

1. **Aspirin Deferral for 5 days**, Section III, A. (Page 5)

The draft guidance recommends increasing the deferral interval for aspirin ingestion from three days to five days.

- AABB 23rd Ed *Standards for Blood Banks and Transfusion Services* currently requires a 36 hour deferral for aspirin ingestion. *The proposed change in the draft guidance is inconsistent with this recognized standard.*

2. **Donation Frequency**, Section III, B. 2 (Page 6)

The draft guidance recommends limiting donor collections to 24 **products** per 12 months rather than the current donation frequency of 24 **donations** in 12 months.

- INBC has not experienced any problems with individuals donating 24 times within 12 months. INBC has been collecting Plateletpheresis donors with automation since 1992. (See collection statistics next page.) INBC has not experienced donor safety problems relating to chronic platelet depletion or other issues related to long term donation schedules.

INBC Apheresis Collection Statistics
1992 – 2004

# Apheresis Donor Visits per Year	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004
1	275	220	193	198	204	154	222	171	135	148	202	273	223
2	119	114	101	138	130	114	106	79	79	104	84	137	133
3	86	49	72	66	75	75	85	64	43	61	51	85	86
4	55	58	38	58	58	49	33	36	49	40	44	59	52
5	41	40	46	35	47	44	38	25	33	35	30	34	46
6	32	26	31	28	32	22	36	13	25	31	21	34	23
7	32	25	19	19	21	24	18	14	32	26	29	18	22
8	21	16	19	27	20	13	22	18	18	20	15	19	14
9	11	8	14	15	12	12	15	20	24	13	13	11	16
10	13	8	15	5	11	13	8	19	11	17	12	12	14
11	9	4	10	8	8	11	7	17	11	14	18	18	11
12	5	6	7	13	11	13	7	11	13	16	11	9	7
13	4	6	3	5	4	5	3	4	6	11	9	8	7
14	2	2	1	4	4	6	5	8	5	8	3	2	6
15	7	4	4	1	4	5	5	7	6	9	6	2	3
16	3	2	3	1	0	2	3	2	6	1	4	3	8
17	3	0	1	2	1	1	1	5	1	4	3	4	3
18	1	0	1	1	2	0	5	3	2	5	1	2	1
19	2	1	0	1	2	0	3	3	1	3	1	3	3

20	0	0	0	1	0	1	1	5		1	3	4	5
21	0	0	0	2	1	2	1	4	1	3	1	2	4
22	0	0	1	0	2	1	1	4	1	0	1	4	2
23	0	0	0	1	1	2	1	1	4	2	6	2	5
24	3	0	2	3	1	3	15	19	1	6	8	6	16
# Apheresis Donors	724	589	581	632	651	572	641	552	507	578	576	751	710
Total # Apheresis Donor Appearances	2584	1971	2201	2405	2464	2419	2750	3047	2469	2930	2699	2986	3279

- Donor screening is performed at each donation for each donor to protect the safety of the donor during the collection process. The donor is deferred if donor safety criteria are not met at each step.
 - Donors must complete medical history screening with a trained historian who is following instructions from the INBC Medical Director. Medical history screening includes specific questions about the donor’s current health and past medical history information. Information is evaluated and found to be acceptable before the donor may proceed through the collection process. Unacceptable history conditions place the donor in deferral status.
 - Donors must complete a physical screening which includes measurements for pulse, temperature, platelet count, white blood cell count and hemoglobin. Any unacceptable value will disqualify the donor.
 - Donors must meet apheresis criteria which includes vein evaluation, height, weight and total blood volume calculations. The donor must meet preset criteria designed to protect donor safety. If criteria are not met, the donor is not approved for the apheresis program.
 - Donors are provided a contact telephone number to contact INBC in the event he/she becomes ill after donation and the number is active 24 hours a day. All donor calls/contacts are followed up and the donor’s continued suitability to donate is determined. In the event an individual is found to not tolerate donation well, he/she is placed in deferral.

- The additional limitation to 24 products per year per donor would significantly and adversely affect the ability of blood centers to maintain adequate inventory of apheresis platelets. In the event Plateletpheresis products are not available, the transfusion service may be required to substitute 6-10 Platelets (prepared from

Whole Blood) for each Plateletpheresis product ordered for the patient. This substitution significantly increases the patient's exposure to more blood donors and increases the possibility of adverse patient outcomes.

The additional donation restriction does not add donor safety over current practices and may adversely impact patient safety.

3. Donation Frequency, Section III, B. 2 (Page 6)

The draft guidance recommends a minimum collection schedule for donors depending upon the previously collected Plateletpheresis product.

- A donor must qualify for each Plateletpheresis procedure. If minimum criteria (described in comment #2) are not achieved, the donor is not collected.
- The proposed donation frequency schedule is not easily supported by computer systems due to the added complexity and manual systems would be a viable alternative method of compliance. Manual methods increase the possibility of error and contribute towards increased donor safety issues during collections.

Mandating minimum donor collection intervals based upon the product previously collected adds complexity to the program without providing additional donor safety measures over current practices.

4. Total Volume Loss Per Donation, Section III, B. 4 (Page 7)

The draft guidance recommends reducing the total volume loss per donor.

- INBC uses Gambro instrumentation to collect Plateletpheresis donors following the approved volume collection requirements. Gambro apheresis instruments are 510K cleared and volume limits were part of the vendor's submission requirements and subsequent approvals. The proposed changes in the total volume loss per donation outlined in the draft guidance are more restrictive than vendor data which was previously reviewed and approved by FDA.
- Apheresis donors are carefully screened (criteria listed in comment #2) and any donor not meeting these requirements is not eligible to donate. Additionally, the total volume collected from each donor is carefully monitored. Donors reaching the current maximum limitation are temporarily deferred. INBC donor reaction data does not support the conclusion that current volume loss limits do not protect donor safety:
- This additional total volume restriction would prevent the collection of concurrent plasma in a significant number of single platelet collections and most double collections; yet these donors have shown a consistent ability to donate these products without adverse effects due to volume loss. The 23rd Ed. AABB

Standards for Blood Banks and Transfusion Services, Standard #5.6.6.1.3 requires a maximum volume deficit of 10.5 mL/kg. This Standard effectively protects the donor's safety during collections.

The proposed volume loss per donation in the draft guidance reduces the volume deficit without adding donor safety.

5. Medical Director Coverage, Section III, D (Page 7)

The draft guidance recommends requiring the Medical Director to be on site during Plateletpheresis collections.

- Currently the Medical Director must be available within 15 minutes and is within contact by cell phone 24 hours a day. INBC staff are trained to identify and care for all levels of donor reactions. Each Collection staff member is certified in CPR and an Automatic External Defibrillator (AED) is readily available. Staff are trained to implement emergency measures in urgent situations in conjunction with SOP instructions and/or Medical Director verbal instructions. An on-site Medical Director is not required to implement these measures. INBC emergency measures have been shown to be effective in managing severe donor reactions during Plateletpheresis collections.
- In the event of a severe adverse donor reaction, 911 is called for on-site donor care. Each of INBC's collection sites are within five minutes of a 911 response from health care professionals trained in responding to a health emergency. Medical Directors in blood centers are not routinely trained in emergency medicine; therefore, the use of 911 is most appropriate. The use of 911 is a universally recognized practice, as evidenced by instructions from physician's offices to call 911 if there is a health emergency.
- The only emergency equipment available at INBC collection sites is an AED. Use of this instrument is described in SOP and staff are trained to use the instrument without a Medical Director on site. Transport of the donor by a 911 response to an equipped emergency room is most appropriate for those rare severe donor reaction events.
- INBC has managed seven severe donor reactions during Plateletpheresis collections since automated collections began in 1992. Two reactions required a 911 response for additional patient care. Donor care was provided by INBC staff on site and in conjunction with the Medical Director. The presence or absence of the Medical Director on site did not change the care provided to the donor. In one instance the Medical Director was off-site and in contact with the collection staff via cell phone. In the other instance, the Medical Director was on-site; however, additional care was not specifically provided by the doctor.

The additional requirement for the Medical Director to be on site during collections does not provide additional donor safety from current practices.

6. WBC Level Per Product, Section VI, D, Table 1 (Page 12)

The draft guidance recommends applying current leukoreduction values to the collected apheresis product prior to dividing or further processing.

- The level of leukoreduction of $< 5.0 \times 10^6$ is currently established as a maximum value for WBCs in blood products labeled as leukoreduced for transfusion after all processing (dividing, etc) has been completed. The draft guidance extends the current leukoreduction value to apply to the collected product before any further processing (dividing) is performed.
 - In the event the collected product is not further divided prior to distribution, the current leukoreduction value applies, even with the proposed change.
 - In the event the collected product is divided, the divided products would contain WBC counts lower than the current established standards. This additional reduction of WBCs has not been shown to be significant for reducing adverse patient outcome.

This additional reduction of WBCs by extending the leukoreduction criteria to the collected product would not provide additional patient safety over current practices.

7. Actual Platelet Yield, Section VII, A. 2. (Page 15)

The draft guidance recommends providing the platelet count of each product to the transfusion facility.

- INBC operates a centralized compatibility testing laboratory and supports seven area hospitals. Product data is routinely available upon request; however, requests for this type of information are very unusual and only requested by the clinician in unusual cases. Patient treatments, plans and therapies are not based upon the availability of this information.
- The physicians and hospital staff have neither requested this information on the product label nor do they know who to interpret or use this information.
- Providing this information for each product would impact product labeling. Additional labeling requirements add additional chance for error. This information would be a manually supported process and would increase the chance of labeling errors.

- This additional labeling requirement is not consistent with ISBT Code 128 standards.

The proposal to provide product platelet counts to the transfusion facility does not add patient safety over current practices.

8. QC Monitoring, Section VII. C. 2. (Page 19)

The draft guidance recommends selecting products for quality control measurements that are not prepared from the same donor.

- This recommendation would apply to products that have been individually processed into Plateletpheresis products once minimum product criteria are met. At the point of QC testing, a donor's identity is long removed from the process and the products are evaluated individually. The current QC testing process requires all divided products from each QC product to be tested. The draft guidance merely modifies this requirement without removing the restriction completely.
- INBC performs QC testing on approximately 70 apheresis platelet products per month under the current system in which we must test all divided products from each collection. Product failures during QC testing occur with approximately 3 products per year. The failures have not been shown to be donor dependent. The need for a requirement concerning the donor source of products selected for QC testing is not supported by INBC QC data.

This proposal for product selection during QC testing continues the requirement for a complex QC process without adding donor or patient safety.

9. Scan statistics, Appendix A (Page 30)

The draft guidance recommends using "total collections" as the baseline to determine sampling size.

- The *Total Collections* value is not clear. The value could be the total number of donors collected during the year, or the total number of products collected in the year. *Clarification of this value is needed.*
- Scan statistics are very complex and the additional value of this approach has not been clearly established over current practices.

10. The proposed changes in the draft guidance are complex and extensive. INBC is requesting FDA extend the comment period currently set to expire on January 03, 2006. An extension would provide additional time to prepare patient and donor safety data for review by FDA.

11. INBC is also requesting FDA conduct a public hearing or workshop on this topic. The recent public workshop on recovered plasma standards was a very effective method to present pertinent data and discuss the topic by knowledgeable individuals. The topic of Plateletpheresis would be very well suited as a hearing or workshop topic.

Thank you for providing this opportunity to express our concerns and issues with draft guidance.