

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

WFOCCT ADDRESS AND PHONE NUMBER One Montvale Avenue Stoneham, MA 02188 (781) 596-7700 FAX: (781) 596-7896 Industry Information: www.fda.gov/oc/industry	DATE OF INSPECTION 05/04/2010 - 05/15/2010 ESTABLISHMENT 1273014
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TO: Paul T. Sullivan, Chief Executive Officer	
FACILITY NAME American Red Cross Blood Services	STREET ADDRESS 298 Farmington Ave
CITY, STATE, ZIP CODE, COUNTRY Farmington, CT 06032-1955	FEDERAL AGENCY OFFICE 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 WE OBSERVED:

OBSERVATION 1

Written standard operating procedures including all steps to be followed in the collection of blood and blood components for further manufacturing purposes are not always followed.

Specifically, (b) (4) and American Red Cross (b) (4) do not give specific environmental conditions or parameters for the set up of mobile sites in regards to temperature. Your firm continued to operate blood drives with deficiencies as noted in the following operation reports:

Temperature:

A.) On 2/27/2010 and 3/13/2010, blood drives were held at the (b) (4). The operation record from the drive on 2/27/2010 states that (b) (4) Director of Collections notified, "Volunteers state they are very uncomfortable with temperature. Colder in history area." The operation record from the drive on 3/13/2010 states, "Very cold in room 62° - maintenance called *** Farmington notified - when temperature dropped to 60°. At 10:45, heat turned on by maintenance."

B. (b) (4) date 2/8/2010, Comments "59° in room at opening - heat not working, closed around 3:15 to move to warmer area in building."

Ventilation:

C. (b) (4) date 4/9/2009, Operational Analysis "3 staff complained of not feeling well due to fumes *** filled out Employee Injury Reports. Also donor felt unwell in Histories."

D. (b) (4) date 5/6/2009, Operational Analysis "Site was very smokey, due to smoking in bar. Even with door to bar closed, several staff were affected by smoke."

E. (b) (4) date 2/22/2010, Comments "Site had smokers in bar next door - smelly. (1) staff had to leave due to

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SEE REVERSE OF THIS PAGE	INSPECTOR NAME Anthony M Crianwa, Investigator A.O. Alice C. Silva, Investigator A.C.S	DATE 05/15/2010
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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

PRODUCT ADDRESS AND PHONE NUMBER

One Montvale Avenue
Stonham, NH 02189
(781) 556-7700 Fax: (781) 596-7826
Industry Information: www.fda.gov/oc/industry

DATE OF INSPECTION

05/04/2010 - 05/15/2010

FORM 482

1273914

DATE AND TIME OF RECEIPT TO STATE/PROVIDER

TO: Paul T. Sullivan, Chief Executive Officer

NAME

American Red Cross Blood Services

STREET ADDRESS

209 Farmington Ave

CITY, STATE, ZIP CODE, COUNTRY

Farmington, CT 06032-1955

TYPE OF ESTABLISHMENT INSPECTED

American Red Cross

smoke issues - fans in place to circulate air."

Noise:

F.) On 3/21/2009 and 3/23/2009, blood drives were held at the (b)(4). The Operation Record from the blood drive on 3/21/2009 states "Noise level was extreme due to several vendors and radio stations playing loud music at the same time (b)(4). The operation record from the drive on 3/23/2009 states, "very loud music playing, unable to hear blood pressures at times - very difficult working conditions."

Privacy:

G. (b)(4) date 3/2/2009, Operational Analysis "Site is very tight - confidentiality is hard to maintain - registration and reading in hallway."

Lighting:

H.) On 2/2/2009, 2/3/2009, and 2/5/2009, blood drives were held at the (b)(4). The operation record from the drive on 2/2/2009 states, "site has inadequate lighting making phlebotomy difficult - extra lights needed." The operation record from the drive on 2/3/2009 state "Very poor lighting at this site making it difficult to see anything, and the operation record for the drive on 2/5/2009 states, "Terrible lighting."

OBSERVATION 2

Written records are not always made of investigations into unexplained discrepancies.

Specifically, there is no quality review of mobile site suitability for continued use.

1.) On 2/2/2009, 2/3/2009, and 2/5/2009, blood drives were held at the (b)(4). The operation record from the drive on 2/2/2009 states, "site has inadequate lighting making phlebotomy difficult - extra lights needed." The operation record from 2/3/2009 states "Very poor lighting at this site making it difficult to see anything, and the operation record for the drive on 2/5/2009 states, "Terrible lighting."

2.) On 2/27/2010 and 3/13/2010, blood drives were held at the (b)(4). The operation record from the drive on 2/27/2010 states, "Very cold in room 59° @ opening - then 61° (b)(4) notified. Volunteers state they are very uncomfortable with temperature. Colder in history area." The operation record from the drive on 3/13/2010 states, "Very cold in room 62° - maintenance called*** Farmington notified - when temperature dropped to 60°. At 10:45, heat turned on by maintenance."

3.) On 3/21/2009 and 3/22/2009, blood drives were held at the (b)(4). The Operation Record from the

AMENDMENT 1

SEE REVERSE OF THIS PAGE	APPROVED SIGNATURE	DATE
	Anthony N Onizawa, Investigator A.N.O. Alice C. Silva, Investigator A.C.S.	05/15/2010

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

SUBJECT AND USE INFORMATION NUMBER One Westvale Avenue Stoneham, MA 02136 (781) 536-7700 Fax: (781) 536-7886 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 05/04/2010 - 06/15/2010 PLAN NUMBER 1273013
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NAME AND TITLE OF PERSON TO WHOM REPORT IS MADE TO: Paul T. Sullivan, Chief Executive Officer	
FIRM NAME American Red Cross Blood Services	STREET ADDRESS 209 Farmington Ave
CITY, STATE AND ZIP CODE, COUNTRY Farmington, CT 06032-1955	TYPE ESTABLISHMENT INSPECTED American Red Cross

blood drives on 3/21/2009 states "Noise level was extreme due to several vendors and radio stations playing loud music at the same time (b) (4) The operation record from the drive on 3/22/2009 states, "very loud music playing, unable to hear blood pressures at times - very difficult working conditions."

OBSERVATION 3

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, mobile blood drives are not adequately staffed per staffing matrix/staff version.

According to your staffing matrix, line staff, charge staffs, and mobile unit assistance (MUA) are required to be present at mobile blood drives. In addition to the above mentioned staffs, team supervisor is required if the blood drive has over 100 donors. ARC Connecticut and New England Region Blood Services Operational Records Addendum reviewed during this inspection reveal blood drives are not staffed adequately.

For Example:

- a.) (b) (4) drive that took place on 4/16/2009 stated that the goal of the drive was (b) (4) productive donors and the total hours of operation for the drive were 5 hours and 15 minutes. According to your firm's staffing matrix, this drive should have been staffed with five phlebotomists. Our audit of operation report for this drive showed there were only three phlebotomists present.
- b.) (b) (4) drive that took place on 2/25/2010 stated that the drive had 100 scheduled donors and the total hours of operation for the drive were 5 hours. According to your firm's staffing matrix, this drive should have been staffed with one team supervisor. There was no Team Supervisor present at this drive.
- c.) (b) (4) drive that took place on 2/15/2010 stated that the drive had 100 scheduled donors and the total hours of operation for the drive were 4 and 1/2 hours. According to your firm's staffing matrix, this drive should have been staffed with one Team Supervisor. There was no Team Supervisor present at this drive.
- d.) (b) (4) drive that took place on 2/15/2010 stated that the drive had 100 scheduled donors and the total hours of operation for the drive was 5 hours. According to your firm's staffing matrix, this drive should have been staffed with 5 phlebotomists, 1 MUA, and 1 Charge. According to the above noted operations record addendum, there were 4 phlebotomists and no charge person present at the blood drive.
- e.) (b) (4) drive that took place on 12/22/2009 stated that the drive had 100 scheduled donors and the total hours of operation for the drive was 6 hours or more. According to the above noted operation record addendum,

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SEE REVERSE OF THIS PAGE	EMPLOYER(S) SIGNATURE Anthony R Onianwa, Investigator A.R.O. Alice C. Silva, Investigator A.C.S.	DATE SIGNED 06/15/2010
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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DATE, ADDRESS AND PHONE NUMBER One Montvale Avenue Storham, MA 02180 (401) 596-1700 Fax: (781) 596-7898 Industry Information: www.fda.gov/oc/industry'	DATE OF VISIT 05/04/2010 - 06/15/2010 FOLLOW UP 12/2010
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TO: Paul T. Sullivan, Chief Executive Officer	VISIT ADDRESS 209 Farmington Ave Farmington, CT 06032-1955 American Red Cross
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there was no charge person present at this drive.

f.) (b)(4) drive that took place on 7/1/2009 stated that the drive had [redacted] scheduled donors and the total hours of operation for the drive was 6 hours or more. According to the above noted operation record addendum, there was no charge person present at this drive.

OBSERVATION 4

Laboratory records do not include the initials or signature of a second person showing that the original records have been reviewed for accuracy, completeness, and compliance with established standards.

Specifically, mobile blood drives operation records are not consistently being reviewed either by supervisor or charge person for accuracy and completeness.

For example:

- a.) American Red Cross Operation Report Addendum for Drive ID: (b)(4), Site (b)(4) and Drive Date 7/13/2009 had no Charge signature.
- b.) American Red Cross Operation Report Addendum for Drive ID: (b)(4), Site (b)(4), Drive Date 1/1/2010 had no Supervisor signature.
- c.) American Red Cross Operation Report Addendum for Drive ID: (b)(4), Site (b)(4), Drive Date 1/21/2010 had no Supervisor signature.
- d.) American Red Cross Operation Report Addendum for Drive ID: (b)(4), Site # (b)(4), Drive Date 12/3/2010 had no Supervisor signature.
- e.) American Red Cross Operation Report Addendum for Drive ID: (b)(4), Site # (b)(4), Drive Date 12/23/2009 had no Supervisor signature.
- f.) American Red Cross Operation Report Addendum for Drive ID: (b)(4), Site (b)(4), Drive Date 7/1/2009 had no Charge signature. Same person signature for Supervisor and Charge operation.
- g.) American Red Cross Operation Report Addendum for Drive ID: (b)(4), Site (b)(4), Drive Date 5/28/2010 had no Charge signature. Same person signature for Supervisor and Charge operation.

OBSERVATION 5

Deviation from the procedural requirements of a decree of injunction.

Specifically, your firm filed inaccurate (b)(4) Reports and Letters of Notification of Suspension of Activity to the

AMENDMENT 1

SEE REVERSE OF THIS PAGE	INSPECTOR SIGNATURE Anthony N Onianwa, Investigator A.O. Alice C. Silva, Investigator A.C.S.	DATE 06/15/2010
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

ESTABLISHMENT IDENTIFICATION NUMBER

One Montvale Avenue
Stonham, MA 02180
(781) 596-7700 Fax: (781) 596-7995
Industry Information: www.fda.gov/oc/industry

DATE OF INSPECTION

05/04/2010 - 06/15/2010*

DATE

1273914

TYPE OF VISIT (e.g., PRELIMINARY, FINAL, COMPLIANCE)

TO: Paul T. Sullivan, Chief Executive Officer

PRIMEVISE

American Red Cross Blood Services

DIRECT ADDRESS

209 Farmington Ave

CITY, STATE, ZIP CODE, COUNTRY

Farmington, CT 06032-1955

TYPE OF ESTABLISHMENT INSPECTED

American Red Cross

USFDA.

A.) On 5/10/2010, your firm submitted a Notification of Significant Corrective Action or Suspension of Activities, (b)(4) to the USFDA. This letter noted that there was a "Notification of Complete Suspension of Activities or Processes." Attached to this letter was (b)(4) Report (b)(4) stated that collection activities at the (b)(4) Blood Drive were suspended at 1:30 p.m. due to extreme temperature conditions.

- 1.) According to donor blood donation record from the (b)(4) Blood Drive, (b)(4) donors were processed for whole blood collection units between 1:30-2:59pm. The whole blood unit # collected between 1:30-2:59 pm are as follows: (b)(4) (b)(4), and (b)(4) with a start time at 2:59pm.

B.) On 5/21/2010, your firm submitted a Notification of Significant Corrective Action or Suspension of Activities (b)(4) to the USFDA. This letter noted that there was a "Notification of Complete Suspension of Activities or Processes." Attached to this letter was (b)(4) Report (b)(4) stated that collection activities were terminated at 1200 hours at the (b)(4) Blood Drive due hot temperatures and no air conditioning.

- 1.) According to donor's blood donation records from (b)(4) Blood Drive, the last phlebotomy for whole blood collections (unit# (b)(4)) was started at 12:32. This phlebotomy lasted 11 minutes.

C. On 5/19/2010, your firm opened (b)(4) Report (b)(4) stated that your firm received a customer concern from (b)(6) regarding equipment issues and staff performance at the (b)(4) Blood Drive that was held on 5/8/2010.

- 1.) During our inspection, we collected a form, titled (b)(4) and an email sent by (b)(6) of ARC Blood Services, Farmington, CT. This customer concern form and e-mail dated 5/10/2010, showed discovery date should have been documented as 5/10/2010, instead of 5/17/2010 as documented in your (b)(4) Report (b)(4)

*** DATES OF INSPECTION:**

05/04/2010(Tue), 05/05/2010(Wed), 05/06/2010(Thu), 05/12/2010(Wed), 05/21/2010(Fri), 05/27/2010(Thu), 05/28/2010(Fri), 06/15/2010(Tue)

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Anthony N Onianwa, Investigator <i>A.O.</i> Alicia C. Silva, Investigator <i>ACS</i>	06/15/2010