The risks of therapeutic procedures must be explained by a knowledgeable, responsible person according to approved policies and procedures. The patient must have the opportunity to ask questions, and should sign a document indicating agreement.

LB.58 The blood bank and transfusion services use appropriate blood and blood components storage devices.

LB.58.1 The blood and blood components storage devices are:

LB.58.1.1 Designed for the intended use.

LB.58.1.2 Equipped with continuous temperature monitoring system (temperature recording).

LB.58.1.3 Equipped with audio/visual alarm systems.

LB.58.2 The device's alarm and monitoring system conforms with the following:

LB.58.2.1 Activates at a temperature that allows for intervention before the contents reaches unacceptable temperature.

LB.58.2.2 Activates at an area staffed 24 hours a day, seven days a week.

LB.58.2.3 Connected to a separate or DC power supply.

LB.58.3 The alarm system is checked weekly.

LB.58.4 Alarm activation temperatures are checked quarterly.

LB.58.5 The inner temperature of blood storage devices is monitored and recorded at least once a day using a standardized thermometric device.

LB.58.6 In the event of failure of continuous temperature monitoring, temperature recording, or alarm systems, the inner temperature is monitored and recorded every four hours.

Standard Intent:

The storage capacity should be large enough to accommodate the optimal inventory of blood and blood components with a margin for expansion, emergencies and other storage device failures**.** Refrigerators, freezers, and platelet incubators for blood component storage are available with continuous temperature monitoring devices that would be able to detect a temperature deviation before blood components might be affected. Automated electronic monitoring devices that are available include:

1. Weekly pen and chart recorder
2. Wireless temperature recording devices
3. Connection to centralized temperature monitoring system.

The blood storage devices must be equipped with audible alarms to alert personnel that temperature ranges are approaching unacceptable levels. Central alarm monitoring

allows facilities that do not have personnel in the vicinity of the equipment to alert the designated staff at another location. Alarm systems must continue to function during a power failure. This may be accomplished by having the alarm on a separate circuit, installing battery power back-up, or having a power failure alarm.

LB.59 The blood bank and transfusion services develop policies and procedures to ensure that the thawed Fresh Frozen Plasma (FFP) units are handled in an appropriate manner.

LB.59.1 Thawed FFP units are prepared by thawing the FFP between 30 and 37°C without direct contact with the water.

LB.59.2 Thawed FFP units are stored under properly controlled conditions between 1 and 6°C.

LB.59.3 Thawed FFP units are transported in properly insulated container between 1 and 10°C.

LB.59.4 Thawed FFP units are assigned an expiration time of twenty-four hours from the thawing time.

LB.59.5 Requirements for FFP preparation, storage, transport and expiration apply.

Standard Intent:

If FFP are thawed in a water bath, an overwrap bag or other similar protection must be used to prevent water from coming in contact with outlet ports and possibly introducing bacterial contamination. FFP, once thawed, has a shelf life of 24 hours. However, at the end of that interval, the plasma can be relabeled as Thawed Plasma, which can be stored for an additional 4 days at 1 to 6°C. Thawed Plasma prepared from FFP and stored for 5 days contains reduced levels of Factor V (>60%) and Factor VIII (>40%).

LB.60 The blood bank and transfusion services develop policies and procedures to ensure that the thawed CRYO units are handled in an appropriate manner.

LB.60.1 Thawed CRYO units are prepared by thawing CRYO units between 30 and 37°C without direct contact with the water.

LB.60.2 Thawed CRYO units are stored and transported at room temperature (between 20 and 24°C).

LB.60.3 Thawed CRYO units are assigned an expiration time of six hours from the thawing time for individual units and four hours from the thawing time of pooled units.

LB.60.4 Requirements for CRYO preparation, storage, transport and expiration apply.

Standard Intent:

If CRYO are thawed in a water bath, an overwrap bag or other similar protection must be used to prevent water from coming in contact with outlet ports and possibly introducing bacterial contamination. Once thawed, CRYO has a shelf life of 6 hours from thawing and only 4 hours from pooling. Thawed CRYO is stored at room temperature (20-24°C), during which the mean rates of decline of Factor VIII levels at 2, 4, and 6 hours are approximately 10%, 20%, and 30%, respectively.