



United States Army Medical Materiel Agency



# Distribution Operations Center (DOC) U.S. Army Medical Materiel Agency (USAMMA)

## Cold Chain Management Briefing

Presented by

USAMMA Pharmacy Consultant  
Deputy Director for Distributions, MILVAX

September 2009





## BRIEFING OUTLINE

**PURPOSE:** Discuss, identify, and apply cold chain management principles

- Apply Cold Chain Management (CCM) principles





## Mission

USAMMA/DOC has the exclusive distribution management mission for the Department of Defense (DoD) of Anthrax and Smallpox vaccines to include other temperature-sensitive medical products (TSMPs). Additionally, we provide consultation and training on CCM principles and procedures



## Vision

To develop state-of-the-art distribution mechanisms for temperature-sensitive medical products in support of DoD objectives and to educate internal and external customers on the proper storage, receipt, and distribution of these products





## The Importance of Maintaining CCM

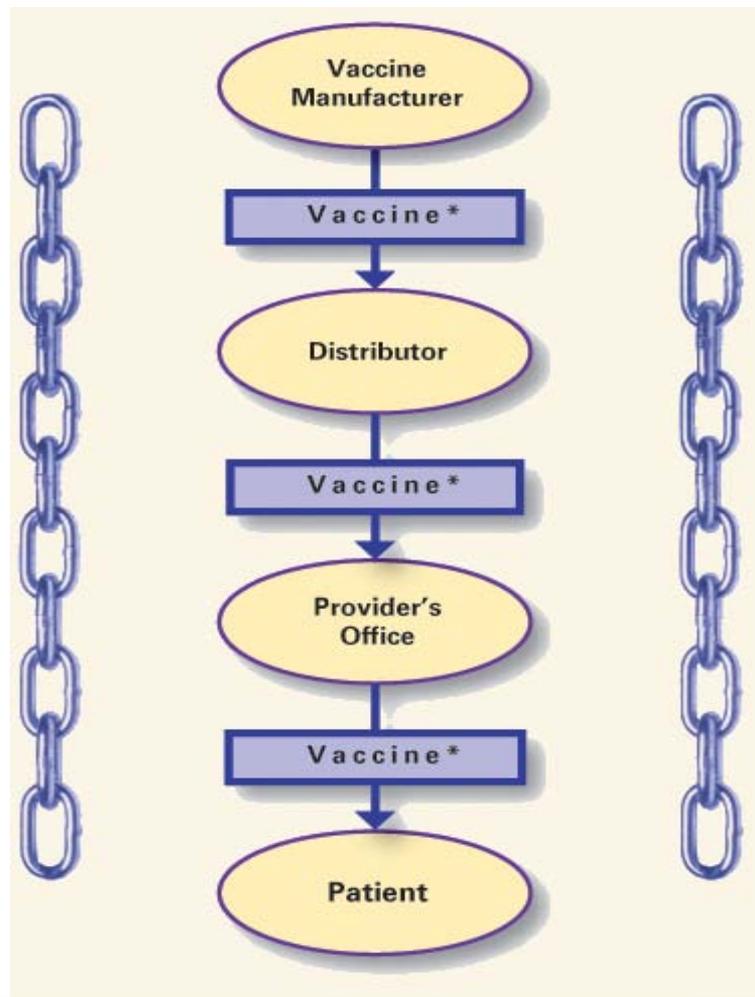
- Excessive heat or cold exposure damages vaccine, resulting in loss of potency. Once potency is lost, it can never be restored.
  
- Furthermore, each time vaccine is exposed to heat or cold, the loss of potency increases and eventually, if cold chain is not correctly maintained, all potency will be lost, and the vaccine becomes useless.
  
- Assures leadership, service members and DoD beneficiaries that vaccine/products is safe to use and fully.
  
- 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 vaccine are in critically short supply



## What Is CCM?

Cold chain begins with the cold storage unit at the vaccine manufacturing plant, extends through the transfer of vaccine to the distributor and then to the provider's office, and ends with the administration of the vaccine to the patient. Proper storage temperatures must be maintained at every link in the chain.

**\*Vaccine is transported in a refrigerated or frozen state, as appropriate (refrigerator 35°– 46°F [2°– 8°C]; freezer 5°F [-15°C] or colder), using an insulated container or a refrigerated truck.**





# 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



## Key Principles of CCM/Distribution

- Use of Validated Shipping Containers to keep products chilled at proper temperature, yet prevent **FREEZING**
- Inclusion of Temperature Monitoring Devices
- Rapid Movement of products - Partnership with Commercial Carrier Guarantees Express Delivery and asset visibility until delivery is completed
- Involvement with knowledgeable customers





## Temperature Monitoring

### Checking and Recording Temperatures at Least Twice a Day

The recommended method to ensure that a refrigerator or freezer is maintaining the proper temperature for vaccine storage is to check and record the temperature at least twice a day. This recommendation applies regardless of whether or not there is a temperature alarm, a chart recorder thermometer, or a digital data logger.

<b>TSMP Storage Log</b>				<b>Month: Current</b>		
					<b>Location: Clinic #3</b>	
<b>Date</b>	<b>Time</b>	<b>Temperature</b>	<b>Intial</b>	<b>Time</b>	<b>Temperature</b>	<b>Intial</b>
1	0700hrs	4°C	DD	1700hrs	4°C	DD
2	0710hrs	4°C	DD	1700hrs	4°C	DD
3	0700hrs	3°C	DD	1645hrs	4°C	DD
4	0710hrs	4°C	DD	1705hrs	5°C	DD
5	0700hrs	5°C	DD	1800hrs	3°C	DD
6	0710hrs	4°C	DD	1700hrs	4°C	DD
7	0706hrs	5°C	DD	1700hrs	5°C	DD
8	0711hrs	3°C	DD	1645hrs	6°C	DD
9	0700hrs	4°C	DD	1705hrs	3°C	DD
10	0710hrs	6°C	DD	1800hrs	4°C	DD
11	0700hrs	4°C	DD	1645hrs	5°C	DD



# Safeguards that can be Implemented to Protect TSMPs

- Training
- Cooperation need with multiple disciplines
- Proper temperature monitoring
- Manual Checks and audible temperature alarm systems on a 24-hour basis
- SRP sites should have minimal stocks
- Alternate backup power for refers/freezers
- Proper labeling of refers/freezers
- Split stocks if possible
- Rotate stocks





# Safeguards that can be Implemented to Protect TSMPs cont...

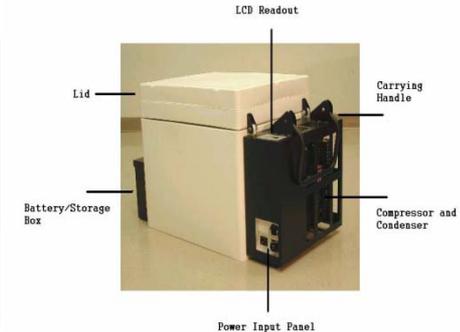
**Standard Operating Procedures (SOP) must be developed with contact information for the following:**

- Logistics, Pharmacy, Provost Marshal and Medical Maintenance personnel
- Refrigerator repair technicians
- Back-up storage areas
- Temperature alarm repair technician
- Dry Ice vendors
- Emergency repair companies
- Vaccine Manufacturers



## Equipment used to support CCM

- Validated shipping containers/boxes
- Temperature monitoring devices
- Gel packs (coolants/refrigerants)
- Packing Protocols
- Audible alarms



## Endurotherm Boxes



Validated shipping containers and packing protocols  
assures product safety and efficacy

## Refrigerants

Polar Gel packs are coolant or refrigerants used to maintain desired temperature levels (refrigerated or frozen) inside the Endurotherm boxes during shipping. When packing refrigerated products gel packs must be refrigerated at +4 Celsius and for frozen products the temperature should be at -21 Celsius for at least 24 hours prior use.

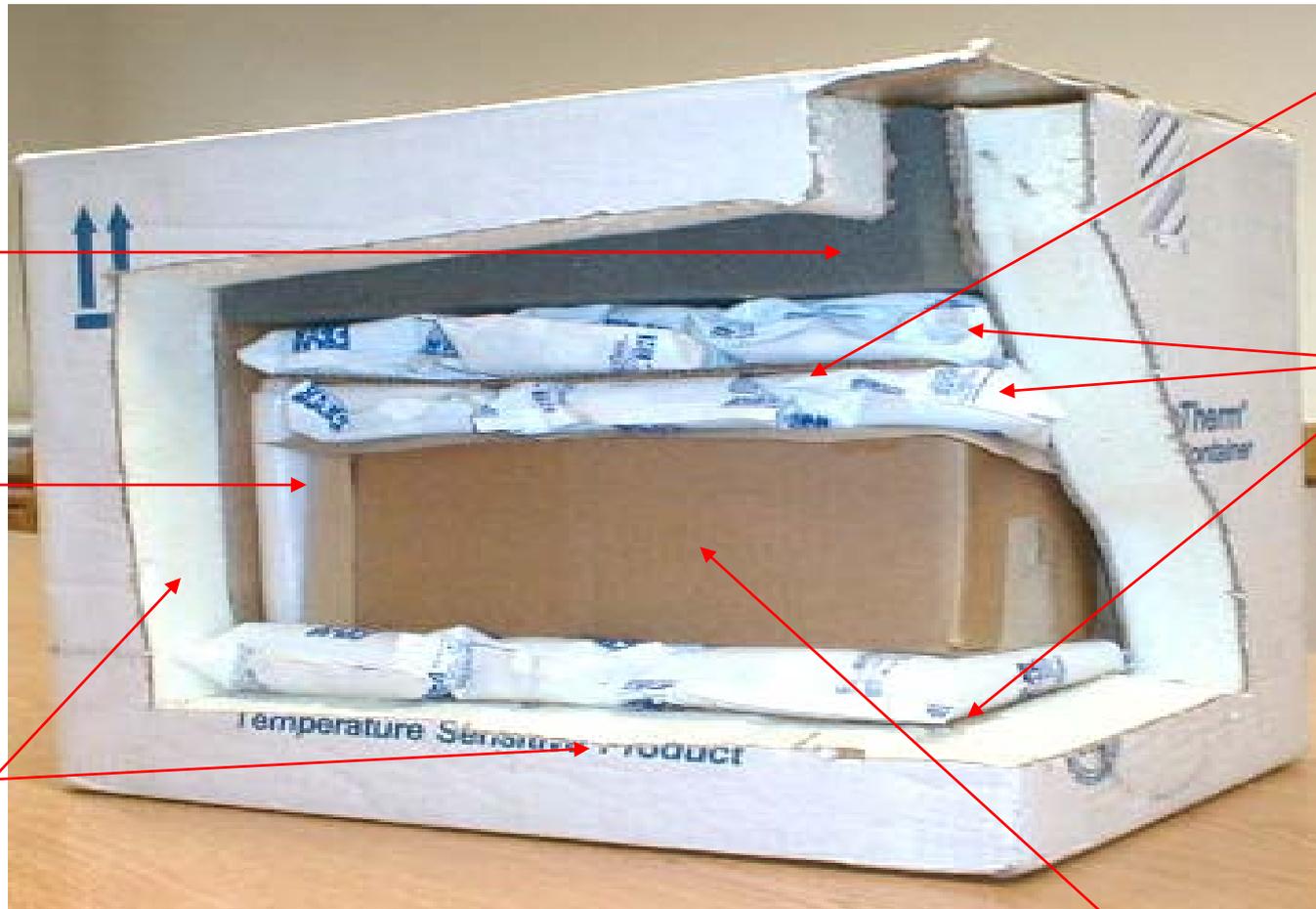


Gel Packs Medium (24 oz ea) are used in Small and Medium Endurotherm Boxes

Large Gel Packs(48 oz ea) are used in Large Endurotherm Boxes only

<u>WEIGHT</u>	<u>DIMENSIONS (in inches)</u>
24 OZ	8 x 6 x 1 ¼"
48 OZ	10 ¼x 8 x 1 ½"

## Endurotherm Insulated Shipping Containers Packaging



Foam Plug

Gel Packs  
Surrounding the  
Product

2" of Polyurethane  
Foam (Insulation)

Fiberboard  
Barrier

Gel  
Packs

Product and TempTale Temperature  
Monitor inside the fiberboard box

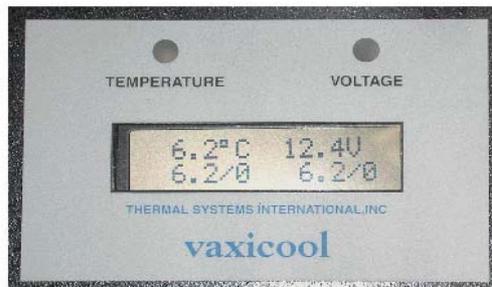
## VaxiCool Dual Mode Container



THE SYSTEM IS COMPRISED OF:  
 a) A SUPER-EFFICIENT COMPRESSOR,  
 b) A SUPER INSULATED CONTAINER USING VACUPANEL INSULATION DESIGNED TO MAINTAIN VACCINES AT APPROPRIATE TEMPERATURE BETWEEN 2-8 CELSIUS

BATTERY BOX CONTAINS  
 (2) 12 VOLT/20 AMPS  
 DRY GEL-CELL BATTERIES

POWER PANEL CONTAINS SOLAR INPUT  
 PLUG, AC POWER FROM 90-270 VOLTS



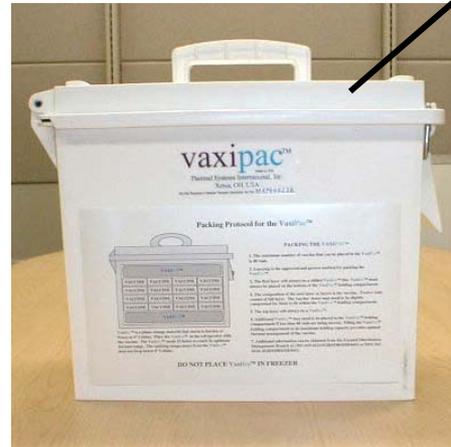
LCD SCREEN DISPLAYS THE TEMPERATURE AND BATTERY VOLTAGE



VAXICOOL HAS AN INSIDE DIMENSION OF 14 (LENGTH) BY 10-1/2 (WIDTH) BY 10 (DEPTH) ITS PAYLOAD

## VaxiPac Shipping Container

VaxiPac is used for transport of small quantities of refrigerated products



EXTERIOR DIMENSION OF 15 (LENGTH) BY 7.75 (WIDTH) BY 11.38 (DEPTH)



WALLS LINED WITH VACUPANEL INSULATION

VAXISAFE IS A PHASE CHANGE MATERIEL (PCM) THAT STARTS TO HARDEN OR FREEZE AT 6 CELSIUS



## Temperature Monitors



Primary Operating Range	-22°F to +158°F (-30°C to +70°C)
Primary Sensor Options	Ambient Temperature only
Primary Sensor Accuracy	2°F from -22°F to 0°F ( 1°C From -30°C to -18°C) 1°F from 0°F to +122°F ( 0.5°C from -18°C to +50°C) 2°F from +122°F to +158°F ( 1°C from +50°C to +70°C)
Memory Size	1,920 Data Points
Temperature Alarms	LCD Alarm for single event or cumulative time out of range
Start-Up Delay	Minimum - 0 Seconds Maximum - 194 Days
Measurement Interval	Minimum - 10 Seconds Maximum - 2 Hours
Primary Sensor Resolution	0.1° (1/10°)

## Instructions for Reading a TempTale 4

- Press and release the **Start** button, each time the **Start** button is pressed it will display the following information in the same order:
- Average temperature during the entire recording cycle.
  - Highest temperature reached during the recording cycle.
  - Cumulative amount of time above the high temperature alarm.
  - Lowest temperature reached during the recording cycle.
  - Cumulative amount of time below the low temperature alarm.

Start Button





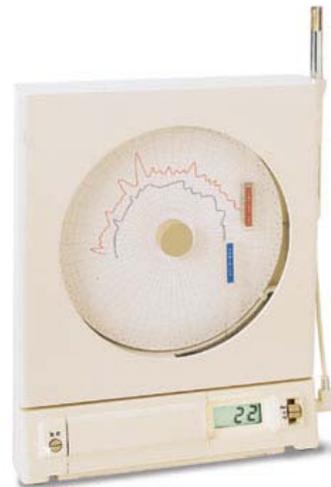
IN RELENTLESS PURSUIT  
OF MEDICAL READINESS

## TempTale Download Data

TempTale4 Trip: 3484811026 Serial: 3484811026 - 3199



## Temperature Recorders with Remote Monitoring and Audible Alarms





## Packing Protocols

The following packing protocols were developed to ensure maximum protection for temperature sensitive medical products requiring storage temperatures between **2 C** and **8 C (35 F and 46 F)** during distribution:

**Cold weather**: Is used when ambient temperature at the receiving site consistently remains below **55 F**. All gel packs used are refrigerated or chilled to **+4 C**

**Moderate weather**: Is used when ambient temperature at the receiving site is between **55 F and 77 F**. Uses a combination of chilled and frozen gel packs

**Warm weather**: Is used when ambient temperature at the receiving site is consistently above **77 F**. Uses a combination of chilled and frozen gel packs

NOTE: Packing protocols are designed to hold **2 C to 8 C** for at least 72 hours or longer



# Anthrax and Smallpox Vaccines Ordering Process

**Customers must register on line (USAMMA/DOC secured website) and create own log-in and password:**

- DOC personnel and local Service POCs validate registration
- DOC personnel enables customer in our DOC's secure server
- Customer receives authorization to access our secure webpage via email



## Approval Process

### Army

301-619-4318 - Validate

301-619-4307 - Approving Officer

### Navy/Marines: - NAVMEDLOGCOM

301-619-8054 - Validate (Navy and Marines)

202-762-3437 - Approving Officer (Navy)

703-955-1405- Approving Official (Marines)

### Air Force: - AFMSA

301-619-4170 - Validate

202-767-4216 - Approving Officer (Active Duty)

301-836-7255 - Approving Officer (ANG)

478-327-1478 - Approving Officer (Air Reserves)

### Coast Guard:

202-267-2622 – Validation and Approving Officer



# Vaccine Inventory

**DoD activities are required for reporting a monthly inventory of the anthrax and smallpox vaccine (Reference DOD-MMQC-07-1073)**

## **Inventory Requirements:**

- Logistics Activities and customers are required to report their physical inventories by the first Friday of each month to their major commands
  - Major Commands are required to report their physical inventories by the second Friday of each month to USAMMA/DOC
- 
- **Vaccine Reports must include:**
    - Number of unopened vials by lot number



# I suspect the vaccine is compromised... What do I do?

- **I will:**
  - Ensure that the vaccines are placed in a working refrigerator.
  - Marked the suspected compromised vaccines and separate them from the unsuspected vaccines.
  - Contact USAMMA/ DOC for further instructions.
  - Prepare **Executive Summary (EXSUM)** and route through chain of command
  - Destroy the vaccine if necessary (after consulting USAMMA)
- **Causes that may compromise your vaccine:**
  - Power failure
  - Reefer/freezer malfunctions
  - Vaccine sitting out of the refrigerator for extended period of time/improper storage of vaccine
  - Shipping mis-sort/frustrated cargo





## EXECUTIVE SUMMARY FORMAT

UNCLASSIFIED  
EXECUTIVE SUMMARY

20 April 20XX

### Example Copy

(U) PREPARATION OF AN EXECUTIVE SUMMARY (EXSUM). (U) (Your location and office symbol)  
An EXSUM is a brief summary in response to a question or to provide information. The EXSUM should not exceed 15 lines. Prepare in a concise and informative style in the active voice. Use approved acronyms and abbreviations; normally, spell out abbreviations the first time. Use Arial 12 pitch font and 1-inch margins. The EXSUM should begin with the overall classification, followed by the subject (capitalized and underlined) and the originator's office symbol, followed by the body of the summary. Identify the originator and indicate EXSUM approval as shown below. The words "PREPARE MEMO" should end the summary.

Lot# \_\_\_\_\_, Qty \_\_\_\_\_, Price \$ \_\_\_\_\_

LTC Staffer/DASG-XX/(703) 681-XXXX

APPROVED BY: COL Boss

UNCLASSIFIED





## Vaccine Disposal

- DoD activities are responsible for disposal of compromised or expired vaccine
- Destruction memorandum should be routed up the chain of command for review and endorsement before faxing to USAMMA/DOC
- Methods of destruction: AVA/Smallpox/FLUMIST: can be disposed in sharps container, autoclaved, incinerated, or use a returns program
- AVA, SMA and Flu disposition instructions can be found on the USAMMA website: <http://www.usamma.army.mil>
- Destruction Codes can be found on the USACHPPM website: <http://chppm-www.apgea.army.mil>





## Example of a Destruction Document

REQUEST FOR ISSUE OR TURN-IN (DA PAM 710-2-1)				ISSUE	SHEET NO.	NO SHEETS	1. REQUEST NO.		2. VOUCHER NO.		
3. SEND TO: INCINERATOR PLANT, FORT DETRICK, MD				<input checked="" type="checkbox"/> TURN-IN	1		5. DODAAC		6. PRIORITY		
8. REQUEST FROM: USAMMA DOC, FORT DETRICK, MD				4. DATE MATERIAL REQUIRED (YYYYMMDD)		9. END ITEM IDENT		9a. NAME/MANUFACTURER		9b. MODEL	
* CODE				ISSUE		TURN-IN		EX-Excess		LT-Lateral Transfer	
				I-Initial		FWT-Fair Wear And Tear					
				R-Replacement		RS-Report of Survey		SC-Smt of Charges			
								10. PUBLICATION		11. JOB ORDER NO.	
12. ITEM NO.	STOCK NO.	ITEM DESCRIPTION.	UNIT OF ISSUE	QUANTITY	CODE*	SUPPLY ACTION	UNIT PRICE	TOTAL COST	j. POSTED		
a	b	c	d	e	f	g	h	i	DATE (YYYYMMDD)	BY	
	6505-00-903-8173	SMALLPOX VACCINE LOT 4020076	KIT	75			189.00	14,175.00			
<p><b>POSTED</b></p> <p>JUN 14 2008</p> <p>TIME 1530</p> <p>Ft Detrick, USAMMA</p> <p>1230</p>											
								SHEET TOTAL	14,175.00		GRAND TOTAL
13. ISSUE/TURN-IN "QUANTITY" COLUMN IS REQUESTED		DATE (YYYYMMDD)	BY	14. ISSUE QTY IN "SUPPLY ACTION" COLUMN		DATE (YYYYMMDD)	BY	15. REC QTY IN "SUPPLY ACTION" COLUMN		DATE (YYYYMMDD)	BY
		20080603	Ph. J.P. Marshall					20080603			

DA FORM 3161, DEC 2000

PREVIOUS EDITION MAY BE USED.

USAPA V1.01





## USAMMA Website

IN RELENTLESS PURSUIT  
OF MEDICAL READINESS



U.S. ARMY



### U.S. ARMY MEDICAL DEPARTMENT

### MEDICAL RESEARCH AND MATERIEL COMMAND

### U.S. ARMY MEDICAL MATERIEL AGENCY

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### The USAMMA Mission

Plan, Synchronize And Provide Medical Logistics For Health Service Support to Forces Conducting Joint And Full Spectrum Operations by:

- Managing Medical Materiel Life Cycle Projects
- Equipping and Sustaining the Medical Force
- Managing Medical Strategic Centralized Programs
- Advancing Performance Excellence



MMQC Messages

MEDSILS

Unit Assemblages



COLONEL JEFFREY M. UNGER

• [Commander's Corner](#)

<http://www.usamma.army.mil/homepage.cfm>





## Distribution Operations Center Links



U.S. ARMY



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#### Data Applications

- [Army Medical Excess Distribution](#)
- [DOD Medical Materiel Quality Control Messages \(MMQC\) & Images](#)
- [FDA Shelf-Life Extension Program \(SLEP\)](#)
- [Medical Services Information Logistics Systems \(MEDSILS\)](#)
  - [How to Search MEDSILS](#)
- [Medical Unit Assemblage \(UA\) Listings](#)

#### Vaccines & Temperature Sensitive Products

- [Anthrax Vaccine Immunization Program \(AVIP\)](#)
- [Cold Chain Management Processes and Procedures for all Medical Temperature Sensitive Products](#)
- [Influenza \(Flu\) Virus Vaccines - H1N1](#)
- [Influenza \(Flu\) Virus Vaccines - Pandemic](#)
- [Influenza \(Flu\) Virus Vaccines - Seasonal](#)
- [Smallpox Vaccination Program \(SVP\)](#)

#### CD-ROM Products

- [USAMMA Cold Chain Management \(CCM\) Educational CD-ROM Vol.II](#)
- [USAMMA CD-ROM](#)
- [Medical Equipment Literature CD-ROMs](#)

<http://www.usamma.army.mil/products.cfm>





## Cold Chain Management Links



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#### News

#### Med Maint Mgt Dir (M3D)

#### PM ICS

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### Cold Chain Management Processes and Procedures for all Medical Temperature Sensitive Products

- [Packing Protocols](#)
- [Equipment Used to Support Cold Chain Distribution](#)
- Equipment Source Information (Equipment sources used by USAMMA-DOC)
  - [Endurotherm Boxes \(Insulating Shipping Containers\)](#)
  - [Polar Packs \(Refrigerant\)](#)
  - [Temperature Monitors](#)
  - [VaxiCool and VaxiPac](#)
- [Cold Chain Management Briefing](#)
- [Guidelines on the International Packaging & Shipping of Vaccine \(World Health Organization\)](#)
- [Guidelines for Maintaining and Managing the Vaccine Cold Chain](#)
- [CDC Vaccine Storage & Handling Toolkit](#)
- Cold Chain Management (CCM) Educational CD-ROM Vol.II
  - [CCM CD-ROM Welcome Message](#)
  - [CCM CD-ROM Order Form](#)
  - [CCM CD-ROM Index/Download](#)
- [Safeguarding Medical Materiel Assets](#) (12 Jan 05 Memorandum Directive)
- [Operations Management Bulletin No. 01-05](#) (Monitoring Temperatures on Refrigerator/Freezer Units Storing Temperature Sensitive Medical Products)
- [Errors in Vaccine Storage & Handling](#)
- [Cold Chain Checklist](#)
- [Vaccine Healthcare Center \(VHC\)](#)
- [About Your Shots VHC Brochure](#)

[http://www.usamma.army.mil/Cold\\_chain\\_mangement.cfm](http://www.usamma.army.mil/Cold_chain_mangement.cfm)





## USAMMA/DOC POCs

**USAMMA Pharmacist Consultant and MILVAX Deputy Director, Distribution Operations  
(301) 619-4307 Office**

**Project Manager**

(301) 619-1197 or **(301) 676-0857 (After duty Cell)**

**Operations Manager**

(301) 619-4318 or **(301)-676-1184 (After duty Cell)**

**Distribution System Analysts**

(301) 619-3017/9539/4128/7235

**Website registration/Technical Support**

(301) 619-4320

**Support Administration**

(301) 619-4198

**Functional Analyst/Web**

(301) 619-4121 or (301) 676-2017 (Cell)

**Flu Program Manager**

(301) 619-3242

**Financial Specialist**

(301) 619-4411

**MMQC Messages**

(301) 619-4300

