DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 W. Jackson Blvd., Suite 1500 Chicago, IL 60661-4716 (312) 353-5863 Fax:(312) 596-4187 Industry Information: www.fda.gov/oc/industry	06/21/2010 - 08/18/2010* FEI NUMBER 1473043

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Lisa A. Mott, Director of Collections

FIRM NAME	STREET ADDRESS
American National Red Cross Heart of America Region	405 W John H Gwynn Jr Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Peoria, IL 61605-2440	American Red Cross

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 I OBSERVED:

OBSERVATION 1

Failure of distribution and receipt procedures to include a system by which the distribution or receipt of each unit can be readily determined to facilitate its recall.

Specifically,

The firm process changed from labeling units of pooled cryoprecipitate with a four digit unit number to a nine digit unit number as of 12/15/2008. Due to the change in the numbering system, consignees potentially would be unable to locate the correct unit number when checking the electronic inventory. Procedures do not provide adequate instructions to ensure that the correct unit number is listed on the consignee notification letters when a unit of pooled cryoprecipitate collected prior to 12/15/2008 is part of a suspect product case, market withdrawal or recall.

The Donor Client Support Center (DCSC) assumed responsibility for consignee notification letters as of 2/2009. The DCSC handled seven cases involving units distributed by the Heart of America Region that required consignee notifications because of unsuitable or potentially unsuitable pooled cryoprecipitate units between 2/2009 and 5/2010. Of the seven cases, four cases involved the DCSC sending notification letters to consignees that contained an incorrect unit number.

Examples where the DCSC notified consignees of units distributed from the HOA region using the incorrect unit number include the following:

A. Case ID200912031643o66, Pooled Cryoprecipitate Unit ID 2399 included Unit 040GL16388. Unit 2399 was included in a market withdrawal when the donor of Unit 040GL16388 provided post donation information on 12/2/2009 related to high risk behavior for having male to male sex. A blood product deviation (BPD) was submitted and a market withdrawal was initiated.

On 12/3/2009, the firm notified the consignee of the market withdrawal regarding pooled Cryoprecipitate Unit 2399 (Exp. 2/28/2009). The unit number was erroneously listed as 040C02399, on the notification letter rather than the actual number 2399 which was listed on the unit label. According to firm's Component Status Change Record (CSCR), employee "(b) (6)", on 1/8/2010 documented that the hospital consignee had notified the firm that Unit 2399 was discarded, however there was no documentation to support this information since the firm reportedly misplaced the consignee return form with documentation stating that Unit 2399 had been discarded.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Laurie A. Haxel, Investigator	DATE ISSUED 08/18/2010

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On 6/24/2010, during the inspection, the firm sent a market withdrawal notification letter, to the consignee with the correct number, Unit 2399. The consignee subsequently reported that Unit 2399 was transfused on 6/26/2008 which contradicts the firm's CSCR documentation indicating that the hospital previously reported that the unit had been discarded.

B. Case ID P200903092250o29, Pooled Cryoprecipitate Unit 3696 included Unit 040GN23727. Unit 3696 was included in a market withdrawal when the firm became aware that the donor of Unit 040GN23727 was also the donor of another unit, Unit 040GN24993; Unit 040GN24993 was associated with increased risk of transfusion related acute lung injury (TRALI) at the time of infusion.

On 8/5/2009, the firm notified the consignee of the market withdrawal regarding the pooled Cryoprecipitate Unit 3696 (exp 9/10/2009) The unit number was erroneously listed as 040C03696 on the letter rather than the actual number 3696 which was listed on the unit label. According to the firm's records, employee "(b) (6)" documented on the CSCR that the unit was transfused. A final disposition notification was returned by the consignee documenting that the unit was transfused on 9/19/08 and the CSCR indicated the same.

During the inspection a corrected letter was sent on 7/2/2010 to the consignee, as of 8/11/2010 ARC has not received an additional return response form from the consignee.

C. Case ID P200904072214o18, Pooled Cryoprecipitate Unit 3675 included Unit 040GV58339. Unit 3675 was included in a market withdrawal when the firm received post donation information on 4/7/2009 indicating that the donor of Unit 040GV58339 was recently diagnosed with a form of cancer.

On 9/22/2009, the firm notified the consignee of the market withdrawal regarding pooled Cryoprecipitate 3675 (exp 9/8/2009). The unit number was erroneously listed as 040C03675 on the notification letter rather than the actual number 3675 which was listed on the unit label. According to firm electronic records, employee "(b) (6)" documented on the CSCR that the unit was transfused. A final disposition notification was returned by the consignee documenting that the unit was transfused on 10/6/2008 and the electronic CSCR indicated the same. Additionally, the firm filed a problem on 9/18/2009 for failure to timely retrieve suspect products.

On 7/2/2010, during the inspection, the firm sent a market withdrawal notification letter, to the consignee with the correct Unit 3675, as of 8/11/2010 ARC has not received an additional return response form from the consignee.

A significant corrective action issue was initiated on 7/19/2010. The firm's record review and ongoing investigation have identified pooled products from other regions, where consignee notifications were conducted by both (DCSC) locations, also involve sending notification letters using incorrect unit numbers. The firm reported that record review indicates 47 of 74 cases involving consignee notifications were done incorrectly by the DCSC, Charlotte, NC and 15 cases were done incorrectly by DCSC, Philadelphia, PA.

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OBSERVATION 2

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

Specifically,

A. Failure to follow standard operating procedure 11.3.009, "Work Instruction: Performing a Retrieval or Notification of Transfusable Components". The procedure states in part, "...Notify consignees of outdated components for retrieval within 48 hours of the decision to retrieve affected components...".

The firm became aware of post donation information on 12/2/2009 that required a market withdrawal of AHF cryoprecipitate pooled Unit 040C02399/2399 and notification to the consignees within forty eight hours. Although the firm notified the consignee on 12/3/2009, the firm did not notify the consignee using the correct unit number until 6/24/2010 when it was discovered after FDA requested records during the inspection. This is more than six months after the firm became aware of the post donation information.

Pooled Cryoprecipitate Unit 2399 included Unit 040GL16388. Unit 2399 was included in a market withdrawal when the donor of Unit 040GL16388 provided post donation information on 12/2/2009 related to high risk behavior for having male to male sex. A blood product deviation (BPD) was submitted and a market withdrawal was initiated.

On 12/3/2009, the firm notified the consignee of the market withdrawal regarding pooled Cryoprecipitate Unit 2399 (Exp. 2/28/2009). The unit number was erroneously listed as 040C02399 on the notification letter rather than the actual number 2399 which was listed on the unit label. According to firm records, employee "(b) (6)" on 1/8/2010 documented that the hospital consignee had notified the firm that Unit 2399 was discarded, however there was no documentation to support this information since the firm reportedly misplaced the consignee return form with documentation stating that Unit 2399 had been discarded.

On 6/24/2010, during the inspection, the firm sent a market withdrawal notification letter, to the consignee with the correct Unit 2399. The consignee subsequently reported that Unit 2399 was transfused on 6/26/2008 which contradicts the firm's electronic documentation indicating that the hospital previously reported that the unit had been discarded.

B. Firm failed to follow standard operating procedure 10.3.011, "Work Instruction: External Customer Complaint Management" and 10.2.9, "Directive: Managing Customer Concerns". The procedures contain instructions for managing complaints or concerns including any written, electronic, or oral communication that alleges deficiencies.

ARC distributes "Blood Drive Sponsor Satisfaction Survey" forms to coordinators and/or chairpersons of mobile blood drives. Part of the survey includes a section that asks the sponsors to evaluate the adequacy of staffing levels. The survey also provides a space for comments. According to management, standard operating procedure Doc No. 10.2.9, "Directive: Managing Customer Concerns", was not written to require information from the comment cards to be captured as concerns.

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The following concerns and/or complaints were received through the Blood Drive Sponsor Satisfaction Survey forms; however, the information was not evaluated or investigated as a concern or a complaint:

1. 11/4/2009 blood drive. The drive coordinator reported in part, a regular donor was sprayed with blood "...on a yellow shirt and face...".

2. 11/6/2009 high school blood drive. The drive coordinator reportedly was dissatisfied with staffing levels to meet the needs of the drive. According to the operations report the staffing level was deficient according to the firm's staffing matrix.

3. 1/13/2010 church blood drive. The drive coordinator reported the following: "...Between 3:15 & 4:15 the staff disappeared. 2 out of 10 beds were being used and the hallway was full of donors waiting. There was an obvious rif/tension among the staff....". According to the operations report the staffing level was deficient according to the firm's staffing matrix.

4. 1/12/2010 church blood drive. The drive coordinator reportedly was very dissatisfied with staffing levels to meet the needs of the drive. The coordinator also reported that, "...some people waited 3 hrs.". According to the operations report, the staffing level was deficient according to the firm's staffing matrix.

5. 12/11/2009 blood drive. The drive coordinator reported, in part, "...Please send staff who can do better sticks ....One employee had ...do stick and blood wasn't flowing fast so... pushed needle in more. After 19 minutes bag wasn't full, so took blood and pitched...Another Employee said they dug around before they found the vein....".

C. Failure to follow standard operating procedure Doc No 10.3.013, "Work Instruction: Trend Identification by Facilities", which states in part, "....Analyze Biological Product Deviation (BPD) codes within a category to determine the factors that have contributed to the trend...".

On 12/22/2009, during the review of Monthly Summary Problem Reports (MSPR) the firm discovered a trend, BC-43, related to the collection of overweight units. The trend continued until closed on May 26, 2010.

The firm identified code BC-43-03, as the major contributing factor, but the firm did not include the failure problems classified as "unknown". The firm's stated rationale for not doing so is that the "unknown" failures were probably related to failure modes already identified. There was no further investigation into the cause of the unknown failures as part of the trend analysis and the "unknown" failures were not included in the trend analysis.

Month	Number of Unknowns
March, 2010	5
April, 2010	1
May, 2010	3
June, 2010	2

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OBSERVATION 3

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

Specifically,

A. There is no Donor Reaction and Injury Record (DRIR), or documentation of an adverse reaction on the Blood Donation Record (BDR) when a donor experienced an adverse reaction at the firm or when the firm received a post donation report indicating that the same donor experienced an adverse reaction at the collection site. Standard operating procedures Doc No 15.3.045, "Work Instruction: Documenting Donor Complications" provides guidance to caregivers and supervisors in documenting donor reactions and Doc No 15.4.ja48, "Job Aid: Donor Complication Codes", instruct collections staff in assigning complication codes on the DRIR and completing a DRIR when a donor experiences a long loss of consciousness and loss of consciousness with injury.

On 5/20/2010 the firm received a complaint in an email that was forwarded by a blood drive coordinator at a high school. The email was from the mother of a sixteen year old donor who donated at a high school blood drive on 5/19/2010. According to the email, the complainant states in part, "...my daughter had one finger pricked and they told her she was anemic so they said that's ok will prick the other finger. After she gave blood they sat her in a chair and she passed out and hit her head very hard on the floor.....My daughter has a large bump on her head and her neck is quite swollen...".

According to an email sent on 5/24/2010 from (b) the team leader at the mobile drive, to supervisor (b) (6) the team supervisor, (b) (6) stated in part, "....this was a CRAZY CRAZY day....We had a lot of donors who refused to perform second finger sticks, but the girl in the below email argued with me that she was 110 pounds, I performed the second stick and got well into the 13's.....when she had her reaction, she said she was fine right after and after assessing her, I didn't believe a DRIR was necessary.....".

During the inspection, team supervisor (b) stated that a volunteer at the drive notified (b) that the donor had a loss of consciousness and had fallen on the floor. (b) did not know the length of time in which the loss of consciousness occurred.

1. No DRIR was initiated at the time the adverse reaction occurred even though it involved a fall and a loss of consciousness for an unknown period of time. The reaction occurred in the canteen area after donating. Also, there was no documentation of an adverse reaction on the BDR.

2. The donor was determined eligible to donate and subsequently donated even though the team supervisor, (b) reported having concerns regarding the donor's ability to meet the weight and height eligibility requirements for donors less than nineteen years of age. Additionally, the donor failed the initial Hemocue test but was retested and passed. There is no documented justification for repeating the Hemocue test.

3. No DRIR was initiated in response to the complaint received on 5/20/2010 until it was discovered after records were requested by FDA during the inspection.

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4. On 6/29/2010, the Region opened a problem report to address failure to initiate a DRIR after receiving the complaint on 5/20/2010. The problem did not additionally address the failure to investigate and/or document the adverse reaction at the time the reaction occurred, even though the reaction occurred in the canteen area subsequent to the donation, until it was discussed during the inspection.

B. There is not always an investigation or documentation of adverse reactions on DRIR's when the firm receives post donation information indicating that a donor has experienced an adverse reaction. In 2010 at least five reported concerns did not have DRIR's according to standard operating procedures.

Standard operating procedures Doc No 15.3.045, "Work Instruction: Documenting Donor Complications", provides guidance to caregivers and supervisors in documenting donor reactions and Doc No 15.4.ja48, "Job Aid: Donor Complication Codes", instructs collections staff in assigning complication codes on the DRIR and completing a DRIR when an adverse reaction is classified as major.

The firm received post donation information regarding adverse reactions; however there was no DRIR or further investigation into the post donation report of the adverse reaction in the following instances. Examples of reports documented on concern-complaint forms involving adverse reactions include the following:

1. On 4/6/2010, according to the Concern/Complaint form, a donor's wife reported in part that her husband, a therapeutic donor, Unit 40LT42429, donated on 3/27/2010 and experienced bruises, "...around his elbow...and now has about a 4 in. bruise...". There is no DRIR or documentation on the BDR related to an adverse reaction. There is no documentation that the donor was provided follow-up care instructions.

2. On 6/8/2010, according to the Concern/Complaint form, Donor 241497, reported after donating on 5/24/2010 in part, "...when he was stuck by the needle it hurt so bad and continued to hurt for a while after the stick....It was not normal...". There is no DRIR or documentation on the BDR of an adverse reaction.

3. On 3/3/2010, according to the Concern/Complaint form, Donor 505120, reported after donating on 2/26/2010 via email in part, "...my blood stopped flowing and I had a extremely large goose egg on my arm because the needle slipped out of my vein and was trying to come out my arm the other side in a through and through...they once again tried moving it around again which just caused horrible pain...It is now March 2nd and have 5 inch bruise on my arm that is very painful...". There is no DRIR, documentation on the BDR that indicates the donor experienced a small hematoma.

4. On 5/21/2010, according to the Concern/Complaint form, Donor 458216, after donating on 5/18/2010 reported in part, "...donor has a black and blue arm with a lump the size of a silver dollar that still hurts...." There is no DRIR.

Additional examples in 2009 include the following:

5. On 4/28/2009, according to the Concern/Complaint form, a donor's mother reported in part that her daughter, "...collapsed at drive. Staff pulled her by her arms, hurting her head and back in the process....". The donor donated unit # 40KC27074

on 9/29/2008 during a high school blood drive. There is no DRIR in response to the post donation complaint or the adverse reaction at the time of donation. There is no documentation on the BDR that the donor experienced an adverse reaction.

6. On 6/5/2009, according to the Concern/Complaint form, Donor 407142 reported in part, "...The past 2 times he has tried to give blood, it was too difficult to stick him. He was left w/bruises 4-5 inches in diameter & the most recent occasion, we had 4 different people trying to stick him....". Donor 407142 donated on 2/16/2009 and 7/6/2007. There is no DRIR in response to the post donation complaint or the adverse reaction at the time of donation. There is no documentation on the BDR that the donor experienced an adverse reaction during either donation.

C. The Medical Director does not perform a complete review of donor adverse reactions. The firm practice is to review only the events related to the current donation and does not consider or determine if any possible adverse reactions may have occurred with the donor during previous donations.

For example, Case ID 040-1078/Case P200912141250o72, Donor 478442 experienced an adverse reaction involving a prolonged loss of consciousness, loss of bowel or bladder control, tetany and nausea. The reaction occurred while donating on 12/11/2009. The medical director reviewed the DRIR on 12/19/2009 and considered the donor eligible to continue to donate. During the donation prior to the 12/19/2009 donation, the donor also experienced an adverse reaction involving loss of consciousness. The medical director reported that he was unaware of the previous adverse reaction. Although the medical director stated that the additional information would not have changed the decision to consider the donor eligible to donate, the information regarding the prior reaction was not considered when determining the donor's ability to continue to safely donate.

The observation was also cited on two, previous FDA 483's (6/12/2007, 10/17/2008). Your response to the 10/17/2008 FDA 483 indicated that the medical director utilizes their medical knowledge and experiences when conducting the assessment of the donor's reaction and future eligibility to donate. During the inspection, FDA discovered ARC is using medical director designees who do not all have the medical knowledge and experience as stated in the response. According to the regional medical director, past records are not reviewed but can be requested based on medical judgment. According to (b) (6) Donor Care and Qualification Specialist, DCSC, Philadelphia, PA, the medical director designee staff are unaware if the donor has experienced a prior adverse reaction unless the donor brings it to the DCSC attention or if there is a note on the donor's record, which is rare....".

Additionally, not all medical director designees have the medical knowledge and experience in conducting the assessment of the donor's reaction since at least 47 of the 73 staff that maintain the title of medical director designee do not have a medical degree or a medical related certificate or license.

As of 2/2009, Heart of America Region (HOA) transitioned to the DCSC and since then the medical director designees routinely review DRIR's to determine final case and donor suitability assessment. Medical director designees are not required to have a background that includes medical and healthcare education and/or medical experience. Employees with the job title of Case Investigator or Donor Counselor may obtain the title of medical director designee after completing additional training in the following Training Implementation Plans: SY14 Final Donor Complication Review-tip, SY14 Performing Donor Complication Activities-tip and SY14 Final Case and Donor Suitability Assessment tip. Medical director duties

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specific to the review of DRIR's include: reviewing all details of the event, treatment, response and outcome and also indicating whether a donor deferral or product quarantine is indicated.

According to procedure Doc No 15.3.055 Version 1.1, "Work Instruction: Performing Final Case and Donor Suitability Assessment" and Doc No 14.4.ja164, "Job Aid: Final Case and Donor Suitability Assessment Code and Case Types", currently in place as of 6/25/2010, medical director (physician) designees may perform the medical director review of DRIR's. Medical director (physician) designees review DRIR's classified as major reactions including: prolonged loss of consciousness, large hematomas and arterial puncture. Medical director (physician) designees reviewed major adverse reactions in the following examples:

1. According to DRIR Case ID#040-1085/Case#P201002011421o72, donor (b) experienced a major adverse reaction involving a long loss of consciousness and seizures/convulsions during collection on 1/29/2010. Employee (b) (6) performed the medical director review of this DRIR on 2/25/2010. Employee (b) (6) has an educational background of medical assistant. The firm reported in part, "…Medical assistants are typically trained to work in a medical office setting handling paperwork, insurance forms, scheduling and some basic medical procedures for example, collection and preparing laboratory specimens…".

2. According to DRIR Case ID#C201002011031o5g, the firm received a call from donor (b) who reported experiencing an adverse reaction involving a large (6" x 3") hematoma subsequent to donating on 1/28/2010. Employee (b) (6) performed the review on 3/6/2010. Employee (b) (6) has a BS degree but no medical related certificates or licenses.

3. According to DRIR Case ID#040-1075/P200912041321o72, donor (b) experienced a major adverse reaction involving a long loss of consciousness and loss of bowel or bladder control during collection on 12/3/2009. Employee (b) (6) performed the medical director review of the DRIR on 12/7/2009. Employee '(b) (6) ' educational background includes Technical College, but no medical related certificates or licenses.

4. According to Case ID C200909231913o3z, firm received a call from donor (b) who reported experiencing a major adverse reaction involving seizures/convulsions subsequent to donating on 9/17/2009. Employee (b) (6) performed the medical director review of the DRIR on 1/8/2009. Employee '(b) (6) ' holds BS/MS degrees but no medical related degrees, certificates or licenses.

D. The Medical Director review of DRIR's are not always conducted within a reasonable amount of time as required by written procedure Doc #15.3.055 titled, Work Instruction: Performing Final Case and Donor Suitability Assessment. Quality reviews of DRIR's are not always conducted within a reasonable amount of time. Of DRIR's reviewed between 3/1/2010 and 5/2/1010, three had not received a timely quality review and/or Medical Director Review. For example:

1. According to DRIR Case ID#040-1098, donor 344575, experienced an adverse reaction involving a large hematoma on 3/15/2010 during an apheresis collection. As of 6/25/2010, more than three months after the occurrence, the DRIR has not had a final quality review. Donor 344575 donated again 4/25/2010, 5/16/2010 and 6/6/2010 even though the DRIR from 3/15/2010 has not had a final quality review. Additionally, the donor experienced an adverse reaction involving another hematoma during the 4/25/2010 donation.

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2. According to DRIR Case ID#C201003011819o4u, Donor "b(6) reported on 4/27/2010 experiencing an adverse reaction involving a large hematoma subsequent to donating on 2/25/2010. The DRIR was not reviewed by quality until 6/24/2010, which was during the inspection and after FDA requested records.

3. According to DRIR Case #C201003071336o5g, Donor "b(6) reported on 3/7/2010 experiencing an adverse reaction involving a large hematoma subsequent to donating on 3/3/2010. The medical director review occurred 4/29/2010, more than seven weeks, after receiving the report and the final quality review occurred 5/15/2010, more than two months after receiving the report.

E. A thorough investigation, including a record, of each adverse reaction was not made in that the firm does not document and investigate all adverse reactions. When a donor adverse reaction involves multiple complications, ARC does not always document each complication.

ARC classifies adverse reactions as major and minor. According to ARC SOP, major adverse reactions require that a DRIR is created. The DRIR provides fields where additional adverse reaction complication information must be documented. However adverse reactions classified as minor, do not require that a DRIR be initiated unless the firm became aware of the adverse reaction through Post Donation Information (PDI). For minor adverse reactions that are observed at the collection site, ARC's practice and procedures only require the documentation of the predominant adverse reaction onto blood donation records (BDR's), therefore not all adverse reaction complications are documented on the BDR.

When a donor experiences an adverse reaction involving more than one complication and when the reaction is not considered major there is no record of any additional adverse reaction complications that may have occurred during an adverse reaction. For example if a donor experiences a loss of consciousness less than one minute and also experiences a small hematoma and a minor citrate reaction, only the predominant adverse reaction code will be documented on the BDR. There is no indication or record that other complications occurred.

The firm maintains a hemovigilance program where a database that contains the BDR and DRIR adverse reaction codes is periodically accessed, however, not all complication codes are included in the data base, only the predominant code of each adverse reaction. The hemovigilance program was most recently used to demonstrate the effectiveness of the interventions for the young donor initiative to reduce complications in the most susceptible donor group.

Adverse reactions are classified as below:

MAJOR	MINOR
Loss of Consciouness (LOC), long (1 minute or more)	Loss of Consciousness, short (less than 1 minute)
Arterial Puncture	Pre-Faint
Allergic, Major	Allergic, minor
Citrate, Major	Citrate, minor
Hematoma, Large, (more than 2x2 inches)	Hematoma, Small (2x2 inches or less)
LOC with injury	Other, minor

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Nerve Irritation	
Prolonged recovery	
Other Major	

OBSERVATION 4

The personnel responsible for the collection of blood or blood components are not adequate in number 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,

According to your staffing matrix, specific numbers of employees are required to be present at mobile blood drives. ARC Heart of America Region operation records reviewed during this inspection reveal blood drives are not staffed adequately and according to the firm's matrix. For example,

1. A high school drive that took place on 10/28/2009 stated that the goal of the drive was 66 projected whole blood procedures and the total number of scheduled drive hours was 6.5. According to your firm's staffing matrix, this drive should have been staffed with 9 employees. According to the operation record, 8 employees were present at the drive.

Additionally, the high school coordinator of the blood drive documented, through the blood drive sponsor survey, dissatisfaction with the staffing levels at the drive.

2. A high school drive that took place on 11/6/2009 stated that the goal of the drive was 169 projected whole blood procedures and the total number of hours scheduled for the drive was 7 hours. According to your firms staffing matrix, this drive should have been staffed with 21 employees. According to the operation record, 20 employees were present at the drive.

Additionally, the high school coordinator of the blood drive documented, through the blood drive sponsor satisfaction survey, dissatisfaction with the staffing levels to meet the needs of the drive.

3. A church drive that took place on 1/13/2010 stated that the goal of the drive was 126 projected whole blood procedures and the total number of hours scheduled for the drive was six hours. According to your firms staffing matrix, this drive should have been staffed with 17 employees. According to the operation record 16 employees were present at the drive.

Additionally, the coordinator of the blood drive documented, through the blood drive sponsor survey, dissatisfaction with the staffing levels to meet the needs of the drive. The sponsor also stated the following, "...Between 3:15 and 4:15 the staff disappeared....There was an obvious rif/tension among the staff and several donors have since relayed this to me...".

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Laurie A. Haxel, Investigator	08/18/2010

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 W. Jackson Blvd., Suite 1500 Chicago, IL 60661-4716 (312) 353-5863 Fax:(312) 596-4187 Industry Information: www.fda.gov/oc/industry	06/21/2010 - 08/18/2010* FEI NUMBER 1473043

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Lisa A. Mott, Director of Collections

FIRM NAME	STREET ADDRESS
American National Red Cross Heart of America Region	405 W John H Gwynn Jr Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Peoria, IL 61605-2440	American Red Cross

4. A church drive that took place on 1/12/2010 stated that the goal of the drive was 15 projected whole blood procedures and the total number of hours scheduled for the drive was 4 hours. According to your firms staffing matrix, this drive should have been staffed with three employees. According to the operation record, two employees were present at the drive. Additionally, the coordinator of the blood drive documented, through the blood drive sponsor survey, that they were very dissatisfied with the staffing levels to meet the needs of the drive.

OBSERVATION 5

Failure to maintain general records.

Specifically,

A. The firm sends suspect product, withdrawal and recall notifications to consignees with requests that the consignees return the response forms indicating the final disposition of the product. The information is then entered electronically into the firm's Component Status Change Records (CSCR's). The firm does not always maintain the hospital response forms that document the final disposition of the product.

For example: Hospital disposition forms are missing from case file P20091203164o66 in the following example:

The DCSC, notified consignee on 12/3/2009 of the withdrawal of Unit 040C02399 and requested that that consignee provide final disposition information through a return form to the DCSC. According to the CSCR, employee (b) (6) documented on 1/8/2010, that the units were discarded by the consignee. There is no return documentation form from the hospital. Additionally, on 6/24/2010, during the inspection, the firm sent a market withdrawal notification letter, to the consignee with the correct Unit 2399. The consignee subsequently reported that Unit 2399 was transfused on 6/26/2008 which contradicts the firm's documentation indicating that the hospital previously reported that the unit had been discarded.

*** DATES OF INSPECTION:**
06/21/2010(Mon), 06/22/2010(Tue), 06/23/2010(Wed), 06/24/2010(Thu), 06/25/2010(Fri), 06/29/2010(Tue), 06/30/2010(Wed), 07/06/2010(Tue), 07/07/2010(Wed), 07/08/2010(Thu), 07/14/2010(Wed), 07/15/2010(Thu), 07/16/2010(Fri), 07/19/2010(Mon), 07/22/2010(Thu), 08/02/2010(Mon), 08/05/2010(Thu), 08/16/2010(Mon), 08/18/2010(Wed)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Laurie A. Haxel, Investigator	08/18/2010