

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

DISTRICT OFFICE ADDRESS AND PHONE NUMBER

19701 Fairchild
Irvine, CA 92612
949 608 2900

DATE(S) OF INSPECTION

8/9/10-9/24/10

FEI NUMBER

2072994

Industry Information: www.fda.gov/oc/industry

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Donna L. Haab, Director of Collections

FIRM NAME

American Red Cross Blood Services

STREET ADDRESS

100 Red Cross Circle

CITY, STATE AND ZIP CODE

Pomona, CA 91768

TYPE OF ESTABLISHMENT INSPECTED

blood bank and donor center

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

NATIONAL DONOR DEFERRAL REGISTRY (NDDR):

1. Information on deferred donors from each ARC Region is sent monthly to the Donor Client Support Center (DCSC) to be incorporated into the NDDR (National Donor Deferral Registry). The updates to the NDDR are shared with all Regions monthly in a table format referred to as NDDR "pushed table" so that any Region can identify these donors as deferred during registration.

However, deferred donors may not be identified during donor registration at the regions because the NDDR "pushed tables" only contain the donor's current information and not also the before images for donors who previously donated under different names. (The **b(4)** digit ARC soundex value is used to identify donors during donor registration at the region).

- a. Any prior last names for deferred donors are not included on NDDR "pushed tables" so are not searchable during registration activities and donors may not be identified as a result. The following are representative examples of deferred donors with prior last names that are found on the NDDR "pushed table" with only current last name information accessible to other regions:
 - i. Deferred merged donor had a newer identity under **(b) (6)** and an original identity under **(b) (6)** and the NDDR "pushed table" contains the current last name only **(b) (6)**
 - ii. Deferred merged donor had a newer identity under **(b) (6)** and an original identity under **(b) (6)** and the NDDR "pushed table" contains the current last name only **(b) (6)**
 - iii. Deferred donor **(b) (6)** provided a prior last name **(b) (6)** on donation 9/30/09; the NDDR "pushed table" contains the current last name only **(b) (6)**

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FOOD AND DRUG ADMINISTRATION

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FIRM NAME American Red Cross Blood Services	STREET ADDRESS 100 Red Cross Circle
CITY, STATE AND ZIP CODE Pomona, CA 91768 3	TYPE OF ESTABLISHMENT INSPECTED blood bank and donor center

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

- b. Since the NDDR "pushed table" only contains a deferred donor's entire hyphenated name, donors may not be identified if attempting to donate using just the **first part of the hyphenated last name** because this name can result in a soundex value that pulls numeric values from the second part of the hyphenated name due to the soundex algorithm. The following are representative examples of deferred donors in the system with their hyphenated last name that has a different soundex value than the first part of the last name:
- i. The last name soundex code for Donor (b) (6) is different for the first part, second part and entire hyphenated name:
 - 1. (b) (6) (entire last name)
 - 2. (b) (6) (first part of last name)
 - 3. (b) (6) (second part of last name)
 - ii. The last name soundex code for Donor (b) (6) is different for the first part, second part and entire hyphenated name:
 - 1. (b) (6) (entire last name)
 - 2. (b) (6) (first part of last name)
 - 3. (b) (6) (second part of last name)
 - iii. The last name soundex code for (b) (6) is different for the first part, second part and entire hyphenated name:
 - 1. (b) (6) (entire last name)
 - 2. (b) (6) (first part of last name)
 - 3. (b) (6) (second part of last name)

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- c. Since the NDDR "pushed table" only contains a deferred donor's current last name (i.e. entire hyphenated name), donors may not be identified if attempting to donate using just the second part of their hyphenated last name because this name results in a different soundex value. The following are representative examples of the entire system:
- i. The last name soundex code for Donor (b) (6) is different for the first part, second part and entire hyphenated name:
 1. (b) (6) (entire last name)
 2. (b) (6) (first part of last name)
 3. (b) (6) (second part of last name)
 4. (b) (6) (there are two 2nd parts of the hyphenated last names entered into NBCS)
 - ii. The last name soundex code for Donor (b) (6) is different for the first part, second part and entire hyphenated name:
 1. (b) (6) (entire last name)
 2. (b) (6) (first part of last name)
 3. (b) (6) (second part of last name)
 - iii. The last name soundex code for Donor (b) (6) is different for the first part, second part and entire hyphenated name:
 1. (b) (6) (entire last name)
 2. (b) (6) (first part of last name)
 3. (b) (6) (second part of last name)

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

INVESTIGATIONS OF POTENTIAL DUPLICATE DONORS ARE INCOMPLETE AND/OR NOT FULLY DOCUMENTED:

2. When potential duplicate donor pairs are determined to be false matches on Utility Reports by recording "verified w/ BDRs", the specific differences in critical donor information used to arrive at this conclusion is not documented. For example:
 - a. Soundex Report (2/1/10-2/8/10) documents the reason for determining these donor pairs as false duplicates was "verified w/ BDRs":
 - i. Donors (b) (6) and (b) (6) with the same last name and birth date (mm/dd/yyyy) – specific rationale is not documented. In addition, the BDR for (b) (6) is handwritten and it is not clear if the first two letters of the first name are (b) (6) or (b) (6).
 - b. Soundex Report (2/9/10-2/16/10) documents the reason for determining these donor pairs as false duplicates was "verified w/ BDRs":
 - i. Donors (b) (6) and (b) (6) with the same last name and birth date (mm/dd/yyyy) – specific rationale is not documented. These two donors also have the same address.
 - ii. Donors (b) (6) and (b) (6) with the same last name and birth date (mm/dd/yyyy) – specific rationale is not documented.

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- c. Soundex Report (2/2/10-2/9/10) documents the reason for determining these donor pairs as false duplicates was "verified w/ BDRs":
- i. Donors (b) (6) and (b) (6) with the same last name and birth date (mm/dd/yyyy) – specific rationale is not documented.
 - ii. Donors (b) (6) and (b) (6) with the same last name and birth date (mm/dd/yyyy) – specific rationale is not documented.
 - iii. Donors (b) (6) and (b) (6) with the same last name and birth date (mm/dd/yyyy) – specific rationale is not documented.
- d. Soundex Report (3/22/10-3/29/10) documents the reason for determining these donor pairs as false duplicates was "verified w/ BDRs":
- i. Donors (b) (6) and (b) (6) with the same last name and birth date (mm/dd/yyyy) – specific rationale is not documented.
 - ii. Donors (b) (6) and (b) (6) with the same last name and birth date (mm/dd/yyyy) – specific rationale is not documented.
 - iii. Donors (b) (6) and (b) (6) with the same last name and birth date (mm/dd/yyyy) – specific rationale is not documented.
- e. Soundex Report (2/8/10-2/15/10) documents the reason for determining these donor pairs as false duplicates was "verified w/ BDRs":
- i. Donors (b) (6) and (b) (6) with the same last name and birth date (mm/dd/yyyy) – specific rationale is not documented.

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- f. Soundex Report (3/8/10-3/15/10) documents the reason for determining these donor pairs as false duplicates was "verified w/ BDRs":
 - i. Donors (b) (6) and (b) (6) with the same last name and birth date (mm/dd/yyyy) – specific rationale is not documented.
 - ii. Donors (b) (6) and (b) (6) with the same last name and birth date (mm/dd/yyyy) – specific rationale is not documented.

- g. Soundex Report (1/31/10-2/6/10) documents the reason for determining these donor pairs as false duplicates was "verified w/ BDRs":
 - i. Donors (b) (6) and (b) (6) with the exact same last name and birth date (mm/dd/yyyy) – specific rationale is not documented.

- h. Soundex Report (2/10/10-2/17/10) documents the reason for determining these donor pairs as false duplicates was "verified w/ BDRs":
 - i. Donors (b) (6) and (b) (6) with the exact same last name and birth date (mm/dd/yyyy) – specific rationale is not documented.

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- i. Soundex Report (2/4/10-2/11/10) documents the reason for determining these donor pairs as false duplicates was "verified w/ BDRs":
 - i. Donors (b) (6) and (b) (6) with the exact same last name and birth date (mm/dd/yyyy) – specific rationale is not documented.
 - ii. Donors (b) (6) and (b) (6) with the exact same last name and birth date (mm/dd/yyyy) – specific rationale is not documented. These donors have the same address.
 - iii. Donors (b) (6) and (b) (6) with the exact same last name and birth date (mm/dd/yyyy) – specific rationale is not documented.

- 3. The following possible duplicate donor pairs were determined to be false matches based solely on information from the Utility Report, but the key donor information used to come to this conclusion was not significantly different. For example:
 - a. Soundex Report (2/9/10-2/16/10) documents the following information as the reason to determine these donor pairs as false duplicates:
 - i. Donors (b) (6) and (b) (6) with the same birth date (mm/dd/yyyy) were determined to be different donors based on different first names and different last names. Last names are off by one letter. Only one donor provided a SSN.
 - ii. Donors (b) (6) and (b) (6) with the exact same birth date (mm/dd/yyyy) were determined to be different donors based on different first names and different last names. The last names are off by one letter. Neither donor provided a SSN.

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

- b. Soundex Report (1/31/10-2/6/10) documents the following information as the reason to determine these donor pairs as false duplicates:
 - i. Donors (b) (6) and (b) (6) with the exact same birth date (mm/dd/yyyy) were determined to be different donors based on different first names and different last names. The last names are off by two letters. Neither donor provided a SSN.
- c. Soundex report (2/7-14/10) documents the following information as the reason to determine these donor pairs as false duplicates:
 - i. Donors (b) (6) vs. (b) (6) with the exact same birth date (mm/dd/yyyy) were determined to be different donors based on different first names and different last names.
4. The following possible duplicate donor pairs were determined to be false matches based solely on information from the Utility Report, but the key donor information used to come to this conclusion was not sound. For example:
 - a. Soundex Report (2/7/10-2/14/10) documents the following information as the basis for concluding these donor pairs as false duplicates:
 - i. (b) (6) and (b) (6) with the same last name were determined to be different donors based on different first names and gender. (b) (6) was listed as female on the report and on his subsequent donation, approximately 4 months later, was corrected to male.
 - b. Soundex report (3/8-15/10) documents the following information as the basis for concluding these donor pairs as false duplicates:
 - i. (b) (6) and (b) (6) with the same last name were determined to be different donors based on different first names and gender.

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UTILITY PROGRAMS:

5. Migration of donor information from prior computer systems to NBCS resulted in deferred donors with inaccurate and/or incomplete information being contained in NBCS. This can affect whether potential duplicate donors will be identified on the Utility Reports and, if identified, can affect evaluating whether the potential duplicate donor pairs are a false or true match. The following incomplete/inaccurate information migrated for deferred donors:
 - a. The donor street address was transferred as "DONOR ADDED FROM DDR" and the home phone transferred as no home phone (i.e. blanks or zeros). As a result, potential duplicate donors can be missed because the Utility Report (matching home phone) will not match a blank or zero home phone value with any record in NBCS. This results in these deferred donors never matching with an existing donor record on the matching home phone Utility Report. The following are representative examples of the system's limitations:
 - i. Donor (b) (6) was deferred with a surveillance deferral code for a positive Hbc test result. Although the BDR (4/22/87) contained a home phone and address, this donor was transferred to NBCS without a home phone and with "DONOR ADDED FROM DDR" in the street address field.
 - ii. Donor (b) (6) was deferred with a surveillance deferral code for a positive Hbc test result. Although the BDR (3/3/89) contained a home phone and address, this donor was transferred to NBCS without a home phone and with "DONOR ADDED FROM DDR" in the street address field.

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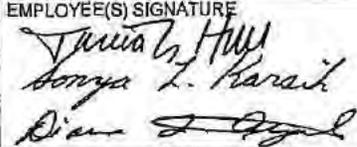
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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

b. The gender for deferred donors transferred as male (i.e. female donors were converted to male). As a result, potential duplicates can be missed because gender is used to investigate whether the donor pair is a true or false match. For example:

- i. Duplicate donor pairs (b) (6) and (b) (6) were missed at the 6/6/08 donation and discovered and merged after the 9/12/08 donation. Donor (b) (6) was deferred for Hepatitis B (code XAA) in 1973 and transferred to NBCS as a male. During registration for a 6/6/08 donation, she was not identified as a potential match with her other identity (b) (6) in the pick pan (if it was performed). She was identified as a potential match with her other identity (b) (6) in the pick pan during registration for the 9/12/08 donation.
- ii. (b) (6) was deferred with a surveillance deferral code for a positive Hbc test result. Although the BDR identifies the donor as female, she transferred to NBCS as male.

6. There is no utility run to search for potential duplicate donor pairs that uses matching addresses as a search criteria and no utility is run that compares home phone numbers with business phone numbers or alternate numbers. (The matching phone report is only checking for matches in the home phone field.) For example: Duplicate donor (b) (6) (b) (6) and (b) (6)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Tania Y. Hall CSO Sonya L. Karsik, CSO Diana L. Ayala, CSO	DATE ISSUED 9/24/10
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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER 19701 Fairchild Irvine, CA 92612 949 608 2900 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 8/9/10-9/24/10
	FEI NUMBER 2072994

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Donna L. Haab, Director of Collections

FIRM NAME American Red Cross Blood Services	STREET ADDRESS 100 Red Cross Circle
CITY, STATE AND ZIP CODE Pomona, CA 91768	TYPE OF ESTABLISHMENT INSPECTED blood bank and donor center

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

THE FOLLOWING DONOR MERGES WERE NOT THOROUGHLY INVESTIGATED:

7. The firm merged the following donors without conducting a thorough investigation:
 - a. The firm merged DID (b) (6) and (b) (6) without having investigated a third last name. When attempting a donation on 1/13/97, donor (b) (6) signed the BDR using the last name (b) (6) which is an entirely different last name than that listed for either DID. There is no documentation that the donor was questioned about this third last name when (s)he was contacted.
 - b. The firm's investigation into why duplicate donor (b) (6) and (b) (6) was not caught at the 6/6/08 donation did not identify deficient procedures as a potential cause.
 - i. At the 6/6/08 donation under DID (b) (6) she provided her former last name (b) (6) on the BDR. However, the duplicate donor (b) (6) was not identified *even though* a before image of her prior last name was created during registration. Per 14.3.081 (WI: Reviewing Registered Donations), the registration reviewers are only required to assure that a before image is created during registration when former names are listed on the BDR **but are not** instructed to verify that registration staff actually checked the prior name for existing records in (b) (4). If the registration staff did not check the donor's prior name, the registration reviewer would not know. Since the two last names do not have the same soundex, they would not show as potential duplicate pairs on the soundex report. There is no independent verification that prior names were actually checked in NBCS during registration and appropriate decisions made in the pick pan.

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

9/24/10
JPH assessing

- c. Although the firm's investigation into duplicate donor (b) (6) and (b) (6) did identify data migration from prior computer systems into NBCS as a potential contributing factor because this deferred female donor transferred as male, it was not reported to FDA in the Biological Product Deviation (BDP) as an identified possible root cause. In addition, this investigation did not address preventing future occurrences of incorrectly accessing potential matching donors listed in the pick-pan at registration as a result of gender discrepancies related to data migration.
 - i. DID (b) (6) was deferred for Hepatitis B (code XAA) in 1973 and transferred to NBCS as a male due to data migration. During registration for the 6/6/08 donation under DID (b) (6) she was not identified as a potential match in the pick pan (if it was performed) with her prior last name - (b) (6). Per 14.3.041 (WI: Evaluating donors in a Pick-Pan in NBCS), the registration staff is to compare first name, last name, DOB, SSN and gender of possible donor matches listed in the pick pan. The procedure does not discuss how to handle discrepancies due to the data migration.
 - ii. In addition, the two donor records do not have matching home phone numbers (the prior record has no home phone or it was removed by data migration) so the duplicate would not appear on that matching home phone report.

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8/9/10-9/24/10

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Industry Information: www.fda.gov/oc/industry

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Donna L. Haab, Director of Collections

FIRM NAME

American Red Cross Blood Services

STREET ADDRESS

100 Red Cross Circle

CITY, STATE AND ZIP CODE

Pomona, CA 91768

TYPE OF ESTABLISHMENT INSPECTED

blood bank and donor center

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

INACCURATE OR UNEXPLAINED INFORMATION IN NBCS AND RECORDS THAT ARE NOT AS DETAILED AS NECESSARY:

8. An inaccurate birth date was entered into NBCS for donor (b) (6) who was deferred for behavior risk on 1/26/09. As a result, if this donor returns to donate he will never match with his prior deferred record in a pick pan during registration or with the NDDR. The pick pan (searching for existing records in the regional NBCS) and the NDDR use a soundex algorithm that is based on a combination of (b) (4) (b) (4). This donor did not provide a SSN and is currently in the NDDR push table with a soundex value of (b) (6).
9. Unexplained home phone numbers exist in NBCS for the following donors with no supporting documentation for the change.
 - a. Donor (b) (6) has a home phone in NBCS (b) (6) that does not match the home phone on the most recent BDR (b) (6). The before images screen identifies the change was made 2/1/01 by (b) (6).
 - b. Donor (b) (6) has a home phone in NBCS (b) (6) that does not match the home phone on the most recent BDR (b) (6). The before images screen identifies the change was made 4/10/01 by (b) (6).
 - c. Donor (b) (6) has a home phone in NBCS (b) (6) that does not match the home phone on the most recent BDR (b) (6). The before images screen identifies the change was made 4/17/01 by (b) (6).

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE <i>Jamaly Hall</i> <i>Sonya L. Karsik</i> <i>Diana L. Ayala</i>	EMPLOYEE(S) NAME AND TITLE (Print or Type) Tamaly Hall CSO Sonya L. Karsik, CSO Diana L. Ayala, CSO	DATE ISSUED 9/24/10
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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

10. Records are not maintained or as detailed as necessary to contain a complete history of work performed.

- a. Procedures allow for shredding eBDRs (WI: Collections – Preparing Blood Donation Records and Operations 15.3.071 and WI: Collections – Completing End-of-Day Activities 15.3.073). For example donor 2039737 attempted a donation on 8/17/10 and this BDR should have been shredded as a “walk out”. However, this donor’s eligibility is in question due to CJD cumulative travel time.
- b. An inquiry made by donor (b) (6) in 2009 after no donations or attempts since 2007 cannot be explained. This inquiry resulted in a donor merge after identifying that this donor had two donor identities. The donor was being allowed to donate under one DID but was permanently or indefinitely deferred under the other DID.
- c. Multiple corrections to critical donor demographics made to two donors (b) (6) DID (b) (6) and (b) (6) in 2003 cannot be explained. There does not appear to be any donations or donation attempts since 2000 for either donor.

AUTOMATED BLOOD DONOR RECORD AND DETERMINING DONOR ELIGIBILITY:

11. BDRs lack documentation necessary to assess whether health historians made proper decisions about eligibility since specific information from the donor such as exposure dates and travel locations (that would be needed to assess eligibility) is not documented in comments and/or remarks unless the health historian has already determined the donor will be deferred.

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- a. On 8/17/10, I (DA) observed donor (b) (6) was not appropriately assessed for travel regarding question #30 (travel for a total of 3 months or more to U.K. for vCJD risk). The donor initially stated multiple trips to England for 2 1/2 to 3 months at a time in 1985 and 1986, then stated she was unsure because she did not remember. Since the health historian (b) (6) accepted this donor, the eBDR only documents less than 3 months and actual travel dates are not documented.
- b. On 8/13/10, I (SLK) observed the donor for WBN 06LH21115 was not appropriately assessed for travel. The donor stated travel to Egypt "about a year ago" for question 29 (malaria risk travel) and no follow-up questions were asked regarding where (since a portion of Egypt has malarial risk) and for exact dates of travel. The health historian did not document Egypt at all on the eBDR.

When the health historian conducts follow-up questions to evaluate a donor's eligibility, all the information provided by the donor is not documented nor is it required to be documented. A drop-down menu with "canned" responses is used to document information on the eBDR. Due to these documentation practices, there is no meaningful secondary review of BDRs since critical information about a donor's answers is not recorded in the comments or remarks sections and cannot be reviewed at a later time.

BLOOD MOBILES:

12. On 8/13/10, we (SK, DA) observed hand warmer "grabbers" that were placed directly over the phlebotomy site (separated by a piece of gauze) during collection at a blood mobile for WBNs 06LH21109, 06LH21115, & 06LH21102. The hand warmer "grabbers" package insert states "***Do not use***On parts of the body other than the hand***on bruising or swelling***" and also states the average temperature range is 135-156°F when used as directed. The package labeling does not support the use we observed.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

13. On 8/17/10, we (SK, DA) observed donor self-administered questions being conducted without visual privacy at a blood mobile using two self-contained buses. Three out of five screening booths lacked visual privacy. For example: WBN 06LC28221 and 06LC28214.
14. On 8-13-10, I (SK) observed Health Historian (b) (6) review the responses from donor (b) (6) (WBN 06LH21115) to the self-administered health assessment questions. I noted the donor had responded "yes" to question 29 (travel outside the US and Canada in past 3 years). When the Health Historian questioned her about her travel, she stated she had traveled to Egypt "about a year ago". The Health Historian asked no further questions to clarify the specific dates of travel and selected the "canned" drop down menu for no travel in the last 12 months. A portion of Egypt is a malarial risk area and this donor was not properly assessed.
15. On 8/17/10, I (DA) observed donor (b) (6) was not appropriately assessed for travel regarding question #30 (travel for a total of 3 months or more to U.K. for vCJD risk). The donor initially stated multiple trips to England for 2 1/2 to 3 months at a time in 1985 and 1986 were made. The health historian (b) (6) then asked the donor if she had lived in England for more than three months at one time (not three months collectively). The donor ultimately stated she was unsure because she did not remember and did not give definite dates of travel so a cumulative total time could not be determined. The health historian accepted this donor and printed the BDR.

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RECORD KEEPING:

16. The Component Labeling Job Aid is based on a 2006 validation study titled "Product Quality Study Plan For ABO/Rh Labeling of Blood Components Version BSL ~~09-286~~, 12/29/2005." The study's purpose was to alleviate documentation by providing labeling staff with maximum time limits for labeling a set number of components outside controlled storage at one time. This study was inadequate and not followed for the following reasons:

- a. There is no documentation on how staffs were selected to perform the study so that it is representative of current work practices and supports that employees can function within the allotted time limits.
- b. The study protocol required ~~(b) (4)~~ runs per shift and there are three (3) shifts per day. Only three (3) runs on one shift were done.
- c. One of the runs is outside of the parameters of the study because the room temperature was outside of the acceptable stated range. The upper room temperature limit was ~~(b) (4)~~ and one run was conducted at ~~26.5°C~~ *26.6°C*.
- d. The study required periodic verification of the batch sizes to assure labeling could be completed within the time/temperature limits established after completion of the study in 2006. There has been no verification performed to date.

*9/24/10
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9/24/10*

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17. When importing blood products, determining whether products were out of controlled storage for no more than 30 minutes is not accurately calculated and does not document the actual end time. BSL 09-052 instructs to determine this time by comparing the documented end of transit time (i.e. the time the box is opened at ARC after receipt) on the import stamp with the time printed on the import report paperwork. (The import report paperwork is printed after all components are scanned into computer inventory to document receipt.) However, the import report is printed before all importing steps have been performed. The importer must still visually compare the component label against the receiving paper work and the printed import report and the second reviewer must independently verify the importer's work before products are placed back into controlled storage. For example:

- a. On 8/12/10, we (TH, DA) observed importing session 193646 (order #341445). Twenty two red blood cell units were received from ARC Lewis and Clark Region. The end transit time was 10:27 and the import report printed at 10:46. However, product was not placed into the refrigerator until after reconciliation of the component labels with the receiving and printed report paper work. It was placed into the refrigerator at 10:48; this time does not get documented. The accurate times are not documented.
- b. On 8/12/10, we (TH, DA) observed importing of ISBT labeled products from an outside supplier, shipping order 637032. Twenty red blood cells were received. The end transit time was 10:50 and the products received report printed at 11:14. However, product was not placed into the refrigerator until after reconciliation of the component labels with the receiving and printed report paperwork. It was placed into the refrigerator at 11:17; this time does not get documented. The accurate times are not documented.

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CITY, STATE AND ZIP CODE Pomona, CA 91768 1/2	TYPE OF ESTABLISHMENT INSPECTED blood bank and donor center
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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) (WE) OBSERVED:

PROCEDURES DO NOT PROVIDE SUFFICIENT DETAIL:

18. Per 14.3.081 (Reviewing Registered Donations), the registration reviewers are required to review the "Before Images Created During Registration Report" to assure that former names listed on the BDR were created during registration. The procedure does not require they verify that the registration staff actually checked for existing records in NBCS for prior names and that they made appropriate decisions in a pick pan. For example: duplicate donor (b) (6) and (b) (6).
19. Work Instruction: Evaluating and Resolving DDR Hits (14.3.087 v. 1.1) does not define what should be considered a "partial" or "questionable" match with the NDDR. For example: whether (b) (6) would be considered significantly different than (b) (6).
20. Procedures related to managing the NDDR (Directive: Management of the National Donor Deferral Register 14.2.014 and WI: Manually Updating the National Donor Deferral Register 14.3.160) do not instruct how to manage donors with hyphenated names. For example: There are two possible second parts to the hyphenated last name for donor (b) (6) that result in two different last name soundex values (b) (6) (b) (6) or (b) (6). This donor is currently in the NDDR "pushed table" as (b) (6).

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE <i>Tania Y. Hall</i> <i>Sonya L. Karsik</i> <i>Diana L. Ayala</i>	EMPLOYEE(S) NAME AND TITLE (Print or Type) Tania Y. Hall, CSO Sonya L. Karsik, CSO Diana L. Ayala, CSO	DATE ISSUED 9/24/10
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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER 19701 Fairchild Irvine, CA 92612 949 608 2900 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 8/9/10-9/24/10 FEI NUMBER 2072994
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
 TO: Donna L. Haab, Director of Collections

FIRM NAME American Red Cross Blood Services	STREET ADDRESS 100 Red Cross Circle
CITY, STATE AND ZIP CODE Pomona, CA 91768	TYPE OF ESTABLISHMENT INSPECTED blood bank and donor center

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

21. Importing blood product procedures are not adequate:

- a. BSL 09-052 requires a secondary review on the import stamp when importing product but this procedure and BSD 74.510M do not provide instructions on how to handle paperwork if this secondary review cannot be done within the 30 minute time limit.
 - i. Since imported product is immediately and directly entered into electronic distributable inventory as the employee performs importing (not after the secondary review is performed), product lacking secondary review already has a computer status of available. Therefore, there would be no assurance that a secondary review was performed before distribution if products are imported and shipped the same day because the time of the secondary review of the import stamp is not documented nor is it required.
 - ii. The procedures require that product be stored physically separated with an orange sign indicating secondary review is pending, but do not address the associated paperwork. Reportedly, the paperwork would be placed on top of the units until secondary review is completed.
- b. BSD 74.510M and BSL 09-052 do not specifically apply to importing products from outside suppliers (b(4)) but it is being used for that purpose.
- c. (b(4)) imports procedures (WI: Delivering (Importing) (b(4)) Labeled Products from Non-American Red Cross Facilities Using SafeTrace TX - 21.3.104) do not discuss or require a second person review and do not discuss placing product in a designated area with associated paperwork until secondary review is completed.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE <i>Tania V. Hall</i> <i>Sonya L. Karsik</i> <i>Diana L. Ayala</i>	EMPLOYEE(S) NAME AND TITLE (Print or Type) Tania V. Hall CSO Sonya L. Karsik, CSO Diana L. Ayala, CSO	DATE ISSUED 9/24/10
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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Donna L. Haab, Director of Collections

FIRM NAME

American Red Cross Blood Services

STREET ADDRESS

100 Red Cross Circle

CITY, STATE AND ZIP CODE

Pomona, CA 91768

TYPE OF ESTABLISHMENT INSPECTED

blood bank and donor center

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22. There is no job aid (or other procedure/instruction) to assist employees in determining the total transit time for blood products received into inventory. Additionally, products can be received from facilities located in other time zones (i.e. MST, EST, etc.) and this must be factored into calculating the total transit time. The total transit time is necessary in verifying the blood shipment was received within the parameters for which the shipping containers were validated. BSD 74.510M v1.8 only instructs that staff must consider the time zone of the originating facility.

JGH
9/24/10

SEE
REVERSE
OF THIS
PAGE

EMPLOYEE(S) SIGNATURE

Tania G. Hall
Sonya L. Karsik
Diana C. Ayala

EMPLOYEE(S) NAME AND TITLE (Print or Type)

Tania G. Hall CSO
Sonya L. Karsik, CSO
Diana C. Ayala, CSO

DATE ISSUED

9/24/10