

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Customhouse, Rm 900 2nd & Chestnut St Philadelphia, PA 19106 (215) 597-4390 Fax:(215) 597-0875	07/21/2008 - 07/29/2008*
	FEI NUMBER
	2573021

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Brigid O'Neill-LaGier, Chief Executive Officer

FIRM NAME	STREET ADDRESS
American National Red Cross, Penn Jersey Region	700 Spring Garden St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Philadelphia, PA 19123-3508	Regional Blood Bank

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 WE OBSERVED:

OBSERVATION 1

Failure to perform a thorough investigation and make a record of the conclusions and follow-up of an unexplained discrepancy.

Specifically, problems are not always investigated and corrective action plans are not always developed in a timely manner. For example:

- a. Exception detail report (b) (4) was discovered on 10/30/07 and logged into the automated problem management system (APMS) on 10/31/07 when a trend for BPD code (b) (4) (supply does not perform as expected or performance is deficient as compared to product specification or package insert claims) was identified in the monthly tracking and trending data for September 2007. The investigation level was listed as (b) (4). On 11/28/07, the problem investigator associate (b) (4) submitted the problem to quality assurance (QA) for review. On 12/3/07, QA requested that the problem investigator associate complete the (b) (4) and vBPD Problem and (b) (4) attach an (b) (4) to the Exception (required for a (b) (4) investigations), and complete the investigation into the problem. No subsequent actions are documented in APMS for this problem.
- b. Exception detail report (b) (4) was discovered and logged into APMS on 3/4/08 when a trend for BPD code (b) (4) (device defect) was identified in the monthly tracking and trending data for January 2008. The investigation level was listed as (b) (4). On 4/2/08, the problem investigator associate (b) (4) requested an extension from QA for developing a corrective action plan (CAP). On 4/4/08, an extension was granted by QA until 5/2/08. The problem investigator associate submitted the CAP to QA for review on 5/2/08. The CAP was rejected by QA on 5/9/08 with a note to see the (b) (4) checklist for corrections needed. No subsequent actions are documented in the APMS for this problem.
- c. Exception detail report (b) (4) was discovered and logged into APMS on 3/4/08 when a trend for BPD code (b) (4) (temperature unacceptable or not documented) was identified in the monthly tracking and trending data for January 2008. The investigation level was listed as (b) (4). On 4/2/08, the problem investigator associate (b) (4) requested an extension from QA for developing a corrective action plan (CAP). On 4/4/08, an extension was granted by QA until 5/2/08. The problem investigator associate submitted the CAP to QA for review on 5/2/08. The CAP was rejected by QA on 5/9/08 with a note to see the (b) (4) checklist of corrections needed. On 6/23/08, the revised CAP was submitted to QA for review. QA rejected the CAP on 6/27/08. No subsequent actions are documented in the APMS for this problem.

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OBSERVATION 2

Written standard operating procedures including all steps to be followed in the collection and processing of blood and blood components for homologous transfusion are not always followed.

Specifically, (b) (4) requires activities or actions to be documented in the APMS within approximately seven calendar days of completion of the activity/action. Documentation of activity/action is not always entered into the APMS within the required timeframe. For example:

Exception Detail Reports (b) (4) were discovered 9/21/07 and logged into the APMS on 9/25/07. Activities/actions regarding these problems initially occurred in September 2007, however, the activities/actions were not documented in the APMS until 3/28/08.

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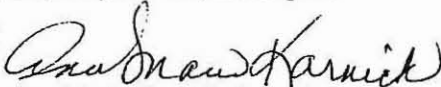
* DATES OF INSPECTION:

07/21/2008(Mon), 07/22/2008(Tue), 07/23/2008(Wed), 07/24/2008(Thu), 07/25/2008(Fri), 07/29/2008(Tue)

FDA EMPLOYEES' NAMES, TITLES, AND SIGNATURES:


Kimberly A. Dux, Investigator


Michele M. Falchek, Investigator


Ann-Marie Karnick, Investigator

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