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action, which shall be signed by a physician.

[40 FR 53532, Nov. 18, 1975, as amended at 64 FR 45371, Aug. 19, 1999; 66 FR 1835, Jan. 10, 2001; 66 FR 40889, Aug. 6, 2001]

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 concerning the following activities performed under §§ 610.46 and 610.47 of this chapter: Quarantine; consignee notification; testing;

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notification of a transfusion recipient, the recipient's physician of record, or the recipient's legal representative; and disposition.

(ix) The donor's postal address provided at the time of donation where the donor may be contacted within 8 weeks after donation.

(x) Records of notification of donors deferred or determined not to be eligible for donation, including appropriate followup if the initial attempt at notification fails, performed under § 630.40 of this chapter.

(xi) Records of notification of the referring physician of a deferred autologous donor, including appropriate followup if the initial attempt at notification fails, performed under § 630.40 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 the person(s) performing the procedure.

(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.

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(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) Biological product deviations.

(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. You must retain individual product records no less than 10 years after the records of processing are completed or 6 months after the latest expiration date for the individual product, whichever is the later date. When there is no expiration date, records shall be retained indefinitely.

(e) *Records of deferred donors.* (1) Establishments must maintain at each location a record of all donors found to be ineligible or deferred at that location so that blood and blood components from an ineligible donor are not collected and/or released while the donor is ineligible or deferred; and

(2) Establishments must maintain at all locations operating under the same license or under common management a cumulative record of donors deferred from donation under §610.41 of this chapter because their donation tested

reactive under §610.40(a)(1) of this chapter for evidence of infection due to HIV, HBV, or HCV. In addition, establishments other than Source Plasma establishments must include in this cumulative record donors deferred from donation under §610.41 of this chapter because their donation tested reactive under §610.40(a)(2) of this chapter for evidence of infection due to HTLV or Chagas disease.

(3) The cumulative record described in paragraph (e)(2) of this section must be updated at least monthly to add donors newly deferred under §610.41 of this chapter due to reactive tests for evidence of infection due to HIV, HBV, or HCV, and, if applicable, HTLV or Chagas disease.

(4) Establishments must revise the cumulative record described in paragraph (e)(2) of this section to remove donors who have been requalified under §610.41(b) of this chapter.

[40 FR 53532, Nov. 18, 1975, as amended at 61 FR 47422, Sept. 9, 1996; 64 FR 45371, Aug. 19, 1999; 65 FR 66635, Nov. 7, 2000; 66 FR 31176, June 11, 2001; 72 FR 48798, Aug. 24, 2007; 80 FR 80651, Dec. 28, 2015; 80 FR 29895, May 22, 2015]

§ 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 can be readily determined to facilitate its recall, if necessary.

(b) Distribution records shall contain information to readily facilitate the identification of the name and address of the consignee, the date and quantity delivered, the lot number of the unit(s), the date of expiration or the date of collection, whichever is applicable, or for crossmatched blood and blood components, the name of the recipient.

(c) Receipt records shall contain the name and address of the collecting facility, date received, donor or lot number assigned by the collecting facility and the date of expiration or the date of collection, whichever is applicable.

§ 606.170 Adverse reaction file.

(a) Records shall be maintained of any reports of complaints of adverse reactions regarding each unit of blood or blood product arising as a result of