

(b) The Commissioner of Food and Drugs may base his approval or disapproval of a watering point upon investigations made by representatives of State departments of health or of the health authorities of contiguous foreign nations.

(c) If a watering point has not been approved, the Commissioner of Food and Drugs may permit its temporary use under such conditions as, in his judgment, are necessary to prevent the introduction, transmission, or spread of communicable diseases.

(d) Upon request of the Commissioner of Food and Drugs, operators of conveyances shall provide information as to watering points used by them.

[40 FR 5620, Feb. 6, 1975, as amended at 48 FR 11431, Mar. 18, 1983; 48 FR 13978, Apr. 1, 1983]

§ 1240.86 Protection of pier water system.

No vessel engaged in interstate traffic shall make a connection between its nonpotable water system and any pier potable water system unless provisions are made to prevent backflow from the vessel to the pier.

§ 1240.90 Approval of treatment aboard conveyances.

(a) The treatment of water aboard conveyances shall be approved by the Commissioner of Food and Drugs if the apparatus used is of such design and is so operated as to be capable of producing and in fact does produce, potable water.

(b) The Commissioner of Food and Drugs may base his approval or disapproval of the treatment of water upon investigations made by representatives of State departments of health or of the health authorities of contiguous foreign nations.

(c) Overboard water treated on vessels shall be from areas relatively free of contamination and pollution.

[40 FR 5620, Feb. 6, 1975, as amended at 48 FR 11431, Mar. 18, 1983]

§ 1240.95 Sanitation of water boats.

No vessel engaged in interstate traffic shall obtain water for drinking and culinary purposes from any water boat unless the tanks, piping, and other appurtenances used by the water boat in

the loading, transportation, and delivery of such drinking and culinary water, have been approved by the Commissioner of Food and Drugs.

[40 FR 5620, Feb. 6, 1975, as amended at 48 FR 11431, Mar. 18, 1983]

PART 1250—INTERSTATE CONVEYANCE SANITATION**Subpart A—General Provisions**

Sec.

1250.3 Definitions.

Subpart B—Food Service Sanitation on Land and Air Conveyances, and Vessels

1250.20 Applicability.

1250.21 Inspection.

1250.22 General requirements.

1250.25 Source identification and inspection of food and drink.

1250.26 Special food requirements.

1250.27 Storage of perishables.

1250.28 Source and handling of ice.

1250.30 Construction, maintenance and use of places where food is prepared, served, or stored.

1250.32 Food-handling operations.

1250.33 Utensils and equipment.

1250.34 Refrigeration equipment.

1250.35 Health of persons handling food.

1250.38 Toilet and lavatory facilities for use of food-handling employees.

1250.39 Garbage equipment and disposition.

Subpart C—Equipment and Operation of Land and Air Conveyances

1250.40 Applicability.

1250.41 Submittal of construction plans.

1250.42 Water systems; constant temperature bottles.

1250.43 Ice.

1250.44 Drinking utensils and toilet articles.

1250.45 Food handling facilities on railroad conveyances.

1250.49 Cleanliness of conveyances.

1250.50 Toilet and lavatory facilities.

1250.51 Railroad conveyances; discharge of wastes.

1250.52 Discharge of wastes on highway conveyances.

1250.53 Discharge of wastes on air conveyances.

Subpart D—Servicing Areas for Land and Air Conveyances

1250.60 Applicability.

1250.61 Inspection and approval.

1250.62 Submittal of construction plans.

1250.63 General requirements.

1250.65 Drainage.

§ 1250.3

- 1250.67 Watering equipment.
- 1250.70 Employee conveniences.
- 1250.75 Disposal of human wastes.
- 1250.79 Garbage disposal.

Subpart E—Sanitation Facilities and Conditions on Vessels

- 1250.80 Applicability.
- 1250.81 Inspection.
- 1250.82 Potable water systems.
- 1250.83 Storage of water prior to treatment.
- 1250.84 Water in galleys and medical care spaces.
- 1250.85 Drinking fountains and coolers; ice; constant temperature bottles.
- 1250.86 Water for making ice.
- 1250.87 Wash water.
- 1250.89 Swimming pools.
- 1250.90 Toilets and lavatories.
- 1250.93 Discharge of wastes.
- 1250.95 Insect control.
- 1250.96 Rodent control.

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

CROSS REFERENCES: For Department of Health and Human Services regulations relating to foreign quarantine and control of communicable diseases, see Centers for Disease Control's requirements as set forth in 42 CFR parts 71 and 72.

SOURCE: 40 FR 5624, Feb. 6, 1975, unless otherwise noted.

Subpart A—General Provisions

§ 1250.3 Definitions.

As used in this part, terms shall have the following meaning:

(a) *Bactericidal treatment.* The application of a method or substance for the destruction of pathogens and other organisms as set forth in § 1240.10 of this chapter.

(b) *Communicable diseases.* Illnesses due to infectious agents or their toxic products, which may be transmitted from a reservoir to a susceptible host either directly as from an infected person or animal or indirectly through the agency of an intermediate plant or animal host, vector, or the inanimate environment.

(c) *Communicable period.* The period or periods during which the etiologic agent may be transferred directly or indirectly from the body of the infected person or animal to the body of another.

(d) *Contamination.* The presence of a certain amount of undesirable sub-

21 CFR Ch. I (4-1-25 Edition)

stance or material, which may contain pathogenic microorganisms.

(e) *Conveyance.* Conveyance means any land or air carrier, or any vessel as defined in paragraph (m) of this section.

(f) *Existing vessel.* Any vessel the construction of which was started prior to the effective date of the regulations in this part.

(g) *Garbage.* (1) The solid animal and vegetable waste, together with the natural moisture content, resulting from the handling, preparation, or consumption of foods in houses, restaurants, hotels, kitchens, and similar establishments, or (2) any other food waste containing pork.

(h) *Interstate traffic.* (1) The movement of any conveyance or the transportation of persons or property, including any portion of such movement or transportation which is entirely within a State or possession, (i) from a point of origin in any State or possession to a point of destination in any other State or possession, or (ii) between a point of origin and a point of destination in the same State or possession but through any other State, possession, or contiguous foreign country.

(2) Interstate traffic does not include the following:

(i) The movement of any conveyance which is solely for the purpose of unloading persons or property transported from a foreign country, or loading persons or property for transportation to a foreign country.

(ii) The movement of any conveyance which is solely for the purpose of effecting its repair, reconstruction, rehabilitation, or storage.

(i) *Possession.* Any of the possessions of the United States, including Puerto Rico and the Virgin Islands.

(j) *Potable water.* Water which meets the standards prescribed in the Environmental Protection Agency's Primary Drinking Water Regulations as set forth in 40 CFR part 141 and the Food and Drug Administration's sanitation regulations as set forth in this part and part 1240 of this chapter.

(k) *State.* Any State, the District of Columbia, Puerto Rico and the Virgin Islands.

Food and Drug Administration, HHS**§ 1250.26**

(1) *Utensil*. Includes any kitchenware, tableware, glassware, cutlery, containers, or equipment with which food or drink comes in contact during storage, preparation, or serving.

(m) *Vessel*. Any passenger-carrying, cargo, or towing vessel exclusive of:

- (1) Fishing boats including those used for shell-fishing;
- (2) Tugs which operate only locally in specific harbors and adjacent waters;
- (3) Barges without means of self-propulsion;
- (4) Construction-equipment boats and dredges; and
- (5) Sand and gravel dredging and handling boats.

(n) *Wash water*. Water suitable for domestic uses other than for drinking and culinary purposes, and medical care purposes excluding hydrotherapy.

(o) *Shellfish*. Any fresh, frozen, or incompletely cooked oysters, clams, or mussels, either shucked or in the shell, and any fresh, frozen, or incompletely cooked edible products thereof.

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

Subpart B—Food Service Sanitation on Land and Air Conveyances, and Vessels**§ 1250.20 Applicability.**

All conveyances engaged in interstate traffic shall comply with the requirements prescribed in this subpart and § 1240.20 of this chapter.

§ 1250.21 Inspection.

The Commissioner of Food and Drugs may inspect such conveyance to determine compliance with the requirements of this subpart and § 1240.20 of this chapter.

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

§ 1250.22 General requirements.

All food and drink served on conveyances shall be clean, wholesome, and free from spoilage, and shall be prepared, stored, handled, and served in accordance with the requirements prescribed in this subpart and § 1240.20 of this chapter.

§ 1250.25 Source identification and inspection of food and drink.

(a) Operators of conveyances shall identify, when requested by the Commissioner of Food and Drugs, the vendors, distributors or dealers from whom they have acquired or are acquiring their food supply, including milk, fluid milk products, ice cream and other frozen desserts, butter, cheese, bottled water, sandwiches and box lunches.

(b) The Commissioner of Food and Drugs may inspect any source of such food supply in order to determine whether the requirements of the regulations in this subpart and in § 1240.20 of this chapter are being met, and may utilize the results of inspections of such sources made by representatives of State health departments or of the health authorities of contiguous foreign nations.

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

§ 1250.26 Special food requirements.

Milk, fluid milk products, ice cream and other frozen desserts, butter, cheese, and shellfish served or sold on conveyances shall conform to the following requirements:

(a) Milk and fluid milk products, including cream, buttermilk, skim milk, milk beverages, and reconstituted milk, shall be pasteurized and obtained from a source of supply approved by the Commissioner of Food and Drugs. The Commissioner of Food and Drugs shall approve any source of supply at or from which milk or fluid milk products are produced, processed, and distributed so as to prevent the introduction, transmission, or spread of communicable diseases. If a source of supply of milk or fluid milk products has not been approved, the Commissioner of Food and Drugs may permit its temporary use under such conditions as, in his judgment, are necessary to prevent the introduction, transmission, or spread of communicable diseases. Containers of milk and fluid milk products shall be plainly labeled to show the contents, the word "pasteurized", and the identity of the plant at which the contents were packaged by name and

§ 1250.27

address, provided that a code may be used in lieu of address.

(b) Ice cream, other frozen desserts, and butter shall be manufactured from milk or milk products that have been pasteurized or subjected to equivalent heat treatment.

(c) Cheese shall be (1) pasteurized or subjected to equivalent heat treatment, (2) made from pasteurized milk products or from milk products which have been subjected to equivalent heat treatment, or (3) cured for not less than 60 days at a temperature not less than 35 °F.

(d) Milk, buttermilk, and milk beverages shall be served in or from the original individual containers in which received from the distributor, or from a bulk container equipped with a dispensing device so designed, constructed, installed, and maintained as to prevent the transmission of communicable diseases.

(e) Shellfish purchased for consumption on any conveyance shall originate from a dealer currently listed by the Public Health Service as holding an unexpired and unrevoked certificate issued by a State authority.

(f) Shucked shellfish shall be purchased in the containers in which they are placed at the shucking plant and shall be kept therein until used. The State abbreviation and the certificate number of the packers shall be permanently recorded on the container.

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

§ 1250.27 Storage of perishables.

All perishable food or drink shall be kept at or below 50 °F, except when being prepared or kept hot for serving.

§ 1250.28 Source and handling of ice.

Ice coming in contact with food or drink and not manufactured on the conveyance shall be obtained from sources approved by competent health authorities. All ice coming in contact with food or drink shall be stored and handled in such manner as to avoid contamination.

21 CFR Ch. I (4-1-25 Edition)**§ 1250.30 Construction, maintenance and use of places where food is prepared, served, or stored.**

(a) All kitchens, galleys, pantries, and other places where food is prepared, served, or stored shall be adequately lighted and ventilated: *Provided, however, That ventilation of cold storage rooms shall not be required.* All such places where food is prepared, served, or stored shall be so constructed and maintained as to be clean and free from flies, rodents, and other vermin.

(b) Such places shall not be used for sleeping or living quarters.

(c) Water of satisfactory sanitary quality, under head or pressure, and adequate in amount and temperature, shall be easily accessible to all rooms in which food is prepared and utensils are cleaned.

(d) All plumbing shall be so designed, installed, and maintained as to prevent contamination of the water supply, food, and food utensils.

§ 1250.32 Food-handling operations.

(a) All food-handling operations shall be accomplished so as to minimize the possibility of contaminating food, drink, or utensils.

(b) The hands of all persons shall be kept clean while engaged in handling food, drink, utensils, or equipment.

§ 1250.33 Utensils and equipment.

(a) All utensils and working surfaces used in connection with the preparation, storage, and serving of food or beverages, and the cleaning of food utensils, shall be so constructed as to be easily cleaned and self-draining and shall be maintained in good repair. Adequate facilities shall be provided for the cleaning and bactericidal treatment of all multiuse eating and drinking utensils and equipment used in the preparation of food and beverages. An indicating thermometer, suitably located, shall be provided to permit the determination of the hot water temperature when and where hot water is used as the bactericidal agent.

(b) All multiuse eating and drinking utensils shall be thoroughly cleaned in warm water and subjected to an effective bactericidal treatment after each use. All other utensils that come in

Food and Drug Administration, HHS**§ 1250.42**

contact with food and drink shall be similarly treated immediately following the day's operation. All equipment shall be kept clean.

(c) After bactericidal treatment, utensils shall be stored and handled in such manner as to prevent contamination before reuse.

§ 1250.34 Refrigeration equipment.

Each refrigerator shall be equipped with a thermometer located in the warmest portion thereof. Waste water drains from ice boxes, refrigerating equipment, and refrigerated spaces shall be so installed as to prevent backflow of contaminating liquids.

§ 1250.35 Health of persons handling food.

(a) Any person who is known or suspected to be in a communicable period or a carrier of any communicable disease shall not be permitted to engage in the preparation, handling, or serving of water, other beverages, or food.

(b) Any person known or suspected to be suffering from gastrointestinal disturbance or who has on the exposed portion of the body an open lesion or an infected wound shall not be permitted to engage in the preparation, handling, or serving of food or beverages.

§ 1250.38 Toilet and lavatory facilities for use of food-handling employees.

(a) Toilet and lavatory facilities of suitable design and construction shall be provided for use of food-handling employees. Railroad dining car crew lavatory facilities are regulated under § 1250.45.

(b) Signs directing food-handling employees to wash their hands after each use of toilet facilities shall be posted so as to be readily observable by such employees. Hand washing facilities shall include soap, sanitary towels and hot and cold running water or warm running water in lieu of hot and cold running water.

(c) All toilet rooms shall be maintained in a clean condition.

§ 1250.39 Garbage equipment and disposition.

Watertight, readily cleanable non-absorbent containers with close-fitting

covers shall be used to receive and store garbage. Garbage and refuse shall be disposed of as frequently as is necessary and practicable.

Subpart C—Equipment and Operation of Land and Air Conveyances**§ 1250.40 Applicability.**

The sanitary equipment and facilities on land and air conveyances engaged in interstate traffic and the use of such equipment and facilities shall comply with the requirements prescribed in this subpart.

§ 1250.41 Submittal of construction plans.

Plans for the construction or major reconstruction of sanitary equipment or facilities for such conveyances shall be submitted to the Commissioner of Food and Drugs for review of the conformity of such plans with the requirements of this subpart, except that submittal of plans shall not be required for any conveyance under reconstruction if the owner or operator thereof has made arrangements satisfactory to the Commissioner of Food and Drugs for inspections of such conveyances while under reconstruction for the purpose of determining conformity with those requirements.

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

§ 1250.42 Water systems; constant temperature bottles.

(a) The water system, whether of the pressure or gravity type, shall be complete and closed from the filling ends to the discharge taps, except for protected vent openings. The water system shall be protected against backflow.

(b) Filling pipes or connections through which water tanks are supplied shall be provided on both sides of all new railway conveyances and on existing conveyances when they undergo heavy repairs. All filling connections shall be easily cleanable and so located and protected as to minimize the hazard of contamination of the water supply.

§ 1250.43

(c) On all new or reconstructed conveyances, water coolers shall be an integral part of the closed system.

(d) Water filters if used on dining cars and other conveyances will be permitted only if they are so operated and maintained at all times as to prevent contamination of the water.

(e) Constant temperature bottles and other containers used for storing or dispensing potable water shall be kept clean at all times and shall be subjected to effective bactericidal treatment as often as may be necessary to prevent the contamination of water so stored and dispensed.

§ 1250.43 Ice.

Ice shall not be permitted to come in contact with water in coolers or constant temperature bottles.

§ 1250.44 Drinking utensils and toilet articles.

(a) No cup, glass, or other drinking utensil which may be used by more than one person shall be provided on any conveyance unless such cup, glass, or drinking utensil shall have been thoroughly cleaned and subjected to effective bactericidal treatment after each individual use.

(b) Towels, combs, or brushes for common use shall not be provided.

§ 1250.45 Food handling facilities on railroad conveyances.

(a) Both kitchens and pantries of cars hereafter constructed or reconstructed shall be equipped with double sinks, one of which shall be of sufficient size and depth to permit complete immersion of a basket of dishes during bactericidal treatment; in the pantry a dishwashing machine may be substituted for the double sinks. If chemicals are used for bactericidal treatment, 3-compartment sinks shall be provided.

(b) A sink shall be provided for washing and handling cracked ice used in food or drink and shall be used for no other purpose.

(c) Lavatory facilities for the use of the dining car crew shall be provided on each dining car. Such facilities shall be conveniently located and used for hand and face washing only: *Provided, however, That where the kitchen and*

21 CFR Ch. I (4-1-25 Edition)

pantry on a dining car hereafter constructed or reconstructed are so partitioned or separated as to impede free passage between them lavatory facilities shall be provided in both the kitchen and the pantry.

(d) Wherever toilet and lavatory facilities required by paragraph (c) of this section are not on the dining car, a lavatory shall be provided on the dining car for the use of employees. The lavatory shall be conveniently located and used only for the purpose for which it is installed.

§ 1250.49 Cleanliness of conveyances.

Conveyances while in transit shall be kept clean and free of flies and mosquitoes. A conveyance which becomes infected with vermin shall be placed out of service until such time as it shall have been effectively treated for the destruction of the vermin.

§ 1250.50 Toilet and lavatory facilities.

Where toilet and lavatory facilities are provided on conveyances they shall be so designed as to permit ready cleaning. On conveyances not equipped with retention facilities, toilet hoppers shall be of such design and so located as to prevent spattering of water filling pipes or hydrants.

§ 1250.51 Railroad conveyances; discharge of wastes.

(a) *New railroad conveyances.* Human wastes, garbage, waste water, or other polluting materials shall not be discharged from any new railroad conveyance except at servicing areas approved by the Commissioner of Food and Drugs. In lieu of retention pending discharge at approved servicing areas, human wastes, garbage, waste water, or other polluting materials that have been suitably treated to prevent the spread of communicable diseases may be discharged from such conveyances, except at stations. For the purposes of this section, "new railroad conveyance" means any such conveyance placed into service for the first time after July 1, 1972, and the terms "waste water or other polluting materials" do not include drainage of drinking water taps or lavatory facilities.

(b) *Nonnew railroad conveyances.* Human wastes, garbage, waste water,

or other polluting materials shall not be discharged from any railroad conveyance, other than passenger conveyances for which an extension has been granted pursuant to paragraph (f) of this section, after December 31, 1977, except at servicing areas approved by the Commissioner of Food and Drugs. In lieu of retention pending discharge at approved servicing areas, human wastes, garbage, waste water, or other polluting materials that have been suitably treated to prevent the spread of communicable diseases may be discharged from such conveyances, except at stations. The terms "waste water or other polluting materials" do not include drainage of drinking water taps or lavatory facilities.

(c) *Toilets.* When railroad conveyances, occupied or open to occupancy by travelers, are at a station or servicing area, toilets shall be kept locked unless means are provided to prevent contamination of the area or station.

(d) *Submission of annual report.* Each railroad company shall submit to the Center for Food Safety and Applied Nutrition (HFS-627), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, an annual report of accomplishments made in modifying conveyances to achieve compliance with paragraph (b) of this section. Annual reports shall be required until a report is submitted showing that 100 percent of the company's conveyances can comply with the requirements of paragraph (b) of this section; annual reports shall be required subsequent to such report if conveyances not capable of complying with the requirements of paragraph (b) of this section are acquired. Every railroad company shall have not less than 10 percent of its nonpassenger conveyances that are in operation capable of complying with the requirements of paragraph (b) of this section by December 31, 1974, not less than 40 percent by December 31, 1975, and not less than 70 percent by December 31, 1976. All conveyances, other than passenger conveyances for which an extension has been granted pursuant to paragraph (f) of this section, in operation after December 31, 1977, shall be capable of complying with paragraph (b) of this section.

(e) *Requirements of annual report.* Annual reports required by paragraph (d) of this section shall be submitted within 60 days of the end of each calendar year. Each report shall contain at least the following information:

- (1) Company name and address.
- (2) Name, title, and address of the company's chief operating official.

- (3) Name, title, address, and telephone number of the person designated by the company to be directly responsible for compliance with this section.

- (4) A statement that all new railroad conveyances placed into service after July 1, 1972 meet the requirements of this section.

- (5) A complete, factual, narrative statement explaining why retrofitting of noncomplying nonnew conveyances is incomplete, if it is incomplete.

- (6) A statement of the percentage of conveyances retrofitted with waste discharge facilities in compliance with this section as of the reporting date and the percentage expected to be completed by December 31st of the following year.

- (7) A tabular report with the following vertical columns: equipment type, e.g., locomotive, caboose, passenger car, and any others having toilets; number of toilets per conveyance; number of each equipment type in operation; and number of each to be retrofitted by December 31st of each year until 100 percent compliance with this section is achieved.

(f) *Variances and extensions*—(1) *Variances.* Upon application by a railroad company, the Director, Center for Food Safety and Applied Nutrition, may grant a variance from the compliance schedule prescribed in paragraph (d) of this section for nonpassenger conveyances when the requested variance is required to prevent substantial disruption of the railroad company's operations. Such variance shall not affect the final deadline of compliance established in paragraph (d) of this section.

(2) *Extensions.* Upon application by a railroad company, the Director, Center for Food Safety and Applied Nutrition, may grant an extension of time for compliance with the requirements of paragraph (b) of this section beyond

§ 1250.52

December 31, 1977, for passenger conveyances operated by railroad companies when compliance cannot be achieved without substantial disruption of the railroad company's operations.

(3) *Application for variance or extension.* Application for variances or extensions shall be submitted to the Food and Drug Administration, Center for Food Safety and Applied Nutrition, Manager, Interstate Travel Sanitation Sub-Program, HFF-312, 5001 Campus Dr., College Park, MD 20740, and shall include the following information:

(i) A detailed description of the proposed deviation from the requirements of paragraphs (b) or (d) of this section.

(ii) A report, current to the date of the request for a variance or extension, containing the information required by paragraph (e) of this section.

(4) *Administration of variances and extensions.* (i) Written notification of the granting or refusal of a variance or extension will be provided to the applying railroad company by the Director, Center for Food Safety and Applied Nutrition. The notification of a granted variance will state the approved deviation from the compliance schedule provided for in paragraph (d) of this section. The notification of a granted extension will state the final date for compliance with the provisions of paragraph (b) of this section.

(ii) A public file of requested variances and extensions, their disposition, and information relating to pending actions will be maintained in the Dockets Management Staff, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

(iii) After notice to the railroad company and opportunity for hearing in accordance with part 16 of this chapter, a variance or extension may be withdrawn prior to its scheduled termination if the Director, Center for Food Safety and Applied Nutrition, determines that such withdrawal is necessary to protect the public health.

21 CFR Ch. I (4-1-25 Edition)

CROSS REFERENCE: For statutory exemptions for "intercity rail passenger service," see section 306(i) of 45 U.S.C. 546(i).

[40 FR 5624, Feb. 6, 1975, as amended at 40 FR 30110, July 17, 1975; 46 FR 8461, Jan. 27, 1981; 48 FR 11432, Mar. 18, 1983; 54 FR 24900, June 12, 1989; 59 FR 14366, Mar. 28, 1994; 61 FR 14481, Apr. 2, 1996; 66 FR 56035, Nov. 6, 2001; 81 FR 49897, July 29, 2016; 88 FR 45067, July 14, 2023]

EFFECTIVE DATE NOTE: For a document staying the effectiveness of § 1250.51 (b) and (d), see 42 FR 57122, Nov. 1, 1977.

§ 1250.52 Discharge of wastes on highway conveyances.

There shall be no discharge of excrement, garbage, or waste water from a highway conveyance except at servicing areas approved by the Commissioner of Food and Drugs.

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

§ 1250.53 Discharge of wastes on air conveyances.

There shall be no discharge of excrement or garbage from any air conveyance except at servicing areas approved by the Commissioner of Food and Drugs.

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

Subpart D—Servicing Areas for Land and Air Conveyances

§ 1250.60 Applicability.

Land and air conveyances engaged in interstate traffic shall use only such servicing areas within the United States as have been approved by the Commissioner of Food and Drugs as being in compliance with the requirements prescribed in this subpart.

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

§ 1250.61 Inspection and approval.

The Commissioner of Food and Drugs may inspect any such areas to determine whether they shall be approved. He may base his approval or disapproval on investigations made by representatives of State departments of health.

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

Food and Drug Administration, HHS**§ 1250.75****§ 1250.62 Submittal of construction plans.**

Plans for construction or major reconstruction of sanitation facilities at servicing areas shall be submitted to the Commissioner of Food and Drugs for review of the conformity of the proposed facilities with the requirements of this subpart.

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

§ 1250.63 General requirements.

Servicing areas shall be provided with all necessary sanitary facilities so operated and maintained as to prevent the spread of communicable diseases.

§ 1250.65 Drainage.

All platforms and other places at which water or food supplies are loaded onto or removed from conveyances shall be adequately drained so as to prevent pooling.

§ 1250.67 Watering equipment.

(a) *General requirements.* All servicing area piping systems, hydrants, taps, faucets, hoses, buckets, and other appurtenances necessary for delivery of drinking and culinary water to a conveyance shall be designed, constructed, maintained and operated in such a manner as to prevent contamination of the water.

(b) *Outlets for nonpotable water.* Outlets for nonpotable water shall be provided with fittings different from those provided for outlets for potable water and each nonpotable water outlet shall be posted with permanent signs warning that the water is unfit for drinking.

(c) *Ice.* If bulk ice is used for the cooling of drinking water or other beverages, or for food preservation purposes, equipment constructed so as not to become a factor in the transmission of communicable diseases shall be provided for the storage, washing, handling, and delivery to conveyances of such bulk ice, and such equipment shall be used for no other purposes.

§ 1250.70 Employee conveniences.

(a) There shall be adequate toilet, washroom, locker, and other essential sanitary facilities readily accessible for use of employees adjacent to places

or areas where land and air conveyances are serviced, maintained, and cleaned. These facilities shall be maintained in a clean and sanitary condition at all times.

(b) In the case of diners not in a train but with a crew on board, adequate toilet facilities shall be available to the crew within a reasonable distance but not exceeding 500 feet of such diners.

(c) Drinking fountains and coolers shall be constructed of impervious, nonoxidizing material, and shall be so designed and constructed as to be easily cleaned. The jet of a drinking fountain shall be slanting and the orifice of the jet shall be protected by a guard in such a manner as to prevent contamination thereof by droppings from the mouth. The orifice of such a jet shall be located a sufficient distance above the rim of the basin to prevent backflow.

§ 1250.75 Disposal of human wastes.

(a) At servicing areas and at stations where land and air conveyances are occupied by passengers the operations shall be so conducted as to avoid contamination of such areas and stations by human wastes.

(b) Toilet wastes shall be disposed of through sanitary sewers or by other methods assuring sanitary disposal of such wastes. All soil cans and removable containers shall be thoroughly cleaned before being returned to use. Equipment for cleaning such containers and for flushing nonremovable containers and waste carts shall be so designed as to prevent backflow into the water line, and such equipment shall be used for no purpose connected with the handling of food, water or ice.

(c) All persons who have handled soil cans or other containers which have come in contact with human wastes shall be required to wash their hands thoroughly with soap and warm water and to remove any garments which have become soiled with such wastes before engaging in any work connected with the loading, unloading, transporting or other handling of food, water or ice.

§ 1250.79

§ 1250.79 Garbage disposal.

- (a) Water-tight, readily cleanable, nonabsorbent containers with close-fitting covers shall be used to receive and store garbage.
- (b) Can washing and draining facilities shall be provided.
- (c) Garbage cans shall be emptied daily and shall be thoroughly washed before being returned for use.

Subpart E—Sanitation Facilities and Conditions on Vessels

§ 1250.80 Applicability.

The sanitation facilities and the sanitary conditions on vessels engaged in interstate traffic shall comply with the requirements prescribed in this subpart, provided that no major structural change will be required on existing vessels.

§ 1250.81 Inspection.

The Commissioner of Food and Drugs may inspect such vessels to determine compliance with the requirements of this subpart.

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

§ 1250.82 Potable water systems.

The following conditions must be met by vessel water systems used for the storage and distribution of water which has met the requirements of § 1240.80 of this chapter.

(a) The potable water system, including filling hose and lines, pumps, tanks, and distributing pipes, shall be separate and distinct from other water systems and shall be used for no other purposes.

(b) All potable water tanks shall be independent of any tanks holding nonpotable water or other liquid. All potable water tanks shall be independent of the shell of the ship unless (1) the bottom of the tank is at least 2 feet above the maximum load water line, (2) the seams in the shell are continuously welded, and (3) there are no rivets in that part of the shell which forms a side of a tank. A deck may be used as the top of a tank provided there are no access or inspection openings or rivets therein, and the seams are continuously welded. No toilet or urinal shall

21 CFR Ch. I (4-1-25 Edition)

be installed immediately above that part of the deck which forms the top of a tank. All potable water tanks shall be located at a sufficient height above the bilge to allow for draining and to prevent submergence in bilge water.

(c) Each potable water tank shall be provided with a means of drainage and, if it is equipped with a manhole, overflow, vent, or a device for measuring depth of water, provision shall be made to prevent entrance into the tank of any contaminating substance. No deck or sanitary drain or pipe carrying any nonpotable water or liquid shall be permitted to pass through the tank.

(d) Tanks and piping shall bear clear marks of identification.

(e) There shall be no backflow or cross connection between potable water systems and any other systems. Pipes and fittings conveying potable water to any fixture, apparatus, or equipment shall be installed in such way that backflow will be prevented. Waste pipes from any part of the potable water system, including treatment devices, discharging to a drain, shall be suitably protected against backflow.

(f) Water systems shall be cleaned, disinfected, and flushed whenever the Commissioner of Food and Drugs shall find such treatment necessary to prevent the introduction, transmission, or spread of communicable diseases.

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

§ 1250.83 Storage of water prior to treatment.

The following requirements with respect to the storage of water on vessels prior to treatment must be met in order to obtain approval of treatment facilities under § 1240.90 of this chapter.

(a) The tank, whether independent or formed by the skin of the ship, deck, tank top, or partitions common with other tanks, shall be free of apparent leakage.

(b) No sanitary drain shall pass through the tank.

(c) The tank shall be adequately protected against both the backflow and discharge into it of bilge or highly contaminated water.

Food and Drug Administration, HHS**§ 1250.93****§ 1250.84 Water in galleys and medical care spaces.**

(a) Potable water, hot and cold, shall be available in the galley and pantry except that, when potable water storage is inadequate, nonpotable water may be piped to the galley for deck washing and in connection with garbage disposal. Any tap discharging nonpotable water which is installed for deck washing purposes shall not be more than 18 inches above the deck and shall be distinctly marked "For deck washing only".

(b) In the case of existing vessels on which heat treated wash water has been used for the washing of utensils prior to the effective date of the regulations in this part, such water may continue to be so used provided controls are employed to insure the heating of all water to at least 170 °F before discharge from the heater.

(c) Potable water, hot and cold, shall be available in medical care spaces for hand-washing and for medical care purposes excluding hydrotherapy.

§ 1250.85 Drinking fountains and coolers; ice; constant temperature bottles.

(a) Drinking fountains and coolers shall be constructed of impervious, nonoxidizing material, and shall be so designed and constructed as to be easily cleaned. The jet of a drinking fountain shall be slanting and the orifice of the jet shall be protected by a guard in such a manner as to prevent contamination thereof by droppings from the mouth. The orifice of such a jet shall be located a sufficient distance above the rim of the basin to prevent backflow.

(b) Ice shall not be permitted to come in contact with water in coolers or constant temperature bottles.

(c) Constant temperature bottles and other containers used for storing or dispensing potable water shall be kept clean at all times and shall be subjected to effective bactericidal treatment after each occupancy of the space served and at intervals not exceeding one week.

§ 1250.86 Water for making ice.

Only potable water shall be piped into a freezer for making ice for drinking and culinary purposes.

§ 1250.87 Wash water.

Where systems installed on vessels for wash water, as defined in § 1250.3(n), 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.

§ 1250.95

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 1251–1270 [RESERVED]

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

Subpart A—General Provisions

Sec.

- 1271.1 What are the purpose and scope of this part?
- 1271.3 How does FDA define important terms in this part?
- 1271.10 Are my HCT/P's regulated solely under section 361 of the PHS Act and the regulations in this part, and if so what must I do?
- 1271.15 Are there any exceptions from the requirements of this part?
- 1271.20 If my HCT/P's do not meet the criteria in §1271.10, and I do not qualify for any of the exceptions in §1271.15, what regulations apply?

Subpart B—Procedures for Registration and Listing

- 1271.21 When do I register, submit an HCT/P list, and submit updates?
- 1271.22 How do I register and submit an HCT/P list?
- 1271.23 How is a waiver from the electronic format requirements requested?
- 1271.25 What information is required for establishment registration and HCT/P listing?
- 1271.26 When must I amend my establishment registration?

21 CFR Ch. I (4-1-25 Edition)

- 1271.27 Will FDA assign me a registration number?
- 1271.37 Will establishment registrations and HCT/P listings be available for inspection, and how do I request information on registrations and listings?

Subpart C—Donor Eligibility

- 1271.45 What requirements does this subpart contain?
- 1271.47 What procedures must I establish and maintain?
- 1271.50 How do I determine whether a donor is eligible?
- 1271.55 What records must accompany an HCT/P after the donor-eligibility determination is complete; and what records must I maintain?
- 1271.60 What quarantine and other requirements apply before the donor-eligibility determination is complete?
- 1271.65 How do I store an HCT/P from a donor determined to be ineligible, and what uses of the HCT/P are not prohibited?
- 1271.75 How do I screen a donor?
- 1271.80 What are the general requirements for donor testing?
- 1271.85 What donor testing is required for different types of cells and tissues?
- 1271.90 Are there exceptions from the requirement of determining donor eligibility, and what labeling requirements apply?

Subpart D—Current Good Tissue Practice

- 1271.145 Prevention of the introduction, transmission, or spread of communicable diseases.
- 1271.150 Current good tissue practice requirements.
- 1271.155 Exemptions and alternatives.
- 1271.160 Establishment and maintenance of a quality program.
- 1271.170 Personnel.
- 1271.180 Procedures.
- 1271.190 Facilities.
- 1271.195 Environmental control and monitoring.
- 1271.200 Equipment.
- 1271.210 Supplies and reagents.
- 1271.215 Recovery.
- 1271.220 Processing and process controls.
- 1271.225 Process changes.
- 1271.230 Process validation.
- 1271.250 Labeling controls.
- 1271.260 Storage.
- 1271.265 Receipt, predistribution shipment, and distribution of an HCT/P.
- 1271.270 Records.
- 1271.290 Tracking.
- 1271.320 Complaint file.