# Table of Contents

**Vaccine Storage and Handling Resources**..............................1

- Defense Health Agency - Immunization Healthcare Branch (DHA-IHB) ............................................................ 2
- United States Army Medical Materiel Agency - Distribution Operation Center (USAMMA-DOC) ........................................................... 2
- Defense Logistics Agency - Troop Support Medical (DLA-TSM) ...... 2
- Centers for Disease Control and Prevention (CDC) .......................... 2
- Immunization Action Coalition (IAC) .................................................. 2

**Forward**..........................................................................................3

**Introduction**..........................................................................................4

**Protecting the Vaccine Supply**..........................................................5

- Cold Chain Management (CCM) ......................................................... 6
- Vaccine Coordinator Duties and Staff Training ............................... 6

**Standard Operating Procedures**.........................................................7

- Routine Management of Vaccine ......................................................... 8
- Emergency Vaccine Response and Retrieval .................................. 8

**Vaccine Storage Equipment**...............................................................9

- Selecting the Proper Vaccine Storage Unit ...................................... 10
- Vaccine Storage Unit Maintenance ...................................................... 10
- Protecting the Power Supply ............................................................... 11

**Storage Unit Temperature Monitoring**..........................................12

- Temperature Ranges ........................................................................ 13
- Adjusting and Stabilizing Temperatures .......................................... 13
Temperature Monitoring Equipment ............................................................... 15
  Digital Data Loggers .................................................................................... 16
  Electronic Monitoring System ..................................................................... 17
  Monitoring and Recording Temperatures .................................................. 17

Routine Vaccine Management ..................................................................... 19
  Inventorying Vaccine ................................................................................. 20
  Redistributing Soon-to-Expire Vaccine ....................................................... 20
  Ordering Vaccine ....................................................................................... 20
  Shipping Vaccine ....................................................................................... 21
  Receiving Vaccine Deliveries ................................................................. 21

Proper Vaccine and Diluent Storage ............................................................ 24
  Placing Vaccine in Storage Unit ................................................................. 25
  Labeling of Vaccine in Storage Unit ......................................................... 25
  Storing Diluent .......................................................................................... 25

Proper Handling of Vaccine and Diluent ...................................................... 26
  Preparing Vaccine for Administration ........................................................ 27
  Single-Dose Vial ....................................................................................... 27
  Multi-Dose Vial ....................................................................................... 27
  Manufacturer-Filled Syringe .................................................................... 28
  Reconstituted Vaccine .............................................................................. 28

Vaccine Transport During Off-Site Events and Emergencies ......................... 29
  Proper Transport of Vaccine ..................................................................... 30
  Validated Transport Containers ............................................................... 30
  Packing Vaccine for Transport ................................................................ 30
<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Off-Site Immunization Events</td>
<td>32</td>
</tr>
<tr>
<td>Predrawing Vaccine</td>
<td>34</td>
</tr>
<tr>
<td>Off-Site Immunization Procedures</td>
<td>33</td>
</tr>
<tr>
<td>Storage and Handling Emergencies</td>
<td>35</td>
</tr>
<tr>
<td>Preparing for Storage Emergencies</td>
<td>36</td>
</tr>
<tr>
<td>Storage Locations WITHOUT Emergency Backup Power</td>
<td>36</td>
</tr>
<tr>
<td>Storage Locations with Emergency Backup Power</td>
<td>36</td>
</tr>
<tr>
<td>Potentially Compromised Vaccine Reporting Process</td>
<td>37</td>
</tr>
<tr>
<td>Vaccine Loss Types and Contributing Factors</td>
<td>38</td>
</tr>
<tr>
<td>Non-Preventable Loss</td>
<td>38</td>
</tr>
<tr>
<td>Personnel Error</td>
<td>38</td>
</tr>
<tr>
<td>Process Failure</td>
<td>38</td>
</tr>
<tr>
<td>Proper Disposal of Vaccine and Diluent</td>
<td>39</td>
</tr>
<tr>
<td>Federal and State/Local Regulations</td>
<td>40</td>
</tr>
<tr>
<td>Pharmaceutical Reverse Distributor Program</td>
<td>40</td>
</tr>
<tr>
<td>When to Return or Discard Vaccine and Diluent</td>
<td>41</td>
</tr>
<tr>
<td>Methods of Disposal</td>
<td>41</td>
</tr>
<tr>
<td>Summary</td>
<td>42</td>
</tr>
</tbody>
</table>
Vaccine Storage and Handling Resources
Defense Health Agency – Immunization Healthcare Branch (DHA-IHB) supports Force Health Protection and Readiness, and the Military Health System (MHS) by developing and promoting programs and services that enhance immunization effectiveness and safety. DHA-IHB provides evidence-based solutions to improve immunization healthcare through policy implementation guidance, strategic communication, education, training, and clinical services worldwide. Contact your regional Immunization Healthcare Specialist (IHS) to discuss training needs, policy, or assistance with storage and handling issues. IHS contact information and areas of responsibility can be found at www.health.mil/ContactYourIHS. For vaccine storage and handling questions, contact the DHA-IHB Monday - Friday (0700-1800 ET) at (877) GET-VACC (438-8222), Option 2, or email DoDvaccines@mail.mil. You can visit DHA-IHB on the web at www.health.mil/coldchain.

United States Army Medical Materiel Agency – Distribution Operation Center (USAMMA-DOC) is the designated agent within the Department of Defense (DOD) responsible for managing and coordinating the distribution of Anthrax, Smallpox, and Adenovirus vaccines, other special Investigational New Drugs (INDs), Chemical Biological Drugs, and other temperature sensitive medical products (TSMPs) that require specialized handling from the manufacturer or storage facility to its first level user (recipient organizations) and redistributions, regardless of Service affiliation or country affiliation. USAMMA-DOC also incorporates the special types of equipment used to handle these vaccines and medical products. Direct communications occur with the Defense Health Agency Immunization Healthcare Branch (DHA-IHB), Air Force Medical Support Agency (AFMSA), Navy Medical Logistics Command (NavyMedLOGCOM), U.S. Army major commands and regional medical commands. USAMMA-DOC is responsible for the Army Influenza Vaccination Program. USAMMA-DOC provides consultation and training on Cold Chain Management (CCM) to logistical and medical units in proper distribution and storage practices for TSMP in support of the DHA-IHB. USAMMA-DOC also provides on-line training via DCS for CCM certification on the first Thursday of each month. Locate the website for online CCM training at www.usamma.amedd.army.mil/net/Pages/doc/coldChainManagement.aspx. USAMMA-DOC is responsible for creating and disseminating all DoD Medical Materiel Quality Control (MMQC) and Army Medical Materiel Information (MMI) messages. For vaccine or other CCM questions during the hours of 0700-1600 EST, call (301) 619-4318/3017. For URGENT after-hour issues only, call (301) 676-1184/0808. You can reach USAMMA-DOC by email at usarmy.detrick.medcom-usamma.mbx.doc@mail.mil. Visit USAMMA-DOC on the web at www.usamma.amedd.army.mil/doc.cfm.

Defense Logistics Agency - Troop Support Medical (DLA-TSM) provides the military medical community the products and services needed every day for every crisis around the world. The Pharmaceutical Division offers most pharmaceuticals, to include vaccines, for purchase by eligible customers. DLA-TSM is the disposition authority for Influenza and Japanese Encephalitis vaccines, as well as Pyrostigmine Bromide tablets, and will provide disposition guidance for most other cold chain materials (to include pharmaceuticals, vaccines, and laboratory supplies). For information about cold chain management, contact the CCM team during the hours of 0730-1800 EST at (215) 737-5537/5365, DSN: 444-5537/5365. For URGENT after-hour issues only, call (215) 284-6586. You can reach DLA-TSM by email at paacoldchainteam@dla.mil or DSCPColdChain@dla.mil. Visit DLA-TSM on the web at DLA/Pharmaceutical/ColdChainPackaging.

Centers for Disease Control and Prevention (CDC) has various storage and handling tools, documents, videos, and training resources available on the web at: www.cdc.gov/vaccines/recs/storage/default.htm

Immunization Action Coalition (IAC) has storage and handling tools that can be customized for individual use, available on the web at: www.immunize.org/clinic/storage-handling.asp
Prior to 2012, the Department of Defense (DoD) did not have a standardized process for reporting potentially compromised vaccines, or for receiving and dispensing formal vaccine disposition guidance. Annual vaccine loss totals were not centrally tracked nor analyzed for trends. The DHA-IHB, in partnership with the USAMMA-DOC and DLA-TSM, created a process to streamline communications and mitigate inconsistent business practices for vaccine disposition among the Services. One of several tools the DHA-IHB developed to improve the workflow is the Potentially Compromised-Temperature Sensitive Medical Products (PC-TSMP) worksheet. The PC-TSMP worksheet provides step-by-step instructions to follow after a product experiences a temperature excursion, and it collects the critical data points required for a disposition. The standardized workflow, along with the use of the PC-TSMP worksheet, has resulted in more timely, accurate, and efficient reporting of vaccine loss events and a reduction in the destruction of viable vaccine.

DHA-IHB received 238 PC-TSMP worksheets from October 2015 through September 2016. Of those incidents, 114 involved either a partial loss or a total loss of vaccine. The worksheet categorizes loss events as non-preventable, personnel error, and/or process failure, and further categorizes the potential loss by contributing factors. Personnel error, such as leaving vaccine out of the storage unit or placing vaccine in the wrong storage unit, accounted for half of the reported loss event types (50%). Non-preventable loss, such as power outages and equipment failure, accounted for the second most common loss event type (36%). Process failures (6%) and a combination of non-preventable, personnel error and process failure (8%) were the other reported loss event types. In over 33% of the reports, process failure occurred secondary to a personnel error or non-preventable loss. The process failures reported most often were vaccine(s) transported incorrectly and vaccine receiving errors. A “combination” loss was frequently associated with a power outage along with an incorrectly programmed alarm system, and staff noncompliance with the posted emergency plan.

Analysis of data collected over the past three years has provided insight into the most frequent causes for vaccine loss so that loss prevention strategies can be identified and shared with the DoD immunization community. One such loss prevention strategy identified from reviewing 2012-2016 loss data was to store M-M-R vaccine in the freezer instead of the refrigerator. Unlike most vaccines, there is no loss of potency when M-M-R is exposed to freezing temperatures; but when exposed to temperatures above 8°C, even for a short period, the vaccine loses potency. The manufacturer recommends freezer storage as an option for M-M-R vaccine and the National Center for Immunization and Respiratory Diseases recommends keeping M-M-R in the freezer along with MMRV, if adequate space is available, which they believe will reduce the risk of inadvertent storage of MMRV in the refrigerator instead of the freezer. DHA-IHB briefed the Service Immunization POCs in August 2015 and released an information paper on the recommendation to store M-M-R vaccine in the freezer versus the refrigerator whenever possible in April 2016. DHA-IHB will continue to review the data to identify loss prevention and process improvement strategies that activities can incorporate into local practices.
Introduction

The DoD has a robust, worldwide immunization program that supports 9.4 million beneficiaries. Our Service members travel to countries where many vaccine-preventable diseases are endemic. For the DoD’s immunization programs to be successful, it is imperative that immunizers store and handle vaccines properly, making sure they are ready for administration whenever our worldwide deployers need them.

Immunizations are delivered in traditional medical settings, such as clinics and patient-centered medical homes, as well as in non-traditional operational environments, like ships afloat, forward deployed locations, and during humanitarian missions. Regardless of where vaccines are administered, all healthcare personnel must adhere to the same stringent storage and handling guidelines.

The purpose of this document is to augment the Eight Standards for Military Immunization, storage and handling guidance, found in Appendix B of the Joint Instruction on Immunizations and Chemoprophylaxis for the Prevention of Infectious Diseases. By understanding and implementing these guidelines, immunization staff can ensure that temperature compromised vaccine won’t affect the health of uniformed Service members and other beneficiaries.
Protecting the Vaccine Supply
Protecting the Vaccine Supply

Cold Chain Management (CCM)

The cold chain is the system developed to maintain and distribute temperature-sensitive medical products (TSMP), like vaccines, at the proper temperature. The cold chain begins at the manufacturer, continues through shipment to medical logistics, then to the delivery location, and ends when the vaccine is administered to a patient. A single shipment of vaccine can immunize thousands of patients, but could become compromised if that shipment is exposed to temperature fluctuations or light.

Failure to ship, store, handle and administer vaccines as outlined in the manufacturers’ package insert, such as exposing them to excessive heat, cold or light, may reduce the vaccine’s potency. Once the potency of a vaccine is lost, it is not reversible. Certain vaccines lose potency when exposed to room temperature for as few as 30 minutes. Freezing damages almost all refrigerated vaccines. Human papillomavirus (HPV), MMR, MMRV, rotavirus, varicella, and zoster vaccines are particularly vulnerable to exposure to light. The vaccine’s appearance may not change after exposure to inappropriate conditions, so appearance is not a reliable indicator for determining whether the vaccine is still viable.

If a patient is administered a compromised or expired vaccine, the vaccination may be considered invalid and need to be repeated. This could result in diminished patient confidence in vaccines and the Military Health System. It is important to ensure that activities incorporate three essential elements into their processes for effective CCM: 1) a well-trained staff, 2) reliable storage and temperature monitoring equipment, and 3) accurate vaccine inventory management. This will help our patients receive the highest possible quality healthcare, and could potentially prevent the waste of thousands of dollars in compromised vaccine.

Vaccine Coordinator Duties and Staff Training

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. All immunization personnel, including temporary staff, should be familiar with the vaccine storage requirements outlined in the manufacturer’s package insert. In addition, they should know the appropriate steps to take to safeguard vaccine during an emergency. Each location should have one trained person designated as the primary vaccine coordinator and at least one other designated as a backup. Vaccine coordinator duties should be written down as part of the activity’s standard operating procedures (SOP). Vaccine coordinators should be well versed in routine and emergency vaccine management including ordering, inventorying, receiving, storing, handling, packaging, transporting and shipping vaccines, monitoring storage unit temperatures, maintaining equipment, and responding to vaccine storage emergencies.

Immunization locations should develop and implement a standardized orientation program for newly assigned personnel, which should include all routine and emergency vaccine storage and handling procedures for their location. This includes not only those who administer vaccine, but also anyone who delivers or receives shipments or has access to areas where vaccines are stored. Additionally, all assigned staff should receive annual cold chain management training, as well as emergent training, when stocking a new vaccine or when a vaccine’s storage requirement changes. Document any continuing education in the staff member’s training folder/record, and include the date and type of training received.
**Routine Management of Vaccine**

Clearly written, detailed, and up-to-date standard operating procedures/operating instructions (SOP/OIs) for both routine and emergency vaccine storage and handling will help your facility stay organized, serve as a reference and training tool, and assure proper vaccine management.

At a minimum, the routine management of vaccine SOP/OI should include information on:

- The primary and backup coordinator’s duties and responsibilities,
- Requirements for storage unit temperature monitoring,
- Storage requirements for each vaccine and diluent in inventory,
- Correct placement of vaccine within the storage unit,
- Proper vaccine handling and administration procedures,
- Procedures for ordering and inventorying vaccine,
- Procedures for receiving vaccine shipments,
- Proper packaging protocols for vaccine transport and shipment,
- Procedures for transporting and storing vaccine during off-site clinics,
- Proper disposal methods for vaccines, diluents, and supplies, and
- Preventive maintenance requirements for storage and handling equipment.

Additionally, it is important to identify and have available current point of contact (POC) information for the primary and backup vaccine coordinators, logistics, pharmacy, vaccine manufacturers, Immunization Healthcare Specialist (IHS), U.S. Army Medical Materiel Agency Distribution Operation Center (USAMMA-DOC), and Defense Logistics Agency Troop Support Medical (DLA-TSM). Current versions of frequently used forms such as temperature logs, emergency forms, PC-TSMP worksheet, etc. should also be available. Post the routine storage and handling SOP/OI near the storage unit and regularly update and review as personnel contact information or duty positions change.

**Emergency Vaccine Response and Retrieval**

The emergency vaccine response and retrieval SOP/OI should describe the immediate corrective actions required to safeguard vaccine and minimize monetary loss. Never leave vaccine in a non-functioning storage unit. The emergency SOP/OI should be developed in advance of emergencies, such as power outages or equipment failures, and include instructions for entering your building and vaccine storage spaces after hours.

It is important to identify alternate storage locations within the medical facility, to serve as temporary storage, while electricity is restored or equipment is fixed. Such locations could include logistic hubs, pharmacy, laboratory, or nearby hospitals (with previously negotiated agreements), health departments, or other DoD installations. Once you identify the alternate storage location, physically visit the site to ensure they have backup power, clearly labeled storage units (e.g., refrigerator or freezer), and appropriate temperature monitoring equipment.

Post the emergency SOP/OI on or near the vaccine storage equipment making it easily accessible to providers, immunization or other medical staff, and housekeeping personnel. Communicate, update, and regularly test (at least annually) the emergency vaccine response and retrieval SOP/OI with staff members. This will ensure they understand the procedures for responding to out-of-range temperatures and for notifying designated staff about any storage equipment problems.
Vaccine Storage Equipment
Selecting the Proper Vaccine Storage Unit

When purchasing a vaccine storage unit, select one that is suitable for vaccine storage, can maintain the required temperature range year-round and store the year’s largest inventory (including flu vaccine) without crowding. The Centers for Disease Control and Prevention (CDC) recommends a self-contained, stand-alone refrigerator or freezer unit that is dedicated to vaccine storage only. These units can vary in size, from compact, under-the-counter or counter-top style to large, pharmaceutical/medical-grade storage units. Pharmaceutical or medical grade storage units ensure temperature consistency, provide ease of serviceability, integrate with electronic temperature monitoring systems, and have compressors that are more efficient and are able to cool more quickly.

If your location’s existing equipment is a household combination refrigerator and freezer unit, the CDC recommends using only the refrigerator compartment to store refrigerated vaccines and to purchase a separate stand-alone freezer unit to store frozen vaccines. Research has found that household combination refrigerator-freezer units do not maintain proper temperatures, particularly during defrost cycles.

Whichever storage unit is used, clearly label it as either a refrigerator or freezer. This simple step could be the difference between refrigerated vaccine being placed in the freezer or frozen vaccine being placed in the refrigerator.

The CDC does not recommend the use of dormitory or bar-style refrigerator/freezers for ANY vaccine storage. A National Institute of Standards and Technology (NIST) study determined that this type of storage unit exhibits severe temperature control and stability issues and is not suitable for use with vaccines.

Vaccine Storage Unit Maintenance

Good air circulation around the storage unit is essential for proper heat exchange and cooling functions. Place storage units in a well-ventilated room, with adequate space between the unit, ceiling, and walls, at an ambient room temperature of 20°-25°C /68°-77°F. If the room temperature is above 25°C/77°F, install an air conditioning unit or add extra ventilation. This will help prevent the refrigerator or freezer from overheating and failing. Check storage units throughout the day and prior to leaving, to confirm that the doors are closed completely (using an open-door alarm and a self-closing door may be helpful) and to verify that the equipment is working properly.

Conduct and document regular, required preventive maintenance on equipment per manufacturer instructions. For example, verify the accuracy of the storage unit temperatures by comparing the readout from two separate temperature devices daily. Defrost the freezer weekly (if applicable). On a monthly basis, check the door seals and clean the coils, motor, and storage unit compartments. Maintain a logbook that includes contact information for service providers, instruction manuals, serial numbers, the date placed in service for each piece of equipment, and the dates of any maintenance or repairs.
Protecting the Power Supply

Plug storage units directly into the wall outlet, preferably into a red emergency power outlet (if available). Do not use extension cords, multi-outlet power strips or surge protectors. To reduce the chance of accidentally unplugging the storage unit, secure the storage unit plug to the electrical outlet, by using a safety-lock plug, an outlet cover, or a cover outlet with a cage. To prevent the power to the storage unit from being turned off, do not plug into outlets that can be activated by a wall switch or outlets with built in circuit switches (may have a reset button).

Post highly visible “DO NOT UNPLUG” warning signs (use multilingual signs for non-English speaking staff) at outlets and on storage units to remind staff, custodians, electricians, and other workers not to unplug the unit (e.g., to plug in a vacuum). Label circuit breaker fuses to alert personnel not to turn off the power, include information on who to contact if the power to the storage units will be turned off due to construction or other electrical work.

Immunization locations storing large vaccine inventories that do not have emergency backup power, should install a generator that automatically provides power to the storage unit in the event of a power outage. Backup generators should have sufficient capacity to run for up to 72 hours, so arrange to have an adequate supply of fuel available. Test backup generators quarterly, at a minimum, to ensure they are connected and functioning properly.
Storage Unit Temperature Monitoring
Temperature Ranges

Proper storage unit temperatures are critical to ensuring vaccines are stored per the guidelines listed in the manufacturers’ package insert and remain potent and effective.

- Refrigerated vaccine
  - Store between 2° and 8°C/36° and 46°F
  - Set thermostat midrange to achieve a temperature of about 5°C/40°F
  - Set the alarm activation at 2°C (low) and 8°C (high)
  - DO NOT expose refrigerated vaccines to freezing temperatures

- Frozen vaccine
  - Store between -50°C and -15°C/-58°F and +5°F
  - Set thermostat at midpoint temperature setting
  - Set the freezer alarm activation at -15°C/+5°F

Adjusting and Stabilizing Temperatures

Only the primary or backup vaccine coordinator should adjust the temperature of the storage unit. Limiting access to the thermostat reduces the risk of improperly adjusting the temperatures and exposing vaccines to temperatures that are too warm or too cold. Post a warning sign on the storage unit with contact information for the primary and backup vaccine coordinator.

Before adjusting the temperatures within a storage unit, confirm the unit is securely plugged into a power source and the doors are completely closed. 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 the temperature does require an adjustment, adjust the thermostat in small increments, monitoring the refrigerator and/or freezer temperatures every half hour, without opening the doors, until the temperature stabilizes and the target is reached.

In a newly installed or repaired refrigerator or freezer, start by setting the empty refrigerator thermostat at 5°C/40°F and the empty freezer thermostat at -15°C/5°F or colder. It may take 2 to 7 days to stabilize the refrigerator temperature and 2 to 3 days for the freezer temperature. When the storage unit temperature is stable at the recommended range for a minimum of 24 hours, place the vaccines into the unit.

The CDC recently updated their recommendation for using water bottles to help maintain stable temperatures in the refrigerator, as well as the freezer, due to frequent opening and closing of the doors or during equipment or power failures. Place containers of water, labeled “Do NOT Drink,” in the refrigerator where vaccines should not be stored, such as the door racks, top shelf, and on the floor and against the walls, in the back, on the floor, and in the door racks of the freezer. Be careful that the water bottles do not
weigh down doors so much that the doors do not close properly.

Testing by the National Institute of Standards and Technology (NIST) has provided scientific support for the use of water bottles as effective thermal stabilizers in vaccine storage units. Water bottles in the refrigerator reduce the risk of freezing temperatures due to the tremendous latent heat released from water prior to freezing. There is no scientific testing data demonstrating that chilled or frozen gel packs provide the same thermal benefits.

If necessary, gel or coolant packs (instead of water bottles) may be acceptable to stabilize temperatures. However, the CDC currently recommends the use of water bottles because of the restrictions required for gel pack use. DLA-TSM, USAMMA-DOC, and vaccine manufacturers often use phase-change coolant packs and employ specific processes to assure that these packs are conditioned to the correct temperatures so vaccine is maintained at the correct storage temperature during shipping. Many of the gel or coolant packs used in distribution are not intended for long-term storage and begin to break down with time, not maintaining the same thermal dynamic properties that they had when new. Additionally, not all phase-change coolant packs are made for storage in a refrigerator – some are designed to be stored in the freezer and then conditioned to a certain temperature for use in shipping or transport of vaccine. Moreover, acceptable temperatures for shipping can be different from long-term vaccine storage temperatures found in the package insert.

If frozen gel or coolant packs are used in the freezer, they should not be used in an emergency to transport refrigerated vaccines to your alternate storage site to preserve them. If frozen water bottles are used in the freezer to provide thermal ballast, they can be conditioned and used for emergency transport of refrigerated vaccines should that become necessary, as outlined in a later section titled “Packing Vaccine for Transport.”
Temperature Monitoring Equipment
Digital Data Loggers

Every vaccine storage unit must have a temperature-monitoring device, and investing in a reliable device is less expensive than replacing vaccines wasted due to inaccurate temperature readings. The 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, DDLs provide detailed information on all temperatures recorded at a preset interval. 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). The temperature data is stored in the DDL's memory, and may be downloaded and viewed on a computer.

CDC recommends DDLs with the following characteristics:

- Detachable probe in a thermal buffered material (e.g., glycol, glass beads, sand, and Teflon)
- Alarm for out-of-range temperatures
- Low battery indicator
- Current, minimum, and maximum temperature indicator
- Accuracy within +/-0.5°C (+/-1° F)
- Logging interval (or reading rate) that can be programmed by the user (e.g., every 30 mins)

Proper placement of the temperature probe is important. 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. Place the temperature probe in close proximity to the vaccines being stored, in the middle, center of the storage compartment away from the walls, ceiling, cooling vents, door, floor, and back of the unit. There should be a primary and backup DDL for each storage unit (refrigerator and freezer). Maintain and recalibrate the DDL per the manufacturers’ instruction.

Review the recorded DDL temperature data (via software or website information) at least weekly to ensure proper temperature recording and to identify any temperature trends that may require action. Train staff to read and analyze DDL temperature data so that when temperatures go out of range they immediately take appropriate corrective actions. There have been many instances within the DoD where temperature excursions were not found by the staff until weeks later when they reviewed recorded temperature data for a potential loss event that just occurred. The previous temperature excursions were not discovered because there was no local requirement or procedure in place to review the recorded temperature data.

An accurate temperature history that reflects actual vaccine temperatures over time is critical for protecting your vaccines. 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 use for vaccine storage and 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. Due to these limitations, they should not be used to measure temperatures in a vaccine storage unit.
Electronic Monitoring System

Electronic monitoring systems are different from DDLs. Electronic monitoring systems generally consist of a network of thermometers connected to a central computer. The computer stores information from each thermometer so staff may view temperatures of multiple storage units at once, making monitoring of a large number of thermometers less burdensome. Depending on the system, the temperatures can be viewed at the storage location or monitored remotely by staff (or an alarm company). These systems sound an alarm or send a notification to alert staff to after-hour temperature excursions.

Properly installed and working alarm systems are essential for staff to respond to an emergency incident in the time frame necessary to protect the vaccines. Vaccine storage locations should have a written SOP/OI for receiving alarms and notifications, including the identification of the person(s) or positions responsible for responding to the alarm and managing the temperature excursion and follow-up.

Include the following requirements in the SOP/OI:

- The system must be programmed to call or page someone “on-call” (a designated responder and at least one back up) who can respond to the alarm within 20-60 minutes, 24 hours per day, 7 days per week.
- The system must generate a call, page or other notification that connects in person to whoever is monitoring the system. Connecting with voicemail, voice messaging, or texting is NOT acceptable.
- The alarm company must call or page the back-up call numbers until a person is contacted. Leaving a voicemail or message is not acceptable.
- Test the phone system to ensure the connection works appropriately.
- Keep the phone contact list updated and in place at all times.

Confirm that current personnel contact information exists on auto-dials, and that appropriate coverage occurs during periods of leave, holidays, and weekends. Test the entire electronic monitoring system, from the storage unit sensor to the remote monitoring station and telephone calls/alerts, at least monthly. Keep results of electronic monitoring system testing for a minimum of three years.

Monitoring and Recording Temperatures

Manually confirm and document on a temperature log, the date, time, and temperature of all storage units a minimum of TWO times per day – once at the beginning of the workday and once at the end of the workday. For storage units located in restricted access areas, ensure the temperature can be checked and recorded and that a light or audible alarm is installed to indicate when the storage unit temperature is out of range, without having to physically enter the restricted area. Instructions for who to contact if a storage unit is alarming in a restricted access area should be included in the emergency response SOP.
On the temperature log, under the day of the month, document initials, the time, ambient room temperature and place an “X” for the temperature that was observed. Documenting the ambient room temperature is important because if the storage unit should lose power or fail the only temperature to base the temperature excursion on is sometimes the room temperature. Additionally, since some diluents are to be stored at room temperature, considered to be between 20°-25°C/68°-77°F, recording the ambient room temperature will ensure they are at the proper temperature range. On the back of the log, record date/time of any storage unit temperature excursions, power outages, and/or failures. Keep temperature logs for at least three years. Local requirements may require maintaining the records for a longer period.

Conduct twice-daily manual documentation of temperatures even with an installed digital data logger and/or electronic monitoring system. Physically checking the storage unit temperatures at the end of the duty day provides staff an opportunity to confirm that the storage unit doors are closed and that the storage units are functioning properly (plugged in). It also allows the staff to reorganize vaccines that were shifted during the workday into an area of the storage unit where the temperature may not be appropriate or stable, such as against the wall, under a cold air vent, or in the door.

The DHA-IHB has received reports of temperature excursions due to unplugged storage units, tripped circuit breakers, or opened storage unit doors. Many of these temperature excursions occurred during normal duty hours but the staff did not discover them until after hours when alerted by the alarm system or the next duty day primarily because the alarm system did not alert them (e.g., not programmed correctly or backup battery failed). Incorporating an end-of-day process for physically checking the storage unit temperatures, and not relying solely on an electronic monitoring system, will help with the early detection and response to out-of-range temperatures.
Routine Vaccine Management
Inventorying Vaccine

Conduct a vaccine and diluent inventory at a minimum monthly to ensure adequate supplies are on hand to meet demand. Ensure that opened and unopened vaccine vials are located in their original packaging, since removing them can make inventory more difficult and can lead to administration errors. Place a rubber band around boxes of like lot numbers, as a simple reminder to alert staff to a change in vaccine lot number. Rotate stock so that vaccines and diluents with the soonest expiration dates are moved to the front and are used first to avoid waste due to expiration.

Check vaccine and diluent expiration dates a minimum of weekly to remove expired items from usable stock. Always check the expiration date before using a vaccine or diluent; use them before or up to the expiration date printed on the label. If the date on the label has a specific month, day and year, the vaccine can be used through the end of that day. If the expiration date on the label is a month and year, the vaccine can be used through the last day of that month.

A multi-dose vial (MDV) of vaccine that has been stored and handled properly and is normal in appearance can be used through the expiration date printed on the vial unless there is a “beyond use date” (BUD) noted in the package insert (e.g., 28 days after opening). The BUD is the date or time after which an opened MDV or reconstituted vaccine cannot be used. Promptly remove expired or mishandled vaccine and diluent from the refrigerator or freezer and dispose of them according to local policy.

Consider asking the following questions during inventory:

- Are the vaccines in their original packaging?
- Are the vaccines expired?
- Are the appropriate diluents available for the vaccine in inventory?
- Are the vaccines in the proper storage unit?
- Are the vaccines placed properly in the unit – away from the walls, coils, cooling vents, ceiling, and floor and not in shelves on the door?

Redistributing Soon-to-Expire Vaccine

If there are vaccines at your location that will expire in 3 months or less that will not likely be used prior to their expiration date, contact your DHA-IHB Immunization Healthcare Specialist (IHS), USAMMA-DOC, DLA- TSM, or pharmacy concerning the proper steps to take for redistributing the vaccines to another immunization clinic or site.

Ordering Vaccine

Determining factors for how much vaccine and diluent to order include projected demand, storage capacity, and current vaccine supply. To estimate your vaccine need, look at the average monthly or seasonal use of each vaccine and order accordingly. Avoid overstocking vaccine - this practice can lead to waste by having outdated vaccine on hand or by losing a large quantity of vaccine, should a temperature excursion occur.

When ordering vaccines, it is best to attempt to restrict ordering to the cooler months of the year. In addition, take into consideration what address is assigned to your DoD Activity Address Code/Unit Identification Code (DoDAAC/UIC). The DoDAAC is a six-position code that uniquely identifies a unit, activity, or organization that has the authority to requisition and/or receive material. If the DoDAAC/UIC address is not where you want your vaccine shipped, you need to submit your orders with the best exception ship-to addressing.

All anthrax and smallpox vaccines are ordered through a USAMMA-DOC dedicated secure website. Any order for anthrax or smallpox vaccine submitted via the Theater Enterprise-Wide Logistics System (TEWLS) or Defense
Medical Logistics Standard Support (DMLSS) will not be processed. The request for ordering anthrax and smallpox vaccine starts with a registration process. The link to register can be found at the following site www.usamma.amedd.army.mil/net/Pages/doc/vaccines.aspx.

Shipping Vaccine

Complete packing and shipping systems are designed to ensure the cold chain is not broken during transport from the DLA-TSM and USAMMA-DOC distribution sites. The insulated shipping containers (e.g., Endurotherm insulated shipping boxes) used by DLA Distribution Depots, OCONUS Prime Vendors and Medical Airbridges, CDC, and USAMMA-DOC have gone through extensive testing procedures, and utilize various packing protocols depending on the amount of material being shipped, time of year and the ambient temperature at the customer destination. When packaged correctly, these boxes can usually maintain the required temperature for a minimum of 3 days, and depending on the environment, up to 5 days. All cold chain shipments from DLA Distribution Depots, OCONUS Prime Vendors and Medical Airbridges, or USAMMA distribution sites will ship with a temperature monitor, which takes temperature readings every 15 minutes for 20 days. Cold chain shipments from DLA Domestic Prime Vendors utilize qualified insulated shipping containers that maintain the required temperature range for up to 48 hours, and temperature indicators that will trigger at any excursion outside of the required temperature range.

The security requirements for your particular location may require all commercial shipments to go to one centralized location, like a base mailroom or logistics hub. In cases like this, you need to pre-coordinate with the central location to notify you immediately when they receive a vaccine shipment. This pre-coordination is especially critical for units that are not staffed on a normal Monday-to-Friday schedule, like National Guard and Reserve units. These extra steps could be the difference between vaccine received in good condition and vaccine inadvertently mishandled or stored improperly over a weekend.

Receiving Vaccine Deliveries

The most common vaccine storage and handling mishap within the DoD is leaving vaccine out of the storage unit. Many times this was the result of not having or not following written procedures for receiving vaccine deliveries or the mistaken assumption that another team member was going to take care it. Instruct staff to immediately notify the primary or backup vaccine coordinator when a vaccine delivery arrives – this will prevent the delivery from being forgotten when things get busy. All personnel who receive vaccine deliveries should be familiar with the storage requirements outlined in the manufacturer’s package insert.

Receiving vaccine deliveries involves three main steps:

1) Verifying that the temperatures were in proper range throughout shipment,

2) Checking the contents against the packing list to confirm they match, and

3) Unpacking the vaccine and placing them in the appropriate storage unit.

The process for receiving anthrax, smallpox, and/or adenovirus vaccines is slightly different.
from other vaccines. Upon receipt of anthrax, smallpox, and/or adenovirus vaccine personnel will follow the “STOP” sign instructions found when opening the shipping container. Personnel will immediately call USAMMA-DOC, and a case manager will instruct and guide them on how to read the temperature monitor. The case manager will use the digital reading of the temperature monitor, to either immediately release the vaccine for use or suspend the vaccine until further guidance is provided. Receiving personnel are to return the temperature monitor in the return envelope included with the shipment within 24 hours of receipt of vaccine. As a reminder, do not place anthrax, smallpox, and/or adenovirus vaccine in the refrigerator while the vaccine is still inside the original-shipping container. Do not use or discard the anthrax, smallpox, or adenovirus vaccines until their integrity is verified and disposition instructions are provided by USAMMA-DOC.

For all other vaccines, begin the delivery check-in process by opening the shipping container, and locating the packet that contains the information and materials for returning the temperature monitors. DLA-TSM distributor cold chain shipments will also include an instruction sheet. Place the packet and instruction sheet aside, and continue the check-in process by locating the temperature monitor included in the shipment. Stop all temperature monitors before handling them whenever possible, because the body heat from your hand could trigger a false alarm.

Review the alarm details to verify that temperature remained in the proper range during transit to your location.

- No alarm: Shipment maintained required temperature range during transit – material is released for immediate use. Disposition is not needed, but the temperature monitor must be returned for audit purposes.
- Alarmed: Shipment experienced a temperature excursion – suspend use of the vaccine. Label as “Do Not Use,” place in an appropriate storage unit, return the temperature monitor, and await disposition instructions.
- Not started or malfunctioning temperature monitors: Treat as an alarmed shipment.

Note: the cause for alarm may not always be that the shipment got too warm (above 8°C/46°F), it could be that it got too cold (below 2°C/36°F), which is actually a greater concern.

If there is no issue with the shipment temperature, as soon as possible after receipt, unpack the vaccines from the shipping container, inventory the contents against the packing list to confirm they match, and place the vaccine in the appropriate storage unit.
If a shipment is alarmed, do not assume the vaccine is ruined. Label the vaccine as “Do Not Use” and place in the appropriate storage unit. Report the alarmed temperature monitor to DLA-TSM. Do not use or discard the vaccine until its integrity is verified and disposition instructions are provided by DLA-TSM.

DLA-TSM will provide guidance for returning the alarmed temperature monitors. When returning temperature monitors to DLA-TSM, make sure to include the instruction sheet, with all of the information at the bottom filled out. The submitting location should retain a copy of the instruction sheet and FedEx Airway bill for tracking purposes. Use the pre-paid/pre-addressed FedEx materials provided with the shipping container to return the temperature monitors. Other shipping methods (e.g., USPS, US Navy Fleet Mail Shipping Offices, etc.) can take up to 2 months to arrive.

DLA-TSM will coordinate the time and temperature information from the temperature monitor with the vaccine manufacturers, taking into account the product’s stability allowance, to determine if the product is still acceptable for use. Once disposition is determined on alarmed shipments, DLA-TSM will email the customer to notify them if the product is acceptable for use to its full expiration dating or if the product’s shelf life has been shortened they will provide a new expiration date. If the vaccine is determined to be compromised and must be discarded, DLA-TSM will do a subsequent analysis to determine the point of failure in the supply chain that caused the damage.

If the cause of the loss is attributable to DLA-TSM or one of their agents (e.g., vaccine manufacturer, FedEx, etc.), then the DLA-TSM cold chain management team will arrange for the original shipment to be credited to the activity’s account. They will either schedule a reshipment of the vaccine at the soonest opportunity, or coordinate with the customer on the reorder process (depending on the source of supply). If the cause of the loss is attributable to the customer (e.g., receiving error), the customer will need to coordinate for a new shipment of vaccine.

Return ALL temperature monitors to DLA-TSM regardless of their alarm status, as soon as possible after receipt, per the instructions included in each vaccine shipment. Because both the Food & Drug Administration (FDA) and the vaccine manufacturers can audit them at any time, they are required to maintain an electronic record of all shipments.
Proper Vaccine and Diluent Storage
Placing Vaccine in Storage Unit

Place vaccines in the center of the storage unit compartment, 2 to 3 inches away from the walls, ceiling, floor, and door. Do not place vaccine in the storage unit door since this practice may expose vaccine to inappropriate temperatures throughout the day when opening and closing the door.

Since the freezing of refrigerated vaccines affects vaccine potency more than other exposure problems, it is especially important to arrange vaccine in the refrigerator in a way that eliminates the chance of inadvertently freezing it. Do not place vaccines in vegetable, deli, or fruit crisper drawers or on the top shelf of the refrigerator if the cooling vent from the freezer opens there – there is a real risk of freezing vaccine near these vents.

To help avoid confusion between vaccines, stack them in rows of like product within the storage unit, or use trays, uncovered containers, or perforated bins to organize the vaccine. Do not pack vaccine stacks or containers tightly together – allow for space between them. This will ensure adequate air circulation and even cooling around and through the vaccine, thus helping to maintain consistent temperatures.

Keep vaccines in their original packaging with the lids on until ready for administration. Do not store loose vials or manufacturer-filled syringes outside of their packaging. This practice makes it more difficult to track expiration dates and manage inventory, increases the risk of administration errors, and exposes vaccine to light (check package insert for vaccine light sensitivity information).

If other biologic specimens must be stored in the same unit as vaccines, specimens should be stored on a lower shelf than the vaccines. This is to ensure that the vaccine will not become contaminated if a specimen leaks. Food and beverages should not be stored in a vaccine storage unit because frequent opening of the unit door can lead to temperature instability.

Labeling of Vaccine in Storage Unit

A disorganized storage unit that does not allow for the easy identification of vaccine may lead to administration errors or can expose the vaccine to repeat temperature excursions as staff try to locate and choose the correct product with the door open.

Strategies to help prevent administration errors and facilitate the quick retrieval of vaccine include:

- Label the tray, slotted container, perforated bin, or shelf where the vaccine is stored to help staff quickly locate and choose the correct product,
- Color code the labels (e.g., one color for pediatric and one for adult vaccines),
- Organize the vaccine within the storage unit by age (e.g., top shelves for pediatric-only vaccines, middle shelves for pediatric-adolescent-adult vaccines and the bottom shelves for adult-only vaccines),
- Prevent the storage of vaccines that sound or look alike next to each other, like DTaP and Tdap, and
- Include additional information such as age indications, gender or other information unique to the vaccine on the label.

Storing Diluent

Some diluents must be refrigerated and others may be stored in the refrigerator or at room temperature (no warmer than 25°C/77°F). Always follow the manufacturer’s guidance in the package insert. Some diluents may contain vaccine antigen and can only be used with their corresponding vaccine, so they should be stored next to each other whenever possible. Label the tray, slotted container, perforated bin, or shelf where the diluent is stored (whether at room temperature or in the refrigerator) to help staff choose the correct diluent when reconstituting a vaccine. Never store diluents in the freezer.
Proper Handling of Vaccine and Diluent
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.

- Vaccine 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 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 Vial

A single-dose vial (SDV) contains one dose of vaccine and should be used one time for one patient. SDVs do not contain a preservative to help prevent the growth of bacteria. Do not open an SDV until ready to use. Once you remove the protective cap, administer the vaccine as soon as possible, because it may not be possible to determine if the rubber seal was punctured and the vaccine contaminated. Discard all SDVs without their protective caps at the end of the duty day.

Multi-Dose Vial

A multi-dose vial (MDV) contains more than one dose of vaccine and can be entered or punctured more than once, because it contains a preservative to help prevent the growth of bacteria. Always use aseptic technique when withdrawing vaccine from an MDV. 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 vaccine in the vial and the expiration date has not been reached. Never use partial doses from two or more vials to create a dose of vaccine.

Mark the MDV with date, time, and initials when the first dose is withdrawn and with a revised “beyond use date” if required and always return the unused vaccine to the storage unit immediately after drawing up a dose. 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 (some MDVs of influenza must be discarded within 28 days once the stopper of the vial has been pierced).
For some vaccines, the expiration rule may be different from the normal 28-day rule for medications. Per a published FAQ post on the Joint Commission website, it states, “Currently, vaccines are exempted from the [28-day rule for medications] requirement. The CDC Immunization Program states that vaccines are to be discarded per the manufacturer's expiration date. The Joint Commission is applying this approach to all vaccines (whether a part of the CDC or state immunization program or purchased by healthcare facilities) with the understanding that the vaccines are stored and handled appropriately (correct temperature is maintained, frequency of temperature checks, etc.).” Always follow the guidance listed in the manufacturer’s package insert to assure the integrity of the vaccine.

Manufacturer-Filled Syringe

A manufacturer-filled syringe (MFS), also known as a pre-filled syringe, is prepared and sealed under sterile conditions by the manufacturer. Do not activate an MFS (e.g., remove the syringe tip cap or attach the needle) until ready to use. MFSs do not contain a preservative to help prevent the growth of bacteria, so once the sterile seal has been broken, use the vaccine or discard it at the end of the duty day. As long as MFSs are stored under appropriate conditions, temperature and light, use them until the date of expiration printed on the syringe.

Reconstituted Vaccine

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 they can be administered. Diluents are not interchangeable. They vary in volume and composition, and are specifically designed to meet volume and chemical requirements of their corresponding vaccine. Additionally, some diluent contain a second part of the vaccine (e.g., DTaP-IPV).

Therefore, use only the specific diluent provided by the manufacturer for each type of vaccine to preserve the potency and safety of the resulting mixture. Never use a stock vial of sterile water or normal saline to reconstitute vaccines. Always check expiration dates on both diluents and vaccines before reconstituting them. Smallpox diluent should be stored at room temperature. If smallpox diluent is inadvertently stored in the refrigerator, make sure to bring it to room temperature, prior to reconstitution. Otherwise, the lyophilized powder will not mix properly. USAMMA-DOC can ship extra smallpox diluent if necessary.

Consult the manufacturers’ package insert for the “beyond use date” (BUD) for reconstituted vaccines since it varies from product to product. For example, once a vial of MMR is reconstituted, use it immediately or keep the reconstituted vial in the refrigerator and use within 8 hours. Do not predraw reconstituted vaccine into a syringe until you are ready to administer it. A manufacturer may specify that an unused reconstituted vaccine can only be stored in the vial for the indicated time. If not used within 30 minutes of being reconstituted, follow manufacturer guidance for storage conditions and time limits. Mark reconstituted MDVs (e.g., smallpox vaccine) with the date, time, and initials when first reconstituted and with a revised "beyond use date", and store at appropriate temperatures when not in use. Promptly remove from the storage unit any reconstituted vaccines that are beyond their revised use date.
Vaccine Transport during Off-Site Events and Emergencies
Proper Transport of Vaccine

The CDC recommends all locations that store or administer vaccine have an SOP/OI for transporting vaccines to off-site locations and/or during an emergency. “Transport” has a different meaning than “shipping,” which usually involves a professional carrier and a longer distance and time for moving vaccines between locations. Transport involves the movement of vaccine over a short time frame and short distance between locations. Transport time should be less than 8 hours and a temperature-stable storage unit should be used. Transport vaccine only when necessary, such as for a mass immunization clinic or in an emergency to save vaccine. Due to their temperature requirements, frozen varicella-containing vaccines should never be transported except in an emergency.

Validated Transport Containers

Portable vaccine refrigerators are recommended when vaccines must be transported. The portable vaccine refrigerator/freezer unit used within the DoD is the AX27L (also known as the VaxiCool). If such a unit is not available, the vaccine should be stored in a validated and approved mobile transport container capable of maintaining the required storage temperatures of 2°-8°C/36°-46°F.

Examples of validated and approved mobile transport containers used within the DoD include:

- PX1L (also known as VaxiPac) or PX6L, and/or
- Hard-sided or Styrofoam™ insulated cooler with at least 2-inch thick walls.

Make sure to use only the phase-change coolant bricks (PXC) with the PX1L or the PCM coolant belts with the PX6L. No other refrigerated or frozen coolant material should be used with these mobile transport containers. During an emergency, Endurotherm insulated shipping boxes can also be used to pack and transport vaccine to your alternate storage location. Thin-walled Styrofoam™ coolers, such as those purchased at a grocery store to hold beverages, are not acceptable.

Note: Vaccine manufacturers do not support reuse of their containers and packing materials for vaccine transport.

Packing Vaccine for Transport

Always use a validated and approved transport container. The contents of the vaccine transport container should be packed in layers. Consult the manufacturer’s instructions for the proper packing protocol for the product you are using. Document the storage unit temperature at the time the vaccine is removed for packing and again during transport.

Vaccine packing reminders for Endurotherm insulated shipping boxes, and/or hard-sided or Styrofoam™ coolers with at least 2-inch thick walls:

- Always include calibrated temperature-monitoring device to track temperatures during transport and storage.
- Record temperatures a minimum of every hour when vaccine is outside of a functioning storage unit.
- Always document on the outside of the transport container the vaccine type, date, time, originating facility, phone number and that the contents are temperature-sensitive.
- Always use an insulating barrier (e.g., bubble wrap, corrugated cardboard, packing foam, etc.) between coolant material and the vaccines.
- NEVER pack refrigerated vaccine with frozen coolant packs.
- Do NOT reuse coolant packs from original vaccine shipping container.
Note: Placing an insulating barrier between the coolant material and vaccines is important because it keeps refrigerated vaccines at the right temperature and prevents them from freezing.

In general, pack the Endurotherm insulated shipping boxes, and/or hard-sided or Styrofoam™ coolers with at least 2-inch thick walls as follows:

- Refrigerated coolant material or conditioned frozen water bottles on bottom of container,
- Sheet of corrugated cardboard (on top layer of coolant materials/conditioned frozen water bottles),
- Insulating material (1 inch layer of bubble wrap, corrugated cardboard, packing foam, etc.),
- Vaccine and temperature monitor (place temperature probe near vaccine and not in direct contact with refrigerated coolant materials/conditioned frozen water bottles),
- Another layer of insulating material (1 inch layer of bubble wrap, corrugated cardboard, packing foam, etc.),
- Second sheet of corrugated cardboard (to support top layer of refrigerated coolant materials/conditioned frozen water bottles),
- Additional refrigerated coolant material/conditioned frozen water bottles.
- This packing protocol can maintain appropriate temperatures for up to 8 hours, but the container should not be repeatedly opened and closed.

To condition frozen water bottles:

- Put frozen water bottles in sink filled with several inches of cool or lukewarm water or under running tap water until you see a layer of water forming near surface of bottle.
- The bottle is properly conditioned if ice block inside spins freely when rotated in your hand.
- If ice “sticks,” put bottle back in water for another minute.
- Dry each bottle.
- Line the bottom and top of cooler with a single layer of conditioned water bottles.

Find additional packing guidance on the USAMMA-DOC web site and emergency transport guidance on the CDC storage and handling web site. When using the PX1L, PX6L, and/or the AX27L follow the manufacturer’s guidance for proper packing procedures. Remember that your IHS, USAMMA-DOC, and DLA-TSM are always available to answer questions concerning proper vaccine packing and transport procedures. IHS contact information and areas of responsibility can found at www.health.mil/ContactYourIHS.
Off-Site Immunization Events
Off-Site Immunization Procedures

The CDC recommends that vaccine be stored inside a properly functioning storage unit (such as a self-contained, stand-alone refrigerator) at the required temperature range during an off-site immunization event. If vaccines cannot be stored in an on-site storage unit, they should be kept in a portable vaccine refrigerator unit, such as the AX27L (formerly VaxiCool), during an off-site event. If a portable vaccine refrigerator unit is not available, use one of the validated transport containers discussed earlier.

It is important to have an SOP/OI that details the proper storage and handling procedures to protect vaccines during off-site immunization events. Include the following requirements in the SOP/OI:

- Identify and assign duties to an off-site vaccine coordinator.
- Pack only the amount of vaccine that is expected to be used (over packing can lead to waste).
- Fill out an issue receipt with the amount and type of vaccine taken. The issue receipt should include a statement in which the off-site vaccine coordinator acknowledges that they must keep the vaccine at the required temperatures.
- Transport the vaccine and diluent in their original packaging inside a validated transport container.
- Document the storage unit temperature when the vaccine is removed for transport and at the final destination to identify any temperature deviations.
- Transport the vaccine directly to the off-site location, and take care to maintain the cold chain at all times.
- When transporting vaccines to an off-site location in a personal or government vehicle, do not place the vaccine in the trunk; the temperature inside the trunk cannot be regulated and could become too hot or too cold for the vaccine.
- Set up separate administration stations for adults and pediatrics and administer only one vaccine type at each station to avoid administration errors.
- Check and document the temperatures within the vaccine transport container a minimum of every hour while vaccine is outside a functioning storage unit.
- Limit the number of times the storage container is opened during the immunization session to minimize temperature changes.
- The total time for transport to and from the off-site and the immunization event should be no longer than 8 hours.
- Document the amount and type of vaccine returned at the conclusion of the event and sign the issue receipt stating that the required temperatures were maintained.
**Predrawing Vaccine**

Vaccine manufacturers do not recommend predrawing vaccines in advance of large immunization events because no data exist on the stability of vaccines stored in general-use syringes that have been filled by end-users. General-use syringes are designed for immediate administration—not for storage. Contamination and growth of bacteria 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.

The CDC recommends using manufacturer-filled syringes for large immunization events or drawing up vaccines only at the time of administration. A manufacturer-filled syringe is labeled with the vaccine name, lot number and expiration date and is designed for both storage and administration, reducing the chance of a medication error. Predrawing can lead to wasted product if more is drawn up than is needed and once vaccines are inside syringes, it is difficult to tell them apart, which can lead to administration errors.

If vaccine must be predrawn (e.g., during a flu drive, deployment line):

- Do not draw up vaccines before arriving at the immunization event – drawing up doses days or even hours before is not acceptable.
- Each person administering vaccines should draw up no more than 1 MDV, or 10 doses, at one time.
- Monitor patient flow to avoid drawing up unnecessary doses.
- Discard any vaccine in predrawn syringes remaining at the end of the duty day and report as a loss.
Storage and Handling Emergencies
Preparing for Storage Emergencies

When the vaccine coordinator believes that an extended power outage may occur, due to planned electrical work or approaching storm, they should take the necessary steps (in advance of the event) to activate their emergency vaccine response and retrieval SOP/OI. Never leave vaccine in a nonfunctioning storage unit. Review with all staff the emergency vaccine response and retrieval SOP/OI and verify alarm response procedures are current.

Storage Locations WITHOUT Emergency Backup Power

- If possible, decrease immunization operations in order to have plenty of time to pack and move product.
- Determine a packing priority list for vaccine in case all vaccine cannot be moved.
- Keep a detailed itemized list along with contact information affixed to outside of the transport container for easy identification.
- Label transport container as “temperature-sensitive" and "Refrigerated" or "Frozen" product.
- Pack and move all vaccine that is not stored in a location supported by back-up power to your designated alternate storage location (e.g., logistics, pharmacy, alternate clinics).
- Document the storage unit temperature when the vaccine is removed for transport and at the final destination to identify any temperature deviations.
- During transport, maintain temperatures for refrigerated vaccines between 2°C - 8°C/36°F - 46°F and frozen vaccines at -15°C/5°F or less.
- Verify that vaccines are placed in the appropriate storage unit, refrigerator vs. freezer, at the alternate storage location.

Storage Locations with Emergency Backup Power

- Ensure ALL storage units are clearly labeled as either a refrigerator or freezer.
- VERIFY that all equipment is functioning properly:
  - Plug storage units and electronic monitoring system into the designated emergency power (normally the red outlets).
  - If your site uses a generator for backup power, make sure it is properly connected and there is sufficient fuel on hand to continuously run the generator for at least 72 hours.
  - If electronic monitoring system has a battery backup, ensure it is charged or has new batteries.
- Program the appropriate designated staff contact information into the automated call system.
- TEST the electronic monitoring system before departing.
- Prepare and have available equipment and supplies for transporting vaccine in the event that backup power fails.
  - Validated transport containers (e.g., Endurotherm insulated shipping boxes, Hard-sided or StyrofoamTM coolers with at least 2 inch thick walls, PX1L, PX6L, and/or AX27L)
  - Refrigerated and/or frozen coolant material or conditioned frozen water bottles.
  - Insulating barrier (e.g., bubble wrap, corrugated cardboard, packing foam, etc.).
• A calibrated temperature-monitoring device for each transport container.

• Verify PX1L (also known as VaxiPac) phase-change bricks (PX/C/VaxiSafe) are fully chilled according to manufacturer instructions and that there are four (4) bricks per PX1L.

• Verify PX6L PCM coolant belts (blue-frozen, white-refrigerated) are fully conditioned according to manufacturer instructions.

• NOTE: Do not use any other cooling item (frozen or refrigerated packs) with the PX1L or PX6L.

• Verify AX27L (also known as the VaxiCool) is fully charged and plugged into emergency power.

• All vaccine storage locations in low-lying areas or in lower levels of the facility that are prone to flooding should move vaccine to a higher-level location.

• Call electronic monitoring system more frequently during the power outage, if possible.

### Potentially Compromised Vaccine Reporting Process

Vaccine experiencing out of range storage temperatures or inappropriate conditions require immediate action. Any temperature reading outside the range recommended in the manufacturer package insert is considered an excursion.

If vaccine is suspected to have been outside the recommended temperature range, the vaccine coordinator, supervisor, or if necessary, the person who discovered the problem should begin to document the event. Record the time and temperature of the storage unit when the power goes out, when the power is restored, and when the thermometer reading is back within the recommended range.

Instructions for reporting a potential vaccine compromise can be found at www.health.mil/coldchain.

• Do not leave vaccine(s) in a nonfunctioning storage unit. Immediately move the vaccine to a working storage unit at proper temperature.

• Label potentially compromised vaccine as “DO NOT USE,” and place them in a separate container apart from other products in the storage unit.

• Do not destroy, discard or use the vaccine until released by USAMMA-DOC and/or DLA-TSM.

• Document the circumstances surrounding the event using the Potentially Compromised-Temperature Sensitive Medical Products (PC-TSMP) Worksheet. The most current version of the worksheet can be found at www.health.mil/coldchain.

• Record room temperature, date/time and temperature prior to event when vaccines were at required temperature.

• Record date/time and temperature post-event when vaccines were back at required temperatures.

• Document the current, high and low temperatures of the refrigerator and/or freezer.

• Document the length of time vaccine was outside the recommended temperature range.

• Describe the situation surrounding the potential loss event.

• Inventory all the vaccine and document vaccines affected, lot numbers, expiration dates and number of doses (include whether MDVs were opened).

• Contact your DHA-IHB Immunization Healthcare Specialist (IHS) for assistance in completing the worksheet. IHS contact information and areas of responsibility can found at www.health.mil/ContactYourIHS.

• Submit the PC-TSMP Worksheet along with copies of your temperature logs through your local leadership, to your IHS.
Stand-by and await vaccine disposition. NEVER discard vaccine until it has been confirmed as a loss by USAMMA-DOC and/or DLA-TSM.

In general, USAMMA-DOC and DLA-TSM use vaccine stability information provided by the manufacturers to analyze the extent 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 viable. Once disposition is provided, either place the vaccine back into inventory or destroy the vaccine per local policy/guidelines.

**Vaccine Loss Types and Contributing Factors**

Vaccine loss types are categorized as non-preventable loss, personnel error or process failure and are further defined by the contributing factors associated with the loss type.

### Non-Preventable Loss

- Power outage – unavoidable and unanticipated causes
- Power outage – unavoidable and unanticipated; no backup power available and/or no alarm installed
- Refrigerator/freezer failure – unavoidable or unanticipated
- Temperature or alarm system sensor failure
- Contracted alert/alarm company did not notify site when storage unit temperature was out of range
- Moved vaccine to alternate site due to anticipated inclement weather/power outage, and alternate site lost power

### Personnel Error

- Alarm system not programmed correctly, not activated and/or battery not charged
- Vaccine(s) left out of refrigerator or freezer
- Frozen vaccine(s) that are supposed to be refrigerated
- Refrigerated vaccine(s) that are supposed to be frozen
- Refrigerator or freezer door left open or ajar, resulting in temperatures outside acceptable range
- Refrigerator or freezer unplugged or electrical service interrupted (tripped circuit breaker or power strip)
- Storage unit not plugged into backup power, mobile storage unit battery not charged, or generator failed (not tested)
- Maintained refrigerator at a temperature that is too cold
- Maintained refrigerator or freezer at a temperature that is too warm

### Process Failure

- Vaccine receiving error (clinic/site closed, staff not available, etc.)
- Transported vaccine inappropriately (no coolant packs, barrier, or thermometer); cold chain not maintained
- Alarm system sounded; emergency response plan not followed or out of date
- Failed to take immediate corrective actions when temperatures out of appropriate range
- No written storage and handling emergency response plan/process in place
- No validated packing/transport equipment/supplies available
- Required manual temperature checks not performed and documented daily
- Staff not trained on proper vaccine storage and handling requirements
- Vaccine stored in dorm style refrigerators or improper refrigeration unit to store the vaccine
- Discarded vaccine doses drawn and/or prepared and not used by the end of the workday
Proper Disposal of Vaccine and Diluent
Proper Disposal of Vaccine and Diluent

Federal and State/Local Regulations

DoD activities are responsible for disposal and/or destruction of regulated medical waste (RMW) based on federal regulation. State or local regulations may be more stringent. RMW is generated in the diagnosis, treatment, research, or immunization of human beings or animals and is capable of causing disease or, if not handled properly, posing a risk to individuals or a community. It is critically important that staff members understand which vaccines are hazardous and require their own labeled disposal container.

- RMW is grouped by waste source.
  - Group 1: Cultures, Stocks, and Vaccines include all discarded human and animal vaccines.
  - Dispose of empty, partially full, unopened (expired or compromised) vials and unused doses of vaccine according to accepted methods for RMW.

- RMW can be classified as “non-hazardous waste” or “hazardous waste.” Several vaccines produced as MDVs are considered hazardous waste because they contain thimerosal, a mercury derivative, added as a preservative.

RMW is also called “medical waste,” “infectious waste,” “biomedical waste,” and “biohazardous waste.” Terms will vary based on locality and host nations, states, or local laws. Make sure to become familiar with disposal and/or destruction terms and policies based on your specific location.

Pharmaceutical Reverse Distributor Program

Whenever possible, unused single-dose vials, multi-dose vials, and manufacturer-filled syringes of vaccine and diluent (expired and/or compromised) may be returnable for credit by using a pharmaceutical reverse distributor program (e.g., Pharma-Logistics). Using this program provides a safe option for managing unused or expired vaccines while maintaining full compliance with regulating agencies. Contact your site’s pharmacy or logistics office for guidance on the use of this program.
When to Return or Discard Vaccine and Diluent

- Unopened manufacturer-filled syringes, vials or diluents that have passed the expiration date printed on the label by the manufacturer should be returned or discarded.
- Any vaccines drawn up and not administered by the end of the workday should be discarded.
- Once a lyophilized vaccine has been reconstituted, its shelf life is limited and varies by product (consult the manufacturer’s package inserts).
- When MDVs are opened (document date/time/initials and new expiration date on vial) the vaccine can be used until the expiration date or the BUD specified in the manufacturer’s package insert, whichever comes first (e.g., some MDV of influenza vaccine must be discarded 28 days after opening, even if the expiration date printed on the vial by the manufacturer has not passed).
- Any vaccine known or suspected to be contaminated.

Methods of Disposal

Hazardous pharmaceutical waste containers (e.g., black sharps container):

- All full or partially used MDVs of vaccine and syringes containing vaccine drawn from an MDV that contains thimerosal,
- MDVs of influenza vaccine that are not completely used, and
- Unused influenza vaccine drawn into a syringe from a MDV.

Biohazard waste containers (red biohazard sharps container or red puncture resistant bag):

- Any empty vaccine and diluents vials,
- Unused vaccine and diluents vials not listed for black container,
- Used needles and syringes,
- Syringes with doses drawn but not administered (except for those listed above for black container),
- Nasal mist vaccine dispensers, and
- The smallpox vaccine vial, its stopper, the diluent syringe, the vented needle used for reconstitution, the bifurcated needle used for administration, and any gauze or cotton that came in contact with the vaccine.
Summary

- Designate a primary and back-up vaccine coordinator within clinics
- Develop detailed, up-to-date, written policies for general vaccine management (e.g., inventory management, delivery, return from off-sites), and emergency response and retrieval
- Place large signs identifying the Refrigerator and Freezer on storage units
- Set low and high refrigerator alarm activation at 2°C/36°F (low) and 8°C/46°F (high)
- All staff members who receive deliveries and/or pack vaccines for transport should be familiar with the storage requirements outlined in the package insert
- Immediately unpack, check the contents against the packing list to confirm they match and account for all the listed vaccine and then place in appropriate storage unit
- Include certified calibrated thermometers as close as possible to vaccine, for continuous temperature monitoring and recording, in all storage units and during transport and at off-site events
- Check unit doors throughout the day and always confirm at the end of the day that all storage unit doors are closed
- To prevent tripping the circuit breaker or switching power off, plug storage unit directly into electrical outlet, do not use multi-outlet power strips/surge protectors
- Confirm that current personnel contact information exists on auto-dialers, and that appropriate coverage occurs during periods of leave, holidays, and weekends
- Test alarm system at least monthly to ensure it is programmed correctly and working
- Sites with continuous temperature monitoring systems – should review recorded data daily
- Do not leave vaccines in a non-functioning unit for an extended period; make preparations in advance to retrieve and/or protect vaccines
- Ensure all staff know the steps to take to respond to a potential vaccine compromise event
- Pack validated insulated containers to maintain the proper temperature during transport or shipment, exposing vaccines to freezing temperatures (even for a short time) can damage them
- If you must transport vaccines in non-commercial vehicles, use the passenger compartment—not the trunk
- Become familiar with the proper vaccine disposal guidelines for your location
- Store M-M-R in freezer verses refrigerator whenever possible
- Bookmark the Defense Health Agency -Immunization Healthcare Branch Storage and Handling website at www.health.mil/coldchain
This page left intentionally blank.
To contact the Immunization Healthcare Branch:
(877) GET-VACC or (877) 438-8222

DoDvaccines@mail.mil