

§ 1270.35

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

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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.

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§ 1270.35 Specific records.

Records shall be maintained that include, but are not limited to:

(a) Documentation of results and interpretation of all required infectious disease tests;

(b) Information on the identity and relevant medical records of the donor, as required by §1270.21(e) in English or, if in another language translated to English and accompanied by a statement of authenticity by the translator which specifically identifies the translated document;

(c) Documentation of the receipt and/or distribution of human tissue; and

(d) Documentation of the destruction or other disposition of human tissue.

Subpart D—Inspection of Tissue Establishments

§ 1270.41 Inspections.

(a) An establishment covered by these regulations in this part, including any location performing contract services, shall permit an authorized inspector of the Food and Drug Administration (FDA) to make at any reasonable time and in a reasonable manner such inspection of the establishment, its facilities, equipment, processes, products, and records as may be necessary to determine compliance with the provisions of this part. Such inspections may be made with or without

notice and will ordinarily be made during regular business hours.

(b) The frequency of inspection will be at the agency's discretion.

(c) The inspector shall call upon a responsible person of the establishment and may question the personnel of the establishment as the inspector deems necessary.

(d) The inspector may review and copy any records required to be kept pursuant to part 1270.

(e) The public disclosure of records containing the name or other positive identification of donors or recipients of human tissue will be handled in accordance with FDA's procedures on disclosure of information as set forth in 21 CFR part 20 of this chapter.

§ 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.

§ 1270.43 Retention, recall, and destruction of human tissue.

(a) Upon a finding that human tissue may be in violation of the regulations in this part, an authorized Food and Drug Administration (FDA) representative may:

(1) Serve upon the person who distributed the tissue a written order that the tissue be recalled and/or destroyed, as appropriate, and upon persons in possession of the tissue that the tissue shall be retained until it is recalled by the distributor, destroyed, or disposed of as agreed by FDA, or the safety of the tissue is confirmed; and/or

(2) Take possession of and/or destroy the violative tissue.

(b) The written order will ordinarily provide that the human tissue be recalled and/or destroyed within 5 working days from the date of receipt of the

order and will state with particularity the facts that justify the order.

(c) After receipt of an order under this part, the person in possession of the human tissue shall not distribute or dispose of the tissue in any manner except to recall and/or destroy the tissue consistent with the provisions of the order, under the supervision of an authorized official of FDA.

(d) In lieu of paragraphs (b) and (c) of this section, other arrangements for assuring the proper disposition of the tissue may be agreed upon by the person receiving the written order and an authorized official of FDA. Such arrangements may include providing FDA with records or other written information that adequately assure that the tissue has been recovered, screened, tested, processed, stored, and distributed in conformance with part 1270.

(e) Within 5 working days of receipt of a written order for retention, recall, and/or destruction of tissue (or within 5 working days of the agency's possession of such tissue), the recipient of the written order or prior possessor of such tissue shall request a hearing on the matter in accordance with part 16 of this chapter. The order for destruction will be held in abeyance pending resolution of the hearing request.

PART 1271—HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS

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