

**§ 1250.90**

**§ 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**

**Subpart A—General Provisions**

Sec.

1270.1 Scope.

1270.3 Definitions.

**Subpart B—Donor Screening and Testing**

1270.21 Determination of donor suitability for human tissue intended for transplantation.

**Subpart C—Procedures and Records**

1270.31 Written procedures.

1270.33 Records, general requirements.

1270.35 Specific records.

**21 CFR Ch. I (4–1–11 Edition)**

**Subpart D—Inspection of Tissue Establishments**

1270.41 Inspections.

1270.42 Human tissue offered for import.

1270.43 Retention, recall, and destruction of human tissue.

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 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.