

DoD Smallpox Response Plan

ANNEX I TO SMALLPOX RESPONSE PLAN MEDICAL LOGISTICS & PRODUCT DISTRIBUTION.

29 September 2002

REFERENCES.

a. United States Army Medical Command. "How To" Guide for Command Surgeons: Implementation Guidelines for Investigational New Drug (IND) Protocols. Falls Church, VA, May 2002.

b. United States Army Medical Command. "How To" Guide for Unit Leaders and Unit Health Care Providers: Implementation Guidelines for Investigational New Drug (IND) Protocols. Falls Church, VA, May 2002.

c. United States Army Medical Command. "How To" Guide for Investigational New Drug (IND) Protocols, Supplement: Smallpox Vaccination (IND # 10664). Falls Church, VA, publication pending.

1. General. This annex describes instructions from the U.S. Army Medical Materiel Agency (USAMMA) for ordering, shipping, storing, controlling, accounting, and disposition of expired or suspended products. Appendix I-1 summarizes this DoD Annex on one page.

2. Mission. USAMMA will coordinate the distribution of the smallpox (vaccinia) vaccine and ancillary supplies to all medical supply activities of each of the Armed Services or other supported organizations. USAMMA will also coordinate the distribution of vaccinia immune globulin (VIG), cidofovir, and other critical medical logistic items that might be needed in implementing the DoD Smallpox Response Plan.

3. Assumptions:

a. The smallpox (vaccinia) vaccine may be either (a) licensed by the Food & Drug Administration (FDA) at the time of vaccination or (b) unlicensed but permitted by FDA to be used under Investigational New Drug (IND) provisions of the Food Drug & Cosmetic Act. If smallpox vaccine is used as an IND medication within the constructs of the DoD Smallpox Response Plan, additional education, documentation, and consent requirements apply. This iteration of Annex I assumes that smallpox vaccine is in IND status.

b. If the licensing status of these products changes during the course of the DoD response, IND products will be removed from inventory and replaced with licensed product as soon as possible.

c. In the event of a smallpox outbreak, DoD will supplement its inventory of smallpox vaccine from the National Pharmaceutical Stockpile (NPS). Appendix I-7 describes

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some features of the NPS vaccine distribution planning and describes four potential types of smallpox vaccine that may be used. Nonetheless, vaccine requisitioning procedures through DoD channels described elsewhere in this annex will be used.

4. Planning Factors:

a. References a, b, and c provide guidance on applicable education, documentation, and consent issues for IND medications, including smallpox vaccine and two medications to treat adverse events after smallpox vaccination (i.e., vaccinia immune globulin (VIG) and cidofovir).

b. IND products require strict procedures for logistical tracking. Medical supply activities will track these medications like controlled substances (e.g., morphine). Activities must document all product movement from the wholesale level down to patient administration.

c. Customers must ensure they have appropriate refrigeration available for storage of the vaccine or the USAMMA's Distribution Operations Center (DOC) cannot ship to the site.

d. The intent of DoD vaccine distribution operations is to arrange door-to-door transportation from supply depot to the pharmacy supporting the clinic that will administer the vaccine. In case distribution operations are overwhelmed by excessive simultaneous demand, less direct arrangements may be required. In such cases, installations may be required to send a courier and vehicle to a prearranged location (e.g., a commercial airhead) to take possession of a vaccine shipment. Depending on circumstances, it may be appropriate for the installation courier to be accompanied by a security detail.

5. Contracting and Sources of Supply.

a. Linen & Waste Management. MTFs will develop plans for handling linens and regulated medical waste (RMW), as well as ensuring adequate medical supplies. All waste generated by smallpox patients will be treated as RMW. Linen may be handled through normal in-house or contract mechanisms as long as provisions have been made for the appropriate protection of the personnel who will be handling the linen (i.e. vaccination and appropriate personal protective equipment).

b. Sources of Supply. MTFs will identify Prime Vendor (PV) capabilities for increased deliveries of all medical supplies and equipment. MTFs will develop contingency plans for requisitioning medical supplies, in case standard channels are inadequate. Just-in-time delivery by prime vendors may not be sufficient to meet needs during outbreaks, based on the large volume of supplies that may be needed throughout a region. Establish delivery protocols for delivery of key supplies and equipment.

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c. Transport of Regulated Medical Waste. Logistics or housekeeping division will be responsible for collecting, packaging, and disposing of RMW according to local, state, and federal regulations, as well as maintaining required documentation (manifests). The environmental science officer or preventive-medicine staff provides guidance as needed. Facilities that perform regulated medical waste handling on site will ensure appropriate coordination with local and state officials.

6. Requisitioning.

a. USAMMA's DOC will not accept automated requisitions for smallpox (vaccinia) vaccine, VIG, or cidofovir. Vaccination sites submit requests to their supporting medical logistics activity, which will validate the requirement and submit a formal request to their strategic logistics agency (i.e., their Service Vaccine Control Center) using a DD Form 1348-6 or acceptable written alternative. A sample DD Form 1348-6 is attached as Appendix I-2.

b. Units may order VIG or cidofovir only in conjunction with IND protocols for their use, except in limited prepositioning situations. Use of VIG or cidofovir is discussed in Annexes B, G, and H.

c. The Service Vaccine Control Centers are:

(1) Navy & Marine Corps – Naval Medical Logistics Command (NAVMEDLOGCOM)

(2) Air Force – Air Force Medical Logistics Office (AFMLO)

(3) Army – U.S. Army Medical Materiel Agency (USAMMA).

(4) Coast Guard -- U.S. Army Medical Materiel Agency (USAMMA).

d. Provide the following information on the DD Form 1348-6 or alternate form:

Item Requested	National Stock Number (NSN)	Unit of Issue (UI)
Smallpox vaccine (<i>Dryvax</i>), full-strength	6505-00-903-8173	PG (100-dose vial with diluent, 100 bifurcated needles, and 100 transfer needles)
Smallpox vaccine (<i>Dryvax</i>), diluted 1:5	6505-01-499-9118	PG (500-dose vial with diluent, 500 bifurcated needles, and 500 transfer needles)
Vaccinia immune globulin, intramuscular (VIG-IM)	6505-01-053-2600	VI (5 ml vial)

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Vaccinia immune globulin, intravenous (VIG-IV)	6505-01-503-5293	pending
Cidofovir (<i>Vistide</i>)	6505-01-501-0628	VI (375 mg/5 ml vial)

e. Also enter:

- (1) Document Number (including requisitioner, date, and serial number) (Army sites only),
- (2) Priority – 02
- (3) Quantity – quantity of units of issue required
- (4) Requester's name,
- (5) Requester's telephone number (commercial and DSN if available),
- (6) Requester's fax number,
- (7) Person who will be the shipment point of contact (POC),
- (8) POC telephone number (commercial and DSN if available),
- (9) POC fax number,
- (10) POC e-mail (if available),
- (11) Alternate POC information (identical information as requested for POC), and
- (12) Shipping address (unit or facility, street address, city, state and zip code).

f. Individuals experiencing difficulties providing this information should contact the DOC at (301) 619-4121, -4128, -4411, -4318, -4198, or -4320 (DSN 343). Updated information appears at <https://usamma-extranet.detrick.army.mil/cpp/index.html>.

g. The Service Vaccine Control Center will provide approved requests to the DOC at fax (301) 619-4468.

h. The DOC will contact customers promptly if requests are incomplete or illegible.

7. Shipping.

a. The DOC will contact the receiving units before their scheduled shipment. During this call, the DOC and the receiving unit will discuss handling requirements. The activity will notify personnel in their receiving area and central receiving mail drop-off area. The activity will clear all gate or installation requirements for shipment delivery. For OCONUS shipments, the DOC will assist the local action officer in preparing documentation required from the Food and Drug Administration or Ministry of Health before the package arrives at Customs for clearance.

b. After calling the activity, the DOC will fax them a copy of the product receipt matrix and handling instructions. A sample of each is attached at Appendix I-3 and Appendix I-4.

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c. The DOC will coordinate packaging and shipping of product(s) directly to the requesting site. In some cases, shipment escorts may be required.

d. The DOC advises the activity to track the shipment using either DHL, Federal Express, or the Defense Logistics Agency (DLA) Distribution Standard System (DSS) Material Release Order (MRO) or Global Transportation Network (GTN) web sites or operators.

(1) DHL: www.DHL.com or 1-800-345-3579.

(2) FedEx: www.fedex.com or 1-800-463-3339.

(3) DLA DSS MRO: <http://wegal.ogden.disa.mil/mrostatus/query.html>.

(4) GTN: <http://gtn.transcom.mil>.

The DOC also tracks each shipment and provides the activity their tracking numbers upon notification of shipment.

e. Upon receipt of the product, the activity inspects the package for damage. If the package is damaged, the activity should call the DOC immediately. If shipment was completed through the DoD supply system, a report of discrepancy (ROD) should be completed for any damaged shipment. The receiving activity must complete all requirements specified on the receiving matrix faxed from the DOC earlier (Appendix I-3).

f. If the receiving activity has an urgent need to use the shipped product(s) immediately upon receipt, follow these steps:

(1) Upon receiving the shipment, the site contacts the DOC before opening the package.

(2) The DOC staff will explain procedures for conducting a check on the shipment's cold-chain maintenance status, recorded by the TempTale[®] temperature-monitoring device, enclosed in each shipment needing refrigeration.

(3) The receiving activity promptly removes the TempTale[®] from the shipping container and follow the steps exactly as described by the DOC staff (within 5 minutes of opening the shipping container).

(4) The response from the TempTale[®] (either Green Light or Red Light) will be relayed back to the DOC staff person, who will either provide verbal authorization to release the product for immediate use, or will tell the receiving activity that further inspection is required.

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(5) The receiving activity will inspect the product and place it in an approved storage container. This is a refrigerator for smallpox vaccine and VIG (2° to 8°C, 36° to 46°F). Cidofovir is stored at controlled room temperature (25°C or 77°F), although refrigeration is acceptable.

g. If immediate release of the product is not necessary, activities should remove the product, inspect it, and store as above. If more than one container arrives, the vials from each container should be segregated and marked with the corresponding TempTale[®] monitor number. This provides accurate identification in case one container's monitor reads outside of required temperature parameters and is determined to be unusable. Contact the DOC to acknowledge receipt of the shipment, confirm quantity received, and confirm the express-mail air bill number for the return envelope.

h. The receiving site express-mail returns the TempTale[®] monitor to USAMMA's DOC, using the enclosed pre-addressed, overnight express mail envelope.

i. Upon receipt, the DOC will download the temperature data from the TempTale[®]. Once validated, the DOC will inform the site it may use the product, first telephonically, then with a follow-up faxed confirmation.

j. If the receiving site is located in CONUS, it returns all shipping and packaging materials using the enclosed, pre-addressed shipping label. Attach the pre-addressed shipping label to the box and send it back to the stockpile location. OCONUS locations may retain the shipping and packaging materials.

k. The DOC will not provide release of product for administration unless a proper green-light release is performed on the TempTale[®] monitor or the monitor is received, downloaded and approved by the USAMMA Pharmacy Consultant.

8. Storing.

a. Like most vaccines and antibody products, smallpox (vaccinia) vaccine and vaccinia immune globulin are stored in the refrigerator at 2 to 8 degrees Celsius (36–46 degrees Fahrenheit). If smallpox vaccine or VIG is exposed to temperatures above or below this level for more than 1 hour, contact the DOC at 301-619-4128, -4121, -4411, -4198, -4318, -4320 (DSN 343) for disposition instructions. Smallpox (vaccinia) vaccine and VIG can tolerate short exposures to other temperatures without degradation.

b. Cidofovir is stored at controlled room temperature (25°C or 77°F).

c. The DOC provides guidance on unusual storage conditions or distribution emergencies. Track all critical products by lot number and quantity.

9. Emergency Storage.

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a. During situations when normal refrigeration systems break down, take every effort to minimize loss of product due to breaks in the cold-chain.

b. In the case of power failure or breakdown of proper storage facilities, the DOC will assist in establishing alternative emergency storage plans. The DOC has several VaxiCool[®] temporary-storage refrigeration units located around the world. These VaxiCools[®] can be used until existing storage facilities return to proper operating order or are replaced. When a power failure or loss of storage is discovered, notify the DOC immediately. DOC personnel will assist with risk assessment, recommend actions to be taken, and assist with redistribution of product or delivery of a VaxiCool[®] for temporary storage. Service POCs also should be contacted shortly after the initial contact with the DOC to inform them of the situation.

10. Redistribution. Guidance for product redistribution can be obtained from the USAMMA website: <https://usamma-extranet.detrick.army.mil/cpp/index.html>. Contact the DOC before redistributing smallpox vaccine, VIG, or cidofovir. The effective movement of product requires constant maintenance of the appropriate storage temperature. To ensure this requirement, the product will be moved in a refrigerated container. DOC personnel must ensure maintenance of cold-chain throughout redistribution and will provide release authorization when redistribution is completed. Information on these containers can be obtained from the above-mentioned web site.

a. The DOC will provide the losing activity detailed packing instructions for the VaxiCool[®] or VaxiPac[®] container or Endurotherm Box. Gaining activities will be provided receiving and processing matrix for the transported product.

b. The DOC will send an empty container with shipping labels and a serial numbered security band to the losing activity. If the container is damaged, notify DOC immediately. If the container is in satisfactory condition, receive and process documents and pack product according to information provided.

c. With the pre-addressed, overnight express-mail label, send the VaxiCool[®] or VaxiPac[®] to the gaining unit. Call DOC to confirm overnight express-mail label account number, air bill and security band serial number for the shipment.

d. Upon receipt of the product, the gaining activity will immediately inspect the container and contents for damage and the security band for serial number accuracy. If the container or contents are damaged, notify the DOC immediately with details. If container is in satisfactory condition, receive and immediately secure product in the required refrigerated storage environment (2° to 8° Celsius or 36° to 46° Fahrenheit). Call DOC to confirm receipt and document the lot number and quantity received.

e. Process documents and product in accordance with the information provided. Call commercial carrier to schedule pickup of VaxiCool[®], VaxiPac[®] or Endurotherm Box. Ship container back to the DOC, using the provided pre-addressed, overnight, express-

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mail label. Call the DOC to confirm overnight express-mail label account number and air bill serial number for the container.

f. Establish stock-record accountability of product in accordance with Service regulations.

g. Do not release the product to end-user until authorized by the DOC.

11. Control and Accountability. The lots of IND products must be handled in accordance with the control and accountability procedures of an investigational pharmaceutical.

a. Logistics activities must maintain readily retrievable records showing receipts and issues to supported activities, clinics, or other vaccination sites. This information includes the lot number and expiration date (if applicable) of the vials received or issued. Logistics sites not possessing an automated method that can readily retrieve reports of this information should implement manual procedures similar to those used for controlled substances (e.g., morphine).

b. Clinics and vaccination sites must also maintain readily retrievable records showing receipts from their supporting logistics activities, including lot number and expiration date, and local administration records showing consumption of the product they have received (i.e., number of doses administered). Vaccination sites not possessing an automated method that can readily retrieve reports on the receipt and gross usage of product should implement manual procedures as would be used for controlled substances. A sample form for a manual process is attached at Appendix I-5.

c. Clinics and vaccination sites will record individual dosage administration in Service-specific medical documentation systems, as discussed in DoD Annex B.

d. The DOC and all activities receiving IND products must provide hard-copy supply status reports to the US Army Medical Materiel Development Agency (USAMMDA) on a monthly basis. These data will include the information discussed above (receipts, issues and vaccination documentation) as well as an updated, validated inventory and will be gathered with a closing date of the last day of each month. Activities will forward/fax these data to USAMMDA for inclusion in the protocol case files not later than the seventh of each month. The USAMMDA fax number is (301) 619-2304 (DSN – 343).

12. Recovery of Unused IND Products. All unopened vials of IND medication will be accounted for and returned to USAMMA. Contact the DOC before movement of any IND medication. DOC personnel will ensure the use of appropriate packing materials and shipping containers, maintenance of cold chain, and will coordinate the movement of all smallpox vaccine to be recovered. Activities may not ship any IND medication without explicit guidance from USAMMA's DOC.

13. Disposal of Unused Non-IND Products. Activities have responsibility for disposal and destruction of unusable products other than IND products. Contact the DOC before

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destruction of any product issued under the DoD Smallpox Response Plan. Activities will report on-hand product inventories to be destroyed to their respective logistic agencies. The report will include information regarding lot numbers and quantities. FDA-licensed smallpox product must be handled as infectious waste. Do not discharge this item into a sanitary sewer.

a. The disposal code for FDA-licensed smallpox vaccine and FDA-licensed vaccinia immune globulin is CA01. [If used in IND status, refer to paragraph 12 above.]

b. Methods for disposal are as follows:

(1) Autoclave/Sanitary Landfill. Autoclave this item at 120 degrees Celsius for 60 minutes at 15 psi before burial in a permitted sanitary landfill.

(2) Incineration. Mix this disposal item with other combustibles and incinerate. To prevent the production of excessive air pollutants, the disposal item or combination of similar items shall not exceed 10% by weight of the total waste load charged to the incinerator at any one time.

(3) Use the following procedures if the aforementioned 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 a pre-addressed, overnight, express-mail container with packing procedures.

(b) Deface the label on each vial with red permanent marker.

(c) The activity will pack the container according to instructions provided and mail the container to DOC.

(d) The activity will call DOC to confirm overnight express-mail account number and air bill serial number for the container.

c. The disposal code for FDA-licensed cidofovir is AC01. [If used in IND status, refer to paragraph 12 above.]

d. Methods for disposal are as follows:

(1) Sanitary Landfill. This item and its container should be crushed/broken prior to burial in a permitted sanitary landfill. Rate shall not exceed 1% by weight per day of the total quantity of refuse collected and buried.

(2) Incineration. Mix this disposal item with relatively dry combustible material and incinerate. To prevent the production of excessive air pollutants, the disposal item or

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combination of similar items shall not exceed 1% by weight of the total waste load charged to the incinerator at any one time.

(3) Use the following procedures if the aforementioned 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 a pre-addressed, overnight, express-mail container with packing procedures.

(b) Deface the label on each vial with red permanent marker.

(c) The activity will pack the container according to instructions provided and mail the container to DOC.

(d) The activity will call DOC to confirm overnight express-mail account number and air bill serial number for the container.

e. Activities will prepare a certificate of disposition/destruction on DA Form 3161, Request for Issue or Turn-In, to document disposal actions and fax a copy to the DOC within 24 hours after final disposition. A sample DA Form 3161 is attached at Appendix I-6. Activities must also prepare an executive summary that documents the circumstances surrounding the wasting of the product and what actions have been taken to prevent loss of product in the future and fax to the DOC at 301-619-4468 (DSN 343).

f. Those charged with the disposal and destruction should address all questions or concerns to USAMMA Pharmacy Consultant.

14. Special Situations.

a. Ships Underway. Naval units requisition via responsible Type Commander (TYCOM) to (NAVMEDLOGCOM).

b. OCONUS Units. Procedures apply as above. For OCONUS shipments, USAMMA will assist the local action officer in preparing documentation required from the Food and Drug Administration or Ministry of Health before the package arrives at Customs for clearance. After delivery, the receiving official must complete a Customs Invoice for the TempTale[®] monitor to be shipped to USAMMA.

c. IND medications may not be shared or diverted without the knowledge and agreement of USAMRIID or the IND sponsor.

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APPENDIX I-1

Medical Logistics & Product Distribution – Summary.

1. The U.S. Army Medical Materiel Agency (USAMMA) Distribution Operations Center (DOC) will coordinate distribution of smallpox vaccine, vaccinia immune globulin (VIG), cidofovir, and other critical medical logistic items to all medical supply activities of each of the Armed Services.

2. Coordinate with the DOC at (301) 619-4121, -4128, -4411, -4318, -4198, or -4320 (DSN 343). Updated information appears at <https://usamma-extranet.detrick.army.mil/cpp/index.html>. The DOC works closely with the Naval Medical Logistics Command (NAVMEDLOGCOM) and the Air Force Medical Logistics Office (AFMLO).

3. Annex I assumes that smallpox vaccine is in Investigational New Drug (IND) status. VIG and cidofovir are in IND status. Medications in IND status involve education, documentation, and consent issues addressed in greater detail in “How To” guides for command surgeons and unit health-care providers, available separately (references a, b, and c).

4. Smallpox vaccine, VIG, and cidofovir require strict logistical tracking. This annex details USAMMA instructions for ordering, shipping, storing, controlling, accounting, and disposition of expired or suspended products.

a. Ordering. Submit requests to supporting medical logistics activity, which validates requirement and submits a formal requisition (e.g., DD Form 1348-6).

b. Shipping. Requesting activities coordinate individually with USAMMA’s DOC before shipment and immediately after receipt. Prevent shipments from sitting unattended at receipt, leading to product exposure to extreme temperatures and resultant wastage. For shipment overseas, plan ahead to prevent delays in customs clearance.

c. Storing. Refrigerate vaccine and VIG. Check refrigerator temperatures at least daily. Consider backup power supply. Store cidofovir at controlled room temperature.

d. Control & Accounting. Logistics activities, clinics, and vaccination sites must maintain readily retrievable records of receipts and issues. All activities must report supply status reports for IND medications monthly to USAMMA.

e. Disposition. Unused IND products must be returned to USAMMA. Unused non-IND products, if expired or suspended, may be disposed of according to USAMMA instructions. Empty containers may be disposed of according to USAMMA instructions.

APPENDIX I-3

Smallpox Vaccine Receiving and Processing Matrix.

1. PURPOSE. To give detailed instructions on the receiving and processing of smallpox (vaccinia) vaccine.

2. GENERAL INFORMATION. The Secretary of Defense assigned the U.S Army as the Executive Agent for DoD's Immunization Program for Biological Warfare Defense, including protocol management for smallpox vaccination. The Surgeon General of the Army is responsible for implementation of this vaccination program.

3. SPECIFIC RESPONSIBILITIES. The local activity's chief of medical logistics designates a Receiving Official and alternate(s). The delegated Receiving Official or Authorized Alternate official is responsible for the receipt, processing, storage, security, and subsequent release to the end-user of this vaccine. This matrix details the necessary receiving and handling instructions to be followed by each Receiving Official or Authorized Alternate. This product must be handled as a critical medical materiel item requiring close control. Due to the sensitivity of this product, the Receiving Official or Authorized Alternate is personally responsible to prevent damage or spoilage caused by negligence.

STEP	CRITICAL EVENTS
1	Service Medical Logistics Agency (USAMMA, AFMLO, NAVMEDLOGCOM) contacts Receiving Official before shipment, to verify ship-to address and convey any special preliminary receipt instructions.
2	DOC calls Receiving Official or Alternate before shipment and verifies: a. Address and any other alternate receiving official(s). b. Receipt time of product (typically 1000-1200 the next day). c. Expected time of phone call (1500-1630 on day of shipment) from DOC with FedEx or DHL tracking/air bill number. d. Receiving Official has been contacted by their Medical Logistics Agency (USAMMA, AFMLO, NAVMEDLOGCOM) to confirm delivery.
3	DOC provides the Receiving Official a briefing on the details and potential risk associated with receipt of this shipment: a. All personnel in receiving area are aware of the incoming product shipment and a policy is in place to contact the Receiving Official or Authorized Alternate immediately for signature. b. Receiving Official must clear all facility (e.g., post, installation, clinic) security requirements (e.g., gate guards notified). c. Receiving Official notifies central receiving mail drop off locations of incoming product shipment from FedEx or DHL. d. Receiving Official verifies that proper refrigeration is available in the receiving area, with constant temperature monitoring capability and

STEP	CRITICAL EVENTS
	<p>proper backup plans.</p> <p>e. Start tracking shipment. Call FedEx or DHL by 0800 the next day (www.DHL.com or 800-345-3579 or www.fedex.com or 800-463-3339).</p> <p>f. Contact DOC if delivery is not made by 1200.</p>
4	<p>USAMMA Distribution Operations Center (DOC) faxes Receiving Official a copy of this matrix and handling instructions a day before shipment.</p>
5	<p>Upon receipt of product, Receiving Official or Authorized Alternate will:</p> <p>a. Ask FedEx/DHL courier to wait for return shipment of TempTale® device included inside package, if possible.</p> <p>b. Check package for signs of damage, then open it and check for damage. If contents are damaged, notify USAMMA immediately.</p> <p>c. Remove handling instruction information paper, FedEx/DHL envelope (for TempTale® return to USAMMA), and FedEx/DHL label from the top of box. Note the airway bill numbers for the FedEx/DHL envelope for returning the TempTale and the FedEx/DHL label for returning the box. You will need to provide this information to the DOC in step 5(e).</p> <p>d. Remove top layers of gel packs, locate and remove the TempTale®, and place it in the FedEx/DHL envelope. If shipment is OCONUS, complete <u>Customs Invoice</u> provided for the return of the TempTale® monitor. Call FedEx or DHL for pickup.</p> <p>e. Call DOC to confirm receipt. If damaged, describe damage to DOC. Provide DOC with TempTale® FedEx/DHL tracking/air bill numbers for both the TempTale return envelope and the shipping box return label.</p> <p>f. Immediately secure product in the required refrigerated storage environment (2 to 8° Celsius, which is equivalent to 36 to 46° Fahrenheit). DO NOT FREEZE.</p> <p>g. Enclose all remaining packaging materials in shipping box and put FedEx/DHL label on box. Call FedEx or DHL for pickup.</p> <p>h. Assure stock record accountability for product is established in accordance with Service regulations. Track lot number and quantity.</p> <p>i. DO NOT RELEASE THE PRODUCT TO END-USER UNTIL AUTHORIZED BY THE DOC.</p>
6	<p>After receiving and downloading the TempTale®, the DOC will:</p> <p>a. Telephone the Receiving Official or Authorized Alternate with results.</p> <p>b. Fax Smallpox Vaccine Release Form to Receiving Official.</p>
7	<p>After receiving release authorization from the DOC, Receiving Official will:</p> <p>a. Notify pharmacy, immunization clinic, or other end user that product is available for clinical use.</p> <p>b. Report receipt of shipment to their Service Medical Logistics Agency.</p>

APPENDIX I-4

Handling Instructions Of Smallpox Vaccine (Insert Into Product Shipments).

1. **PURPOSE.** To give detailed instructions on the receiving and processing of the smallpox (vaccinia) vaccine.
2. **GENERAL INFORMATION.** The Secretary of Defense assigned the U.S Army as the Executive Agent for DoD's Immunization Program for Biological Warfare Defense, including protocol management for smallpox vaccination. The Surgeon General of the Army is responsible for implementation of this vaccination program.
3. **SPECIFIC RESPONSIBILITIES.** This paper details the necessary receiving and handling instructions to be followed by each activity. This product must be handled as a critical medical materiel item requiring the utmost control. Accountability by lot number and quantity is required.
4. **SMALLPOX (VACCINIA) VACCINE INFORMATION.** The product must be refrigerated and maintained at temperatures between 2 to 8 degrees Centigrade (36 to 46 degrees Fahrenheit). **DO NOT FREEZE.** The refrigerator's temperature must be monitored electronically or manually and recorded on a routine basis. The National Stock Number (NSN) for this vaccine is 6505-01-399-6828.
4. **SHIPPING.** The carrier will be DHL or FedEx. Shipment tracking information for DHL is available at www.DHL.com or 1-800-225-5345 and for Federal Express at www.fedex.com or 1-800-463-3339. USAMMA's Distribution Operations Center (DOC) will notify each receiving activity with the shipment tracking number (air bill number).
5. **RECEIPT INFORMATION.** Upon receipt of the package:
 - a. Check package for signs of damage, then open it and check for damage. If contents are damaged, notify the DOC immediately.
 - b. Remove handling instruction information paper, FedEx/DHL envelope (for TempTale[®] return to USAMMA), and FedEx/DHL label from the top of box. Note the airway bill numbers for the FedEx/DHL envelope for returning the TempTale and the FedEx/DHL label for returning the box. You will need to provide this information to the DOC in step 5(e).
 - c. Remove top layers of gel packs, locate and remove the TempTale[®], and place it in the FedEx/DHL envelope. If shipment is OCONUS, complete Customs Invoice provided for the return of the TempTale[®] monitor. Call FedEx or DHL for pickup.
 - d. Call DOC to confirm receipt. If damaged, describe damage to DOC. Provide DOC with TempTale[®] FedEx/DHL tracking/air bill numbers for both the TempTale return envelope and the shipping box return label.

e. Immediately secure product in the required refrigerated storage environment (2 to 8° Celsius, which is equivalent to 36 to 46° Fahrenheit). DO NOT FREEZE. If more than one container arrives, segregate the vials from each shipping container with the corresponding TempTale[®] monitor number. This provides accurate identification in case one container's monitor reads outside of required temperature parameters and is determined to be unusable.

f. Enclose all remaining packaging materials in shipping box and put FedEx/DHL label on box. Call FedEx or DHL for pickup.

g. If contents are in satisfactory condition, receive and process documents in accordance with local procedures. Assure stock record accountability for product is established in accordance with Service regulations. Track lot number and quantity.

h. DO NOT RELEASE PRODUCT TO END-USER UNTIL AUTHORIZED BY USAMMA's DOC. Release authorization will be electronically transmitted to the receiving activity once the temperature control monitors are received, downloaded and approved by USAMMA staff pharmacist.

6. SECURING SHIPMENT. DO NOT FREEZE! Products must be refrigerated at temperatures between 2 to 8 degrees Celsius (36-46 degrees Fahrenheit).

7. FINAL STEPS. After receiving release authorization from the DOC:

a. Notify pharmacy, immunization clinic, or other end user that product is available for clinical use.

b. Report receipt of shipment to your Service Medical Logistics Agency.

APPENDIX I-5
 Sample Investigational Drug Accountability Record.

Investigational Drug Accountability Record for _____(product) Organization / Unit _____							
Line #	Date	Recipient / Patient's Name	Recipient / Patient's ID #	Quantity Dis- pensed or Re- ceived	Balance Forward _____ Balance	Manu- facturer & Lot #	Initials of person dis- pensing drug
X		XXXXXXXXXX	XXXXXXXXXX	XXXXXX		XXXXXXXXXX	XXXXXXXXXX
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							
11							
12							
13							
14							
15							
16							
17							
18							
19							
20							

APPENDIX I-7

Mass Vaccination: Vaccine Delivery & Packaging Logistics.

1. In a smallpox outbreak, after federal authorities authorize release of smallpox vaccine for mass vaccination, the initial vaccine shipment to a location may be provided in a self-contained shipping and storage unit called a Vaxicool®. One Vaxicool unit contains approximately 300 vials of vaccine and can also be used for continued storage of up to 300 vials of vaccine with an appropriate 110-volt power source. The number of vaccine vials contained within a Vaxicool unit may depend upon the specific brand of smallpox vaccine dispensed from the National Pharmaceutical Stockpile (e.g., Wyeth, Aventis, Acambis, or Baxter vaccine) and the potential need for refrigeration of the specific diluent during shipping.

2. Diluent for vaccine reconstitution and needles for single-use vaccine administration will be included in all vaccine shipments, but may be in containers separate from the vaccine. Shipments will contain vial holders to secure the vial and prevent accidental tipping during preparation and vaccination.

3. Subsequent vaccine shipments will be in Styrofoam® shipping containers. These Styrofoam shippers can support 100 to 1500 vials of vaccine, depending upon the shipment size required. Vaccine shipped in Styrofoam containers will require arrangements for refrigerated storage at 2 to 8°C upon arrival. The need to store subsequent vaccine shipments should be incorporated into all vaccine storage plans at the installation and clinic levels.

4. Current plans for rapid, large-scale shipment of vaccine through the National Pharmaceutical Stockpile (NPS) system allow for shipment of up to 500 Vaxicool systems on the first day (75 million vaccine doses), with up to 615 additional vaccine shipments per day in Styrofoam shipping containers on days 2 through 6. This plan provides for distribution of 280 million doses of smallpox vaccine from the NPS storage sites to field sites within 5 to 7 days.

5. Security Considerations. Incorporate specific security needs into planning efforts for large-scale vaccination programs. Appropriate security should provide for the following:

a. Vaccine storage sites (clinic and non-clinic), including security personnel and locked, limited access areas for vaccine storage.

b. Identify backup power sources (e.g., generators) for all sites where vaccine is stored (i.e., vaccination clinics, storage sites).

c. Vaccination clinic sites: Security personnel for crowd control, traffic movement, clinic personnel safety, and related security issues.

d. Vaccine transportation to storage sites and dispensing clinics.

Potential Smallpox Vaccine Formulations for Mass Vaccination.

Vaccine (Manufacturer)	Doses per Vial	Standard Storage	Reconstitution/Storage
ACAM1000 (Acambis)	100	2 to 8°C	0.25 ml of accompanying diluent. Store at 2 to 8°C once reconstituted.
ACAM2000 (Baxter)	100	2 to 8°C	0.25 ml of accompanying diluent. Store at 2 to 8°C once reconstituted.
generic (Aventis Pasteur)	100 (see also later instructions)	0°C or below (see also later instructions)	0°C or below (see also later instructions).
Dryvax (Wyeth)	500	2 to 8°C	1.25 ml of accompanying diluent. Store at 2 to 8°C once reconstituted.

NOTE: Because the brand of vaccine to be used will not be known beforehand, review storage and handling instructions for the specific vaccine being used with *all* staff before they begin their shift.