DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612 (949) 608-2900 Fax: (949) 608-4417 Industry Information: www.fda.gov/oc/industry	09/07/2010 - 09/15/2010* FEI NUMBER 3002345935

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Cathy D. Grimes, Quality Manager

FIRM NAME	STREET ADDRESS
American National Red Cross, The	7139 E Broadway Blvd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Tucson, AZ 85710-1404	Donor Center

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

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

Specifically, there was no problem logged, investigation or corrective action entered into the automated problem-management system (APMS) as required for Case ID# C201006061555o6p. Donor (b) (6) had an injury involving a contaminated needle stick to her during the venipuncture procedure. The phlebotomist reported while removing the needle cap she "poked" her finger (no blood or visible injury noted) and proceeded to stick the donor with the unsterile needle. Afterwards she "noticed a drop of blood" on her glove and informed the donor of the incident. The medical director was not notified of the donor injury until 07/20/10 by the Donor and Client Support Center (DCSC). The donor was temporarily deferred for 12 months on 07/23/10.

OBSERVATION 2

A thorough investigation of each reported adverse reaction was not made.

Specifically, the Medical Director review of Donor Reaction and Injury Records (DRIR) are not always conducted within a reasonable amount of time as required by written procedure Doc No 15.3.055, Version 1.1 titled, Work Instruction: Performing Final Case and Donor Suitability Assessment. Of the DRIR's reviewed between 10/2009 and 06/2010, 11 of 13 records had not received a timely review by the Medical Director, and/or Final Quality Review. In addition, four of the 13 DRIR's have not had a Final Quality Review performed.

a) Case ID# C200911120116o4g, Donor (b) (6) an adverse reaction was reported involving dizzy/light-headedness and prolonged recovery on 11/10/09. The medical directors' review occurred on 11/19/09 and the final quality review did not occur until 05/05/10 (approximately 6 months later).

b) Case ID# C200911161408olm, Donor (b) (6) an adverse reaction was reported involving dizzy/light-headedness with LOC less than 1 minute on 11/14/09. The medical directors' review occurred on 11/24/09 and the final quality review did not occur until 01/05/10 (approximately 6 weeks later).

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Tonia L. Sawyer, Investigator	09/15/2010

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c) Case ID# C20091229125505r, Donor (b) (6) an adverse reaction was reported involving LOC less than 1 minute, head and right elbow injury on 12/28/09. The medical directors' review occurred on 01/05/10 and the final quality review did not occur until 03/21/10 (approximately 6 weeks later).

d) Case ID# P200912291348o72, Donor (b) (6) donation occurred on 12/28/09; donor reported an adverse reaction on 12/29/09 involving a sore left arm at the VP site. The medical directors' review occurred on 06/01/10 and the final quality review occurred on 06/07/10 (approximately 6 months later).

e) Case ID# C201001021035o3n, Donor (b) (6) an adverse reaction was reported involving sharp shooting pain down left arm on 12/31/09. The medical directors' review occurred on 01/04/10 and there is no final quality review documented.

f) Case ID# C201001121821o6p, Donor (b) (6) donation occurred on 01/09/10; donor reported an adverse reaction on 01/12/10 involving dizzy/light-headedness, headache, sweating, weakness and 2 to 3 episodes of diarrhea. The medical directors' review occurred on 01/29/10. There in no final quality review documented. Units were discarded on 01/12-13/10.

g) Case ID# P201003011858o51, Donor (b) donation occurred on 03/01/10; donor reported an adverse reaction that evening involving bruising/discoloration on the left arm at VP site. The medical directors' review occurred on 06/14/10 (approximately 3 ½ months later). There in no final quality review documented.

h) Case ID# C201003171636o4u, Donor (b) donation occurred on 03/16/10; donor reported an adverse reaction on 03/17/10 involving short LOC and received outside medical care and released the same day. The medical directors' review occurred on 05/04/10 (approximately 7 weeks later). There in no final quality review documented.

i) Case ID# C201003241737o4g, Donor (b) (6) an adverse reaction was reported involving a large hematoma on 03/19/10. The medical directors' review occurred on 07/14/10 (approximately 4 months later). There in no final quality review documented.

j) Case ID# C201006061555o6p, Donor (b) an adverse reaction/injury was reported involving a contaminated needle stick to the donor by the phlebotomist on 06/05/10. The medical director was notified of the donor injury by the Donor and Client Support Center (DCSC) via email on 07/20/10, and the donor was temporarily deferred for 12 months. The medical director signed the DRIR on 08/09/10 (approximately 3 weeks later). There is no final quality review documented. The unit was discarded on 06/06/10.

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k) Case ID# C201006102131o6p, Donor (b) (6) an adverse reaction was reported involving LOC 1 minute or more and a head injury (struck face/head) on 06/09/10. The medical directors' review occurred on 08/02/10 and the final quality review occurred on 08/04/10 (approximately 2 months later).

*** DATES OF INSPECTION:**
09/07/2010(Tue), 09/08/2010(Wed), 09/09/2010(Thu), 09/10/2010(Fri), 09/15/2010(Wed)

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	Tonia L. Sawyer, Investigator Tonia L Sawyer	09/15/2010