LB.56 The transfusion services establish a process for the release of incompletely tested blood/blood components.

LB.56.1 There are implemented policies, processes and procedures to ensure that incompletely tested blood/blood components can be released under the following circumstances:

LB.56.1.1 For urgent need only.

LB.56.1.2 Upon the discretion of the medical director of the transfusion medicine, the agreement of the attending physician and the consent of the patient or next of kin, when applicable.

LB.56.1.3 Approved only for a particular patient and one transfusion event.

LB.56.1.4 The released blood products are conspicuously labeled to this effect.

LB.56.2 Testing of the blood/blood components must be completed and reported promptly to the attending physician.

LB.56.3 Deviations and exceptions standard in this chapter applies.

Standard Intent:

Some blood components require emergency release because of high demand or very short storage time such is the case for platelet concentrates. Emergency release of untested or incompletely tested blood require blood bank medical director and treating physician approval and a label or tie tag to indicate that testing was incomplete at the time of release.

LB.57 The blood bank has a process for request, approval, and execution of therapeutic procedures.

LB.57.1 The process ensures all therapeutic procedures are ordered and justified by an authorized physician.

LB.57.2 The process ensures the blood bank medical director or designee is responsible for reviewing therapeutic procedures orders for appropriateness and evaluating patient clinical and laboratory data before approving the procedure.

LB.57.3 The process ensures therapeutic procedures are explained to the patient and consented.

LB.57.4 The process ensures that blood/ blood components discarded immediately after collection.

Standard Intent:

The transfusion service's medical director must approve all therapeutic procedures and accept medical responsibility for the patient undergoing this procedure. This involvement is in addition to responsibility for overall management of the therapeutic procedures' program, establishment of eligibility criteria for therapeutic procedures, provision of medical support for reactions, and oversight of quality assurance measures.

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