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.

§ 1270.33 Records, general requirements.
(a) Records shall be maintained concurrently with the performance of each significant step required in this part in the performance of infectious disease screening and testing of donors of human tissue. All records shall be accurate, indelible, and legible. The records shall identify the person performing the work, the dates of the various entries, and shall be as detailed as necessary to provide a complete history of the work performed and to relate the records to the particular tissue involved.
(b) All human tissue shall be quarantined until the following criteria for donor suitability are satisfied:
  (1) All infectious disease testing under §1270.21 has been completed, reviewed by the responsible person, and found to be negative; and
  (2) Donor screening has been completed, reviewed by the responsible person, and determined to assure freedom from risk factors for and clinical evidence of HIV infection, hepatitis B, and hepatitis C.
(c) All human tissue processed or shipped prior to determination of donor suitability must be under quarantine, accompanied by records assuring identification of the donor and indicating that the tissue has not been determined to be suitable for transplantation.
(d) All human tissue determined to be suitable for transplantation must be accompanied by a summary of records, or copies of such original records, documenting that all infectious disease
testing and screening under §1270.21 has been completed, reviewed by the responsible person, and found to be negative, and that the tissue has been determined to be suitable for transplantation.

(e) Human tissue shall be quarantined until the tissue is either determined to be suitable for transplantation or appropriate disposition is accomplished.

(f) All persons or establishments that generate records used in determining the suitability of the donor shall retain such records and make them available for authorized inspection or upon request by FDA. The person(s) or establishment(s) making the determination regarding the suitability of the donor shall retain all records, or true copies of such records required under §1270.21, including all testing and screening records, and shall make them available for authorized inspection or upon request from FDA. Records that can be retrieved from another location by electronic means meet the requirements of this paragraph.

(g) Records required under this part may be retained electronically, or as original paper records, or as true copies such as photocopies, microfiche, or microfilm, in which case suitable reader and photocopying equipment shall be readily available.

(h) Records shall be retained at least 10 years beyond the date of transplantation if known, distribution, disposition, or expiration, of the tissue, whichever is latest.


§ 1270.42 Human tissue offered for import.

(a) When human tissue is offered for entry, the importer of record must notify the director of the district of the Food and Drug Administration having jurisdiction over the port of entry through which the tissue is imported or offered for import, or such officer of the district as the director may designate to act in his or her behalf in administering and enforcing this part.

(b) Human tissue offered for import must be quarantined until the human tissue is released by FDA.