**Section 490.760 Blood Storage**

a) Refrigerators and Freezers

1) The refrigerator compartment in which blood is stored shall contain only blood, blood components donor samples, or blood bank reagents. It shall be provided with a fan for circulating air.

2) Refrigerators and freezer for storage shall have a system to monitor temperature continuously and to record the temperature at least every 4 hours.

3) Whole Blood or non-frozen Red Blood Cell components shall be stored in a refrigerator with the sensor for the temperature recording system in a container holding no more than 250 ml of liquid with heat transfer characteristics similar to those of the blood and blood container (i.e. 10% glycerol in water).

4) Alarm systems with audible signals shall be on all refrigerators and freezers. The alarm systems shall be set to activate when the temperature falls outside the acceptable 1 to 6 degrees Centigrade range.

5) Written procedures shall delineate actions to be taken when a refrigeration system fails to maintain blood or blood components within the specified temperature range (See Section 490.40(c)(7) of this Part).

b) Temperatures – containers – expiration dates

 Expiration date is the last day on which the blood or blood component is considered useful for transfusion purposes. Whole blood, red blood cells, frozen red blood cells, washed and deglycerolized red blood cells, leukocyte poor red blood cells, single donor plasma, platelet concentrate, and any other blood component shall be stored within temperature ranges, in containers, and used before expiration dates as specified by Food and Drug Administration (FDA) (21 CFR 640)(1987).

c) Reissue of blood

1) Blood which has been returned to the blood bank shall not be reissued unless the following conditions have been met.

A) The container closure has not been disturbed.

B) The blood has been continuously refrigerated at 1 to 10 degree Centigrade (preferable 1 to 6 degrees Centigrade).

C) Blood bank records indicate that the blood has been reissued.

D) The pilot tube or segment has remained attached to the container if the blood has left the premises of the issuing facility.

2) If the blood has remained on the premises of the issuing facility, a removed pilot tube may be reidentified by the originally attached label and number which shall correspond with the number on the container.