

§ 1270.21

21 CFR Ch. I (4-1-08 Edition)

(p) *Processing* means any activity performed on tissue, other than tissue recovery, including preparation, preservation for storage, and/or removal from storage to assure the quality and/or sterility of human tissue. Processing includes steps to inactivate and remove adventitious agents.

(q) *Quarantine* means the identification of human tissue as not suitable for transplantation, including human tissue that has not yet been characterized as being suitable for transplantation. Quarantine includes the storage of such tissue in an area clearly identified for such use, or other procedures, such as automated designation, for prevention of release of such tissue for transplantation.

(r) *Reconstituted blood* means the extracorporeal resuspension of a blood unit labeled as "Red Blood Cells" by the addition of colloids and/or crystalloids to produce a hematocrit in the normal range.

(s) *Recovery* means the obtaining from a donor of tissue that is intended for use in human transplantation.

(t) *Relevant medical records* means a collection of documents including a donor medical history interview, a physical assessment of the donor, laboratory test results, medical records, existing coroner and autopsy reports, or information obtained from any source or records which may pertain to donor suitability regarding high risk behaviors, clinical signs and symptoms for HIV and hepatitis, and treatments related to medical conditions suggestive of such risk.

(u) *Responsible person* means a person who is authorized to perform designated functions for which he or she is trained and qualified.

(v) *Storage* means holding tissue.

(w) *Summary of records* means a condensed version of the required testing and screening records that contains the identity of the testing laboratory, the listing and interpretation of all required infectious disease tests, and a listing of the documents reviewed as part of the relevant medical records, and the name of the person or establishment determining the suitability of the human tissue for transplantation.

(x) *Vascularized* means containing the original blood vessels which are in-

tended to carry blood after transplantation.

[62 FR 40444, July 29, 1997, as amended at 69 FR 68680, Nov. 24, 2004]

Subpart B—Donor Screening and Testing

§ 1270.21 Determination of donor suitability for human tissue intended for transplantation.

(a) Donor specimens shall be tested for the following communicable viruses, using Food and Drug Administration (FDA) licensed donor screening tests in accordance with manufacturers' instructions:

(1) Human immunodeficiency virus, Type 1 (e.g., FDA licensed screening test for anti-HIV-1);

(2) Human immunodeficiency virus, Type 2 (e.g., FDA licensed screening test for anti-HIV-2);

(3) Hepatitis B (e.g., FDA licensed screening test for HBsAg); and

(4) Hepatitis C (e.g., FDA licensed screening test for anti-HCV).

(b) In the case of a neonate, the mother's specimen is acceptable for testing.

(c) Such infectious disease testing shall be performed by a laboratory certified under the Clinical Laboratories Improvement Amendments of 1988 (CLIA).

(d) Human tissue shall be accompanied by records indicating that the donor's specimen has been tested and found negative using FDA licensed screening tests for HIV-1, HIV-2, hepatitis B, and hepatitis C. FDA licensed screening tests labeled for cadaveric specimens must be used when available.

(e) Human tissue for transplantation shall be accompanied by a summary of records or copies of the original records of the donor's relevant medical records as defined in §1270.3(t) which documents freedom from risk factors for and clinical evidence of hepatitis B, hepatitis C, or HIV infection. There shall be a responsible person designated and identified in the original record and summary of records as having made the determination that the human tissue is suitable for transplantation.

(f) Determination by the responsible person that a donor of human tissue intended for transplantation is suitable shall include ascertainment of the donor's identity, and accurately recorded relevant medical records (as defined in §1270.3(t)) which documents freedom from risk factors for and clinical evidence of hepatitis B, hepatitis C, and HIV infection.

(g) For corneal tissue procured under legislative consent where a donor medical history screening interview has not occurred, a physical assessment of the donor is required and other available information shall be reviewed. The corneal tissue shall be accompanied by the summary of records documenting that the corneal tissue was determined to be suitable for transplantation in the absence of the donor medical history interview. Corneal tissue procured under legislative consent shall be documented as such in the summary of records.

(h) Human tissue shall be determined to be not suitable for transplantation if from:

(1) A donor whose specimen has tested repeatedly reactive on a screening test for HIV, hepatitis B, or hepatitis C;

(2) A donor where blood loss is known or suspected to have occurred and transfusion/infusion of more than 2,000 milliliters (mL) of blood (i.e., whole blood, reconstituted blood, or red blood cells), or colloids within 48 hours; or more than 2,000 mL of crystalloids within 1 hour; or any combination thereof prior to the collection of a blood specimen from the tissue donor for testing, unless:

(i) A pretransfusion or preinfusion blood specimen from the tissue donor is available for infectious disease testing; or

(ii) An algorithm is utilized that evaluates the volumes administered in the 48 hours prior to collecting the blood specimen from the tissue donor to ensure that there has not been plasma dilution sufficient to affect test results; or

(3) A donor who is 12 years of age or less and has been transfused or infused at all, unless:

(i) A pretransfusion or preinfusion blood specimen from the tissue donor is

available for infectious disease testing; or

(ii) An algorithm is utilized that evaluates the volumes administered in the 48 hours prior to collecting the blood specimen from the tissue donor to ensure that there has not been plasma dilution sufficient to affect test results.

Subpart C—Procedures and Records

§ 1270.31 Written procedures.

(a) There shall be written procedures prepared and followed for all significant steps in the infectious disease testing process under §1270.21 which shall conform to the manufacturers' instructions for use contained in the package inserts for the required tests. These procedures shall be readily available to the personnel in the area where the procedures are performed unless impractical. Any deviation from the written procedures shall be recorded and justified.

(b) There shall be written procedures prepared and followed for all significant steps for obtaining, reviewing, and assessing the relevant medical records of the donor as provided in §1270.21. Such procedures shall be readily available to personnel who may perform the procedures. Any deviation from the written procedures shall be recorded and justified.

(c) There shall be written procedures prepared and followed for designating and identifying quarantined tissue.

(d) There shall be written procedures prepared, validated, and followed for prevention of infectious disease contamination or cross-contamination by tissue during processing.

(e) In conformity with this section, any facility may use current standard written procedures such as those in a technical manual prepared by another organization, provided the procedures are consistent with and at least as stringent as the requirements of this part.

§ 1270.33 Records, general requirements.

(a) Records shall be maintained concurrently with the performance of each significant step required in this part in