DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6000 Metro Drive Suite 101 Baltimore, MD 21215 (410) 779-5455	8/3-6, 9-13/10
	FEI NUMBER 1173010

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Robert A. Eaton, Chief Executive Officer

FIRM NAME	STREET ADDRESS
American National Red Cross	352 Church Avenue SW
CITY, STATE AND ZIP CODE Roanoke, VA 24016	TYPE OF ESTABLISHMENT INSPECTED Blood Bank

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 homologous transfusion are not always followed.

1. Failure to follow Work Instruction 15.3.55, Performing Final Case and Donor Suitability Assessment. This Work Instruction states that reviews for performing final case and donor suitability assessment need to be performed within a reasonable amount of time.

The following Donor Reaction and Injury Records, were missing the Medical Director Review, Recommendation and Signature. These records are also missing the Final Quality Review:

case # P201001291211o8d dated 1/29/10
case # P201002171436o32 dated 2/16/10
case # P201002171417o32 dated 2/16/10
case # P201002171923072 dated 2/17/10
case # C201004291504o2u dated 4/29/10

2. Failure to follow Work Instruction 15.3.56, Final Donor Complication Quality Review. This Work Instruction requires quality staff to perform a final review of donor complication cases to ensure all required steps have been taken to complete and document a donor complication investigation.

The following Donor Reaction and Injury Records were missing the Final Quality Review:

donor (b)(6) dated 11/19/09
donor (b)(6) dated 12/15/09
case # C201001290035o4g dated 1/29/10
case # C201002031957o7a dated 2/3/10
case # P201002181701o72 dated 2/17/10
case # C201003022227o3z dated 3/2/10
case # P201003101906o72 dated 3/10/10
case # P201003101724o72 dated 3/10/10
case # C201003261155o1k dated 3/26/10

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
		Nancy L. Naiger, Investigator Carrie L. Dauphin, Investigator	8/13/10

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case # P201004021528o32 dated 4/1/10
case # C201004292336o3z dated 4/29/10
case # C201004291919o3w dated 4/29/10

3. Failure to follow Form Instruction 17.4frm503 v-2.0, Irradiation Batch Record – Gamma Irradiation – Multiple Components Per Irradiation Cycle. These instructions require staff to document the time the first unit is removed from controlled storage and the time the last unit is placed back into controlled storage. Work Instruction 17.3.513 v-1.1, Converting and Re-labeling Irradiated Components, states that labeling can continue after irradiation or can be labeled at a later time. A review of the Irradiation batch records from October 2009 through August 2010 found the following deviations:

a. The following Irradiation Batch Record was documented as a two-step process; however, the units were relabeled immediately after irradiation as part of a continuous process.

Units 35FJ11070, 35FV23994, 35FV24001, 35FV24003, 35FV24018, 35GE41617, 35LW38047 and 35LW38050 were irradiated on 8/4/10. These units were removed from controlled storage at 1400 and the time these units are returned to controlled storage is documented as 1418. The Convert Session Report shows that these units were converted and labeled between 1423 and 1426. In this example the end of the irradiation process was erroneously noted on the Irradiation Batch Record as the time the units were returned to controlled storage.

b. The following Irradiation Batch Records document the units were returned to controlled storage during the conversion/labeling process.

Units 35Z28610, 35X15243, 35P73214 and 35Z28611 were irradiated on 2/15/10. These units were removed from controlled storage at 11:55 and the time these units are returned to controlled storage is documented as 1215. The Convert Session Report shows that these units were converted and labeled between 1214 and 1217.

Units 35P72555 and 35P72553 were irradiated on 12/18/09. These units were removed from controlled storage at 12:21 and the time these units are returned to controlled storage is documented as 12:31. The Convert Session Report shows that these units were converted and labeled between 1230 and 1232.

Units 35P72377, 35P72381, 35FW23854 and 35FX47767 were irradiated on 12/5/09. These units were removed from controlled storage at 11:23 and the time these units are returned to controlled storage is documented as 11:41. The Convert Session Report shows that these units were converted and labeled between 1136 and 1142.

Units 35P72568 and 27GF27198 were irradiated on 12/21/09. These units were removed from controlled storage at 14:46 and the time these units are returned to controlled storage is documented as 1457. The Convert Session Report shows that these units were converted and labeled between 1456 and 1458.

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		Nancy L. Neiger, Investigator Carrie L. Dauphik, Investigator	8/13/10

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c. The following Irradiation Batch Record documents that the unit was returned to controlled storage 4 minutes after it was removed from controlled storage; however, the irradiation timer setting is for (b) (4) [redacted]

Unit 35P72035 was irradiated on 11/9/09. This unit was removed from controlled storage at 2148 and the time this unit was returned to controlled storage is documented as 2152. The Timer Setting for the irradiator is (b) (4) [redacted] however this unit was documented as being out ot controlled storage for only 4 minutes.

4. Failure to follow Work Instruction 17.3.513,v-1.1, Converting and Re-labeling Irradiated Components. This Work Instruction states that if an irradiated product is to be labeled at a later time or by another staff, staff must place a mark through the ABO/Rh label of the component to provide a visual reminder the component is to be re-labeled.

On 8/11/10, units 35GE41619, 35S83685, 35S83689 and 35EW27593 were irradiated between 9:14 and 9:22. The units were then relabeled by a different staff member from 9:49 to 9:52. These units were stored in the refrigerator but were not marked through the ABO/Rh label as per Work Instruction.

5. Failure to follow Work Instruction 15.3.086 v-1.1, Daily Function Check of the Automatic Trip Scale. This Work Instruction states to perform the functional test of the trip scale. If the scale does not trip, staff is to repeat the functional test one time, which includes tapping the scale arm to ensure it moves smoothly and ensuring the scale is level. If the scale does not trip after the repeat test, staff is to quarantine the trip scale.

During a mobile on 8/10/10, it was noted during set-up that trip scale # 035.143 had failed the initial function test. The staff had failed the trip scale on the initial function test but continued to adjust the scale three additional times before ultimately failing the scale.

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