

Vaccine Storage and Handling Guide

Defense Health Agency
Immunization Healthcare Division

May 2022

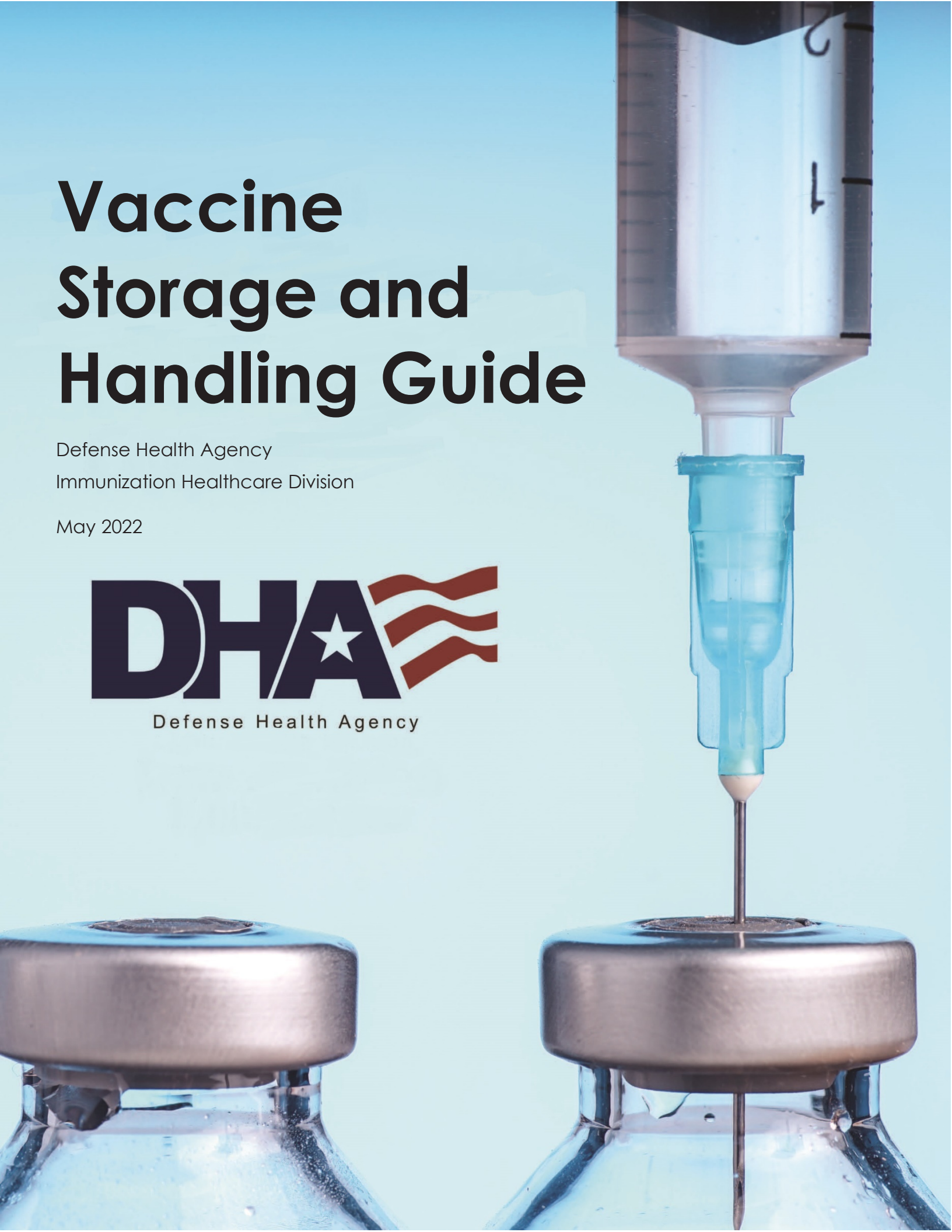


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Introduction

The Department of Defense (DOD) has a robust, worldwide immunization program that supports 9.6 million beneficiaries. Immunizations are delivered in traditional medical settings, such as clinics and patient-centered medical homes, as well as non-traditional operational environments, like ships afloat, forward deployed locations, and during humanitarian missions. Regardless of where vaccines are administered, all healthcare personnel (HCP) must adhere to the same stringent storage and handling guidelines.

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 wherever our entire DOD family needs them.

The Defense Health Agency-Immunization Healthcare Division (IHD), in partnership with the Defense Logistics Agency-Troop Support Medical (DLA-TSM) and United States Army Medical Materiel Agency-Distribution Operations Center (USAMMA-DOC), provide expert guidance and support to the DOD immunization community on proper distribution, storage and handling of vaccines. They developed a process for reporting vaccine compromise incidents and receiving disposition on the affected products.

The Potentially Compromised-Temperature Sensitive Medical Products (PC-TSMP) worksheet (DHA Form 177) is a tool the DHA-IHD developed to report vaccine compromise incidents. 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 use of the PC-TSMP worksheet has standardized the disposition process, resulting in more timely, accurate, and efficient reporting of potential vaccine loss events and a reduction in the destruction of viable vaccine.

Analysis of data collected over the past seven 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.

The loss events are categorized as non-preventable, personnel error, and/or process failure, and are further broken down by contributing factors.

The most frequently identified contributing factor associated with a loss of vaccine is "vaccine left out of the storage unit," at 22%, followed by "vaccine placed in the wrong storage unit" at 12%. These failures are often the result of not having or not following written routine storage and handling plans for receiving a vaccine delivery, returning vaccines once an off-site immunization event has ended or transporting vaccine during an emergency.

It is important for staff members handling vaccines to never leave deliveries unattended after arrival. Always unpack, check the contents against the packing list to confirm they match and account for all the listed vaccines, and immediately place the vaccines into the appropriate storage unit. Additionally, check the storage requirements for vaccines that are stocked in your area to ensure they are being placed in the correct storage unit.

The purpose of this storage and handling guide 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 and DHA-AI 4140.01, Medical Logistics Temperature Sensitive Medical Products Management. If there is a difference between what is written in this guide and official DHA policy, follow the more stringent guidance.





Vaccine Cold Chain Management

Cold Chain Management (CCM)

The cold chain is a temperature-controlled environment used to maintain and distribute temperature-sensitive medical products (TSMP), like vaccines, in optimal condition. The cold chain begins at the manufacturer, continues through shipment to medical logistics, then to the vaccination site, and ends at administration of the vaccine to the patient.

Failure to adhere to required specifications for shipping, storing, and handling vaccines as outlined in the manufacturers' package insert found at: <https://www.health.mil/packageinserts>, may reduce the vaccine's potency resulting in inadequate protection against disease. A single shipment of vaccine can immunize thousands of patients, but could become compromised if that shipment is exposed to temperature fluctuations or light.

Some vaccines lose potency when exposed to room temperature for as few as 30 minutes; while almost all refrigerated vaccines are damaged by freezing temperatures. Many vaccines are particularly vulnerable to exposure to light. Refer to the "Light Sensitive Vaccines" document on the IHD Vaccine Storage and Handling website for a list of light sensitive vaccines. 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 immunization may be considered invalid and need to be repeated, resulting in diminished patient confidence in vaccines and the Military Health System.

Three essential elements of an effective CCM program include:

- 1) A well-trained and competent staff,
- 2) Reliable storage and temperature monitoring equipment, and
- 3) Accurate vaccine inventory management.

CCM Program Oversight

DOD activities will designate a primary and backup vaccine coordinator in writing, with the overall responsibility for monitoring the vaccine CCM program for their activity. They must be experts in routine and emergency vaccine management, ensuring policies are in place and procedures



followed to safeguard vaccines. The backup vaccine coordinator will ensure 100% coverage during periods when the primary vaccine coordinator is unavailable.

Vaccine coordinator responsibilities will be written down as part of the activity's standard operating procedures (SOP) and will include:

- Ordering vaccines and documenting vaccine inventory,
- Overseeing proper receipt and storage of vaccine deliveries,
- Organizing vaccines within the storage unit,
- Setting up temperature monitoring devices,
- Checking and recording temperatures at the start and end of each workday,
- Reviewing and analyzing temperature data at least weekly for any shifts in temperature trends,
- Responding to temperature excursions,
- Rotating stock at least weekly so vaccines with earliest expiration dates are used first,
- Removing expired and compromised vaccine from storage units,
- Disposing of expired and compromised waste (see section on proper disposal of vaccines) and reporting of vaccine waste IAW with policy (e.g., AVA, SVP, Influenza, COVID-19, etc.),
- Maintaining all documentation, such as inventory and temperature logs,
- Organizing vaccine-related training and ensuring staff completion of training,
- Monitoring operation of vaccine storage equipment and systems,
- Overseeing proper vaccine transport and emergency preparations.

Vaccine coordinator responsibilities will be completed by the coordinator or delegated to appropriately trained staff.

CCM Training

All staff that store, handle, receive, and deliver vaccines, including temporary staff, must be properly trained on the manufacturer's storage requirements outlined in the package insert and familiar with the appropriate steps to take to safeguard vaccine during an emergency. DOD activities will establish a formal CCM orientation and competency skills training program for newly assigned personnel that includes all routine and emergency vaccine storage and handling procedures for their location.

All assigned staff, including anyone who delivers or receives shipments or has access to areas where vaccines are stored, will complete annual and "just in time" cold chain management training:

- 1) As part of new staff orientation,
- 2) Annually as refresher for all staff involved in vaccine storage and handling activities,
- 3) Whenever new vaccines are added to inventory, and
- 4) Whenever recommendations for storage and handling of vaccines are updated.

The best practice and most comprehensive training resource for Vaccine Storage and Handling is CDC's "You Call the Shots," which is available on the web at

<https://www.cdc.gov/vaccines/ed/youcalltheshots.html>.

The vaccine coordinator will maintain any documentation for orientation and competency skills training, along with annual CCM training certificates in the staff member's training folder/record for 3 years.





Standard Operating Procedures

Routine Management of Vaccine

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

At a minimum, the routine management of vaccine SOP 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 administration and handling procedures,
- Procedures for ordering and inventorying vaccine, and for receiving vaccine shipments,
- Process for reporting excess or soon to expire vaccine,
- Procedures for setting up, testing, and maintaining the continuous temperature alarm system with current contact information,
- Process for checking back-up or battery power,
- 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.

Emergency Response and Retrieval of Vaccine

Emergencies like equipment failures, power outages, severe weather conditions, or natural disasters usually happen without warning and may compromise vaccine storage conditions. It is

important to have an Emergency Response and Retrieval of Vaccine SOP that prepares staff to respond to emergencies. Refer to the "Emergency Vaccine Retrieval and Storage Plan" worksheet available on the IHD Storage and Handling website.

The Emergency Response and Retrieval of Vaccine SOP will be developed in advance of emergencies and include information on:

- Immediate corrective actions required to minimize vaccine loss,
- Proper completion and submission of the PC-TSMP worksheet (DHA Form 177),
- Proper vaccine packaging protocols,
- Procedures for transporting and storing vaccine during an emergency,
- Instructions for entering the vaccine storage space after hours,
- Instructions for who to contact if a storage unit is alarming in a restricted access area,
- Identification of alternate storage locations to serve as temporary storage while equipment is fixed or electricity is restored.

Note: Storage locations that are entered using a key-card may not work when the power is out, so ensure there is another way to enter the storage location.

Once you identify the alternate storage location (e.g., medical logistics, pharmacy, laboratory, and/or other DOD installations) and develop a negotiated agreement, physically visit the site to ensure they have backup power, clearly labeled storage units (e.g., refrigerator or freezer), and appropriate temperature monitoring equipment.

The emergency response SOP will also include the requirements for receiving and responding to electronic monitoring system (EMS) alarm notifications after hours, including:

- Identification of the person(s) and/or positions responsible for responding to the EMS alarm and managing the temperature excursion and follow-up,
- Ensuring the system is programmed to call or page someone "on-call" (a designated responder and at least one backup) who can respond to the alarm within 20-60

minutes, 24 hours per day, 7 days per week,

- The system is setup to generate a call, page, or other notification that connects in person to whoever is monitoring the system,
- The system is setup to continue to call or page the on-call person until a person is contacted. Connecting with voice-mail, voice messaging, or texting is NOT acceptable,
- Requirement to test the phone system regularly to ensure the connection works appropriately, and
- Duty position responsible for ensuring current contact information is programmed into the EMS.

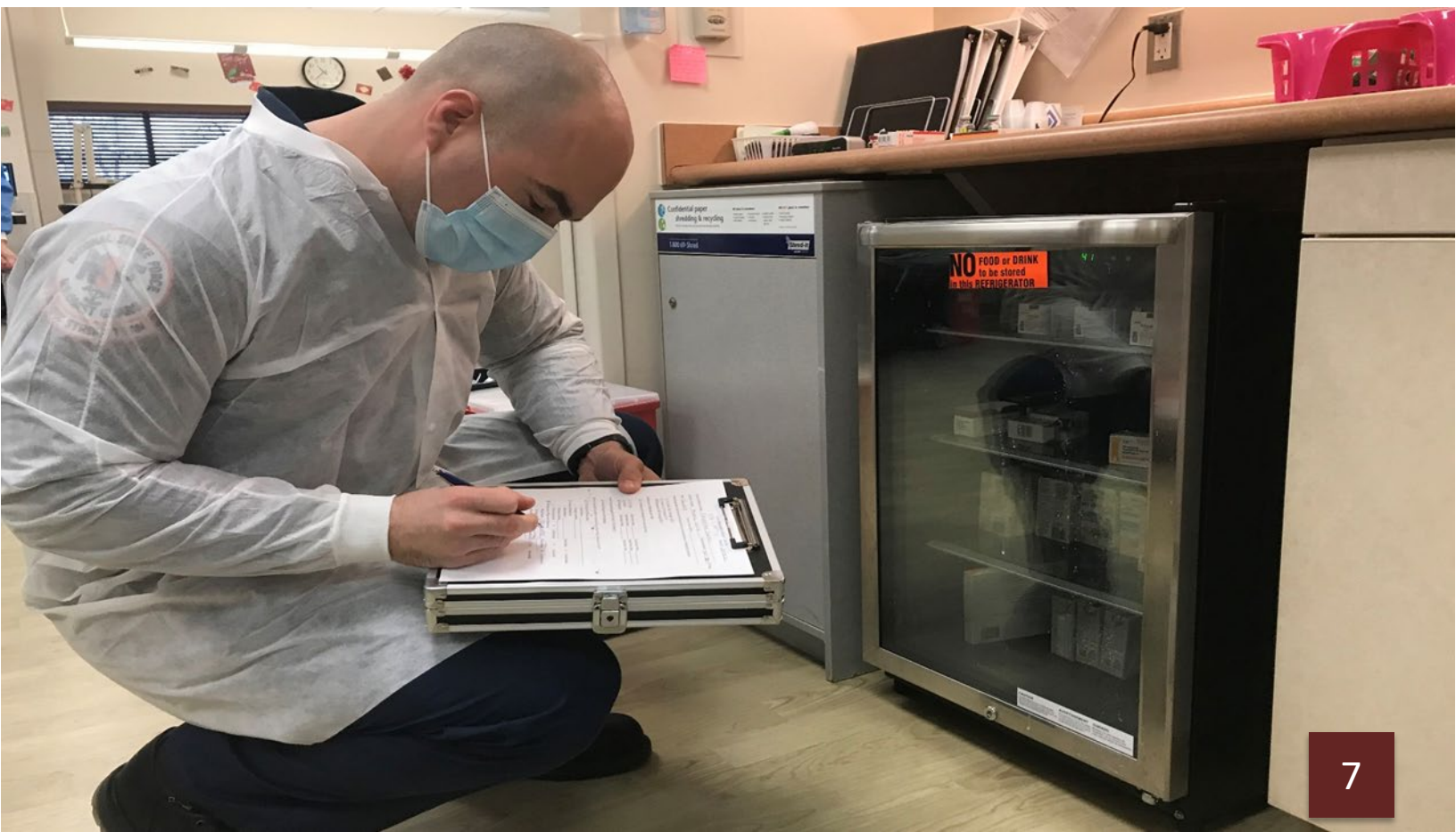
Communicate and regularly test (at least annually) the Emergency Response and Retrieval of Vaccine SOP with staff members. This will ensure they understand the procedures for

responding to out-of-range temperatures and for notifying designated staff about any storage equipment problems.

Regularly update and review your SOPs as personnel contact information or duty positions change. Ensure current information for the primary and backup vaccine coordinators, logistics, facilities management, equipment repair, Defense Health Agency - Immunization Healthcare Specialist (DHA-IHS), USAMMA-DOC, DLA-TSM, pharmacy, and vaccine manufacturers is readily available.

Also, keep available current versions of frequently used forms such as inventory worksheets, temperature logs, emergency forms, PC-TSMP worksheet (DHA Form 177), etc.

Post the Routine Management of Vaccine and Emergency Response and Retrieval of Vaccine SOPs on or near the vaccine storage unit making them easily accessible to all medical, administrative, and housekeeping personnel.





REFRIGERATOR

Vaccine Storage Equipment

Appendix A
Checks to be performed daily (Check every 24 hours)

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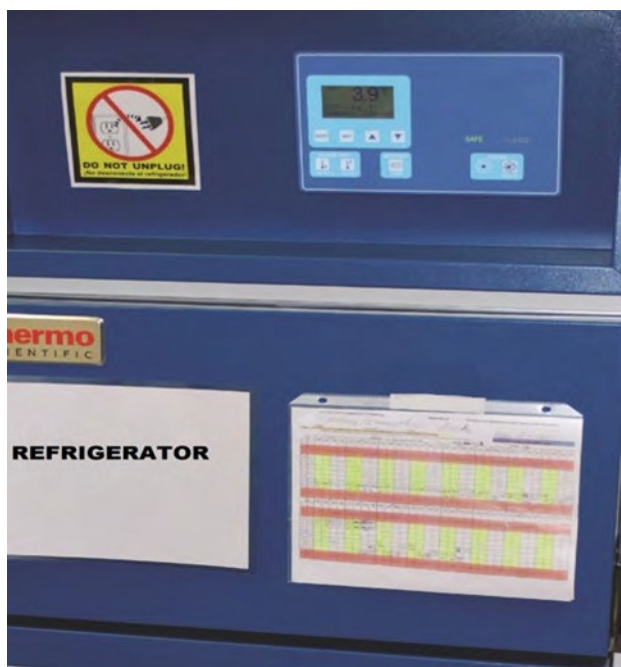
TIME	TEMPERATURE (°C)	TEMPERATURE (°F)	STATUS
06:00	3.9	39	OK
08:00	3.9	39	OK
10:00	3.9	39	OK
12:00	3.9	39	OK
14:00	3.9	39	OK
16:00	3.9	39	OK
18:00	3.9	39	OK
20:00	3.9	39	OK
22:00	3.9	39	OK
00:00	3.9	39	OK
02:00	3.9	39	OK
04:00	3.9	39	OK

Vaccine Storage Unit Recommendations

When selecting a vaccine storage unit, select one that is:

- 1) Suitable and dedicated to vaccine storage,
- 2) Can maintain required temperature range year-round, and
- 3) Store the year’s largest inventory (including flu vaccine) without crowding.

The CDC recommends using purpose-built or pharmaceutical-grade storage units designed to either refrigerate or freeze. These units can vary in size, from compact, under-the-counter or counter-top styles to large units. They ensure temperature consistency, provide ease of serviceability, integrate with temperature monitoring systems, and have compressors that are more efficient and able to cool more quickly.



Household-grade, combination refrigerator-freezer units, can be an acceptable alternative to pharmaceutical-grade vaccine storage units. As the name implies, these units are primarily designed and marketed for home use. However, the freezer compartment of this type of unit is not recommended to store vaccines and there may be other areas of the refrigerated compartment that should be avoided as well. If your facility provides frozen vaccine, a separate stand-alone freezer unit is necessary.

Clearly label the storage units 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.

A door that is not sealed properly or left open not only affects the temperature in a unit, it also exposes vaccines to light, which can reduce potency of some vaccines. Consider using safeguards to ensure the doors of the unit remain closed- for example, self-closing door hinges, door alarms, or door locks.”

Dormitory or bar-style refrigerator/freezers are not authorized for ANY vaccine storage. This type of storage unit has been shown to pose a significant risk of freezing vaccines even when used for temporary storage.

Vaccine Storage Unit Maintenance

Place storage units in a well-ventilated room, with adequate space between the unit, ceiling, and walls, at an ambient room temperature of 20°C-25°C /68°F-77°F. If the room temperature is above 25°C/77°F, adding extra ventilation will help prevent the refrigerator or freezer from overheating and failing.

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 service provider contact information, 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. Plug only one storage unit per electrical outlet to avoid creating a fire



hazard or triggering a safety switch that turns the power off. Do not plug into outlets that can be activated by a wall switch or outlets with built in circuit switches (e.g., GFI outlets which have a reset button). Do not use extension cords, multi-outlet power strips and/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.



Post highly visible “DO NOT UNPLUG” 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).



Where feasible, label circuit breaker fuses to alert staff not to turn off the power and include information on who to contact if the power to the storage unit will be turned off due to construction or other electrical work.



Refer to the IHD Storage and Handling website for “Storage Unit Sticker Template” reminder stickers.

Connect the vaccine storage units to a red emergency outlet (if available), backup battery power source or backup generator (if available - should have sufficient capacity to run for up to 72 hours - have adequate supply of fuel available) to ensure proper storage conditions are maintained during commercial power interruptions.

If a backup battery source is used, make sure it is rated to carry the maximum current required to run the refrigerator or freezer if commercial power is interrupted.


In addition to testing the backup power and generators quarterly, CDC Storage and Handling Toolkit also recommends annual servicing.




Certificate of Regulatory Compliance

Plasma Therms: DHC, DHA, DHB
Digital Thermometer: DT1
Cell Washer: URM200
Plasma Incubators: FC100, FC100A, FC100B, FC100C, FC100D, FC100E, FC100F, FC100G, FC100H, FC100I, FC100J, FC100K, FC100L, FC100M, FC100N, FC100O, FC100P, FC100Q, FC100R, FC100S, FC100T, FC100U, FC100V, FC100W, FC100X, FC100Y, FC100Z
Patient Agitators: PA10, PA10A, PA10B, PA10C, PA10D, PA10E, PA10F, PA10G, PA10H, PA10I, PA10J, PA10K, PA10L, PA10M, PA10N, PA10O, PA10P, PA10Q, PA10R, PA10S, PA10T, PA10U, PA10V, PA10W, PA10X, PA10Y, PA10Z
Refrigerators: RR100, RR100A, RR100B, RR100C, RR100D, RR100E, RR100F, RR100G, RR100H, RR100I, RR100J, RR100K, RR100L, RR100M, RR100N, RR100O, RR100P, RR100Q, RR100R, RR100S, RR100T, RR100U, RR100V, RR100W, RR100X, RR100Y, RR100Z
Freezers: FF100, FF100A, FF100B, FF100C, FF100D, FF100E, FF100F, FF100G, FF100H, FF100I, FF100J, FF100K, FF100L, FF100M, FF100N, FF100O, FF100P, FF100Q, FF100R, FF100S, FF100T, FF100U, FF100V, FF100W, FF100X, FF100Y, FF100Z

Helmer Inc. hereby certifies that the above-mentioned products are manufactured and/or processed under a quality system that is compliant with FDA 21CFR Part 820 (QMP), certified to ISO 14883:2018 and ISO 13485:2016. Our FDA establishment registration number is 1481837. All devices are listed with the FDA and unless exempted, have been cleared for market through the 510k notification process. FDA and AABB requirements for performance are used as design criteria for applicable devices. Our products are certified to applicable safety standards by a Nationally Recognized Testing Laboratory. Each device is labeled with a unique control number. Calibrated instrumentation traceable to NIST standards and ISO 17025 is utilized in the design, manufacturing, and inspection processes. Precision design, manufacturing, and test records are maintained in accordance with the certified quality management system requirements.

 June 5, 2020
Director of Regulatory Affairs Date

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Storage Unit Temperature Equipment and Monitoring



NO FOOD
LAB STORE

REFRIGERATOR TEMPERATURES
2°C TO 8°C
38°F TO 46°F
AIM FOR 40°F

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Temperature Ranges

Proper storage unit temperatures are critical to ensure that vaccines remain effective and are stored per the manufacturers' guidelines listed in the package insert.

Refrigerator Temperatures:

- Maintain between 2°C and 8°C/36°F and 46°F
- Set thermostat midrange to achieve a temperature of about 4°C/40°F
- Set the alarm activation at 2°C (low) and 8°C (high)
- DO NOT expose refrigerated vaccines to freezing temperatures.

Freezer Temperatures:

- Maintain between -50°C and -15°C/-58°F and +5°F
- Set thermostat temperature at mid-point temperature (-20°C or -4°F)
- Set the freezer alarm activation at -15°C or +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 the temperatures being improperly adjusted - exposing vaccines to temperatures that are too warm or too cold. Post a warning sign on the storage unit with the primary and backup coordinator contact information.

Before adjusting the temperatures, confirm the storage 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 4°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 temperature in the refrigerator and 2 to 3 days in the freezer.

When the temperature in the storage unit is stable at the required range for a minimum of 24 hours, place the vaccines into the unit.



Place water bottles on the top shelf and floor and in the door racks of storage units. Putting water bottles in the units can help maintain stable temperatures in storage unit when doors are frequently opened or during a power outage.

Place water bottles carefully so they cannot dislodge, preventing the door from closing securely or weighing the door down so the seals are not tight. Label all water bottles "Do Not Drink." Water bottles are not recommended for use with certain pharmaceutical-grade and purpose-built units. For such units, follow the manufacturer's guidance.

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.

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 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 shipping temperatures can be different from long-term vaccine storage temperatures found in the package insert.

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 “Preparing for Storage and Handling Emergencies.” 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 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.

Temperature Monitoring Equipment

An accurate temperature history that reflects actual vaccine temperatures is critical for

protecting your vaccines. That is why each vaccine storage unit and transport container must have its own certified and calibrated temperature-monitoring device (TMD).

The CDC recommends a specific type of TMD called a "digital data logger" (DDL). DDLs provide the most accurate and detailed storage unit temperature data, including details on how long a unit has been operating outside the required temperature range. Unlike a simple minimum / maximum thermometer, which only shows the warmest / coldest temperatures reached in a unit, a DDL provides detailed information on all temperature recorded at preset intervals.



Select DDLs with the following characteristics:

- Detachable probe that best reflects accurate vaccine temperatures (e.g., a probe buffered with glycol, glass beads, sand, or Teflon®),
- Alarm for out-of-range temperatures,
- Low battery and current, minimum, and maximum indicator with accuracy within +/- 0.5°C (+/-1°F),
- Logging interval that can be programmed to measure and record temperatures at least every 30 minutes.

The TMD used should have a Certificate of Calibration Testing, also known as a Report of Calibration. Calibration testing is done to ensure the accuracy of a TMD's readings against nationally accepted standards. Calibration testing should be done every two to three years or according to the manufacturer's suggested

timeline. TMDs can experience a “drift” over time, affecting their accuracy. This testing ensures the accuracy of the device continues to conform to nationally accepted standards.

A DDL's Certificate of Calibration testing will include:

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

Refer to CDCs most recent version of the Vaccine Storage and Handling Toolkit, which is available on the web at:

<https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html> for guidance on how to determine if a Certificate of Calibration Testing or Report of Calibration was issued by an appropriate entity.

A DHA-IHD information paper on the “Digital Data Logger Calibration with the Ice Melting Point Validation Method,” can be found on the IHD Storage and Handling website at:

<https://www.health.mil/coldchain>.

Temperature data from a DDL can be downloaded to a computer using special software or retrieved from a website. Reviewing DDL data is critical for vaccine viability, so it is important to decide whether independent software or a website program works best for your facility.

Proper temperature probe placement is important. Place the temperature probe in close proximity to the stored vaccines, in the middle, center of the storage compartment away from the walls, ceiling, cooling vents, door, floor, and back of the unit.

Due to accuracy concerns, and because they only show the temperature at the exact time they are read, the following TMDs are not recommend for use in a vaccine storage unit: chart recorders,

alcohol or mercury thermometers (even if placed in a fluid-filled biosafe liquid vial), bi-metal stem, food or infrared TMDs, and TMDs that do not have a current and valid Certificate of Calibration Testing.



Electronic Monitoring System (EMS)

A properly installed and functioning EMS is essential for staff to respond to a temperature excursion in the time frame necessary to protect the vaccines. An EMS generally consists of a network of thermometers connected to a central computer, they work differently than DDLs.

The EMS computer stores data from each thermometer so staff may view temperatures of multiple storage units at once, making monitoring of a large number of storage unit 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.

It is important to confirm that current personnel contact information exists on auto-dialers, and that appropriate coverage occurs during periods of leave, holidays, and weekends.

Test the entire EMS, from the storage unit sensor to the remote monitoring station and telephone call/alert, at least monthly. A DHA-IHD recommendation, is to document monthly EMS testing on the front and back of the temperature log. This way the monthly testing information will be available if requested. The results of

the EMS test should be kept for a minimum of three years.

Monitoring and Recording Temperatures

Place a temperature monitoring log sheet on each storage unit door and physically check and record, the following information, a minimum of two times per day - once at the beginning of the workday and once at the end of the workday:

- Minimum/maximum temperature or current temperature if no minimum/maximum temperature is available,
- Ambient room temperature, considered to be between 20°C-25°C/68°F-77°F,
- Date, time and name or initials of person who checked and recorded the temperatures,

Note: The minimum/maximum temperatures recorded should be those obtained since the last workday when the minimum/maximum temperatures were reset. Additionally, documenting the ambient room temperature is important because if the storage unit should lose power or fail, the only temperature to base the excursion on is room temperature.

remote and isolated vaccine storage locations (away from the main activity). For locations without backup power and the ability to monitor temperatures remotely 24 hours a day/7 days a week, implement procedures to minimize on-hand material and return remaining vaccine to a properly monitored and alarmed storage location at the end of each duty day.

The activity commander may designate specific remote vaccine storage locations where travel or personnel staffing prevents the daily return of vaccine to a designated location as exempt from monitoring and/or physical temperature check requirements during non-duty hours. In this instance, activities should incorporate a TMD that is capable of recording and storing temperatures (e.g., DDL) so that verification of nightly storage temperatures can be reviewed at the start of each workday to ensure the proper temperature range was maintained, preventing the administration of potentially compromised vaccine.

DHA-IHD has received numerous 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).

Conduct twice-daily manual documentation of temperatures even with an installed digital data logger and/or an EMS. Incorporating an end-of-day process for physically checking that the storage units are functioning, the storage unit doors are closed, and not relying solely on an EMS, will help with the early detection and response to out-of-range temperatures.

Review storage unit temperature readings and continuous DDL software or website information weekly to identify temperature trends that might require action. File this information so it can be analyzed for long-term trends and/or recurring problems. Keep temperature log sheets and data for 3 years.

Temperature Log for Refrigerator – Celsius Month/year _____ Page 4 of 4
 DAYS 1-15 Facility Name _____

Monitor temperatures closely!

1. Write your initials below in "Staff Initials," and enter the time in "Time Taken."
2. Record temperature once each day.
3. Be sure the vaccine storage unit is closed and locked - preferably, at the end of the day.
4. Do not open the refrigerator door for any reason.
5. If the unit is out of range, stop and see the notes on the right.
6. Record the location of the excursion in the "Location of Excursion" column at the end of the log.
7. If the unit is out of range, stop and see the notes on the right.
8. If the unit is out of range, stop and see the notes on the right.

Take action if temp is out of range - low warm (above 8°C) or too cold (below 2°C).

1. The unit has a backup power source and is in the proper storage location.
2. Label the unit with a "TEMP" sticker and place a "TEMP" sticker on the door.
3. Do not open the door.
4. Do not move the unit.
5. Do not use the unit for anything else.
6. Do not use the unit for anything else.
7. Do not use the unit for anything else.
8. Do not use the unit for anything else.
9. Do not use the unit for anything else.
10. Do not use the unit for anything else.
11. Do not use the unit for anything else.
12. Do not use the unit for anything else.
13. Do not use the unit for anything else.
14. Do not use the unit for anything else.
15. Do not use the unit for anything else.

Day of Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Staff Initials															
Exact Temp															
Min/Max Temp															
Location of Excursion															
Time Taken															

Temperature Range Alerts:

- Temperature above 8°C are low warm. Write out of range temps and exact temp on the back of the log and contact DHA, IHD and/or USAMRIID immediately.
- Temperature below 2°C are too cold. Write out of range temps and exact temp on the back of the log and contact DHA, IHD and/or USAMRIID immediately.

Place storage units in a well-ventilated room at an ambient room temperature of 68°F-77°F/20°C-25°C.

If you have a vaccine TSP storage issue, also complete a PC-TSP worksheet (DHA Form 177). A link to the form can be found at www.health.mil/accs.

DHA-TSM CCM Team Phone: (215) 735-5537/5365, DSN 5444, Urgent after hours: (215) 244-4056, email: ESCPC@dcd.hhs.mil or pasofid@icmccm.dhs.mil
USAMRIID Phone: (301) 493-4313/4317, DSN 5413, Urgent after hours: (301) 676-1184/8908, email: escpc@cdc.hhs.gov or usamaa.ccm@usamriid.gov

DHA Form 177 (Feb 2022) 877-687-1433 www.health.mil/accs

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.

Proper temperature monitoring procedures must be maintained when vaccines are stored at



Recommended Vaccine and Diluent Storage and Handling Practices

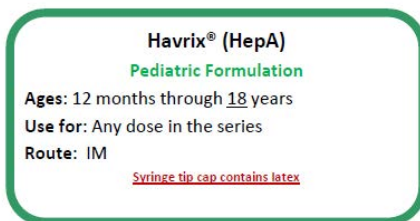
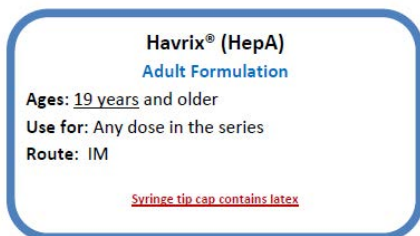


Organizing the Vaccine Storage Unit

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

To confirm vaccines are stored correctly and to minimize the risk of administration errors, implement the following practices:

- Store each type of vaccine or diluent in its original packaging and in a separate container.
- Label shelves and containers to clearly identify where each type of vaccine and diluent is stored. Refer to the “Vaccine Bin Label” examples found on the IHD Storage and Handling website.
- Color code the labels (e.g., one color for pediatric and one for adult vaccines).



- Store vaccines and diluents with similar packaging or names or with pediatric and adult formulations on different shelves.
- Position vaccines and diluents two to three inches from the unit walls, ceiling, floor, and door - avoid storing vaccines and diluents in any part of the unit that may not provide stable temperatures or sufficient air flow.
- Arrange vaccines and diluents in rows and allow space between them to promote air circulation.

- Place vaccines and diluents with earliest expiration dates in front of those with later expiration dates.
- Whenever possible, store diluent with the corresponding refrigerated vaccine. Never store diluent in a freezer. Diluents that require room temperature storage should not be exposed to temperatures warmer than 25°C/77°F.

Note: CDC and DHA-IHD recommend that MMR vaccine be stored in the freezer vs. refrigerator whenever possible. The MMR package insert recommends the freezer as an option for storage. An information paper titled “Cold Chain Management of MMR Vaccine” can be found on the IHD Storage and Handling website.

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 from vaccines. Potentially contaminated items (e.g., blood, urine, etc.) should be properly contained and stored below vaccines due to risk of contamination from drips or leaks. No food or drink should ever be stored in the unit with vaccines.

Vaccine Shelf-Life after Opening

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. Discard all SDVs without their protective caps at the end of the duty day.

Manufacturer-Filled Syringe

A manufacturer-filled syringe, also known as a pre-filled syringe (PFS), is prepared and sealed under sterile conditions by the manufacturer. PFSs do not contain a preservative to help prevent the growth of bacteria.

Keep tip cap in place until ready for use. Attach

needles to a PFS just prior to administration.

Discard needle and syringe if the vaccine is not administered before the end of the clinic day or vaccination session in accordance with the manufacturer's package insert. If no time line is provided in the package insert, discard after 8 hours.

Multi-Dose Vial

A multi-dose vial (MDV) contains more than one dose of vaccine and can be entered or punctured more than once - always use aseptic technique when withdrawing vaccine from a MDV. MDVs contain a preservative (e.g., Thimerosal) to help prevent the growth of bacteria.

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.

MDVs of vaccine 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). Always follow the guidance listed in the package insert to assure the integrity of the vaccine.

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 that states:

"Vaccines are exempt from the 28-day requirement. The CDC Immunization Program states that vaccines are to be discarded per the manufacturer's expiration date. The Joint Commission applies this approach to all vaccines – whether a part of the CDC or state immunization program or purchased by healthcare facilities - with the expectation that the vaccines are managed in accordance with the product manufacturer's instructions for use

(correct temperature, frequency of temperature checks, etc.) and any applicable regulatory requirements."

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 its original packaging and place in the storage unit immediately after drawing up a dose.

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 designed to meet volume and chemical requirements of their corresponding vaccine.

Additionally, some diluents contain a second part of the vaccine, an antigen or an adjuvant (e.g., DTaP-IPV), needed for vaccine effectiveness. Even if the diluent is composed of sterile water or saline, use only the diluent supplied with the vaccine to reconstitute it to preserve the potency and safety of the resulting mixture.

Always consult the manufacturers' package insert for the reconstituted vaccine "beyond use date" (BUD), 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 draw reconstituted vaccine into a syringe until you are ready to administer it because the manufacturer's guidance may specify that an unused reconstituted vaccine can only be stored in the vial for the indicated time.

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.

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.

Preparing Vaccine for Administration

Vaccine preparation is the final step in the cold chain before administration. Prepare vaccine in a designated area away from any space where potentially contaminated items are placed.

The setting in which vaccines are prepared and administered should have adequate space to prepare a vaccine using aseptic technique to prevent vial contamination.

Consider the following:

- There is clear physical separation of the medication storage/preparation area from the administration area. A barrier, such as a wall, etc., is NOT required.
- The MDV of vaccine remains in the medication preparation area and does not cross into the patient administration area (exception is for Smallpox/ACAM-2000 vaccine).
- Any item taken into the administration area (e.g. needle, syringe, medication vial, bandage, etc.) does not return to the medication storage / preparation area.
- Staff utilizing the room have been trained on procedures required to prevent cross contamination.
- All vaccination and administration supplies must be secured or under constant surveillance to ensure cross contamination does not occur.
- Confirm you have selected the correct vaccine and diluent (if applicable). Use only

the specific diluent provided by the manufacturer for each type of vaccine.

- Always check expiration dates on both diluents and vaccines before reconstituting them.
- Never use a stock vial of sterile water or normal saline to reconstitute vaccines or administer vaccine reconstituted with the wrong diluent.
- Do not mix individual vaccines in the same syringe unless specifically licensed for such use.
- Do not transfer vaccine between syringes.
- Only prepare vaccines when you are ready to administer them.
- Administer vaccine shortly after withdrawal from a SDV or MDV, in accordance with the manufacturer's package insert.

Smallpox vaccine is accessed by dipping a bifurcated needle directly into the vaccine MDV. Access the MDV in the immediate patient area to reduce environmental contamination by vaccine virus. To prevent vial contamination, make sure the patient area is clean and free of potentially contaminated equipment.

Only administer vaccines you have prepared. This is an issue with quality control and patient safety as well as a medication administration best practice standard. 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.

Discard vaccine and diluents when stored or handled inappropriately or expired.



Pre-drawing Vaccine

The CDC recommends using manufacturer-filled syringes for large immunization events. These syringes are labeled with the vaccine name, lot number and expiration date. They are also designed for both administration and storage, reducing the chance of a medication error.

Vaccine manufacturers do not recommend pre-drawing 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 pre-drawn vaccine that does not contain a preservative.
- Vaccine components may interact with polymers in a plastic syringe over time, potentially reducing vaccine potency.

In certain circumstances in which a single vaccine type is being used, filling a small number of syringes, may be considered based on the following conditions:

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





Routine Vaccine Management

Inventorying Vaccine

At a minimum, conduct a vaccine and diluent inventory monthly to ensure adequate levels are on-hand to meet demand.

Consider asking the following questions during inventory:

- 1) Are vaccines in their original packaging?
- 2) Are vaccines expired?
- 3) Are appropriate diluents available for the vaccine in inventory?
- 4) Are vaccines in the proper storage unit?
- 5) Is MMR vaccine in freezer vs. refrigerator when possible, per the package insert and CDC and DHA-IHD recommendation?
- 6) Are vaccines placed properly in unit (away from the walls, coils, cooling vents, ceiling, and floor and not on the door shelves)?
- 7) Are rubber bands around boxes of like lot numbers as a reminder to alert staff to a change in vaccine lot number?

Check vaccine and diluent expiration dates a minimum of weekly to remove expired items from usable stock - use them before or up to the date printed on the label. Rotate stock so that vaccine and diluent with the soonest expiration dates are moved to the front and are used first to avoid waste due to expiration.

- If the expiration 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.



Promptly remove expired or mishandled vaccine and diluent, opened MDVs of vaccine and reconstituted MDVs past their revised "beyond use date" printed on the vial from the storage unit and dispose of them according to local policy.

Redistributing Soon-to-Expire/Excess Vaccine

During inventory, if vaccine is identified that is excess (e.g., mission cancelled) or will expire in 3 months or less and will not likely be used prior to their expiration date, contact your Immunization Healthcare Specialist (IHS), USAMMA-DOC, or DLA-TSM concerning the proper steps to take for redistributing the vaccine to another DOD activity.

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.

When ordering vaccines, it is best to attempt to restrict ordering to the cooler months of the year. Avoid over-stocking 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.

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 at:

<https://www.amlc.army.mil/USAMMA/Logistics/Distribution-Operations-Center-Vaccine/Vaccine-Ordering/>. Any order for these vaccines

submitted via the Theater Enterprise-Wide Logistics System (TEWLS) or Defense Medical Logistics Standard Support (DMLSS) will not be processed.

Shipping Vaccine

All DLA Distribution Depots, OCONUS Prime Vendors/Medical Air Bridges (MAB), and/or USAMMA distribution sites utilize qualified insulated shipping containers (e.g., ThermoSafe) that have gone through extensive testing procedures for their cold chain shipments.

Various packing protocols are used based on the time of year, amount of material being shipped, and the ambient temperature at the final destination. When packaged correctly, these shipping containers can usually maintain the required temperature for a minimum of 3 days, and depending on the environment, up to 5 days. These containers will include a temperature monitor, which takes temperature readings every 15 minutes.

Cold chain shipments from DLA Domestic Prime Vendors utilize pre-qualified insulated shipping containers that maintain the required temperature range for up to 48 hours. Currently, temperature monitoring devices are not required in these shipments. Suspected temperature deviations and/or delays in shipping past 48 hours should be immediately reported to DLA-TSM so that they can coordinate with the Prime Vendor, product manufacturers, and end customer for disposition.

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

Receiving Vaccine Deliveries

The most common DOD vaccine storage and handling mishap 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 of it.

All personnel who receive vaccine deliveries should be trained on the manufacturer's storage requirements outlined in the package insert.

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.

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.

Begin the delivery check-in process by opening the shipping container, and locating the packet that contains the shipment information. DLA-TSM distributor cold chain shipments will also include an instruction sheet and materials for returning temperature monitors. Place the packet and instruction sheet aside, and continue the check-in process by locating the temperature monitor included in the shipment (if applicable).

USAMMA-DOC Shipments:

The process for receiving anthrax, smallpox, and/or adenovirus vaccines is slightly different from other vaccines. Upon receipt of these vaccines personnel will follow the USAMMA-DOC "STOP" receiving card 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.

Do not use or discard the anthrax, smallpox, or adenovirus vaccines until their integrity is verified and disposition instructions are provided by USAMMA-DOC.

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. This may expose the vaccine to freezing temperatures which will affect the vaccine potency.



DLA-TSM and Prime Vendor Shipments:

For shipments that include a temperature monitor there will be instructions on reading the monitor, and materials for returning them. Stop all temperature monitors prior to handling them as body heat from your hand(s) could trigger a false alarm.

Review the alarm details to verify that the 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.
- Alarmed: Shipment experienced a temperature excursion – suspend use of the vaccine. Label as “Do Not Use,” segregate by TMD, annotate with TMD serial number, and place in an appropriate storage unit.
- Not started or malfunctioning temperature monitors: Treat as an alarmed shipment.

If there is no issue with the temperature during shipment, immediately unpack the vaccine from the shipping container, inventory the contents against the packing list to confirm they match, place the vaccine in the appropriate storage unit, and process the no-alarm TMD to DLA-TSM per the instructions included in the shipping container.

If a shipment is alarmed, do not assume the vaccine is ruined. Label the vaccine as “Do Not Use,” segregate by TMD, annotate with TMD serial number, and place in the appropriate storage unit. Report the alarmed temperature monitor to DLA-TSM per the instructions included in the shipping container. Do not use or discard the vaccine until its integrity is verified and disposition instructions are provided by DLA-TSM.

DLA-TSM will coordinate the temperature and time information from the 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 revised 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.), the DLA-TSM cold chain 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.

Since DLA-TSM is subject to audit by the Food and Drug Administration (FDA) and the manufacturer, they are required to maintain an electronic record of all shipments. Due to this requirement, receiving personnel are to return ALL monitors as soon as possible after receipt, regardless of alarm status, per the instructions included with the shipment.

Where applicable, utilize provided temperature monitoring hardware and software sets to transmit the temperature monitor data and completed/scanned instruction sheet to DLA-TSM via email.

If the hardware and software is unavailable and/

or the site is unable to transmit the data electronically, 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. 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, until the shipment has been confirmed complete.





Recommended Practices for Off-Site Immunization Events

Off-Site Immunization Procedures

It is important to have an SOP that details the proper procedures to protect vaccines during off-site immunization events.

Include the following requirements in the SOP:

- Identify and assign duties to an off-site vaccine coordinator. The coordinator will be responsible for filling out the “Best Practices for Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations” checklist found on the IHD Storage and Handling website.
- Pack only the amount of vaccine that is expected to be used (overpacking can lead to waste). Keep vaccine and diluent in their original packaging.
- Fill out an “Off-site Clinic Vaccine Inventory Issue/Return Receipt” found on the IHD website. Include the amount and type of vaccine taken, and ensure the off-site vaccine coordinator acknowledges that they must keep the vaccine at the required temperatures during the off-site event.
- 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 inside a validated transport container and take it directly to the off-site location, taking 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 during the off-site event.
- 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 Vaccine Inventory Issue/Return Receipt stating that the required temperatures were maintained.

Proper Transport of Vaccine to Off-site Events

“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 (less than 8 hours) and short distance between storage locations.

Transport vaccine only when necessary, such as for an off-site immunization event or during an emergency to save vaccine. Due to their temperature requirements, frozen varicella-containing vaccines should never be transported except in an emergency.

It is recommended 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 AX56L.

If a portable refrigerator unit is not available, store the vaccine in a DOD validated and approved mobile transport container, such as the PX1L or PX6L, and/or a hard-sided or Styrofoam™ insulated cooler with at least 2-inch thick walls.

Note: Thin-walled Styrofoam™ coolers, such as those purchased at a grocery store to hold beverages, are NOT acceptable.

Vaccine packing reminders:

- When using the PX1L, PX6L, and/or the AX56L, follow the manufacturer’s owner’s manual for proper packing procedures.

- Make sure to use only the phase-change coolant bricks (PXC) with the PX1L or the PCM coolant belts with the PX6L. No other coolant material should be used with these mobile transport containers.
- **NEVER pack refrigerated vaccine with frozen coolant packs.** Refrigerated vaccines that are exposed to freezing temperatures, even for a short period of time, will be ruined.
- Always include calibrated TMD to track temperatures during transport and storage.
- Document the storage unit temperature at the time the vaccine is removed for packing. Record temperatures a minimum of every 2 hours when vaccine is in a transport container and outside of a functioning storage unit.
- Keep a detailed, itemized list along with contact information (originating facility, phone number), and the date/time affixed to outside of the transport container for easy identification. Label transport container as "Refrigerated" or "Frozen" product and "temperature sensitive."
- Always use an insulating barrier (e.g., bubble wrap, corrugated cardboard, packing foam, etc.) between coolant

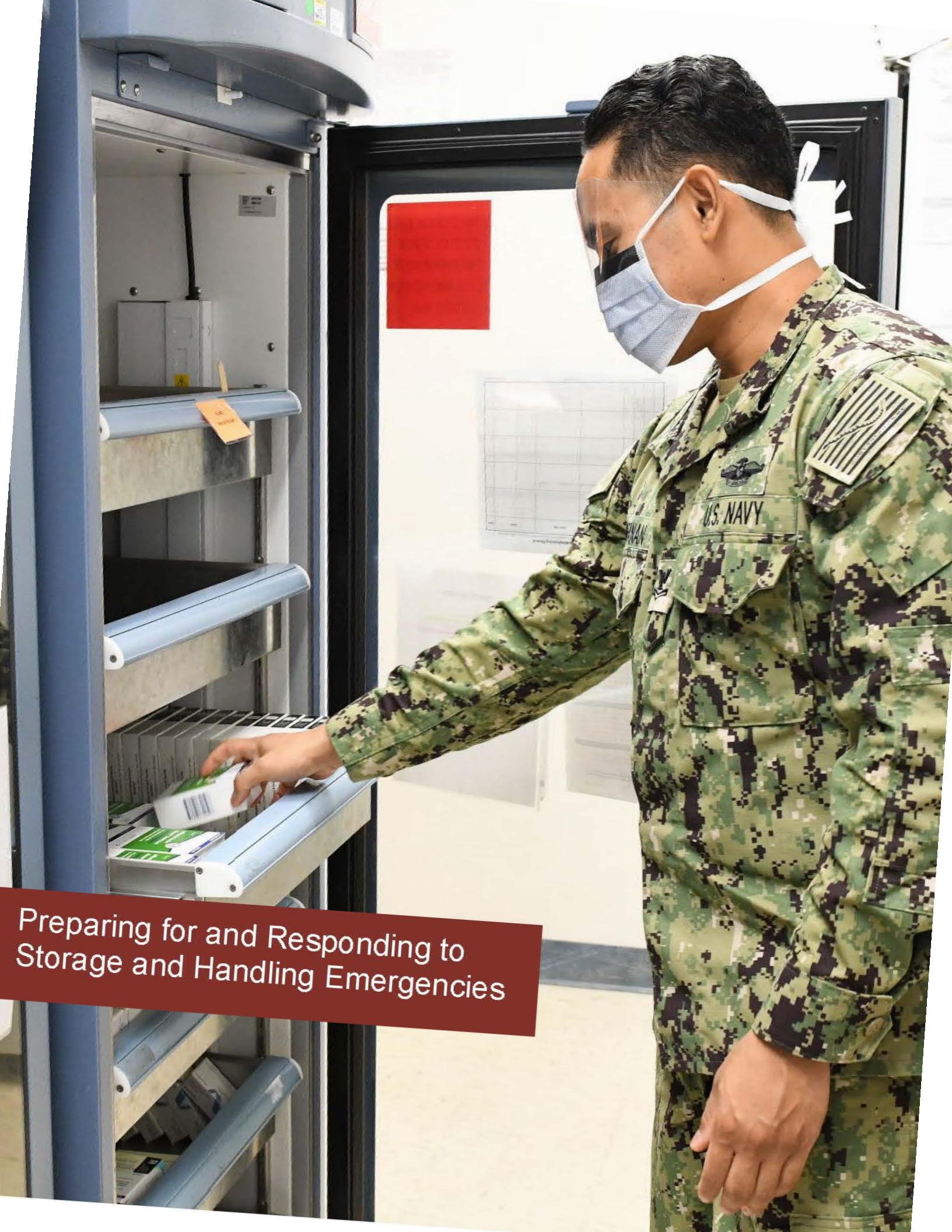
material and the vaccines. Placing an insulating barrier between the coolant material and vaccines is important because it keeps refrigerated vaccines at the right temperature and prevents them from freezing.

- *Note:* "chux or chucks" pads do not provide an adequate insulating barrier.
- If you use a hard-sided or Styrofoam™ cooler with at least 2-inch thick walls for the off-site immunization event, go to the "Preparing and Responding to Vaccine Emergencies" section for information on vaccine packing protocols.
- *Note:* Vaccine manufacturers do not support the reuse of their containers, coolant packs, and packing materials for vaccine transport.

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 <https://www.health.mil/ContactYourIHS>.

Find additional packing guidance and protocols DLA-TSM website (see hyperlink on "[Resources](#)" page under "Defense Logistics Agency - Troop Support Medical (DLA-TSM).")





Preparing for and Responding to Storage and Handling Emergencies

Preparing for Storage Emergencies

When the vaccine coordinator believes that an extended power outage may occur due to an impending storm or planned power outage, they should take the necessary steps to activate their Emergency Response and Retrieval of Vaccine SOP and review it with staff in advance of the event. Refer to the “Emergency Vaccine Retrieval and Storage Plan” worksheet available on the IHD Storage and Handling website.

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.
- Pack and move all vaccine that is not stored in a location supported by backup power to your designated alternate storage location (e.g., logistics, pharmacy, alternate clinics).
- Label transport container as "Refrigerated" or "Frozen" product and "temperature sensitive." Keep a detailed, itemized list along with contact information affixed to outside of the transport container for easy identification.
- 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 refrigerated vaccine temperatures between 2°C-8°C or 36°F-46°F and frozen vaccines at -15°C/5°F or cooler.
- Verify that vaccines are placed in the appropriate storage unit, refrigerator vs. freezer, at the alternate storage location.
- **Important:** DO NOT place enclosed transport container with vaccine directly into storage unit. Either open the top or remove vaccines from container and place in proper storage unit.
- If no alternate storage location is available,

notify your DHA-IHD IHS for assistance.
<https://www.health.mil/ContactYourIHS>.

Storage Locations with Emergency Backup Power

- VERIFY that all equipment is functioning properly and ALL storage units are clearly labeled as either a refrigerator or freezer.
- Plug storage units and alarm system into the designated emergency power (normally the red outlets). If the alarm system has a battery backup, ensure it is charged or has new batteries.
- Verify that the alarm alert information is current. Program the appropriate designated staff contact information into the automated call system.
- TEST the alarm system before departing. Call the alarm system more often to ensure it is working during power outage.
- 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.
- Move all vaccine in storage locations prone to flooding to a higher level location.
- Prepare and have available equipment and supplies for transporting vaccine in the event that backup power fails.
 - Validated transport container (e.g., ThermoSafe insulated shipping boxes, Hard-sided or Styrofoam™ coolers with at least 2 inch thick walls, PX1L, PX6L, and/or AX56L).
 - Insulating barrier (e.g., bubble wrap, corrugated cardboard, packing foam, etc.).
 - A calibrated TMD for each transport container.
 - Verify AX56L is fully charged and plugged into emergency power.

- If using shipping boxes or coolers, ensure there is an adequate number of refrigerated and/or frozen coolant material or conditioned frozen water bottles.
- If using a PX1L, verify the phase-change bricks (PXC/VaxiSafe) are fully chilled according to manufacturer instructions and that there are four (5) bricks per PX1L.
- If using a PX6L, verify the 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.

In general, pack ThermoSafe 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 and protocols at the DLA-TSM website (see hyperlink on "[Resources](#)" page under "Defense Logistics Agency - Troop Support Medical (DLA-TSM)."



Potentially Compromised Vaccine Reporting Process

Vaccines suspected to have experienced a temperature excursion (considered any temperature reading outside recommended range in the manufacturer's package insert), and/or have been exposed to light (if the package insert states they are light sensitive), require

immediate action to be taken.

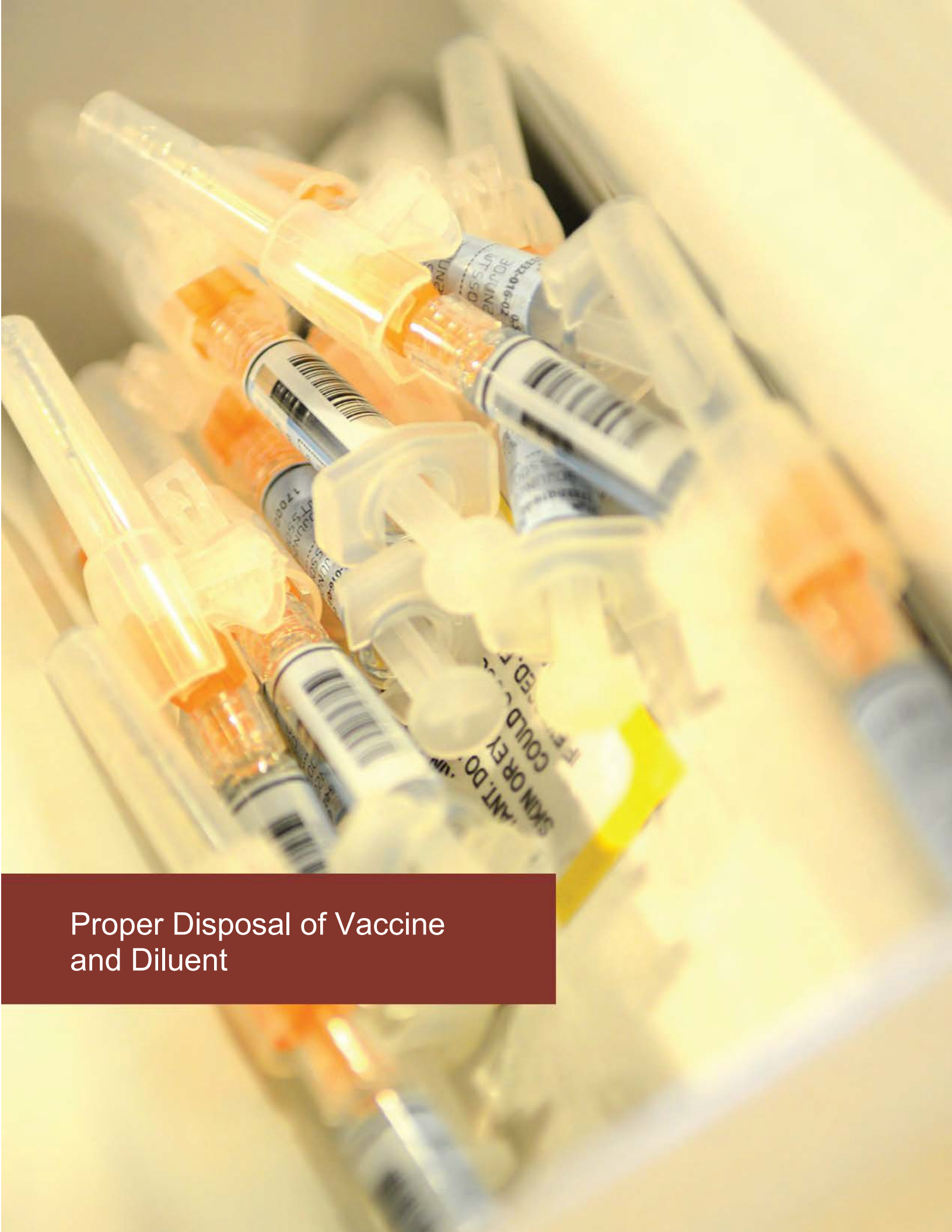
The vaccine coordinator or the person who discovered the problem should follow these steps for responding to, documenting, and reporting a potential vaccine compromise due to a temperature excursion or exposure to light:

- Do not leave vaccine(s) in a non-functioning storage unit or at inappropriate storage conditions. Immediately move the vaccine to a working storage unit at the proper temperature or storage conditions.
- Label potentially compromised vaccine as “DO NOT USE,” and segregate them from other products in the storage unit.
- Document the circumstances surrounding the event using the PC-TSMP Worksheet (DHA Form 177). Contact your DHA-IHS for assistance in completing the worksheet. IHS contact information can found at <https://www.health.mil/ContactYourIHS>.
- Record room temperature, date/time and/or temperature prior to event when vaccines were at required temperature or storage conditions and the date/time and/or temperature post-event when vaccines were back at required temperature or storage conditions.
- Document the current, high and low temperatures of the refrigerator and/or freezer and the length of time vaccine was outside the required recommended temperature range or the improper storage conditions.
- Inventory all the vaccine and document vaccines affected, lot numbers, expiration dates and number of doses (include whether MDVs were opened).

- Indicate whether the vaccines involved were previously exposed to out of range temperatures or improper storage conditions, since exposure will be cumulative.
- Submit the current version of the PC-TSMP Worksheet (DHA Form 177) along with copies of your temperature logs or data to DLA-TSM, USAMMA-DOC, and to your IHS.
- Stand by and await vaccine disposition - do not use, destroy, or discard the vaccine until disposition is provided by DLA-TSM and/or USAMMA-DOC.
- In general, DLA-TSM and USAMMA-DOC 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 (indicated with the specific excursion time and temperature) or destroy the vaccine per local policy/guidelines, as appropriate.
- *Note:* If light sensitive vaccines have been stored improperly, contact the vaccine manufacturer for disposition guidance and report the findings to your DHA-IHS.

Additional guidance for reporting a potential vaccine compromise and a link to the current version of the PC-TSMP worksheet (DHA Form 177) is located at <https://www.health.mil/coldchain>.





Proper Disposal of Vaccine
and Diluent

Disposal of Waste/Expired Vaccine

Waste vaccines are those that have expired or are considered to be waste. Waste vaccines include:

- Vaccine drawn into a syringe from a multi-dose vial that is not administered within the same day.
- Vaccine remaining in a multi-dose vial that has exceeded the manufacturers' recommended storage after the first withdrawal from the vial.
- Vaccine where proper cold chain management was not or may not have been maintained.
- Vaccine that is contaminated or otherwise determined to be unusable.
- Vaccine and diluent which has passed its expiration date.
- Open vials, broken vials and syringes, manufacturer-filled syringes that have been activated, and vaccine pre-drawn and not used by end of duty day.

Pharmaceutical Reverse Distributor

Some unopened expired and compromised single-dose vials, multi-dose vials, and manufacturer-filled syringes of vaccine may be returned to the vaccine manufacturer for credit using the Prime Vendor pharmaceutical reverse distributor program. This program is a safe option for managing vaccine waste while maintaining full compliance with regulating agencies. Contact your pharmacy or medical logistics for information on the use of this program.

If the vaccine cannot be returned (e.g., open vials, broken vials and syringes, manufacturer-filled syringes that have been activated, and vaccines pre-drawn by healthcare personnel) using the reverse distributor program, then proper disposal guidelines need to be followed.

Types of Vaccine Waste

Proper disposal of vaccine is everyone's responsibility in order to protect the environment. Healthcare personnel should manage and dispose of vaccine in accordance with all applicable state and federal laws.

To dispose of vaccines appropriately you need to know if they are either hazardous waste or infectious waste or both or neither. Those that are neither are considered industrial solid waste (normal trash).

To dispose of these materials appropriately, you need to know if they contain any of the following:

Hazardous Waste

Vaccines are considered hazardous waste if they contain mercury (such as Thimerosal) as a preservative. These are most commonly found in multi-dose vials of influenza.

Hazardous waste must be disposed of in a hazardous waste container and not placed in a red sharps container or regular trash. Most military health systems already have policies and procedures for handling hazardous waste.

A full or partially used sharp syringe containing a vaccine with Thimerosal should be disposed of as dual hazardous and biohazardous waste.

Any vial that is not empty¹ and any unused syringes (without needles) prefilled by healthcare personnel containing vaccine with mercury (Thimerosal) must be appropriately segregated and managed as hazardous waste.

Note: It may be permissible to dispose into a sharps container only if the medical waste disposal company responsible for disposal of the container has a license to dispose of hazardous waste; specifically vaccines that contain mercury (Thimerosal).

¹A vial is considered empty when there is 3% or less of the original vaccine remaining and all vaccine that can be removed by normal means (syringe) has been removed. Single or multi-dose vials that have been fully administered may still contain extra vaccine, however, just because there is not enough vaccine left for a dose does not mean the vial is empty. The vial needs to be disposed of properly.

Medical/Biohazard Waste (Infectious Waste)

Medical/biohazard (Infectious) waste has the potential to transmit disease to humans and includes any waste that contains infectious material or potentially infectious substances, such as blood, and should be disposed of in a medical waste bin, bag, or sharps container.

Healthcare personnel are required to designate which of their wastes are infectious or potentially infectious so that the waste can be managed and disposed of properly. Immunization activities generate used syringes, needles, vaccine vials, cotton balls, gauze, alcohol wipes, personal protective equipment like gloves, and occasionally unused vaccines and should be disposed of as medical/ biohazard waste.

Used syringes with a sharp (a needle) are considered medical/biohazard waste and need to be disposed of in a sharps container. Used live attenuated vaccine sprayers and empty rotavirus vaccine dispensing tube or oral applicator are

considered medical waste and should be disposed of in a medical waste bin, bag, or sharps container.

Non-hazardous/Non-infectious (normal trash)

Nonhazardous and noninfectious waste is waste that can be disposed of in the normal trash. It is also called solid waste or industrial solid waste.

You can assume that empty vials that contained preservative-free vaccine and empty single-dose manufacturer pre-filled syringes (without needles) are non-hazardous and not considered medical waste and do not require disposal in a biomedical waste container.

Disposal of Vaccine Vials, Syringes, Applicators and Sprayers		
Waste Item	Type of Waste	Proper Disposal
Empty preservative-free vaccine vials and syringes without needles	Non-infectious and non-hazardous	Normal trash
Empty manufacturer-filled syringe and preservative-free end user-filled syringe with needle	Medical/biohazard (infectious) waste and non-hazardous	Sharps container
Used or partially used multi-dose vials of vaccine with thimerosal (vaccines with 0.01% thimerosal that meet the maximum concentration requirements: Afluria [®] , Flucelvax [®] , and Fluzone [®])	Non-infectious and hazardous	Hazardous waste container and management
Vaccine drawn into a syringe from a multi-dose vial that is not administered within the same day (may also be due to syringe malfunctions during use)	Medical/biohazard (infectious) waste and hazardous	Hazardous waste container that also meets sharps container requirements; management compliant with both hazardous and infectious waste requirements
Used live vaccines: <ul style="list-style-type: none"> • LAIV (live attenuated influenza vaccine) • Rotavirus vaccine oral applicator • Vial 	Non-infectious and non-hazardous	<ul style="list-style-type: none"> • Medical waste bag or bin • Sharps container (needle attached to syringe must be disposed in Sharps container)
Unused vaccines (single-dose, multi-dose and manufacturer-filled syringes – expired or compromised)	Non-infectious and non-hazardous (multi-dose vials with thimerosal are hazardous)	DLA contracted Prime Vendor pharmaceutical reverse distributor program



Summary

Summary

- Designate a primary and backup vaccine coordinator within locations that store, handle or administer vaccines.
- Develop detailed, up-to-date, written policies for general vaccine management (e.g., inventory management, delivery, return from off-sites, process for excess or soon-to-expire vaccine, etc.), and emergency response and retrieval.
- All staff members who receive deliveries and/or pack vaccines for transport should be trained on the storage requirements outlined in the package insert.
- Place large signs identifying the storage units as - Refrigerator and Freezer.
- Set low and high refrigerator alarm activation at 2°C/36°F (low) and 8°C/46°F (high)
- Physically 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.
- 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.
- 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 EMS auto-dialers, and that appropriate coverage occurs during periods of leave, holidays, and weekends. Sites with an EMS should review recorded data daily.



- Test EMS at least monthly to ensure it is programmed correctly and working.
- Do not leave vaccines in a non-functioning unit - 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 refrigerated 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 or truck bed.
- Become familiar with the proper vaccine disposal guidelines for your location.
- Store MMR in freezer verses refrigerator whenever possible.
- Bookmark the Defense Health Agency-Immunization Healthcare Division Storage and Handling website at <https://www.health.mil/coldchain>.



Vaccine Storage and Handling
Resources

Defense Health Agency - Immunization

Healthcare Division (DHA-IHD): 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-IHD 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:

<https://www.health.mil/ContactYourIHS>.

For vaccine storage and handling questions, contact the DHA-IHD Monday - Friday (0700-1800 ET) at (877) GET- VACC (438-8222), Option 2, or email DHA.dodvaccines@health.mil. You can visit DHA-IHD on the web at:

<https://www.health.mil/coldchain>

United States Army Medical Materiel Agency - Distribution Operation Center (USAMMA-DOC):

The designated agent within the DOD responsible for managing and coordinating the distribution of Anthrax, Smallpox, Adenovirus, CONUS COVID-19 vaccines, and the Army seasonal influenza vaccine. They also are responsible for creating and disseminating all DOD Medical Materiel Quality Control (MMQC) and Army Medical Materiel Information (MMI) messages.

In support of DHA-IHD, USAMMA-DOC provides CCM consultation and training on proper distribution and storage practices to logistical and medical unit personnel. USAMMA-DOC provides on-line CCM Certification training via DCS on the first Thursday of each month. The training can be found at: www.amlc.army.mil/USAMMA/Logistics/Distribution-Operations-Center-Vaccine/Cold-Chain-Management/.

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.usamma.mbx.doc@army.mil. Visit USAMMA-DOC on the web at:

www.amlc.army.mil/USAMMA/Logistics/Distribution-Operations-Center-Vaccine/.

Defense Logistics Agency - Troop Support

Medical (DLA-TSM): The Department of Defense (DOD) Subject Matter Expert (SME) on Cold Chain Management (CCM) and author of the Joint Publication for preparing medical Cold Chain material for shipment, DLAR (JP) 4145.21. DLA-TSM is the disposition authority for Influenza, Japanese Encephalitis and OCONUS Covid-19 vaccines, 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 (267) 738-2854. You can reach DLA-TSM by email at DSCPColdChain@dla.mil or paacoldchainteam@dla.mil.

Visit DLA-TSM on the web at <https://www.medical.dla.mil/> (CAC authentication required. After authentication, click on "Pharmaceuticals" across the top of the page, then click "Cold Chain Packaging" on the left-hand menu, the second-to-last bullet under "Division Info.")

Centers for Disease Control and Prevention (CDC)

has various storage and handling tools, documents, videos, and training resources available on the web at:

<https://www.cdc.gov/vaccines/hcp/admin/storage-handling.html>. For information on the proper storage and handling for COVID-19 vaccines, refer to the "COVID-19 Vaccine Addendum" in the CDC Vaccine Storage and Handling Toolkit. DOD requires individuals that administer, store or handle COVID-19 vaccines to complete CDC's You Call the Shots (<https://www.cdc.gov/vaccines/ed/youcalltheshots.html>) vaccine storage and handling training course.

Immunize.org (formerly Immunization Action Coalition (IAC)) has storage and handling tools that can be customized for individual use, available on the web.



Defense Health Agency

**To contact the Immunization Healthcare Division:
(877) GET-VACC or (877) 438-8222, Option 2
Or
DHA.dodvaccines@health.mil**

