

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:601 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1248 (June 2002).

§1149. Water
[formerly paragraph 6:162]

A. The water employed in the manufacture of beverages and for rinsing bottles or other containers shall be free from substances deleterious to health and shall conform to the regulations of this Code and to the standards for potable water.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:601 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1248 (June 2002).

§1151. Prohibited Preservatives
[formerly paragraph 6:163]

A. No antiseptic, disinfectant or preservative prohibited by federal or state food and drug or health laws (21 CFR I et seq.; R.S. 40:601 et seq.), shall be used in beverages.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:601 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1248 (June 2002).

**§1153. Allowable Acids and Flavors;
Prohibited Mineral Acids**
[formerly paragraph 6:164]

A. Citric, tartaric or other edible organic acids, and their salts, may be used. Mineral acids, other than phosphoric acid or its salts, are prohibited in carbonated beverages. Acids and flavors shall be stored in covered containers, properly labeled, and protected against contamination.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:601 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1248 (June 2002).

§1155. Colors Additives
[formerly paragraph 6:165]

A. Only caramel, U. S. certified coal tar, or approved vegetable colors as described in the food additive statutes—21 USC 409 or 21 CFR 170 shall be used.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:601 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1248 (June 2002).

§1157. Employee Health
[formerly paragraph 6:166]

A. The requirements of Part I, §117, Part II, §§501 and 503 and Part VI, §§305-309 shall be met.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:601 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1248 (June 2002).

Chapter 13. Cold Storage and Ice Plants

§1301. Definitions
[formerly paragraph 6:167]

A. Unless otherwise specifically provided herein, the following words and terms used in this Part of the sanitary code, and all other Parts which are adopted or may be adopted, are defined for the purposes thereof as follows.

Cold Storage Plants or Cold Storage Rooms—places artificially cooled by refrigerating machinery or ice, or other means in which articles of food are stored at a temperature of 45°F or lower; provided, however, that frozen food lockers for the convenience of individuals who rent such lockers for the storage of privately owned foods not intended for sale are not included.

Cross Connection—a physical connection through which a supply of potable water could be contaminated or polluted and/or a connection between a supervised potable water supply and an unsupervised supply of unknown potability.

Ice Plant—any building, or group of buildings, used or maintained for the manufacture of ice.

Personnel—any person who may in any manner come in contact with artificial ice during its manufacture, storage or distribution or with foods in cold storage.

Proprietor—any person, firm, corporation or governmental agency owning or operating an artificial ice or cold storage plant.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:601 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1248 (June 2002).

§1303. Plans Review
[formerly paragraph 6:168]

A. Plans for the construction of new ice plants and cold storage plants and rooms, or for major changes in existing plants, shall be submitted to the state health officer for approval. Construction, or improvements, shall not begin before approval of the state health officer is obtained.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:601 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1248 (June 2002).

**§1305. Building Construction: Ice Plants,
Cold Storage Plants or Cold Storage Rooms**
[formerly paragraph 6:169]

A. Storage in any basement, room or receptacle which is subject to sewerage or waste water backflow, or in any place having defective drain pipes or appliances, is prohibited.

Floors shall be constructed of tight, sound, smooth material, free from cracks and easily cleanable. The cold storage rooms shall be constructed and maintained to prevent entrance of rodents, in accordance with Part V (Disease Vector Control) of this Code.

B. All cold storage rooms shall be properly lighted by natural or artificial means.

C. No new ice plant shall hereafter be constructed nor shall major alterations be made to existing ice plants without the prior written approval of, and unless in accordance with plans and specifications approved in advance by the state health officer.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:601 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1248 (June 2002).

§1307. Potable Water Supply
[formerly paragraph 6:170]

A. The water supply used by an artificial ice plant to make ice shall meet the requirements of Part XII of this Code for safe water supplies.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:601 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1249 (June 2002).

§1309. Cross Connections
[formerly paragraph 6:171]

A. Physical connections between a potable water supply and a water of unknown or questionable quality are prohibited.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:601 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1249 (June 2002).

§1311. Sewage Disposal
[formerly paragraph 6:172]

A. Sewage disposal facilities shall be provided in compliance with Part XIII of this Code.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:601 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1249 (June 2002).

§1313. Toilet and Lavatory Facilities
[formerly paragraph 6:173]

A. Every artificial ice plant and cold storage plant shall be provided with toilet and hand washing facilities for employees as required by LAC 51:XIV.411, titled "Minimum Plumbing Fixtures". Handwashing facilities shall be located conveniently to all toilet facilities. These facilities shall be kept clean. Toilet room doors shall be self-closing.

AUTHORITY NOTE: Promulgated in accordance with provisions of R.S. 40:4(A)(1)(a). Also see 40:601 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1249 (June 2002), amended LR 38:2792 (November 2012).

§1315. Air Blowers
[formerly paragraph 6:174]

A. The air intake of air blowers used at artificial ice plants shall be so located and protected as to ensure the use of a safe and clean air supply.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:601 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1249 (June 2002).

§1317. Outside Entrances
[formerly paragraph 6:175]

A. Outside doors shall be self-closing.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:601 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1249 (June 2002).

§1319. Permits
[formerly paragraph 6:176]

A. Cold storage and ice plants must obtain permits from the state health officer, in accordance with Part I of this Code.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:601 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1249 (June 2002).

§1321. Employee Health
[formerly paragraph 6:177]

A. The requirements of Part I, §117, and Part II, §§501-503.C shall be met.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:601 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1249 (June 2002).

§1323. Spitting
[formerly paragraph 6:178]

A. Spitting in the ice plant and cold storage rooms is prohibited.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:601 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1249 (June 2002).

§1325. Cleanliness
[formerly paragraph 6:179]

A. Floors of the brine rooms, ice storage and cold storage rooms, toilets and all other appurtenances shall be kept

clean. Employees working on brine tanks or in ice storage rooms shall wear rubber boots, which shall be worn in these areas only.

B. [formerly paragraph 6:180] Cold storage plants shall be kept free from rust, growths, molds and slime.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:601 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1249 (June 2002).

§1327. Storage of Meats and Foods
[formerly paragraph 6:181]

A. Meats and foods shall not be placed in direct contact with ice, or upon the flooring of cold storage rooms. Bins, racks or other receptacles used for the storage of meats and foods shall be kept in a sanitary condition.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:601 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1249 (June 2002).

§1329. Ice Removal from Cans
[formerly paragraph 6:182]

A. Submerging or spraying of ice cans for removal of ice cakes in other than potable water is prohibited.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:601 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1249 (June 2002).

§1331. Transportation, Distribution and Storage of Ice
[formerly paragraph 6:183]

A. Ice intended for human or domestic consumption shall not be placed on streets, sidewalks, roads or alleys, or transported through such streets, sidewalks, roads or alleys, unless protected in a sanitary manner.

1. [formerly paragraph 6:184] Trucks and other vehicles from which ice is sold or delivered, and all factories, shops, storerooms, pantries and other places where ice is handled for sale, service or consumption, shall be thoroughly clean and in a sanitary condition, and shall be kept free from all dirt, dust, trash or any other substance or matter which is liable to become mixed with or enter into the ice or anything prepared with ice, so as to contaminate or render it unclean or insanitary.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:601 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1250 (June 2002).

§1333. Grinding, Crushing and Packaging of Ice
[formerly paragraph 6:185]

A. Crushed or ground ice intended for human consumption or use shall be crushed or ground and packaged in a sanitary manner so as to prevent contamination by filth,

foreign material, dust, insects, rodent filth such as hairs, droppings, etc.

1. [formerly part of paragraph 6:185] The crushing or grinding and packaging of ice on wagons, trucks or other vehicles used to deliver ice to be used for human or domestic consumption is strictly prohibited.

2. [formerly part of paragraph 6:185] Ice intended to be used for human or domestic consumption shall be thoroughly washed before being placed in the crusher or grinder. The facilities for crushing or grinding and packaging of ice shall be located in a satisfactorily enclosed building or structure, and shall be maintained in a sanitary condition so that the ice will be protected from dust, dirt, flies, insects, rust and other contaminating sources during the grinding or crushing and packaging operations.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:601 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1250 (June 2002).

§1335. Records
[formerly paragraph 6:186]

A. It shall be the duty of every person, firm or corporation operating a cold storage plant to keep an accurate record of the receipts and withdrawals of all goods stored therein. All goods stored in such an establishment shall be identified by a code or lot number, which number shall be entered in the record book at the time such goods are accepted for cold storage. The state health officer shall have free access to these records at any reasonable time during working hours.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:601 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1250 (June 2002).

§1337. Unwholesome Food
[formerly paragraph 6:187]

A. No article of food shall be placed in cold storage if it shows evidences of decomposition, such as, but not limited to, spoilage, rodent defilement, insect infestations, chemical or pesticide contamination, filth and foreign object contamination, swollen cans, etc., or of other conditions which would make it unfit for food.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:601 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1250 (June 2002).

§1339. Reserved.

§1341. Sale of Cold Storage Goods; Prohibited
"Fresh" Food Claims
[formerly paragraph 6:189]

A. It shall be a violation of the state sanitary code to sell or offer or expose for sale uncooked articles of food which have been held in cold storage without advising or notifying persons purchasing, or intending to purchase, such articles of food that they have been held in cold storage; and it shall be

unlawful to represent or advertise as "fresh," articles of food which have been held in cold storage.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:601 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1250 (June 2002).

**§1343. Transfer of Cold Storage Goods;
Prohibited Return to Cold Storage
[formerly paragraph 6:190]**

A. It shall be a violation of the sanitary code to return to cold storage any article of food which has once been released from storage, except that nothing in these regulations shall be construed as preventing the transfer of goods from one cold storage plant to another; provided, such goods are refrigerated at a temperature of 45°F or lower during such transfer; and, provided further, that such transfer is not made for the purpose of evading any provision.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:601 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1250 (June 2002).

Chapter 15. Current Good Manufacturing Practices in the Manufacture of Drugs

**§1501. Definitions
[formerly paragraph 6:191]**

A. Unless otherwise specifically provided herein, the following words and terms used in this Part of the sanitary code, and all other Parts which are adopted or may be adopted, are defined for the purposes thereof as follows.

Active Ingredient—any component which is intended to furnish pharmacological activity or other direct effect in the diagnosis, care, mitigation, treatment or prevention of disease or to affect the structure of any function of the body of man or other animals. The term shall include other components which may undergo chemical change in the manufacture of the drug or be present in the finished product in a modified form intended to furnish the specified activity or effect.

Batch—a specific quantity of a drug that has uniform character and quality within specified limits, and is produced according to a single manufacturing order.

Component—any ingredient intended for use in the manufacture of drugs in dosage form, including those that may appear in the final product.

Factory—see Chapter 1, §101 of this Part.

Inactive Ingredient—any component other than an Active Ingredient present in a drug.

Lot—a batch or any portion of a batch of a drug or, in the case of a drug manufactured in a continuous process, an amount of drug product in a unit of time or quantity in a manner that assures its uniformity and in either case which is

identified by a distinctive lot and has uniform character and quality within specified limits.

Lot Numbers or Control Numbers—any distinctive combination of letters or numbers, or both from which the complete history of the manufacture, control, packaging and distribution of a batch or lot of drug can be determined.

Materials Approval Unit—any organizational element having the authority and responsibility to approve or reject components, in processing materials, packaging components and final products.

Strength—

a. the concentration of the drug substance (for example: w/w, w/v or unit dose/volume basis); and/or

b. the potency, that is the therapeutic activity of the drug substance as indicated by appropriate laboratory test or by adequately developed or clinically controlled data expressed (for example: in terms of units by reference to a standard).

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:601 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1250 (June 2002).

**§1503. Permits
[formerly paragraph 6:192]**

A. No person shall operate any factory or process or repackage any drug within the state of Louisiana, without first applying for, paying the required fee and obtaining a permit to operate, issued by the state health officer.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:601 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1251 (June 2002).

**§1505. Public Display of Permits
[formerly part of paragraph 6:192]**

A. Every establishment regulated by this Part shall have displayed, at all times, in a place designated by the state health officer, a permit to operate.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:601 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1251 (June 2002).

**§1507. Permit Exemptions
[formerly paragraph 6:193]**

A. The following shall be exempt from the above permit procedures.

1. [formerly paragraph 6:193-1] Pharmacies that are operating under applicable state laws regulating the dispensing of prescription drugs and that do not manufacture, prepare, propagate, compound or process drugs for sale other than in the regular course of the profession of pharmacy including the dispensing and selling of drugs at retail.