

May 21, 2004

Mr. Mark W. Rivero, Compliance Officer  
Food and Drug Administration  
New Orleans District  
Southeast Region  
6600 Plaza Drive, Suite 400  
New Orleans, LA 70127

**Re: Warning Letter NO. 2004-NOL-26**

Dear Mr. Rivero:

Thank you for your letter dated May 7, 2004 in reference to your inspection of our Blood Bank, which we received May 10, 2004. First, please let us assure you that the Medical Center takes its obligations under the Current Good Manufacturing Practice regulations very seriously. Our goal is to continue to improve the quality of service to our blood donors and to help assure the safety of blood for patients in our community. In response to your observations, we have revised our policies and procedures relating to these observations, we have re-educated personnel and have integrated the changes into our practice. Our detailed corrective actions for your observations are as follows:

**Form 483 Observation 1.**

Failure to perform a thorough investigation and make a record of the conclusions and follow-up of an unexplained discrepancy

**Corrective Actions**

The Donor Record verification process has been revised and implemented by taking the following steps:

**1. Policy Change**

The Donor Record Review Standard Operating Procedure (SOP) was revised to include the following changes (Attachment 1):

- Allogeneic products prepared from units for which records are missing blood pressure, pulse, temperature or donor arm inspections will be discarded. [Attachment 1, Page 5, Item F. 3. b ]
- Allogeneic products prepared from units for which records are missing hemoglobin results can be qualified for use by testing the hemoglobin on a suitable processing sample collected at the time of donation. If the hemoglobin is greater than or equal to [redacted], allogeneic products prepared from the donation can be used. If the hemoglobin is less than

**[redacted]** the products will not be used and a pathologist will be consulted to determine whether donor notification is indicated.

[Attachment 1, Page 5, Item F. 3. c., i., ii ]

- Methods to help assure accurate identification and privacy for the donor when telephone follow-up is necessary were added. [Attachment 1, Page 3, Items F, 3. a & Page 4, Item F. 3. a. iv ]
- The Donor Record Review is included as part of the Infectious Disease testing truth table. Only products prepared from donors with complete donor records can be released for use. [Attachment 1, Page 2, Item E. 1 & Page 3, Item F. 2 ]
- The revised SOP also addresses the handling of missing donor signature, missing interviewer signature, and missing phlebotomist initials. All products are quarantined until the investigation is completed. [Attachment 1, Page 5, Item F. d & Page 6, Items F. f, g, & h ]
- The “Donor Record Non-Conformance Report” form [Attachment 2] is now attached to the donor record as documentation of investigation and follow-up. This document remains a permanent part of the donor record. [Attachment 1, Page 3. Item F. 1 ]

## **2. Monitoring Compliance**

The following corrective actions have been taken to reduce the number of inaccurate and incomplete donor records:

- The blood donor staff member performing the phlebotomy will conduct a secondary review of the record at bedside before the phlebotomy. [Attachment 1, Page 2, Item C ]
- The Manager of the Blood Bank, or his designee, will perform the follow-up on all incomplete or inaccurate donor records. This change was implemented while the FDA Surveyors were on site. Items requiring follow-up will be investigated and completed before products prepared can be released for use. [Attachment 1, Page 6, Item 3. h ]
- The number of incomplete or inaccurate donor records will be tracked monthly. The Manager of the Blood Bank is responsible for review of these monthly statistics and will take appropriate corrective measures, including disciplinary action.
- The FDA approved AABB Full Length Donor History Questionnaire has been adopted. The new forms have been ordered and will be in use by June 11, 2004.
- The Manager of the Blood Bank will meet with the Medical Director of the Blood Bank and the Divisional Director of the Laboratory monthly to review department operations and compliance.

### **3. Education**

- 22 of 23 (96%) of the Blood Donor Techs have received education and training on the new processes to decrease the number of incomplete or inaccurate records. The remaining employee is PRN staff and is scheduled to receive training on May 25, 2004. Attachment 3 is a copy of the sign-in sheets and educational content of the meetings.
- Mobile and in-house team leaders are responsible for periodically reviewing records during the day.

### **Form 483 Observation 2.**

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

### **Corrective Action**

To help assure that all records will be concurrently documented and maintained, the following steps have been taken:

#### **1. Policy Change (Observation 2.a.)**

Blood products prepared from a donor whose donor record has been lost will be discarded. [Attachment 1, Page 5, Item F. 3. e]

#### **2. Policy Change (Observation 2.b.c. and d.)**

As noted above the revised Donor Record Review SOP includes the following changes:

- Allogeneic products prepared from units for which records are missing blood pressure, pulse, temperature or donor arm inspections will be discarded. [Attachment 1, Page 5, Item F. 3. b ]
- Allogeneic products prepared from units which records are missing hemoglobin results can be qualified for use by testing the hemoglobin on a suitable processing sample collected at the time of donation. If the Hemoglobin is greater than or equal to **[redacted]** allogeneic products prepared from the donation can be used. If the hemoglobin is less than **[redacted]** the products will not be used and a pathologist will be consulted to determine whether donor notification is indicated. [Attachment 1, Page 5, Item F. 3. c., i, ii ]

### **3. Education**

- During the employee education and training sessions the employees were advised that concurrent documentation is required.
- A Blood Donor Employee Attestation (Attachment 4) regarding concurrent documentation has been created. All blood donor employees will be required to read and sign the Attestation. This procedure was implemented on May 19, 2004 and will be completed by May 28, 2004.

- The education and attestation will be added to the Blood Bank new employee orientation.

#### **4. Monitoring Compliance**

The Manager of the Blood Bank, or his designee, is responsible for investigation and follow-up of incomplete donor records consistent with the revised Donor Record Review SOP. This will provide for standardized management of records and products.

#### **Form 483 Observation 3.**

Failure to maintain written standard operating procedures including all steps to be followed in the collection, processing, and distribution of blood and blood components for homologous transfusion, autologous transfusion, and further manufacturing purposes

#### **Corrective Actions**

##### **1. Policies Revised (Observation 3. A.)**

The Blood Bank Management Team revised the following policies:

- The Donor Record Review SOP (Attachment 1) addresses the steps to be followed in the collection, processing and distribution of blood and blood components for homologous transfusion, autologous transfusion, and further manufacturing purposes. The SOP addresses the steps required to determine the suitability of a donor when donor records are not completed at the time of the donation.
- The Whole Blood Collection SOP (Attachment 5) has been revised to prohibit blotting of the site. [Attachment 5, Page 2, Item III, 7, b]

##### **2. Education (Observation 3. B. C. & D.)**

Blood Donor Staff have been re-educated on the following items:

- Verification and concurrent documentation of the serial number and the appropriate normal range for the [----redacted----] currently in use.
- The importance of proper mixing of the blood with anticoagulant on mobile blood drives was reviewed. (Attachment 3)

Training and competency testing on the new donor arm preparation has been developed and will be presented to all Blood Donor employees by May 28, 2004. Annual employee competency testing has been revised to include this change.

##### **3. Document Change Control (Observation 3. E.)**

All areas have been inspected and old forms removed. Obsolete forms will be removed from service when a revised form is placed into use. The Blood Bank Quality Assurance staff will be responsible for removing obsolete forms when a new revision is implemented.

**4. Monitoring Compliance**

The Blood Bank Manager or his designee will monitor and enforce compliance with the requirements for the collection, processing, and distribution of blood and blood components for homologous transfusion, autologous transfusion, and further manufacturing purposes.

**Form 483 Observation 4.**

Failure to provide adequate space for private examination of individuals to determine their suitability as blood donors

**1. Environmental Change to Provide Privacy**

Donor bus drapes have been installed to provide visual privacy for the donor while completing their medical history questionnaire. In addition, the number of donors allowed on the bus will be limited to assure adequate privacy.

**Form 483 Observation 5.**

Failure of equipment to perform in the manner for which it is designed as to assure compliance with the official requirements prescribed in 21 CFR 606.

**1. Corrective Actions**

The use of the [-----redacted-----] has been discontinued for blood product testing pending validation studies. Currently, the samples are being sent to a reference laboratory in [-----redacted-----]. Validation studies to support testing of alternate specimen types on the [-----redacted-----] are currently being performed.

Our Lady of the Lake has enjoyed a long and successful history of providing Blood Bank services to our community. We are committed to continuing this service in a safe, high-quality manner consistent with the regulations spelled out by the FDA as well as all oversight organizations. We are confident that the corrective actions detailed above will address the survey observations from April 2, 2004 and reflect our commitment to excellence. If you have any questions, please contact Dr. Peggy Polk, Blood Bank Medical Director at [--redacted-----].

\_\_\_\_\_  
[-----redacted-----],[-----redacted-----]

\_\_\_\_\_  
Date

\_\_\_\_\_  
[-----redacted-----], [-----redacted-----]

\_\_\_\_\_  
Date

\_\_\_\_\_  
Kirk G. Wilson, President and COO

\_\_\_\_\_  
Date