DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Failure to perform a thorough investigation of a failure of a lot or unit to meet any of its specifications.

Specifically, 1) Investigation of exception report E-0632596 (I-0003622) failed to consider frozen red blood cells as potentially affected by the error resulting in a failure to recall frozen red blood cells (pcode 06200) unit #18FZ24606 as required by written procedure #11.2.002, Directive: Management of Suspect Products. Exception report #E-0632596 was initiated for an employee who was found not performing an arm scrub for 30 seconds and was not waiting or aware of the need to wait 30 seconds prior to performing the phlebotomy during whole blood collections. The cMRB decision was to recall all in dated transfusable components from 09/17/2001 to 08/10/2009. The cMRB decision failed to include frozen red blood cells (pcode 06200) in the evaluation. The firm had manufactured two frozen red blood cell units affected by this exception report with one unit (unit #18FZ24606) being shipped to a customer on 1/29/02.

OBSERVATION 2

A thorough investigation of each reported adverse reaction was not made.

Specifically, Medical Director reviews of Donor Reaction and Injury Records (DRIR) are not conducted within a reasonable amount of time as required by written procedure Doc #15.3.055 titled, Work Instruction: Performing Final Case and Donor Suitability Assessment. Review of November 2009 DRIR's found 3 of 47 records had not been reviewed by the Medical Director as of this inspection, 1 DRIR was reviewed about three months after the date of the incident and 1 was reviewed 2 months after the date of the incident:

Case id # C200911141848o7a was for a donor reaction involving dizzy/lightheadedness and a prolonged recovery on 11/12/09. This record has not had Medical Director Review or Final Quality Review as of
4/22/10.

Case id # C20091120163504m was for a donor reaction involving a 4 1/2" bruise reported by donor call back on 11/20/09. This record has not had Medical Director Review or Final Quality Review as of 4/22/10.

Case id # C20091105155706z was for a donor reaction involving dizzy/lightheadedness and a bruise/swelling a little larger than a golf ball reported by donor call back on 11/5/09. The donor subsequently called in and stated she experienced additional lightheadedness and was transported by EMS to the hospital. This record has not had Medical Director Review or Final Quality Review as of 4/22/10.

Case id # 018-D-C20091128084003n was for a donor reaction involving large hematoma on 11/27/09. This record had Medical Director Review and Final Quality Review on 2/19/10.

Case id # C20091127190207a was for a donor reaction involving dizzy/lightheadedness and seizure/convulsion on 11/25/09. This record had Medical Director Review on 1/26/10 and Final Quality Review as of 2/19/10.