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

§ 1270.33 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