

do not comply with the requirements of a potable water system, prescribed in §1250.82, they shall be constructed so as to minimize the possibility of the water therein being contaminated. The storage tanks shall comply with the requirements of §1250.83, and the distribution system shall not be cross connected to a system carrying water of a lower sanitary quality. All faucets shall be labeled "Unfit for drinking".

§ 1250.89 Swimming pools.

(a) Fill and draw swimming pools shall not be installed or used.

(b) Swimming pools of the recirculation type shall be equipped so as to provide complete circulation, replacement, and filtration of the water in the pool every six hours or less. Suitable means of chlorination and, if necessary, other treatment of the water shall be provided to maintain the residual chlorine in the pool water at not less than 0.4 part per million and the pH (a measure of the hydrogen ion concentration) not less than 7.0.

(c) Flowing-through types of salt water pools shall be so operated that complete circulation and replacement of the water in the pool will be effected every 6 hours or less. The water delivery pipe to the pool shall be independent of all other pipes and shall originate at a point where maximum flushing of the pump and pipe line is effected after leaving polluted waters.

§ 1250.90 Toilets and lavatories.

Toilet and lavatory equipment and spaces shall be maintained in a clean condition.

§ 1250.93 Discharge of wastes.

Vessels operating on fresh water lakes or rivers shall not discharge sewage, or ballast or bilge water, within such areas adjacent to domestic water intakes as are designated by the Commissioner of Food and Drugs.

CROSS REFERENCE: For Environmental Protection Agency's regulations for vessel sanitary discharges as related to authority under the Federal Water Pollution Control Act, as amended (33 U.S.C. 1314 *et seq.*), see 40 CFR part 140.

[40 FR 5624, Feb. 6, 1975, as amended at 48 FR 11432, Mar. 18, 1983]

§ 1250.95 Insect control.

Vessels shall be maintained free of infestation by flies, mosquitoes, fleas, lice, and other insects known to be vectors in the transmission of communicable diseases, through the use of screening, insecticides, and other generally accepted methods of insect control.

§ 1250.96 Rodent control.

Vessels shall be maintained free of rodent infestation through the use of traps, poisons, and other generally accepted methods of rodent control.

PARTS 1251-1269 [RESERVED]

PART 1270—HUMAN TISSUE INTENDED FOR TRANSPLANTATION

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AUTHORITY: 42 U.S.C. 216, 243, 264, 271.

SOURCE: 62 FR 40444, July 29, 1997, unless otherwise noted.

Subpart A—General Provisions

§ 1270.1 Scope.

(a) The regulations in this part apply to human tissue and to establishments or persons engaged in the recovery, screening, testing, processing, storage, or distribution of human tissue.

(b) Regulations in this chapter as they apply to drugs, biologics, devices, or other FDA-regulated commodities

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do not apply to human tissue, except as specified in this part.

(c) Regulations in this chapter do not apply to autologous human tissue.

(d) Regulations in this chapter do not apply to hospitals or other clinical facilities that receive and store human tissue only for transplantation within the same facility.

§ 1270.3 Definitions.

(a) *Act* for the purpose of this part means the Public Health Service Act, section 361 (42 U.S.C. 264).

(b) *Blood component* means any part of a single-donor unit of blood separated by physical or mechanical means.

(c) *Colloid* means a protein or polysaccharide solution that can be used to increase or maintain osmotic (oncotic) pressure in the intravascular compartment such as albumin, dextran, hetastarch; or certain blood components, such as plasma and platelets.

(d) *Contract services* are those functions pertaining to the recovery, screening, testing, processing, storage, or distribution of human tissue that another establishment agrees to perform for a tissue establishment.

(e) *Crystalloid* means a balanced salt and/or glucose solution used for electrolyte replacement or to increase intravascular volume such as saline, Ringer's lactate solution, or 5 percent dextrose in water.

(f) *Distribution* includes any transfer or shipment of human tissue (including importation or exportation), whether or not such transfer or shipment is entirely intrastate and whether or not possession of the tissue is taken.

(g) *Donor* means a human being, living or dead, who is the source of tissue for transplantation.

(h) *Donor medical history interview* means a documented dialogue with an individual or individuals who would be knowledgeable of the donor's relevant medical history and social behavior; such as the donor if living, the next of kin, the nearest available relative, a member of the donor's household, other individual with an affinity relationship, and/or the primary treating physician. The relevant social history includes questions to elicit whether or not the donor met certain descriptions or engaged in certain activities or be-

haviors considered to place such an individual at increased risk for HIV and hepatitis.

(i) *Establishment* means any facility under one management including all locations, that engages in the recovery, screening, testing, processing, storage, or distribution of human tissue intended for transplantation.

(j) *Human tissue*, for the purpose of this part means any tissue derived from a human body and recovered before May 25, 2005, which:

(1) Is intended for transplantation to another human for the diagnosis, cure, mitigation, treatment, or prevention of any condition or disease;

(2) Is recovered, processed, stored, or distributed by methods that do not change tissue function or characteristics;

(3) Is not currently regulated as a human drug, biological product, or medical device;

(4) Excludes kidney, liver, heart, lung, pancreas, or any other vascularized human organ; and

(5) Excludes semen or other reproductive tissue, human milk, and bone marrow.

(k) *Importer of record* means the person, establishment or their representative responsible for making entry of imported goods in accordance with all laws affecting such importation.

(l) *Legislative consent* means relating to any of the laws of the various States that allow the medical examiner or coroner to procure corneal tissue in the absence of consent of the donor's next-of-kin.

(m) *Person* includes an individual, partnership, corporation, association, or other legal entity.

(n) *Physical assessment* means a limited autopsy or recent antemortem or postmortem physical examination of the donor to assess for any signs of HIV and hepatitis infection or signs suggestive of any risk factor for such infections.

(o) *Plasma dilution* means a decrease in the concentration of the donor's plasma proteins and circulating antigens or antibodies resulting from the transfusion of blood or blood components and/or infusion of fluids.