

1. **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The draft guidance recommends limiting donor collections to 24 **products** per 12 months rather than the current donation frequency of 24 **donations** in 12 months.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. INBC has collected 8061 donors in 34,204 collections since 1992. INBC has not experienced donor safety problems relating to chronic platelet depletion or other issues related to long term donation schedules.
- 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.

2. 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 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.

3. 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.
4. 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.