

The draft guidance contains a number of issues that are of concern to our facility. The most serious of the proposed changes is the limitation of the number of components that can be collected in 12 months from a donor. To change the requirement from 24 collections to 24 components would result in an annual loss to our facility of 417 apheresis platelet units based on the last 12 months of collections. This would have a significant adverse effect on our ability to fulfill area hospital needs for apheresis platelets. We are aware of no adverse impact multiple collections have on our donors. The proposed guidelines require (1) that a post-donation platelet count be performed and (2) that monitoring of the platelet recovery of multiple component donors be conducted. These additional steps should confirm that frequent multiple-component donors are not affected by their donations under the current guidelines. We request that the current guidance document remain unchanged to allow 24 procedures in a twelve month period as long as donors are otherwise qualified and the monitoring system of the draft guidance is implemented.

A related change in the proposed guidance of some concern to us is the change of the donation interval between collections of double Platelets, Pheresis or triple Platelets, Pheresis and subsequent collection of Platelets, Pheresis. This change would add considerably to the recordkeeping and tracking requirements.

Another proposed change that would place a burden on our organization is the requirement to have a physician available within 15 minutes for emergency care of donors. In our opinion, trained EMT staff are fully able to provide emergency care for donors and have the needed equipment and experience required to handle any emergency. Our organization has some collection sites as far as two hours from the center where our medical director is located, but in all cases, hospital EMT teams are within minutes of each facility. We request that the use of EMTs via the 911 emergency system be allowed in areas where the medical director is more than 15 minutes away.

We also question the proposed changes to the deferral period for donors who have taken aspirin or aspirin-containing products and NSAIDS. These changes are inconsistent with the Standards for Blood Banks and Transfusion Services, 23<sup>rd</sup> Edition, published by the AABB.

Section VII, A, 2, Additional Provisions Applicable to SOP's, bullet point "Component Storage and Shipping" states that "(i)f sterile docking of an additional container(s) is necessary....You should use containers from the same manufacturer (of the automated blood cell separator)." In the case of Trima systems, the manufacturer (Gambro) does not make such a container, and containers from a third party manufacturer must be used in the event a triple platelet is drawn. We request that this section be reworded to state that third party containers be allowed if the separator manufacturer does not make such a bag for sterile docking.

We recognize the need for a strong validation and quality control program for the apheresis process. However, there are some requirements in the proposal that appear to be inordinately restrictive. One of these is the requirement for 500 consecutive collections without a bacterial testing failure. For a center our size, and smaller centers, this will lengthen the time required for validation considerably. It could take six months to perform 500 platelet collections at some of our lower volume collection sites. In light of the fact that 60 consecutive singles collections (or equivalent) are required for platelet yield, pH, volume, visible RBCs, residual WBC count and percent recovery, we question the selection of such a high number for bacterial testing during the performance qualification.

In addition, we request clarification on the use of the “scan statistics” plan for QC monitoring. For low volume collection sites, we assume that the four sample minimum number of samples will remain acceptable. What will be the requirements for facilities which collect between four hundred eighty components per year (requiring four samples per month to be tested) and four thousand components per year (400 samples per month to be tested)?

We also question the requirement that during product performance qualification components be tested throughout the dating period. This requirement adds more complexity to the recordkeeping and should be optional.

Due to the number and complexity of the proposed changes, we respectfully request that CBER provide for an open meeting or forum to discuss the draft guidance. We would request that individual centers or associations of blood collection organizations be allowed to present relevant data through the scientific and medical resources available to them.

Thank you again for allowing our organization to present its perspective on the changes.