



DEPARTMENT OF DEFENSE  
ARMED SERVICES BLOOD PROGRAM OFFICE  
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REPLY TO  
ATTENTION OF

ASBPO (40-2b)

30 December 2005

MEMORANDUM FOR DIVISION OF DOCKETS MANAGEMENT (HFA-305)  
FOOD AND DRUG ADMINISTRATION  
5630 FISHERS LANE, 1061  
ROCKVILLE, MD 20852

SUBJECT: Comments to Draft Guidance for Industry and FDA Review Staff-Collection of Platelets by Automated Methods - Docket. 2005D-0330

1. The Armed Services Blood Program Office (ASBPO) was established by the Assistant Secretary of Defense for Health Affairs to coordinate the blood programs of the Military Services and the Unified Commands. In that respect, the ASBPO is submitting comments to the Draft Guidance for Industry and FDA Review Staff-Collection of Platelets by Automated Methods - Docket. 2005D-0330 (Attachment 1).
2. In addition to the attached comments, the ASBPO noted the use of the ASBPO website as Reference #9 in Section XII. ASBPO respectfully requests the website not be used as a reference because it is not a static tool, evident in this instance by the use of the website ([www.tricare.osd.mil/asbpo](http://www.tricare.osd.mil/asbpo)) which is no longer current. The ASBPO Donor Deferral Criteria is not a published document and is intended for DoD use only.
3. Thank you for the opportunity to comment on this draft guidance. My point of contact for these comments is Major Antoinette Mattoch at (703) 681-8011.

*Antoinette Mattoch for*

MICHAEL C. LIBBY  
CDR, USN, MC  
Director

2005 D-0330

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**Final DoD Comments**  
**Draft Guidance for Industry and FDA Review Staff**  
**Collection of Platelets by Automated Methods**

1. Section III-A (Donor Selection) Prior to the first donation, test Platelets, Pheresis donors for levels of the following laboratory values that are acceptable under the manufacturer's directions for use:

WBC count: Cannot find the acceptable level per GAMBRO Trima guidelines

2. Section III-B2 (Donor Management-Donation Frequency). Bullet #1 "A donor should undergo no more than 24 total Platelets, Pheresis **collections** in a 12 month period" appears to repeat and be in conflict with the first sentence of Bullet #2 " You should collect no more than 24 total Platelet, Pheresis **components** in a 12 month period". Is it supposed to be **collections** or **components**? If it is components, then that is a significant change from the October 1988 "Revised Guideline for the Collection of Platelets, Pheresis" which is not listed under the changes to the prior recommendations. Changing the word to components would severely impact the platelet supply. If the concern is volume of plasma taken and donor protein status, recommend performing some sort of testing to ensure donor safety than loose potential collections. We should be able to evaluate the donor each time and grant approval if medical examination is acceptable. Twenty-four (24) total products is too low of a requirement for donors. When a post donation platelet count exceeds 150,000, donors should be able to donate.

3. Section III-B2 (Donor Management-Donation Frequency). Bullet#2 A double is defined as two collections ("double collection") and not one. A triple is defined as three collections ("triple collection") and not one. Using that definition of double collection, 24 collections would be only 12 procedures and for triple collection, 24 collections would be only 8 procedures. The definition of "collection" needs to be clarified and standardized.

4. Section III-B2 (Donor Management-Donation Frequency). Bullet#6 "A post-donation platelet count should be performed after each collection". We have not seen any data that suggests a change is required due to a patient safety risk. What data is this based on?

5. Section III-B4. Recommend adding the following statement beneath "Total volume loss per collection procedure": "To protect the donor from significant volume loss, we recommend that:" Adding this statement, which is similar to the one in Section III-B4, will make this section more complete.

6. Section VI (Process Validation)

A. This section may be very burdensome to facilities. Validation of counting devices (including flow cell), pH meters, boxes, scales, welders, etc. are not always within the control of the Blood Bank. This section requires the Blood Bank to maintain their validation requirements.

**Final DoD Comments**  
**Draft Guidance for Industry and FDA Review Staff**  
**Collection of Platelets by Automated Methods**

B. In regards to the recommendation to use a pH meter as opposed to pH paper. We get a pH in the >7 range almost 100% of the time. There's never a doubt that it's above 6.2. This is a cost/effort issue for us.

7. Section VI-B (Validation Protocol)

A. Bullet #2- Sub #1 "Total volume (**after removal of samples...**)". Section III-B4 Does not include the phrase "**after removal of samples**" but addresses the same subject.

B. Bullet #2-Sub #4 "The validation protocol should include at least the following: Residual WBC count for the collection (if leukocyte reduced) and percent recovery. " What is the percent recovery?

8. Section VI-D (Product Performance Qualification). Under qualification should include testing for the actual platelet yield, pH, volume, residual WBC count and percent component recovery (for leukocyte reduced components), RBC/hematocrit (if applicable) and bacterial contamination testing:

A. How is the percent component recovery determined?

B. Change RBC/hematocrit (if applicable) to RBC/hematocrit (if visible rbc's are present)

C. Following this validation protocol will require extensive amounts of product to be collected for just validation 60 consecutive products [single (very costly and time consuming).]

9. Section VI-Table 1. Under residual WBC count; component recovery, it states that the acceptance criteria for component retention should be greater than or equal to 85% or per the container/cell separator manufacturer's specifications. How is component recovery calculated?

10. Section VIIA1 (SOPs) and Record Keeping. **Total Volume Loss**. Should this say Total Plasma Volume Loss? See Section VIIB3-**Total Plasma Volume Loss**. They are the same item, but they do not match.

11. Section VIIC2 (Component Testing-QC Monitoring)

A. First paragraph-it states that: "Each month four units prepared from different donors must be tested at the end of the storage period for pH and platelet count..." Is this four units per machine used, or four units total?

B. Include a definition of storage period in the document. This can defer depending on the type of facility. In a hospital, it could be at expiration. In a donor center, it could be when it is shipped to another facility.

**Final DoD Comments**  
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**Collection of Platelets by Automated Methods**

C. Bullet#11 under “As part of your QC protocol should ”seems confusing and seems contradictory because it states the: “Actual platelet yield and pH may be done on one container of a double or triple collection.” Previously, it states to count both bags of a double.

12. Section VIIC2 (Component Testing-QC Monitoring-Acceptance Criteria) Under residual WBC count; it states that the acceptance criteria for component recovery should be greater than or equal to 85% or per the container/cell separator manufacturer's specifications. How is component recovery calculated?