DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax: (313) 393-8139 Industry Information: www.fda.gov/oc/industry	08/~~20~~ 24/2010-09/27/2010
	FEI NUMBER 1873044

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Diane E. Ward, CEO

FIRM NAME	STREET ADDRESS
American Red Cross ~~Southeastern~~ Southeastern Michigan Region	100 Mack Avenue
CITY, STATE AND ZIP CODE Detroit, MI 48201	TYPE OF ESTABLISHMENT INSPECTED 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

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

Specifically,

A) Donor Reaction and Injury Reports were not always completed as required by standard operating procedures.

1. Work Instruction: Final Donor Complication Quality Review 15.3.56 explains the steps for reviewing a donor complication case for closure. The steps ensure documentation is complete, accurate and legible and any issues related to product safety, quality, identity, purity or potency (SQuiPP) have been handled appropriately. The steps also ensure donor deferrals and notifications recommended by the medical director have been applied to the donor's record when required. Twenty-two donor complication cases opened from 11/18/09 through 02/13/10 lack final quality review. Seven donor complication cases opened from 11/13/09 through 12/28/09 had final quality review performed ~~6~~ 3 months or more after the cases were opened.

2. Work Instruction: Determining the Need for Risk Management Notification ~~14.3.174 v1.1~~ 15.3.51 v1.0 **and Work Instruction: Performing Donor Complication Activities 14.3.173 v1.0** states at minimum the following incidents must be reported to the risk management officer (RMO): donor requires transport to a medical facility... donor sought medical treatment. Eight donor reaction and injury cases reported/occurring on 11/10/08, 11/12/08, 11/16/08, 02/22/09, 03/10/09, 03/17/09, 04/06/09 and 12/23/09 were not reported the risk management officer.

13FR05077 – On 11/10/08 donor 160898 fell at the collection site, causing a cut to her lip with some bleeding. She went to the emergency room and had stitches placed in her lower lip.

13FP59551 – On 11/12/08 donor 161084, while at the collection site, experienced tetany of the fingers and a swollen tongue with bluish color. The donor had a change of speech and was transported to the hospital via emergency medical service (EMS).

13FW69297 – On 11/16/08 donor 161109 became dizzy and incontinent secondary to donation and was taken to the emergency room by his son.

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	Barbara A. Rusin L'Oreal D. Fowlkes Sherri J. Blessman	Barbara A. Rusin, Investigator L'Oreal D. Fowlkes, Investigator Sherri J. Blessman, Investigator	12/15/2010

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax: (313) 393-8139 Industry Information: www.fda.gov/oc/industry	08/~~20~~ 24/2010-09/27/2010
	FEI NUMBER 1873044

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Diane E. Ward, CEO

FIRM NAME	STREET ADDRESS
American Red Cross ~~Southeastern~~ Southeastern Michigan Region	100 Mack Avenue
CITY, STATE AND ZIP CODE Detroit, MI 48201	TYPE OF ESTABLISHMENT INSPECTED 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.

13GP60311 - On 02/22/09 donor 940623 passed out at the collection site and was transported to the hospital via EMS.

13FP60609- On 03/10/09 first time donor (b)(6) reported experiencing sharp shooting pain for which she sought treatment at an emergency room.

13GY43479 - On 03/17/09 donor 377371 experienced prolonged recovery and was admitted to the hospital.

13GE80462 - On 04/06/09 ~~donor~~ first time donor (b)(6) experienced numbness, coldness and pain and was treated in the emergency room.

C20091228130105 - On 12/23/09 donor 842103 experienced a loss of consciousness/head injury and laceration over her right eye and was transported to the emergency room.

3. Work Instruction 14.3.173 v1.0 requires notification to the facility medical director and collections director and DCSC medical director immediately following donor complications requiring transport to a medical facility from the collection site and/or treatment in an emergency room. Additionally, the work instruction requires notification to the chief executive officer, facility quality assurance director and DCSC executive director within one day. Two cases meeting the criteria for notification were not reported appropriately:

Case C20091228130105r reported donor 842103(b)(6) experienced a loss of consciousness/head injury and laceration over her right eye on 12/23/09 after donation. She was transported to the emergency room via wheelchair. The case was not reported to any of the above mentioned individuals. The case has not had medical review or final quality review.

Case C2010202074205r reported donor 501030/(b)(6) experienced a loss of consciousness/head injury and laceration requiring transport to the hospital via emergency medical service (EMS) on 02/01/10. The case was not reported to the DCSC medical director or DCSC executive director. Medical review was performed on 02/18/10. Final quality review was performed on 06/10/10.

4. Work Instruction: Performing Final Case and Donor Suitability Assessment 14.3.174 v1.1 requires review of all details (including treatment, response and outcome) of the donor complication case as recorded on the DRIR, BDR and any supplemental documents within ten days of completion of the investigation. The following 3 donor complication cases were not reviewed/ assessed within 10 days of case completion:

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
		Barbara A. Rusin, Investigator L'Oreal D. Fowlkes, Investigator Sherri J. Blessman, Investigator	12/15/2010

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax: (313) 393-8139 Industry Information: www.fda.gov/oc/industry	08/~~20~~ 24/2010-09/27/2010
	FEI NUMBER 1873044

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Diane E. Ward, CEO

FIRM NAME	STREET ADDRESS
American Red Cross ~~Southeastern~~ Southeastern Michigan Region	100 Mack Avenue
CITY, STATE AND ZIP CODE Detroit, MI 48201	TYPE OF ESTABLISHMENT INSPECTED 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.

C2010061020130o6p (complete 06/10/10-Final Assessment 09/07/10)
P201006031731o72 (complete 06/03/10- Final Assessment 07/02/10)
C20100608135o6m (complete 07/08/10-Final Assessment 07/20/10)

X

B) Standard operating procedures were found to not always be followed in regards to management of donor and component records related to BacT alerts.

1. Form: Component Status Change Record (CSCR) 11.4.frm9 v-1.1 prescribes how this form is to be accomplished, to include completion of the Product Code, Consignee/Staff Notification, Written Notification and Final Disposition sections. During review of BacT alert files it was found that 9 of 16 records did not have a CSCRs completed, or did not have one ~~ore~~ or more of these sections completed as required. Examples of such files include:

   c200909031436o1u
   c2010041023110o5v
   c200909181530o1u
   c200909301929o6t
   c200909130123o6h
   c200909280945o4a
   c20100106055603t
   c200907220721o4q
   c200910040532o4g

2. Work Instruction: Process Verification 11.3.028 requires that "A process verifier performs process verification after all required actions are completed and confirms or substantiates that the process was followed, all tasks were performed, appropriate actions taken, required documentation is provided or available, and the process is complete." Process verification was not documented on CSCRs, was documented when CSCRs were not completed according to applicable standards, or was documented more than 3 months after initiation of the case in 12 of 16 cases, to include the following:

   c200909031436o1u
   c2010041023110o5v
   c200909181530o1u
   c200909301929o6t
   c200910130952o7b
   c200909130123o6h

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
		Barbara A. Rusin, Investigator L'Oreal D. Fowlkes, Investigator Sherri J. Blessman, Investigator	12/15/2010

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax: (313) 393-8139 Industry Information: www.fda.gov/oc/industry	08/~~20~~ 24/2010-09/27/2010
	FEI NUMBER 1873044

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Diane E. Ward, CEO

FIRM NAME	STREET ADDRESS
American Red Cross ~~Southeasten~~ Southeastern Michigan Region	100 Mack Avenue
CITY, STATE AND ZIP CODE Detroit, MI 48201	TYPE OF ESTABLISHMENT INSPECTED 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.

c200909280450o4a
c201001060556o3t
c200907220721o4q
c200911121228o7b
c200912051557o4q
c200907170710o4q

3. Form: Donor Status Change Record (DSCR) 11.4.frm007 provides how this form is to be completed. Sections of the form described herein include Donor Information, Third-Party Source, Follow-up Donor Contact, Registration Hold Resolution, Process Verification of Part I, Evaluation, and Follow-up to Evaluation and Related Cases (Process Verification). In at least 13 of 16 files reviewed, the directives in this standard were found to either not be followed, or the form to have been process verified although errors were found upon review by FDA investigators.

4. Work Instruction: Process Verification 11.3.028 requires that "A process verifier performs process verification after all required actions are completed and confirms or substantiates that the process was followed, all tasks were performed, appropriate actions taken, required documentation is provided or available, and the process is complete." In addition, Form: Donor Status Change Record (DSCR) 11.4.frm007 requires that a DSCR have the "signature of staff member who completed process verification and date that process verification was completed. DSCRs which were either not process verified, or were verified more than 3 months after initiation of the case, were located in ~~11~~ 10 of 16 files reviewed, to include the following examples:

c200910302218o4d
c201002250809o7b
c201004102311o5v
c200910130931o7b
c200909180939o4a
c200909280500o4a
c201001060556o3t
c200912051557~~0~~o4q
~~c200907170710o4q~~
~~c200911121255o7b~~
c200907220721o4q

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
		Barbara A. Rusin, Investigator L'Oreal D. Fowlkes, Investigator Sherri J. Blessman, Investigator	12/15/2010

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax: (313) 393-8139 Industry Information: www.fda.gov/oc/industry	08/~~20~~ 24/2010-09/27/2010
	FEI NUMBER 1873044

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Diane E. Ward, CEO

FIRM NAME	STREET ADDRESS
American Red Cross ~~Southeastern~~ Southeastern Michigan Region	100 Mack Avenue
CITY, STATE AND ZIP CODE Detroit, MI 48201	TYPE OF ESTABLISHMENT INSPECTED 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.

5. Work Instruction: Process Verification 11.3.028 provides guidelines for operational review and process verification of work performed and of documentation on records. The work instruction states "A process verifier performs process verification after all required actions are completed and confirms or substantiates that the process was followed, all tasks were performed, appropriate actions taken, required documentation is provided or available and the process is complete." Twelve of 16 Positive Bacterial Culture Case Files reviewed for alarms occurring in September 2009, October 2009, January 2010, lack operational review, or the review was completed more than 3 months after the case was initiated.

C) Emergency/Exceptional Releases were found to not always be managed according to the relevant standards of practice to include the following examples.

1. BSD 48.101M, Exceptional and Emergency Release of Blood Components, requires for both the exceptional and emergency processes that "Each region's chief executive officer (CEO) must appoint, in writing, a regional coordinator and one (1) or more designees to oversee the following elements..." It was found during the inspection that the SEM Region did not have, in writing, an appointed regional coordinator for either the exceptional releases or the emergency releases of blood products. An exception was written for this problem during the inspection (E-0863390).

2. BSD 48.101M, Exceptional and Emergency Release of Blood Components, requires that the regional coordinator (or designee) reviews, signs and dates the authorization form once completed by the requesting physician or medical director of the transfusion service. Designee (b) (6) was found to have reviewed 6 exceptional releases of those evaluated during this inspection. Of these, 3 were found to have been reviewed, signed and dated by her prior to the adequate completion of authorization by the requesting physician or transfusion service medical director. A problem was logged for this finding as exception number E-0844309 during the inspection. Designee (b) (6) reviewed 1 file and signed a and dated an authorization for that file which was not signed by the requesting physician or the medical director of the transfusion facility.

3. ~~Two~~ Three of 18 reviewed exceptional releases were found to have been completed with discrepancies relative to standard operating procedures. For example, such discrepancies included 1 authorization being accepted as complete although it was not signed off by either the requesting physician or transfusion service medical director, 1 was found to have been reviewed as complete although not all required forms were in the case file, and 1 authorization was found to have two separate components approved on a single form. These discrepancies were logged into the problem management system during the inspection as exceptions ~~E-0861555 and~~ E-0863934.

D) Twenty-six possible transfusion reaction/recipient complication cases were reviewed during this inspection. Seven of 19 managed by the SEM Region, and 4 of 7 cases managed by the Donor Client Support Center (DCSC) were not managed as required.

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
		Barbara A. Rusin, Investigator L'Oreal D. Fowlkes, Investigator Sherri J. Blessman, Investigator	12/15/2010

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax: (313) 393-8139 Industry Information: www.fda.gov/oc/industry	08/~~20~~ 24/2010-09/27/2010
	FEI NUMBER 1873044

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Diane E. Ward, CEO

FIRM NAME	STREET ADDRESS
American Red Cross ~~Southeastern~~ Southeastern Michigan Region	100 Mack Avenue
CITY, STATE AND ZIP CODE Detroit, MI 48201	TYPE OF ESTABLISHMENT INSPECTED 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.

1. Job Aid: Timing Guidelines for Recipient Complication Investigations 11.4.ja056 v-1.0 requires that "within 3 months of opening the case" the case investigator "complete the case or document why the case remains open." Case ~~DCSC-C-014-TR-ORX00246~~ DCSC-C-013-TR-ORX00246 was opened on 07/09/09 and was closed on 05/22/10. There was no documentation in the file to justify as to why the case remained open for over 3 months. This lack of documentation was discovered by an FDA investigator and was logged as exception E-0871869.

2. The standard operating procedure Form: Component Status Change Record (CSCR) 11.4.frm9 v-1.1 allows optional use of the Final Disposition section of the CSCR. If used, this section is to be completed using "the legend on the form … or a valid disposition to indicate the final disposition."

   In case ~~DCSC-C-014-TR-ORX00246~~ DCSC-C-013-TR-ORX00246, all products from the current donation for donor #6 were to be discarded. The final disposition of the red blood cells (04730) from this donor was recorded on the CSCR as Expired In-House Destroyed (EID). However, this product was destroyed by the consignee who was credited for the unit, so the final disposition should have been Destroyed by Consignee (DC).

   In case ~~DCSC-C-014-TR-ORX00246~~ DCSC-C-013-TR-ORX00246, all current donation products for donor #3 were to be discarded. The final disposition of the plasma (19701) was recorded on the CSCR as Destroyed (D), but the product was shipped to (b) (4) on 09/17/09 so this disposition is also in error. These errors, as discovered by an FDA investigator were logged as exception E-0871887.

3. BSD 93.101T, Possible Transfusion Reaction Investigation v-2.2 requires "If the case involved a fatality or was a high probability (P5 or P6) case as listed on the Monthly Tally of closed Possible Transfusion Reaction Cases (10.4.frm019), send a copy of the file to the National DRCP…" and to "Document case closure activities on the checklist." In addition Instructions for Use: Possible Transfusion Reaction Checklist 93101t06.frm requires that the case investigator "Date and initial the line items on the form as they are completed. If an item is not applicable to the case, indicate this with N/A." The line item "Copies of the complete case files for any P5 or P6 cases have been sent to National DRCP office" was not completed in ~~6~~ 7 of 26 reviewed files to include the following examples:

   13TRL08-009
   ~~18TRL08-008~~
   18TRL08-006
   18TRL09-004
   18ALL08-001
   ~~DCSC-C-0130-TR-TRL00502~~
   DCSC-C-013-TR-ORX00467

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
		Barbara A. Rusin, Investigator L'Oreal D. Fowlkes, Investigator Sherri J. Blessman, Investigator	12/15/2010

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax: (313) 393-8139 Industry Information: www.fda.gov/oc/industry	08/~~20~~ 24/2010-09/27/2010
	FEI NUMBER 1873044

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Diane E. Ward, CEO

FIRM NAME	STREET ADDRESS
American Red Cross ~~Southeasten~~ Southeastern Michigan Region	100 Mack Avenue
CITY, STATE AND ZIP CODE Detroit, MI 48201	TYPE OF ESTABLISHMENT INSPECTED 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.

E). During inspection of the Detroit Donor Center, located inside the SEM Region offices, nurse b(6) was observed to complete an arm scrub for WBN 13GN15657. The collection set and tubes used for this donation were scanned into the handheld device by nurse (b) (6) prior to (b) performing the scrub and venipuncture. Upon review of records, it was discovered that venipuncture identification (VPID) utilized on the handheld device to document phlebotomy was that of (b) (6) Work instruction: Use of the Handheld Device to Document the Phlebotomy 15.3.095 requires that "If a different phlebotomist needs to take over, [following completion of scanning the collection set and tubes] follow these steps:" and requires that the new phlebotomist rescan the collection set and tubes prior to performance of the arm scrub and venipuncture. Following the observance of this error by FDA investigators, E-0863936 was logged by (b) to investigate this occurrence.

OBSERVATION 2

Education and training of personnel as documented in the Learner Management System (LMS) is not accurate.

Specifically,

A. Review of education and training records for Medical Director b(6) revealed several discrepancies in his training to Emergency and Exceptional Release of Components, which he regularly performs to include 18 exceptional releases and 18 emergency releases between 07/01/09 and 07/30/10.

1. Medical Director b(6) was found to have received training to BSD 66.102, Emergency and Exceptional Release on 03/10/1998. This BSD was in effect until 01/11/1999 at which time b(6) was required to receive BSD 48.101M version 1.0 Chapters 1 and 2. He was found to be documented as having received training to Chapter 2 of this BSD on 12/02/01. He had no documented training to Chapter 1, Exceptional Release of Blood Components.

2. Medical Director ~~b(6)~~ does not have documented training to BSD 48.101M versions 1.1.1, 1.2 or 1.3. He does have documented training to versions 1.4 (on 06/09/03) and 1.5 (on ~~06/09/03~~ 06/11/04) to include both Chapter 1, Exceptional Release of Blood Components and Chapter 2, Emergency Release of Blood Components.

B. Phlebotomists were found to have been documented in the Learner Management System (LMS) as receiving training to the course BHQ-15.4-TC105 v1.0 (Use of the Phlebotomy Handheld) although this training was not completed and the SEM Region did not implement this version of the procedure.

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
		Barbara A. Rusin, Investigator L'Oreal D. Fowlkes, Investigator Sherri J. Blessman, Investigator	12/15/2010

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax: (313) 393-8139 Industry Information: www.fda.gov/oc/industry	08/~~20~~ 24/2010-09/27/2010
	FEI NUMBER 1873044

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Diane E. Ward, CEO

FIRM NAME	STREET ADDRESS
American Red Cross ~~Southeasten~~ Southeastern Michigan Region	100 Mack Avenue
CITY, STATE AND ZIP CODE Detroit, MI 48201	TYPE OF ESTABLISHMENT INSPECTED 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.

1. Phlebotomist (b) (6) is document as having received the training on 04/14/08.
2. Phlebotomist (b) (6) is documented as having received the training on 04/14/08.
3. Review of remaining phlebotomy staff LMS records indicates that all additional 153 phlebotomists on staff at the SEM Region are documented as having received training to this procedure, but have not.

C. The procedure BHQ-15.4-TC105 v1.1 Communication (Use of the Phlebotomy Handheld) was transmitted and became effective on 02/05/07. Data in the LMS does not accurately reflect the date phlebotomists completed training to this procedure.

1. Phlebotomist (b) (6) is documented as having completed training and received a waive to this communication on 04/13/07, although the actual date of completion of the waive to training should have been 02/05/07, the date of the TIP implementation.
2. Phlebotomist (b) (6) is documented as having completed training to this communication on 11/05/07, although the actual date of completion of the waive to training should have been 02/05/07, the date of the TIP implementation.
3. Review of remaining phlebotomy staff LMS records indicates that all additional 150 ARC SEM phlebotomists completed the training to the communication on 04/13/07, although this date is not in agreement with date of implementation of the TIP for which all of these incumbent personnel should have received a waive status.

D. The procedure BHG-15.4.TC105 v1.2 (Use of the Phlebotomy Handheld) became effective in the SEM Region on 10/01/07. (b) (6) was not an employee of the SEM Region at that time, but she returned from retirement on 12/03/07 and should have had a documented waive to this communication on that date. Instead, she was granted an equivalency and the date of documentation for the equivalency was 06/25/08.

OBSERVATION 3

~~The phlebotomy site is not prepared by a method that gives maximum assurance of a sterile container of Whole Blood.~~

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
		Barbara A. Rusin, Investigator L'Oreal D. Fowlkes, Investigator Sherri J. Blessman, Investigator	12/15/2010

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax: (313) 393-8139 Industry Information: www.fda.gov/oc/industry	08/~~20~~ 24/2010-09/27/2010
	FEI NUMBER 1873044

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Diane E. Ward, CEO

FIRM NAME	STREET ADDRESS
American Red Cross ~~Southeasten~~ Southeastern Michigan Region	100 Mack Avenue
CITY, STATE AND ZIP CODE Detroit, MI 48201	TYPE OF ESTABLISHMENT INSPECTED 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.

Specifically, during inspection of the Detroit Donor Center on 08/26/10, phlebotomist [redacted] (b) (6) was observed to perform 4 arm scrubs during which she did not wait 30 seconds between the end of the second scrub and performing the venipuncture. Work Instruction: Collections: Preparing the Venipuncture Site 15.3.32 requires that phlebotomists "Wait at least 30 seconds before performing the venipuncture." Involved whole blood numbers included 013GN15657, ~~013GN05658~~ 013GN15658, 013GN15661 and 013GN15667. After the FDA investigator brought this to the attention of Donor Center management, the collected units were destroyed and exception E-0863935 was logged for this problem.

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Barbara A. Rusin L'Oreal D. Fowlkes Sherri J. Blessman	Barbara A. Rusin, Investigator L'Oreal D. Fowlkes, Investigator Sherri J. Blessman, Investigator	12/15/2010