DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
250 Marquette Avenue, Suite 600 Minneapolis, MN 55401 (612) 334-4100 Fax:(612) 334-4134 Industry Information: www.fda.gov/oc/industry	04/05/2010 - 04/23/2010
	FEI NUMBER 2173028

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Gregory L. Novinska, Chief Exective Officer

FIRM NAME	STREET ADDRESS
American National Red Cross (The)	4860 Sheboygan Avenue
CITY, STATE, ZIP CODE, COUNTRY Madison, WI 53705	TYPE ESTABLISHMENT INSPECTED American 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 WE OBSERVED:

OBSERVATION 1

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

1.) Work Instruction 15.3.51, Determining the Need for Risk Management Notification, states that when a donor sought medical treatment as a result of a complication, the incident must be reported to the Risk Management Officer. Three cases, dated 4/22/2009, 6/30/2009, and 10/5/2009 involved donors visiting their personal physician after donating. Staff failed to document on the Donor Reaction and Injury Record that Risk Management was notified. The DRIR's dated 4/22/2009 and 6/30/2009 include both the Medical Director Signature and the Final Quality Review. The DRIR dated 10/5/2009 is missing both the Medical Director Signature and the Final Quality Review.

2.) Work Instruction 15.3.55, Performing Final Case and Donor Suitability Assessment, states that reviews for performing final case and donor suitability assessment need to be performed within a reasonable amount of time. Four Donor Reaction and Injury Records, dated 7/10/2009, 10/5/2009, 10/26/2009 and 11/25/2009 are all missing the Medical Director Review, Recommendation and Signature. These records are also missing the Final Quality Review.

3.) Work Instruction 15.3.56, Final Donor Complication Quality Review, 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. Thirteen Donor Reaction and Injury Records were identified between 4/1/2009 and 12/29/2009 that are missing the Final Quality Review.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Karen M. LaBounty, Investigator Karen M. LaBounty Susan M. Miller, Investigator	04/23/2010