DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
11155 Dolfield Boulevard, Suite 117 Owings Mills, MD 21117 (410)779-5455 Fax:(410)779-5707	5/28/2025-6/3/2025* FEI NUMBER 1177704

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Colonel Elba M. Villacorta, Director

FIRM NAME	STREET ADDRESS
Department of Defense - Navy	Alexander T. Augusta Military Medical Center, 9300 Dewitt Loop
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Fort Belvoir, VA 22060-5285	Military Hospital Blood Bank and Transfusion Services

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Equipment used in the storage and distribution of blood and blood components is not observed, standardized and calibrated on a regularly scheduled basis as prescribed in the SOP Manual.

Specifically,

A. The dose mapping of the irradiator was not performed (b) (4) in accordance with SOP #TS 9.901 PR, "Irradiating Blood Products," and the manufacturer's instructions. For example, according to the dosimetry records, dose mapping of the RS 3400 irradiator was performed on (b) (4). Over (b) (4) months had lapsed between (b) (4) and (b) (4). Over (b) (4) had lapsed between (b) (4) and (b) (4). Additionally, records indicating that (b) (4) dose mapping of the RS 3400 irradiator had been performed since (b) (4) were requested but could not be provided by your establishment.

B. **[REPEAT]** The qualification of coolers used to transport red blood cells and plasma was not performed and/or documented annually (every 12 months) in accordance with Standard Operating Procedures, "Transfusion Services Blood Transport Cooler Validation Plan," Versions 2024 and 1 July 2020. According to the procedures, "Each cooler is to be validated at least annually. If there are any noticeable failures in the cooler or lid, it is to be removed from service and discarded." Examples of qualification that was not performed and/or documented annually are provided per the table below:

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	La-Tasha M Gunter, Investigator	X La-Tasha M Gunter Investigator Signed By: LATASHA GUNTER - S Date Signed: 06-03-2025 09:34:36	6/3/2025

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TYPE ESTABLISHMENT INSPECTED
Military Hospital Blood Bank and Transfusion Services

Cooler	2022 Qualification	2023 Qualification	2024 Qualification
1	2/16-17/22	*Failed to provide records	11/23/24-12/3/24
2	2/16-17/22	*Failed to provide records	11/23/24-12/3/24
3	2/16-17/22	*Failed to provide records	11/23/24-12/3/24
4	2/16-17/22	4/14/23 (new cooler)	11/23/24-12/3/24 *Performed approximately19 months later
5	2/16-17/22	4/14/23 (new cooler)	11/23/24-12/3/24 *Performed approximately 19 months later
6	2/16-17/22	*Failed to provide records	11/23/24-12/3/24
7	N/A	4/14/23 (new cooler)	11/23/24-12/3/24 *Performed approximately 19 months later
8	N/A	4/14/23 (new cooler)	11/23/24-12/3/24 *Performed approximately 19 months later

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OBSERVATION 2

Records including signature by the physician requesting the procedure are not maintained of all emergency transfusions.

Specifically,

2023-2025 Emergency release of blood product records were reviewed. The records did not include the signature of the physician requesting the emergency release of blood products as required by SOP #TS 5.001, "PR Emergency Release- Massive Transfusion".

Examples included the following:

1. The manual emergency release of blood product forms for patient (b) (4), (b) (6), (b) (7)(C) dated 2/24/25, did not include the signature of the physician requesting red blood cells for emergency release. Electronic emergency release records provided included the signature of a (b) (6), (b) (7)(C) instead of a requesting physician.

2. The manual emergency release of blood product forms dated 3/3/23 for patient (b) (4), (b) (6), (b) (7)(C), included the signature of a (b) (6), (b) (7)(C) instead of a requesting physician.

OBSERVATION 3

Written standard operating procedures including all steps to be followed in the processing, storage and distribution of blood and blood components for allogeneic transfusion and autologous transfusion were not always maintained.

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Specifically,

A. The dose mapping of the RS 3400 irradiator must be performed (b) (4) in accordance with SOP #TS 9.901 PR, "Irradiating Blood Products," and the manufacturer's instructions. However, SOP #TS 1.118 PR, "Irradiator Machine Maintenance SOP," stated (b) (4) (b) (4)

B. **[REPEAT]** Part of the procedural steps for the qualification of coolers were omitted or not clearly stated. The procedures under the "Transfusion Services Blood Transport Cooler Validation Plan," version 2024 and 1 July 2020 stated:

(b) (4)

The procedures above did not state what should be done with (b) (4). This discrepancy applied to the qualification of coolers with (b) (4) units. Additionally, the instructions for qualification of coolers with (b) (4) units stated, (b) (4) (b) (4) units," instead of (b) (4) units".

***DATES OF INSPECTION**
5/28/2025(Wed), 5/29/2025(Thu), 6/02/2025(Mon), 6/03/2025(Tue)

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."