

**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 Industry Information: www.fda.gov/oc/industry	09/07/2010 - 09/24/2010*
	FEI NUMBER
	2573016

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Timothy A. Miller, Director Collections

FIRM NAME	STREET ADDRESS
American Red Cross Greater Alleghenies Region	250 Jari Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Johnstown, PA 15904	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

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

Specifically, the final quality review of adverse donor reactions, as documented on the internal form titled Donor Reaction and Injury Records (DRIR), are not always completed, are not always completed within a reasonable amount of time or are not always completed in accordance with the three month limit directed by the internal document dated June 1, 2010 and titled Request for Temporary Authority. For example:

- A. Case ID# P201008021649o48-DRIR, occurred on February 23, 2010 and detailed an adverse donor reaction, experienced by Donor 027-69707 that included donor loss of consciousness for less than one minute, dizzy/lightheaded, pale skin/lips, prolonged recovery and phlebotomy site bruising/discoloration. The Donor was transported, via ambulance, to a local medical facility and was hospitalized for three days. This DRIR did not have a final quality review until six months later on August 23, 2010.
- B. Case ID# C201005150818o3n-DRIR, occurred on May 14, 2010, was reported to the Region on May 15, 2010 and detailed an adverse donor reaction, experienced by Donor ID 21572 that included a major headache. As of September 17, 2010, this DRIR did not have a final quality review. Additionally, this donor donated subsequent blood components on July 2 (unit KC14909), and September 10, 2010 (unit KC15228) which was prior to the conclusion of the donor's May 14, 2010 adverse donation reaction.
- C. Case ID# C201004060826o9i-DRIR, occurred on April 6, 2010 and detailed an adverse donor reaction, experienced by Donor ID 569012 that included donor dizzy/lightheaded and nausea. As of September 17, 2010, this DRIR did not have a final quality review.

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	Travis R. Hunt, Investigator Marjorie L. Davis, Investigator	09/24/2010

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- D. Case ID# P201004071707o31-DRIR, occurred on April 2, 2010, was reported to the Region on April 7, 2010 and detailed an adverse donor reaction, experienced by Donor (b) (6) that included bruising / discoloration, swelling / raised area of 3.5" x 4.5" around the phlebotomy site. This DRIR did not have a final quality review until August 25, 2010.
- E. Case ID# P201003121317o32-DRIR, occurred on March 11, 2010 and detailed an adverse donor reaction, experienced by Donor (b) (6) that included an arterial puncture. This DRIR did not have a final quality review until July 1, 2010.
- F. Case ID# C201003052155o7a-DRIR, occurred on March 1, 2010, was reported to the Region on March 5, 2010 and detailed an adverse donor reaction, experienced by Donor ID 1226916 that included a nerve injury. As of September 17, 2010, this DRIR did not have a final quality review.

OBSERVATION 2

The personnel responsible for the collection of blood or blood components are not adequate in training and experience, including professional training as necessary to assure competent performance of their assigned functions, and to ensure that the final product has the safety, purity, potency, identity and effectiveness it purports or is represented to possess.

Specifically, on December 4, 2008, Region employee (b) (6) further identified as the Assistant Director of Collections, sent a memorandum to "All Collection Staff" that directed the utilization of hand warmers on the hands of donors prior to the performance of a finger stick. The finger stick is the method of obtaining a donor's blood specimen for further hemoglobin analysis. This analysis is part of donor qualification criteria prior to the performance of the collection phlebotomy. The Region has failed to create and implement training specific to the utilization of hand warmers.

OBSERVATION 3

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

For example,

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- A. On December 4, 2008, Region employee (b) (6) further identified as the Assistant Director of Collections, sent a memorandum to "All Collection Staff" that directed the utilization of hand warmers on the hands of donors prior to the performance of a finger stick. The finger stick is the method of obtaining a donor's blood specimen for further hemoglobin analysis. This analysis is part of donor qualification criteria prior to the performance of the collection phlebotomy. The Region has failed to create an internal written procedure detailing this blood and blood component manufacturing step.
- B. Our September 7, 2010 review of the internal written procedures titled Form: Collection Site Set-Up Daily Supply Log (Doc No 15.4.firm033 Version 2.2) and Work Instruction: Independent Review of Collection Site Set-Up Activities (Doc No 15.3.091 Version 1.1) revealed that these two procedures are not accurate in that the two written procedures direct conflicting actions. Specifically, Form: Collection Site Set-Up Daily Supply Log directs that day-of-use supplies, utilized in the collection of blood and blood components, are to be documented on the form titled Collection Site Set-Up Daily Supply Log. However, Work Instruction: Independent Review of Collection Site Set-Up Activities directs that all supplies available for the operation are to be listed on the Collection Site Set-Up Daily Supply Log.
- Additionally, on September 7, 2010, during the Region's mobile drive identified as 158359, the Collection Site Set-Up Daily Supply Log identified three packages of Fenwal brand triple collection bags (lot numbers FM10612024, FM10612024 and FM10F10020). The collection bags identified as lot FM10612024 were actively available for use in that they were removed from the packaging and stored on a supplies table. However, the package containing the Fenwal brand triple collection bags, identified as lot FM10F10020, remained unopened and was stored separately from the other collection bags.
- C. Our September 8, 2010 review of quarantined blood and blood components stored in quarantine refrigerators 027.04 and 027.96 revealed that blood and blood components are maintained in gray plastic totes within the refrigerators. Furthermore, some of the totes are labeled with an applied paper label that read "H-QUAR" or "H-QCIN" or "H-IDAB" while other gray totes not labeled. The Region employee identified as (b) (6) stated "default is QUAR if the bin is not labeled." The Region has failed to create, maintain and implement a written procedure directing the applied labeling of quarantine totes.

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Marjorie L. Davis, Investigator

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OBSERVATION 4

Written procedures are not reviewed and approved by the quality control unit.

Specifically, your written procedure titled Work Instruction: Performing an Annual Content Review of Controlled Documents and identified as document number 03.3.003, version 2.1, directs the performance of an annual review of written procedures. You fail to always perform an annual review of written procedures. For example:

- A. The written procedure titled Work Instruction: Independent Review of Collection Site Set-Up Activities and identified as document number 15.3.091, version 1.1 was approved on May 30, 2006. This written procedure was not reviewed annually in that the subsequent annual reviews were conducted on June 25, 2007, September 26, 2008 and October 16, 2009.
- B. The written procedure titled Work Instruction: Performing the Health History Interview with Direct Oral Questioning (DOQ) and identified as document number 14.3.10, version 1.0 was approved on July 15, 2004. This written procedure was not reviewed annually in that some of the subsequent annual reviews were conducted on August 7, 2008 and October 6, 2009.

OBSERVATION 5

Deviation from the procedural requirements of a decree of injunction.

Specifically,

The Amended Consent Decree of Permanent Injunction (Civil No. 93-0949) (Decree) paragraph IV.C.6 requires the performance and documentation of the training of American Red Cross (ARC) employees. Since 2007, the Learning Management System segment of the Biomedical Training System (BiTS) has been utilized to electronically document employee training. BiTS is not designed to maintain or provide verification of the employee's attendance and competency assessment of a specific training task. Furthermore, the internal written procedure titled Work Instruction: Conducting and Completing Training and identified as document number 04.3.006 and version 2.1 reads in part: "**** Hard-copies of assessment tools, including performance checklists and the attendance list must be discarded after recording and verifying the data in the LMS ***." The Region's training records are not always

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adequate as documented. For example:

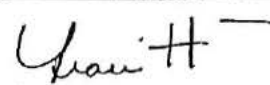
Our September 7, 2010 review of BiTS data for Region employee (b) (6) further identified as Learner ID 38578, revealed that (b) (6) completed the training course identified as BHQ-PROCESS BHQ-14.4-TC074 c.1.2 and titled Measuring Hemoglobin on May 3, 2010. However, the Region failed to provide documentation of (b) (6) attendance and demonstrated competency assessment of this training.

Furthermore, our September 16, 2010 review of BiTS data revealed that Region employee (b) (6) further identified as Learner ID 16136, was the instructor for the training course identified as BHQ-PROCESS BHQ-14.4-TC074 c.1.2 and titled Measuring Hemoglobin. (b) (6) completed v.1.1 of this same course on February 29, 2008 and was granted equivalency for the current version (i.e., v.1.2) of this course on October 27, 2008. However, the Region failed to provide documentation of (b) (6) attendance and demonstrated competency assessment of this training.

Additionally, our September 16, 2010 review of BiTS data revealed that Region employee (b) (6) was granted classroom instructor privileges within BiTS after the August 5, 2010 completion of the training course identified as SUP-APP BHQ-04-SA-026N (Rev 4/13/2010) and titled Instructor, Classroom. However, the Region failed to provide documentation of (b) (6) attendance and demonstrated competency assessment of this training.

*** DATES OF INSPECTION:**

09/07/2010(Tue), 09/08/2010(Wed), 09/09/2010(Thu), 09/10/2010(Fri), 09/15/2010(Wed), 09/16/2010(Thu), 09/17/2010(Fri), 09/24/2010(Fri)

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