



Food and Drug Administration  
1401 Rockville Pike  
Rockville MD 20852-1448

**Date:** December 4, 1995

**From:** Director, Center for Biologics Evaluation and Research

**Subject:** Donor Deferral Due to Red Blood Cell Loss During Collection of Source Plasma by Automated Plasmapheresis

**To:** All Registered Blood and Source Plasma Establishments

**INTRODUCTION**

This memorandum addresses the temporary deferral of Source Plasma donors who have lost red blood cells due to technical difficulties during an automated plasmapheresis procedure. Any person who has donated one unit or more of whole blood (450 mL) or who has lost the equivalent amount of red blood cells should not serve as a donor of Source Plasma for eight weeks [21 CFR 640.63(e)]. The issue of red blood cell loss during automated plasmapheresis was presented by the Food and Drug Administration (FDA) to the Blood Products Advisory Committee in a public meeting on June 21, 1994. The majority of the Committee members agreed that the volume, as stated below, of red blood cell loss during automated plasmapheresis procedures for the collection of Source Plasma would not compromise donor safety.

**POLICY**

FDA provides the following guidance on deferral of donors who have lost red blood cells during automated plasmapheresis for the collection of Source Plasma and believes that safeguards to protect Source Plasma donors will not be compromised by this guidance.

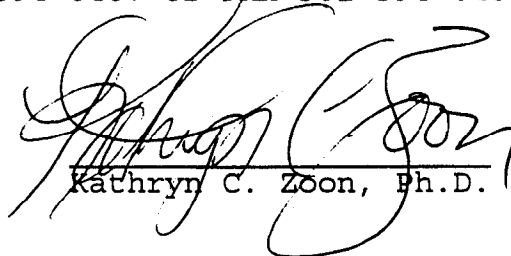
Prior to the collection of Source Plasma from each donor, records should be reviewed to determine if any red cell loss has occurred during the past eight weeks.

1. If a red blood cell loss occurred during an automated plasmapheresis procedure, the volume of loss recorded should be the total extracorporeal red blood cell volume calculated as described by the manufacturer of the apheresis equipment. No attempt should be made to open the system in order to measure the red blood cell loss, because to do so would lead to an unnecessary exposure to biohazardous agents.

2. If a donor loses more than 200 mL of red blood cells during a plasmapheresis procedure, as calculated above, the donor should be deferred for eight weeks. However, it would not be necessary to defer a donor for any single incident as long as the red blood cell loss does not exceed 200 mL.
3. During the eight week period following the first observable red blood cell loss of less than 200 mL, a second observable red blood cell loss (exceeding any residual red blood cells remaining in the tubing) should result in an eight week deferral from the date of the most recent red blood cell loss.

The recommendations in this memorandum may be implemented immediately without prior approval from FDA. Licensed Source Plasma establishments should submit by official correspondence a statement to their product license file indicating the date that the revised standard operating procedures (SOPs) consistent with these recommendations have been established and implemented. Receipt of this statement will be acknowledged. It is not necessary to submit revised SOPs to CBER for review and approval. If an establishment believes that an alternative approach would provide equivalent protection, the establishment is invited to discuss the approach with FDA for FDA's evaluation.

Please refer technical questions to the Division of Blood Applications, Office of Blood Research and Review, Center for Biologics Evaluation and Research, FDA, HFM-375, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-594-6487 or FAX 301-594-6431.



Kathryn C. Zoon, Ph.D.