

(5) Instructions to store at room temperature after thawing and to begin administration as soon as possible but no more than 4 hours after entering the container or after pooling and within 6 hours after thawing.

(6) A statement that 0.9 percent Sodium Chloride Injection U.S.P. is the preferred diluent.

(7) Adequate instructions for pooling to ensure complete removal of all concentrated material from each container.

(8) The statement: “Good patient management requires monitoring treatment responses to Cryoprecipitated AHF transfusions with periodic plasma factor VIII or fibrinogen assays in hemophilia A and hypofibrinogenemic recipients, respectively.”

[50 FR 35470, Aug. 30, 1985, as amended at 53 FR 116, Jan. 5, 1988]

EFFECTIVE DATE NOTE: The information collection requirements contained in § 606.122 will not become effective until OMB approval has been obtained. FDA will publish a notice of OMB approval in the FEDERAL REGISTER.

### Subpart H—Laboratory Controls

#### § 606.140 Laboratory controls.

Laboratory control procedures shall include:

(a) The establishment of scientifically sound and appropriate specifications, standards and test procedures to assure that blood and blood components are safe, pure, potent and effective.

(b) Adequate provisions for monitoring the reliability, accuracy, precision and performance of laboratory test procedures and instruments.

(c) Adequate identification and handling of all test samples so that they are accurately related to the specific unit of product being tested, or to its donor, or to the specific recipient, where applicable.

#### § 606.151 Compatibility testing.

Standard operating procedures for compatibility testing shall include the following:

(a) A method of collecting and identifying the blood samples of recipients to ensure positive identification.

(b) The use of fresh recipient serum samples less than 48 hours old for all pretransfusion testing.

(c) The testing of the donor’s cells with the recipient’s serum (major crossmatch) by a method that will demonstrate agglutinating, coating and hemolytic antibodies, which shall include the antiglobulin method.

(d) A provision that, if the unit of donor’s blood has not been screened by a method that will demonstrate agglutinating, coating and hemolytic antibodies, the recipient’s cells shall be tested with the donor’s serum (minor crossmatch) by a method that will so demonstrate.

(e) Procedures to expedite transfusions in life-threatening emergencies. Records of all such incidents shall be maintained, including complete documentation justifying the emergency action, which shall be signed by the physician requesting the procedure.

### Subpart I—Records and Reports

#### § 606.160 Records.

(a)(1) Records shall be maintained concurrently with the performance of each significant step in the collection, processing, compatibility testing, storage and distribution of each unit of blood and blood components so that all steps can be clearly traced. All records shall be legible and indelible, and shall identify the person performing the work, include dates of the various entries, show test results as well as the interpretation of the results, show the expiration date assigned to specific products, and be as detailed as necessary to provide a complete history of the work performed.

(2) Appropriate records shall be available from which to determine lot numbers of supplies and reagents used for specific lots or units of the final product.

(b) Records shall be maintained that include, but are not limited to, the following when applicable:

(1) Donor records:

(i) Donor selection, including medical interview and examination and where applicable, informed consent.

- (ii) Permanent and temporary deferrals for health reasons including reason(s) for deferral.
  - (iii) Donor adverse reaction complaints and reports, including results of all investigations and followup.
  - (iv) Therapeutic bleedings, including signed requests from attending physicians, the donor's disease and disposition of units.
  - (v) Immunization, including informed consent, identification of the antigen, dosage and route of administration.
  - (vi) Blood collection, including identification of the phlebotomist.
  - (vii) Records to relate the donor with the unit number of each previous donation from that donor.
  - (viii) Records of quarantine, notification, testing, and disposition performed pursuant to §§ 610.46 and 610.47 of this chapter.
- (2) Processing records:
- (i) Blood processing, including results and interpretation of all tests and retests.
  - (ii) Component preparation, including all relevant dates and times.
  - (iii) Separation and pooling of recovered plasma.
  - (iv) Centrifugation and pooling of source plasma.
  - (v) Labeling, including initials of person(s) responsible.
- (3) Storage and distribution records:
- (i) Distribution and disposition, as appropriate, of blood and blood products.
  - (ii) Visual inspection of whole blood and red blood cells during storage and immediately before distribution.
  - (iii) Storage temperature, including initialed temperature recorder charts.
  - (iv) Reissue, including records of proper temperature maintenance.
  - (v) Emergency release of blood, including signature of requesting physician obtained before or after release.
- (4) Compatibility test records:
- (i) Results of all compatibility tests, including crossmatching, testing of patient samples, antibody screening and identification.
    - (ii) Results of confirmatory testing.
- (5) Quality control records:
- (i) Calibration and standardization of equipment.
  - (ii) Performance checks of equipment and reagents.
  - (iii) Periodic check on sterile technique.
  - (iv) Periodic tests of capacity of shipping containers to maintain proper temperature in transit.
  - (v) Proficiency test results.
  - (6) Transfusion reaction reports and complaints, including records of investigations and followup.
  - (7) General records:
    - (i) Sterilization of supplies and reagents prepared within the facility, including date, time interval, temperature and mode.
    - (ii) Responsible personnel.
    - (iii) Errors and accidents.
    - (iv) Maintenance records for equipment and general physical plant.
    - (v) Supplies and reagents, including name of manufacturer or supplier, lot numbers, expiration date and date of receipt.
    - (vi) Disposition of rejected supplies and reagents used in the collection, processing and compatibility testing of blood and blood components.
  - (c) A donor number shall be assigned to each accepted donor, which relates the unit of blood collected to that donor, to his medical record, to any component or blood product from that donor's unit of blood, and to all records describing the history and ultimate disposition of these products.
  - (d) Records shall be retained for such interval beyond the expiration date for the blood or blood component as necessary to facilitate the reporting of any unfavorable clinical reactions. The retention period shall be no less than 5 years after the records of processing have been completed or 6 months after the latest expiration date for the individual product, whichever is a later date. When there is no expiration date, records shall be retained indefinitely.
  - (e) A record shall be available from which unsuitable donors may be identified so that products from such individuals will not be distributed.
- [40 FR 53532, Nov. 18, 1975, as amended at 61 FR 47422, Sept. 9, 1996]

**§ 606.165 Distribution and receipt; procedures and records.**

- (a) Distribution and receipt procedures shall include a system by which the distribution or receipt of each unit