

U.S. Department of
Homeland Security

**United States
Coast Guard**



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Health, Safety and Work-Life
Service Center

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HSWLSCTD 2014-012
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HEALTH, SAFETY AND WORK-LIFE SERVICE CENTER TECHNICAL DIRECTIVE 2014-012

Subj: TACTICS, TECHNIQUES, AND PROCEDURES FOR THE ADMINISTRATION OF IMMUNIZATIONS

- Ref:
- (a) Commandant Operating Facility Change Order (OFCO) Number 040-10
 - (b) VCG memo 5400 of 26 Oct 2012 Organizational Modification
Request: Health Safety and Work-life Service Center
 - (c) DCMS Field Support Concept of Operations 21 Oct 2011
 - (d) Coast Guard (CG) Tactics, Techniques, and Procedures 1-01B, CGTTP 1-01B
 - (e) Immunizations and Chemoprophylaxis for the Prevention of Infectious Diseases, COMDTINST M6230.4(series)
 - (f) CG Medical Manual, COMDTINST M6000.1(series), Chapter 7.C
 - (g) CG Medical Manual, COMDTINST M6000.1 (series), Chapter 6
 - (h) Civilian Employee Health Care and Occupational Health Program, COMDTINST M12792.3 (series)
 - (i) Centers for Disease Control and Prevention (CDC) Vaccine Storage and Handling: <http://www.cdc.gov/vaccines/recs/storage/default.htm>
 - (j) Military Vaccine (MILVAX) Agency, Vaccine Storage and Handling Guidelines, June 2013: <http://www.vaccines.mil/default.aspx>
 - (k) U.S. Army Medical Material Agency (USAMMA)/Distribution Operations Center (DOC), Packing Protocols for Temperature Sensitive Medical Products Requiring Storage and Transportation Temperatures Between 2C-8C (36F-46F)
 - (l) Department of the Army, Destruction of Vaccine Standard Operating Procedures
 - (m) United States Coast Guard Regulations 1992, COMDTINST M5000.3 (series)
 - (n) CG Medical Manual, COMDTINST M6000.1 (series), Chapter 13.K, Patient Safety and Risk Management Program
 - (o) Vaccine Adverse Event Report System (VAERS): <http://vaers.hhs.gov/index>

DISTRIBUTION – SDL No. 165

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NON-STANDARD DISTRIBUTION: CG-11, HSWL SC Staff Divisions, Director of Operational Logistics (DOL-3)

- (p) Immunization Action Coalition (IAC): <http://www.immunize.org/>
- (q) CDC Vaccine Information Statements:
<http://www.cdc.gov/vaccines/pubs/vis/default.htm>
- (r) Recommendations of the Advisory Committee on Immunization Practices (ACIP), Centers for Disease Control and Prevention (CDC):
<http://www.cdc.gov/vaccines/recs/acip/default.htm>
- (s) Vaccine Healthcare Centers Network (VHC): www.VHCinfo.org

1. **PURPOSE.** A Technical Directive (TD) is authoritative guidance issued by the Health, Safety and Work-life Service Center (HSWL SC) in order to establish and maintain configuration control of and/or standardize Health, Safety and Work-life (HSWL) systems of service delivery in situations where complex, overlapping and/or conflicting organizational relationships may require clarification of the configuration and use of systems, processes, and resources that fall under the responsibilities and authorities of HSWL SC.
2. **ACTION.** The Immunizations TD establishes that all personnel involved with the administration of immunizations will read, understand, and comply with this TD and all Standing Orders for Vaccine Administration. Internet release is authorized.
3. **DIRECTIVES AFFECTED.** None.
4. **DISCUSSION.** This TD applies to all United States Coast Guard (USCG) health care facilities, CG health care personnel, and all personnel employed by or detailed to the CG for the purposes of delivering health care. The provisions of this TD are intended to ensure that all immunizations are stored, safeguarded and administered safely and effectively. This TD is intended to help simplify the immunization process by compiling direction and requirements from the array of references into one document. This TD provides the framework for a fully functioning immunization program that meets the requirements from all references and includes best practices to use in the execution of this program. In the case of any conflicting guidance, personnel should defer to the referenced document and bring this issue to the attention of the Service Center.
5. **DISCLAIMER.** This guidance is not a substitute for applicable legal requirements, nor is it itself a rule. It is intended to provide operational guidance for CG personnel and is not intended to nor does it impose legally-binding requirements on any party outside the CG.
6. **ENVIRONMENTAL ASPECT AND IMPACT CONSIDERATIONS.** Environmental considerations were examined in the development of this instruction and have been determined to be non-applicable.
7. **DISTRIBUTION.** No paper distribution will be made of this TD. An electronic version will be located on the HSWL SC Portal:
<https://cgportal2.uscg.mil/units/hswlsc/SitePages/Unit%20Directives.aspx>.
8. **RECORDS MANAGEMENT CONSIDERATIONS.** This TD has been thoroughly reviewed during the directives clearance process, and it has been determined there are not further records scheduling requirements, in accordance with Federal Records Act, 44 U.S.C. 3101 et seq., National Archives and Records Administration (NARA) requirements, and the Information and Life Cycle Management

Manual, COMDTINST M5212.12 (series). This policy does not have any significant or substantial changes to existing records management requirements.

9. AUTHORITIES. References (a) through (d) establish the responsibilities and authorities of HSWL SC to provide authoritative guidance. Reference (a) designates HSWL SC as the Military Treatment Facility (MTF) Commander and Intermediate Service Representative for all USCG medical and dental practice locations. Reference (b) states that HSWL SC retains the authority to provide technical direction over HSWL organizational elements at all types of CG units. Reference (c) establishes that Logistics and Service Centers provide technical and professional guidance and direction...meaning they oversee the systems used, services rendered, techniques and practices followed, as well as the utilization and prioritization of resources in the field in the delivery of services/support. Reference (d) defines Techniques, Tactics, and Procedures (TTP). References (e-s) provide the policy and technical guidance for the execution of this TD.

10. COMPLIANCE. All staff members handling immunizations are required to follow the requirements of this TD.

11. FORMS/REPORTS. None.

12. REQUEST FOR CHANGES. Individuals may recommend changes by writing via the chain of command to: HSWL SC (om); 300 E. Main Street; Suite 1000; Norfolk, Virginia 23510-9109.

TY W. RINOSKI /s/
Captain, U.S. Coast Guard
Commanding Officer, Health, Safety & Work-life Service Center

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ENCLOSURES

- (1) Steps for Potentially Compromised Vaccine Event
- (2) Potentially Compromised Vaccine/TSMP Worksheet
- (3) USAMMA Executive Summary (EXSUM)
- (4) Destruction of Vaccine Standard Operating Procedures
- (5) Hurricane Preparation: Emergency Vaccine Storage and Handling

CHAPTER 1. INTRODUCTION

A. Purpose.

1. A successful immunization program entails the delivery of effective vaccine through proper pharmaceutical care methodology. Over the last few years, vaccine stability and storage has been a concern within the Military Health System. Additionally, vaccinations are a critical component of readiness which is the center piece of Quadruple Aim. Therefore, it is essential that all pertinent health care workers understand and take into account proper vaccine storage and handling practices, appropriate vaccine trainings, and effective patient care practices. CG procedures relating to immunizations will follow guidelines set forth by the CDC, the Military Vaccine Agency (MILVAX), the Department of Defense, and the USCG.
2. Detailed information on adult vaccines can be found in Medical Services Immunizations and Chemoprophylaxis, COMDTINST M6230.4 (series). Additional information can also be found in the CG Medical Manual, COMDTINST M6000.1 (series), Chapter 7.C., Preventive Medicine: Immunizations and Allergy Immunotherapy.
3. All personnel involved with the administration of immunizations will read and understand this TD and all Standing Orders for Vaccine Administration.
4. This TD will be reviewed and updated by the Office of Health, Safety, and Work-life (HSWL) Service Center Pharmacist or designee annually or earlier if policies and procedures change. All updates will be vetted through CG-1121.

B. Responsibility.

1. Senior Medical Officer (SMO).
 - a. Immunizers are the responsibility of the SMO.
 - b. Where available, a Medical Officer (MO) shall be present when routine immunizations are given. In the event a MO cannot be present, a registered nurse (RN) or Health Services Technician (HS) who has been trained and certified by the SMO, can administer vaccines.
 - c. Responsible for reviewing and approving Standing Orders.
 - d. Medical Officers shall be on site for all civilian immunizations.
2. Deputy of Immunizations.
 - a. A MO can be designated in writing as the Deputy of Immunizations to oversee and manage the delivery of immunizations and all of its processes within the clinic.

- b. In this case, the Deputy shall review and approve all standing orders, training, and certifications for immunizations provided in the clinic and sickbays within the area of responsibility (AOR).

3. Pharmacy Officer.

- a. Responsible for ordering and receiving vaccines.
- b. Ensures proper storage and handling procedures within their AOR.
- c. Provides guidance to staff on current immunization requirements.

4. HSs/RNs.

- a. The primary immunizers. Each will be responsible for the safe administration of vaccines.
- b. HSs will be trained in the immunization process and follow all protocols set forth by policy, CDC recommendations, and FDA guidelines.
- c. Immunizers must document 8 hours of vaccine training annually.
- d. Civilians shall not be immunized unless a MO is on site.

C. Personnel to be Immunized.

- 1. Military Members: Immunizations for active duty and reserve members are administered in accordance with Medical Services Immunizations and Chemoprophylaxis, COMDTINST M6230.4 (series), the CG Medical Manual, COMDTINST M6000.1 (series), Chapter 7.C., Preventive Medicine, and the CG Medical Manual, COMDTINST M6000.1 (series), Chapter 6., Medical Readiness/Deployment Health.
- 2. Beneficiaries: Routine immunizations for eligible beneficiaries are administered in accordance with command policy and vaccine availability.
- 3. Civilian employees: Immunizations for civilian personnel are in accordance with COMDTINST M12792.3 (series), Civilian Employee Health Care and Occupational Health Program, and current CG-11 guidance. Employees should be screened by a MO prior to vaccination.

CHAPTER 2. VACCINE PROCUREMENT, STORAGE AND HANDLING/COLD CHAIN MANAGEMENT

A. Cold Chain Management.

1. Cold Chain Management is the process of maintaining temperature-sensitive vaccines within a recommended temperature range from the time the vaccine leaves the manufacturer to the moment it is administered to the patient.
2. Preserving Cold Chain Management will:
 - a. Ensure each patient receives an uncompromised vaccine.
 - b. Reduce inventory loss and monetary waste.
 - c. Contribute to a higher quality of healthcare via immunity and medical readiness.
3. It is mandatory, as part of the required 8 hours annual immunization training, that all personnel involved with storing, handling, and administering vaccines annually complete the MILVAX Cold Chain Management training course. Record of completion should be documented in the member's training file.

B. Immunization Designation Letters.

1. Individuals in charge of vaccine storage sites and immunizers will require documentation to perform such duties. Therefore, two types of designation letters will be used.
 - a. A designation letter certifying individuals are proficient in immunizations and have maintained basic competencies. This designation letter shall be updated annually with training requirements.
 - b. A designation letter indicating the individual is in charge of the work site's vaccine program. The vaccine program responsibility may be written in conjunction with the site's Pharmacy Designation Letter.
2. Designation Letters shall be placed in training records.

C. Storage Equipment.

1. CDC strongly recommends the use of stand-alone units that only refrigerate or freeze. Dormitory style refrigerator/freezers are not recommended for vaccine storage. Storage units should be large enough to store the year's largest inventory in the middle of the unit without crowding the vaccines.

2. Stand-alone units should be maintained in a well ventilated and temperature controlled room. MILVAX recommends a regular maintenance routine be scheduled with documentation for each storage unit.
3. Packing containers must be validated storage devices approved for transportation. Approved containers are Endurotherm insulated boxes and hard-sided plastic and/or Styrofoam™ with walls at least 2 inches thick.
4. Mobile temperature management units, i.e. PX1L or the AX27L, may be purchased. Follow manufacturer guidelines for storage and packing functions of these units.

D. Vaccine Procurement.

1. Vaccines are procured through several mechanisms and shall be processed through the Regional Pharmacy Executives and in coordination with the HSWL SC (Operational Medicine and/or the Business Cell).
2. Most vaccines will be ordered and received through the Prime Vendor system. Exceptions to this process are the seasonal influenza, smallpox, and anthrax vaccines.
3. Seasonal influenza vaccine is coordinated and purchased through the HSWL SC Operational Medicine Pharmacy Officer (om-ph). The Regional Pharmacy Executives will provide/validate the requested quantities for the AOR and delivery points. HSWL SC (om-ph) will coordinate the ordering and distribution to the receiving units via Defense Logistics Agency (DLA).
4. Anthrax and smallpox vaccines are requested through the United States Army Medical Material Agency (USAMMA) web ordering system by approved sites. Designated clinic staff must be approved to order smallpox/anthrax vaccines through USAMMA. All smallpox/anthrax requests require 10 business days (excludes weekends/holidays) for fulfillment, and a justification for requests shall be entered in the comment section when submitting requests. USAMMA will only deliver vaccines midweek and receiving units shall comply with instructions for receiving vaccines as outlined by USAMMA.

E. Inventory Management.

1. Routinely check vaccine and diluent expiration dates. MILVAX recommends weekly expiration checks but vaccines must be reviewed at least monthly and with each use of product.
2. Maintain inventory by ensuring shorter expiration dates are rotated to the front for first use. Contact your Regional Pharmacy Executive (RPE) for short dated vaccines to consider reaching out to sites that can use soon-to-expire vaccine to decrease wastage.
3. Multi-dose vials.

- a. Date and time the vial when the vaccine has been opened.
 - b. Due to the expense of vaccines, the expiration of a multi-dose vial is not held to the 28 day expiration range when opened but is permitted to expire on the vial's manufactured printed expiration date.
 - c. Review manufacturer's stability guidelines for each vaccine as some multi-dose vials are indicated to expire within a specific time frame after the vial has been opened.
4. Remove expired vaccines from the storage unit and dispose of them according to USAMMA or local policy. Live vaccines may require autoclaving prior to disposal.
 5. Compromised vaccine that has not expired should be quarantined and labeled "DO NOT USE" and kept in the storage unit until an investigation has been completed. Follow the steps outlined per MILVAX's Steps for Potentially Compromised Vaccine Event, Enclosure (1). Many vaccines have been proven to be still viable after exposure to temperatures outside recommended range. MILVAX will review data and make a determination.
 - a. Submit the Potentially Compromised Vaccine/TSMP Worksheet to MILVAX and USAMMA, Enclosure (2).
 - b. Submit the Executive Summary to the HSWL Pharmacy Officer, Enclosure (3).
 - c. For computer entry, the Potentially Compromised Vaccine/TSMP Worksheet can be found at
http://www.vaccines.mil/documents/1628_Potentially_Compromised_Vaccine_TSM_P_Worksheet.pdf.
 6. Vaccines distributed by USAMMA that require destruction are required to be destroyed in accordance with Destruction of Vaccine Standard Operating Procedures, Enclosure (4).
 - a. Smallpox vaccine.
 - b. Anthrax vaccine.
 - c. Influenza vaccine.
 7. USAMMA DOC is the DoD agency responsible for temperature sensitive medical product management and storage.
 - a. To contact USAMMA DOC for vaccine loss guidance call: 301-619-4318/1197/4198 (0700-1700 EST).
 - b. For after-hours urgent issues: 301-676-1184/0857 or 301-256-8072.

c. Email at usammadoc@amedd.army.mil.

F. Vaccine Storage.

1. Store vaccines in a stand-alone refrigerator/freezer in the middle of the compartment, 3 inches from each wall and ceiling, and not tightly packed allowing the air to circulate around the vaccines.
2. Place temperature buffering material like water bottles or cold packs to help stabilize the refrigerator temperature.
3. Maintain refrigerator temperatures between 2°- 8°C (35°-46°F). DO NOT expose refrigerated vaccines to freezing temperatures.
4. Maintain freezer temperatures at -15°C (5°F) or less.
5. To reduce immunization errors, individual storage bins shall be labeled. Other information such as age range, vaccine route, specific diluent, etc., can be added to the labels to aid in choosing the correct vaccine. Any excess stock unable to fit in the labeled bin should be in the immediate vicinity of the labeled bin.
6. Refrigerator/freezer temperatures are required to be manually checked twice daily and recorded on a temperature log. The temperature log needs to be kept on file for 3 years. Record on the back of the log any deviation that occurs with the temperature. Include the date and time of the occurrence and the action taken on the back of the log. Weekly temperature recording wheels shall be affixed to the back of the corresponding temperature log when used.
7. Only calibrated thermometers certified for traceability and calibration are to be used for vaccine monitoring;
 - a. Calibrate thermometers as required per the manufacturer's recommendations.
 - b. The CDC highly recommends thermometers that are digital and those that retain data that can be recalled (digital data loggers).
 - c. Place thermometers in the middle of the refrigerator away from walls, floors, and the fan.
8. For units that cannot provide daily coverage, digital data loggers are recommended so temperatures can be logged and documented on days without coverage.
9. All vaccine refrigerators must be alarmed.
 - a. Refrigerator temperature alarms shall monitor continuously 24/7.

- b. The alarm system and contact procedures shall be tested at least monthly.
 - c. Documentation of the results must be saved for a minimum of 3 years.
10. It is recommended that vaccines be stored in dedicated storage units. However, if other biologic specimens must be stored in the same unit as vaccines, specimens should be stored on a lower shelf than the vaccines to ensure that the vaccines will not be contaminated if a specimen leaks.

G. Transporting Vaccines.

- 1. For site visits or delivery to nearby clinics via GOV/POV;
 - a. Only pack enough vaccine expected to be used for the immunization session/clinic.
 - b. Do not pre-fill vaccine syringes prior to vaccinations.
 - c. It is recommended that the vaccine be maintained in its original packing.
 - d. Transport vaccines in validated insulated containers capable of maintaining appropriate temperatures as described in Chapter 2.C, Storage Equipment.
 - e. Site visits.
 - (1) To ensure cold chain management, it is recommended for site visits that a thermometer be placed in the storage unit to monitor vaccine temperature especially when the storage unit may be frequently opened to access vaccines for injections.
 - (2) Ensures vaccine is still viable when returned to pharmacy of origin to be placed back in stock.
- 2. For delivery via a commercial service;
 - a. Use USAMMA's guidelines for packing vaccine filled packages.
 - b. Guidelines are provided for cold, moderate, and warm weather conditions.
<http://www.usamma.amedd.army.mil/assets/docs/Packing%20Protocols%20-%20Endurotherm.pdf>.
 - c. MILVAX recommends the inclusion of a mobile temp monitoring device with the vaccine to ensure Cold Chain Management for overnight deliveries.

H. Power Failures.

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1. In the event of power failure or suspected cold chain compromise, notify a Pharmacy representative for further guidance. If the compromise occurs after-hours, the duty section shall notify the RPE.
2. Each facility shall ensure that vaccine refrigerators are plugged into backup emergency power outlets.
3. For facilities with a large inventory of vaccines, an emergency backup plan is required for an alternate storage site for when no electricity is available.
4. For facilities that may be impacted by a hurricane, USAMMA DOC has provided guidelines that can be useful in the event of power loss by hurricane. Refer to Hurricane Preparedness: Emergency Vaccine Storage and Handling, Enclosure (5).

CHAPTER 3. IMMUNIZATION PROCESS

A. Administration.

1. Immunizations are to be administered only during normal clinic hours or in accordance with local policy.
2. Immunizations may be provided outside of normal hours if approved by a MO.

B. Screening.

1. Active Duty members should be screened for immunizations during routine medical visits and at the time of their Periodic Health Assessment (PHA) in accordance with the CG Medical Manual, COMDTINST M6000.1 (series), Chapter 6, Medical Readiness/Deployment Health.
 - a. Review medical profile for readiness immunizations.
 - b. Also, screen for potential immunizations that members may have an indication for use, i.e. human papillomavirus vaccine, pneumococcal vaccine, meningococcal vaccine, etc.
2. Health care workers should review the Medical Readiness Reporting System (MRRS) and the DD2766 for vaccination information.
3. Patients receiving immunizations will be screened for contraindications and referred to a MO for review. Some types of contraindications may include:
 - a. Hypersensitivity or allergy to vaccine component i.e.; eggs.
 - b. Latex allergy.
 - c. Pregnancy.
4. Screening forms shall be utilized when available such as with Influenza and Adenovirus vaccines.

C. Standing Orders.

1. Standing orders will be created and used for all routine immunizations in lieu of individual written prescriptions. Sample standing orders can be found at <http://www.immunize.org/standing-orders/>.
2. Standing orders will be reviewed annually by the RPE and SMO and signed for by the SMO.

D. Documentation.

1. All immunizations for Active Duty personnel are entered into the MRRS.
 - a. Ensure vaccines have been accurately documented in MRRS.
 - b. Clinic personnel or the Independent Duty Health Services Technician (IDHS) must be mindful of the use of the proper medical and administrative exemption codes within MRRS. The information icon provides a detailed explanation of the various codes.
 - c. The medical administrator must ensure that all exemption codes are accurate within MRRS.
 - d. Medical temporary codes and administrative temporary codes must be reviewed and verified by the medical administrator every 365 days and 90 days, respectively.
 - e. Permanent exemption codes will be reviewed periodically (PHA) where fitness for duty will be examined and addressed.
 - f. Vaccines entered into MRRS will automatically populate DD 2766, Chronic Care Flow Sheet.
2. Immunizations do not have to be entered into PGUI.
3. When required, a PHS-731 can be completed for each Active Duty member (for reserve personnel when ordered to Active Duty for Training).
 - a. This form is only required when performing international travel.
 - b. When properly completed and authenticated, the PHS-731 contains a valid certificate of immunization for international travel and quarantine purposes in accordance with World Health Organization Sanitary Regulations.
4. Immunization Log.
 - a. In the absence of Medical Readiness Reporting System (MRRS), a log of all immunizations will be completed when administering vaccines in the outpatient setting. The immunization log should contain the following information:
 - (1) Patient's name.
 - (2) Last 4 of Social Security Number.

(3) Date.

(4) Vaccine.

(5) Manufacturer.

(6) Lot number.

(7) Expiration date.

- b. All entries are to be initialed by the administering HS/RN, their supervisor, and the ordering MO.

E. Vaccine Information Statement.

1. Every patient who receives a vaccine shall have a Vaccine Information Statement (VIS) made available from the CDC or MRRS.
2. For medical appointments, staff members will annotate in the medical record note that a VIS was provided to the patient and that any questions concerning the vaccine were answered.
3. Refer all questions about a vaccination to a MO or RPE.
4. All VIS stored in paper form will be inspected for most current edition.

F. Consent and Refusal of Treatment.

1. United States Coast Guard Regulations, COMDTINST M5000.3 (series), states in Section 8.2.1 that:
 - a. "Persons in the Coast Guard shall not refuse to submit to necessary and proper medical or dental treatments to render them fit for duty, or refuse to submit to a necessary and proper operation not endangering life."
 - b. "Persons in the Coast Guard shall permit such action to be taken to immunize them against disease as is prescribed by competent authority."
2. Personnel who refuse mandatory immunizations will be processed for separation from the Coast Guard unless granted a medical or administrative exemption in accordance with Immunizations and Chemoprophylaxis for the Prevention of Infectious Diseases, COMDTINST M6230.4 (series).

G. Reconstituted vaccines.

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1. Specific diluents are required for each vaccine. Review the package insert for reconstitution procedure and expiration dating of the product once reconstituted.
2. Diluents are single use vials.
3. The date and time of reconstitution will be noted on a multi-dose vials.
4. When the expiration date is reached, the vaccine shall be disposed of in the proper manner.

H. Inactivated vaccines.

1. Inactivated vaccines can be administered within any time frame in relation to other vaccines without affecting the desired immune response.
2. Safe in pregnancy.

I. Live vaccines.

1. Live virus vaccines are either provided simultaneously or at least 4 weeks apart from other live vaccines.
2. Live virus vaccines will not be administered to pregnant females. Females shall be cautioned against becoming pregnant within 4 weeks after receiving a live vaccine.
3. Live virus vaccines are preferred to be autoclaved to assure destruction of the vaccine prior to disposal.

J. Disposal.

Dispose of all materials used during immunizations in accordance with the CG Medical Manual COMDTINST M6000.1 (series), Chapter 13.K, Patient Safety and Risk Management Program.

K. Sharps and needle sticks.

Follow local guidance on use of needles, needle sticks, and post exposure prophylaxis protocols.

L. Vital signs.

Routine vital signs are not required for immunization-only encounters.

M. Post vaccination.

All patients shall remain in the facility for 20 minutes after their immunization for observation of any adverse reactions.

CHAPTER 4. VACCINE TRAINING

A. Training.

1. Personnel who administer vaccines must be appropriately trained. Training may include but is not limited to:
 - a. Vaccine storage and handling.
 - b. Vaccine characteristics and contraindications.
 - c. Patient interviewing techniques.
 - d. Injection technique.
 - e. Documentation.
 - f. Managing and reporting of adverse events.
2. Personnel who administer vaccines must complete at least 8 hours of annual continuing education and training on current immunization guidance.
3. Annual MILVAX Cold Chain Management is mandatory training for all personnel handling vaccines.
4. Ensure designation letters to administer immunizations are maintained in accordance with the CG Medical Manual, COMDTINST M6000.1(series), Chapter 7.C.

B. MILVAX.

1. MILVAX will be the principal reference for vaccine and immunization training; live (Immunization Basic Course, Immunization Leader's Course) or online (i.e. smallpox, influenza, VAERs, etc). Other training resources include CDC and live conferences sponsored by local or State Health Departments.
2. All personnel who administer vaccines should register for Immunization University through the MILVAX website (www.vaccines.mil).
3. Local training will be coordinated thru the training officer.

C. Training Log.

Immunization training shall be logged into the unit's training log with documents maintained in the individual's training record.

D. Quality Improvement.

1. MILVAX developed a quality improvement tool called the Continuous Quality Immunization Improvement Process (CQIIP). This process was created to assist facilities in assessing their compliance with immunization standards practiced in the Military Health System.
2. The eight immunization standards that have been adopted by the Military are:
 - a. Immunization availability.
 - b. Information and education before immunization.
 - c. Vaccine storage and handling.
 - d. Indications and contraindications to immunization.
 - e. Immunization recordkeeping.
 - f. Training.
 - g. Adverse events after immunization.
 - h. Vaccine advocacy to protect military family.
3. More information about these standards can be located in Immunizations and Chemoprophylaxis for the Prevention of Infectious Diseases, COMDTINST M6230.4 (series), Appendix B, Standards for Military Immunizations.
4. The CQIIP instructions and tool can be downloaded through MILVAX at <http://www.vaccines.mil/CQIIP>.
5. RPE shall complete the CQIIP for each site that stores vaccines and evaluate the immunization practice during their annual site inspection.

CHAPTER 5. EMERGENCY MANAGEMENT

A. Emergency Management.

1. All immunization sites must have the capability to administer emergency medical care if anaphylaxis or other allergic reactions occur. The SMO or Deputy of Immunizations must certify in writing that the RN or HS selected to administer immunizations is qualified to do so, because he or she has received instruction and displayed proficiency in these areas:
 - a. Vaccine dosages.
 - b. Injection techniques.
 - c. Recognizing vaccine contraindications.
 - d. Recognizing and treating allergic and vasovagal reactions resulting from the vaccination process.
 - e. Proper use of anaphylaxis medications and related equipment (e.g., oxygen, airways).
 - f. Verification of current certification in Basic Life Support (BLS).
 - g. Knowledge of Vaccine Adverse Event Reporting System (VAERS).
2. Emergency Medical Services with Advanced Cardiac Life Support (ACLS) capability must be within a 10-minute response time of the immunization site or the site must be within 10 minutes of an ACLS staffed health care facility.
3. IDHS will only administer vaccines to Active Duty members while in port with close proximity (i.e. 10 minutes) to advanced medical care.

B. Equipment for Anaphylaxis.

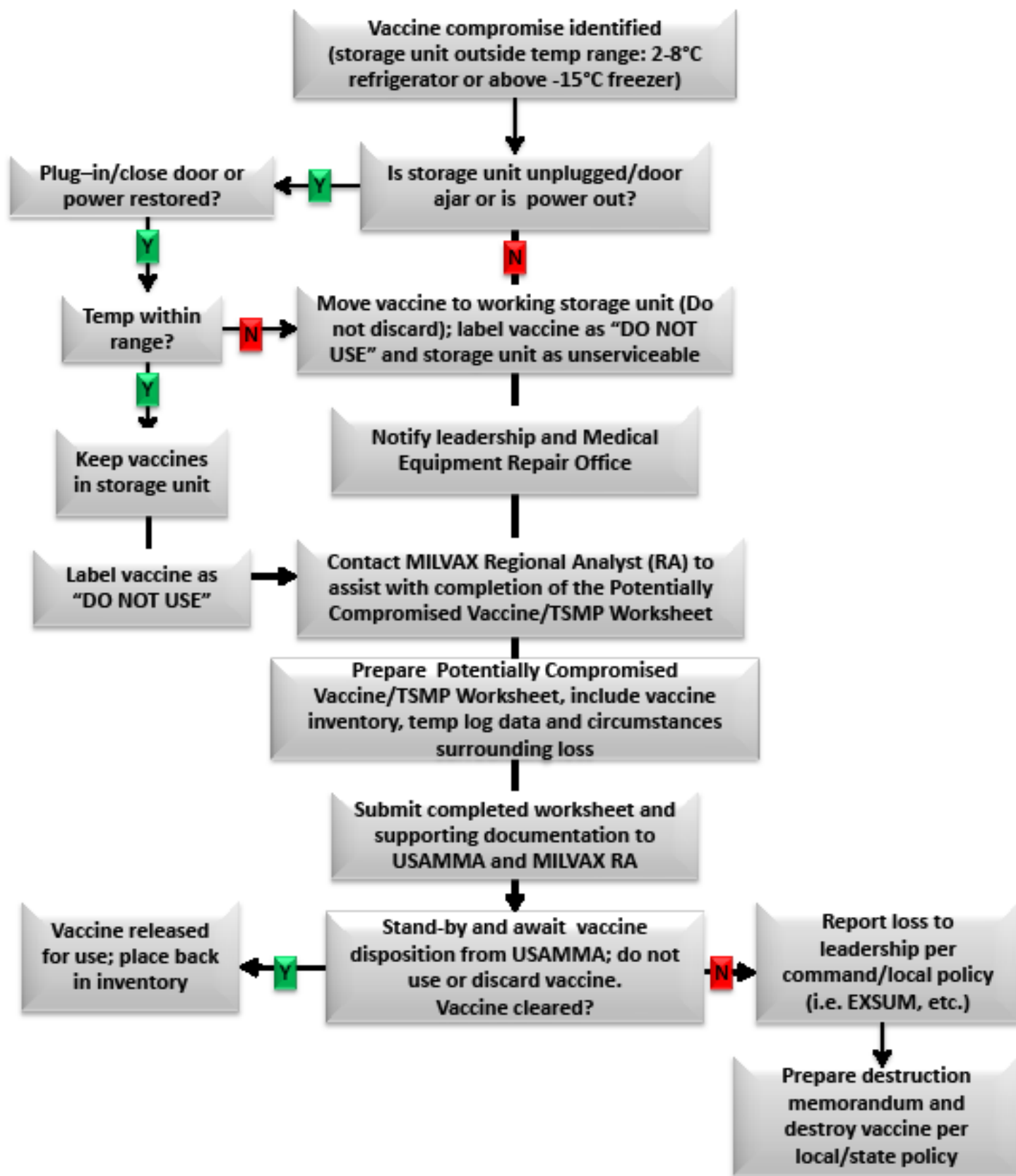
1. An emergency Anaphylaxis Kit must be available at all times with the minimum contents:
 - a. 3 doses of 1:1000 aqueous solution of epinephrine.
 - b. Diphenhydramine 50mg for injection.
 - c. Support equipment, i.e. syringes, needles, alcohol pads.
2. The immunization site must have the following equipment available:
 - a. Emergency airways.
 - b. Oxygen.

- c. Bag valve mask (BVM).
 - d. Intravenous (IV) fluids with an IV injection set.
3. The emergency kit shall be located wherever immunizations are administered, shall be inspected and inventoried monthly, and will be labeled as an ANAPHYLAXIS KIT.

C. Vaccine Adverse Event Reporting System (VAERS).

- 1. If an adverse reaction to a vaccine is suspected, by anyone including the patient, the facility shall notify the Vaccine Adverse Event Reporting System (VAERS) using the form VAERS-1.
- 2. VAERS is a post-marketing safety surveillance program that collects information about adverse events that occur after the administration of vaccines. VAERS information can be reviewed at <http://vaers.hhs.gov>.
- 3. The relationship between the observed adverse reaction and the vaccine does NOT need to be verified by a MO.
- 4. The VAERS form can be obtained at http://vaers.hhs.gov/resources/vaers_form.pdf.
- 5. Units providing vaccinations shall maintain a supply of these forms for patients who request them.
- 6. VAERS can be submitted online at <http://vaers.hhs.gov/esub/index#Online>.
 - a. Reports can also be faxed or mailed.
 - b. If filing online, print a copy of the form before clicking on the “submit” button.
- 7. A copy of each submitted VAERS-1 needs to be forwarded to the Pharmacy & Therapeutics Committee.
- 8. The primary objectives of VAERS are to:
 - a. Detect new, unusual, or rare vaccine adverse events.
 - b. Monitor increases in known adverse events.
 - c. Identify potential patient risk factors for particular types of adverse events.
 - d. Identify vaccine lots with increased numbers or types of reported adverse events.
 - e. Assess the safety of newly licensed vaccines.

Steps to take for Potentially Compromised Vaccine Event



Potentially Compromised Vaccine/TSMP Response Worksheet

Facility Name: Date:

Service: Component: Document #:

POC: Phone #:

Email:

Follow these steps in the event of a suspected compromise:

1. Move vaccine(s)/TSMP to a working storage unit at proper temperature.
2. Label the vaccine(s) or other TSMP as "DO NOT USE."
3. Do NOT destroy/discard the vaccine(s) or other TSMP.
4. Activate emergency plan and contact MILVAX Regional Analyst (RA).
5. Complete this worksheet with ALL required information.
6. Submit completed worksheet to USAMMA/DOC and MILVAX RA.
7. Standby for further instructions on disposition of vaccine/TSMP.

Required information:

1. Refrigerator temperature(s): current warmest coldest
2. Freezer temperature(s): current warmest coldest
3. Air temperature of room where storage unit(s) are located:
4. Estimated amount of time the unit's temperature was outside normal range:
refrigerator freezer
5. Date time & time of day of next annual check.
6. Use table below to list vaccines or other TSMP in the unit during event.
7. Complete back of this worksheet with information on disposition of affected products.

Vaccines (or other TSMP) Stored in Refrigerator

Brand name and manufacturer	NDC/Part #	Quantity affected (#)	Lot #	Expiration date	Total cost of affected products

Vaccines (or other TSMP) Stored in Freezer

Brand name and manufacturer	NDC/Part #	Quantity affected (# doses)	Lot #	Expiration date	Total cost of affected products

Other Conditions

1. Prior to this event, was the vaccine or other TSMP exposed to temperatures outside the recommended range? Y N
2. Were water bottles in the refrigerator at the time of this event? Y N
3. Were ice packs in the freezer at the time of this event? Y N

4. Other:

Resources

MILVAX Regional Analyst (RA) name/phone #: Brian Canterbury, 813-827-4874 Find your RA: www.vaccines.mil/POCMap/RAMap.aspx
 USAMMA/DOC phone #: (301) 619-4318/1197, after hours: (301) 676-1184/0857, or email: usarmy.detrick.medcom-usamma.mbx.doc@mail.mil
 Defense Logistics Agency - Troop Support Medical (DLA - TSM) phone #: (215) 737-5537, or email: pancoldchainteam@dla.mil or DSCPColdchain@dla.mil

Adapted by the MILVAX Agency, courtesy of the Immunization Action Coalition

Executive Summary for Vaccine Loss

Coast Guard (CG) clinics and sickbays are responsible for reporting any loss of vaccine product(s), due to expiration, or loss of efficacy by another means, i.e. exceeding required temperature parameters.

The following Executive Summary (EXSUM) requirements must be reported in memorandum format:

- a. CG clinics and sickbays will prepare the EXSUM within 24 hours upon discovery of compromised vaccine.
- b. No longer than one page in length.
- c. Explain the circumstances surrounding the loss of vaccine potency or why the activity did not use the vaccine.
- d. Complete list of lot number(s).
- e. Complete count of whole vial(s).
- f. Detailed explanation of course of corrective action to preclude future losses of vaccine/products.
- g. List of names and telephone numbers of points of contacts.

The EXSUM shall be sent to the HSWL SC Pharmacy Officer.



DEPARTMENT OF THE ARMY
US ARMY MEDICAL MATERIEL AGENCY
DMLC Building, 693 Neiman Street
FORT DETRICK, MD 21702-5001

MCMR-MMO-OD

19 February 2010

DESTRUCTION OF VACCINE STANDARD OPERATING PROCEDURES (SOP)

1. PURPOSE: To provide procedural guidance for the proper disposition of compromised and/or expired vaccines distributed by the United States Army Medical Materiel Agency (USAMMA), Distribution Operations Center (DOC).

2. REFERENCES:

a. MEDCOM Regulation 40-35, Management of Regulated Medical Waste, 29 July 2008. <http://chppm-www.apgea.army.mil/hmwp/document%20Library/Final40-35July08.pdf>

b.. Technical Guide 177, A Commander's Guide to Regulated Medical Waste Management at Army Medical Treatment Facilities, September 2001. <http://chppm-www.apgea.army.mil/documents/tg/techguid/tg177.pdf>.

3. APPLICABILITY: The procedures contained herein are applicable to all Department of Defense (DoD) activities receiving anthrax and smallpox vaccine, and Department of the Army activities receiving influenza seasonal/H1N1 vaccine.

4. DISPOSAL REQUIREMENTS: DoD Activities are responsible for disposal of compromised or expired vaccine.

a. Activities will report vaccine inventories for destruction to their Service medical logistic agency.

b. Activities must prepare a destruction document.

5. HOW TO PREPARE A DESTRUCTION DOCUMENT: Activities that have a standardized destruction document already in place do not need to prepare any additional destruction documents. The destruction document needs to be faxed to the USAMMA/DOC and must include the following information:

a. Date when the vaccine was destroyed.

b. List of lot number(s) destroyed.

c. Number of unopened vials destroyed.

d. Method of destruction.

e. For Navy ships, where was the vaccine acquired, i.e. FISC, another ship (include ship name), etc.

f. Signature block, e-mail, and phone number.

6. METHODS FOR DISPOSAL: Vaccines are to be disposed of according to accepted methods for hazardous or medical waste. Military item disposal instructions are categorized and delineated by code.

a. The disposal codes for the vaccines are: Anthrax vaccine adsorbed = A003, Smallpox (vaccinia) vaccine = A003, Influenza Seasonal/H1N1 vaccine (intramuscular) = CA01, and Influenza Seasonal/H1N1 vaccine (intranasal) = CA01.

b. Explanations for the disposal codes are reflected in the U.S. Army Center for Health Promotion and Preventive Medicine (CHPPM) Military Item Disposal Instructions (MIDI) website (<http://usachppm.amedd.army.mil/MIDI>).

7. SPECIAL DISPOSAL INSTRUCTIONS:

a. Anthrax Vaccine Adsorbed (AVA) Vaccine: Considered non-hazardous waste. This vaccine can be disposed of in a sharps container if the facility has a Biohazard Program in place, autoclaved, incinerated, or can be returned through a guaranteed returns program.

b. Influenza Seasonal/H1N1 Vaccine:

(1) Influenza Seasonal/H1N1 (injectable) Vaccine: Also considered non-hazardous waste. This vaccine can be disposed of in a sharps container if the facility has a Biohazard Program in place, autoclaved, incinerated, or can be returned through a guaranteed returns program.

(2) Influenza Virus Vaccine, Live, Intranasal Seasonal/H1N1 (Flu Mist®): This vaccine can be disposed of in a sharps container if the facility has a Biohazard Program in place, autoclaved, or incinerated.

c. Smallpox Vaccine ACAM2000

(1) Prior to Reconstitution - Smallpox vaccine when received from the distributor – vials will be labeled with an 18 month expiration date, after 18 months vaccine can be disposed of in a sharps container if the facility has a Biohazard Program in place, autoclaved, incinerated or via a returns program if one is in place. In places where medical waste is buried, it may be soaked in a 1:10 dilution of bleach for at least 10 minutes prior to disposal.

(2) After Reconstitution - Smallpox vaccine expires 30 days after reconstitution. The expiration clock begins on the date that the vaccine is mixed. After the 30 days have expired, vaccine can be disposed of in a sharps container if the facility has a Biohazard Program in place, autoclaved, incinerated or via a returns program if one is in place. In places where medical waste is buried, it may be soaked in a 1:10 dilution of bleach for at least 10 minutes prior to disposal.

DO NOT DISCHARGE ANY OF THESE ITEMS INTO A SANITARY SEWER.

8. DESTRUCTION DOCUMENT SHOULD BE FAXED TO:

U.S. ARMY (Executive Agent)
Fax: [Comm \(301\)619-4468](tel:3016194468), [DSN 343-4468](tel:3013434468)
USAMMA Distribution Operations Center (DOC)
693 Neiman Street
Fort Detrick, MD 21702-5001
Comm (301)619-4318, 7235, or 3017
DSN 343-XXXX
Email: usammadoc@amedd.army.mil

9. INSTRUCTIONS FOR ACTIVITIES THAT ARE UNABLE TO DISPOSE OF VACCINE AT THEIR FACILITY: The following procedures should be followed in the event the above mentioned disposal methods are not available or immediate disposal is necessary:

- a. Contact the DOC and provide information regarding lot numbers and quantities. The DOC will provide further shipping guidance.
- b. Remove each vial from its package.
- c. Tear or shred the insert and package and dispose of the insert and package as regular waste.
- d. Deface the label on each vial with red permanent marker.
- e. The activity will pack the container according to instructions provided and mail the container to DOC.
- f. The activity will call the USAMMA/DOC, and provide overnight express-mail tracking number for the container.

10. QUESTIONS OR CONCERNS: Personnel responsible for the disposal/destruction of vaccines should address all questions or concerns to (301)619-4307, DSN 343-4307, Fax X-4468. **Any proposed changes or updates to this SOP must be brought to the attention of the Distribution Operations Center (DOC), UNITED STATES ARMY MEDICAL MATERIEL AGENCY (USAMMA).**

Pharmacy Consultant,
U.S. Army Medical Materiel Agency (USAMMA)
Deputy Director, Distribution Operations,
Military Vaccine Agency (MILVAX)

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Hurricane Preparedness: Emergency Vaccine Storage and Handling

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 - 5. Procedures for Reporting Vaccine Loss**
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1. Checklist for Clinics and Sickbays without Backup Power

- Move all vaccines that are not stored in a location supported by backup power to your facilities' designated alternate site (i.e., logistics, pharmacy, alternate clinics).
- When moving vaccine, ensure it is packed and labeled correctly and that it stays within the proper temperature range during transport. Label container as "temperature sensitive" and "refrigerated" or "frozen" product. For easy identification, keep a detailed itemized list, along with contact information, affixed to the outside of the transport container. Place the vaccine in the appropriate storage unit (i.e., refrigerator or freezer), upon arrival at the alternate site.
- If possible, decrease immunization operations prior to the storm, in order to have plenty of time to pack and move product. Determine a packing priority list for vaccine in case not all vaccine can be moved.
- If no alternate storage site is available, immediately notify your MILVAX Regional Analyst for assistance.

2. Checklist for Clinics and Sickbays on Backup Power

- Clearly label all storage units within your facility or sickbay as either a "refrigerator" or "freezer" as appropriate.
- Clinics or sickbays with backup power must VERIFY functionality of all equipment:

- Ensure that refrigerator and/or freezer are plugged into designated emergency power outlets (normally the red outlets).
 - Verify that all alarm and call systems are plugged into emergency power or they will not operate if the power fails during the storm.
 - If alarm or call system have a battery backup, ensure system is charged or has new batteries installed.
 - Check the automated call system (if applicable) to ensure it is programmed with current staff contact information.
 - TEST the call and/or alarm systems before departing clinic.
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- Verify that officer-of-the-day alarm response procedures and policies are current.
 - Prepare supplies within the clinic or sickbay for an emergency movement of vaccine. Ensure that validated storage containers, refrigerator packs, and thermometers, along with packing protocols, are readily accessible for responders.
 - If your facility or sickbay has a VaxiCool, ensure that it is fully charged and plugged into emergency power.
 - If your facility or sickbay has VaxiPacs, ensure the silver phase-change bricks are fully chilled according to manufacturer instructions, and that there are three (3) bricks per VaxiPac. Do not use any other cooling item (frozen or refrigerated packs) with the VaxiPac.
 - Review your Emergency Vaccine Storage and Handling Plan with all staff, and make it readily available for quick response.
 - All clinics or sickbays in potentially low-lying areas or lower levels of the facility, that may incur flooding, should move all vaccine to higher ground.
 - Whenever possible, call your continuous temperature tracking alarm system (i.e., Sensaphone, REES) more frequently during the storm to verify that it is functioning properly.

3. Resources for Emergency Response

Emergency Vaccine Retrieval and Storage Plan Worksheet: A tool that your facility or sickbay can use to list alternate storage sites, POC and equipment repair company emergency contact information. The prepared worksheet should have current information, be readily accessible to staff and be included as part of your emergency standard operating procedure.

Potentially Compromised Vaccine Worksheet: Utilized when a power failure has occurred to identify and manage potentially compromised vaccines.

Temperature logs: For vaccine temperature tracking when stored in local storage units, and when transporting or storing vaccines at off- site locations.

Vaccine Storage and Handling Guidelines: 40-page storage and handling guide that identifies proper daily and emergency vaccine management procedures.

http://www.vaccines.mil/documents/1437_MILVAX_S_and_H_Guidelines_FullVer_8_Jul_11.pdf

4. Packing Protocols for Moving Vaccine

All packing protocols are available from USAMMA at:

http://www.usamma.army.mil/cold_chain_management.cfm

Vaccine packing reminders:

- Always use validated storage containers (e.g., Endurotherm shipping boxes, Styrofoam coolers with at least 2-inch thick walls, manufacturer-shipping containers, VaxiPac, VaxiCool).
- Always include calibrated thermometer to track temperatures during transport and storage.
- Always document vaccine type, date, time, originating facility, and phone number and identify the contents as fragile and temperature sensitive on the outside of the container.
- Always use insulating barrier (e.g., crumpled paper, bubble wrap) between cold packs and the vaccines. Never place vaccine directly on frozen packs.
- Record temperatures a minimum of every hour when vaccine is stored outside of a functioning refrigerator or freezer.

5. Procedures for Reporting Vaccine Loss

Sometimes vaccine loss cannot be prevented. If you suspect that vaccines have been stored outside the safe temperature range, take immediate action:

- Segregate and label potentially compromised vaccine as “DO NOT USE”. Immediately place in a functioning storage unit, do not leave in non-working storage unit.
- Record temperature of storage unit when vaccine discovered and length of time vaccine was exposed to temperatures outside the recommended range.
- Inventory all vaccines affected, include lot numbers and cost. Report the potentially compromised vaccine event through Service-specific channels, to USAMMA DOC and to your local MILVAX Regional Analyst.
- Prepare an Executive Summary (EXSUM), describing the circumstances surrounding the incident, temperatures, vaccine information and corrective actions taken.
- NEVER discard vaccine until USAMMA DOC has confirmed the loss.

USAMMA DOC is the DoD agency responsible for temperature sensitive medical product management and storage.

Enclosure (5) to HSWLSCTD 2014-012

To contact USAMMA DOC for vaccine loss guidance call: 301-619-4318/1197/4198
(0700-1700 EST)

For after-hours urgent issues: 301-676-1184/0857 or 301-256-8072

Email at usammadoc@amedd.army.mil

For more information and tools to assist with proper vaccine storage and handling, visit:

MILVAX Storage and Handling webpage:

http://vaccines.mil/Storage_and_Handling

CDC Vaccine Storage and Handling webpage:

<http://www.cdc.gov/vaccines/recs/storage/default.htm>

Military Vaccine Agency

<http://www.vaccines.mil>

<http://www.smallpox.mil>

<http://www.anthrax.mil>

(877) GET-VACC

<mailto:vaccines@amedd.army.mil>