DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6751 Steger Drive Cincinnati, OH 45237-3097 (513) 679-2700 Fax: (513) 679-2772 Industry Information: www.fda.gov/oc/industry	08/27/2010 - 09/23/2010*
	FEI NUMBER 1573019

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: David H. Plate, President/CEO

FIRM NAME	STREET ADDRESS
American Red Cross Blood Services	3747 Euclid Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Cleveland, OH 44115-2501	American National Red Cross

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

Records are not concurrently maintained with the performance of each significant step in the storage of each unit of blood and blood components so that all steps can be clearly traced.

Specifically,

Specifically, on April 6, 2009, staff performed the Weekly Inventory Reconciliation; however, staff documented that the inventory was invalid because the record was not verified by a second person. Staff then completed the Weekly Inventory Reconciliation on April 7, 2009. The record that was generated on April 6, 2009 was discarded.

OBSERVATION 2

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

Specifically,

1. Failure to follow Job Aid 15.4.ja037, Short Loss of Consciousness. This Job Aid requires staff to handle all reactions where the donor has seizures or convulsions or loss of bladder or bowel control as a long loss of consciousness to ensure follow-up (15.4.ja038).

a. A donor donated on 2/9/2009 (case # C2009021015160 2w) and had a loss consciousness for less than a minute 3 times during donation. The donor also lost bladder control. Staff documented the reaction as a Major Other (XO) and a Prolonged Recovery (XP). The donor was not treated as a Long Loss Of Consciousness (XF).

b. On 4/22/10, the donor had a Loss of Consciousness with a loss of bladder control (case # C2010042323040 7a); however, the Final Complication Code in the Medical Director Review and Recommendation section was documented as Large Hematoma (XH). The code should be documented as a Long Loss of Consciousness (XF).

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Nancy L. Neiger, Investigator	DATE ISSUED 09/23/2010

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2. Failure to follow Work Instruction 15.3.56, Final Donor Complication Quality Review. This Work Instruction requires quality staff to perform a final review of donor complication cases to ensure all required steps have been taken to complete and document a donor complication investigation.

The following Donor Reaction and Injury Records were missing the Final Quality Review:

Case # C2010021118080o7a dated 2/9/10
Case # C2010021118480o7a dated 2/4/10
Case # C2010041322310o7a dated 4/8/10
Case # C2010042322510o7a dated 4/21/10
Case # C2010042321500o7a dated 4/21/10
Case # C2010042322580o7a dated 4/22/10

3. Failure to follow Form Instruction: Donor Reaction and Injury Record procedure 15.4.frm015 and Work Instruction: Documenting Donor Complications 15.3.045. The Work Instruction and Form Instructions require a supervisor/designee review to ensure the donor complication was properly treated.

The firm received a call back from a donor on 2/13/09 (case # C2009021321070o3a). Sections 1-5 were completed on 2/13/09; however the Follow-up Contact attempts were not made until 3/1/09, 10/16/09 and 10/18/09. The Supervisor review was not completed until 10/13/09 and the Medical Director review was performed on 10/22/09 and Final Quality review was completed on 10/23/09.

4. Failure to follow Job Aid: Guidelines for Self-Detected Problems, 10.4.ja032. The Job Aid states that a self-detected problem is detected by the person that caused the problem and is detected on the same date or shift of occurrence.

On 2/10/09, staff (b) [redacted] received a call back from a donor. During the initial call on 2/10/09, the donor's reaction was documented as a bruising/discoloration of the right arm more than 2x2 inches. Hives/itchy skin were also documented. Attempts were made to contact the donor regarding the reaction. Staff (b) [redacted] documented contact with a relative of the donor on 2/25/09 and the Medical Director documented the Final Complication Codes as Prolonged Recovery (XP) and Large Hematoma (XH). The Medical Director signed off on the review on 5/4/09.

On 5/2/09 staff (b) [redacted] made the following changes on the DRIR: changed the reaction codes from Prolonged Recovery to Large Hematoma (section 5); crossed out the comment made by staff (b) [redacted] on the Follow-up Contact information (section 7); and changed the Final Complication Codes (section 9) made by the Medical Director. An exception report was not initiated/completed for these changes and no reason was given for the corrections.

5. Failure to follow firm's procedure for completing the Hospital Services Weekly Inventory Reconciliation Checklist is to be completed by the person performing the reconciliation and by the person verifying the information.

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On June 1, 2009, June 8, 2009 and June 22, 2009, staff (b) [redacted] was performing the second person verification for the Hospital Services Weekly Inventory Reconciliation; however, staff (b) [redacted] initialed the "Performed By" column of the Hospital Services Weekly Inventory Reconciliation Checklist and the Supervisor initialed the "Verified By" column of the checklist. Staff that actually performed the inventory reconciliation did not initial the Hospital Services Weekly Inventory Reconciliation Checklist

*** DATES OF INSPECTION:**
08/27/2010(Fri), 08/30/2010(Mon), 08/31/2010(Tue), 09/01/2010(Wed), 09/03/2010(Fri), 09/14/2010(Tue), 09/16/2010(Thu), 09/17/2010(Fri), 09/20/2010(Mon), 09/23/2010(Thu)

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	Nancy L. Neiger, Investigator	09/23/2010