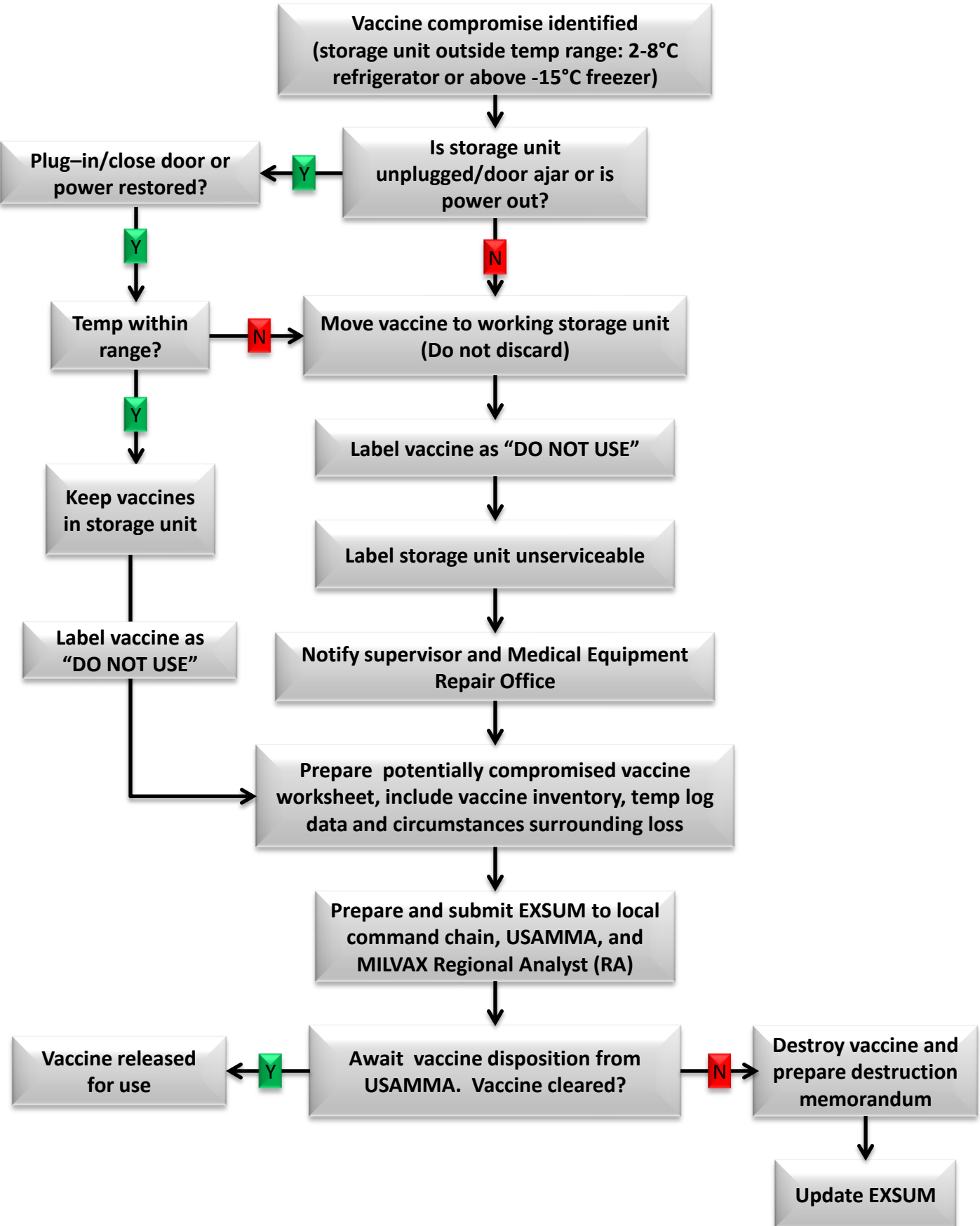


Steps to take for Potentially Compromised Vaccine Event



Potentially Compromised Vaccine Response Worksheet

Steps to take in the event of suspected Temperature Sensitive Medical Product (TSMP) compromise due to storage temperatures outside of the recommended range

Follow these procedures:

1. Move vaccine(s) or other TSMP to a working storage unit.
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 your facilities Emergency Retrieval and Storage Plan.
5. Contact USAMMA/DOC, your MILVAX Regional Analyst and your local/regional chain of command and standby for further instructions on the disposition of the vaccine or other TSMP.
6. Prepare an Executive Summary (EXSUM).

Required information*:

1. Temperature of refrigerator: current 40 max. 48 min. 40
2. Temperature of freezer: current N/A max. N/A min. N/A
3. Air temperature of room where refrigerator is located: 72
4. Estimated amount of time the unit's temperature was outside normal range:
refrigerator 60 mins freezer N/A
5. Vaccines or other TSMP in the refrigerator/freezer during the event (use the table below)

* Use the back of this worksheet to document the circumstances surrounding the potential loss of vaccine or other TSMP (i.e., pharmacologic and laboratory products). Record the date, time, location of the vaccine or TSMP, current and last recorded correct temperature of storage units, personnel notified and actions taken once the potentially compromised vaccine or TSMP was identified.

Vaccines (or other TSMP) Stored in Refrigerator

Brand name and manufacturer	NDC/Part #	Quantity affected	Lot #	Expiration date	Total cost of affected products
Anthrax, Emergent Biosolutions	64678-211-05	1 vial/10 doses	FAV 305	20 Jul 13	\$300.50 x 1 = \$300.50
Typhim Vi, sanofi-pasteur	49281-0790-20	1 vial/20 doses	G1130-1	18 Mar 13	\$674.93 x 1 = \$674.93
Influenza, Flumist, CSL	66019-109-10	62 syringes	14549121-A	28 Jun 12	\$15.61 x 62 = \$967.82
Hep A (adult), sanofi-pasteur	00006-4841-00	30 vials/30 doses	AHAVB406AA	10 Sep 12	\$35.04 x 30 = \$1062.00
Hep B (adult), Merck	00006-4995-00	10 vials/10 doses	AHBVBC004AA	23 Sep 13	\$23.15 x 10 = \$231.50
Yellow Fever, sanofi-pasteur	49281-915-05	25 vials	UF786AA	1 Jul 12	\$245.79 x 25 = \$6144.75
MMR, Merck	0006-4681-00	9 vials	0009AA	18 Dec 12	\$35.10 x 9 = \$315.90
TwinRix, sanofi-pasteur	58160-815-46	1 syringe	AHABB223CA	7 Oct 13	\$43.83 x 1 = \$43.83
Tdap, GSK	58160-842-11	10 vials/10 doses	AC52B073CA	20 Oct 13	\$247.13 x 1 = \$247.13
Meningococcal, sanofi-pasteur	49281-0489-01	5 vials/5 doses	U4004AA	2 May 13	\$75.14 x 5 = \$375.70

Vaccines (or other TSMP) Stored in Freezer

Brand name and manufacturer	NDC/Part #	Quantity affected	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 and ice packs in the freezer at the time of this event? Y N
3. Other:

Resources

USAMMA/DOC phone #: (301) 619-4318/1197, after hours: (301) 676-1184/0857

MILVAX Regional Analyst name and phone #:

Defense Logistics Agency - Troop Support Medical (DLA - TSM) phone #: (215) 737-5537

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

Potentially Compromised Vaccine Response Worksheet (continuation sheet)

Record date, time, personnel notified and actions taken after potentially compromised vaccine or other TSMP were identified. It is recommended that you submit this completed worksheet and copies of your temperature logs with the EXSUM.

Date:	11 Mar 12	Time:	1147	Facility/Unit Name:	Stone Island Arsenal
POC (name/email/phone #): HM2 Sammy Fox, sammy.fox@navy.mil, 666-666-6666					
Action Taken					
<p>11 Mar 2012 - car knocked down a power pole on base and caused a partial power outage to include the NOSC Stone Island</p> <p>11 Mar 2012/1147 - immunization clinic Sensaphone called the Command Duty Officer (CDO) cell phone with a message stating the power was off.</p> <p>11 Mar 12/1203 - CDO contacted the medical department LPO, HM2 Sammy Fox, to inform him that the power was off via text message and via phone call at 1230</p> <p>11 Mar 12/1230 - HM2 Fox told the CDO and the immunization clinic SOP should cover the procedures for caring for the vaccines</p> <p>11 Mar 12 - the Sensaphone continued to call the CDO until the temperature was in normal range (approx. 30-60 minutes). The vaccines were not removed from the refrigerator during the power outage and the doors were not opened.</p> <p>11 Mar 12/1400 - HM2 Fox conducted an inventory of all the vaccines in the affected storage unit, total cost \$10,364.06, marked vaccines as "DO NOT USE", until cleared by USAMMA/DLA-TS.</p> <p>12 Mar 12/0800 - prepared EXSUM and submitted copy to local command (i.e., OIC, Pharmacy Chief and Logistics Chief), USAMMA and RA for further guidance and disposition of vaccines.</p> <p>Will schedule Sensaphone procedure training with all the CDOs within next week.</p>					
<p>For USAMMA/DOC use only</p> <p>Per USAMMA/DOC - after reviewing the submitted EXSUM and temperature logs, the 1 vial of Anthrax vaccine has been "released for use". However, USAMMA will not ship any future anthrax and/or smallpox vaccine to this site until they prove that they have an adequate storage plan in place. Your RA will be in touch to offer assistance in getting a storage plan in place.</p> <p>Per DLA-TS - after review of all information, all other vaccines, have been released for use. Please contact us for further guidance.</p>					

EXAMPLE