D5555
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§493.1271 Standard: Immunohematology

(c) Blood and blood products storage. Blood and blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected.

Interpretive Guidelines §493.1271(c)

Blood shall be stored in a clean and orderly environment in a manner to prevent mix-ups. No expired blood should be in the routine inventory. Unacceptable units should be segregated from routine inventory.

(c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period.

(c)(2) Inspections of the alarm system must be documented.

Interpretive Guidelines §493.1271(c)

Acceptable temperature ranges must be established and actual readings of temperature-controlled storage areas must be recorded during the time that blood or blood products for transfusion are stored. Whole Blood, Red Blood Cells, and Liquid Plasma should be stored between 1 and 6º C; room temperature Platelets and Platelet Rich Plasma between 20 and 24º C or 1 and 6º C as indicated on the product label. Fresh Frozen Plasma, Plasma, and Cryoprecipitated AHF should be stored at -18º C or colder. Temperatures continuously monitored by a recording thermograph or central monitoring system are acceptable. The charts or central monitoring system must be retained to document that temperatures are maintained within acceptable limits as stated on the blood component label.

Verify that the laboratory regularly inspects the alarm system(s) according to its established policy. When the facility performs alarm checks, the temperature at which the alarm sounds should be compared to the temperature on the recording chart. Verify that the alarm activates at the appropriate temperature(s).

Reissue requirements are as follows: The container must have a tamper-proof seal which remains unbroken; records should indicate that the blood was maintained at 1 - 10º C while outside the control of the establishment; and the unit must be inspected prior to reissue. The laboratory must have a process for ensuring that blood components are maintained within acceptable limits while out of control of the laboratory.

Probes §493.1271(c)

Does the laboratory ensure that the freezer(s) used to store blood products is maintained at the recommended temperature(s) on a continuous basis?

Does the laboratory document and explain unacceptable storage temperatures? Use D5793.

What are the laboratory's criteria for determining blood or blood product suitability for reissue? Are they following their policy?

How are untested autologous units, potentially infectious units and reagents stored and

segregated to prevent contamination?

If the laboratory does not have an emergency power source for the blood storage equipment and temperature alarm system, how does the laboratory ensure that blood is maintained at the appropriate temperature when a power failure occurs?

If the laboratory is not staffed 24 hours a day, seven days a week, how does it ensure prompt response to an activated alarm (evenings, weekends, and holidays)?