

# Temperature Sensitive Medical Products (TSMPs)

## Good Distribution Practices (GDP)

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



***“Medically Ready Force...Ready Medical Force”***

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

**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** – DHA Immunization Healthcare Branch (formerly known as Military Vaccine Agency – Vaccine Healthcare Centers Network (MILVAX-VHCN) replaced MEDCOM as AVIP policy developer/clinical guidance

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.



DOC is also responsible for DoD Medical Materiel Quality Control (MMQC) messages. As of March 2019 USAMMA DOC is migrating our source for MMQC messages to ECRI Institute, Hazard Alerts and Recalls (HAR) Notifications.

## Message Subscription Management

Due to the upcoming migration with ECRI Institute, USAMMA is no longer accepting new subscriptions. Customer can request access and become a member of ECRI Institute to receive the Hazard Alerts and Recalls (HAR) notification. In order to do so, please complete the following form: [PDF DoD - ECRI User Registration20181212.pdf](#)

Once completed, please submit to your perspective agency for approval listed below:

READ ONLY ACCESS: Customers requesting read only access can submit their forms directly via email to: [usarmy.detrick.medcom-usamma.mbx.quad-service-mmqc@mail.mil](mailto:usarmy.detrick.medcom-usamma.mbx.quad-service-mmqc@mail.mil).

## POC for submission of ECRI Request (other than Read Only):

### AIRFORCE

Email: [usaf.detrick.afmoa.mbx.sgmp-scs-alerts@mail.mil](mailto:usaf.detrick.afmoa.mbx.sgmp-scs-alerts@mail.mil)

### Army

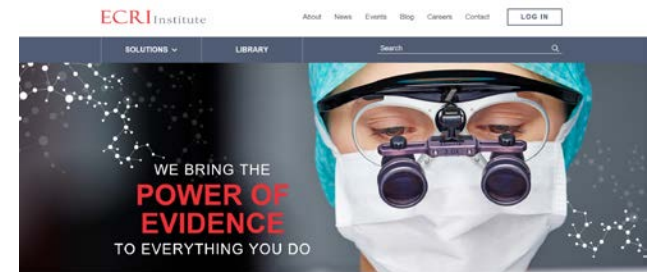
Email: [usarmy.detrick.medcom-usamma.mbx.quad-service-mmqc@mail.mil](mailto:usarmy.detrick.medcom-usamma.mbx.quad-service-mmqc@mail.mil)

### Navy/Marines

Email: [usn.detrick.navmedlogcomftdmd.list.mmqc@mail.mil](mailto:usn.detrick.navmedlogcomftdmd.list.mmqc@mail.mil)

### Coast Guard

Email: [daniel.L.Hasenfang@uscg.mil](mailto:daniel.L.Hasenfang@uscg.mil)



## ECRI Institute Training Guides

[Alerts Tracking User](#)

[Alerts Tracker Reference Guide.pdf](#)

[Alerts Tracking Coordinator](#)

***“Medically Ready Force...Ready Medical Force”***

- Anthrax Vaccine
- Smallpox Vaccine (ACAM2000)
- Influenza Vaccine
- Adenovirus Vaccine (Type 4 & Type 7)
- Vaccinia Immune Globulin intravenous (VIGIV)
- 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 thousands of dollars each year in vaccine losses due to 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

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 tax payers 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



## US Pharmacopeia (USP) Temperature Standards

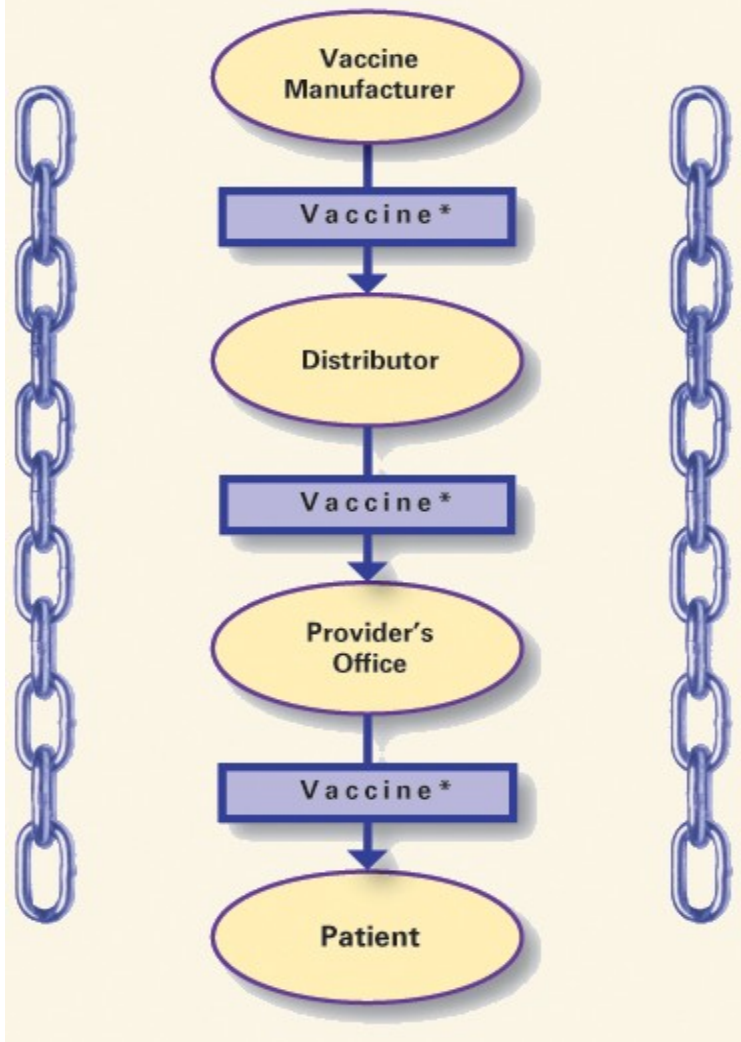
- Refrigerated Storage - Thermostatically controlled from 2°C to 8°C; approximately 35°F to 46°F
- Frozen Storage - Thermostatically controlled from -20°C to -10°C; approximately -4°F to 14°F
- Room Temperature - Thermostatically controlled from 20°C to 25°C; approximately 68°F to 77°F

Always follow Manufacturer's Package insert.

Cold chain begins with the cold storage unit at the vaccine manufacturing plant

Extends through the transfer of vaccine to the distributor

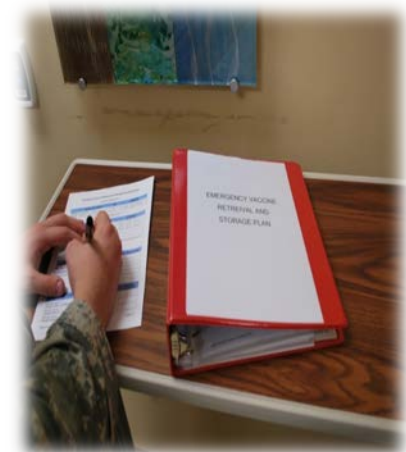
The Chain is most Compromised at the point of 'Provider to Patient'



## Responsible for:

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

- ✓ Current contact information for the primary and back-up vaccine coordinators
- ✓ Pharmacy, logistics, local Immunization Healthcare Specialist (formerly known as Regional Analysts), USAMMA
- ✓ Vaccine manufacturers, the medical equipment repair 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)676-0808/1184
  - Defense Logistics Agency – (215)737-6658 – (215) 284-6586
  - DHA IHB 24/7 Vaccine related clinical consultation (877) GETVACC (438-822) (Option 1)
  - Immunization Healthcare Specialist

EMERGENCY VACCINE RETRIEVAL AND STORAGE PLAN WORKSHEET

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

Emergency Staff Contact List			
Name	Title	Telephone Numbers home/cell/other	Email Address

Emergency Resources Contact List			
Emergency Resource Name	Contact Person (Title)	Telephone Numbers home/cell/other	Email Address
U.S. Army Medical Materiel Agency (USAMMA-DOC) <a href="http://www.usamma.army.mil/Pages/DOC-Home.aspx">www.usamma.army.mil/Pages/DOC-Home.aspx</a>	Operations Manager	301-619-4518/3017, DSN 343-4318/3017 After hour emergency: 301-676-1184/0808	usarmy.detrick.medcom- usamma.mba.doc@gmail.com
Defense Logistics Agency-Troop Support Medical (DLA-TSM) <a href="http://www.medical.dla.mil/DWAN/Home/contact">http://www.medical.dla.mil/DWAN/Home/contact</a>	Cold Chain Program Manager	215-757-5557/5565 DSN: 444-5557/5565	OSCPColdchain@dlm.mil oscpcoldchainbeam@dlm.mil
Medical Equipment Maintenance Office			
Generator Repair Company			
Storage Unit Repair Company			
Temperature Monitoring System Company			
Electric Power Company			

Emergency Resources and Packing Material Suppliers Contact List			
Emergency Resource Name	Contact Person Name/Title	Telephone Numbers home/cell/other	Email Address
Portable vaccine refrigerator/freezer units			
Qualified containers and pack-out materials			
Packing materials			
Coolant packs			

DHA-IHB (10 Jul 18) 877-GET-VACC [www.health.mil/vaccines](http://www.health.mil/vaccines)

## Storage Unit Selection and Characteristics

- Medical 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 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



- 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

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



Based on studies of thermometers conducted by NIST in 2012, the CDC recommends using a digital data logger thermometer with a detachable buffered temperature probe. 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.

- At least one reading/15 min
- Memory storage : \*39 days recording
- Battery life: 6 months minimum



- 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



- 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



- 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

- Identify and be accurate when ordering a supply of vaccines
- Disposal of expired vaccine leads to costly waste of taxpayers 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

- 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)
  - 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

- 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 administering



## 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



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





- 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.

## PERFORMANCE OF ACUTEMP PXC (+7°C)

- **AcuTemp PXC (+7°C)** is a safe replacement for ice to keep vaccines and other temperature sensitive goods cold in the **AcuTemp PX1L** without accidental freezing.
- Used according to the instructions, the **AcuTemp PX1L** system will maintain vaccines/products between 2-8°C (35 – 46°F) for more than 20 hours at an ambient temperature of 24°C (75°F).
- As the ambient temperature increases, the hold time will decrease:
  - a. 15 hours @ 30°C (86°F)
  - b. 12 hours @ 37°C (99°F)
  - c. 9 hours @ 48°C (118°F)



**PXC (+7°C) must be chilled at 3°C (±1°C) for 24 hours.**



**A maximum of 24 vials can be placed in the VaxiPac (a full layer consists of 12 vials).**



**When placing PXC's in the PX1L, be sure to keep the pull-tab "UP" so that the pack can be removed easily**

- Handheld container for small-scale transportation of TSMPs
- Holds approximately 88 vials
- Used according to the instructions, the AcuTemp PX6L will maintain vaccines/products between 2-8°C (35 – 46°F) for up to 48 hours at an ambient temperature of 24°C (75°F).



\*\*Comes with a carrying strap and handle for ease of transportation



The AcuTemp AX27L mobile refrigerator/freezer addresses the need for a small, non-chlorofluorocarbon refrigeration unit that offers energy efficiency, precision temperature control and easy portability. With a 27 liter payload capacity and two temperature set-points (+4°C or -22°C) to accommodate payloads requiring refrigeration or freezing, this mobile thermal management unit is designed to safely transport and store temperature-sensitive vaccines, drugs, specimens and other bio-medical materials

## Power Sources

Grid power (standard): 115 VAC or 230 VAC, 50-60 Hz

Battery (standard): Two 21 amp. hr. gel cell batteries

Car lighter outlet (available): 12 VDC

This versatile cold chain solution is capable of operating for up to five days on battery power only, making it perfect for global distribution of small, temperature-sensitive loads

Payload Volume:  
27 liters (1 ft 3 in)

Payload Dimensions  
(H x W x L): 26.7 cm x  
27.3 cm x 37.5 cm  
(10.5 in x 10.75 in x  
14.75 in)

Tare Weight: 52  
kg (114.4 lb)



## 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 (formerly known as MILVAX Regional Analyst (RA) 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



## Potentially Compromised (PC) Vaccine

1. If a vaccine compromise has been identified, move the vaccine to a working refrigerator/freezer and label as **"DO NOT USE."** [Steps to Take for Potentially Compromised Vaccines.pdf](#)
2. Contact your [Immunization Healthcare Specialist \(IHS\)](#) for assistance with the reporting process for potentially compromise vaccine. To find the IHS for your region, you can use the Immunization Clinic Finder by searching for and then selecting your clinic site.
3. Download and save the [PC-TSMP Worksheet.pdf](#) to your system. If you need additional space to list vaccine, please download the [PC-TSMP Worksheet Continuation.pdf](#)
4. Complete worksheet to include vaccine inventory, temp log data, and circumstances surrounding loss.
5. Click "Submit by Email" button at the bottom of completed worksheet. This will send your form to USAMMA and your DHA Immunization Healthcare Branch IHS.
6. Stand-by for vaccine disposition from USAMMA; do not use or discard vaccine. If released for use, place back in a verified working refrigerator/freezer. If not released, report loss per command/local policy and prepare destruction memorandum to destroy vaccine per local/state policy ([Vaccine Disposition SOP 2017.pdf](#))



**PC-TSMP Worksheet**

Date: [ ] Site/Clinic Name/Address: [ ]  
 County/City: [ ] Site/Clinic Type: [ ] State: [ ]  
 Phone: [ ] Fax: [ ]  
 Required temperature and storage unit information: [ ]  
 1a. Temp recorded in F or C: [ ] 1b. Vaccine/Other TSMP left out of refrigerator or freezer? [ ] Room temperature where vaccine/other TSMP located? [ ]  
 1c. Vaccine/Other TSMP stored in proper storage unit and under no freeze? [ ] 1d. If 1b, 1c, 1d, 1e, 1f, 1g, 1h, 1i, 1j, 1k, 1l, 1m, 1n, 1o, 1p, 1q, 1r, 1s, 1t, 1u, 1v, 1w, 1x, 1y, 1z, 1aa, 1ab, 1ac, 1ad, 1ae, 1af, 1ag, 1ah, 1ai, 1aj, 1ak, 1al, 1am, 1an, 1ao, 1ap, 1aq, 1ar, 1as, 1at, 1au, 1av, 1aw, 1ax, 1ay, 1az, 1ba, 1bb, 1bc, 1bd, 1be, 1bf, 1bg, 1bh, 1bi, 1bj, 1bk, 1bl, 1bm, 1bn, 1bo, 1bp, 1bq, 1br, 1bs, 1bt, 1bu, 1bv, 1bw, 1bx, 1by, 1bz, 1ca, 1cb, 1cc, 1cd, 1ce, 1cf, 1cg, 1ch, 1ci, 1cj, 1ck, 1cl, 1cm, 1cn, 1co, 1cp, 1cq, 1cr, 1cs, 1ct, 1cu, 1cv, 1cw, 1cx, 1cy, 1cz, 1da, 1db, 1dc, 1dd, 1de, 1df, 1dg, 1dh, 1di, 1dj, 1dk, 1dl, 1dm, 1dn, 1do, 1dp, 1dq, 1dr, 1ds, 1dt, 1du, 1dv, 1dw, 1dx, 1dy, 1dz, 1ea, 1eb, 1ec, 1ed, 1ee, 1ef, 1eg, 1eh, 1ei, 1ej, 1ek, 1el, 1em, 1en, 1eo, 1ep, 1eq, 1er, 1es, 1et, 1eu, 1ev, 1ew, 1ex, 1ey, 1ez, 1fa, 1fb, 1fc, 1fd, 1fe, 1ff, 1fg, 1fh, 1fi, 1fj, 1fk, 1fl, 1fm, 1fn, 1fo, 1fp, 1fq, 1fr, 1fs, 1ft, 1fu, 1fv, 1fw, 1fx, 1fy, 1fz, 1ga, 1gb, 1gc, 1gd, 1ge, 1gf, 1gg, 1gh, 1gi, 1gj, 1gk, 1gl, 1gm, 1gn, 1go, 1gp, 1gq, 1gr, 1gs, 1gt, 1gu, 1gv, 1gw, 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15h, 15i, 15j, 15k, 15l, 15m, 15n, 15o, 15p, 15q, 15r, 15s, 15t, 15u, 15v, 15w, 15x, 15y, 15z, 16a, 16b, 16c, 16d, 16e, 16f, 16g, 16h, 16i, 16j, 16k, 16l, 16m, 16n, 16o, 16p, 16q, 16r, 16s, 16t, 16u, 16v, 16w, 16x, 16y, 16z, 17a, 17b, 17c, 17d, 17e, 17f, 17g, 17h, 17i, 17j, 17k, 17l, 17m, 17n, 17o, 17p, 17q, 17r, 17s, 17t, 17u, 17v, 17w, 17x, 17y, 17z, 18a, 18b, 18c, 18d, 18e, 18f, 18g, 18h, 18i, 18j, 18k, 18l, 18m, 18n, 18o, 18p, 18q, 18r, 18s, 18t, 18u, 18v, 18w, 18x, 18y, 18z, 19a, 19b, 19c, 19d, 19e, 19f, 19g, 19h, 19i, 19j, 19k, 19l, 19m, 19n, 19o, 19p, 19q, 19r, 19s, 19t, 19u, 19v, 19w, 19x, 19y, 19z, 20a, 20b, 20c, 20d, 20e, 20f, 20g, 20h, 20i, 20j, 20k, 20l, 20m, 20n, 20o, 20p, 20q, 20r, 20s, 20t, 20u, 20v, 20w, 20x, 20y, 20z, 21a, 21b, 21c, 21d, 21e, 21f, 21g, 21h, 21i, 21j, 21k, 21l, 21m, 21n, 21o, 21p, 21q, 21r, 21s, 21t, 21u, 21v, 21w, 21x, 21y, 21z, 22a, 22b, 22c, 22d, 22e, 22f, 22g, 22h, 22i, 22j, 22k, 22l, 22m, 22n, 22o, 22p, 22q, 22r, 22s, 22t, 22u, 22v, 22w, 22x, 22y, 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69d, 69e, 69f, 69g, 69h, 69i, 69j, 69k, 69l, 69m, 69n, 69o, 69p, 69q, 69r, 69s, 69t, 69u, 69v, 69w,

- 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.medcom-usamma.mbx.doc@mail.mil](mailto:usarmy.detrick.medcom-usamma.mbx.doc@mail.mil) or faxing to (301) 619-4468.

## 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.usamma.amedd.army.mil/PublishingImages/Pages/Forms/AllItems/Vaccine%20Disposition%20SOP%202017.pdf>

# TSMP Issues, Responses and Prevention Strategies

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 A

Facts presented from an actual reported TSMP compromise with no identifying information of the facility or location.

Total dollar value vaccines

Issue	Response
	✓ Prevention strategy

## 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.

### Negligence

#### Vaccines remained in the same unit.

- ✓ In a potentially compromised vaccine event, immediately label all vaccines as “do not use” and move to alternate storage location.

## Example # 2

Site received notification at 09:35, from the Administrative Officer of the Day (AOD) who stated that temps in the fridge had been out of range all night (1600 previous evening until the next morning at 08:00). Vaccines remained in the unit for the entire time the temperatures were out of range, no attempt to relocate vaccines were made. After reviewing the OmegaView temperature charts it was noted that the temps actually went in and out of range beginning 6 days prior. Manual checks were not being completed so it was unknown until the event happened.

**Total value: \$95,204.26**

### NonCompliance

**Vaccines were not relocated to a working refrigerator.**

- ✓ Manual checks not done
- ✓ Appropriate POC's could not be reached.
- ✓ Alarm system sounded; emergency response plan not followed or out of date

### Remember!

Communication between all personnel handling vaccines is key (i.e. warehouse, clinic, off-sites clinic personnel)

## Example # 3

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. Once notified the vaccines were 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 # 4

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**

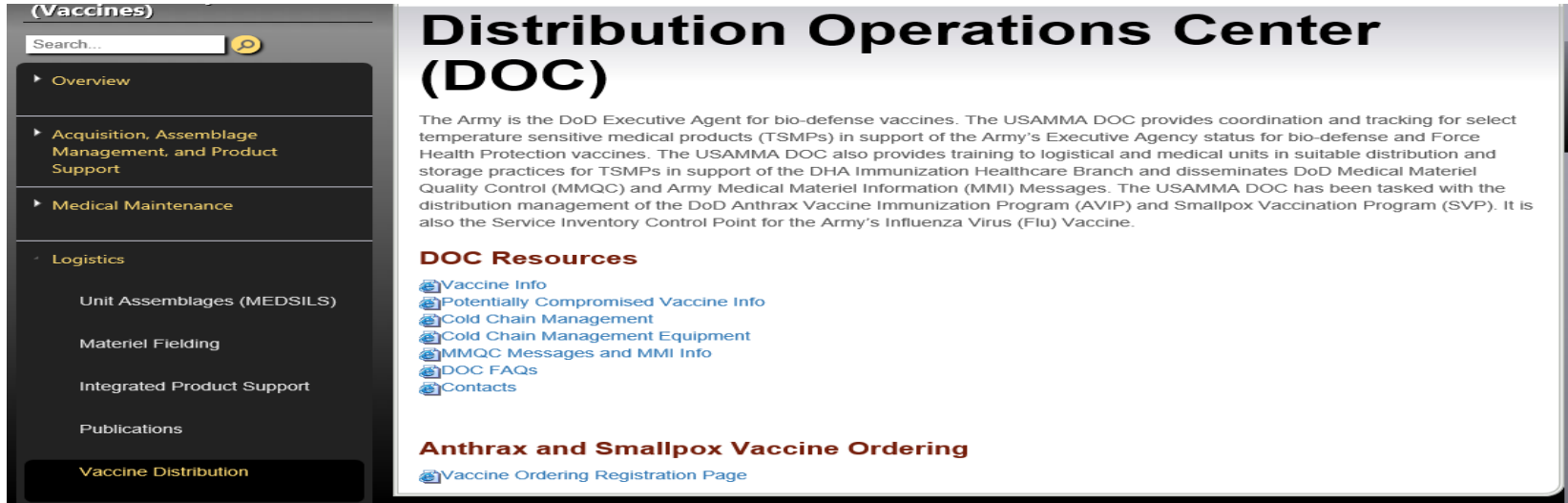
**Compressor malfunction.**

✓ 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).



**(Vaccines)**

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- Overview
- Acquisition, Assemblage Management, and Product Support
- Medical Maintenance
- Logistics
  - Unit Assemblages (MEDSILS)
  - Materiel Fielding
  - Integrated Product Support
  - Publications
  - Vaccine Distribution

## Distribution Operations Center (DOC)

The Army is the DoD Executive Agent for bio-defense vaccines. The USAMMA DOC provides coordination and tracking for select temperature sensitive medical products (TSMPs) in support of the Army's Executive Agency status for bio-defense and Force Health Protection vaccines. The USAMMA DOC also provides training to logistical and medical units in suitable distribution and storage practices for TSMPs in support of the DHA Immunization Healthcare Branch and disseminates DoD Medical Materiel Quality Control (MMQC) and Army Medical Materiel Information (MMI) Messages. The USAMMA DOC has been tasked with the distribution management of the DoD Anthrax Vaccine Immunization Program (AVIP) and Smallpox Vaccination Program (SVP). It is also the Service Inventory Control Point for the Army's Influenza Virus (Flu) Vaccine.

### DOC Resources

- Vaccine Info
- Potentially Compromised Vaccine Info
- Cold Chain Management
- Cold Chain Management Equipment
- MMQC Messages and MMI Info
- DOC FAQs
- Contacts

### Anthrax and Smallpox Vaccine Ordering

- Vaccine Ordering Registration Page

USAMMA:

<https://www.usamma.army.mil/Pages/Main01.aspx>

DOC Homepage:

<https://www.usamma.army.mil/Pages/DOC-Home.aspx>

DOC Cold Chain Management:

<https://www.usamma.army.mil/Pages/DOC-CCM.aspx>

DOC Potentially Compromised Vaccine:

<https://www.usamma.army.mil/Pages/DOC-Compromised-vaccine.aspx>

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