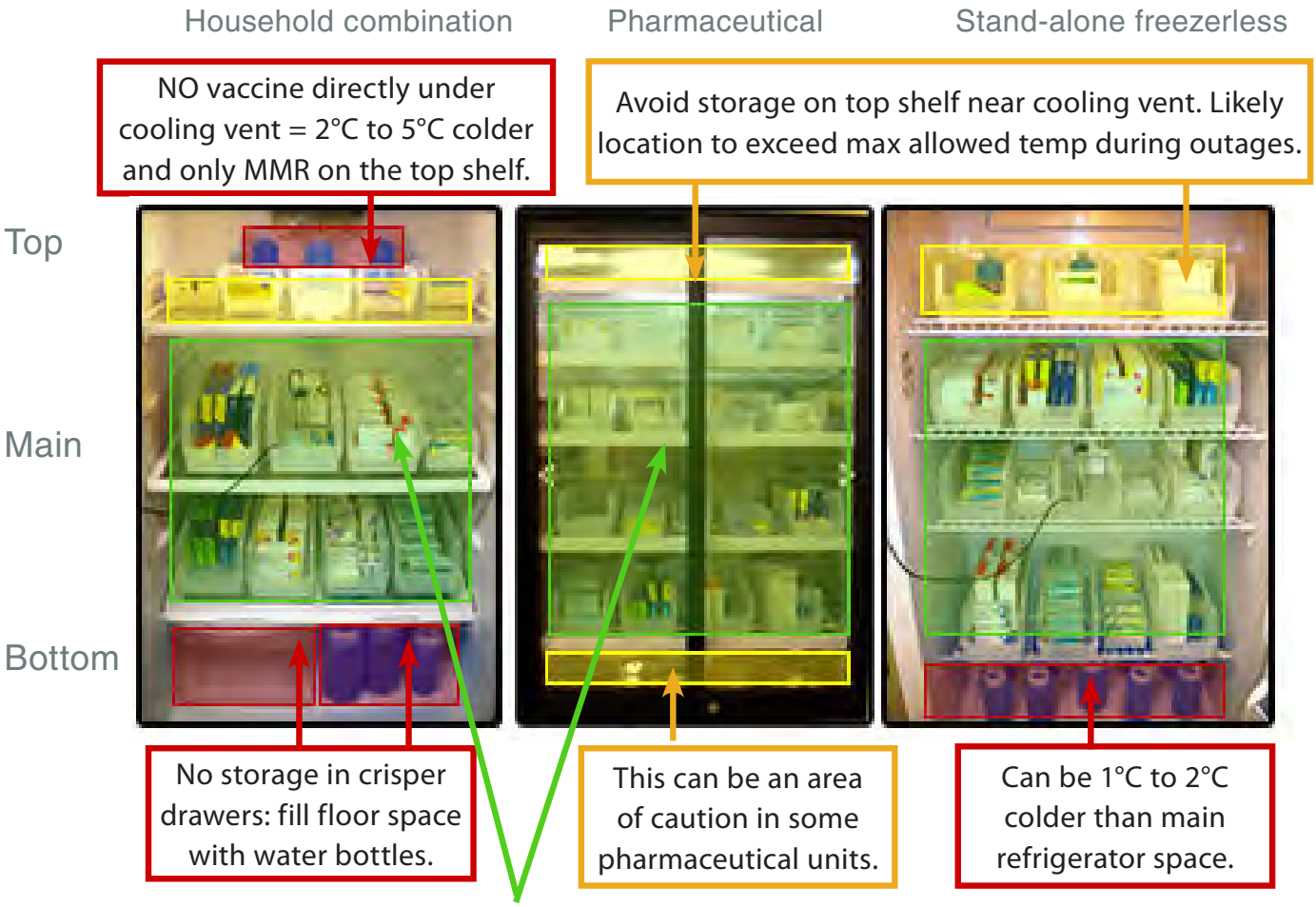


Water bottles on unit floor

Water bottles in unit door

- Store each type of vaccine or diluent in a separate container.
- Attach **labels to shelves and containers** to clearly identify where each type of vaccine and diluent is stored. If diluent is stored separately from the corresponding vaccine, label the container where it is stored.
- Store vaccines and diluents with similar packaging or names (e.g., DTaP and Tdap or Hib and HepB) or with both pediatric and adult formulations on different shelves to minimize the risk of administration errors. Make sure to label the formulation "pediatric" or "adult," if applicable.
- Place vaccines and diluents in the center of the unit, 2 to 3 inches away from walls, ceiling, floor, and door. Avoid storing vaccines and diluents in any part of the unit that may not provide stable temperatures or sufficient air flow, such as directly under cooling vents, in drawers, or in shelves on the door.` The instability of temperatures and air flow in these areas may expose them to inappropriate storage temperatures.

Recommended vaccine storage locations in the refrigerator



Best storage practice—place vaccines in center refrigerator space, contained in original packaging, inside designated storage trays positioned 2 to 3 inches from refrigerator walls.

- Do not store vaccines in deli, fruit, or vegetable drawers, or in the door. Temperatures in these areas are not stable and can differ from those inside the main part of the unit.
- Arrange vaccines and diluents in rows, allowing space between rows to promote air circulation. This helps each vaccine and diluent maintain a consistent temperature.
- Place vaccines and diluents with the earliest expiration dates in front of those with later expiration dates.
- Do not pack a storage unit too tightly. This can restrict air circulation and impact vaccine temperature.

Storing Vaccine in a Freezer Unit

Varicella-containing vaccines (varicella, zoster, and MMRV) should always be stored in a freezer unit between 50° C and -15° C (-58° F and +5° F) until reconstitution and administration. Measles, mumps, and rubella (MMR) vaccine can be stored in either a refrigerator or a freezer. **Never store any diluent in the freezer**.

Best practices for storing vaccine in a freezer unit include:

- **Always store vaccines in their original packaging with lids closed until ready for administration.** This protects them from light and provides additional thermal protection/stability. **Never store loose vials or manufacturer-filled syringes outside of their packaging.** This increases the risk of administration errors, exposes vaccine to light, and makes it more difficult to track expiration dates and manage inventory.
- **Place water bottles against the walls, in the back, on the floor, and in the door racks.** Putting water bottles in the unit can help maintain stable temperatures caused by frequently opening and closing unit doors or a power failure. It can also prevent vaccines from being stored in areas where there is a greater risk of out-of-range temperatures (such as the floor and door). Place water bottles carefully so they cannot dislodge, preventing the door from closing securely or weighing the door down so the seals are not tight. Label all water bottles, "DO NOT DRINK."
- Store each type of vaccine in a separate container.
- Attach **labels to shelves and containers** to clearly identify where each type of vaccine is stored.
- Store vaccines with similar packaging or names (e.g., VAR and HZV) or with both pediatric and adult formulations on different shelves to minimize the risk of administration errors. Make sure to label the formulation "pediatric" or "adult," if applicable.
- Place vaccines in the center of the unit, 2 to 3 inches away from walls, ceiling, floor, and door. Avoid storing vaccines in any part of the unit that may not provide stable temperatures or sufficient air flow, such as directly under cooling vents or shelves on the door. The instability of temperatures and air flow in these areas may expose them to inappropriate storage temperatures.

- Arrange vaccines in rows, allowing space between rows to promote air circulation. This helps each vaccine maintain a consistent temperature.
- Place vaccines with the earliest expiration dates in front of those with later expiration dates.
- Do not pack a storage unit too tightly. This can restrict air circulation and impact vaccine temperature.

Avoid Placing Other Items in Vaccine Storage Units

If possible, no items other than vaccines, diluents, and water bottles should be placed or stored in the units.

Food and beverages should never be stored in the unit with vaccines. Doing so can lead to frequent opening of the door to access food, putting vaccines at risk of temperature fluctuations and excessive light exposure. It can also result in spills and contamination.

Do NOT store food or beverages inside a vaccine refrigerator or freezer.

If other medications and biological products must be stored in the same unit as vaccines, never store these products in the same container with vaccines. Always store them below vaccines and on a different shelf. This prevents contamination and reduces the likelihood of medication errors.

†More information about storage of specific diluents can be found at **www.immunize.org/catg.d/p3040.pdf**.
‡Some refrigerator units, particularly pharmaceutical-grade units, may have specific guidance about the use of water bottles. Check the manufacturer's guidance for your unit.
§Avoid storing vaccines on the top shelf. If the top shelf must be used, place water bottles close to the vent and only store MMR vaccines on this shelf.

If other medications/biologics are stored in same unit with vaccines, store on a lower shelf.

Placement of Temperature Monitoring Device

To help ensure vaccines are stored at appropriate temperatures, it is important to follow recommended best practices for placement of a digital data logger (DDL) in a storage unit.

- **Place the buffered probe of the DDL in the center of the unit with the vaccines surrounding it.** A device placed near the walls, floor, vent, ceiling, or door may indicate temperatures that are colder or warmer than the actual vaccine temperature. This may not be true for pharmaceutical units because air flow and temperature are better regulated. Refer to your owner's manual for instructions on temperature monitoring device placement.
- Place the DDL's active digital display outside the unit so temperatures can be read without opening the door and disturbing the probe. **The DDL should be set to measure temperatures at least every 30 minutes.**

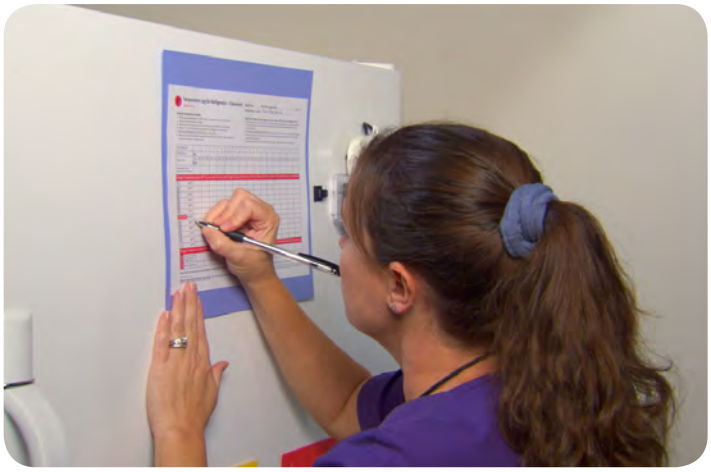
Monitoring Vaccine Temperature and Vaccine Storage Equipment

Monitoring vaccine storage equipment and temperature is a daily responsibility to ensure the safety of your vaccine supply and your patients. Implementing routine monitoring activities can help you identify out-of-range temperatures quickly and take immediate action to correct them, preventing loss of vaccines and the potential need for revaccination of patients.

Monitor and Record Storage Unit Temperature

CDC recommends on a **twice daily** basis:

- Check and record storage unit temperature readings each workday—in the morning when you arrive and in the evening before leaving. This should be done even if there is a temperature alarm or a DDL temperature monitoring device. A temperature monitoring log sheet[†] should be placed on each storage unit door (or nearby), and the following information should be recorded:
  - Temperature
  - Date
  - Time
  - Initials of person recording the data



If a reading is missed, leave a blank entry in the log.

The twice-daily checks provide an opportunity to inspect the storage unit, reorganize any misplaced vaccines, and remove any expired vaccines.

Check unit doors throughout the day and always at the end of the day to ensure they are tightly closed. A door left open not only affects temperature in the unit, but can also expose vaccines to light, putting them at risk of reduced potency.

CDC recommends on a **weekly** basis:

- Review storage unit temperature readings and review continuous DDL software or website information for changes in temperature trends that might require action (adjusting unit temperature or repairing/replacing storage or temperature monitoring equipment).
- File this information so it can be analyzed for long-term trends and/or recurring problems. Temperature data should be kept for 3 years (unless state statutes or rules require a longer period).

If there appears to be any fluctuation in temperature, **troubleshoot the problem based on additional information provided in this toolkit**, manufacturer manuals, and/or your office storage and handling SOPs.

Out-of-range Temperatures

Out-of-range storage temperatures or inappropriate conditions for any vaccine require immediate action. Any temperature reading outside ranges recommended in the manufacturers' **package inserts*** is considered a temperature excursion. In general, manufacturers analyze information about the magnitude of the temperature excursion and the total amount of time that temperatures were out of range, as well as information about the vaccine in question, to determine whether a vaccine is likely to be viable.

If there is any question about whether vaccines may have been exposed to a temperature excursion because the unit became too cold or too hot, CDC recommends the following steps:

1. Any staff member who hears an alarm or notices a temperature excursion on the DDL should notify the primary or alternate vaccine coordinator immediately or report the problem to their supervisor.
2. Label exposed vaccines, "DO NOT USE," and place them in a separate container apart from other vaccines in the storage unit (**do not discard these vaccines**).
3. The vaccine coordinator, supervisor, or if necessary, the person reporting the problem should begin to document the event:†

Label exposed vaccines, "DO NOT USE," and place them in a separate container apart from other vaccines in the storage unit.

   a. Date and time of the temperature excursion
   b. Storage unit temperature and room temperature, if available (including **minimum/maximum temperatures** during the time of the event, if available)
   c. Name of the person completing the report
   d. Description of the event:‡
      - General description (i.e., what happened)
      - If using a DDL, determine the length of time vaccine may have been affected
      - Inventory of affected vaccines
      - List items in the unit (including water bottles) other than vaccines
      - Any problems with the storage unit and/or affected vaccines before the event
      - Other relevant information
4. Contact your **immunization program*** and/or **vaccine manufacturer(s)** per your SOPs for further guidance on whether to use affected vaccines and for information about whether patients will need to be recalled for revaccination.§ Be prepared to provide documentation of the event (e.g., temperature log data) to ensure you receive the best guidance.
5. Implement your facility SOPs to adjust unit temperature to the appropriate range. At a minimum, check the temperature monitoring device to make sure it is appropriately placed in the center of the vaccines.
6. Complete your documentation of the event, including:
   a. Action taken
      i. What you did with vaccine and the time
      ii. Whom you have contacted and instructions received
      iii. What you have done to prevent a similar future event
   b. Results
      i. What happened to affected vaccines
      ii. Other comments

If you are a VFC provider or have other vaccines purchased with public funds, contact your **immunization program*** about required actions and special instructions or forms to be completed in the event of a temperature excursion.

Never allow vaccines to remain in a nonfunctioning unit for an extended period of time. If you believe the unit has failed, begin to implement your **emergency vaccine SOPs**.

*Manufacturers' package inserts: **www.immunize.org/packageinserts/**
Immunization programs: **www.cdc.gov/vaccines/imz-managers/awardee-imz-websites.html**
†The Immunization Action Coalition has developed a **Temperature Monitoring Log** (**www.immunize.org/handouts/temperature-logs.asp**) and a **Vaccine Storage Troubleshooting Record** (**www.immunize.org/catg.d/p3041.pdf**) to support these activities.
‡Responses from vaccine manufacturers to events depend on information given by the provider to the manufacturer. If different information about the same event is provided to the same manufacturer, this can lead to different recommendations on whether vaccine can be used or whether patients need to be revaccinated. In addition, each event is unique, and manufacturer recommendations based on existing stability data cannot be applied to future events that may appear to be similar.
§In the General Recommendations on Immunization, ACIP recommends "vaccine exposed to inappropriate temperatures that is inadvertently administered generally should be repeated."

Regular Maintenance of Vaccine Storage Units and Temperature Monitoring Devices

Storage units and temperature monitoring devices need regular maintenance to ensure proper operation, maintain required temperatures, and extend the useful life of the equipment. Check the manufacturer's product information for cleaning instructions and recommended maintenance schedules. Document maintenance tasks and repairs as indicated in your storage and handling SOPs.

Storage Unit Maintenance

The following routine maintenance tasks are recommended for all storage units:

- Check storage unit door seals regularly for signs of wear and tear. Seals should not be torn or brittle, and there should be no gaps between the seals and the body of the unit when the door is closed. If seals need to be replaced, contact a repair technician immediately.
- Check door hinges and adjust so that the door opens and closes smoothly and fits squarely against the body of the unit.
- Clean unit coils and motor. Dust and dirt buildup can affect transfer of heat from the coils and prevent the unit from working efficiently.
- Clean inside of units to discourage bacterial and fungal growth. Cleaning must be done quickly to minimize the risk of the temperature going out of range.
- Defrost manual-defrost freezers when the frost exceeds either 1 cm or the manufacturer's suggested limit. Follow the manufacturer's instructions. While defrosting, store vaccines temporarily in another unit with appropriate freezer temperatures.

Refrigerator coils

Unit doors pose a particular risk to maintaining appropriate internal temperatures of vaccine storage units. A door that is not sealed properly or that is left open unnecessarily not only affects the temperature in a unit, it also exposes vaccines to light, which can reduce potency of some vaccines. Leaving the door open can cause the thermostat to respond to warmer room temperatures, and the unit will work harder to maintain the correct temperature inside. The unit will continue to adjust its output of cool air, and the temperature may become very cold in some parts of the unit, possibly freezing refrigerated vaccine. Using an open-door alarm and a self-closing door may be helpful.

If your facility has a backup generator, it should be tested quarterly and serviced annually (check the manufacturer's guidance for testing procedures and maintenance schedules).

Temperature Monitoring Device Maintenance

Because all temperature monitoring devices experience "drift" over time that affects their accuracy, calibration testing should be done every 1 to 2 years or according to the manufacturer's suggested timeline.†

If calibration testing indicates your temperature monitoring device is no longer accurate within +/-.5° C (+/-1° F), it should be replaced. Adjustments to correct accuracy of the device are not recommended. You may prefer to replace the device rather than submitting it for calibration testing. Any new temperature data logger must have a current and valid Certificate of Calibration Testing (also known as Report of Calibration).

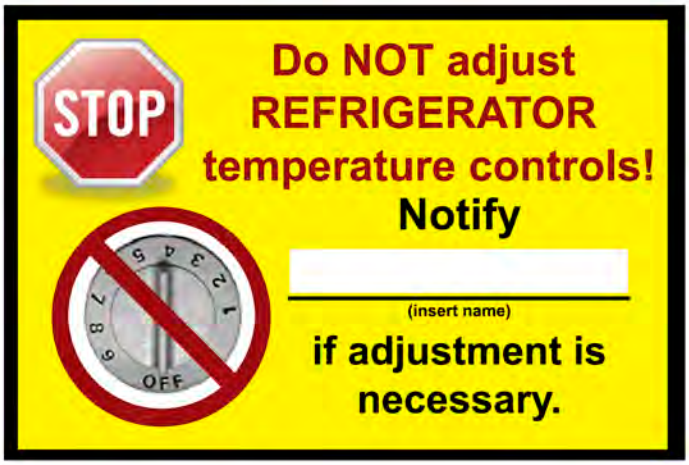
†Providers who receive VFC vaccines or other vaccines purchased with public funds should consult their **state or local immunization program** (**www.cdc.gov/vaccines/imz-managers/awardee-imz-websites.html**) about the required time frame for calibration testing.

Troubleshooting Equipment Problems

Adjusting Storage Unit Temperatures

Storage unit temperatures will likely need to be adjusted over time. In some situations, thermostats may need to be reset in summer and winter, depending on room temperature.

- Thermostat adjustments should only be made by the primary or alternate vaccine coordinator, based on information from digital data loggers and temperature monitoring logs.
- Post a **warning sign** on all storage units stating, "Do NOT adjust temperature controls. Notify (name of vaccine coordinator) if adjustments are necessary."
- Temperature adjustments should not be done during a busy clinic day when the unit door is being frequently opened and closed.



Thermostat adjustments should only be made by the primary or alternate vaccine coordinator, based on information from digital data loggers and temperature monitoring logs.

Remember that temperatures within any storage unit will vary at least slightly, even with normal use. Therefore, before making any adjustment:

- Confirm the unit is securely plugged into a power source.
- Check the temperature inside the storage unit.
- Wait 30 minutes, without opening the door, to allow the temperature to stabilize, and check it again to verify the thermostat should be adjusted. If you believe there could be an issue with your monitoring device, use your backup device to confirm the temperature.

If you confirm that an adjustment is needed:

- Refer to the owner's manual for detailed instructions.
- Turn the thermostat knob slowly to avoid going outside the correct temperature range, and make a small adjustment toward a warmer or colder setting as necessary.
- Allow the temperature inside the unit to stabilize for 30 minutes without opening the door.
- Recheck the temperature.
- Repeat these steps as needed until the temperature has stabilized at around 5° C (40° F) for a refrigerator or between -50° C and -15° C (-58° F and +5° F) for a freezer.
- Consider placing additional water bottles in the unit to help improve temperature stability.

If you are using a combination storage unit, please note that adjustments to the freezer temperature can adversely affect the refrigerator compartment temperature, possibly resulting in frozen refrigerated vaccines.

Do not leave vaccines in a storage unit that does not maintain temperatures within the recommended range. If you are unable to stabilize the temperature in your unit within the required range, or temperatures in the unit are consistently at the extreme high or low end of the range, your vaccine supply is at high risk. Use your emergency storage, handling, and transport SOPs to identify an alternative unit with appropriate temperatures and sufficient storage space until the primary unit can be repaired or replaced.

Repeated Alarm Alerts

If the temperature alarm goes off repeatedly, do not disconnect the alarm until you have determined and addressed the cause. Do basic checks of the unit door, power supply, and thermostat settings. If the alarm continues to trigger or the temperature remains out of range, transfer vaccines to a backup unit as directed by your emergency storage and handling SOPs. A repair technician should check your equipment to determine the need for repair or replacement.

Temperature Monitoring Device Equipment

Mishandling a temperature monitoring device can affect its accuracy. CDC recommends that if a DDL is dropped, hit against the side of a storage unit, or potentially damaged in any other way, its accuracy should be checked against another calibrated temperature monitoring device. If there is any question about accuracy, the device should be sent for calibration testing or replaced.

It is common with some devices to see a slight variation in temperature from one reading to another, even when the unit thermostat is set at a particular temperature. Temperatures within any storage unit will vary at least slightly, even with normal use. If you observe no fluctuation in your temperature monitoring device, the device may be faulty and may need calibration testing or replacement.

Contact your **immunization program*** for resources on checking the accuracy of your temperature monitoring device.

*Immunization programs: **www.cdc.gov/vaccines/imz-managers/awardee-imz-websites.html**

Vaccines are expensive, so it's important to make sure they are unpacked and stored correctly, and to account for every dose received and used by your facility, whether administered, wasted, compromised, expired, or transferred. Keeping accurate records to assist you in ordering and rotating stock on a regular basis will ensure that your facility has available the vaccines your patients need.

Vaccine Deliveries

Scheduling and Receiving Deliveries

All staff members who might receive vaccine deliveries must be aware of the importance of maintaining the cold chain. They should be trained to immediately notify the vaccine coordinator or alternate when deliveries arrive so that vaccines are checked in and stored quickly.

The person arranging for deliveries should know which staff member will be available to receive them, considering holidays, vacations, and any changes in the facility's hours of operation. Ideally, the vaccine coordinator or alternate should be available to receive deliveries.

Never leave a vaccine shipping container unpacked and unattended. If vaccines and diluents inside get too warm, they cannot be used. Be sure all staff members know that vaccine deliveries require immediate attention.

Unpacking Deliveries

Vaccines and diluents must be carefully unpacked, stored at recommended temperatures, and documented immediately after they arrive. Do not place an unopened and/or unpacked shipment box in a vaccine storage unit.

When unpacking deliveries:

- Examine the shipping container and vaccines for signs of physical damage.
- Check the contents against the packing list to be sure they match.
  - For varicella-containing (frozen) vaccines, the packing list will show the maximum time vaccines can be in transit based on shipment date.
- If the shipment includes **lyophilized** (freeze-dried) vaccines, make sure they came with the correct type and quantity of diluents. (Diluents for varicella-containing [frozen] vaccines are stored in a separate compartment in the lid of the shipping container and should be stored separately in the refrigerator.)
- Check both vaccine and diluent expiration dates to ensure you have not received any expired or **soon-to-expire products**.

- Check the **cold chain monitor** (CCM) for any indication of a temperature excursion during transit. CCMs are stored in a separate compartment of the shipping container (a CCM may not be included when vaccines are shipped directly from the manufacturer). Note: CCMs are for one-time use and should be thrown away after being checked.

If there are discrepancies between the contents and the packing list or other concerns about the contents, immediately notify the **vaccine manufacturer**. If you are a VFC provider or receive other vaccines purchased with public funds, contact your **immunization program***.

*Immunization programs: **www.cdc.gov/vaccines/imz-managers/awardee-imz-websites.html**

Vaccine Inventory Accounting

Expiration Dates

Understanding expiration dates is a key component of managing your vaccine inventory. Vaccine and diluent expiration dates indicate when the product must be discarded if it has not been used. These dates are printed on vials, manufacturer-filled syringes, and packages.

When the expiration date has only a month and year, the product may be used up to and including the last day of that month. If a day is included with the month and year, the product may only be used through the end of that day.

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

Be aware of instances when vaccines expire before the expiration date on the label.

Sometimes vaccines must be used before the expiration date—by an earlier date known as the "**beyond use date**" (BUD). The BUD is calculated based on the date the vial is first entered and

the storage information in the package insert. The BUD replaces the expiration date and should be noted on the label along with the initials of the person making the change. Examples include:

- **Reconstituted vaccines** have a limited time frame for use once the vaccine is mixed with a diluent. This time frame or BUD is noted in the package insert. For example, if the package insert states that the reconstituted vaccine must be used within 30 minutes, it must be discarded if not used by that time. This time frame might only apply as long as the reconstituted vaccine is still in the vial—not after it is drawn into a syringe—so check the package insert carefully.
- **Multidose vials** might have a specified time frame for use once they have been entered with a needle. For example, the package insert may state that the vaccine must be discarded 28 days after it is entered. If the vial is entered on 06/01/2017, the BUD is 06/29/2017. The vaccine should not be used after the BUD.

Manufacturer-shortened expiration dates may apply when vaccine is exposed to inappropriate storage conditions. The manufacturer might determine that the vaccine can still be used, but will expire on an earlier date than the date on the label.

Stock Record

A **stock record** helps you keep track of your vaccine inventory. These records can be in paper or electronic form, or part of an immunization information system (IIS) with the capacity to manage vaccine inventory. Many state and local programs that have an IIS with vaccine inventory accounting functions will require VFC providers to use the IIS to track their inventory. The stock record should be updated weekly.

You should account for and document every dose of vaccine on a stock record, including:

- Date of delivery (and initials of the person who unpacked the delivery)
- Vaccine and diluent name and manufacturer
- Number and expiration date for each lot (including expiration dates based on beyond use date guidance in the product information)
- Number of doses received
- Condition of each vaccine and diluent upon arrival (i.e., did vaccine arrive in good condition at the proper temperature?)
- Cold chain monitor (CCM) reading if a CCM is included in the shipping container (and actions taken if the monitor was triggered, signaling a possible temperature excursion)
- Number of doses used (i.e., administered, wasted, compromised, expired, or transferred [and destination])
- Balance of remaining doses after subtracting the amount used

If you receive multiple doses of the same vaccine in the same **presentation** from the same lot with the same expiration date, you can document these doses as one entry on the stock record. Indicate the total number of doses received, regardless of how many vials or syringes the doses came in. For example, if you receive 10 single-dose vials of the same vaccine with the same lot number and expiration date, you can make a single entry on the stock record, noting that 10 doses were received.

Doses of diluents that come with lyophilized (freeze-dried) vaccines should be documented on a separate stock record. Quantities of vaccines and their corresponding diluents should be equal at all times.

Tally Sheets

Use **tally sheets** to help you keep your stock record up to date. Place tally sheets outside the storage unit door (or another easily accessible location), and have staff use tick marks to keep a count of every dose removed from the unit (with columns for those administered, wasted, compromised, expired, or transferred).

At least weekly, add up the dose counts on the tally sheet and transfer that information to the stock record.

Stock Rotation and Removal

Vaccine stock should be rotated and checked for expired doses regularly.

The vaccine coordinator (or other designated person) should rotate vaccine and diluent stock at least once a week, as well as each time your facility receives a vaccine delivery. Arrange stock in the storage unit so that for each vaccine type, doses with the earliest expiration dates are placed in front of those with later expiration dates.

⚠ Check expiration dates on vaccines and diluents at least once a week, and **immediately remove any expired vaccines and diluents to avoid inadvertently administering them**. Be sure to document expired doses on the tally sheet and stock record. If expired vaccines were purchased with public funds, contact your **immunization program*** to find out if they can be returned.

Stock Counts

At least once a month and before placing any vaccine order, count all vaccine and diluent doses to make sure the number of doses in the storage unit matches the number of doses documented in the stock record. Always check expiration dates while counting stock and remove any expired doses immediately.

If the numbers do not match, enter the correct number based on your count on a separate line below the old balance. Make a note next to the new entry indicating that your count confirmed the new balance and sign it. Use the corrected balance for calculating stock quantities in the future.

At the end of each month, determine the total number of vaccine and diluent doses used during the month and the amount of stock still available. At the end of each year, use your stock record to determine the number of doses received for the year and add up your monthly dose counts to get a total number of doses used. This information will help you determine your facility's needs and guide you in ordering in an effort to minimize future waste and reduce the need for transfer and transport of vaccines.

*Immunization programs: **www.cdc.gov/vaccines/imz-managers/awardee-imz-websites.html**

Vaccine Ordering

The information in your stock record will help you determine the type and amount of vaccine your facility should stock to meet the needs of your patients. Make sure you are only ordering the vaccines and presentations that are appropriate for the ages and types of patients your facility serves.

CDC recommends that providers should order and stock only enough vaccine to meet patient needs.† Storing a larger volume than your facility needs can increase the risk of wasting vaccines if they expire before they can be used or they are compromised in some way (e.g., due to mechanical failure of a storage unit).

Most facilities should also reorder based on patient needs after doing a stock count. Vaccine orders usually arrive within 1 to 2 weeks, but keep in mind there could be delays. If possible, avoid placing last-minute or rush orders to prevent the risk of running out of vaccines.

† An adequate supply of vaccine for most providers or facilities would typically be enough to last 60 days, with a reordering threshold of 30 days.

Vaccine Disposal

Medical waste disposal requirements are set by state environmental agencies. Contact your **immunization program*** or state environmental agency for guidance to ensure your facility's vaccine disposal procedures (and any related documentation) comply with state and federal regulations.

General disposal guidelines for:

- **Vaccine doses that have expired or been compromised**—contact your **immunization program*** and/or the **vaccine manufacturer**. Sometimes unused vaccine and diluent doses,

unopened vials, expired vials, and potentially compromised vaccine may be returned for credit, even if they must be discarded.

- **Open vials and broken vials and syringes, as well as manufacturer-filled syringes that have been activated and vaccine predrawn by providers**—these cannot be returned and should be discarded according to your state requirements.
- **Empty vaccine vials**—most are not considered hazardous or pharmaceutical waste and do not require disposal in a biomedical waste container.† However, check your state requirements before disposal.

*Immunization programs: **www.cdc.gov/vaccines/imz-managers/awardee-imz-websites.html**
† While vials are not usually considered hazardous or pharmaceutical waste, an empty RV dispensing tube or oral applicator is considered medical waste and should be disposed of in a medical waste container.

Vaccine Transport to Off-site or Satellite Facilities

"Transport" has a different meaning than "shipping," which usually involves a professional carrier and a longer distance and time period for moving vaccines between locations. Transport involves the movement of vaccine over a short time frame and distance between providers. The time needed to transport should be fewer than 8 hours and vaccine should be placed in a stable storage unit as quickly as possible. **CDC does not recommend any shipment of vaccines from your vaccine supply or any routine transport of vaccines.**

Vaccines should only be transported when absolutely necessary (e.g., for a mass immunization clinic, in an emergency, or to ensure vaccines that are about to expire† can be used rather than wasted). **Frozen varicella-containing vaccines should never be transported except in an emergency.**

CDC does not recommend reshipping vaccines after receiving them from a commercial distributor or manufacturer because doing so would put the cold chain, and ultimately, the viability of the vaccines, at risk.

Transport of Refrigerated Vaccines

Vaccines that will be used at an off-site or satellite facility should be delivered directly to that facility. If that is not possible, transport of vaccines should be done using a portable vaccine refrigerator with a temperature monitoring device placed with the vaccines. If this is not available, **qualified containers and pack-outs** can be used with a temperature monitoring device. If you must transport vaccines, transport only what is needed for the workday. The total time for transport and workday should be a maximum of 8 hours. If you must transport vaccines in non-commercial vehicles, use the passenger compartment—not the trunk.

Immediately upon arrival at an off-site/satellite facility, vaccines should be stored in an appropriate storage unit with a temperature monitoring device, and temperatures should be read and recorded a minimum of 2 times during the workday.

If vaccines cannot be stored in an on-site storage unit, they should be kept in the portable vaccine refrigerator during an off-site clinic:

- **Place a temperature monitoring device** (preferably with a probe in a thermal buffer) as close as possible to the vaccines, and read and record temperatures at least hourly.
- Keep the container closed as much as possible.
- Remove only 1 multidose vial or 10 doses at a time for preparation and administration by each person administering vaccines.

Transport of Diluents

Transport diluents with their corresponding vaccines to ensure there are always equal amounts of vaccines and diluents for reconstitution. Follow the manufacturer's guidance for specific temperature requirements.

Diluents that contain antigen (e.g., DTaP-IPV diluent used with Hib lyophilized vaccine and MenCWY diluent used with MenA lyophilized vaccine) should be transported with the corresponding vaccines at refrigerator temperature.

If diluents that are stored at room temperature (68°F to 77°F or 20°C to 25°C) are going to be transported with refrigerated vaccines, they should be refrigerated in advance for as long as possible so they do not raise the container temperature when placed with refrigerated vaccines.

If you have concerns about vaccines or diluents that may have been compromised (exposed to inappropriate conditions or temperatures or handled improperly), label them "DO NOT USE" and store them in appropriate refrigerated conditions (set apart from other vaccines). Immediately contact your **immunization program*** or **vaccine manufacturer(s)** for guidance. Do not discard the vaccines or diluents unless directed to do so by the immunization program or manufacturer.

Emergency Transport

CDC recommends all vaccine providers have emergency plans and SOPs for transporting vaccines. Portable vaccine refrigerators are recommended when vaccines must be transported. Qualified containers and pack-outs can be used in an emergency. See the section on **Emergency Vaccine Storage, Handling, and Transport Preparations** for more information related to emergency transport.

*Immunization programs: **www.cdc.gov/vaccines/imz-managers/awardee-imz-websites.html**
Packing Vaccines for Transport during Emergencies: **www.cdc.gov/vaccines/hcp/admin/storage/downloads/emergency-transport.pdf**
†If you are a VFC provider, or have other vaccines purchased with public funds, and must transfer vaccine to another facility so it can be used before it expires, contact your **immunization program*** (www.cdc.gov/vaccines/imz-managers/awardee-imz-websites.html) for guidance on vaccine transport.

Preparing Vaccine for Administration

Vaccine preparation is the final step in the cold chain before administration. Handling vaccines with care is equally as important as storing them properly.

- Vaccines should be prepared in a designated area away from any space where potentially contaminated items are placed.
- **Only prepare vaccines when you are ready to administer them.** Always check expiration dates and confirm that you have selected the correct vaccine.
- **Only administer vaccines you have prepared.** This is a quality control and patient safety issue and a best practice standard of medication administration. If vaccine is drawn up by one person but administered by another, the person administering the vaccine cannot be sure what is in the syringe and whether it is safe.

Single-dose Vials

A single-dose vial (SDV) contains ONE dose and should be used ONE time for ONE patient. Do not combine leftover vaccine from one SDV with another to obtain a dose.

Single-dose vials do not contain a preservative to help prevent the growth of microorganisms. There have been outbreaks of infections caused by pooling contents and/or storing contents for future use.

Do not open an SDV until ready to use. Before you remove the protective cap, always check the vial to make sure you have the correct vaccine. Once you remove the cap, you must use the vaccine because it may not be possible to determine if the rubber seal has been punctured. Discard any unused SDVs without a protective cap 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.

Multidose Vials

A multidose vial (MDV) contains more than one dose of vaccine. Because MDVs typically contain a preservative to help prevent the growth of microorganisms, they can be entered or punctured more than once. Only the number of doses indicated in the manufacturer's package insert should be withdrawn from the vial. After the maximum number of doses has been withdrawn, the vial should be discarded, even if there is residual and the expiration date has not been reached.

MDVs can be used until the expiration date printed on the vial unless the vaccine is contaminated or compromised in some way or there is a **beyond use date (BUD)** noted in the package insert.

Never use partial doses from two or more vials to obtain a dose of vaccine.

Manufacturer-filled Syringes

A manufacturer-filled syringe (MFS) is prepared and sealed under sterile conditions by the manufacturer. **Do not activate an MFS (i.e., remove the syringe cap or attach the needle) until ready to use.** MFSs do not contain a preservative to help prevent the growth of microorganisms. Once the sterile seal has been broken, the vaccine should be used or discarded at the end of the workday.

Manufacturer-filled syringes

Reconstitution

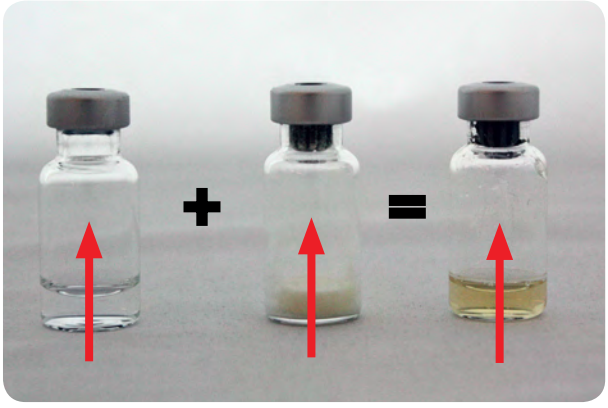
Lyophilized (freeze-dried) vaccines may be in the form of a powder or pellet that must be mixed with a liquid (diluent) in a process known as "reconstitution" before being administered.

Liquid diluents vary in volume and composition, and are specifically designed to meet volume, pH (acid/alkaline balance), and chemical requirements of their corresponding vaccine. Some diluents contain antigen (e.g., DTaP-IPV).

Diluents are not interchangeable unless specified by the manufacturer (e.g., those for MMR, varicella, zoster, and MMRV). Even if the diluent is composed of sterile water or saline, use only the diluent supplied with the vaccine to reconstitute it. **Never use a stock vial of sterile water or normal saline to reconstitute vaccines.**

Never administer vaccine reconstituted with the wrong diluent. If the vaccine has already been administered, contact your **immunization program*** and/or **vaccine manufacturer** for guidance on revaccination.

Always check expiration dates on both diluents and vaccines before reconstituting them.



Diluent + lyophilized powder = Reconstituted vaccine

Predrawing Vaccines

CDC recommends drawing up vaccines only at the time of administration. Once vaccines are inside syringes, it is difficult to tell them apart, which can lead to administration errors. Predrawing can also result in vaccine waste if more is drawn up than is needed.

General-use syringes are designed for immediate administration—not for storage. Contamination and growth of microorganisms can occur in syringes with predrawn vaccine that does not contain a preservative. In addition, vaccine components may interact with polymers in a plastic syringe over time, potentially reducing vaccine potency.

Vaccine manufacturers do not recommend predrawing vaccines in advance of influenza vaccination clinics because no data exist on the stability of vaccines stored in general-use syringes that have been filled by providers.

As an alternative to predrawing vaccines, CDC recommends using manufacturer-filled syringes for large immunization clinics.

If vaccine must be predrawn:

- Set up a separate administration station for each vaccine type to prevent medication errors.
- **Do not draw up vaccines before arriving at the clinic site.** Drawing up doses hours or even days before a clinic is not acceptable.
- Each person administering vaccines should draw up no more than one MDV, or 10 doses, at one time.
- Monitor patient flow to avoid drawing up unnecessary doses.
- Discard any remaining vaccine in predrawn syringes at the end of the workday.
- Do not predraw reconstituted vaccine into a syringe until you are ready to administer it. If not used within 30 minutes of being reconstituted, follow manufacturer guidance for storage conditions and time limits. A manufacturer may specify that an unused reconstituted vaccine can only be stored in the vial for the indicated time.
- Never transfer predrawn reconstituted vaccine back into a vial for storage.

*Immunization programs: **www.cdc.gov/vaccines/imz-managers/awardee-imz-websites.html**

Emergencies usually happen without warning. Various situations—equipment failures, power outages, severe weather conditions, or natural disasters—may compromise vaccine storage conditions. **Vaccines should never be allowed to remain in a nonfunctioning unit for an extended period of time.** Therefore, making preparations in advance to retrieve and/or protect vaccines as quickly as possible during a potentially compromising situation could save your facility costly vaccine loss.

Emergency Backup Options

Backup Equipment

No piece of vaccine storage equipment is infallible. At some point, equipment will fail because of a power outage, breakdown, or normal wear and tear.

At a minimum, every facility should have:

- Backup digital data logger(s)
- Spare batteries
- Flashlights (in case of a power outage)
- **Vaccine transport containers and materials**

Your facility may also choose to have a backup storage unit so that vaccine may not have to be packed and/or moved to an alternative storage facility if the primary storage equipment fails.

Generators

An on-site generator can prevent having to transport vaccine to an alternative storage facility during a power outage. Keep sufficient fuel on hand to continuously run the generator for at least 72 hours.

Backup generator

Alternative Vaccine Storage Facility

Even if you have backup equipment or a generator, you should establish a working agreement with at least one alternative storage facility with a backup generator where vaccines can be appropriately stored and monitored in an emergency. Hospitals, long-term care facilities, state depots, the Red Cross, fire stations, packing plants, and commercial pharmacies are some of the facilities that may be able to assist you.

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

An agreement with an alternative facility should allow you to store vaccines when:

- Severe weather conditions are expected. If there is reasonable cause to believe weather circumstances might impact your facility, implement emergency procedures in advance of the event.
- Equipment fails or power cannot be restored before the storage unit temperature rises above the recommended range.

Always make sure you can have 24-hour access to the alternative facility.

If an Alternative Vaccine Storage Facility is Not Available

If you cannot find an alternative vaccine storage facility with a backup generator within a reasonable distance, or if you cannot reach your alternative facility, **you can use qualified containers and pack-outs*** to store vaccines temporarily and safely at your facility. Always place a temperature monitoring device with the vaccines. Temporary storage containers should remain closed, and vaccines should only be stored for as long as the qualified containers and pack-outs are validated to maintain proper storage temperatures.

*Packing Vaccines for Transport during Emergencies: **www.cdc.gov/vaccines/hcp/admin/storage/downloads/emergency-transport.pdf**

Accessing Your Building After Hours

An emergency situation can arise outside of business hours, and having a relationship with your facility's building manager and/or security staff can be essential to protecting your vaccines. Meet with the manager and/or security personnel regularly and always introduce them to new staff members. Your storage and handling SOPs should have written instructions for accessing your vaccine storage units when the building is closed.

Provide anyone who needs access to vaccine storage units during an emergency with written instructions, a building diagram/map, and locations of:

- Spare batteries
- Flashlights
- Keys
- Locks
- Circuit breakers
- Packing materials

Keep information on after-hours building access and security procedures (including alarm codes) with the SOPs, and also make sure relevant staff members (and building management and security staff, if appropriate) have copies of this information available at home.

Power Outages

During a power outage, never open the storage unit door until power is restored or it is determined that vaccines need to be packed in separate storage containers and/or transported to an alternative storage facility.

Monitoring Unit Temperature during a Power Outage

Units with Outside Temperature Monitoring Devices

If you can monitor the temperature of the storage unit from the outside without opening the door, take the following steps:

- Record room temperature (if possible) and the temperature inside the unit as soon as the power goes out.
- Record minimum and maximum temperatures reached inside the unit during the outage.
- If temperatures have fallen outside of the recommended range, follow your procedures for **out-of-range temperatures/excursions**.

- If you are unsure how long the power interruption will last, or you determine power will not be restored in time to maintain proper temperatures inside the unit, implement your **emergency vaccine storage, handling, and transport procedures**.

Units without Outside Temperature Monitoring Devices

If you cannot monitor the temperature inside the unit without opening the door, wait until the power is restored, then take the following steps:

- Record the room temperature (if possible) and the temperature inside the unit.
- If using a digital data logger, document the length of time power was off and the minimum and maximum temperatures during that period.
- If temperatures inside the unit have already fallen outside of the recommended range, follow your procedures for **out-of-range temperatures/excursions**.
- If you are unsure how long the power interruption will last, or you determine power will not be restored in time to maintain proper temperatures inside the unit, implement your **emergency vaccine storage, handling, and transport procedures**.

The Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration (FDA) offers general guidance concerning storage and use of temperature-sensitive biological products that have been involved in temporary electrical power failure or flood conditions, **Impact of Severe Weather Conditions on Biological Products**.†

†Impact of Severe Weather Conditions on Biological Products: **www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ProductSecurity/ucm147243.htm**

Vaccine Transport Containers and Materials

For the safe transport and storage of vaccines, proper supplies are essential. Your facility should have a sufficient supply of materials needed for emergency vaccine transport of your largest annual inventory.

Appropriate materials include:

- Portable vaccine refrigerator/freezer units† (recommended)
- Hard-sided insulated or Styrofoam™†
- Coolant materials: frozen 16.9- or 8-ounce **water bottles that can be conditioned** or 4° C to 5° C **phase change materials** (PCMs)
- Insulating materials such as bubble wrap or corrugated cardboard—enough to form two layers per container
- Digital data logger for each container

Do not use soft-sided coolers. Most commercially available soft-sided coolers are poorly insulated and likely to be affected by room or outdoor temperatures.

Coolant Materials

Frozen water bottles can be used as coolant packs if they are **properly conditioned**, which should take only a few minutes:

- Hold the bottles under running tap water or submerge them in a sink filled with tap water until you can easily see a layer of water forming near the surface of the plastic.
- Once the ice block inside the bottle can spin freely, the bottle is ready to be used for packing. The inner block of ice will continue to melt while maintaining a constant temperature in the cooler.
- Use appropriate insulating materials, such as bubble wrap, to protect vaccines from direct contact with the water bottles.

Phase change materials (PCMs) at 4° C –5° C (39° F –41° F) can also be purchased to maintain proper temperatures. Follow the manufacturer's instructions for use to reduce the risk of freezing vaccines during transport.

Do not use frozen gel packs or coolant packs from vaccine shipments to pack refrigerated vaccines. Even if they are conditioned or appear to be "sweating," they can still freeze vaccines.

†If these items are not available, the manufacturer's original shipping boxes may be used for emergency transport.

Emergency Vaccine Packing and Transport

Improper packing for transport is as risky for vaccines as a failed storage unit. To help make sure your vaccines arrive safely, follow your facility's emergency retrieval and transport SOPs. These should include, at a minimum, the following procedures and protocols:

Packing

- If possible, suspend vaccination activities before the onset of emergency conditions to allow more time for packing and transport.
- Contact the alternative vaccine storage facility before packing any vaccine to confirm their generator is working and they can accept your vaccines for storage.
- Take an inventory of your vaccines and **record actions** taken to protect the vaccines. Be sure to note whether there were water bottles in the unit at the time of the event.

- Open unit doors only when absolutely necessary and only after completing all preparations for packing and moving vaccines.
- Use appropriate materials for packing. CDC has compiled recommendations on the methods and materials to use for emergency vaccine transport, **Packing Vaccines for Transport during Emergencies**.*

Transport

- Identify primary and backup vehicles and drivers in advance.
- Consider renting a refrigerated truck if you have a large quantity of vaccines or need to transport vaccines an extended distance.
- If using a noncommercial vehicle, only transport vaccines inside the passenger compartment (not in the trunk).
- Move transport containers directly to a preheated or precooled vehicle.
- Avoid leaving containers in areas where they are exposed to direct sunlight.
- Check vaccine temperature upon arrival at the alternative vaccine storage facility, and store vaccines at recommended temperatures immediately.
- Check with your **immunization program*** for additional guidance and resources on emergency transport of vaccines, particularly in major emergencies.

Transport of Diluents

Transport diluents with their corresponding vaccines to ensure there are always equal amounts of vaccines and diluents for reconstitution. Follow the manufacturer's guidance for specific temperature requirements.

Diluents that contain antigen (e.g., DTaP-IPV diluent used with Hib lyophilized vaccine and MenCWY diluent used with MenA lyophilized vaccine) should be transported with the corresponding vaccines at refrigerator temperature.

If diluents that are stored at room temperature (68°F to 77°F or 20°C to 25°C) are going to be transported with refrigerated vaccines, they should be refrigerated in advance for as long as possible so they do not raise the container temperature when placed with refrigerated vaccines.

Place an insulating barrier (e.g., bubble wrap) between the diluents and conditioned water bottles or phase change materials.

Never freeze diluents, not even during transport.

Transport of Varicella-containing (Frozen) Vaccines

The manufacturer does not recommend transporting frozen vaccines (varicella, zoster, MMRV).

If these vaccines must be transported during an emergency, CDC recommends using a portable vaccine freezer unit (available for rent in some areas) or qualified container and pack-out that maintains temperatures between -50° C and -15° C (-58° F and +5° F).

Follow these steps for transporting frozen vaccines:

- Place a calibrated temperature monitoring device (preferably with a buffered probe) in the container as close as possible to the vaccines.
- Record the time vaccines are removed from the storage unit and placed in the container, the temperature during transport, and the time at the end of transport when vaccines are placed in a stable storage unit.
- Immediately upon arrival at the destination, place vaccines in a freezer at a temperature range between -50° C and -15° C (-58° F and +5° F). Any stand-alone freezer that maintains these temperatures is acceptable.

Do not use dry ice, even for temporary storage. Dry ice might expose the vaccines to temperatures colder than -50° C (-58° F).

If necessary, varicella-containing vaccines that have not been reconstituted may be transported at refrigerator temperatures between 2° C and 8° C (36° F and 46° F). Varicella-containing vaccines can be refrigerated for up to 72 continuous hours before reconstitution. **Transported varicella-containing vaccines cannot be put back in the freezer. They must be used or discarded.**

Transport of Multidose Vials

If absolutely necessary, a partially used vial may be transported to or from an off-site/satellite facility operated by the same provider, as long as the cold chain is properly maintained. However, **a partially used vial cannot be transferred from one provider to another or across state lines.**

Temperature Monitoring During Transport

Use a digital data logger for continuous temperature monitoring and recording while transporting vaccines:

- The digital data logger should have an accuracy of +/-.5° C (+/-1° F).
- Place liquid or solid buffered probe material in a sealed vial directly with the vaccines.
- Keep the data logger display on top of vaccines so you can easily see the temperatures.

CDC does not recommend using cold chain monitors during transport since they provide limited data on temperature excursions that may occur.

If you have concerns about vaccines or diluents that may have been compromised (exposed to inappropriate conditions or temperatures or handled improperly), label them "DO NOT USE" and store them in appropriate refrigerated conditions (set apart from other vaccines). Immediately contact your **immunization program*** or **vaccine manufacturer(s)** for guidance. **Do not discard the vaccines or diluents unless directed to do so by the immunization program or manufacturer.**

*Packing Vaccines for Transport during Emergencies: **www.cdc.gov/vaccines/hcp/admin/storage/downloads/emergency-transport.pdf**
Immunization programs: **www.cdc.gov/vaccines/imz-managers/awardee-imz-websites.html**

Vaccine Storage and Handling Standard Operating Procedures (SOPs)

Clearly written, detailed, and up-to-date storage and handling standard operating procedures (SOPs) will help your facility stay organized, serve as a reference and training tool, and assure proper vaccine management. Without SOPs, there is no way to be sure proper procedures will be followed or that problems will be identified, reported, or corrected. SOPs should also provide guidance for emergency situations such as equipment malfunctions, power failures, or natural disasters. SOPs are a critical component in protecting your vaccine supply and, ultimately, your patients.

If you have multiple facilities, the details of your SOPs may differ depending on local policies.

Storage and Handling SOP Sections

Storage and handling SOPs should be reviewed and updated annually and should contain plans and information for three major areas (**Vaccine Storage and Handling SOP Worksheet**):

- General information—includes contact information for vaccine manufacturers, equipment service providers, and important facility staff, as well as job descriptions, regularly used forms, and staff training requirements
- Routine storage and handling—includes all routine aspects of vaccine inventory management, from ordering to monitoring storage conditions
- Emergency vaccine storage, handling, and transport—outlines steps to be taken in the event of equipment malfunctions, power failures, natural disasters, or other emergencies that might compromise vaccine storage conditions

General Information†

General information should include:

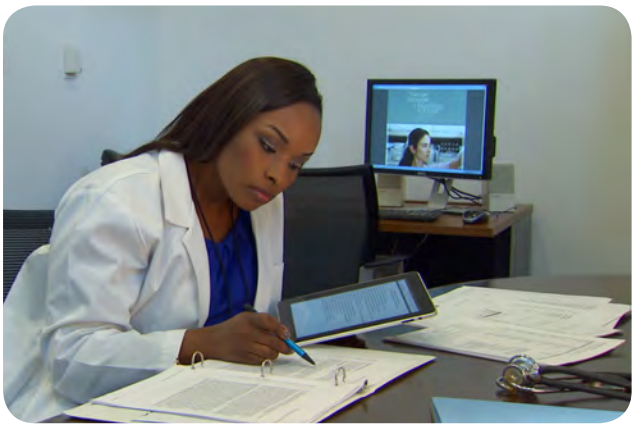
- Contact information for:
  - Primary vaccine coordinator
  - Alternate vaccine coordinator
  - Additional staff to assist in emergencies
  - **Immunization program***
  - **Vaccine manufacturers**
  - Refrigerator and freezer maintenance and repair companies
  - Temperature monitoring device (DDL) companies
  - Utility/power company

  - Vaccine storage unit alarm company (if applicable)
  - Generator repair company (if applicable)
  - Sources for qualified containers and pack-outs and calibrated temperature monitoring devices
- Descriptions of roles and responsibilities of primary and alternate **vaccine coordinators**
- Information for each storage unit, including serial number, links to equipment websites, installation dates, and routine maintenance and repair records
- Samples of all vaccine-related forms used in your facility
- Protocols for staff education and training

Routine Storage and Handling†

Routine storage and handling information should include protocols for:

- **Ordering** and **accepting** vaccine deliveries
- Receiving and **unpacking deliveries**
- **Managing inventory**
- **Storage requirements** for each vaccine and diluent in your inventory (**package inserts***)
- **Placing vaccines and diluents in storage units**
- **Handling vaccines prior to administration**
- **Disposing of vaccines** and supplies
- **Monitoring storage unit** and temperature
- **Maintaining storage equipment** and temperature monitoring devices
- **Responding to storage and handling problems**
- **Transporting vaccines to off-site/satellite facilities**



Each facility should have routine and emergency plans.

Emergency Storage, Handling, and Transport†‡§††

Because emergencies can happen at any time, it is important that in addition to facility staff, custodians, security officers, and/or building managers are aware of the emergency plan and know how to notify appropriate staff about any problems with vaccine storage equipment or power outages.

Copies of the emergency SOPs should be stored with the emergency supplies, kept with vaccine coordinator staff at their homes, and shared with others as appropriate, such as security officers or building managers.

Emergency storage, handling, and transport information should include:

- A primary and alternate staff contact for each type of emergency (e.g., power outage, weather conditions, equipment failure), as well as designated drivers for transporting vaccines and transport vehicle information (contact information should be reviewed quarterly)
- Name and address of alternative vaccine storage facility, names and numbers of contact persons, and 24-hour access information for facility
- Names and numbers for companies or private drivers to transport vaccines to alternative vaccine storage facilities
- Sources of qualified containers and pack-outs and calibrated temperature monitoring devices
- Vaccine storage unit specifications, including brand name, model number, serial number, and maintenance and repair company contact information
- A facility floor diagram showing the locations of important elements, including doors, flashlights, spare batteries, keys, locks, circuit breakers, and packing materials
- Protocols for:
  - Monitoring vaccines during a **power outage**
  - **Packing vaccines** and diluents for emergency transport
  - **Transporting vaccines** to and from an alternative vaccine storage facility
  - **Assessing whether vaccine can be used** after an emergency
  - **Accessing your building and facility after hours**

If you are a VFC provider or have other vaccine purchased with public funds, contact your **immunization program*** for guidance regarding routine and emergency SOPs.

*Immunization programs: **www.cdc.gov/vaccines/imz-managers/awardee-imz-websites.html**
Manufacturers' package inserts: **www.immunize.org/packageinserts/**
†Additional resources are available in **Resources** and from the Immunization Action Coalition (IAC): Clinical Resources – Storage and Handling (**www.immunize.org/clinic/storage-handling.asp**) and Emergency Response Worksheet (**www.immunize.org/catg.d/p3051.pdf**).
‡Contact your immunization program for details about specific state or local regulations impacting this activity.
§The Federal Emergency Management Agency (FEMA) offers a wide range of information on disaster preparedness: **www.fema.gov/**.
††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: **www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ProductSecurity/ucm147243.htm**.

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Stock Record

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Tally Sheet

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- Open Immediately 80
  - **Refrigerate** 80
  - **Freeze** 80
- **Fragile** 81
- **Perishable** 82

Buffered temperature probe	Temperature probe designed to prevent false readings by protecting the thermometer from sudden changes in temperature that can occur when opening a refrigerator door. A probe is "buffered" by immersing it in a vial filled with liquid (e.g., glycol, ethanol, glycerin), loose media (e.g., sand, glass beads), or a solid block of material (e.g., Teflon®, aluminum).
Beyond use date (BUD)	The date or time after which a vaccine should not be administered, stored, or transported. The BUD should never exceed the manufacturer's original expiration date.
Calibration	Professional measurement of the accuracy of a temperature monitoring device's readings against nationally accepted standards.
Cold chain monitor (CCM)	Generally, a single-use device that monitors the temperature inside of a vaccine shipping container.
Conditioned water bottles	Frozen water bottles that have been submerged under lukewarm water until the ice block inside can spin freely.
Diluent	A diluting agent (e.g., a liquid) added to reconstitute lyophilized vaccine before administration. Manufacturers of freeze-dried vaccine also supply the matching diluents.
Dormitory-style (bar-style) storage unit	A combination refrigerator/freezer unit with one exterior door and an evaporator plate (cooling coil), which is usually located inside an icemaker compartment (freezer) within the refrigerator. These units have been shown to pose a significant risk of freezing vaccines, even when used for temporary storage.
Fan-forced air circulation	Technology using powerful fans or multiple cool air vents inside the unit that promote uniform temperature and fast temperature recovery.
Lyophilized	Freeze-dried; usually referring to a vaccine that is freeze-dried into a powder or wafer.
Minimum/maximum temperature	A vaccine storage unit's coldest and warmest temperature readings during a set period of time.

Phase change materials (PCM)	Engineered packing supplies that help control container temperatures during vaccine transport or shipping.
Potency	A vaccine's strength or effectiveness; in the context of this toolkit, potency refers to a vaccine's response to environmental conditions.
Presentation	Type of packaging for a vaccine (e.g., single-dose vial, multidose vial, manufacturer-filled syringe, etc.).
Qualified container and pack-out	A type of container and supplies specifically designed for use when packing vaccines for transport. They are "qualified" through laboratory testing under controlled conditions to ensure they achieve and maintain desired temperatures for a set amount of time.
Soon-to-expire products	Products that will expire within the next month.
Temperature excursion	Any temperature reading that is outside the recommended range for vaccine storage as defined by the manufacturer's package insert.
Tolerance	Compliance with nationally accepted standards for the calibration limits of temperature monitoring equipment. The equipment can either be considered "in" or "out of" tolerance.
Traceability	An unbroken chain of measurements and associated uncertainties.
Uncertainty	The quantification of the doubt about the measurement result.

Additional References

General Vaccine Storage and Handling Information

- CDC Vaccine Storage and Handling home page
  (www.cdc.gov/vaccines/recs/storage/default.htm)
- CDC Vaccine Price List
  (www.cdc.gov/vaccines/programs/vfc/awardees/vaccine-management/price-list/)
- National Institute of Standards and Technology (NIST) "Storage and Monitoring of Vaccines"
  (www.nist.gov/pml/div685/grp01/vaccines.cfm)
- Advisory Committee on Immunization Practices Recommendations
  (www.cdc.gov/vaccines/acip/recs/index.html)
- Contact Information for State/Local Immunization Programs
  (www.cdc.gov/vaccines/imz-managers/awardee-imz-websites.html)
- Specific Immunization Questions: E-mail CDC at **NipInfo@cdc.gov**

Vaccine Labels for Storage Units (can be printed and reproduced)

- Vaccine Label Examples
  (www.cdc.gov/vaccines/hcp/admin/storage/guide/vaccine-storage-labels.pdf)
- 2016-2017 Influenza Vaccine Label Examples
  (www.cdc.gov/vaccines/hcp/admin/storage/index.html)

Emergency Vaccine Storage and Handling Resources

- Packing Vaccines for Transport during Emergencies
  (www.cdc.gov/vaccines/recs/storage/downloads/emergency-transport.pdf)

Immunization Action Coalition Resources

- Vaccine Manufacturers' Package Inserts
  (www.immunize.org/packageinserts/)
- Handouts: Clinic Resources on Storage and Handling
  (www.immunize.org/handouts/vaccine-storage-handling.asp)
- Temperature Monitoring Log
  (www.immunize.org/handouts/temperature-logs.asp)
- Vaccine Storage Troubleshooting Record
  (http://www.immunize.org/catg.d/p3041.pdf)
- Emergency Response Worksheet
  (www.immunize.org/catg.d/p3051.pdf)
- Vaccines with Diluents: How to Use Them
  (www.immunize.org/catg.d/p3040.pdf)
- State Immunization Program websites
  (www.immunize.org/states/)

Emergency Management Resources

- The National Oceanic and Atmospheric Administration (NOAA) provides up-to-date information on U.S. weather conditions:
  www.weather.gov/
  goes.noaa.gov/
- The Federal Emergency Management Agency (FEMA) offers a wide range of information on disaster preparedness:
  www.fema.gov/
- 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:
  www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ProductsSecurity/ucm147243.htm
- International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement Signatories:
  ILAC.org/ILAC-MRA-and-signatories/

Vaccine Storage and Handling SOP Worksheet

Complete the following checklist and forms and store this information in an easily accessible area near the vaccine storage unit.

Checklist of General Information

- ❑ Up-to-date contact information
  - – Primary vaccine coordinator
  - – Alternate vaccine coordinator
  - – Additional staff to assist in emergencies
  - – Immunization program
  - – Vaccine manufacturers
  - – Refrigerator and freezer maintenance and repair companies
  - – Temperature monitoring device companies
  - – Utility/power company
  - – Vaccine storage unit alarm company (if applicable)
  - – Generator repair company (if applicable)
  - – Sources for qualified containers and pack-outs
- ❑ Descriptions of the roles and responsibilities of the primary and alternate (backup) vaccine coordinators
  - – Information for each storage unit, including serial number, links to equipment websites, installation dates, and routine maintenance and repair records
  - – Samples of all vaccine-related forms used in your facility
  - – Protocols for staff education and training

Checklist for Routine Storage and Handling

- ❑ Protocols for:
  - – **Ordering** and **accepting** vaccine deliveries
  - – Receiving and **unpacking deliveries**
  - – **Managing inventory**
  - – **Storage requirements** for each vaccine and diluent in your inventory (package inserts)
  - – **Placing vaccines and diluents in storage units**
  - – **Handling vaccines prior to administration**
  - – **Disposing of vaccines** and supplies
  - – **Monitoring storage unit** and temperature
  - – **Maintaining storage equipment** and temperature monitoring devices
  - – **Responding to storage and handling problems**
  - – **Transporting vaccines to off-site/satellite facilities**

Checklist of Emergency Vaccine Storage, Handling, and Transport

- ❑ All contact information in General Information as well as up-to-date contact information for:
  - Alternative vaccine storage facility(ies)
  - Transportation of vaccines
- ❑ Vaccine storage unit specifications (type, brand, model number, serial number)
- ❑ Diagram of facility showing important elements, including doors, flashlights, packing materials, batteries, circuit breakers
- ❑ Protocols for:
  - Monitoring vaccines during a **power outage**
  - **Packing vaccines** and diluents for emergency transport
  - **Transporting vaccines** to and from an alternative vaccine storage facility
  - **Assessing whether vaccine can be used** after an emergency
  - **Accessing your building and facility after hours**

Store emergency information with emergency supplies. Keep copies in multiple off-site locations, including homes of the vaccine coordinator staff, alternative storage facility(ies), and with the building/facility manager and security office (if appropriate).

Staff Contact List			
Name	Title	Telephone Numbers home/cell/other	E-mail Address
	Primary Vaccine Coordinator		
	Alternate Vaccine Coordinator		

Emergency Staff Contact List*			
Name	Title	Telephone Numbers home/cell/other	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 and Handling SOP Worksheet

General Resources Contact List			
Resources	Contact Person Name/Title	Telephone Numbers home/cell/other	E-mail Address
Local Health Department Immunization Program			
State Health Department Immunization Program			
Vaccine Manufacturers			
Refrigerator Repair Company			
Freezer Repair Company			
Utility/Power Company			
Temperature Monitoring Device Company			
Vaccine Storage Unit Alarm Company (if applicable)			
Generator Repair Company (if applicable)			

Alternate Vaccine Storage Facilities			
Alternate Vaccine Storage Facility Name/Address	Contact Person Name/Title	Telephone Numbers home/cell/other	E-mail Address
1.			
2.			
3.			
4.			

Transportation to Alternate Vaccine Storage Facilities			
Emergency Resources Name/Address	Contact Person Name/Title	Telephone Numbers home/cell/other	E-mail Address
Refrigeration Company			
Refrigeration Company (alternate)			
Private Vehicle			
Private Vehicle (alternate)			

Packing Material Suppliers Contact List			
Emergency Resources Company Name	Contact Person Name/Title	Telephone Numbers home/cell/other	E-mail Address
Portable vaccine refrigerator/ freezer units			
Qualified containers and pack-out materials			
Qualified containers and pack-out materials (alternate)			
Packing materials			
Packing materials (alternate)			

Vaccine Storage Unit Specifications			
Type of Unit (Refrigerator or Freezer)	Brand	Model Number	Serial Number
1.			
2.			
3.			
4.			
5.			

Vaccine Manufacturer/Distributor Contact List

Manufacturer/Distributor Websites	Telephone Number/E-mail	Products
ACAM2000 Sanofi Pasteur www.sanofipasteur.us/vaccines/ACAM2000	800-822-2463 www.sanofipasteur.us/contact	Smallpox
bioCSL www.seqirus-us.com/products.htm	888-435-8633 or 855-358-8966 cs.flu@seqirus.com	IIV
Centers for Disease Control and Prevention www.cdc.gov/ncidod/srp/drugs/drug-service.html www.cdc.gov/laboratory/drugservice/index.html	404-639-3670 drugservice@cdc.gov	Distributor for anthrax vaccine adsorbed (AVA), diphtheria antitoxin, smallpox vaccine
CSL Limited (Merck Distributor) www.merckvaccines.com/	800-637-2590	IIV
Emergent BioDefense Operations Lansing, Inc. www.biothrax.com/	877-246-8472 productsafety@ebsi.com	Anthrax vaccine adsorbed (AVA)
GlaxoSmithKline (GSK) www.gskvaccines.com/	866-475-8222 vaccine.service-center@gsk.com	DTaP, DTaP-HepB-IPV, DTaP-IPV, HepA, HepB, HepA-HepB, Hib, Hib- MenCY, 2vHPV, IIV, JE, MenB-4C, MenACWY-CRM, Rabies, RV1, Tdap
Massachusetts Biological Labs www.umassmed.edu/massbiologics/	800-457-4626	Td
MedImmune www.medimmune.com/	877-633-4411 medicalinformation@medimmune.com	LAIV

Vaccine Manufacturer/Distributor Contact List

Manufacturer/Distributor Websites	Telephone Number/E-mail	Products
Merck & Co., Inc www.merckvaccines.com/	877-829-6372	HepA, HepB, Hib, Hib-HepB, 4vHPV, 9vHPV, HZV, MMR, MMRV, PPSV23, RV5, VAR
Novartis www.novartis.com/about-us/contact	877-683-4732 Vaccineinfo.us@novartis.com	IIV, JE, MCV4, Rabies
PaxVax www.paxvaxconnect.com/vivotif	(800) 533-5899 customercare@paxvax.com	Typhoid (oral)
Pfizer/Wyeth pfizerpro.com/	800-438-1985	MenB-FHbp, PCV13
Protein Sciences www.flublok.com/professionals.html	800-488-7099 www.flublok.com/contact.html	IIV
Sanofi Pasteur www.vaccineshoppe.com/	800-822-2463	DT, DTaP, DTaP-IPV/Hib, DTaP-IPV, Hib, IIV, IPV, MenACWY-D, MPSV4, Rabies, Td, Tdap, TT, Typhoid, YF

Fahrenheit to Celsius and Celsius to Fahrenheit Conversion

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

°C	°F	°C	°F
-30	-22	13	55.4
-29	-20.2	14	57.2
-28	-18.4	15	59
-27	-16.6	16	60.8
-26	-14.8	17	62.6
-25	-13	18	64.4
-24	-11.2	19	66.2
-23	-9.4	20	68
-22	-7.6	21	69.8
-21	-5.8	22	71.6
-20	-4	23	73.4
-19	-2.2	24	75.2
-18	-0.4	25	77
-17	1.4	26	78.8
-16	3.2	27	80.6
-15	5	28	82.4
-14	6.8	29	84.2
-13	8.6	30	86
-12	10.4	31	87.8
-11	12.2	32	89.6
-10	14	33	91.4
-9	15.8	34	93.2
-8	17.6	35	95
-7	19.4	36	96.8
-6	21.2	37	98.6
-5	23	38	100.4
-4	24.8	39	102.2
-3	26.6	40	104
-2	28.4		
-1	30.2		
0	32		
1	33.8		
2	35.6		
3	37.4		
4	39.2		
5	41		
6	42.8		
7	44.6		
8	46.4		
9	48.2		
10	50		
11	51.8		
12	53.6		

Stock Record

Instructions: Use the monthly stock record to document inventory from new vaccine/diluent shipments and track weekly accounts of doses used. At the end of each month, count inventory in storage unit(s) and compare with recorded balance. If physical count and recorded balance are different, record the actual (physical count) balance next to the previous recorded balance. Note the cause of the discrepancy or if it is unknown. Start a new stock record every month, listing at the top the previous month's balance as the new month's starting balance.

Vaccine Type: *PPSV23*

Month and Year: *August 2017*

Date Received or Usage Tallied	Person Receiving Shipment *	Arrival Condition **	Vaccine or Diluent Name	Manufac-turer	Vial Type (SDV, MDV, MFS)***	Lot Number	Expiration Date	Expiration Date After Reconstitu-tion	Doses Received/ Balance Forward	Doses Used †	Balance (Doses)
08/02/17	BEGINNING BALANCE FOR THE MONTH								2	N/A	2
08/09/17										1	1
08/15/17	LST	G	PPSV23	Merck	MDV	03958	02/15/18	N/A	5	3	3
08/23/17										1	2
08/29/17										0	2

Vaccine Totals	7	5	2 ††

Physical Stock Check (In Doses)	2
Difference ("Balance" minus Physical Stock Check)	0
Balance Carried Forward (In Doses)	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 = Manufacturer-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."

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

Stock Record

Instructions: Use the monthly stock record to document inventory from new vaccine/diluent shipments and track weekly accounts of doses used. At the end of each month, count inventory in storage unit(s) and compare with recorded balance. If physical count and recorded balance are different, record the actual (physical count) balance next to the previous recorded balance. Note the cause of the discrepancy or if it is unknown. Start a new stock record every month, listing at the top the previous month's balance as the new month's starting balance.

Vaccine Type: _____ Month and Year: _____

Date Received or Usage Tallied	Person Receiving Shipment *	Arrival Condition **	Vaccine or Diluent Name	Manufac-turer	Vial Type (SDV, MDV, MFS)***	Lot Number	Expiration Date	Expiration Date After Reconstitu-tion	Doses Received/ Balance Forward	Doses Used †	Balance (Doses)
	BEGINNING BALANCE FOR THE MONTH									N/A	

Vaccine Totals			††

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

* 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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Some state or local health department immunization programs have developed their own stock record for immunization providers. Contact program staff for information. If stock record 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 or near the refrigerator and freezer doors. Record the week (by date or week number). Write the vaccine/diluent names and indicate the storage location (refrigerator = R, freezer = F). Make a tick mark in the appropriate box for each dose of vaccine/diluent removed from the unit (i.e., each dose administered, wasted, unusable, expired, or transferred). At the end of the week, add the tick marks for each vaccine/diluent and update the totals on the appropriate stock record. File the completed tally sheet and replace with a new sheet.

Week: *August 19-23, 2017 (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	~~IIII~~ III (8)	I				9
R	DTaP	~~IIII~~ ~~IIII~~ II (12)					12
R	HepB	~~IIII~~ ~~IIII~~ II (12)					12
R	IPV	~~IIII~~ ~~IIII~~ II (12)		II			14
R	HepA (pediatric)	II (2)					2
R	PPSV23	I (1)					1
		( )					
		( )					
		( )					
		( )					
		( )					
		( )					
		( )					
		( )					

* R = Refrigerator
F = Freezer

** Some unusable 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 or an Immunization Information System (IIS), this tally sheets may be used.

Tally Sheet

Instructions: Place a copy of this sheet on or near the refrigerator and freezer doors. Record the week (by date or week number). Write the vaccine/diluent names and indicate the storage location (refrigerator = R, freezer = F). Make a tick mark in the appropriate box for each dose of vaccine/diluent removed from the unit (i.e., each dose administered, wasted, unusable, expired, or transferred). At the end of the week, add the tick marks for each vaccine/diluent and update the totals on the appropriate stock record. File the completed tally sheet and replace with a new sheet.

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 unusable 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 or an Immunization Information System (IIS), this tally sheets may be used.

PROTECT YOUR VACCINE
PROTECT YOUR PATIENTS

Handle with Care!

Vaccine Storage Rules

- Keep your storage units and vaccines within the appropriate temperature ranges.
- Review and record refrigerator and freezer temperatures at least 2 times each workday.
- 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 VAR, HZV, and MMRV frozen.
- Check expiration dates and rotate your vaccine stock.

Freezer

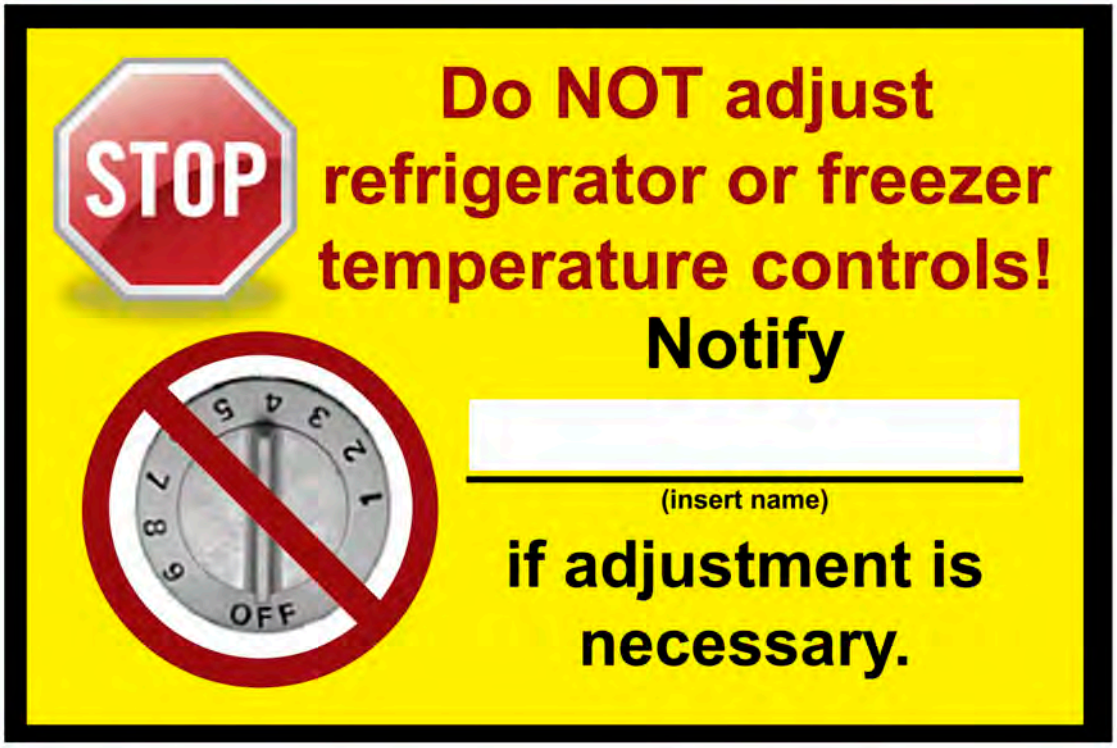
Store vaccines between
-50°C and -15°C
(-58°F and +5°F)

Refrigerator

Store vaccines
between
2°C and 8°C
(36°F and 46°F)

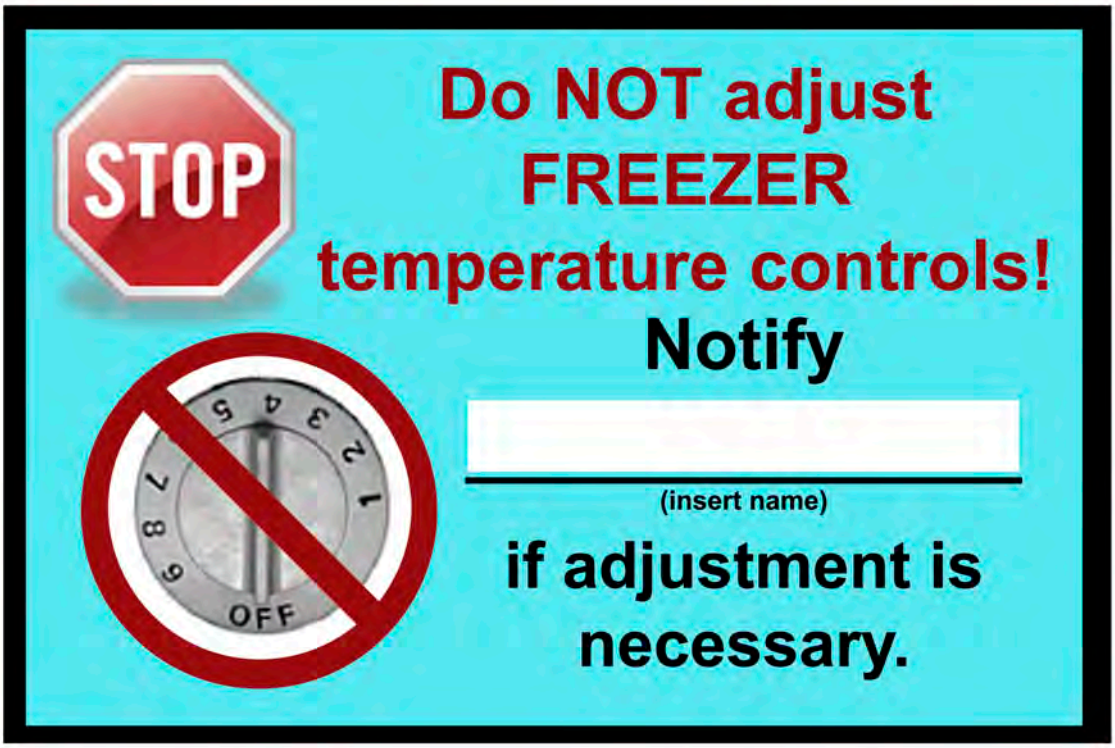
Warning Labels

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 Stop Power to Circuit Breaker (English)

WARNING!

EXPENSIVE VACCINE IN STORAGE

DO NOT STOP POWER TO CIRCUIT BREAKER _____

IN THE EVENT OF ELECTRICAL PROBLEM, IMMEDIATELY

CONTACT _____ AT _____

Warning! Do Not Unplug Refrigerator (English)

Warning! Do Not Unplug Refrigerator (Spanish)

Warning! Do Not Unplug Freezer (English)

WARNING!

Do not unplug the FREEZER or break circuit. Expensive vaccine in storage.

In the event of electrical problem, immediately contact:

_____

Warning! Do Not Unplug Freezer (Spanish)

¡AVISO!

No desconecte el CONGELADOR ni corte el circuito. ¡Contiene vacunas caras!

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

_____

Do Not Unplug Refrigerator (English)

Do Not Unplug Refrigerator (Spanish)

Do Not Unplug Freezer (English)

Do Not Unplug Freezer (Spanish)

Transport Labels

Refrigerate Upon Arrival

Freeze Upon Arrival

Open Immediately: Refrigerate Upon Receipt

Open Immediately: Freeze Upon Receipt

Fragile: Handle with Care

Fragile

Perishable—Rush