

Potentially Compromised (PC) Temperature Sensitive Medical Product (TSMP) Worksheet

Steps to follow in response to a Potentially Compromised (PC) Temperature Sensitive Medical Product (TSMP)* Event

* TSMP collectively refers to: vaccines, some pharmaceuticals, temperature sensitive laboratory supplies, and other temperature sensitive medical items.

Step 1. Activate Site/Clinic Emergency Response Plan:

- Do not leave TSMP in non-functioning storage unit. Immediately move the TSMP to a working storage unit at proper temperature (*refrigerator: 2-8°C/36-46°F, freezer: below -15°C/5°F, ultra-cold freezer: below -80°C/-112°F*).
- Label exposed TSMP as "DO NOT USE," and place them in a separate container apart from other products in the storage unit.
- DO NOT destroy, discard or use TSMP until released by:
 - Defense Logistics Agency Troop Support Medical (*DLA-TSM*) for all vaccines (*other than those covered by USAMMA-DOC below*) and all other TSMP.
 - U.S. Army Medical Materiel Agency Distribution Operations Center (*USAMMA-DOC*) for anthrax, smallpox or adenovirus.
- Notify your local leadership of the potential loss.
- For incidents that involve vaccines, contact your Defense Health Agency-Immunization Healthcare Specialist (*IHS*) for assistance with reporting the potential loss: www.health.mil/ContactYourIHS

Step 2. Complete the PC-TSMP Worksheet:

- Complete **ALL** required information on the attached PC-TSMP worksheet, this will reduce the possibility of delays in receiving disposition for your products.
- Save document as "PC-TSMP_enter clinic name and location_enter current date" using the following example: PC-TSMP_NBHC Key West FL_01 AUG 23.
- For vaccines only, when possible, send completed worksheet along with copies of your temperature logs to your IHS for review to confirm all information is appropriately documented.
- Click the "Submit by email" button, ensure the "Desktop Email Application" button is selected and click "OK".
- Attach temperature logs/data and click the send button; it will forward completed worksheet directly to the DLA-TSM and USAMMA-DOC organizational mailboxes: DSCPColdchain@dlia.mil, paacoldchainteam@dlia.mil, and usarmy.detrick.usamma.mbx.doc@army.mil.
- For vaccines only, include your IHS's email address (*if known*) on the "To" line when the message opens up.
- If the "Submit by email" button does not work at your location, add all the above email addresses to the "To" line, attach temperature logs/data, and click the send button.
- Standby for further instructions from DLA-TSM and/or USAMMA-DOC. They will provide disposition for your TSMP.
- Contact DLA-TSM, USAMMA-DOC and/or your IHS (*vaccines only*) if disposition has not been received within 48-hours of submitting the completed worksheet.
- Contact information for DLA-TSM and USAMMA-DOC:
 - DLA-TSM Cold Chain Team: (215) 737-5537/5365, DSN: 444-5537/5365, or for URGENT after-hours issues only: (267) 738-2854. E-mail: DSCPColdchain@dlia.mil, paacoldchainteam@dlia.mil
 - USAMMA DOC: (301) 619-4318/3017, after hours: (301) 676-1184/0808.

NOTE: If your product or COVID-19 vaccine is not listed in the drop-down menu on page 4, manually enter the product information to include the brand name, NDC/part number, manufacturer and the cost per dose.

1. FACILITY NAME: (SELECT FROM DROP-DOWN OR ENTER REQUIRED INFORMATION)		2. SERVICE:	3. COMPONENT:	4. DATE (YYYYMMDD):
5. TSMP STORAGE LOCATION:		6. IMMUNIZATION HEALTHCARE SPECIALIST (IHS):		
7. POC:		8. EMAIL:		9. TELEPHONE:
REQUIRED TEMPERATURE AND STORAGE UNIT INFORMATION:				
10. <u>Room temperature</u> where TSMP located: _____				
a. TSMP left out of refrigerator or freezer? <input type="checkbox"/> YES <input type="checkbox"/> NO		b. Stored in transport container? <input type="checkbox"/> YES <input type="checkbox"/> NO		c. TSMP stored in proper storage unit (refer vs. freezer)? <input type="checkbox"/> YES <input type="checkbox"/> NO
d. If the answer to 'a' and 'b' is YES or 'c' is NO, how long? _____ hrs				
11. Prior to event: date/time of last manual temp check when temps were within normal range? a. DATE (YYYYMMDD): _____ b. TIME (HHMM): _____ c. REFER TEMP: _____ d. FREEZER TEMP: _____				
12. Post event: date/time when TSMP were back within normal temp range? a. DATE (YYYYMMDD): _____ b. TIME (HHMM): _____ c. REFER TEMP: _____ d. FREEZER TEMP: _____				
13. Are TSMP located in refrigerator and/or freezer during this event? <input type="checkbox"/> YES (complete a. - e.) <input type="checkbox"/> NO				
a. Water bottles in refer? <input type="checkbox"/> YES <input type="checkbox"/> NO		b. Water bottles or ice packs in freezer? <input type="checkbox"/> YES <input type="checkbox"/> NO		c. REFER TEMP: current: _____ warmest: _____ coldest: _____ d. FREEZER TEMP: current: _____ warmest: _____ coldest: _____
e. Estimated # of hours TSMP were exposed to temps outside the recommended range: REFER: _____ hrs FREEZER: _____ hrs				
14. PACKING PROCEDURES INFORMATION				
a. Product removed from nonworking unit & transported to working storage unit?		<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A		
b. Proper packing procedures used for transport (e.g., CDC)?		<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A		
c. Refrigerated coolant packs used to pack refrigerated TSMP?		<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A		
d. Frozen coolant packs used to pack frozen TSMP?		<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A		
e. Dry ice used to pack ultra-cold COVID-19 frozen vaccine?		<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A		
f. Temperature monitoring device placed in transport container near vaccine(s)/TSMP?		<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A		
g. Transport container temperature: _____				
15. If M-R was affected, was it stored in the freezer? <input type="checkbox"/> NO <input type="checkbox"/> N/A <input type="checkbox"/> YES				
16. Prior to this current temp excursion, were these same vaccine(s)/TSMP exposed to temps outside the recommended range at anytime? Provide prior excursion data in block 17 below. <input type="checkbox"/> YES <input type="checkbox"/> NO				
17. Did a patient receive a dose of the potentially compromised vaccine? Y/N. If yes, contact your Immunization Healthcare Care Specialist for situational awareness. <input type="checkbox"/> YES <input type="checkbox"/> NO				
18. Document in the space below the circumstances surrounding the potential compromise. Include date, time, current location of TSMP, personnel notified, and actions taken once incident was identified. List all products affected on following page.				

19. Please select all event types that apply:

a. Non-preventable loss:

b. Personnel Error:

c. Process Failure:

USAMMA-DOC/DLA-TSM Use Only:

