Vaccine Storage and Handling Toolkit

With Key Resources and Addendum for SNS-supplied Jynneos

JULY 2026

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Vaccine Storage and Handling Toolkit: 2026 Key Updates

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- Updated instructions for storage, handling, and transport of monkeypox vaccine (Jynneos)

Disclaimer: This document provides guidance and best practices on storage, handling, and transport of immunization products and their diluents. It also provides information about Vaccines for Children (VFC) program product storage and handling requirements. 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 Centers for Disease Control and Prevention (CDC).

Introduction

Proper vaccine storage and handling practices are essential for protecting patients by ensuring product efficacy and quality, preventing unnecessary revaccination, minimizing vaccine wastage, and ensuring a viable vaccine supply. Ultimately, adhering to vaccine storage and handling guidelines helps improve patients' health by preventing disease.

The Centers for Disease Control and Prevention (CDC) *Vaccine Storage and Handling Toolkit* provides valuable information, guidance, and resources to help providers store and handle vaccines properly. This information also applies to RSV monoclonal antibody products. The toolkit brings together content from manufacturer information, findings from scientific studies, *General Best Practices for Immunization*, and *Epidemiology and Prevention of Vaccine-Preventable Diseases* (the "Pink Book").

Where to Find Current, Product-specific Storage and Handling Guidance

The source of vaccine storage and handling guidance depends on whether the vaccine is *approved* (also referred to as *licensed*) by the U.S. Food and Drug Administration (FDA) or *authorized* by FDA under an Emergency Use Authorization (EUA).

- FDA-approved vaccines: Refer to the manufacturer's package insert.
- EUA-authorized vaccines: Refer to the EUA Fact Sheet for Healthcare Providers. More information on EUAs is available at Emergency Use Authorization | FDA.

Note: Vaccine manufacturers may occasionally revise expiration or beyond-use dates after the release of the package insert or EUA Fact Sheet. These updates are typically communicated through the FDA's Expiration Dating Extension website or in a "Dear Health Care Provider" letter.

Vaccines for Children Program

The Vaccines for Children (VFC) program provides vaccines to children whose parents or guardians may not be able to afford them. VFC providers play a crucial role in ensuring VFC-eligible children receive effective, quality immunization products.

The VFC Operations Guide is the primary source of guidance for VFC participants. This toolkit complements the VFC Operations Guide by providing background on many VFC storage and handling requirements and highlighting best practices essential for safeguarding the public vaccine supply. VFC participants are encouraged to implement all guidance and best practices outlined in the toolkit in addition to the requirements and guidance from the VFC Operations Guide.

VFC participants and other providers who administer vaccines purchased with public funds should consult their state or local immunization program (referred to throughout this document as "immunization program") to ensure compliance with all mandatory jurisdiction-specific storage and handling requirements.

Note: The terms "VFC-compliant," "CDC-compliant," or "satisfies VFC requirements" are sometimes used in equipment vendor marketing materials or on their websites. In this context, "compliance" and related terms may lead consumers to incorrectly believe that CDC or the VFC program has independently assessed and verified the quality of these products. CDC, including the VFC program, is not authorized to assess, validate, verify, or endorse the products or services of private companies. Should providers encounter this type of language in vendor marketing materials, please keep in mind that neither CDC nor the VFC program has validated any product or service for compliance with CDC or VFC program requirements or standards.

Introduction

Additional CDC Vaccine Storage and Handling Training and Information:

- Vaccine storage and handling home page: www.cdc.gov/vaccines/hcp/storage-handling/
- Vaccine storage and handling resources page: www.cdc.gov/vaccines/hcp/storage-handling/resources.html
- Epidemiology and Prevention of Vaccine-Preventable Diseases (the "Pink Book"): https://www.cdc.gov/pinkbook/hcp/table-of-contents/chapter-5-vaccine-storage-and-handling.html
- General Best Practices for Immunization: Storage and Handling of Immunobiologics: www.cdc.gov/vaccines/hcp/imz-best-practices/storage-handling-immunobiologics.html
- You Call the Shots: Vaccine Storage and Handling
  - www2a.cdc.gov/nip/isd/ycts/mod1/courses/sh/ce.asp (Full training module)
  - www2.cdc.gov/vaccines/ed/vfc/sh/ (Refresher Test for VFC Providers)

Providers with Specific Questions Can Contact:

- State/local immunization programs: www.cdc.gov/vaccines/php/imz-program-resources/awardee-websites.html
- CDC's immunization inquiry service (NIPINFO): nipinfo@cdc.gov
- CDC's vaccine storage and temperature monitoring equipment experts (for VFC awardees only): izcoldchain@cdc.org

Icon Guide for the Vaccine Storage and Handling Toolkit

This list explains the icons used throughout the toolkit and what they represent.

ICON	DESCRIPTION
	CDC Guidance – Essential action to protect the vaccine supply
	CDC Best Practice – Additional actions, practices, and procedures to enhance protection of the vaccine supply
	Vaccines for Children (VFC) Requirements – Highlights VFC program-specific storage and handling requirements

Section One: Vaccine Cold Chain

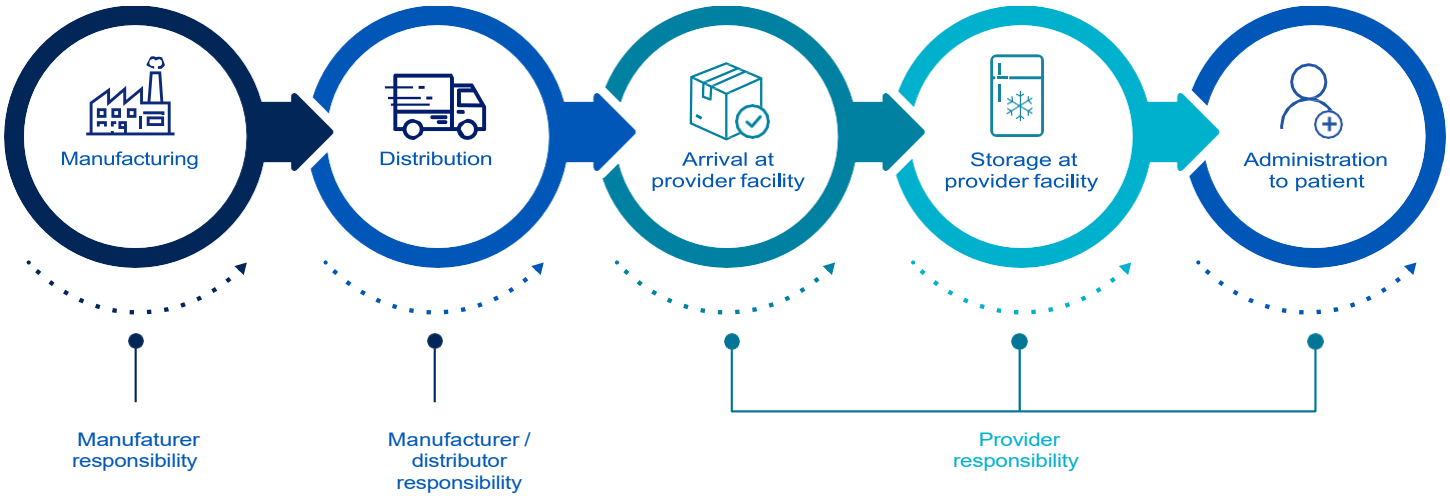
Proper vaccine storage and handling plays a critical role in efforts to prevent vaccine-preventable diseases. Vaccines and other immunizing agents (e.g., RSV monoclonal antibodies) exposed to temperatures outside the recommended ranges may lose potency, resulting in decreased protection and the need to revaccinate patients.

VFC providers and other health care professionals who administer vaccines purchased with public funds should contact their immunization program for state-specific requirements related to procedures for maintaining an effective cold chain.

Cold Chain Basics

Effective storage and handling starts with maintaining a reliable vaccine cold chain—a temperature-controlled supply chain that includes all vaccine-related equipment and procedures. The cold chain begins with the cold storage unit at the manufacturing plant, extends to the transport and delivery of the vaccine and correct storage at the provider facility, and ends with administration of the vaccine to the patient.

Vaccine Cold Chain Flowchart



Source: CDC

An effective cold chain depends on three key elements:

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

Why the Cold Chain Matters

Failure to maintain the cold chain can cause vaccines to lose potency so they become unusable. Potency decreases every time a vaccine is exposed to improper conditions, such as temperatures outside the recommended range at any point in the cold chain. For some vaccines, exposure to light also reduces vaccine potency. Once potency is lost, it cannot be restored. For refrigerated vaccines, a single exposure to freezing temperatures (0°C [32°F] or colder) can completely destroy vaccine potency.

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 visual indication of reduced or lost potency.

According to *General Best Practices for Immunization*,

- Vaccines stored at inappropriate temperatures should not be administered unless public health authorities or the manufacturer confirm they are safe and effective based on stability data.
- If such vaccines have already been administered, doses should generally be repeated.

Failure to maintain the cold chain can result in extra doses for patients, increased wastage and costs for providers, and damage to public confidence in vaccines. Most importantly, patients refusing revaccination can remain unprotected from potentially serious, vaccine-preventable diseases. By following proper storage and handling practices, providers can ensure patients receive effective vaccines.

Section Two: Staffing and Training

Effective vaccine storage and handling practices depend on knowledgeable, well-trained staff. All staff who receive vaccine deliveries, handle vaccines, or administer vaccines should be trained in general storage and handling practices and be familiar with their facility's storage and handling standard operating procedures (SOPs).

VFC providers and others who administer vaccines purchased with public funds should contact their immunization program for state-specific requirements related to training, policies, and procedures.

Storage and Handling Standard Operating Procedures (SOPs)

SOPs help facilities stay organized, serve as a reference and training tool, and support proper vaccine management. They also play a critical role in identifying, reporting, and correcting problems. To ensure SOPs are practical and comprehensive, providers should follow the guidance below.

Each facility should develop and maintain clearly written, detailed, and up-to-date SOPs for vaccine storage and handling. SOPs should address three main areas:

1. General Information
   - Updated contact lists (e.g., primary and backup vaccine coordinators, vaccine manufacturers, service providers)
   - Equipment details (e.g., serial numbers, maintenance records)
   - Staff roles and responsibilities
   - Commonly used forms
   - Documentation of staff training
2. Routine Storage and Handling Procedures
   - Vaccine ordering, receipt, storage, and inventory control
   - Stock rotation and management of expired, spoiled, or wasted vaccines
   - Use of an appropriate temperature monitoring device and current calibration certificates
   - Daily temperature monitoring and recording
   - Procedures for temperature excursions
   - Vaccine handling and preparation
3. Emergency Procedures
   - Plans to monitor, pack, and transport vaccines in the event of equipment failure, power outages, natural disasters, or other emergencies affecting storage conditions

The Vaccine Storage and Handling SOP Worksheet in the toolkit's Resources section contains additional information to assist with developing these procedures.

Keep SOPs near vaccine storage units and ensure staff know their location.

Review and update SOPs at least annually to confirm accuracy and relevance.

Staff Roles and Responsibilities

Designate a primary vaccine coordinator. This person will be responsible for ensuring all vaccines are stored and handled correctly and should be an expert on their facility's related SOPs.

Appoint a backup (alternate) vaccine coordinator. This person will act in the absence of the primary coordinator. The backup coordinator, like the primary coordinator, should be an expert on the facility's storage and handling SOPs.

The coordinator's responsibilities may be completed by the coordinator or delegated to appropriately trained staff. Their competency for the specific tasks assigned should be documented.

Coordinator's responsibilities should include

- Ordering vaccines
- Overseeing proper receipt and storage of vaccine deliveries
- Documenting vaccine inventory information
- Organizing vaccines within storage units
- Rotating stock at least weekly, so vaccines with the earliest expiration dates are used first
- Removing expired vaccines from storage units
- Setting up temperature monitoring devices
- Checking and recording in temperature logs the minimum/maximum temperatures at the start of each workday
- Reviewing and analyzing temperature data at least weekly to identify any shifts in temperature trends
- Responding to temperature excursions (out-of-range temperatures)
- Maintaining all documentation, such as inventory and temperature logs
- Organizing vaccine-related training and ensuring staff complete training
- Monitoring the operation of vaccine storage equipment and systems
- Overseeing proper vaccine transport
- Preparing for emergencies:
  - Tracking inclement weather conditions
    - The National Oceanic and Atmospheric Administration (NOAA) provides up-to-date information on U.S. weather conditions including active storms.
  - Ensuring appropriate handling of vaccines during a disaster or power outage
    - The Federal Emergency Management Agency (FEMA) offers a wide range of information on disaster preparedness.
    - 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.

Staff Training

All staff members who are involved in vaccine management—from receiving shipments to administering vaccines—should be trained in general storage and handling practices and be familiar with their facility's storage and handling SOPs.

VFC providers and others who administer vaccines purchased with public funds should contact their immunization program for state-specific requirements regarding annual training. CDC offers a free training module *You Call the Shots: Vaccine Storage and Handling* that may fulfill these requirements.

Train staff on routine vaccine storage and handling and emergency procedures. Document all training completed, including dates and participant names.

Ensure storage and handling training is completed at key times:

- During new employee orientation (and at the time of VFC provider enrollment)
- Annually, as a refresher for all staff involved in vaccine storage and handling activities
- Whenever a new vaccine product is added to the inventory
- Whenever storage and handling requirement are updated (e.g., changes to a package insert)

Section Three: Vaccine Storage and Temperature Monitoring Equipment

Each facility should have proper storage and temperature monitoring equipment that is set up correctly, maintained appropriately, and repaired as needed.

VFC providers and others who administer vaccines purchased with public funds should contact their immunization program for state-specific requirements related to storage and temperature monitoring equipment.

Vaccine Storage Units: Refrigerator and Freezer

Four types of units are suitable for storing vaccines and are listed below in order of preference.

1. Units that conform to National Sanitation Foundation/ American National Standards Institute (NSF/ANSI) Standard 456
   A unit that conforms to NSF/ANSI Standard 456 is preferred. These units can come in various forms and have been rigorously tested for vaccine storage.

2. Purpose-built units
   Purpose-built units are the next best option because they are specifically designed for vaccine storage. They can be compact, under-the-counter style, or large units, and are typically designed for either refrigerating or freezing vaccines. However, some units (i.e., combination units) are designed to do both. Additional information about purpose-built units can be found in the toolkit's Resources section.

Dormitory-style Combined Units

Never use dormitory- or bar-style combined refrigerator/freezer units for vaccine storage. These units have a single exterior door and an evaporator plate/cooling coil, usually located in an icemaker/freezer compartment. These units pose a significant risk of freezing vaccines, even when used temporarily.

Not all small storage units are dormitory- or bar-style. Compact, purpose-built units for biologics are acceptable for vaccine storage.

3. Pharmaceutical-grade units
   Pharmaceutical-grade units are the third best option because they are specifically engineered to store pharmaceuticals or biologics. These units often have
   - Microprocessor-based temperature control with a digital temperature sensor (thermocouple, resistance temperature detector [RTD], or thermistor), and
   - Fan-forced air circulation with powerful fans or multiple cool air vents that promote uniform temperature and fast temperature recovery from an out-of-range temperature.

4. Household-grade units (for vaccine refrigeration only)
   Household-grade units may be used as a last option, but only for refrigerated vaccines. Never store vaccines in the freezer compartment of household-grade combination refrigerator/freezer units because they have cold spots and temperature fluctuations. If the facility stocks frozen vaccine, a separate stand-alone freezer unit is necessary.

Temperature variations can occur with the refrigerator compartment of a household-grade unit also. Air circulating from the freezer may expose refrigerated vaccines to freezing temperatures. So avoid storing vaccines on the top shelf directly under cooling vent. Do not turn off the freezer compartment, as this will

prevent the refrigerator from maintaining proper temperatures. Avoid storing vaccines and diluents in any part of the unit that may not provide stable temperatures or sufficient air flow. These areas include directly under cooling vents; in deli, fruit, or vegetable drawers; or on refrigerator door shelves.

Use units with enough space to accommodate the maximum inventory without crowding. Crowding blocks cold air circulation, leading to temperature fluctuations that can compromise vaccine viability.

Best Practices for Using Water Bottles in a Household-grade Unit

- Place water bottles on the top shelf, in the door racks, and on the unit floor of household-grade units. Doing so can help guard against temperature fluctuation caused by a power failure or frequent door opening and closing.
- Water bottles are not recommended for use with the majority of pharmaceutical-grade and purpose-built units. For such units, follow the manufacturer's guidance.

Storage Unit Placement

Good air circulation around the outside of the storage unit is essential. Always refer to the manufacturer-supplied owner's manual for storage unit placement. In general, position the storage unit in a well-ventilated room, leaving at least 2 inches (5 cm) of clearance from the ceiling and 1 to 2 inches (2.5 to 5 cm) from any adjacent walls. The cover of the motor compartment should not be blocked. The unit should be level and stable, with the bottom of the unit 1 to 2 inches above the floor. The unit door should open and close smoothly, fitting squarely against the body of the unit. If not properly secured, unit doors can compromise the internal temperature of vaccine storage units. Studies have found that most units work best when placed in an area with standard indoor room temperatures, typically between 20°C and 25°C (68°F and 77°F).

Storage Unit Doors

A door that is not sealed properly or is left open not only affects the unit's temperature but also exposes vaccines to light, which can reduce the potency of some vaccines. Consider using safeguards, such as self-closing door hinges, door alarms, or door locks, to ensure unit doors remain closed.

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, and 2 to 3 days for a freezer. Before using a unit for vaccine storage, check and record the minimum and maximum temperatures each workday for 2 to 7 days. If temperatures cannot be recorded digitally, check and record temperatures at least twice each workday. After 2 consecutive days of temperatures recorded within the recommended range, the unit is considered stable and ready for use.

Temperature Ranges

Storage units must maintain the following temperature ranges at all times:

- Refrigerators between 2°C and 8°C (36°F and 46°F)
- Freezers between -50°C and -15°C (-58°F and +5°F)
- Ultra-cold freezers between -90°C and -60°C (-130°F and -76°F)

Thermostats should be set at the factory-set or midpoint temperature—for example, 5°C (41°F) for refrigerators or -20°C (-4°F) for freezers—to help reduce the risk of temperature excursions. 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 of a vaccine storage unit is to measure and monitor it with a temperature monitoring device.

Temperature Ranges May Differ

Certain COVID-19, monkeypox, and RSV vaccines have specific temperature requirements for storage. For example, mResvia, an RSV vaccine, if stored frozen, must be stored at temperatures between -40°C and -15°C (-40°F and 5°F). This is a narrower range than many other frozen vaccines, which are stored between -50°C and -15°C. If you store mResvia alongside other frozen vaccines, ensure the storage unit temperature does not fall below -40°C.

Always review the manufacturer's package insert or EUA Fact Sheet for Healthcare Providers to verify immunization product storage requirements and ensure that the correct temperature range is maintained.

Temperature Monitoring Devices

Every vaccine storage unit must have a temperature monitoring device (TMD). An accurate temperature history that reflects actual vaccine temperatures is critical for ensuring vaccine quality and potency. In addition, investing in a reliable device helps avoid the financial hardships of replacing vaccines that have lost their potency due to storage at out-of-range temperatures.

Digital Data Logger

A digital data logger (DDL) is a specific type of TMD that has the capability for continuous monitoring and provides 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"). Unlike a simple minimum/maximum thermometer, which only shows the coldest and warmest temperatures reached in a unit, a DDL provides detailed information on all temperatures recorded at preset intervals.

Many DDLs use a buffered temperature probe, a device that provides the most accurate measurement of vaccine temperatures. In contrast, standard thermometers typically measure air temperature. Probes permanently embedded in a buffer are acceptable if the temperature monitoring system for the entire unit can be calibration-tested. Since certain DDLs cannot monitor ultra-cold temperatures, it's crucial to use a probe intended for ultra-cold environments.

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

Use DDLs for routine, on-site vaccine storage; during vaccine transport; and in temporary, mobile, off-site, satellite, and community vaccination clinics.

Place a DDL or other appropriate TMD in each vaccine storage unit and each transport unit.

Have at least one backup DDL or TMD in case a primary device breaks, malfunctions, or requires calibration.

Best Practices for Temperature Monitoring Devices

- Have a supply of extra batteries* on hand.
- Use DDLs with the following features:
  - Detachable probe that best reflects vaccine temperatures (e.g., a probe buffered with glycol, glass beads, sand, or Teflon®)
  - Alarm for out-of-range temperatures
  - Low battery indicator*
  - Current, minimum, and maximum temperature display
  - Recommended uncertainty of ±0.5°C (±1°F)
  - Logging interval (or reading rate) that can be programmed to measure and record temperatures at least every 30 minutes

*Battery changes may affect temperature accuracy and may warrant checking against a known, calibrated TMD. Check with

Temperature Monitoring Device Placement

It is important to position the TMD correctly so that it accurately reflects the temperature of the vaccines. Refer to the owner's manual for detailed instructions for TMD placement.

If using a 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 unit's walls, floor, vent, ceiling, or door may indicate temperatures that are colder or warmer than the actual vaccine temperature. Certain purpose-built units may recommend alternate locations or have designated areas for probe placement. Consult the owner's manual for detailed instructions on proper TMD placement in these units.
- Place the DDL's active digital display outside the unit so temperatures can be read without opening the door and disturbing the probe.

Temperature Monitoring Device Limitations

Some types of TMDs have significant limitations and should not be used to measure temperatures in vaccine storage units. These devices can be difficult to read and only display the temperature at the moment they are checked, which means they may fail to detect temperature excursions.

CDC does not recommend the following TMDs:

- Alcohol or mercury thermometers, even if placed in a fluid-filled, biosafe, liquid vial
- Bimetal stem TMDs
- TMDs used for food
- Chart recorders
- Infrared TMDs
- TMDs that do not have a current and valid Certificate of Calibration Testing

Important: Some devices sold in hardware and appliance stores are designed to monitor temperatures for household food storage. They are not calibrated or accurate enough to ensure vaccines are stored within correct temperature ranges. Using these devices can pose a significant risk of damaging vaccines.

Always review the manufacturer's package insert or EUA Fact Sheet for Healthcare Providers to verify immunization product storage requirements and ensure that the correct temperature range is maintained.

Calibration Testing of Temperature Monitoring Devices

Calibration testing ensures that TMDs provide accurate readings in line with nationally accepted standards.

Calibration testing should be performed every 2 to 3 years, or according to the manufacturer's recommended schedule.

Over time, TMDs may experience a "drift," affecting their accuracy. Testing verifies that the device's accuracy continues to meet nationally accepted standards.

Mishandling a TMD can also affect its accuracy. If a TMD is dropped, hit against the side of a storage unit, or is potentially damaged in any way, its accuracy should be checked against another calibrated TMD. If there is any question about accuracy, the device should be replaced or sent for calibration testing.

Certificate of Calibration Testing

Each DDL or appropriate TMD should have a current and valid Certificate of Calibration Testing. Keep Certificates of Calibration easily accessible for reference whenever needed.

To determine if an appropriate entity issued a Certificate of Calibration Testing or Report of Calibration, check to see if the certificate indicates one or more of the following:

- 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

- 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 or higher
- Refers to another acceptable accuracy validation method, such as comparison to other traceable reference standards or tests at thermometric fixed points

Each Certificate of Calibration Testing should include

- Model/device name or number
- Serial number
- Date of calibration (report or issue date)
- Recommended uncertainty of ±0.5°C (±1°F) or less
- Confirmation that the instrument passed testing (or instrument is in tolerance)
  - Some vendors that perform calibration testing only issue certificates for units that pass. In these instances, the certificate may not explicitly state "passed." If there is no indication of a passing result on the certificate, a statement from the vendor outlining their certification process may be kept on file as an alternative.

If calibration testing indicates that a TMD is not accurate within ±0.5°C (±1°F), the TMD must be replaced.

Power Supply

Even with appropriate equipment and temperature monitoring practices in place, power disruption can occur and result in destruction of the entire vaccine supply. Precautions should always be taken to protect the storage unit's power supply.

Plug in only one storage unit per electrical outlet to avoid a fire hazard and power source overload, which could cause the power to shut off.

Use a safety-lock plug or an outlet cover to prevent the unit from being unplugged.

Post "DO NOT UNPLUG" warning signs at electrical outlets and storage units to help ensure staff, custodians, electricians, and others do not unplug units.

Label fuses and circuit breakers (e.g., with "DO NOT STOP POWER signage) to alert people not to turn off power to a storage unit.

Use caution when using power outlets that can be tripped or switched off. Avoid using

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

If built-in circuit switches, Uninterruptible Power Supply (UPS) unit, or power strip surge protection must be used, make sure the device is rated to carry the maximum current as specified by the storage unit's manufacturer. Additionally, consider how the device manages when the power is restored. Whether the device automatically restarts and allows the equipment to run or must be manually switched on should be considered and represented in Emergency Plans and SOPs. Contact the unit manufacturer for any additional questions or guidance regarding circuit switches, power strips, UPS, or surge protection.

If the entire storage unit is affected by a temperature excursion because of a power supply issue, unit malfunction, or other issue, refer to the facility's emergency SOPs.

Vaccine Temperature Monitoring

Regular temperature checks also provide an opportunity to inspect the storage unit, reorganize misplaced vaccines, and remove expired vaccines.

At the start of each workday, check and record minimum and maximum temperatures.

If the TMD does not read minimum/maximum temperatures, check and record the current temperature a minimum of two times per workday (at the start and end of the workday).

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

Record:

- Minimum/maximum temperature
- Date
- Time
- Name of person who checked and recorded the temperature
- Any actions taken if a temperature excursion occurred

Best Practices for Temperature Monitoring

- Check the temperature each time vaccines are accessed in the unit.
- Review storage unit temperature readings weekly to identify changes in temperature trends that might require action.
- Troubleshoot any fluctuation in temperature based on additional information provided in this toolkit, manufacturer manuals, and/or office storage and handling SOPs.
- Implement emergency SOPs if the storage unit may have failed. Never allow vaccines to remain in a malfunctioning unit for an extended period.

Some TMDs require resetting minimum/maximum temperatures to start tracking new readings for the next temperature check. Always follow the manufacturer's instructions for proper use.

Keep temperature logs for 3 years to track trends and recurring issues.

VFC providers and others who administer vaccines purchased with public funds should contact their immunization program for state-specific requirements related to record keeping.

Organizing and Storing Vaccines

Correct vaccine organization and placement helps prevent conditions that could reduce vaccine potency.

Store vaccines in their original packaging, with lids closed, until ready for administration.

The original packaging for vials and manufacturer-filled syringes contains critical information, including product identification, storage requirements, and expiration dates. It also protects vaccines from light, which is essential for many products to maintain potency. Loose vials can also be confused with other vaccines, increasing the risk of inventory and administration errors. However, for certain purpose-built units, storing vaccines outside their original packaging is recommended. If this is the case, always follow the manufacturer's guidance for proper storage.

If vaccines must be removed from the original packaging (e.g., for transport to an off-site clinic or when moving doses from the freezer for thawing), protect them from light by using a resealable, opaque container such as an envelope, opaque plastic bag, or clear plastic bag lined with paper.

Best Practices for Vaccine Organization and Storage

- Store each type of vaccine or diluent in its original packaging and in a separate container.
- Position vaccines and diluents 2 to 3 inches from the unit walls, ceiling, floor, and door. If using a household-grade unit, 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 deli, fruit, or vegetable drawers; or on refrigerator door shelves. The instability of temperatures and air flow in these areas may expose vaccines to inappropriate storage temperatures.
- Label shelves and containers to clearly identify where each type of vaccine and diluent is stored.
- Store vaccines and diluents with similar packaging or names, or with both pediatric and adult formulations, on different shelves.
- Whenever possible, store diluent with its corresponding refrigerated vaccine. Never store diluent in a freezer.
- Avoid placing or storing any items other than vaccines, diluents, and water bottles inside storage units. Never store food and beverages in the unit with vaccines. Frequent opening of the refrigerator door to retrieve food items can adversely affect the internal temperature of the unit and potentially damage the vaccines.
  - If other medications and biological products must be stored in the same unit as vaccines, they must be clearly marked and stored in separate containers or bins.
    - Potentially contaminated items (e.g., blood, urine, stool) should be properly contained and stored below vaccines due to risk of contamination from drips or leaks.
    - The freezer of a household-grade unit may be used for non-vaccine medical storage, so long as the use does not compromise the temperature range within the refrigerator compartment.
- To promote air circulation, arrange vaccines and diluents in rows and allow space between them.
- Place vaccines and diluents with the earliest expiration dates in front of those with later dates.

Temperature Excursions

Temperature excursions or inappropriate storage conditions for any immunization product require immediate action. Any temperature reading outside the recommended range in the manufacturer's package insert or EUA factsheet is 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 still be viable.

Vaccine Administration and Temperature Excursions

- Vaccines stored at inappropriate temperatures should not be administered unless the manufacturer provides guidance that vaccine safety and effectiveness have not been compromised. For guidance regarding whether the exposed vaccines remain viable, contact the vaccine manufacturer or the immunization program at the state or local health department.
- If vaccines exposed to inappropriate temperatures are inadvertently administered, the doses generally need to be repeated. For guidance on timing and spacing of revaccination, contact CDC at nipinfo@cdc.gov.

Perform the following steps in the event of a temperature excursion:

1. Any staff member who hears an alarm or notices a temperature excursion on the TMD should immediately notify the primary or backup vaccine coordinator, or report the problem to their supervisor.
2. Label exposed vaccines "DO NOT USE—TEMPERATURE EXCURSION" and move them to the correct storage conditions. Place them in a separate container apart from other vaccines in the unit. Do not discard these vaccines.
3. The vaccine coordinator or other appropriate staff person should begin to document information about the event:
   a. Date and time of the temperature excursion
   b. Storage unit temperature as well as room temperature, if available (including min/max temperatures during the time of the event, if available)
   c. Name of the person completing the report
   d. Description of the event:
      - General description of what happened
      - The length of time vaccine may have been affected, if using a DDL
      - Inventory of affected vaccines, including lot numbers and whether purchased with public (e.g., VFC) or private funds
      - List of items in the unit other than vaccines, including water bottles in the refrigerator and/or frozen cooler packs in the freezer
      - Any problems with the storage unit or affected vaccines before the event
      - Other relevant information, such as a cracked door seal in the affected unit or extreme room temperature fluctuations in the storage unit area
4. Implement the facility SOPs to adjust unit temperature to the appropriate range. At a minimum, check the TMD to make sure it is appropriately placed in the center of the vaccines.
5. Contact the state or local health department's immunization program or the vaccine manufacturers per SOPs to determine if it is safe and effective to use the impacted vaccines. Be prepared to provide documentation of the event (e.g., temperature log data) for the best guidance.
6. Complete documentation of the event, including
   a. Action taken
      - What happened to the affected vaccine, and how long it took to act
      - Who was contacted, and what instructions were received
      - What prevention measures were implemented to avoid a similar event
   b. Results
      - Final disposition of affected vaccines (e.g., shortened expiration date per manufacturer, discarded, or returned)

CDC's Vaccine Storage Troubleshooting Worksheet, located in the toolkit's Resources section, can be used to document these steps.

Regular Maintenance of Vaccine Storage Units and Temperature Monitoring Devices

Storage units and TMDs require regular maintenance to ensure proper operation 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 the facility's routine storage and handling plan and SOPs.

Conduct routine maintenance on all vaccine storage units and related equipment to ensure they function at maximum efficiency.

- Check seals and door hinges.
- Clean coils and other components per the manufacturer's directions.
- Manual-defrost freezers should be defrosted 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.
- Clean the interior of each unit as needed to discourage bacterial and fungal growth. Do so quickly to minimize the risk of a temperature excursion.
- Test any backup generator quarterly and have it serviced annually.

Troubleshooting Equipment Problems

Adjusting Storage Unit Temperatures

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

Temperature adjustments should be

- Made by the primary or backup vaccine coordinator, based on information from the TMD and temperature monitoring log.
- Performed at a time when the unit door is not being frequently opened and closed.

Adjusting Storage Unit Temperatures

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

Remember that temperatures within any storage unit will vary 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 then recheck it to determine if the thermostat needs to be adjusted.

If there could be an issue with the TMD, use the backup device to confirm the temperature. After confirming that an adjustment is needed,

1. Refer to the owner's manual for detailed instructions.
2. Make a slight adjustment toward a warmer or colder setting by turning the thermostat knob slowly to avoid going outside the correct temperature range.
3. Once the adjustment is made, allow the temperature inside the unit to stabilize for 30 minutes without opening the door.
4. Recheck the temperature.
5. Repeat these steps as needed until the temperature has stabilized
    - Between 2°C and 8°C (36°F and 46°F) for a refrigerator.
    - Between -50°C and -15°C (-58°F and +5°F) for a freezer.
    - Between -90°C and -60°C (-130°F and -76°F) for an ultra-cold freezer.
6. If appropriate for the unit, consider adding extra water bottles to improve temperature stability.

Never leave vaccines in a storage unit that does not maintain temperatures within the recommended range. If the unit is unable to stabilize the temperature within the required range, or if temperatures in the unit consistently fall at the extreme high or low end of the range, the vaccine supply is at high risk of losing its potency. Refer to the facility's 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 sounds repeatedly, do not disconnect it until the cause is identified and addressed. Do basic checks of the unit door, power supply, and thermostat settings. If the alarm continues to trigger or the temperature remains outside the range, transfer the vaccines to a backup unit as directed by the facility's SOPs. A repair technician should check the equipment to determine the need for repair or replacement.

Section Four: Vaccine Inventory Management

Proper vaccine inventory management is essential for accurate vaccine ordering and effective stock rotation, ensuring each facility has the necessary vaccines for its patients.

VFC providers and others who administer vaccines purchased with public funds should contact their immunization program for state-specific requirements related to vaccine inventory management. State and local programs that have an immunization information system (IIS) with vaccine inventory accounting functions require VFC providers to use the IIS to track their inventory.

Vaccine Delivery

Scheduling and Receiving Deliveries

Maintaining the cold chain is the first step in vaccine inventory management. Staff members who might accept vaccine deliveries should be trained to immediately notify the primary or backup vaccine coordinator when deliveries arrive. Vaccines must always be immediately checked and appropriately stored upon arrival.

Unpacking Deliveries

Vaccines and diluents must be carefully unpacked, stored at the recommended temperatures, and documented immediately upon arrival.

Do not place an unopened or unpacked shipment box in a vaccine storage unit, as the cool packs shipped with the vaccine may cause the packaged vaccine to become too cold.

Unpacking Vaccine Deliveries

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

Immediately inspect shipments to ensure receipt of the correct vaccine types and quantities, and to look for any signs of damage.

- Examine the shipping container and vaccines for signs of physical damage.
- Immediately check the cold chain monitor (CCM)—a single-use device that tracks vaccine temperatures during transport—for any signs of a temperature excursion, if one was included. After reviewing, discard the CCM as it cannot be reused.
- Immediately check both the vaccine and diluent expiration dates to ensure the products are not expired or soon to expire.
- Verify the contents against the packing list to ensure they match.
  - For frozen vaccines, the packing list will show the maximum time vaccines can be in transit based on the shipment date.
- If the shipment includes lyophilized (freeze-dried) vaccines, ensure the correct type and quantity of diluents accompany them.

Vaccine Inventory Accounting

Stock records are used to determine the type and number of vaccines each facility should carry to meet the needs of its patients. Stock records help maintain accurate inventory and can be in either paper or electronic form.

- At least once a month and before placing any vaccine orders, count all vaccines 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 immediately remove any expired doses.
- Diluents should be documented on a separate stock record. Make sure the number of diluents matches the number of corresponding vaccines.
- If the numbers in the storage unit do not match the doses documented in the stock record, providers should enter the correct number based on the count on a separate line below the old balance on the stock record. Make a note next to the new entry indicating that the count confirmed the new balance, and sign it. Use the corrected balance for calculating future stock quantities.
- If providers receive multiple doses of the same vaccine in the same presentation from the same lot with the same expiration date, they 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 providers receive 10 single-dose vials of the same vaccine with the same lot number and expiration date, they can make a single entry on the stock record, noting that 10 doses were received.
- If there are discrepancies between the contents and the packing list or other concerns about the contents, immediately notify the vaccine manufacturer. VFC or other providers who receive vaccines purchased with public funds should contact their immunization program.

Best Practices for Recording Vaccine Stock

To keep track of the inventory, use a stock record to account for and document every dose of vaccine.

- Place the stock record 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.
- Update the stock record weekly and include the vaccine delivery information below:
  - Date of delivery and initials of the person who unpacked the box
  - Vaccine and diluent name and manufacturer
  - Number and expiration date for each lot
  - Number of doses received
  - Condition of each vaccine and diluent upon arrival
  - CCM reading if included in the shipping container
  - Number of doses used
  - Balance of remaining doses after subtracting the amount used

At the end of each month, determine the total number of vaccine and diluent doses used that month and the amount of stock still available. At the end of each year, the stock record shows the number of doses received and used for the year. This information will help determine the facility's needs and guide future ordering to minimize waste and reduce the need for vaccine transfer and transport. It will also help to ensure a sufficient supply to meet patient needs.

Vaccine Ordering

Order and stock only enough vaccine to meet patient needs. Plan ahead.

Order vaccines after verifying current inventory and anticipating patient needs. To reduce the risk of loss during shipment or storage, place smaller, more frequent orders rather than large, infrequent ones.

Storing a larger volume than the facility needs can increase the risk of wasting vaccines if they expire or are compromised in some way (e.g., during shipping incident or due to mechanical failure of a storage unit).

Vaccine orders typically arrive within 1 to 2 weeks; however, delays may occur. When possible, avoid placing last-minute or rush orders to lessen the risk of running out of vaccines. As a general guide, reorder when inventory reaches a 4-week supply.

Best Practices for Vaccine Organization and Storage

- Rotate vaccine and diluent stock at least once a week, as well as each time the facility receives a vaccine delivery. This will ensure that vaccines expiring sooner are used first.
- Remove expired vaccine and diluent immediately from the

Stock Rotation and Removal

Regularly rotate and check vaccine stock for expired doses.

Arrange stock for each vaccine type so that doses with the earliest expiration dates are placed in front of those with later expiration dates. Remove expired vaccines and diluents immediately to avoid inadvertent administration.

Vaccine Disposal

Administration of vaccines necessarily results in waste (e.g., empty vials), and despite best efforts, sometimes unused vaccines must be disposed of. General vaccine disposal guidelines exist for

- Empty vaccine vials – Most are not considered hazardous or pharmaceutical waste and do not require disposal in a biomedical waste container. However, check and comply with state requirements for disposal.
  - While vials are not usually considered hazardous or pharmaceutical waste, an empty rotavirus dispensing tube or oral applicator is considered medical waste and should be disposed of in a medical waste container.
- Expired or compromised vaccine – 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. Contact the immunization program or the vaccine manufacturer for vaccine-specific disposal information.
- Open and broken vials and syringes, manufacturer-filled syringes that have been activated, and vaccine predrawn by providers – These cannot be returned and should be discarded according to state requirements.

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

Understanding Expiration Dates

Properly identifying when a vaccine or diluent expires is essential for managing vaccine inventory and preventing administration errors. All vaccine products have an expiration date (sometimes called an expiry date), which marks the final day the manufacturer guarantees the vaccine will meet standards for strength, quality, and purity. Never administer vaccines past their expiration date.

How Expiration Dates Are Determined

The Food and Drug Administration (FDA) requires manufacturers to submit stability data to support each product's proposed expiration date and storage conditions. These data verify that the vaccine remains potent and safe throughout its labeled shelf life. The expiration date is therefore the last day the manufacturer guarantees full potency and safety.

How to Read Expiration Dates

If an expiration date shows only a month and year, the vaccine may be used through the last day of that month. For example, a product labeled 12/2026 is valid through 11:59 p.m. on December 31, 2026, and expires at 12:00 a.m. on January 1, 2027.

If the expiration date includes a specific day, the vaccine may be used only through the end of that day. For example, a product labeled 6/15/2027 is valid through 11:59 p.m. on June 15, 2027, and expires at 12:00 a.m. on June 16, 2027.

For vaccines requiring reconstitution, the diluent and antigen components may have different expiration dates, even when packaged together.

When Manufacturers Update Expiration Dates

Manufacturers may extend an expiration date when new stability data become available. If the expiration date is extended beyond what appears on the label, manufacturers typically communicate the change through the FDA's Expiration Dating Extension website or through mass communications such as "Dear Health Care Provider" letters. Manufacturer-extended expiration dates should be written on the vial or manufacturer-filled syringe, initialed by the person making the change, and recorded in inventory records.

If a vaccine has been exposed to inappropriate storage conditions such as a temperature excursion, the manufacturer might determine the vaccine can still be used but expires earlier than the date on the label. The manufacturer-shortened expiration date must be written on the vial or manufacturer-filled syringe, initialed, and documented in inventory records. This ensures clarity for all staff and prevents inadvertent use of compromised vaccine.

Understanding Beyond-Use Dates

Some vaccines must be used before the expiration date because they have a beyond-use date (BUD)—an earlier deadline after which the product should not be used. Unlike the manufacturer-set expiration date, the BUD is calculated by the provider based on manufacturer guidance.

The BUD is the last date or time a vaccine can be safely used after it has been

- Moved from one storage state to another (e.g., frozen to refrigeration).
- Prepared for administration (e.g., reconstituted).
- First punctured with a needle (for multidose vials).

The BUD varies by product and by type of transition. A BUD that falls on the same day might instead be called the beyond-use *time*.

Not all vaccines have a BUD. The manufacturer's package insert or Emergency Use Authorization (EUA) Fact Sheet for Healthcare Providers will specify when a BUD applies. Always review these materials to confirm BUD requirements.

Calculating a BUD

- Begin counting with day 0, the date the vaccine was transitioned (e.g., moved to refrigerator).
- Calculate the number of days or hours allowed, based on manufacturer guidance.
- Write the BUD on the vaccine label and initial it.
- The BUD replaces the manufacturer's expiration date, but never extends it. Always use the earlier date.

When a BUD Applies

Vaccines transitioned between storage states

Once a vaccine is moved from one storage condition to another, it has a limited time for use. Frozen vaccines must be thawed before administration. Always follow the guidance in the manufacturer's package insert for thawing instructions and the correct BUD.

- *Example:* Previously frozen lyophilized varicella vaccine may be stored in the refrigerator for up to 72 hours before reconstitution. Once placed in refrigeration, the unopened vial's BUD is 72 hours.
- *Example:* Moderna RSV vaccine, mResvia, may be stored in the refrigerator for up to 90 days or at room temperature for up to 24 hours before administration. In this case, the syringe's BUD is 90 days refrigerated or 24 hours at room temperature.

Reconstituted vaccines

Once mixed with its diluent, a vaccine has have a short window for use. If not administered immediately, follow manufacturer guidance for storage conditions and time limits.

- *Example:* Varicella-containing vaccines must be administered within 30 minutes of reconstitution. The beyond-use time is 30 minutes.
- *Example:* MMR vaccines (except MMRV) must be administered within 8 hours of reconstitution. The beyond-use time is 8 hours.

Multidose vials

Some multidose vials must be discarded a certain number of days after first puncture with a needle.

- *Example:* If the package insert states the vaccine must be discarded 28 days after first puncture, and the vial is first punctured on 06/01/2026, the BUD is 06/29/2026. Do not use the vaccine after this date.

Monitoring BUDs

Before preparing vaccines, staff must check the BUD on the vial or syringe. In addition, vaccine coordinators should create and maintain a system for tracking BUDs, such as a visible log near storage units, to ensure timely vaccine use and proper disposal. CDC has product-specific storage and BUD labels to help providers comply with vaccine storage requirements.

Section Five: Vaccine Preparation

Vaccine preparation is the next-to-last step in the cold chain. Handling vaccines with care is equally as important as storing them properly. Preparation and administration guidance depends on the type of vaccine presentation.

Types of Vaccine Presentations

- Single-Dose Vials

  A single-dose vial (SDV) contains one dose and should be used one time for one patient. SDVs typically do not contain antimicrobial preservatives, making them susceptible to contamination and potential sources of infection when used improperly. Never combine leftover vaccine from one SDV with another. Open an SDV when you are ready to use it. Before removing the protective cap, always check the vial to verify it's the correct vaccine. Once the cap is removed, the vaccine must be used because it may not be possible to determine if the rubber seal has been punctured. At the end of the workday, discard all unused SDVs without a protective cap.

- Multidose Vials

  A multidose vial (MDV) contains more than one dose of vaccine. Because MDVs typically contain a preservative to help prevent microorganism growth, 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 vaccine left and the expiration date has not been reached.

  MDVs can be used through the expiration date printed on the vial, unless the vaccine is contaminated or compromised in some way or there is a BUD noted in the package insert. The BUD should be noted on the vaccine vial along with the initials of the person making the calculation. Never use partial doses from two or more vials to obtain a dose of vaccine.

  Based on safe injection practices, CDC does not recommend using vial adapters, spikes, or other vial access devices when withdrawing vaccine from a multidose vial. Leaving a vial access device inserted into a vial septum provides a direct route for microorganisms to contaminate the vaccine.

- Manufacturer-Filled Syringes

  A manufacturer-filled syringe (MFS) is prepared and sealed under sterile conditions by the manufacturer. Activate an MFS by removing the syringe cap or attaching the needle only when ready to use it. An MFS does not contain a preservative to help prevent the growth of

Best Practices for Vaccine Preparation

Follow standards of medication administration:

- Use a designated, clean medication area that is not adjacent to areas where contaminated items are placed. For example, do not prepare vaccines in a specimen collection area.
- Follow strict aseptic medication preparation practices.
- Use a separate, sterile needle and syringe for each injection.
- Prepare vaccines for one patient at a time.
- Before preparing the vaccine, always check the
  - Vial to ensure it is the correct vaccine.
  - Expiration date and beyond-use date/time to ensure neither has passed.
- Prepare and draw up vaccines just before administration.
- Providers should administer vaccines they have prepared themselves. This is a quality control and patient safety issue, as well as a standard of medication administration.

microorganisms. Once the sterile seal has been broken, the vaccine should be used or discarded by the end of the workday.

- Manufacturer-Filled Nasal Sprayer
  Live, attenuated influenza vaccine (LAIV [FluMist]) is administered by the intranasal route using a manufacturer-filled nasal sprayer. A dose-divider clip, located on the plunger, separates the total vaccine dose of 0.2 mL into two equal parts of 0.1 mL each.

- Oral Applicator
  Because oral vaccines are prepared differently and may have different types of oral applicators, providers should be familiar with how to prepare and administer the brand stocked in their facility.

Vaccine Reconstitution

Before being administered, lyophilized (freeze-dried) vaccines such as MMR vaccines or recombinant zoster vaccine (Shingrix) are in either powder or pellet form and must be mixed with a liquid (diluent) in a process known as "reconstitution." Diluents vary in volume and composition and are specifically designed to meet volume, pH balance, and chemical requirements of their corresponding vaccines. Some diluents contain a vaccine component or an adjuvant needed for vaccine effectiveness.

- Establish a process to keep diluents and their corresponding vaccines together if storage requirements do not differ. Sometimes all vaccine components are package together; other times the diluent is separate.

- Never freeze diluents. All diluents can be stored at refrigerated temperatures, and some can also be stored at room temperature. Always refer to the manufacturer's package insert for product-specific guidance on storage and handling.

- Before reconstitution, always check the expiration date of both the vaccine and diluent.
  - Each vaccine component has a separate lot number and expiration date.
  - Never use an expired diluent or vaccine.
  - VFC or other providers who have vaccines purchased with public funds and must transfer vaccine to another facility so it can be used before it expires, should contact their immunization program for guidance on vaccine transport.

- Use only the diluent provided with the vaccine.
  - Diluents are not interchangeable unless specified by the manufacturer.
  - Using the wrong diluent is a serious vaccine administration error that may result in incorrect doses and possible contamination.

- Never use a stock vial of sterile water or normal saline to reconstitute vaccines. Even if the diluent is composed of sterile water or saline, use only the specific diluent supplied with the vaccine.

- Never administer vaccine reconstituted with the wrong diluent. If an incorrectly reconstituted vaccine is administered, contact the immunization program or the vaccine manufacturer for revaccination and safety guidance.

Predrawing Vaccine

Draw up vaccines only at the time of administration. Predrawing vaccines is discouraged for many reasons, including

- Risk of compromising the stability of the vaccine. Disposable syringes are meant for administering vaccines, not for storing them.
- Increased risk for vaccination errors if predrawn syringes are labeled improperly, or if one person draws up vaccine doses while others administer them.
- Vaccine wastage if predrawn doses do not match the number of vaccine recipients.

Use Manufacturer-Filled Syringes

As an alternative to predrawing vaccines, use manufacturer-filled syringes for large vaccination clinics.

In rare circumstances, such as during large off-site vaccination clinics, predrawing vaccine doses might be the only option. If vaccines must be predrawn, adhere to the following best practices:

- Set up a separate administration station for each vaccine type.
- Draw up vaccines only after arriving at the vaccination site.
- Once each predrawn dose is prepared, label the syringe with the vaccine name and dosage, the beyond-use date and time, lot number, and the preparer's initials. Additional pertinent information can be added, such as age range or if the dose is intended for use as primary or booster dose.
- Each vaccinator should draw up only one MDV at a time, regardless of whether it contains 2 or 10 doses. Likewise, no vaccinator should activate more than 10 MFSs at a time or predraw more than 10 doses from SDVs.
- Predraw reconstituted vaccine into a syringe only when ready to administer, as it has limited beyond-use time. If not used within 30 minutes, follow the manufacturer's guidance for storage and time limits.
- Monitor patient flow to avoid drawing up unnecessary doses.
- Store predrawn syringes at manufacturer-recommended temperatures. Discard any doses that were stored improperly.
- Discard all remaining predrawn syringes no later than the end of the workday. Never transfer predrawn reconstituted vaccine back into a vial.

Section Six: Non-Emergency Vaccine Transport

Non-emergency vaccine transport guidance might vary by vaccine product. Carefully review manufacturer guidance for each vaccine to ensure the cold chain is preserved.

For this document's purpose, "transport" involves the movement of vaccine between providers or other locations over a short distance and time frame and is appropriate for events such as off-site clinics or to ensure vaccines that are about to expire can be used rather than wasted.

VFC providers and others who administer vaccines purchased with public funds should contact their immunization program for state-specific requirements related to vaccine transport.

General Principles of Transport

Vaccine transport to off-site or satellite facilities is different from both shipping and emergency transport. Shipping usually involves a professional carrier and a longer distance and timeframe for moving vaccines between locations. Emergency transport usually involves relocating vaccines to protect them when a facility's ability to store vaccines is compromised because of a power outage, for example.

Vaccine Transport

Vaccines should not be routinely transported. In instances where non-emergency transportation of vaccines is necessary, take precautions to protect the vaccines by using appropriate packing materials and procedures that provide the maximum protection.

Use a transport temperature monitoring log to document temperatures and how long the vaccine is in the portable storage container. Regardless of how the vaccine is transported (car, professional carrier, snowmobile, boat, small plane, etc.), if vaccines are packed by a provider, the BUD should be applied using the manufacturer's guidance. For example, if a frozen vaccine may be stored at refrigerated temperatures for 24 hours, transport is included in this time frame.

Best Practices for Protecting Vaccine Supply

- Vaccine that will be used at an off-site or satellite facility should be delivered directly to that facility.
- When delivering to a specific site, adequate storage equipment and staff should be in place to provide appropriate oversight.
- If delivery to the specific site is not possible, then vaccine can be transported in a stable storage unit and monitored with a TMD.
- Limit the total time for transport alone or transport plus clinic workday to a maximum of 8 hours, unless the manufacturer provides different guidance.* For example, if transport to an off-site clinic is 1 hour each way, the clinic may run for up to 6 hours.
- If the facility doesn't have the capacity to refrigerate the vaccines, a portable vaccine storage unit or qualified container and packout may be used with a DDL.
- Develop an emergency plan or SOPs for transporting vaccines and include procedures and protocols for packing and transport.

*Follow the manufacturer's guidance if the transport limitation differs.

Ensure your facility has enough supplies to transport your largest annual inventory (e.g., during respiratory virus season). Appropriate materials include

- Vaccine transport containers, such as
  - Portable vaccine refrigerator/freezer/ultra-cold freezer units (preferred option).
    - Qualified containers and packouts if appropriate portable refrigeration units are not available.
    - Soft-sided containers specifically engineered for vaccine transport are acceptable. Do not use commercially available soft-sided food or beverage coolers, as most are poorly insulated and are likely to be affected by room or outdoor temperatures.
- Coolant materials, such as
  - Phase change materials (PCMs) that can be conditioned between 4°C and 5°C (39°F and 41°F).
  - Conditioned frozen 16.9- or 8-ounce water bottles.
- Insulating materials such as bubble wrap and corrugated cardboard—enough to form two layers per container.
- TMDs for each vaccine transport container.

Equipment and Materials for Vaccine Transport

It is always safest to have vaccines delivered directly to a facility with a vaccine storage unit ready to receive the shipment, but this is not always possible. If necessary, vaccines may be transported using a portable vaccine refrigerator with a temperature monitoring device placed with the vaccines. If a portable vaccine refrigerator is not available, qualified containers and packouts with a TMD in each container can be used. For transport to an off-site clinic, bring only what is needed for the workday.

Important note: *Do not transport vaccines using the original shipping materials from the distributor or manufacturer. Commercial distributors and manufacturers use validated* packouts *with their vaccine shipments. The packout materials used are conditioned to certain temperatures and have specifically designed placement. Reusing them can compromise the cold chain and jeopardize vaccine viability.*

Non-Emergency Transport Systems

Container	Transport for Off Site Clinic, Satellite Facility, or Relocation of Stock
Portable Vaccine Refrigerator or Freezer	Yes
Qualified Container and Packout	Yes
Conditioned Water Bottle Transport System	No
Manufacturer's Original Shipping Container	No
Food/Beverage Coolers	No

Coolants for Transport

PCMs between 4°C and 5°C (39°F and 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 original vaccine shipments to pack refrigerated vaccines. They can still freeze vaccines even if they are conditioned or appear to be "sweating."

Transport Planning and Preparation

Improper packing for transport is as risky for vaccines as a failed storage unit.

Include vaccine packing and transport guidance in routine and emergency storage and handling sections of the facility's SOP.

At a minimum, include the following in all staff-facilitated transport procedures and protocols:

- In advance, identify trained staff to pack vaccines, as well as primary and backup drivers and vehicles for transport.
- Consider renting a refrigerated truck for transporting a large quantity of vaccines or transporting vaccines for an extended distance.
- Take an inventory of vaccines and record actions taken to protect the vaccines during transport.
- Open storage unit doors only when necessary and only after completing all preparations for packing and moving vaccines.
- If using a company or personal vehicle, transport vaccines only inside the passenger cabin, not in the trunk or truck bed, which may be too hot or too cold.
- Move transport containers directly to a vehicle that is already at a comfortable temperature, neither too hot nor too cold.
- Avoid leaving containers in areas exposed to direct sunlight.
- Check vaccine temperature upon arrival at the alternative vaccine storage facility, and immediately store vaccines at recommended temperatures.
- Check with the immunization program for additional guidance and resources on emergency transport of vaccines, particularly in major emergencies.

Best Practices for Transporting mRNA Vaccines

- Transport vials and MFSs in the original packaging whenever possible.
- Protect vials and MFSs as much as possible from drops, shocks, and vibration.
- Secure storage containers during transport.
- Protect from light. Avoid exposing mRNA vaccines to direct sunlight or ultraviolet (UV) light when handling.
- Refer to the manufacturer's package insert for additional guidance.

Transporting Opened Multidose Vials

In rare circumstances, a partially used vial may need to be transported to or from an off-site/satellite facility operated by the same provider. In these instances, the cold chain must be properly maintained, and use after transport must align with expiry date or BUD. However, a partially used vial cannot be transferred from one provider to another, or across state lines. Contact your immunization program for specific state or local regulations impacting this activity.

Transporting Predrawn Syringes

It is best practice to transport vaccine in unopened vials or manufacturer-filled syringes. However, there may be rare instances, such as large off-site vaccine clinics, when the only option is to transport vaccines in predrawn syringes. Predrawn syringes should be properly labeled and stored according to the manufacturer's guidance. Additional information on predrawn vaccine is found in Section 5.

Transporting Vaccine 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.

If diluents stored at room temperature (20°C to 25°C [68°F to 77°F]) 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.

Never freeze diluents—not even during transport. Place an insulating barrier like bubble wrap between the diluents and conditioned water bottles or phase change materials.

Transporting Frozen Vaccines

- If frozen vaccines must be transported, use a portable vaccine freezer unit or qualified container and packout that maintains temperatures between -50°C and -15°C (-58°F and +5°F) or between -90°C and -60°C (-130°F and -76°F) for ultra-cold transport.

  Follow these steps for transporting frozen vaccines:

  - Place a TMD (preferably with a buffered probe) in the container as close as possible to the vaccines.
  - Immediately upon arrival at the destination, unpack the vaccines and place them in a freezer at a temperature range between -50°C and -15°C (-58°F and +5°F) or -90°C and -60°C (-130°F and -76°F) for ultra-cold freezer storage. Any stand-alone freezer that maintains these temperatures is acceptable.
  - Record the
    - Time that vaccines are removed from the storage unit and placed in the transport container.
    - Temperature during transport.
    - Time at the end of transport when vaccines are placed in a stable storage unit.

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

Temperature Monitoring During Transport

Use a continuous TMD, preferably a DDL with the capability to measure minimum/maximum temperatures, for monitoring and recording temperatures while transporting vaccines.

- Use a TMD or DDL that has an accuracy of ±0.5°C (±1°F).
- Place the buffered temperature probe directly with the vaccines.
- Keep the TMD display on top of vaccines so the temperature can be easily seen.
- Record the time and minimum/maximum temperature at the beginning of transport.

Temperature Monitoring After Transport

Immediately upon arrival at the destination, store vaccines in an appropriate storage unit with a TMD.

Be sure to follow these guidelines for monitoring and recording storage unit temperature:

- If the device displays minimum/maximum temperatures, this information should be checked and recorded as soon as the vaccines are stored.
- VFC providers must review and document temperature data every hour using a DDL with a digital display and a probe in buffered material.
- If the device does not display minimum/maximum temperatures, then the current temperature should be checked and recorded at least twice daily (at the start and end of the workday).

If vaccines cannot be stored in an on-site storage unit, they should be kept in the portable vaccine storage unit using the following guidance:

- If using a DDL that records minimum/maximum temperatures, check and record temperatures each time the portable vaccine storage unit is opened. Do not open the unit just to check the temperature.
- If the TMD measures current temperatures only, place the probe as close as possible to the vaccines, and check and record temperatures hourly.
- Keep the container closed as much as possible.
- In off-site clinic settings, each person preparing and administering vaccines should remove no more than one multidose vial or 10 doses at a time.

Section Seven: Emergency Vaccine Storage and Transport

Emergency vaccine storage and transport guidance may differ from non-emergency situations. To ensure proper cold chain maintenance during emergencies, carefully review both transport sections in this toolkit, along with the manufacturer's guidance for impacted vaccines.

Emergencies such as equipment failures, power outages, severe weather conditions, or natural disasters sometimes happen without warning and might compromise vaccine storage conditions. Providers should make plans for vaccine storage or transportation during emergencies. 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 affected by flooding or a temporary power outage.

VFC providers and others who administer vaccines purchased with public funds should contact their immunization program for state-specific requirements related to vaccine transport.

Power Outages

Temperature Monitoring During a Power Outage

If the storage unit has an external temperature monitoring display that can be checked without opening the unit 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.
- Temperature excursions should be avoided, if possible, by using emergency plans and SOPs for transport and alternative storage. However, if temperatures fall outside of the recommended range, providers should follow procedures for temperature excursions.

If it is not possible to monitor the temperature inside the unit without opening the door, and there is no access to an alternative facility with power for vaccine storage or established emergency vaccine storage procedures, wait until power is restored before taking the following steps:

- Record the room temperature (if possible) and the temperature inside the unit.
- If using a DDL, document the length of time the power was off and the minimum and maximum temperatures during that period.

Vaccine Storage During Emergencies

- During an emergency, vaccines may remain inside a nonfunctioning unit if appropriate temperatures are maintained. With the unit door closed, monitor the DDL to determine when additional action should be taken.
- During a power outage, only open the storage unit door if
  - Power is restored or
  - It is determined that the vaccines need to be packed in separate storage containers and/or transported to an alternative storage facility.

- If temperatures inside the unit have already fallen outside of the recommended range, follow procedures for temperature excursions. If possible, move the vaccines to an alternative storage unit or location where they can be stored at appropriate temperatures. Make sure to separate and mark these vaccines "DO NOT USE—TEMPERATURE EXCURSION" until a decision can be made about whether the vaccines can still be used.

Generators and Backup Battery Power Sources

Having an on-site generator prevents the need to transport vaccines to an alternative storage facility during a power outage.

- Test the generator quarterly and have it serviced annually.
- Keep sufficient fuel on hand to continuously run the generator for at least 72 hours.

A backup battery power source can be used in lieu of a generator.

- Test backup battery power sources quarterly and have them serviced annually.
- Check the manufacturer's guide for testing.

Accessing Your Facility After-Hours

Emergency situations can arise outside of normal business hours, so providers should maintain a relationship with the facility's building manager or security staff. Ensure all staff members are familiar with emergency SOPs, including after-hours roles and responsibilities. The facility's storage and handling SOPs should include instructions for accessing the vaccine storage units when the building is closed, with a building map/diagram and locations of

- Spare batteries
- Flashlights
- Keys
- Locks
- Circuit breakers
- Emergency transport equipment and materials

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 needed, such as security officers or building managers.

Vaccine Transport During Emergencies

Emergency transport usually involves relocating vaccines to protect them when a facility's ability to store vaccines is compromised because of a power outage, weather event, or other mishap.

During emergencies, two provisional vaccine transport options can be used:

- A transport system that uses conditioned water bottles and hard-sided insulated containers or Styrofoam™, in conjunction with The *Packing Vaccines for Transport During Emergencies* tool
- Manufacturers' original shipping containers (only as a last resort)

Transporting Vaccines During an Emergency

The *Packing Vaccines for Transport During Emergencies* tool describes a system in which properly conditioned frozen water bottles can be used as a coolant when transporting vaccines during emergency situations.

Container	Transport for Emergencies Only
Portable Vaccine Refrigerator or Freezer	Yes
Qualified Container and Packout	Yes
Conditioned Water Bottle Transport System	Yes
Manufacturer's Original Shipping Container	Yes (last resort only)
Food/Beverage Coolers	No

Alternative Storage Facility

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.

Establish a working agreement with at least one alternative storage facility, even if providers have a generator as backup equipment.

- Ensure 24-hour access to this facility. Hospitals, long-term care facilities, state depots, the Red Cross, fire stations, packing plants, grocery stores, funeral homes, and commercial pharmacies are some of the facilities that might be able to assist.
- Ensure the alternative storage facility has a dedicated unit or shared space that can maintain temperatures at the appropriate range. Please note that shared spaces may not be able to maintain temperatures within the recommended ranges for the vaccine supply.
- Before packing any vaccines, confirm with the alternative vaccine storage facility that they can accept them for storage.

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

Temperature Monitoring at Alternative Storage Sites

Vaccine temperature should be maintained when stored at an alternative facility during an emergency. Temperatures should be monitored and documented in temperature logs when storing vaccines during an emergency. Sometimes getting temperature logs before an emergency is not feasible. However, the provider should confirm that the emergency unit can maintain the required temperature range. To confirm, locate online specifications for the make and model of the storage unit.

If an Alternative Vaccine Storage Facility Is Not Available

If providers cannot find an alternative vaccine storage facility within a reasonable distance or cannot reach the alternative facility, they can use portable vaccine refrigerator/freezer units (if power source is available), qualified containers and packouts, or a hard-sided insulated container or Styrofoam™ using the *Packing Vaccines for Transport during Emergencies* tool. Always place a TMD with the vaccines, and carefully monitor the TMD to ensure vaccines remain within the appropriate temperature range. Temporary storage containers should remain closed, and vaccines can only be stored safely for as long as the containers are validated to maintain proper storage temperatures.

Glossary

Beyond-Use Date (BUD)	The last date or time a product can be safely used after it has been moved from one storage state to another (e.g., frozen to refrigerated) or prepared for administration (e.g., reconstituted). The BUD is calculated by the provider and should never exceed the manufacturer's expiration date.
Buffered temperature probe	A temperature probe designed to prevent false excursions 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).
Calibration	Professional measurement of the accuracy of the reading from a temperature monitoring device against nationally accepted standards.
Cold chain	A temperature-controlled supply chain that includes all vaccine-related storage equipment and procedures.
Cold chain monitor (CCM)	Single-use device that monitors the temperature inside a vaccine shipping container. CCMs should be thrown away after being checked. CCMs are stored in a separate compartment of the shipping container (a CCM might not be included when vaccines are shipped directly from the manufacturer).
Conditioned water bottles	Frozen water bottles that have been submerged under lukewarm water until the ice block inside can spin freely.
Digital data logger (DDL)	An electronic device that records data digitally over time or in relation to location either with a built-in or external instrument or sensor.
Diluent	A diluting agent (e.g., a liquid) added to reconstitute lyophilized vaccine before administration. Manufacturers of these vaccines also supply the matching diluent. Some diluents contain a vaccine component or an adjuvant needed for vaccine effectiveness.
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.
Expiration (expiry) date	The last day that the manufacturer guarantees the product's potency and safety; therefore, the final day it can be administered.
Fan-forced air circulation	Technology using powerful fans or multiple cool air vents inside the unit that promote uniform temperature and fast temperature recovery.

Household-grade storage unit	A storage unit that is primarily sold for home use.
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 reading during a set period of time.
Packout	See *Qualified container and packout*.
Pharmaceutical-grade unit	A unit that is specifically designed to store pharmaceuticals or biologics.
Phase change materials (PCMs)	Engineered packing supplies that help control container temperatures during vaccine transport or shipping.
Portable vaccine storage unit	A type of powered refrigerator or freezer unit specifically designed for use during vaccine transport. These are passive units that require a power source to function. Please note that some active units are "qualified" to maintain desired temperatures for a set amount of time in the event of a power loss.
Potency	A vaccine's strength or effectiveness. In the context of this toolkit, potency refers to a vaccine's response to environmental conditions.
Presentation	The physical form in which a vaccine is supplied by the manufacturer: single-dose vial, multidose vial, manufacturer-filled syringe, etc.
Purpose-built unit	A unit that is specifically designed to store vaccines.
Qualified container and packout	A type of container and supplies specifically designed for use when packing vaccines for transport. These containers are "qualified" through laboratory testing under controlled conditions to ensure they achieve and maintain desired temperatures for a set amount of time.
Reconstitution	Process of adding a diluent to a dry ingredient to make it a liquid.
Standard operating procedures (SOPs)	A set of step-by-step instructions compiled by an organization to help workers carry out complex routine or emergency operations. SOPs aim to achieve efficiency, quality output, and uniformity of performance, while reducing miscommunication and preventing failure to comply with industry regulations and best practices.
Stand-alone storage unit	A storage unit that operates independently of any other device or system for its desired function. For example, a refrigerator that functions only as a refrigerator or a freezer that functions only as a freezer.

Temperature excursion	Any temperature reading that is outside the recommended range for vaccine storage as defined in the manufacturer's package insert.
Tolerance	Compliance with nationally accepted standards for the calibration limits of temperature monitoring equipment. The equipment can be considered either "in" or "out" of tolerance.
Traceability	An unbroken chain of measurements and associated uncertainties.
Uncertainty	The quantification of doubt about the measurement result.
VFC awardees	The 63 state, local, and territorial immunization programs that receive operational funding from the CDC to implement and oversee their VFC Programs.