

§493.1103 Standard: Requirements for transfusion services

(c) Blood and blood products storage and distribution. (1) If a facility stores or maintains blood or blood products for transfusion outside of a monitored refrigerator, the facility must ensure the storage conditions, including temperature, are appropriate to prevent deterioration of the blood or blood product.

Interpretive Guidelines §493.1103(c)(1)

Determine where blood and blood products are stored. There may be various unconventional blood storage areas such as operating rooms, nursing stations, long-term care facilities, and dialysis units. Determine that the facility ensures the appropriate temperature is maintained and documented for each storage area during the time blood and blood products are stored.

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 Thawed Plasma should be stored between 1 and 6°C; Platelets and Thawed Cryoprecipitated AHF should be stored between 20 and 24°C; Fresh Frozen Plasma, Plasma Frozen within 24 hours after Phlebotomy, and Cryoprecipitated AHF should be stored at -18°C or colder.

Facilities that provide transfusion services (not certified for the specialty of Immunohematology) and perform nonwaived testing are held to the requirements for the storage and distribution of blood and blood products. The laboratory providing the blood or blood products may supply these facilities with the following:

- Policies for the proper storage and transportation of blood or blood products;
- Procedures to alert the laboratory of blood storage problems;

- Policies to ensure the positive identification of a blood or blood product recipient (use D3023);
- Procedures to identify a possible transfusion reaction (use D3025); and
- Procedures to notify the laboratory of a possible transfusion reaction (use D3025).

Determine how the appropriate temperatures of blood storage areas are maintained during a power failure.

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.

Probes §493.1103(c)(1)

If frozen blood products are stored, how does the facility ensure products are maintained at appropriate temperatures to prevent thawing and re-freezing of the products?