Temperature Sensitive Medical Products (TSMPs)

Good Distribution Practices (GDP)

United States Army Medical Materiel Agency (USAMMA)
Distribution Operations Center (DOC)

"Globally Responsive – Ready and Resilient"

Objectives

- ❑Historical Events
- ❑USAMMA DOC Functions
- ❑Core Products Overview
- ❑Why Are We Here
- ❑Cold Chain Management (CCM) Process and Procedures
- ❑Safeguarding Temperature Sensitive Medical Products(TSMPs)
- ❑CCM Equipment
- ❑Cold Chain References/Guides

USAMMA DOC Historical Events

1997 – Secretary of Defense approved Department of Defense (DoD) Anthrax Vaccine Immunization Program (AVIP)
**Army designated Executive Agent (EA)

1998 – Loss of 200,000 doses of Anthrax Vaccine (AVA).

1998 – USAMMA tasked to perform DoD distribution of AVA
**Created Distribution Operations Center (DOC) to manage DOD AVA Distribution
**Cold Chain Management Principles/Procedures (CCM) were developed

1999 – Military Vaccine Agency – Vaccine Healthcare Centers Network (MILVAX-VHCN) replaced MEDCOM as AVIP policy developer/clinical guidance

2014 - DHA Immunization Healthcare Division (DHA-IHD) replaced MILVAX-VHCN and provides clinical consultative services, educational support, and training resources for the entire Department of Defense (DoD) family.

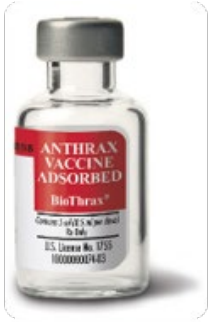
USAMMA DOC FUNCTIONS

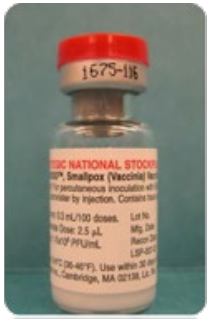
The Distribution Operations Center (DOC) manages critical vaccines and pharmaceutical products which may or may not require Cold Chain Distribution, to include; the packaging, storage and special handling requirements of the medical material requiring refrigeration; the management of the shipment; and the oversight of the product from initial requesting agency to end user, in support of DoD personnel and operations.

"Globally Responsive – Ready and Resilient"

Core Products Overview

- Anthrax Vaccine - change October 2019. AVA is now certified to remain usable for 28 days after being opened or punctured ("Best Used Date") when stored at the recommended storage conditions of 2°C to 8°C (36°F to 46°F).
- Smallpox Vaccine (ACAM2000)
- Influenza Vaccine (Army/DHA)
- Adenovirus Vaccine (Type 4 & Type 7)
- Vaccinia Immune Globulin intravenous (VIGIV)
- COVID Vaccine (CONUS and US Territory ONLY)
- MPOX Vaccine (Jynneos)
- Investigation New Drug (IND) products
- Foreign Military Sales (FMS)
- Other Temperature Sensitive Medical Products (TSMP's)-(He-Bat, Rabies etc..)
- Other Non-Temperature Sensitive Critical products





Why are we here?

- The great loss of 1998 – Over 200,000 doses of Anthrax Vaccine was compromised due to freezing
- Sites contribute to thousand of dollars each year in vaccine losses due the following Major Factors:
  - Mechanical Failures - such as alarm system and power outages/supply malfunctions
  - Human Process Failures - such as poor cold chain management techniques
  - Failure to follow policies - procedures and local regulations
  - Training

Cold Chain Management (CCM) Process and Procedures

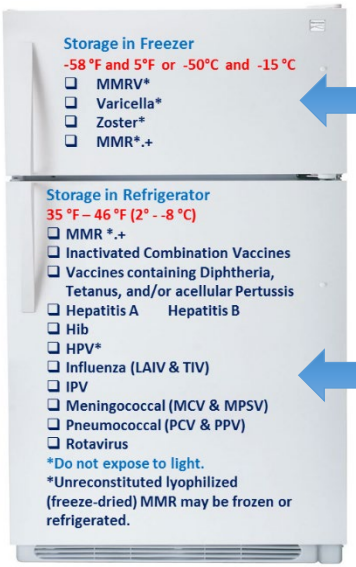
Vaccines are sensitive biological substances that can lose their potency and effectiveness if exposed to heat, extreme cold and/or light

- **Minimize waste/save thousands of taxpayer's dollars**
  - Prevent vaccine from being compromised
  - Assures vaccine maximum shelf life and suitability for use by minimizing the rate of deterioration
  - Some vaccines are in critically short supply
- The loss of vaccine potency **CANNOT** be reversed
- Assures leadership, service members and DoD beneficiaries that vaccine/products are safe to use and at full potency when administered

Cold Chain Management (CCM) Process and Procedures

US Pharmacopeia (USP) Temperature Standards

- ❑ Refrigerated Storage - Thermostatically controlled from 2C to 8C; approximately 36F to 46F
- ❑ Frozen Storage - Thermostatically controlled from -50C to -15C; approximately -58F to 5F
- ❑ Ultra Cold – Thermostatically controlled from -90C and -60C approximately -130F and -76F.
- ❑ Controlled Room Temperature- Thermostatically controlled from 15C to 30C; approximately 59F to 86F
  - ❑ Always follow Manufacturer's Package insert.



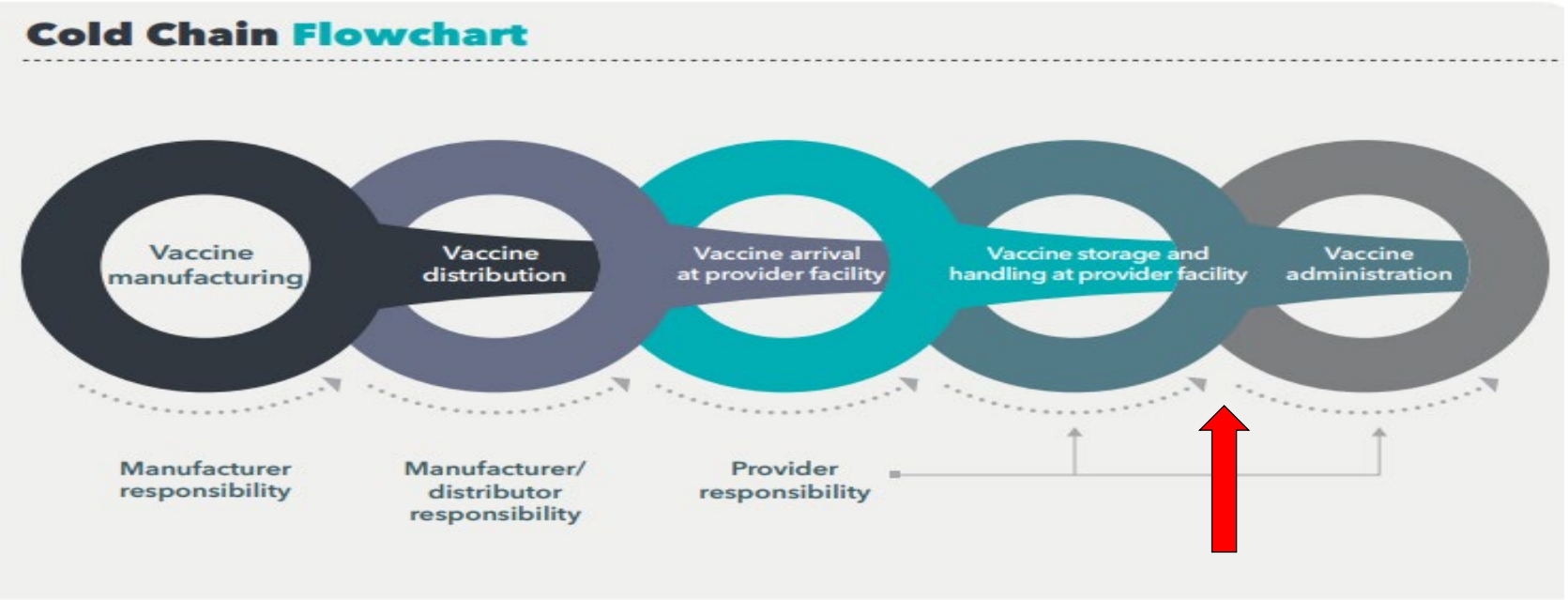
COVID
MPOX

Anthrax
JEV
Rabies
Smallpox
Typhoid
Yellow Fever
COVID (BUD Changes)
MPOX (BUD Changes)

COVID (PFIZER)

"Globally Responsive – Ready and Resilient"

Cold Chain Management



What is Cold Chain Management?

❑Cold Chain Management is the process of preparing temperature sensitive medical products for shipment utilizing approved systems and procedures, maintaining required temperatures during all phases of distribution from the time it leaves the manufacturer until administration of the vaccine to the patient.

❑Importance of Cold Chain Management

- ❑ Maintaining proper vaccine temperatures during storage and handling
  - ❑ Exposure to temperatures outside of recommended ranges can affect potency therefore reducing protection of Vaccine Preventable Diseases (VPD)

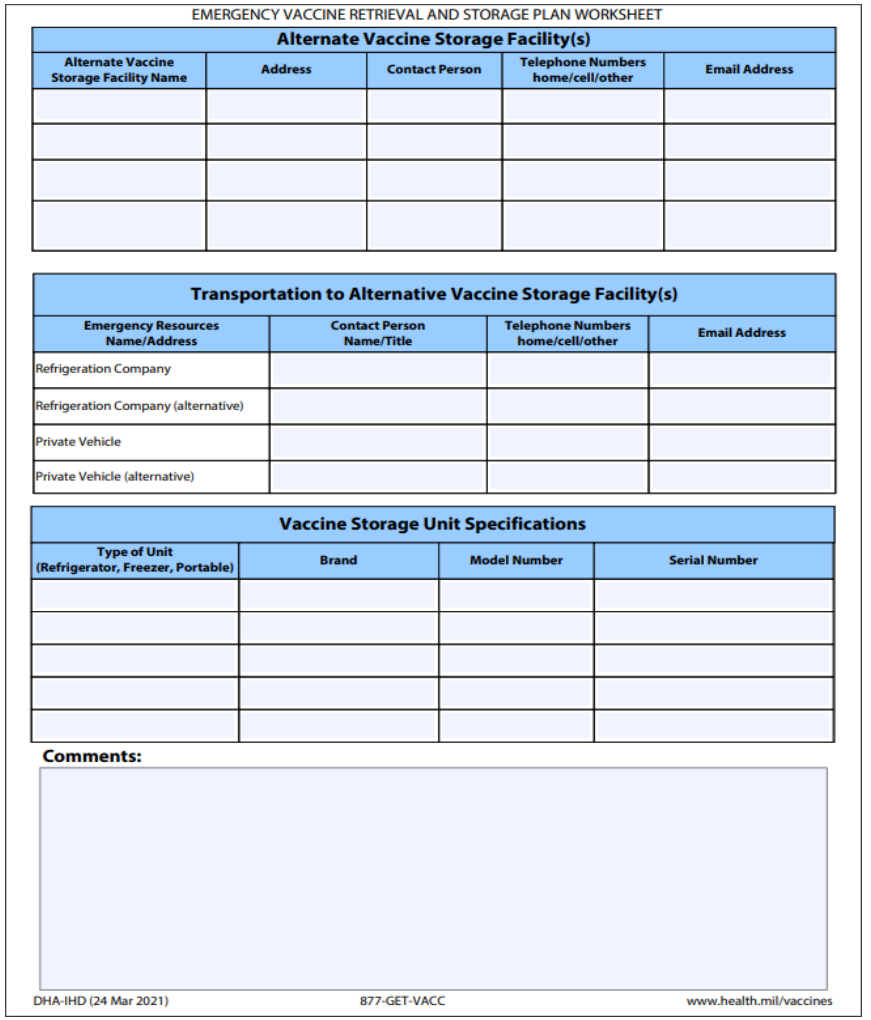
TSMP Coordinator

Responsible for: Developing a Routine Vaccine Storage and Handling plan, kept in a visible location near all vaccine storage units.

- ❑ Appoint a primary and alternate vaccine coordinators and ensure current contact information are listed.
- ❑ Pharmacy, logistics, local Immunization Healthcare Specialist (formally known as Regional Analysts), USAMMA
- ❑ Vaccine manufacturers, the medical equipment repa office.
- ❑ Storage unit alarm company
- ❑ Written emergency plan – natural disasters, power outages etc.
- ❑ Temporary placement of vaccine in a working refrigerator

Emergency TSMP Retrieval and Storage Plan Worksheet

- Vaccine Coordinators – Telephone (Home and Cell)
- Emergency Staff Contact List – Telephone (Home and Cell)
- Refrigerator repair technician, Dry Ice Vendor, Electric Power Company, Temperature Alarm/Generator Repair Company(s)
- Alternate Vaccine Storage Facility(s)
  - Location, Contact Person, Address, Telephone Number
- Emergency Resources Contact List
  - **USAMMA/DOC** – 24 hour Emergency Line
    - (301)676-1184 and (301)326-8383
  - **Defense Logistics Agency** –
    - (215)737-6658 – (215) 284-6586
  - **DHA IHD 24/7** Vaccine related clinical consultation (877) GETVACC (438-822)
    - CCM (Option 2)
  - Immunization Healthcare Specialist



EMERGENCY VACCINE RETRIEVAL AND STORAGE PLAN WORKSHEET

Alternate Vaccine Storage Facility(s)

Alternate Vaccine Storage Facility Name	Address	Contact Person	Telephone Numbers home/cell/other	Email Address

Transportation to Alternative Vaccine Storage Facility(s)

Emergency Resources Name/Address	Contact Person Name/Title	Telephone Numbers home/cell/other	Email Address
Refrigeration Company			
Refrigeration Company (alternative)			
Private Vehicle			
Private Vehicle (alternative)			

Vaccine Storage Unit Specifications

Type of Unit (Refrigerator, Freezer, Portable)	Brand	Model Number	Serial Number

Comments:

DHA-IHD (24 Mar 2021) 877-GET-VACC www.health.mil/vaccines

"Globally Responsive – Ready and Resilient"

TSMP Storage & Handling Equipment

Storage Unit Selection and Characteristics

- Pharmaceutical grade stand-alone refrigerators and freezers (over-the-counter type) are the most highly recommended

- Combination refrigerator and frost-free freezer for home use is acceptable but only the Refrigerated section is recommended due to the freezer going through defrosting cycle

- **NOT AUTHORIZED (SB 8-75-11)** – Dormitory style refrigerators, due to National Institute of Standards and Technology (NIST) vaccine study, showed the units displayed severe **temperature control and stability issues**

Medical Grade Refrigerators/Freezers

- Medical grade refrigerators/freezers ensure temperature consistency
- Provides ease of serviceability, integrate with wireless temperature monitoring systems
- Able to bring temperatures down much more quickly than non-medical grade units
- Greater efficiency of compressors in medical grade refrigerators

Features / Checklist

- ❑ Consider serviceability
- ❑ Storage volume
- ❑ Ability to maintain consistent temperature
- ❑ Front-mounted compressor will allow for easier service

Construction Material:

- ❑ Stainless steel refrigerators are highly durable
  - ❑ Non-medical grade refrigerators - plastic and other less sophisticated components
  - ❑ Cheap or flimsy hinges and seals will result in temperature leaks and an overburdened compressor
  - ❑ Glass front doors, which allow you to visually inspect product without opening the door; fewer openings will positively impact the life of the unit.

When determining the cubic volume, you require

- ❑ Consider your current as well as future storage needs

Thermometers

Accurate thermometer readings are essential to determine whether vaccines are maintained at the required temperature

- Storage units should have a National Institute of Standards and Technology (NIST) certified and calibrated thermometer – in each compartment (refrigerator/freezer)
- Continuous graphic recorder thermometer, monitors ranges and durations is recommended
- Uncertified liquid (**mercury or alcohol**) thermometers and dial-type are not authorized
- Thermometers should be placed in the center of the compartment away from coils, walls, floor, and fan
- Certain types of temperature monitoring devices have significant limitations and should not be used to measure temperatures in a vaccine storage unit.

Thermometers

Based on studies of thermometers conducted by NIST in 2012, the CDC recommends using a digital thermometer with a detachable probe that is kept in a glycol-filled bottle. NIST studies found that these probes in glycol-filled bottles can determine the actual temperature of the vaccine vial temperature when it is placed in the same area where the vaccine is stored.

Use DDLs with the following features:

- ❑ Detachable probe that best reflects vaccine temperatures (e.g., a probe buffered with glycol, glass beads, sand, or Teflon®)
- ❑ Alarm for out-of-range temperatures
- ❑ Low-battery indicator
- ❑ Current, minimum, and maximum temperature display‡
- ❑ Recommended uncertainty of +/-0.5° C (+/-1° F)
- ❑ Logging interval (or reading rate) that can be programmed by the user to measure and record temperatures at least every 30 minutes

Use DDLs with a current and valid Certificate of Calibration Testing.

Monitoring & Recording Temperatures

- Manually confirm the temperature of ALL vaccine storage units a minimum of **TWO** times a day – once at the beginning of the workday and once at the end of the workday

- Applies regardless of whether or not there is a 24-hour/7-day temperature alarm system, chart recorder thermometer, or a digital data logger

THERE IS NO SUBSTITUTE FOR MANUALLY CHECKING/ DOCUMENTING THE TEMPERATURE TWICE A DAY

- Document the date, time, and temperature on a vaccine log

- Pay special attention to any trend in deviation of temperature as this could indicate a possible future mechanical malfunction or power outage of the storage unit

Temperature Monitoring

DHA TEMPERATURE LOG FOR REFRIGERATOR - CELSIUS DAYS 1-15 | Month/Year | Facility Name

Monitor temperatures closely!

1. Write your initials below in "Staff Initials," and note the time in "Exact Time."
2. Record temps twice each workday.
3. Record the min/max temps once each workday - preferably in the morning.
4. Put an "X" in the row that corresponds to the refrigerator's temperature.
5. If any out-of-range temp, see instructions to the right.
6. Reminder to perform monthly alarm system testing and document the temperature in the"out- of-range" block below and complete the remaining portion on the back.

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

1. Do not leave vaccine/TSMP in non-functioning storage unit or in inappropriate storage conditions. Immediately move the vaccine/TSMP to a working storage unit at proper temperature.
2. Label exposed vaccine/TSMP "do not use," and place them in a separate container apart from other products in the storage unit.
3. Do not discard vaccine/TSMP unless directed to by *DLA-TSM and/or *USAMMA-DOC.
4. Notify your TSMP coordinator, and call your Immunization Healthcare Specialist for guidance.
5. Document the action taken on a PC-TSMP worksheet (*DHA 177*). A link to the form can be found at www.health.mil/coldchain.

Day of Month	1		2		3		4		5		6		7		8		9		10		11		12		13		14		15	
Staff Initials																														
Exact Time	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
Min/Max Temp (*since previous reading*)	Min	Max	Min	Max	Min	Max	Min	Max	Min	Max	Min	Max	Min	Max	Min	Max	Min	Max	Min	Max	Min	Max	Min	Max	Min	Max	Min	Max	Min	Max

Danger! Temps above 8˚C are too warm! Write any out-of-range temps and room temp on the lines below and contact DLA-TSM and/or USAMMA -DOC immediately!

Temperatures	8˚C	
	7˚C	
	6˚C	
Aim for 5˚	5˚C	
	4˚C	
Acceptable	3˚C	
	2˚C	

Danger! Temps below 2˚C are too cold! Write any out-of-range temps and room temp on the lines below and contact DLA-TSM and/or USAMMA-DOC immediately!

	Write any out-of-range temps (*above 8˚C or below 2˚C*) here.	
on	Room Temperature*	

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/TSMP storage issue, also complete a PC-TSMP worksheet (*DHA Form 177*). A link to the form can be found at www.health.mil/coldchain.

*DLA-TSM CCM Team Phone: (215) 737-5537/5365, DSN (444), Urgent after hours: (215) 284-6586, email: DSCPColdChain@dla.mil or paacoldchainteam@dla.mil

*USAMMA/DOC Phone: (301) 619-4318/3017, DSN (343), Urgent after hours: (301) 676-1184/0808, email: usarmy.detrick.usamma.mbx.doc@army.mil

DHA FORM 303, OCT 2022

Page 1 of 4
AEM Designer 6.5

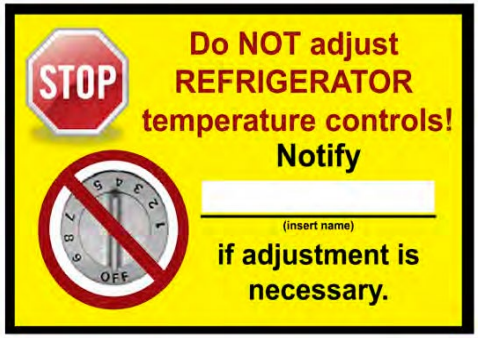
DHA Temperature logs available at Vaccine Storage and Handling | Health.mil

"Globally Responsive – Ready and Resilient"

Protecting the Power Supply

- Avoid using power outlets with built-in circuit switches, power switches, or outlets that can be activated by a wall switch
- Use a safety-lock plug or an outlet cover to reduce the chance of a storage unit becoming inadvertently unplugged
- Post a warning sign at the plug and on the refrigerator and freezer unit as well as label fuses and circuit breakers to alert people not to turn off the power to the storage unit

- Labels/SOPs should include who to call and the steps to take if the power is interrupted and checked periodically by the TSMP coordinator



Safeguarding Alarming Devices

- Alarms should be monitored electronically and physically 24 hours a day, seven days a week – **NO EXCEPTIONS**
- At the time of a power failure the system should
  - **IMMEDIATELY** notify an accountable person
  - The system should be able to provide continuous temperature monitoring in order to verify that the integrity of the vaccine stayed within the proper temperature during storage.
- **Monthly** testing of the entire system insures POCs and phone numbers are accurate
  - records should be kept for three years
- Backup generators should be capable to run for 72 hours

Safeguarding TSMPs

- Store vaccines on the middle shelves **NEVER** store vaccines on the doors or vegetable bins
- Proper air circulation is imperative – leave adequate space between packages to maintain proper air flow
- Proper storage of vials within the storage unit
  - eliminates the wrong type of vaccine being administered
  - monthly inventory more accurate
  - expiration and tracking of the vaccine easier
- Store each vaccine in its own labeled section
- Bins and/or baskets with slotted sides should also be labeled
- Verify the type of vaccine and expiration date before administrating

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

Receiving TSMP Shipments

- Upon delivery – open the package as soon as possible
  - Verify that the amount received matches the packing slip
  - Check the expiration dates on the vaccines (using the shortest-dated vaccine first)
  - **DO NOT** refrigerate shipping container with material **SEALED** inside.
    - •Failure to comply may result in freezing, destroying the material.
  - Refrigerate vaccines in their original box – removing exposes the vaccine to room temperature and light
  - Immediately place vaccine in the proper storage container within the refrigerator/freezer

Anthrax Vaccine/Smallpox Vaccine/Adenovirus Vaccine

Once the box is delivered, call USAMMA DOC immediately, a case manager will instruct you to read the TempTale, place it in the appropriate return envelope, pending the digital reading from the TempTale will determine if the vaccine is ‘verbally released’ or suspended

TSMP Inventory Management

- Identify and be accurate when ordering a supply of vaccines
- Disposal of expired vaccine leads to costly waste of taxpayer's money
- Vaccines are expensive and the cost is continuously rising
- **DO NOT OVERSTOCK** vaccine, if a compromise occurs there is a risk of losing a large amount of vaccine
- Monitor vaccine usage and rotate stock

TSMP Transport Procedures

Protecting Vaccines at Off-Site Immunizations Sessions

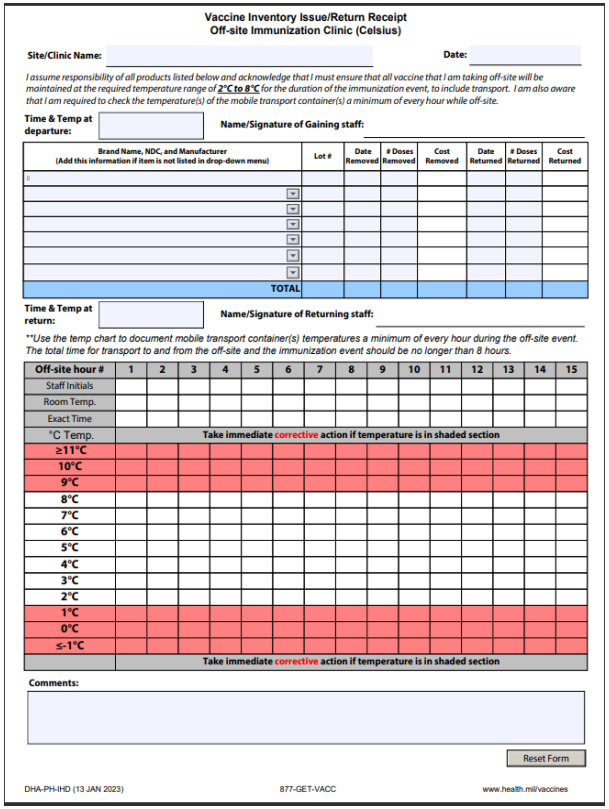
- ❑ Pack only the expected amount that will be used during the immunization session

- ❑ Minimize the number of times the container is opened

- ❑ Transport vaccine in an approved/validated insulated container **ONLY**.
  - No brown paper bags
  - No uncertified Styrofoam coolers

- ❑ Vaccines taken to an off-site clinic
  - fill out an issue receipt/number/type of vials taken
  - vaccine must be maintained at proper temperature

- ❑ Returning vaccine
  - document the number/type of vials returned
  - verify the vaccine was maintained at proper temperature



Vaccine Inventory Issue/Return Receipt
Off-site Immunization Clinic (Celsius)

Site/Clinic Name: **Date:**

*I assume responsibility of all products listed below and acknowledge that I must ensure that all vaccine that I am taking off-site will be maintained at the required temperature range of **2°C to 8°C** for the duration of the immunization event, to include transport. I am also aware that I am required to check the temperature(s) of the mobile transport container(s) a minimum of every hour while off-site.*

Time & Temp at departure: **Name/Signature of Gaining staff:**

Brand Name, NDC, and Manufacturer (Add this information if item is not listed in drop-down menu)	Lot #	Date Removed	# Doses Removed	Cost Removed	Date Returned	# Doses Returned	Cost Returned
1.							
TOTAL							

Time & Temp at return: **Name/Signature of Returning staff:**

***Use the temp chart to document mobile transport container(s) temperatures a minimum of every hour during the off-site event. The total time for transport to and from the off-site and the immunization event should be no longer than 8 hours.*

Off-site hour #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Staff Initials															
Room Temp.															
Exact Time															
°C Temp.	Take immediate corrective action if temperature is in shaded section														
≥11°C															
10°C															
9°C															
8°C															
7°C															
6°C															
5°C															
4°C															
3°C															
2°C															
1°C															
0°C															
≤-1°C															
	Take immediate corrective action if temperature is in shaded section														

Comments:

Reset Form

DHA-PH-IHD (13 JAN 2023) 877-GET-VACC www.health.mil/vaccines

"Globally Responsive – Ready and Resilient"

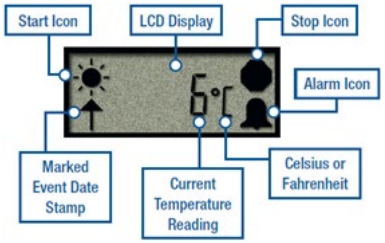
DoD Approved Equipment Used for Cold Chain Distribution

"Globally Responsive – Ready and Resilient"

CCM Equipment - Temperature Monitors

The TempTale multiple use temperature monitor system provides complete time and temperature history on all of our temperature sensitive product shipments. Data collected is used to validate that the products have preserved their integrity during distribution from the manufacturer to the end user. The TempTale temperature monitor is manufactured by Sensitech, Inc. This device can be set to read every ten (10) minutes for approximately two (2) weeks and record 2,000 data points

TempTale®4 Reader
Downloads time-and-temperature data
recorded by the monitor to your PC.



"Globally Responsive – Ready and Resilient"

CCM Equipment Insulated Shipping Container

- The Insulated shipping container (endurotherm box) is used to ensure the cold chain distribution process is not broken during transporting TSMP's.
- There are four different sizes: small, medium, large and extra large. The boxes have gone through various testing protocols, and they can maintain the required temperature guarantee for 3 days and depending upon environment up to 7 days.

AcuTemp PX6L Courier

No Longer available on ECAT.

Purchase: Medex Supply

MFR Name: CSAFE GLOBAL
https://medexsupply.com/mobility/walker-accessories/carry-pouches-baskets/

MFR Part #: PX6L-S-2-8-12 or PX6L-S-2-8-48

Nomenclature: AcuTemp Courier PX6L Seasonal Refrigeration (Summer) . (12HR or 48 HR)

Refrigerant: PCM Belts (patent pending)
Payload Temp: 2-8°C
Performance: 12 hours or 48 hours

Outer Dimensions
LxWxH Inches: 13 x 13 x 11.3

Inside Dimensions
LxWxH Inches: 10.75 x 10.75 x 8

Payload Dimensions
LxWxH Inches: 8 x 8 x 8

Total Weight lbs (kg): 13.8 (6.27)

Holds approximately 88 vials

Acutemp® PX6L Packing Protocols

AcuTemp a CSafe brand

Temperature-Sensitive Courier
12-hour 2°C - 8°C User Information

Packing Instructions

1. Place instruction card in plastic sleeve located on the inside lid of the courier.
2. Freeze(blue)/refrigerate(white) belts for a least 24 hours. Lay belts flat/not folded
3. Place the freezer belt into the insulated courier, lining the four walls.
4. Place the refrigerated belt into the insulated courier, lining the freezer belt.
5. Load product into payload area. **DO NOT add additional gel packs**
6. Place an a appropriate data logger, **TempTale monitor**, into the courier
7. Close and zip the lid of the courier.
8. **Do not** use temperature-sensitive product if you notice the belts are not properly refrigerated/frozen (blue belts must be frozen and white belts must be refrigerated) when packing the courier.
9. Use the courier to transport refrigerated product for up to 12 hours.
10. Properly lift courier to/from vehicle.

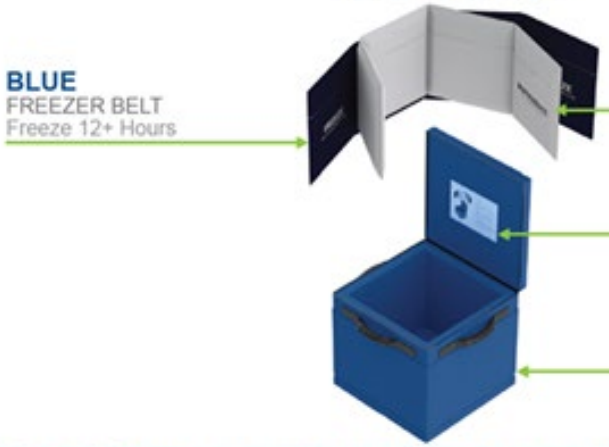
Liz version 4-20-23

2900 Dryden Road, Dayton, Ohio 45439 USA • Tel. 1.866.312.0114 • Fax. 937.312.1277

AcuTemp a CSafe brand

Temperature-Sensitive Courier
12-hour 2°C - 8°C User Information

2°C - 8°C Pack Out



2900 Dryden Road, Dayton, Ohio 45439 USA • Tel. 1.866.312.0114 • Fax. 937.312.1277

"Globally Responsive – Ready and Resilient"

AcuTemp AX56L Mobile Refrigerator/Freezer

NSN: 4110-01-629-9593 (Item is on the DLA Medical Master Catalog and can be ordered via ECAT.)

MFR Name: CSAFE GLOBAL

MFR Part #: HMC-MIL-1

Nomenclature: Refrigerator-Freezer, Mechanical

The AX56L is CE certified and registered with the FDA to adhere to 21 CFR Part 820 and is a 510(K) exempt Class II medical device.

Temperature Range:
Operating: -20°C to 49°C (-4°F to 120°F)
Storage: -30°C to 65°C (-22°F to 149°F)

Payload Volume: 56.6 liters (2 ft3)
Payload Dimensions (LxWxH): 18 in x 14 in x 13 in
External Dimensions (LxWxH): (39.2 in x 23.2 in x 22.8 in)

Empty Weight: 65.9 kg (145.0 lbs)

Data logging technology to monitor and verify payload temperature – aiding regulatory compliance

Payload safety alarm system

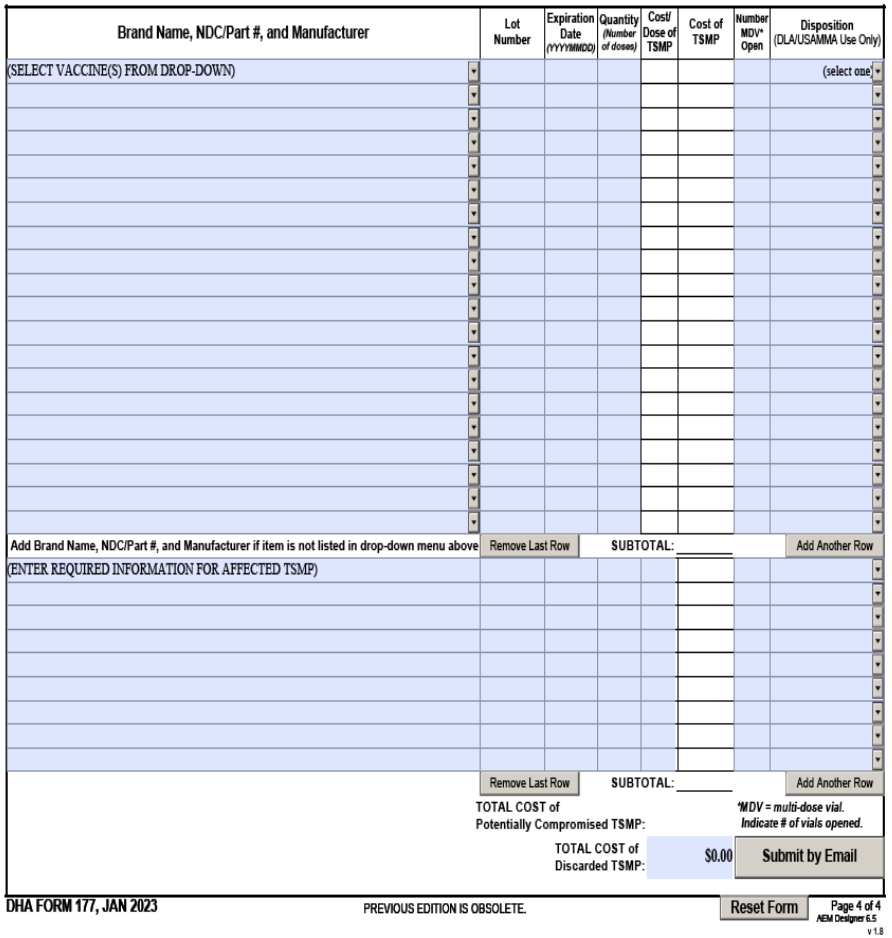
Highly visible LCD display shows internal temperature, battery condition and data log information

"Globally Responsive – Ready and Resilient"

Responding to TSMP Storage and Handling Problems

Potentially Compromised Vaccine Procedures

- Ensure that the vaccines are placed in a working refrigerator and/or freezer
- Label the vaccines with the words **"DO NOT USE"**
- **DO NOT** destroy the vaccines
- Complete a Potentially Compromised Vaccine Response Worksheet
- Contact USAMMA DOC as well as your Immunization Healthcare Specialist and stand-by for further instructions
- Prepare an Executive Summary (EXSUM) if Command requires
- A refrigerator and/or freezer should have a stabilized temperature and power supply for at least 24hrs before vaccines are placed back in the unit



Brand Name, NDC/Part #, and Manufacturer	Lot Number	Expiration Date (YYYYMMDD)	Quantity (Number of doses)	Cost/ Dose of TSMP	Cost of TSMP	Number MDV* Open	Disposition (DLA/USAMMA Use Only)
(SELECT VACCINE(S) FROM DROP-DOWN)							(select one)

Add Brand Name, NDC/Part #, and Manufacturer if item is not listed in drop-down menu above | Remove Last Row | SUBTOTAL: | Add Another Row

(ENTER REQUIRED INFORMATION FOR AFFECTED TSMP)

Remove Last Row | SUBTOTAL: | Add Another Row

TOTAL COST of Potentially Compromised TSMP:

*MDV = multi-dose vial. Indicate # of vials opened.

TOTAL COST of Discarded TSMP: $0.00

Submit by Email

DHA FORM 177, JAN 2023 PREVIOUS EDITION IS OBSOLETE. Reset Form Page 4 of 4 AEM Designer 6.5 v 1.8

https://www.amlc.army.mil/USAMMA/Logistics/Distribution-Operations-Center-Vaccine/Cold-Chain-Management/Potentially-Compromised-Vaccine-Info/

TSMP's DISPOSAL

- DoD activities are responsible for disposal of compromised or expired vaccines
- Destruction memorandums pertaining to Anthrax, Smallpox, Adenovirus, VIGIV and Army Influenza vaccines should be routed up the chain of command for review and endorsement before scanning and emailing to usarmy.detrick.usamma.doc@army.mil.

Methods of Destruction:

- Vaccine vials can be destroyed using the local hospital clinics disposal procedures for all biohazard/hazard materials
- Can be disposed using return programs when applicable
- Disposition instructions available: https://www.amlc.army.mil/Portals/73/Documents/Vaccine_Disposition_SOP_10Feb2017.pdf?ver=2020-07-07-145709-637

TSMP Issues, Responses and Prevention Strategies

Properly stored

Can you spot the difference?

Improperly stored

TSMP Issues

Three categories of issues may lead to compromised vaccines:

- **Non-Preventable Loss**
  - Equipment/Alarm system failure
  - Power outage during a natural disaster/storm
- **Negligence**
  - Refrigerated vaccines placed in freezer; frozen vaccines placed in refrigerator
  - Storage unit unplugged
  - Vaccines not returned to a storage unit
  - Alarm batteries not charged
- **Non-Compliance**
  - No validated packing/transport equipment available
  - No temperature log was posted on storage unit
  - Staff did not record temperatures on temperature log
  - Emergency plan was not current or not properly followed

Example # 1

Site received notification at 0636 via text message that refrigerator alarm was going off. At 0910, POC checked unit and noticed that the temperature had been out of range for about 3 hours. Upon further inquiry, site POC learned that the loss of power to the unit was the result of a scheduled outage and the storage unit location housing the vaccines was not connected to emergency back-up power. Refrigerator was restored at 1245 and reached appropriate temperature range by 1310. Vaccines remained in the unit for the entire time that the power was off and temperature out of range, no attempt to relocate vaccines was made.

Total value: $25,699.58

Negligence	**Delayed response time after alarm.** ✓ Please attend to your vaccines as quickly as possible after notification that it may have gone out of range.
Negligence	**No backup power during a scheduled power outage .** ✓ Ensure the unit has a back-up power source and test monthly. ✓ Plan for a scheduled outage and move vaccines to a designated temporary storage facility.
Non-Compliance	**Vaccines were not relocated to a working refrigerator.** ✓ In a potentially compromised vaccine event, immediately label all vaccines as “do not use” and move to alternate storage location.

Example # 2

Immunizations were delivered to Pharmacy in a shipping container packed with gel packs early in the morning but were never placed in immunization refrigerator. Vaccines remained in shipping containers for approximately 30 hours before any of the staff noticed. Immediately transferred to refrigerator at 5*C.

Total value: $62,136.24

Negligence	**Vaccines left out of storage unit.**
	✓ Ensure personnel pay close attention to TSMP items being delivered to location. ✓ POC who discovered the compromise responded appropriately by immediately moving vaccine to the proper storage unit and following Potentially Compromised Vaccine Event steps. ✓ Emergency Storage & Handling plan had clear instructions on who to contact and steps to take.

Example # 3

Refrigerator alarmed at 1700 and alarm facility paged two on-duty personnel. One pager was on mute and the other was not acknowledged. After an hour of no acknowledgment, alarm facility monitor called the clinic to notify about the temperature being out of range. Technicians found the thermometers fluid bath had leaked resulting in the compressor to malfunction and freeze.

Total value: $157,170.98

Non-Preventable Loss	**Compressor malfunction.**
	✓ Establish routine maintenance procedures for storage units.

Non-Compliance	**Appropriate POCs could not be reached by alarm facility.**
	✓Alarm alerts should be set up to notify POCs through multiple devices (i.e work phone, after duty phone, email, mobile phone).

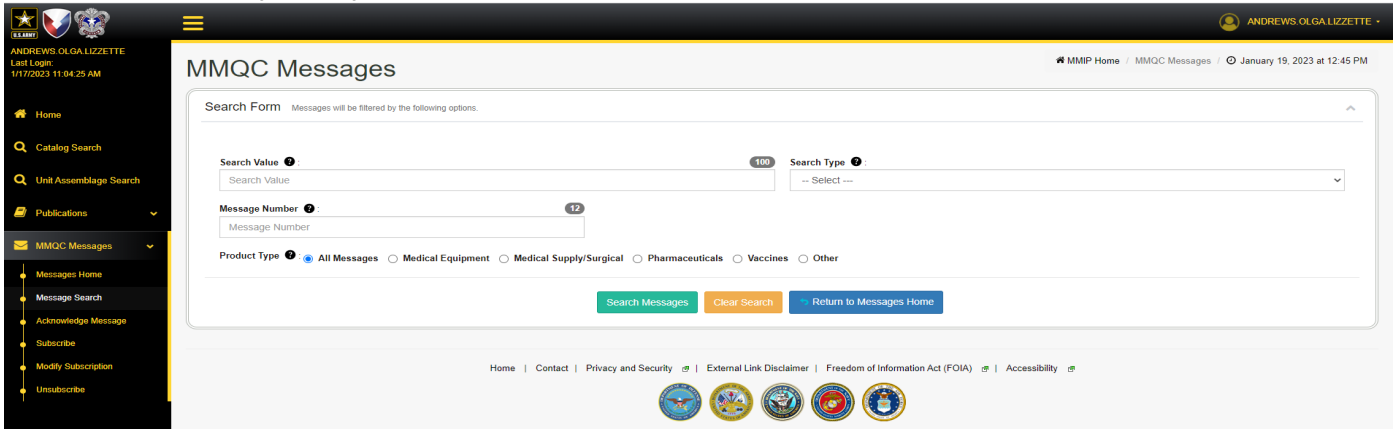
USAMMA Website/Cold Chain Links

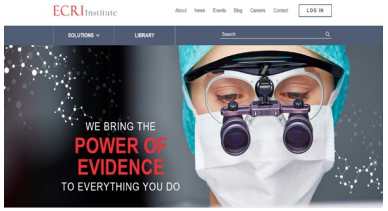
https://www.amlc.army.mil/USAMMA/Logistics/Distribution-Operations-Center-Vaccine/

MMQC Messages

USAMMA's Distribution Operations Center (USAMMA DOC) primary focus with the DoD MMQC messages is to support the service specific logisticians, supply managers, and/or pharmacists in assuring the proper suspension of use, handling, and return of recalled materiel is accomplished. USAMMA DOC is responsible for disseminating MMQC on behalf of the Defense Logistics Agency in support of the combat combatant leaders, deployed service members and MHS registered customers.

MHS DMLSS USER: March 2019 DHA MEDLOG has established the ECRI Hazard Alerts and Recalls (HAR) Notifications.





https://www.amlc.army.mil/USAMMA/Distribution-Operations-Center-Vaccine/MMQC-Messages-and-MMI-Info/

Point of Contact Information

USAMMA DOC: 301-619-4318

After Hours: 301-676-1184.

TEAMS GROUP NUMBER: 571-644-7893

DLA-TSM Cold Chain Team: 215-737-5537/5365, DSN: 444-5537/5365, or for URGENT **after-hours issues only: 267-738-2854**.
Email: DSCPColdchain@dla.mil and paacoldchainteam@dla.mil

DHA Vaccine Storage and Handling Questions
Call 1-877-GETVACC, Option 2 (1-877-438-8222), available 24/7
Email: DHAVaccines@health.mil

Cold Chain References/Guides

U.S. Army Medical Materiel Agency (USAMMA)/Distribution Operations Center(DOC). Available at http://www.usamma.amedd.army.mil/net/Pages/doc/coldChainManagement.aspx

Centers for Disease Control and Prevention. General Recommendations of Immunizations. Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2011; Vol. 60 (No. 2).

Centers for Disease Control and Prevention. Epidemiology and Prevention of Vaccine-Preventable Diseases (Pink Book). Atkinson W, Wolfe S, Hamborsky J, eds. 12th ed. Washington DC: Public Health Foundation, 2011; 61-74.

Centers for Disease Control and Prevention (CDC). Notice to Readers: Guidelines for Maintaining and Managing the Vaccine Cold Chain. Recommendations of the Advisory Committee on Immunization Practices. MMWR 2003; 52(42); 1023-1025.

Centers for Disease Control and Prevention, Vaccine Storage and Handling Toolkit. Available at http://www.cdc.gov/vaccines/recs/storage/toolkit/default.htm

Department of the Army, MEDCOM Memorandum, "Safeguarding Temperature Sensitive Medical Products (TSMP)," dated 05 March 2010. Available at http://www.usamma.amedd.army.mil/assets/docs/SAFEGUARDING%20TSMP.PDF

SB-8-75-11, Department of the Army Medical Department Supply Bulletin. Section 3-65: Temperature Sensitive Medical Products (TSMP) Storage and Handling (pg 62) Available at http://www.usamma.amedd.army.mil/net/assets/doc/pdf/CCM/Policy_Safeguarding_TSMPs.pdf

Questions