§ 606.100 Standard operating procedures.

(a) In all instances, except clinical investigations, standard operating procedures shall comply with published additional standards in part 640 of this chapter for the products being processed; except that, references in part 640 relating to licenses, licensed establishments and submission of material or data to or approval by the Director, Center for Biologies Evaluation and Research, are not applicable to establishments not subject to licensure under section 351 of the Public Health Service Act.

(b) Written standard operating procedures shall be maintained and shall include all steps to be followed in the collection, processing, compatibility testing, storage and distribution of blood and blood components for transfusion and further manufacturing purposes. Such procedures shall be available to the personnel for use in the areas where the procedures are performed. The written standard operating procedures shall include, but are not limited to, descriptions of the following, when applicable:

1. Criteria used to determine donor suitability, including acceptable medical history criteria.

2. Methods of performing donor qualifying tests and measurements, including minimum and maximum values for a test or procedure when a factor in determining acceptability.

3. Solutions and methods used to prepare the site of phlebotomy to give maximum assurance of a sterile container of blood.

4. Method of accurately relating the product(s) to the donor.

5. Blood collection procedure, including in-process precautions taken to measure accurately the quantity of blood removed from the donor.

6. Methods of component preparation, including any time restrictions for specific steps in processing.

7. All tests and repeat tests performed on blood and blood components during manufacturing.

8. Pretransfusion testing, where applicable, including precautions to be taken to identify accurately the recipient blood samples and crossmatched donor units.


10. Storage temperatures and methods of controlling storage temperatures for all blood products and reagents as prescribed in §§600.15 and 610.53 of this chapter.

11. Length of expiration dates, if any, assigned for all final products as prescribed in §610.53 of this chapter.

12. Criteria for determining whether returned blood is suitable for reissue.

13. Procedures used for relating a unit of blood or blood component from the donor to its final disposition.

14. Quality control procedures for supplies and reagents employed in blood collection, processing and pretransfusion testing.

15. Schedules and procedures for equipment maintenance and calibration.

16. Labeling procedures, including safeguards to avoid labeling mixups.

17. Procedures of plasmapheresis, plateletpheresis, and leukapheresis, if performed, including precautions to be taken to ensure reinfusion of a donor’s own cells.

18. Procedures for preparing recovered plasma, if performed, including details of separation, pooling, labeling, storage, and distribution.

19. Procedures under §§610.46, 610.47, and 610.48 of this chapter:

(i) To identify previously donated blood and blood components from a donor who later tests reactive for evidence of human immunodeficiency virus (HIV) infection or hepatitis C virus (HCV) infection when tested under §610.40 of this chapter, or when a blood establishment is made aware of other reliable test results or information indicating evidence of HIV or HCV infection;
(ii) To quarantine in-date blood and blood components previously donated by such a donor that are intended for use in another person or further manufacture into injectable products, except pooled components intended solely for further manufacturing into products that are manufactured using validated viral clearance procedures;

(iii) To notify consignees to quarantine in-date blood and blood components previously donated by such a donor intended for use in another person or for further manufacture into injectable products, except pooled components intended solely for further manufacturing into products that are manufactured using validated viral clearance procedures;

(iv) To determine the suitability for release, destruction, or relabeling of quarantined in-date blood and blood components;

(v) To notify consignees of the results of the HIV or HCV testing performed on the donors of such blood and blood components;

(vi) To notify the transfusion recipient, the recipient’s physician, or the recipient’s legal representative that the recipient received blood or blood components at increased risk of transmitting HIV or HCV, respectively.

(20) Procedures for donor deferral as prescribed in §610.41 of this chapter; and procedures for donor notification and autologous donor referring physician notification, including procedures for the appropriate followup if the initial attempt at notification fails, as prescribed in §630.6 of this chapter.

Subpart G—Finished Product Control

§ 606.120 Labeling, general requirements.

(a) Labeling operations shall be separated physically or spatially from other operations in a manner adequate to prevent mixups.

(b) The labeling operation shall include the following labeling controls: