

§ 1270.31

21 CFR Ch. I (4–1–07 Edition)

(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