

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION**

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

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

**TO:** Diane E. Ward, CEO

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

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**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 (b) (4) 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 months or more after the cases were opened.
  2. Work Instruction: Determining the Need for Risk Management Notification (b) (4) 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.
    - (b) (6) - On 11/10/08 donor (b) (6) fell at the collection site, causing a cut to (b) (6) lip with some bleeding. (b) (6) went to the emergency room and had stitches placed in (b) (6) lower lip.
    - (b) (6) - On 11/12/08 donor (b) (6) 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).
    - (b) (6) - On 11/16/08 donor (b) (6) became dizzy and incontinent secondary to donation and was taken to the emergency room by (b) (6)
    - (b) (6) - On 02/22/09 donor (b) (6) passed out at the collection site and was transported to the hospital via EMS.

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

(b) (6) On 03/17/09 donor (b) (6) experienced prolonged recovery and was admitted to the hospital.

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

(b) (6) - On 12/23/09 donor (b) (6) experienced a loss of consciousness/head injury and laceration over (b) (6) right eye and was transported to the emergency room.

3. Work Instruction (b) (4) 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 (b) (6) reported donor (b) (6) experienced a loss of consciousness/head injury and laceration over (b) (6) right eye on 12/23/09 after donation. (b) (6) 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 (b) (6) reported donor (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: (b) (4) (b) (4) 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:

(b) (6) (complete 06/10/10-Final Assessment 09/07/10)  
(b) (6) (complete 06/03/10- Final Assessment 07/02/10)  
(b) (6) (complete 07/08/10-Final Assessment 07/20/10)

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

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1. Form: Component Status Change Record (CSCR) (b) (4) 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 more of these sections completed as required. Examples of such files include:

(b) (6)

2. Work Instruction: Process Verification (b) (4) 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:

(b) (6)

3. Form: Donor Status Change Record (DSCR) (b) (4) provides how this form is to be completed. Sections of the form described herein include (b) (4)

(b) (4)

In at least 13

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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 (b) (4) 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) (b) (4) 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 of 16 files reviewed, to include the following examples:

(b) (6)

5. Work Instruction: Process Verification (b) (4) 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. (b) (4) requires for both the exceptional and emergency processes that (b) (4)

(b) (4) ... it was found during the inspection that the SEM Region did not have, in writing, (b) (4) for either the exceptional releases or the emergency releases of blood products. An

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exception was written for this problem during the inspection (b) (4)

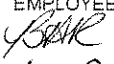

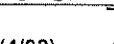
2. (b) (4) requires that the regional coordinator (or designee) reviews, signs and dates the authorization form once completed by the requesting physician or medical director of the transfusion service. Designee (b) (6) was found to have reviewed 6 exceptional releases of those evaluated during this 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 (b) (4) during the inspection. Designee (b) (6) reviewed 1 file and signed a dated an authorization for that file which was not signed by the requesting physician or the medical director of the transfusion facility.
3. Two 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 (b) (4) and (b) (4).

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.

1. (b) (4) requires that "within 3 months of opening the case" the case investigator "complete the case or document why the case remains open." Case (b) (4) 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 (b) (4).
2. The standard operating procedure Form: Component Status Change Record (CSCR) (b) (4) 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 (b) (4) all products from the current donation for donor (b) (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 (b) (4) all current donation products for donor (b) (6) 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

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disposition is also in error. These errors, as discovered by an FDA investigator were logged as exception (b) (4)

- (b) (4) requires "If the case involved a fatality or was a high probability (b) (4) case as listed on the Monthly Tally of closed Possible Transfusion Reaction Cases (b) (4), 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 (b) (4) 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 (b) (4) cases have been sent to National DRCP office" was not completed in 6 of 26 reviewed files to include the following examples:

(b) (4)  
(b) (4)

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 (b) (4). The collection set and tubes used for this donation were scanned into the handheld device by nurse (b) (6) prior to (b) (6) 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 (b) (4) 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, (b) (4) was logged by (b) (6) to investigate this occurrence.

**OBSERVATION 2**

Education and training of personnel as documented in the (b) (4) is not accurate.

Specifically,

- Review of education and training records for Medical Director BHN 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

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between 07/01/09 and 07/30/10.

1. Medical Director BHN was found to have received training to (b) (4) Emergency and Exceptional Release on 03/10/1998. This (b) (4) was in effect until 01/11/1999 at which time Dr. Newman was required to receive (b) (4) Chapters 1 and 2. He was found to be documented as having received training to Chapter 2 of this (b) (4) on 12/02/01. He had no documented training to Chapter 1, Exceptional Release of Blood Components.
  2. Medical Director BHN does not have documented training to (b) (4) versions (b) (4). He does have documented training to versions (b) (4) (on 06/09/03) and (b) (4) (on 06/09/03) 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 (b) (4) as receiving training to the course (b) (4) (Use of the Phlebotomy Handheld) although this training was not completed and the SEM Region did not implement this version of the procedure.
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 (b) (4) records indicates that all additional (b) (4) phlebotomists on staff at the SEM Region are documented as having received training to this procedure, but have not.
- C. The procedure (b) (4) Communication (Use of the Phlebotomy Handheld) was transmitted and became effective on 02/05/07. Data in the (b) (4) 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 (b) (4) 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 (b) (4) implementation.
  3. Review of remaining phlebotomy staff (b) (6) records indicates that all additional (b) (4) 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 (b) (4) for which all of these incumbent personnel should have received a waive status.
- D. The procedure (b) (4) (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 (b) (6) returned from retirement on 12/03/07 and should have had a

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documented waive to this communication on that date. Instead, (b) (6) 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.

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

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EMPLOYEE(S) SIGNATURE

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