**Section 490.780 Hemapheresis, Also Known as Plasmapheresis**

a) Hemapheresis procedures for which the donor is paid, shall be performed only when a physician is physically present and repsonsible for all phases of hemapheresis. All other hemapheresis procedures shall be performed only when emergency medical care is available within 15 minutes. The medical director shall develop a written protocol specifying how emergency medical care will be available if an emergency should arise.

b) Criteria of selection and care of the donors shall be those for whole blood donations. (See Section 490.720 of this Part). Hemapheresis of donors who do not meet the donor requirements shall be performed only when a physician who is aware of the health status of the donor has certified in writing that the donor's health permits hemapheresis.

c) The consent of a prospective donor or parent or legal guardian shall be obtained after a physician or other medical director's designee explains the hazards of the procedure to the prospective donor in such a manner that he is offered an opportunity to refuse consent.

d) Donor suitability, hemapheresis procedures, donor immunization, and laboratory testing shall meet the requirement specified by FDA (21 CFR 640)(1987).

e) Therapeutic hemapheresis

1) The medical director of the blood bank, in consultation with the patient's physician, shall decide if the procedure is to be performed, the appropriate location, replacement fluids to be used, and the need for special life-support procedures.

2) There shall be a written procedure manual which describes the procedures used, as outlined in 21 CFR 640 (1987). Records shall contain patient identification, date and time when the procedure is performed, diagnosis, therapeutic procedure, hemapheresis method, amount of blood removed and returned, replacement fluids used, adverse reactions, and any medication administered.