DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

FROM: FDA BRUNSWICK OHIO
FAX NO.: 330-225-7477
Oct. 01 2010 10:22AM P3

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Records are not concurrently maintained with the performance of each significant step in the storage of each unit of blood and blood components so that all steps can be clearly traced.

Specifically,

Specifically, on April 6, 2009, staff performed the Weekly Inventory Reconciliation; however, staff documented that the inventory was invalid because the record was not verified by a second person. Staff then completed the Weekly Inventory Reconciliation on April 7, 2009. The record that was generated on April 6, 2009 was discarded.

OBSERVATION 2

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

Specifically,

1. Failure to follow Job Aid 15.4.Ja037, Short Loss Of Consciousness. This Job Aid requires staff to handle all reactions where the donor has seizures or convulsions or loss of bladder or bowel control as a long loss of consciousness to ensure follow-up (15.4.Ja038).

a. A donor donated on 2/9/2009 (case # C200902101516a2w) and had a loss consciousness for less than a minute 3 times during donation. The donor also lost bladder control. Staff documented the reaction as a Major Other (XO) and a Prolonged Recovery (XP). The donor was not treated as a Long Loss Of Consciousness (XF).

b. On 4/22/10, the donor had a Loss of Consciousness with a loss of bladder control (case # C201004221304a07a); however, the Final Complication Code in the Medical Director Review and Recommendation section was documented as Large Hematoma (XH). The code should be documented as a Long Loss Of Consciousness (XF).
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:

- Case # C2010021118067a dated 2/9/10
- Case # C2010022118487a dated 2/4/10
- Case # C2010041322317a dated 4/8/10
- Case # C2010042322517a dated 4/21/10
- Case # C2010042322557a dated 4/21/10
- Case # C2010042322557a dated 4/22/10

3. Failure to follow Form Instruction: Donor Reaction and Injury Record procedure 15.4.3.0.15 and Work Instruction: Documenting Donor Complications 15.2.0.45. The Work Instruction and Form Instructions require a supervisor/designee review to ensure the donor complication was properly treated.

The firm received a call back from a donor on 2/13/09 (Case # C20090213210703a). Sections 1-5 were completed on 2/13/09; however, the Follow-up Contact attempts were not made until 3/1/09, 10/16/09 and 10/19/09. The Supervisor review was not completed until 10/13/09 and the Medical Director review was performed on 10/22/09 and Final Quality review was completed on 10/23/09.

4. Failure to follow Job Aid: Guidelines for Self-Detected Problems, 10.4.3.0.32. The Job Aid states that a self-detected problem is detected by the person that caused the problem and is detected on the same date or shift of occurrence.

On 2/10/09, staff received a call back from a donor. During the initial call on 2/10/09, the donor's reaction was documented as a bruising/discoloration of the right arm more than 2x2 inches. Hives/itchy skin were also documented. Attempts were made to contact the donor regarding the reaction. Staff documented contact with a relative of the donor on 2/25/09 and the Medical Director documented the Final Complication Codes as Prolonged Recovery (XP) and Large Hematoma (XII). The Medical Director signed off on the review on 3/4/09.

On 5/3/09 staff made the following changes on the DRIR: changed the reaction codes from Prolonged Recovery to Large Hematoma (section 5); crossed out the comment made by staff on the Follow-up Contact information (section 7); and changed the Final Complication Codes (section 9) made by the Medical Director. An exception report was not initiated/completed for these changes and no reason was given for the corrections.

5. Failure to follow firm's procedure for completing the Hospital Services Weekly Inventory Reconciliation Checklist is to be completed by the person performing the reconciliation and by the person verifying the information.

REVIEWED AND APPROVED BY: Nancy L. Neiger, Investigator

DATE: 09/23/2010
On June 1, 2009, June 8, 2009 and June 22, 2009, staff were performing the second person verification for the Hospital Services Weekly Inventory Reconciliation; however, staff did not initial the "Performed By" column of the Hospital Services Weekly Inventory Reconciliation Checklist and the Supervisor initialed the "Verified By" column of the checklist. Staff that actually performed the inventory reconciliation did not initial the Hospital Services Weekly Inventory Reconciliation Checklist.

* DATES OF INSPECTION:
08/27/2010(Fri), 08/30/2010(Mon), 08/31/2010(Tue), 09/01/2010(Wed), 09/03/2010(Fri), 09/14/2010(Tue), 09/16/2010(Thu), 09/17/2010(Fri), 09/20/2010(Mon), 09/23/2010(Thu)