DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000	7/28/08-9/26/08
	FEI NUMBER 3002957282

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Kay E. Schwartz, CEO

FIRM NAME	STREET ADDRESS
American Red Cross Blood Services	825 John Street
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
West Henrietta, NY 14586	American Red Cross Regional Office

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

Observation #1

Your firm has failed to thoroughly and adequately investigate, develop root cause, correct and take steps to prevent the recurrence of biological product deviations (BPD).

Specifically,

a. Problem Report (b) (4) a trend discovered on 9/28/06 for BPD code (b) (4) (failure to adequately manage non-conforming product-product not released), was assigned as a (b) (4) investigative problem and was closed on 7/30/07 after all Effectiveness Checks were successful. One month later Exception Detail Report (b) (4) (associated (b) (4) (b) (4) discovered on 8/29/07 for BPD code (b) (4) was assigned also as a (b) (4) investigative problem and resulted in multiple corrective actions including the implementation of a (b) (4) corrective action project for on-going problems with BPD code (b) (4) This problem report was closed on 2/4/08 after determining that the CAP was successful. Due to on-going Problem Reports for the past 1 ½ years related to BPD code (b) (4) ARC Biomedical Headquarters determined in 2/08 that a (b) (4) was needed and this plan is still being implemented at the time of this inspection.

Problem Reports related to BPD code (b) (4) have been initiated for almost two years and the problem is still unresolved at the time of this inspection. For example, Exception Detail Reports (b) (4) with a date of occurrence 7/5/08 and Exception Detail Report (b) (4) with a date of occurrence 6/10/08 are more recent Problem Reports initiated and associated with BPD code (b) (4)

b. Problem Report (b) (4) occurred on and was discovered on 5/11/06 as a (b) (4) Problem for BPD code (b) (4) (b) (4) (Incorrect Documentation during an Entry into eBDR at the Collection Site of Donor's First Name, Last Name, MI, Sex, SSN, DOB, or Home Phone Number). Trend Problem Report 2006-001-1557903 was created on 12/19/06 as a response to a failed Effectiveness Check for trend (b) (4) for BPD code (b) (4) Problem Report (b) (4) was closed on 8/29/07 after Effectiveness Checks failed. Exception Detail Report (b) (4) (associated (b) (4) , discovered on 8/17/2007 for BPD code (b) (4) , was assigned as a (b) (4) trend investigative problem. Corrective actions included in (b) (4) included a review of Best Practices for the verification of donor demographic fields and a request to Biomedical Services Headquarters (BHQ) for a Software Enhancement to prevent recurrence of BPD code (b) (4) problems. The Effectiveness Check for Best Practice implementation for (b) (4) failed on 4/22/08. In addition, at the time of this inspection, you still were not aware of an ARC headquarter decision for your Corrective Action request for a Software Enhancement (submitted to the Office of Change Management in BHQ in December 2007).During this inspection documentation was obtained from BHQ documenting that a decision on implementation of this corrective action is still pending.

A query was conducted during this inspection, dated 1/1/08 through 8/28/08, which revealed at least 10 Exception Detail Reports with a Corrective Action linked to (b) (4) There have been on-going problem reports for close to three years and the problem is still unresolved at the time of this inspection. For example, Exception Detail Reports (b) (4) with a date of occurrence of 5/13/08 and (b) (4) with a date of occurrence of 3/18/08 are examples of more recent Problem Reports initiated and associated with BPD code (b) (4) Investigation, root cause determination and corrective actions to prevent recurrence of BPD code (b) (4) are reportedly in the process of being "reworked."

SEE REVERSE THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	Karen L. Kosar	Karen L. Kosar CSO	9/26/08

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c. Problem Report (b) (4), with a date discovered of 12/22/06 and date occurred of 11/30/06, was initiated for failure to manage BPD code (b) (4) Problem Management: Operations Review of Problem Not Performed/Timely. This BPD codes covers Late Corrective Action Reports, those not developed within 30 days as required. Problem Report (b) (4) (b) (4) failed its final Effectiveness Check for those corrective actions developed to prevent recurrence of Late CAP's. Your firm developed another Corrective Action Plan, Exception Detail Report, (b) (4) dated 7/3/07, for managing Late CAP's. However, the corrective actions in (b) (4) also failed the final Effectiveness Check in 6/6/08. Your firm continues to have on-going Problem Reports associated with BPD code (b) (4) for almost 2 years and the problem is still unresolved at the time of this inspection. For example, Exception Detail Reports, (b) (4) with a date of occurrence of 7/6/08, (b) (4) with a date of occurrence of 6/13/08 and (b) (4) with a date of occurrence of 3/6/08, are examples of more recent Problem Reports initiated and associated with BPD code (b) (4)

Observation #2

Corrective Action Plans developed to prevent the recurrence of problems are not always submitted to the Quality Assu rance Department within 30 calendar days of the date of problem discovery as required. Your written procedure, (b) (4) (b) (4) requires that you develop a formal Corrective Action Plan (CAP) for (b) (4) Problem types within 30 calendar days of problem discovery.

Specifically,

During this inspection a Late CAP code query was requested for the time period of October 1, 2007 through August 6, 2008. This Late CAP query for BPD code (b) (4) Problem Management: Operations Review of Problem Not Performed/Timely identified a total of 57 problems during that time period. These include:

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

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(b) (4) (b) (4) (b) (4) (b) (4) (b) (4)
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Your firm continues to have on-going Problem Reports associated with BPD code (b) (4). For example, Exception Detail Report (b) (4) with a date of occurrence of 5/17/08 and date of discovery of 6/13/08, was initiated because the Corrective Action Plan for (b) (4) was not developed within the required 30 day time frame. Exception Detail Report E-0360363, with a date of occurrence of 3/27/08 and a date of discovery of 5/2/08, was initiated because the Corrective Action Plan for (b) (4) was not developed within the required 30 day time frame. Currently your facility is in the middle of formulating a formal CAP for this problem.

Observation #3

Your firm does not always perform Effectiveness Checks, developed as part of the formal Corrective Action Plan (CAP) for (b) (4) Problems, (b) (4) Problems and for Trends by their due date. Your written procedure, (b) (4) (b) (4) requires that your firm perform the Effectiveness Checks as a measure of corrective action effectiveness and managed according to target completion dates.

Specifically,

During the current inspection a Late Completion/Documentation of Corrective Actions (CA)/Effectiveness Checks (EC) code query was requested for the time period of October 1, 2007 through August 12, 2008. This Late CA's/EC's query for BPD code (b) (4) (Problem Management: Immediate or Corrective Action Incomplete/Timeline Not Met) and (b) (4) (Problem Management: Other) identified a total of 155 problem reports not performed by their due date during that time period.

For example, the CAP for (b) (4) (date discovered 7/12/07) Effectiveness Check 2, print screen checks, was documented as completed on 4/25/08 although it was due on 2/27/08 and Effectiveness Check 3, QA-Regulatory Review of files received, was completed on 5/19/08 although it was due on 2/12/08. Also, the CAP for (b) (4) (date of discovery 12/26/07) Effectiveness Check 2, a 90 day monitoring period for BPD code (b) (4), was completed on 5/30/08 although it was due on 5/25/08.

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Observation #4

Corrective Action Plans are not always reviewed by QA within 5 days as required. Your written procedure, (b) (4) (b) (4) requires that the QA review CAP's and reject or approve within five business days of submission and the review will be documented in the APMS.

Specifically,

a. During this inspection I requested a query for the Late QA review of CAP's from 10/01/07 through 8/11/08 which revealed one occurrence. Exception Detail Report, (b) (4), with a date of discovery of 5/21/08 and a date of occurrence of 5/8/08, was initiated in response to a Corrective Action Plan (b) (4) that was not QA approved or rejected within five business days of receipt by QA (b) (4) was routed to QA on 4/30/2008 but not QA approved until 5/12/2008.

b. During my review of all (b) (4) Problem Reports, queried from 6/1/07 through 7/28/08, I noted that Exception Detail Report, (b) (4) (associated (b) (4) with a discovery date and date of occurrence of 4/15/08, was not QA approved or rejected within five business days of receipt by QA as required. (b) (4) was assigned as a (b) (4) investigation, concerns WBN (b) (6) not being placed on registration hold during the process of resolving a gender discrepancy. It was routed to QA on 5/12/08 but not QA approved until 5/22/08.

Observation #5

Your firm failed to follow your written procedure, (b) (4) in that you do not always submit a copy of the Monthly Summary Report to the Medical Director as required prior to submitting them to BHQ..

Specifically,

During a review of the Monthly Summary Reports, 6/07 to 7/08 I noted that for the months of March 2008, April 2008, May 2008, June 2008 and July 2008 the monthly Summary Reports for Quality Process Reviews were not submitted to the Medical Director prior to submitting them to BHQ.

Observation #6

Your written procedure, (b) (4) defines those steps to be followed when investigating a problem at ARC. It is written in Step 6 of (b) (4) that based on the investigation level and problem type, you determine the questions to ask and document in the Automated Problem Management System (APMS). You failed to accurately answer (b) (4) for the (b) (4) Questions regarding "which supervisors were involved" and (b) (4) "work load."

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Specifically, during a review of all (b) (4) Problem Reports (53 total), from the date discovered period of 06/01/07 through 07/28/08, I noted several discrepancies that occurred between documented answers to the Investigation & Questions form and the root cause statement (b) (4) or investigation summary (b) (4) as follows:

a. In Exception Detail Report, (b) (4) (associated (b) (4) , date occurred 12/29/07 and a date discovery of 12/31/07, involving a failure to place a registration hold for WBN (b) (6) , the probable root cause documented was that the involved staff member had consulted her supervisor on what needed to be done regarding the resolution for a date of birth discrepancy. In the (b) (4) your answer to (b) (4) for "which supervisors were involved?" was "No."

b. In Exception Detail Report, (b) (4) (associated (b) (4) , date occurred 4/26/07 and a date discovery of 4/26/07, involving a mix-up in line connections, the staff member admitted to his supervisor as documented in the Investigation summary that due to a staff person calling in sick that day he felt he had to try and work faster to accommodate the donors. In the (b) (4) your answer to (b) (4) "Was work load higher than usual?" was "No."

Observation #7

Your firm's QA-approved Corrective Actions and Effectiveness Checks are not always completed in the manner that they were designed and approved for. Your written procedure, (b) (4) (b) (4) requires that the Problem Manager design and perform the EC's in order to demonstrate that the CAP did or did not make a measurable impact per the success criteria.

Specifically, during a review of (b) (4) Problem Reports (53 total), from the date discovered 06/01/07-07/28/08, I noted several EC's that were not performed as intended and as approved.

a. For Exception Detail Report (b) (4) (associated (b) (4) , date discovered 11/27/07, involving the failure to adequately manage potentially non-conforming product (product not released), an immediate corrective action (ICA) was initially signed-off by the Problem Manager as completed on 1/4/08. This ICA consisted of reviewing Best Practice for Managing PTDs (Prior Type Discrepancy) with the Quarantine and Labeling Department. The Problem Manager later received additional documentation on 7/7/08 per E-0387110 that the ICA was really completed 6/30/08. As a result the Effectiveness Check (staff member-(b) for (b) (4) consisting of a 60 day monitoring period via the Automated Problem Management System, documented as completed during the time frame of 1/5/08-3/5/08, was done prior to the implementation of the ICA. The incorrect time frame for the EC was not further addressed.

b. For Exception Detail Report E-(b) (4) (associated (b) (4) , date discovered 11/27/07, involving the failure to adequately manage potentially non-conforming product (product not released), the Effectiveness Check (staff member-(b) Survey Staff, required that all Quarantine and Labeling staff must answer the questions with 100% accuracy for successfulness. The Problem Manager reported on 2/1/08 that the staff responded to the Survey with 100% accuracy. On review of the EC Survey answers sheets for the Quarantine and Labeling staff as compared with the Survey Answer Key provided the QA noted that for the EC Survey a total of 4 staff members responded with incorrect answers. The EC however was reported as successful.

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c. For Exception Detail Report (b) (4) (associated (b) (4) , dated October 4, 2007, the Problem Manager conducted the wrong (b) (4) report on 10/31/07. The (b) (4) report is generated for informational reasons related to the frequency of occurrence of a BPD code problem for an individual or an identified problem as part of a problem investigation or for the purpose of determining effectiveness of a CAP. The Problem Manager queried a (b) (4) report on 10/31/07 for BPD Code (b) (4) (instead of BPD code (b) (4)) for the time period 2/1/07 to 10/31/07 which returned no other problems. This BPD code baseline data discrepancy was noted during this inspection. A (b) (4) report was requested for the appropriate BPD code (b) (4) during this inspection for the time period 7/1/07 through 9/16/08, which returned one other problem with the same nature occurring the month prior (8/24/07). Your firm was unable explain why the Problem Manager conducted a (b) (4) report based on the wrong BPD code.

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