



DEPARTMENT OF THE ARMY
U.S. ARMY MEDICAL MATERIEL AGENCY
1423 SULTAN DRIVE, SUITE 100
FORT DETRICK, MARYLAND 21702-5001

REPLY TO
ATTENTION OF:

MCMR-MMO-SO

1 Oct 2007

EXECUTIVE SUMMARY (EXSUM) STANDARD OPERATING PROCEDURES (SOP)

1. PURPOSE: To provide procedural guidance on how to prepare an Executive Summary (EXSUM) that addresses the prominent facts and circumstances when an activity suspects that vaccine has become compromised.

2. REFERENCES:

a. MEDCOM Regulation 40-35, Management of Regulated Medical Waste, 22 November 1999. <http://chppm-www.apgea.army.mil/hmwp/document%20library/r40-35.pdf>.

b. Change 1 to MEDCOM Regulation 40-35, 11 June 2001. http://chppm-www.apgea.army.mil/hmwp/document%20library/c1_r40-35.pdf.

c. 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>.

d. Centers for Disease Control and Prevention, CDC Policy on Unused Smallpox Vaccine, 1 June 2003. <http://www.bt.cdc.gov/agents/smallpox/vaccination/pdf/unusedvaccinepolicy.pdf>.

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

4. EXSUM REQUIREMENTS:

a. DoD activities are required to prepare an EXSUM when it is suspected that there is a potential loss of vaccine potency (i.e. vaccine has exceeded required temperature parameters of 2° to 8°C).

b. Must be prepared in Memorandum format (no longer than one page in length) and submitted to the United States Army Medical Materiel Agency (USAMMA) Distribution Operations Center (DOC) within 24 hours upon discovery of potentially compromised vaccine.

c. The EXSUM must be routed up the chain of command for review and endorsement before faxing to the USAMMA/DOC.

d. An EXSUM is not required for vaccine that has reached its expiration date. (See Destruction SOP for disposal instructions).

5. HOW TO PREPARE AN EXSUM: The EXSUM must contain the following information:

- a. Detailed explanation of the circumstances surrounding the potential loss of vaccine potency.
- b. Location in which the vaccine was discovered.

- c. Temperature of the location in which the vaccine was discovered.
- d. List of lot number(s) affected.
- e. Number of unopened vials.
- f. Detailed explanation of corrective action(s) to preclude future loss of vaccine.
- g. Point of Contact (POC) information to include name(s) and phone number(s).

EXECUTIVE SUMMARY FORMAT

UNCLASSIFIED

EXECUTIVE SUMMARY

20 April 20XX

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

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

APPROVED BY: COL Boss

UNCLASSIFIED

6. UPON RECEIPT OF THE EXSUM: Once the EXSUM is received at USAMMA/DOC, the USAMMA Pharmacy Consultant will review it and provide further guidance on the use or disposition of the suspected compromised vaccine.

7. REPLACEMENT OF VACCINE: The DOC must receive an EXSUM from activities that have identified the potential loss of vaccine potency prior to shipment of a replacement product.

8. FAX: EXSUMs should be faxed to:

U.S. ARMY (Executive Agent)

Fax: Comm (301)619-4468, DSN 343-4468

USAMMA Distribution Operations Center (DOC)

1419 Sultan Dr.

Fort Detrick, MD 21702-5001

Comm (301)619-4318, 7235, or 3017

DSN 343-XXXX

Email: usammadoc@amedd.army.mil

9. QUESTIONS OR CONCERNS: Those charged with the preparation of the EXSUM should address all questions or concerns to the USAMMA Pharmacist/COTR at Comm (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).

Deputy Director, Distribution Operations,
Military Vaccine Agency (MILVAX), USAMMA