DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Ste. 5900, Detroit, MI 48207	5/27/2008-7/2/2008
	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 Michigan Region	100 Mack Avenue
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Detroit, MI 48201	Blood Bank

DURING AN INSPECTION OF YOUR FIRM "I" OBSERVED:

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observation, 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 impelement, corrective action in response to an observation, you may discuss the objection or action with FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any question, please contact FDA at the phone number and address above.

1. Problem reports have continued to be open due to Corrective Action Plan (CAP) rejection, resubmission, and/or delayed QA review. (b) (4) states (b) (4) CAP development is to be completed within 30 days of discovery and QA review within 5 business days of CAP submission. There is no timeframe documented for when a rejected cap must be resubmitted. Examples are as follows:

a. The problem for (b) (4) was discovered on 2/26/2008. The problem involved distribution of product that did not meet specifications. This is a (b) (4) problem. Whole blood number ranges from several mobiles were not recorded on the (b) (4) Log. One WBN range was found to not have an electronic hold. The (b) (4) has the CAP submitted to QA for initial review on 4/2/2008 and was rejected. The CAP was resubmitted on 4/7/2008. QA rejected the CAP on 6/6/2008, 43 business days from the date of submission. As of 6/19/2008, the CAP was still open.

b. The problem for (b) (4) was discovered on 12/12/2007. The problem involved an autologous red cell with a (b) (4) hold not moved physically to (b) (4) This is a (b) (4) problem. The (b) (4) has the CAP submitted to QA and rejected on 1/29/2008. It was resubmitted to QA on 3/19/2008 and was approved by QA on the same date. The resubmission of the CAP from the first rejection was 50 days.

c. The problem for (b) (4) was discovered on 2/27/2008. The problem involved the donors associated with the positive platelet pool (b) (6) not having assertions placed on the donors within 5 days. This is a (b) (4) problem. The (b) (4) has the CAP submitted to QA on 3/25/2008 and was rejected on 4/2/2008. The CAP was submitted again on 4/30/2008 and rejected on 5/21/2008 which was 15 business days from submission. As of 6/ 16/2008 there still is not an approved CAP.

2. (b) (4) addresses the performance of ECs as a measure of corrective action effectiveness, provides guidelines as to the required frequency of ECs, including sustained corrective actions, and provides for establishment of due dates for ECs. These due dates have not been followed, resulting in corrective actions remaining unassessed, and problems remaining open as per the following examples:

a. Problem (b) (4) was discovered on 06/15/07 and involved product placement in the wrong physical location but correct electronic location. This is a (b) (4) problem. In the (b) (4) the EC query was to be run from 9/7/2007 through 12/07/2007. As of 06/19/2008, this EC had still not been completed (195 days since the EC end date). The problem has remained open for 369 days as of date of review (06/19/08).

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Catherine V. Quinlan	Catherine V. Quinlan, Investigator	7/2/08

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2b. Problem (b) (4) was discovered on 07/03/2007. This problem involved the lack of verification of expiration dates on leukoreduced washed red cell units prior to release. This is a (b) (4) problem. (b) (4) had the quantitative EC with a target due date of 11/05/2007. The sign off by the Problem Manager was 3/6/2008. The Problem Manager completed and routed the problem to QA on 06/05/2008 (214 days since the EC due date). The problem has not been closed and has remained open for 342 days as of date of review (06/05/2008).

c. Problem (b) (4) was discovered on 11/23/2007. This problem involved consignee receipt of pooled platelet pheresis product without the number of units in the pool recorded on the label. This is a (b) (4) problem. In (b) (4) the sustained EC target due date for this problem was 04/30/2008. It had not been completed as of 06/13/2008. This problem has remained open for 203 days as of date of review (06/13/2008).

d. Problem (b) (4) was discovered on 06/15/2007 and involved the irradiation batch record not being reviewed prior to release of product to a consignee. This is a (b) (4) problem. In (b) (4) the EC query target due date for this problem was 01/14/2008. The EC was completed on 06/05/2008 (143 days after target due date). This problem remains open and has been open for 359 days as of date of review (06/09/08).

3. According to the (b) (4) information must be gathered to present to the Material Review Board (MRB) within 10 calendar days of initially discovering a problem. Material Review Board decisions have not been made in a timely manner. Example:

The problem for (b) (4) was discovered on 5/11/2007. The date logged was 5/30/2007. This involved personnel performing tasks with no/incomplete training. An employee was not released to task. This was discovered during the review of annual competency. This was a (b) (4) problem. As per the (b) (4) the MRB met on 8/29/2007 and made the decision that no recall/no market withdrawal would be done for the distributed product. The meeting of the MRB was 110 days from the date of discovery.

4. Random platelet pools with positive bottle alarms are not always managed within a timely manner and according to the appropriate standard operating procedures. Examples are as follows:

a. There were two platelet pools, # (b) and # (b) that had positive bottle alarms in the bacterial detection system. No Exception Detail Reports were completed as per the (b) (4) (b) (4)

b. The platelet pool # (b) had a positive bottle alarm on 3/13/2008. A specimen was sent to the external testing laboratory. On or about 4/1/2008 test results were received back at the Region. Laboratory results found the sample to have gram positive bacilli. On 6/9/2008 the firm initiated completion of the (b) (4) (b) (4) Report and other supporting documentation.

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4c. The platelet pool #(b) had a positive bottle alarm on 1/29/2008. A specimen was sent to the external testing laboratory. Results are documented as sent via fax to the ARC on 6/10/2008 and with the results of no growth. The (b) (4) were completed with product disposition on/or about 6/17/2008. The (b) (4) (b) (4) Report was completed on 6/10/2008. The (b) (4) were in the process of completion on 6/12/2008. The hospitals receiving the red cells were notified of the release of the quarantined units on 6/11/2008.

d. The (b) (4) Report and (b) (4) Reports were not always completed as per the (b) (6). The (b) (4) Report and (b) (4) (b) (4) Report for the initial positive pool #(b) were not signed by the supervisor. There were no (b) (4) and (b) (4) reports printed and signed for the initial positive pool #(b) (6) There was no printed and signed (b) (b) (4) Report for the initial positive pool #(b)

5. The (b) (4) indicates sampling strategies for several blood products. In addition, the (b) (4) (b) (4) establishes the minimum requirement for QC monitoring of products manufactured and distributed by ARC Biomedical Services. The sampling guidelines established in the Job Aids have not been adhered to as documented in the following examples:

a. Random Platelet Concentrates are to be sampled at a rate of (b) (4) (b) (4). For the month of March 2008, all QC was performed on 03/24/2008, upon product collected on 03/19/2008, with an expiration date of 03/24/2008. Product QC was performed on product collected only within the third week of the month.

For the month of May 2008, QC was not performed on product collected the last week of the month as demonstrated in the following table:

# Products	QC Completed	Date Collected	Week	Expiration
(b) (4)	5/13/2008	5/8/2008	(b) (4)	5/13/2008
	5/21/2008	5/15/2008		5/21/2008
	5/27/2008	5/22/2008		5/27/2008

b. QC of RBC products collected by (b) (4) is to be completed on a (b) (4) (b) (4). For the months of March and May 2008, the following tables represent the samples taken for QC week of the month. No QC samples were taken in week 3 of either month.

March 2008

Week of the Month	# of Samples Taken	Date(s) Product Collected
(b) (4)	(b) (4)	03/02/2008
		03/10 and 03/13/2008
		N/A
		03/24; 03/27; 03/28; 03/29/2008
	Total: (b	

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May 2008

Week of the Month	# of Samples Taken	Date(s) Product Collected
(b)(4)	(b)(4)	05/05/2008
		05/12 and 05/13/2008
		N/A
		05/27; 05/28; 05/31/2008
	Total: (b)(4)	

6. As of June 18, 2008, there was no written documentation to support that nursing employees (b) and (b) received training on Performing the Physical Exam for (b) (4) Allogeneic/Directed and Autologous Apheresis Double Red Cell Donors prior to transferring from apheresis collections to whole blood collections in September 2007.

a. The (b) (4) documents employee (b) with the (b) (4) for (b) (4) (b) (4) and (b) (4) for the Performing Physical Exam for (b) (4) Allogeneic/Directed Apheresis Double Red Cell Donors and Autologous Apheresis Red Cell Donors respectively on 11/5/2007.

b. The (b) (4) documents employee (b) with the (b) (4) on 3/23/2007 for (b) (4) Performing Physical Exam for (b) (4) Allogeneic/Directed Apheresis Double Red Cell Donors.

7. Authorized curricula were not always found to be signed and completed by the learner (staff) and the supervisor. According to the (b) (4) the Authorized to Perform Curriculum contains curriculum items for all process training that is required for front line staff prior to authorization to perform independently. Two signature items are mandatory with this curriculum: supervisor authorization and the staff agreement. Examples of this are as follows:

a. As of 6/17/2008, the curricula for employee (b) was not signed by staff and/or management. Nursing staff employee (b) has a (b) (4) status of incomplete as of 10/5/2007. Neither the supervisor nor staff member had signed off. The staff member has signed off and is awaiting supervisor approval for the new curricula under the (b) (4) series, dated 6/6/2008.

b. From the time period of 3/7/2008 to 4/25/2008 there was no signed curricula for employee (b). Nursing staff employee (b) has a (b) (4) status of incomplete as of 3/7/2008. Neither the supervisor nor staff member has signed off. The staff member and the supervisor have signed and approved the new curricula under the (b) (4) series which was signed on or about 4/25/2008.

c. Components staff employee (b) was referenced as part of a corrective action on (b) (4) The corrective action resulted in a memo dated 11/15/2007 that included employee (b) as staff that can review the QC of

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the irradiator. According to the training records curriculum, (b) (4) (b) (4) this employee signed as the learner (b) (4) on 10/18/2007. The Supervisor (b) (4) did not sign until 4/14/2008. There was an almost 6 month timeframe where the employee had an incomplete curricula for this task. The corrective action memo was signed on 11/15/2007 and was still posted as of June 11, 2008.