Title 51
PUBLIC HEALTH—SANITARY CODE
Part VI. Manufacturing, Processing, Packing and Holding of Food, Drugs and Cosmetics

Chapter 1. General Regulations, Definitions, Permits, Registration, Machinery, Equipment and Utensils, Premises and Buildings, Temperature Control

§101. Definitions
[formerly paragraph 6:001]

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

Adulterated Foods, Filth, and *Contamination*—are defined in R.S. 40:607.

Advertisement—includes all representations of fact or opinion disseminated to the public in any manner or by any means other than by the labeling.

Bakery—any establishment operating to manufacture any bread or bread products, pies, cakes, cookies, crackers, doughnuts, or other similar products.

CCP—see *Critical Control Point*.

Confirmed Positive Test Result—any result obtained from a laboratory test of an ingredient, equipment, container, or finished product that indicates the presence of an adulterant, as defined by R.S. 40:607 et seq., in excess of any tolerance specified in state or federal law or regulations.

Control—to manage the conditions of an operation to maintain compliance with established criteria, *control* also means that correct procedures are being followed and criteria are being met.

Control Measure—any action or activity that can be used to prevent, eliminate, or reduce a significant *hazard* that is managed as a *critical control point*.

Control Point—any step at which biological, chemical or physical factors can be controlled.

Corrective Action—procedures followed when a *deviation* occurs.

Cosmetic—includes all substances and preparations intended for cleansing, altering the appearance of, or promoting the attractiveness of a person. The term includes soaps only when medicinal or curative qualities are claimed by the use thereof.

Critical Control Point (CCP) —a step at which *control* can be applied and is essential to prevent or eliminate a *food*, *drug*, or *cosmetic* safety *hazard* or reduce it to an acceptable level.

Critical Limit—the value(s) to which a biological, chemical or physical parameter must be controlled at a *CCP* to prevent, eliminate or reduce to an acceptable level the occurrence of a *food*, *drug*, or *cosmetic* safety *hazard*.

Deviation—a failure to meet a *critical limit*.

Device—includes all substances and preparations intended for use in diagnosis, treatment or prevention of disease in man or beast, or intended to affect the structure of any function of the body.

Drug—includes all substances and preparations recognized in the official compendium, as herein defined. It includes all substances and preparations intended for use in the diagnosis , treatment or prevention of disease in man or beast, and all substances and preparations, other than food and cosmetics, intended to affect the structure or any function of the body.

Factory—any establishment operating to manufacture, process, can, bottle, pack, or hold any food, drug or cosmetic unless covered by other specific provisions of this state sanitary code.

Food—includes all substances and preparations used for, or entering into the composition of food, drink, confectionery, chewing gum, condiment, for consumption by humans or other animals and includes water and alcoholic beverages.

Food Processing Plant—a commercial operation that manufactures *food* for human consumption and does not provide *food* directly to a consumer from that location. Such term shall not include a commercial operation that produces raw agricultural commodities and whose end product remains a raw agricultural product.

GMP—see *good manufacturing practices*.

Good Manufacturing Practices—practices, methods, and controls used in the manufacturing, processing, packing or holding of *foods*, *drugs* or *cosmetics* that comply with the requirements in this Part and for *foods*, with 21 CFR 110.10, 110.19, 110.20, 110.35, 110.37, 110.40, 110.80, and 110.93, to assure that *foods*, *drugs* or *cosmetics* for human consumption or use are safe and have been prepared, packed and held under sanitary conditions.

HAACP—see *hazard analysis critical control point*.

HAACP Plan—the written document which is based upon the principles of *HACCP* and which delineates the procedures to be followed.

HACCP System—the implemented *HACCP plan* and *pre-requisite programs* including any other applicable requirements.

Hazard—a biological, chemical, radiological or physical agent that is reasonably likely to cause illness or injury in the absence of its *control*.

Hazard Analysis Critical Control Point (HAACP)—a systematic approach to the identification, evaluation and control of significant *food*, *drug*, or *cosmetic* safety *hazards*.

Label—the principal display or displays of written, printed or graphic matter upon any food, drug device, or cosmetic, or the immediate container, thereof, or upon the outside container or wrapper, if any, of the retail package of any food, drug, device or cosmetic.

Labeling—includes all labels and other written, printed and graphic matter in any form whatsoever, accompanying any food, drug, device or cosmetic.

LSPC—Louisiana State Plumbing Code, i.e., Part XIV (Plumbing) of this Code (LAC 51:XIV).

Manufacturing Confectionary—any establishment operating to manufacture any candy, either plain, chocolate or chocolate coated, mixed with nuts, fruits, or other fillers, covered with chocolate or other coatings and shaped, molded or formed in various shapes.

Medical Opinion—the opinion, within their respective fields, of the practitioners of any branch of the medical profession, the practice of which is licensed by law in this state.

Monitor—to conduct a planned sequence of observations or measurements to assess whether a *CCP* is under control or to assess the conditions and practices of all required *Pre-Requisite Programs (PPs)* and to produce an accurate record for future use in *verification*.

Offal—waste parts, especially of a butchered animal, including but not limited to bones, cartilage, fatty tissue and gristle.

Patent or Proprietary Medicine—trademarks, registered or unregistered, consisting of word or words, device, symbol, brand or logo which serves to designate the source or origin of the drug or drug product.

Plant—the building or buildings or plants thereof, used for or in connection with the manufacturing, processing, packaging, labeling, or holding of food products.

PP—see *Pre-Requisite Program*.

Pre-Requisite Program (PP)—procedures, including *good manufacturing practices*, that address operational conditions providing the foundation for the *HACCP system*.

Sanitize—adequate treatment of surfaces by a process that will destroy vegetative cells of pathogenic bacteria and will substantially reduce other microorganisms. Such treatment shall not adversely affect products and shall be safe and non-toxic.

Scientific Opinion—the opinion, within their respective fields, of competent pharmacologists, physiologists or toxicologists. [R.S. 40:602 (12)]

State Health Officer—the legally appointed or acting State Health Officer of the Department of Health and Hospitals having jurisdiction over the entire state of Louisiana, and includes his/her duly authorized representative in accordance with R.S. 40:4 and 40:5.

Validation—the element of *verification* focused on collecting and evaluating scientific and technical information to determine whether the *HACCP plan*, when properly implemented, will effectively control the *hazards*.

Verification—those activities, other than *monitoring*, that determine the validity of the *HACCP plan* and that the system is operating according to the plan.

AUTHORITY NOTE: The first source of authority for promulgation of the *Sanitary Code* is in R.S. 36:258(B), with more particular provisions found in Chapters 1 and 4 of Title 40 of the *Louisiana Revised Statutes*. This Part is 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 28:1230 (June 2002), amended LR 36:2283 (October 2010), amended LR 38:2791 (November 2012).

§103. Permits
[formerly paragraph 6:002]

A. No person shall manufacture, process, pack, or hold food within the state of Louisiana without a valid permit to operate, issued by the state health officer.

B. [formerly paragraph 6:003] A permit shall be issued upon receipt of an application which shall be made on a form provided for that purpose by the state health officer; provided that no permit shall be issued until an inspection has been made of the factory and it has been found to be operating in compliance with the provisions of these regulations. The permit fee for a person operating as soft drink manufacturers shall be assessed a permit fee established by R.S. 40:713.

C. [formerly paragraph 6:004] Any permit to operate, issued by the state health officer, may be suspended or revoked if the establishment is found to be operating contrary to these regulations. The operation of such an establishment without a valid permit, or the continued operation after a permit has been revoked or suspended, shall constitute a violation of this code. Each day of noncompliance constitutes a separate violation.

D. [formerly paragraph 6:005] Permits to operate shall expire 12 months from the date of issue but may be renewed without inspection (if previous inspection within six months has shown them to be in compliance), on or before the expiration date; provided that any establishment shall be subject to inspection by the state health officer at any reasonable time during working hours.

E. [formerly paragraph 6:006] Permits shall be issued only to the person or persons responsible for the operations of the factory and shall not be transferable.

F. [formerly paragraph 6:007] No permit shall be issued to any individual to process in any way any filthy or contaminated food product to remove evidence of filth or contamination from the food in an attempt to recondition such material for human consumption; except where the process has been approved 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 28:1231 (June 2002).

§105. Registration of Foods, Drugs, Cosmetics and Prophylactic Devices [formerly paragraph 6:008-1]

A. Registration Provisions. In accordance with the provisions of R.S. 40:627, all processed foods, proprietary or patent medicines, prophylactic devices and cosmetics, in package form, must be registered annually with the Louisiana Food and Drug Control Unit of the OHSEQ/DHHR. Application for registration may be accomplished by using the appropriate form supplied by the Food and Drug Control Unit.

B. [formerly paragraph 6:008-2] Application for Registration, Firm Name. Application for registration shall be made in the name of the firm appearing on the labels.

C. [formerly paragraph 6:008-3] Safety and Efficacy. Products containing new ingredients cannot be registered unless the application for registration includes sufficient evidence to prove that they have been properly tested and found to be safe and effective for use.

D. [formerly paragraph 6:008-4] Seizure. Foods, drugs, prophylactic devices and cosmetics not meeting the provisions of R.S. 40:601 et seq., shall be seized.

E. [formerly paragraph 6:008-5] Penalty. All firms shall apply for annual registration of their products. These certificates of registration expire 12 months from the date of issuance. Any applications received in the Food and Drug Control Unit Office more than 45 days after expiration of the previous certificate shall be assessed a late registration fee as stipulated in R.S. 40:627(1).

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 28:1231 (June 2002).

§107. Prohibited Equipment; Exception [formerly paragraph 6:009-1]

A. The presence in a factory of any article of equipment, designed for processing filthy or contaminated foods in any way, whereby evidence of filth or contamination can be removed in whole or in part, is prohibited, except where such equipment is to be used in preparing such filthy or contaminated food for use in animal or stock feeds; or for other uses whereby the filthy or contaminated food cannot be diverted to use for human consumption; or where the process has been approved by the state health officer.

B. [formerly paragraph 6:009-2] When any such article of equipment is found in any food handling establishment or factory, except as provided above, it shall be prima facie evidence of intent to violate the State Food, Drug and Cosmetic Law (R.S. 40:601 et seq.), and there shall be affixed thereto, by the state health officer, a tag stating that such article is in violation of these regulations and the owner or operator of said equipment shall have it immediately removed from the establishment.

C. [formerly paragraph 6:009-3] No equipment so tagged shall again be used in connection with any food for human consumption, nor shall said tag be removed by any one other than the state health officer and then only after the article of equipment has been rendered unfit for further use, as evidenced by its dismantling.

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 28:1232 (June 2002).

§109. Lighting/Ventilation, Plans Submission, Construction and Materials; Insect and Rodent Control; Sanitary Facilities [formerly paragraph 6:010]

A. All factory buildings shall be well lighted with not less than 40 foot-candles on all working surfaces, and shall be well ventilated. In accordance with LAC 51:XIV.405.A.1.b, toilet rooms shall be provided with mechanical exhaust ventilation.

B. [formerly part of paragraph 6:011] Plans for new establishments shall be submitted to the state health officer for review and approval before construction.

C. [formerly part of paragraph 6:011] The manufacturing, processing, canning, bottling, packing or storage of any food intended for sale or distribution to the general public is prohibited in private residences or in buildings having direct openings to private residences.

D. [formerly paragraph 6:012] All floors, walls, ceilings, tables, and other fixtures shall be maintained in such a condition that they may be readily made clean and sanitary. This condition may be met by tables constructed entirely of either stainless steel or aluminum, and walls and ceilings constructed of marine plywood covered with a high solids epoxy paint. Fixtures and equipment meeting National Sanitation Foundation standards are also acceptable under this provision. If not in such condition they shall be promptly repaired and replaced. The floors of all rooms used for manufacturing shall be watertight and where there is necessity for drainage, shall have sufficient pitch to insure drainage. Floors may be constructed of cement or tile laid cement, or of any other materials impermeable to water. Portable or loose floor gratings shall be provided around blanchers, washers and other places where overflow is unavoidable.

E. [formerly paragraph 6:013] Walls, ceilings and other overhead coverings shall be tight and smooth; parts thereof not finished in tile, glazed, or other similar material shall be

kept well painted with a light colored paint so that they may be easily cleaned whenever they become soiled or dirty.

F. [formerly paragraph 6:014] Windows, window ledges or any other places where dirt and dust may accumulate shall be kept clean.

G. [formerly paragraph 6:015] All fixtures, utensils or other apparatus used in the manufacture, handling or storing of foods shall be of material approved by the state health officer as to be easily cleanable and shall be kept clean.

H. [formerly paragraph 6:016] Factories shall be free of flies, rats, mice and other vermin. All insecticides or pesticides used in any room where foods are processed, prepared, packed or stored shall be of a type accepted by the state health officer. Insecticides shall be used and applied according to label directions on each container as required by the United States Environmental Protection Agency (or its successor) and the Louisiana Department of Agriculture.

I. [formerly paragraph 6:017] Every factory shall be provided with toilet and hand washing facilities as required by LAC 51:XIV.411, entitled "Minimum Plumbing Fixtures." Handwashing facilities shall be located convenient to all restrooms and food processing areas. Facilities shall be equipped with hot and cold water under pressure, delivered through a mixer faucet. Soap and sanitary towels or air dryer shall be provided at each lavatory.

J. [formerly paragraph 6:018] Every factory using brine or syrup shall be equipped with a room known as a syrup or brine room in which all syrups or brines shall be mixed or compounded. Such syrup or brine room shall be separated from the other rooms of the factory and shall be well lighted, ventilated, and protected against insects and vermin.

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 28:1232 (June 2002), amended LR 38:2791 (November 2012).

§111. Premises—Drainage, Litter and Waste or Refuse, Weeds and Grass [formerly paragraph 6:019]

A. All grounds on which factories, warehouses and other buildings or structures used in connection with any food manufacturing plant are located, shall be properly graded to provide a natural drainage, thus preventing accumulation of stagnant water and other material.

B. [formerly paragraph 6:020] No litter, wastes or refuse shall be allowed to accumulate in or around the building or yards. Garbage and trash shall be removed from the premises as often as necessary, but not less than twice weekly so that it will not accumulate and provide a breeding and harborage area for rodents and insects.

C. [formerly paragraph 6:021] Weeds and grass surrounding and on plant grounds shall not exceed 6 inches in height. Ornamental shrubbery shall be trimmed and maintained so as not to foster harborage and breeding of rodents, insects or other vermin. Dusts of premises shall not exceed the following limits.

Fibrosis Producing and Nuisance Dusts	
Dusts	**Particles per Cubic Foot of Atmosphere**
Silica (Si02)(Product of particles per cubic foot times per cent free silica, expressed as a decimal, not to exceed 5,000,000).	5,000,000 to 100,000,000
Compounds containing silicon (Si) such as talc, emery, and Carborundum.	50,000,000
Nuisance Dusts	100,000,000
No asbestos dust is acceptable.	

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 28:1233 (June 2002).

§113. Water Supply—Ample Supply, Not Cross-Connected, Drinking Fountains [formerly paragraph 6:022]

A. An ample supply of potable water under pressure shall be provided on the premises for drinking, cleansing, washing or other purposes. Such water supply shall not be cross connected to any other supply. Water supply lines connected to plant equipment such as picking tables, bottle or can washers, cookers, retorts, or other utensils shall have the water lines properly installed or protected to prevent contamination of the water supply through back-siphonage or backflow.

B. [formerly paragraph 6:023] Drinking fountains shall be provided as required by LAC 51:XIV.411, entitled "Minimum Plumbing Fixtures." Drinking fountains shall meet the specifications as described in LAC 51:XIV.415.C or obtain approval of the state health officer.

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 28:1233 (June 2002), amended LR 38:2791 (November 2012).

§115. Machinery, Equipment and Utensils [formerly paragraph 6:024]

A. All machinery, equipment, and utensils shall be so arranged as to be easily accessible for cleaning and shall be kept clean.

B. [formerly paragraph 6:025] An ample supply of steam, water, sanitizing agent, hoses, or other equipment necessary for proper cleaning of equipment shall be available. Hose ends or nozzles shall not be allowed to lie or rest on the floor but shall be hung or racked when not in use so as to be protected at all times from contamination. Faucets threaded for hoses shall be provided with vacuum breakers to prevent back-siphonage.

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 28:1233 (June 2002).

§117. Containers
[formerly paragraph 6:026]

A. Containers to be filled with beverage shall be stored in tight containers on shelving so as to prevent contamination by dust, rodents, birds, insects or other vermin.

B. [formerly paragraph 6:027] Lofts or other storage areas in which containers are stored shall be kept free from accumulations of waste paper or other litter.

C. [formerly paragraph 6:028] Only non-toxic containers and closures shall be used. (Glass, high-density polyethylene, and polypropylene containers are examples which meet this requirement.) All containers and closures shall be sampled and inspected to ascertain that they are free from contamination. At least once each three months, a bacteriological swab and/or rinse count should be made from at least four containers and closures selected just prior to filling and sealing. No more than one of the four samples may exceed more than one bacteria per milliliter of capacity or one colony per square centimeter of surface area. All samples shall be free of coliform organisms. Tests shall be performed either by qualified plant personnel or a competent commercial laboratory.

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 28:1233 (June 2002).

§119. Bottle Washers
[formerly paragraph 6:029]

A. Mechanical bottle washers shall be provided for sterilization of multi-use containers. Bottle washers shall sterilize containers as required by the State Second Hand Containers Law (R.S. 40:681 et seq.), and the regulations promulgated thereunder.

B. [formerly paragraph 6:030] Can washers and feeder lines shall be so arranged as to prevent the waste water from dripping on employees or dripping back into the cleaned cans or those filled with food products. Can washers with overhead devices shall be located in areas that are not designated employee work areas.

C. [formerly paragraph 6:031] If secondhand bottles or other containers are used, they shall be cleaned and sterilized in compliance with R.S. 40:681.

D. [formerly paragraph 6:032] Employee Health: 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 28:1233 (June 2002).

§121. By-Products and Waste Material
[formerly paragraph 6:033]

A. By-products to be used for ensilage should be put in silos, but if stacked in the open at the factory, a foundation of concrete or other impervious material shall be provided to prevent soil pollution.

B. [formerly paragraph 6:034] Drainage must be provided to take care of ensilage juices. Drains shall be of size and construction as specified in Table 725.A.1, "Building Drains and Sewers," of the LSPC.

C. [formerly paragraph 6:035] Cribbing shall be provided for all open stacks of refuse to ensure retention of the material on the foundation.

D. [formerly paragraph 6:036] All waste material such as waste peas, trimmings from vegetables and other waste products shall be separated from the waste or wash water and conveyed to silo or stacked or removed from the premises daily.

E. [formerly paragraph 6:037] Covered gutters or drains that can be easily cleaned and kept in efficient operating condition shall be provided within the building for collecting and conducting waste or wash water to a dump or drainage pit, which shall be provided with a suitable screen or separator for removing all coarse waste material from the water.

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 28:1234 (June 2002), amended LR 38:2791 (November 2012).

§123. Temperature Control
[formerly paragraph 6:038]

A. Foods requiring temperature control shall be held below 45°F or above 145°F, or in the case of frozen food, shall be held at or below 0°F.

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 28:1234 (June 2002).

§125. Food Processing Plan

A. This Section shall become effective on January 1, 2011.

B. All food processing plants operating within the state of Louisiana shall maintain on-site a written food processing plan that shall be available for review upon request by the state health officer.

C. The food processing plan shall include, at a minimum, the following information:

1. a list of processing steps used to manufacture products, including potential biological, chemical, radiological or physical hazards that may be inherent to or introduced to the product at each step;

2. a description of preventative controls used in each step to control listed hazards;

3. a description of monitoring methods used to verify efficacy of preventative controls;

4. records of any corrective actions taken as a result of such monitoring; and

5. records of any amendments to the plan as a result of corrective actions.

D. Any food processing plant that currently holds and maintains a HACCP plan meeting the requirements of United States Department of Agriculture or Food and Drug Administration regulations shall be considered to be in compliance with this Section.

E. Any person or firm operating a food processing plant that violates the provisions of this Section shall be subject to a civil fine of not more than $500.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4(A)(1)(a), R.S. 40:5(2)(3)(5)(8)(15)(17)(19)(21) and R.S. 40: 652.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 36:2284 (October 2010).

§127. Food Recall Plan

A. This Section shall become effective on January 1, 2011.

B. General. All food processing plants operating within the state of Louisiana shall maintain a written food recall plan that shall be available for review upon request by the state health officer. The owners and operators shall amend their written food recall plan with any recommendations deemed necessary by the state health officer to make such plan effective for food safety concerns.

C. Notification. The food recall plan shall include, at a minimum, the provision for notification of representatives of the Food and Drug Unit of the Office of Public Health of the Department of Health and Hospitals. In addition, for any products subject to recall that may have been involved in interstate commerce, the food recall plan shall have additional provisions to notify the Food and Drug Administration. Notification shall include, at a minimum, the following information:

1. the identity of the product(s) under recall, including name and lot number or batch code;

2. the reason for the recall;

3. the date and means of discovery of the reason for the recall;

4. total amount of product and amount estimated to be in distribution;

5. list of consignees that have or may have received affected product;

6. contact information for a responsible person at the firm who will oversee the recall; and

7. proposed strategy for conducting the recall.

D. Suppliers and Consignees. The food processing plant shall maintain a current list of suppliers and consignees for all ingredients and finished goods used in the manufacturing or distribution of the firm's products. Such list(s) shall be available for review by the state health officer.

E. Communication with the Public. The food recall plan shall include the proposed mode(s) of public communication including, as necessary, telephone, letter, website, and media outlet (newspaper, television, radio, and/or other sources) notifications.

F. Level(s) of Recall. The food recall plan shall include a method or procedure for evaluating whether the recall needs to be conducted at the wholesale, retail, or consumer levels, or if some combination is appropriate.

G. Effectiveness Checks. The food recall plan shall include provisions for conducting effectiveness checks, at the appropriate level(s) as determined necessary in Subsection F of this Section, by means of telephone interviews, site visits, or other effective means of communication.

H. Post Recall Evaluation. The food recall plan shall require a re-evaluation of all elements of the recall plan after a recall has been conducted to correct deficiencies or enhance overall effectiveness.

I. Nothing in this Section shall prevent the state health officer from exercising his authority to protect the public from adulterated or misbranded products by seizure and/or destruction of defective products in accordance with R.S. 40:632 and §105.D of this Chapter.

J. Any person or firm operating a food processing plant that violates the provisions of this Section shall be subject to a civil fine of not more than $500.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40: 4(A)(1)(a), R.S. 40:5(2)(3)(5)(8)(15)(17)(19)(21) and R.S. 40: 653.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 36:2284 (October 2010).

§129. Laboratory Test Reporting Requirements and Additional Test Mandate

A. When a person or firm operating a food processing plant in the state of Louisiana receives information from an in-house or external laboratory analyzing samples or specimens of finished foods or finished ingredients which indicates a confirmed positive test result signifying that the food or ingredient may be adulterated (in accordance with the definitions provided in R.S. 40:607, et seq.) or may otherwise constitute an imminent health hazard, the person or firm shall report this confirmed positive test result to representatives of the Food and Drug Unit of the Office of Public Health of the Department of Health and Hospitals within 24 hours of obtaining such information.

B. The state health officer may, based upon a demonstration of probable cause by the Department of

Health and Hospitals indicating that a food processing plant is producing food which may be adulterated (in accordance with the definitions provided in R.S. 40:607 et seq.) or in such a manner as to cause an imminent health hazard, order the food processing plant to submit samples to a laboratory specified by the department for testing at the food processing facility's expense. A copy of the written or electronic results of such testing, including a reference to test methods used, shall be furnished by the food processing plant or by the laboratory to the department as soon as a confirmed test result (either positive or negative) is available but no later than 24 hours of obtaining such information.

C. Any person or firm operating a food processing plant that violates the provisions of this Section shall be subject to a civil fine of not more than $1,000.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40: 4(A)(1)(a), R.S. 40:5(2)(3)(5)(8)(15)(17)(19)(21) and R.S. 40: 654.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 36:2284 (October 2010).

Chapter 3. Current Good Manufacturing Practices in Manufacturing, Processing, Packing or Holding Human Food

§301. General Provisions; Code of Federal Regulations [formerly paragraph 6:039]

A. The Criteria in 21 CFR 110.10, 110.19, 110.20, 110.35, 110.37, 110.40, 110.80, and 110.93 (Code of Federal Regulations) shall apply in determining whether the facilities, methods, practices, and controls used in the manufacturing, processing, packing or holding of food are in conformance with or are operated or administered in conformity with good manufacturing practices to assure that food for human consumption is safe and has been prepared, packed and held under sanitary conditions.

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 28:1234 (June 2002).

§303. Definitions [formerly paragraph 6:040]

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.

Adequate—shall be explained in each case in which it is used.

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

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

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 28:1234 (June 2002).

§305. Requirements Affecting Employees; Personnel [formerly paragraph 6:041]

A. The plant management shall take all reasonable measures and precautions to assure the following.

B. [formerly paragraph 6:042] Disease Control. Employees shall meet the requirements of Part I, §117 of this Code.

C. [formerly paragraph 6:043] Cleanliness. All persons, while working in direct contact with food preparation, food ingredients, or surfaces coming into contact therewith shall comply with the following Paragraphs in this Section.

1. [formerly paragraph 6:044] Wear clean outer garments, maintain personal cleanliness, and conform to hygienic practices (as defined in the following regulations) while on duty, to the extent necessary to prevent contamination of food products.

2. [formerly paragraph 6:045] Thoroughly wash their hands and the exposed portions of their arms with soap and warm water before starting work, during work as often as is necessary to keep them clean, and after smoking, eating, drinking, or using the toilet. Employees shall keep their fingernails clean and trimmed.

3. [formerly paragraph 6:046] Remove all insecure jewelry and, during periods where food is manipulated by hand, remove from hands any jewelry that cannot be adequately sanitized.

4. [formerly paragraph 6:047] If gloves are used in food handling, maintain them in an intact, clean and sanitary condition. Smooth impermeable gloves can be used in such operations as sandwich preparation or other indirect food contact. Leather or cloth type gloves shall not be used in direct food contact.

5. [formerly paragraph 6:048] Wear hair nets, headbands, caps, or other effective hair restraints.

6. [formerly paragraph 6:049] No store clothing or other personal belongings, eat food or drink beverages, or use tobacco in any form in areas where food or food ingredients are exposed or in areas used for washing equipment or utensils.

7. [formerly paragraph 6:050] Take any other necessary precautions to prevent contamination of foods with microorganisms or foreign substances including, but not limited to, perspiration, hair, cosmetics, tobacco, chemicals, and medications.

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 28:1234 (June 2002).

§307. Education and Training [formerly paragraph 6:051]

A. Personnel responsible for identifying sanitation failures or food contamination should have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe food. Food handlers and supervisors should receive appropriate training in proper food handling techniques and food protection principles and should be cognizant to the danger of poor personal hygiene and insanitary practices.

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 28:1235 (June 2002).

§309. Supervision of Personnel [formerly paragraph 6:052]

A. Responsibility for assuring compliance by all personnel with all requirements of this Part shall be clearly assigned to competent supervisory personnel.

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 28:1235 (June 2002).

§311. Plants and Grounds [formerly paragraph 6:053]

A. The grounds about a food plant under the control of the operator shall be free from conditions which may result in the contamination of food including, but not limited to, the following Paragraphs in this Section.

1. [formerly paragraph 6:054] Improperly stored equipment, litter, waste, refuse, and uncut weeds or grass within the immediate vicinity of the plant buildings or structures that may constitute an attractant, breeding place, or harborage for rodents, insects, and other pests. For example, unused equipment shall not be stored in the yard; grass shall not be allowed to grow over 6 inches in height; garbage, refuse, litter, waste, etc., cannot be stored in uncovered containers or in bags.

2. [formerly paragraph 6:055] Excessively dusty roads, yards, or parking lots that may constitute a source of contamination in areas where food is exposed.

3. [formerly paragraph 6:056] Inadequately drained areas that may contribute contamination to food products through seepage or food-borne filth and by providing a breeding place for insects or microorganisms.

a. If the plant grounds are bordered by grounds not under the operator's control of the kind described in §311.A.1-3 of this Chapter, care must be exercised in the plant by inspection, extermination, or other means to effect exclusion of pests, dirt, and other filth that may be a source of food 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 28:1235 (June 2002).

§313. Plant Construction and Design [formerly paragraph 6:057]

A. Plant buildings and structures shall be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-processing purposes. The plant and facilities shall comply with the following paragraphs.

1. [formerly paragraph 6:058] Provide sufficient space for such placement of equipment and storage of materials as is necessary for sanitary operations and production of safe food. Floors, walls, and ceilings in the plant shall be of such construction as to be readily cleanable and shall be kept clean and in good repair. Fixtures, ducts, and pipes that drip or produce condensate may contaminate foods, raw materials or food-contact surfaces, and shall not be suspended over working areas. Aisles or working spaces between equipment and walls shall be unobstructed and of sufficient width to permit employees to perform their duties without contamination of food or food contact surfaces with clothing or personal contact.

2. [formerly paragraph 6:059] Provide separation by partition, location, or other effective means for those operations which may cause contamination of food products with undesirable microorganisms, chemicals, filth or other extraneous material.

3. [formerly paragraph 6:060] Provide at least 40 foot-candles of lighting to hand washing areas, dressing and locker rooms, and toilet rooms and to all areas where food or food ingredients are examined, processed, or stored and where equipment and utensils are cleaned. Light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation shall be of the safety type or otherwise protected to prevent food contamination in case of breakage.

4. [formerly paragraph 6:061] Provide adequate ventilation or control equipment to minimize odors and noxious fumes or vapors (including steam) in areas where they may contaminate food. Such ventilation or control equipment shall not create conditions that may contribute to food contamination by airborne contaminants.

5. [formerly paragraph 6:062] Provide, where necessary, effective screening or other protection against birds, animals, and vermin (including, but not limited to, insects and rodents).

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 28:1235 (June 2002).

§315. Sanitary Facilities and Controls [formerly paragraph 6:063]

A. Each plant shall be equipped with adequate sanitary facilities and accommodations including, but not limited to, the following Paragraphs in this Section.

1. [formerly paragraph 6:064] Water Supply. The water supply shall be sufficient for the operations intended and shall be derived from a potable source. Any water that contacts foods or food contact surfaces shall be safe and of sanitary quality. Running water at a suitable temperature and under pressure as needed shall be provided in all areas where the processing of food, the cleaning of equipment, utensils, or containers, or employee sanitary facilities require.

2. [formerly paragraph 6:065] Sewage Disposal. Sewage disposal shall be made into a sewerage system or by other means approved 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 28:1235 (June 2002).

§317. Plumbing [formerly paragraph 6:066]

A. Plumbing shall be of size and design and installed and maintained according to Part XIV of this Code.

B. [formerly paragraph 6:067] Plumbing shall also meet the following requirements:

1. [formerly paragraph 6:067-1] carry sufficient quantities of water to required locations throughout the plant;

2. [formerly paragraph 6:067-2] properly convey sewage and liquid disposable water from the plant;

3. [formerly paragraph 6:067-3] not constitute a source of contamination to foods, food products or ingredients, water supplies, equipment, or utensils or create an insanitary condition;

4. [formerly paragraph 6:067-4] provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release discharge water or other liquid waste on the floor.

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 28:1236 (June 2002).

§319. Toilet Facilities [formerly paragraph 6:068]

A. Each plant shall provide its employees with toilet and associated hand washing facilities within the plant according to requirements of LAC 51:XIV.411 and each toilet shall be furnished with toilet tissue. The facilities shall be maintained in a sanitary condition and kept in good repair at all times. Doors to toilet rooms shall be self-closing and shall not open directly into areas where food is exposed to airborne contamination except where alternate means have been taken to prevent such contamination (such as double doors, positive air flow systems, etc.). Signs shall be posted directing employees to wash their hands with cleaning soap or detergents after using the toilet.

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 28:1236 (June 2002), amended LR 38:2791 (November 2012).

§321. Hand Washing Facilities [formerly paragraph 6:069]

A. Facilities for hand washing and, where appropriate, sanitizing solution shall be provided at each location in the plant where good sanitary practices require employees to wash or sanitize and dry their hands, and at least in areas where foods are handled. Numbers of lavatories shall be provided as required in LAC 51:XIV.411. Such facilities shall be furnished with running water at a suitable temperature for hand washing, effective hand cleaning and sanitizing preparations, sanitary towel service or suitable drying devices, and, where appropriate, easily cleanable waste receptacles.

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 28:1236 (June 2002), amended LR 38:2791 (November 2012).

§323. Rubbish and Offal Disposal [formerly paragraph 6:070]

A. Rubbish and any offal shall be so conveyed, stored, and disposed of as to minimize the development of odor, prevent waste from becoming an attractant and harborage or breeding place for vermin, and prevent contamination of food, food contact surfaces, ground surfaces, and 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 28:1236 (June 2002).

§325. Sanitary Operations—General Maintenance [formerly paragraph 6:071]

A. All buildings, fixtures, and other physical facilities of the plant shall be kept in good repair and shall be maintained in a sanitary condition.

B. [formerly a part of paragraph 6:071] Cleaning operations shall be conducted in such a manner as to minimize the danger of contamination of food and food-contact surfaces. (For example, floors shall be sprinkled to hold down dust prior to sweeping operations.)

C. [formerly a part of Paragraph 6:071] Detergents, sanitizers, and other supplies employed in cleaning and sanitizing procedures shall be free of significant microbiological contamination and shall be safe and effective for their intended uses. Only such toxic materials as are required to maintain sanitary conditions, for use in laboratory testing procedures, for plant and equipment maintenance and operation, or in manufacturing or processing operations shall be used or stored in the plant. These materials shall be identified and used only in such manner and under conditions as will be safe for their intended uses.

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 28:1236 (June 2002).

§327. Animal, Vermin and Pest Control [formerly paragraph 6:072]

A. No animals or birds, other than those essential as raw material, shall be allowed in any area of a food plant. Measures shall be taken to exclude pests from the processing areas and to protect against the contamination of foods in or on the premises by animals, birds, and vermin (including, but not limited to, rodents and insects). The use of insecticides or rodenticides is permitted only under such precautions and restrictions as will prevent the contamination of food or packaging materials with illegal residues. Insecticides and rodenticides shall be used and applied according to label directions on each container as required by the United States Environmental Protection Agency or its successor.

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 28:1236 (June 2002).

§329. Sanitation of Equipment and Utensils [formerly paragraph 6:073]

A. All utensils and food contact surfaces of equipment shall be cleaned as frequently as necessary to prevent contamination of food and food products. Non-food contact surfaces of equipment used in the operation of food plants shall be cleaned as frequently as necessary to minimize accumulation of dust, dirt, food particles, and other debris. Single-service articles (such as utensils intended for one-time use, paper cups, paper towels, etc.) shall be stored in appropriate containers and handled, dispensed, used and disposed of in a manner that prevents contamination of food or food contact surfaces. Where necessary to prevent the introduction of undesirable microbiological organisms into food products, all utensils and product contact surfaces of equipment used in the plant shall be cleaned and sanitized prior to such use and following any interruption during which such utensils and contact surfaces may have become contaminated.

B. [formerly a part of paragraph 6:073] Where such equipment and utensils are used in continuous production operation, the contact surfaces of such equipment and utensils shall be cleaned and sanitized on a predetermined schedule using effective methods for cleaning and sanitizing. Sanitizing agents shall be effective and safe under conditions of use. Any facility, procedure, machine, or device may be acceptable for cleaning and sanitizing equipment utensils if it is established that such facility, procedure, machine, or device will routinely render equipment and utensils clean and provide adequate sanitizing treatment.

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 28:1237 (June 2002).

§331. Storage and Handling of Equipment and Utensils [formerly paragraph 6:074]

A. Storage and handling of cleaned portable equipment and utensils with product contact surfaces should be stored in such a location and manner that product contact surfaces are protected from splash, dust, and other 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 28:1237 (June 2002).

§333. Equipment and Procedures—General [formerly paragraph 6:075]

A. All plant equipment and utensils shall be:

1. suitable for their intended use;

2. so designed and of such material and workmanship as to be easily cleanable; and

3. properly maintained.

B. The design, construction, and use of such equipment and utensils shall preclude the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants. All equipment shall be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces.

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 28:1237 (June 2002).

§335. Use of Polychlorinated Biphenyls (PCB) in Food Plants [formerly paragraph 6:076]

A. Polychlorinated biphenyls (PCB's) represent a class of toxic industrial chemicals manufactured and sold under a variety of trade names, including: Aroclor (United States); Phenoclor (France); Colohen (Germany); and Kanaclor (Japan). PCB's are highly stable, heat resistant, and nonflammable chemicals. Industrial uses of PCB's include, or did include in the past, their use as electrical transformer and capacitor fluids, heat transfer fluids, hydraulic fluids, and plasticizers, and in formulations of lubricants, coatings, and inks. Their unique physical and chemical properties, and widespread, uncontrolled industrial applications, have caused PCB's to be a persistent and ubiquitous contaminant in the environment which may cause the contamination of certain foods. In addition, incidents have occurred in which PCB's have directly contaminated animal feeds as a result of industrial accidents (leakage or spillage of PCB's fluids from plant equipment). These accidents in turn cause the contamination of food intended for human consumption (meat, milk, and eggs).

B. Since PCB's are toxic chemicals, the PCB contamination of food as a result of these accidents represents a hazard to human health. It is therefore necessary to place certain restrictions on the industrial uses of PCB's in the production, handling, and storage of food.

1. [formerly a part of paragraph 6:076] New equipment, utensils, and machinery for handling or processing food in or around a food plant shall not contain PCB's so as to preclude accidental PCB contamination of 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 28:1237 (June 2002).

§337. Management and Abatement of PCB within Food Plants [formerly paragraph 6:077]

A. The management of food plants shall meet the following requirements:

1. [formerly paragraph 6:077-1] have the heat exchange fluid used in existing equipment or machinery for handling of processing food sampled and tested to determine whether it contains PCB's, or verify the absence of PCB's in such formulations by other appropriate means. Any such fluid formulated with PCB's shall be replaced with a heat exchange fluid that does not contain PCB's;

2. [formerly paragraph 6:077-2] eliminate from the food plant any PCB contact surfaces of equipment or utensils and any PCB containing lubricants for equipment or machinery that is used for handling or processing foods;

3. [formerly paragraph 6:077-3] eliminate from the food plant any other PCB containing materials wherever such materials could cause food to become contaminated with PCB's either as a result of use of or as a result of accident, breakage, or other mishap.

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 28:1237 (June 2002).

§339. Toxicity of PCB Replacement Fluids [formerly paragraph 6:078]

A. The toxicity and other characteristics of fluids selected as PCB replacements shall be adequately determined so that the least potentially hazardous replacement is used. In making this determination with respect to a given fluid, consideration should be given to: (a) its toxicity; (b) the maximum quantity that could be spilled onto a given quantity of food before it would be noticed, taking into account its color and odor; (c) possible signaling devices in the equipment to indicate a loss of fluid, etc; and (d) its environmental stability and tendency to survive and be concentrated through the food chain. The judgment as to whether a replacement fluid is sufficiently nonhazardous is to be made on an individual installation and operation basis.

1. [formerly paragraph 6:079] For the purposes of this Section, the provisions do not apply to electrical transformers and condensers containing PCB's in sealed containers.

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 28:1238 (June 2002).

Chapter 5. Bakeries and Manufacturing Confectioneries

§501. Definitions [formerly paragraph 6:080]

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.

Bakery—see Chapter 1, §101 of this Part of this Code.

Manufacturing Confectionery—see Chapter 1, §101 of this Part 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 28:1238 (June 2002).

§503. Required Permits [formerly paragraph 6:081]

A. Bakeries and manufacturing confectioneries shall have a permit from the state health officer, in accordance with the provisions of Chapter 1, §103 of this Part 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 28:1238 (June 2002).

§505. Building Construction Requirements [formerly paragraph 6:082]

A. Any building used or maintained as a bakery or manufacturing confectionery shall comply with the following requirements in this Section.

1. [formerly paragraph 6:083] Adequate plans and specifications for new establishments shall be submitted to the state health officer for approval before construction. Plans for establishments to sell only at retail shall be submitted to the local health unit.

2. [formerly paragraph 6:083-1] Floors shall be constructed with concrete, tile, glazed brick or other impervious materials sloped to drain quickly and effectively so that they may be easily cleaned. All drains shall be trapped.

3. [formerly paragraph 6:083-2] Walls and ceilings shall be smooth, tight, impervious and light colored and shall be kept clean.

4. [formerly paragraph 6:083-3] All outside openings shall be protected against flies and other vermin.

5. [formerly paragraph 6:083-4] Any bakery or manufacturing confectionery maintaining or operating a retail salesroom in connection therewith, shall provide a separate room for such retail operations and only personnel engaged in the manufacture, baking, cooking, molding or otherwise preparing bakery or confectionery products shall be permitted in the processing area except on permission from the management; provided, any duly authorized representative of the state health officer shall have access during reasonable working hours to make inspections and to collect samples for examination to determine whether the products sampled are adulterated, misbranded or otherwise manufactured, packed, prepared or held in violation of the sanitary code, or of the State Food, Drug and Cosmetic Law (R.S. 40:601 et seq.).

6. [formerly paragraph 6:083.5] All rooms shall be well lighted, either naturally and/or artificially, and shall be well ventilated. A minimum of 40 foot-candles shall be provided for all work surfaces. When necessary to prevent accumulations of smoke, fumes heat or odors, forced draft ventilation shall be provided.

7. [formerly paragraph 6:083-6] A supply of potable water shall be available. Running hot and cold water delivered through a mixer faucet shall be required in amounts sufficient to give an abundance of water for all cleaning operations in and about the establishment. No cross-connection between the potable water supply and any unapproved water supply or any sewage disposal system shall be permitted.

8. [formerly paragraph 6:083-7] The building shall be constructed so as to exclude rats, mice, roaches or other vermin. Domestic pets shall be excluded in any part of the establishment.

9. [formerly paragraph 6:083-8] A locker room, separate from the food preparation rooms, shall be provided for employees.

10. [formerly paragraph 6:083-9] Storage space separate from preparation and manufacturing areas shall be provided for all raw ingredients, packing boxes or other goods to be used in the manufacture, storage, packing or preparation of any food product. Storage space shall be rodent and vermin proof and so constructed and maintained as to permit easy fumigation, fogging, crack and crevice treatment and other established methods of pest control.

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 28:1238 (June 2002).

§507. Equipment [formerly paragraph 6:084]

A. All equipment used or connected in any way with the manufacture, baking, cooking or other processing, handling, packing or storing of any bakery or confectionery product shall comply with the following:

1. [formerly paragraph 6:084-1] be maintained in a clean and sanitary manner, be free from cracks and wherever possible, be of non-corroding, metal or other smooth, impervious material giving an easily cleanable surface. Stationary or not readily movable equipment shall be so installed as to provide for easy cleaning;

2. [formerly paragraph 6:084.2] refrigeration shall be provided so that all perishable food products used in the manufacturer processing of any kind connected with the production, distribution or sale of bakery or confectionery products shall be maintained at a temperature not to exceed 45°F;

3. [formerly paragraph 6:084-3] adequate show or display cases shall be provided so that no bakery or confectionery product shall be openly exposed;

4. [formerly paragraph 6:084-4] sinks, adequate in size to clean the largest piece of movable equipment, and sufficient in number for washing, rinsing and sanitizing of utensils used in and around the establishment shall be provided. Sinks shall be of three compartment construction;

5. [formerly paragraph 6:084-5] equipment too large to permit washing in the sinks shall be cleaned in a manner approved by the state health officer;

6. [formerly paragraph 6:084-6] all barrels, boxes, tubs, pails, kneading troughs, machines, racks, pans or other receptacles used for holding materials from which bakery or confectionery products are manufactured shall be kept clean and sanitary and shall be so constructed as to be easily cleanable;

7. [formerly paragraph 6:084-7] all food contact surfaces shall be cleaned and sanitized after each day's production.

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 28:1239 (June 2002).

§509. General Provisions; Time/Temperature Controls for Preparation of Fresh Custard and Cream Fillings [formerly paragraph 6:085]

A. Supplies used in the manufacture of bakery and confectionery products shall be stored outside of the preparation areas or rooms. flour, sugar and other similar products shall be protected from dampness and vermin. All ingredients shall be stored on racks or shelves at least 6 inches off the floor, and so arranged as to permit cleaning around and under the containers. No spoiled, rancid or unwholesome ingredients of any type shall be used in the manufacture of any bakery or confectionery product, nor shall such material be permitted to remain in such a manufacturing plant.

B. [formerly paragraph 6:086] No box, paper, trash, furniture or other article not used in the preparation of any bakery or confectionery product shall be allowed in food preparation rooms, nor shall an accumulation of boxes, rubbish, trash or waste be permitted about the establishment, nor shall any slops of waste matter be thrown or emptied on the ground about the premises. Garbage shall be kept in water tight receptacles with tightly fitting lids. Garbage and trash shall be removed from the premises as often as necessary so that it will not accumulate and provide a breeding and harborage area for rodents and insects.

C. [formerly paragraph 6:087] Every bakery or manufacturing confectionery shall provide toilet facilities for employees as required by LAC 51:XIV.411. All toilet rooms shall have at least 20 foot-candles of lighting and, in accordance with LAC 51:XIV.405.A.1.b, mechanical exhaust ventilation. Toilet rooms shall be kept clean and in good repair.

D. [formerly paragraph 6:088] Lavatory (hand washing) facilities shall be provided in all restrooms in accordance with LAC 51:XIV.411 and an additional lavatory/lavatories shall be conveniently located in each of the food processing and handling areas. Facilities shall be equipped with hot and cold water under pressure, delivered through a mixer faucet. Soap and sanitary towels or air dryer shall be provided at each lavatory.

E. [formerly paragraph 6:089] All employees of any bakery or manufacturing confectionery shall comply with §§305-309 of Chapter 3 of this Part.

F. [formerly paragraph 6:090] No bed or cot shall be permitted in any bakery or manufacturing confectionery, nor shall any living quarters open directly into the preparation rooms of such establishments.

G. [formerly paragraph 6:091] No bakery or confectionery product shall be delivered to any retailer by placing such products in a box or other receptacle located outside of the retail establishment, unless this receptacle has been approved by the state health officer.

H. [formerly paragraph 6:092] Only pasteurized milk or milk products shall be used in the preparation of custard and cream-filled bakery products.

I. [formerly paragraph 6:093] All custard or cream-filled mixtures shall be cooked, the temperature and time of heating of the mix, to be as a minimum, the equivalent of a temperature of 145°F for a period of not less than 30 minutes.

J. formerly paragraph 6:094] Upon completion of the cooking of the mix, it shall be immediately transferred into previously sanitized containers, properly covered and chilled as rapidly as possible to 45°F or below and maintained at such a temperature until used.

K. [formerly paragraph 6:095] The apparatus and food contact surfaces used in adding any custard or cream filling to a bakery product shall be of impervious material and shall be thoroughly cleaned and sanitized after each use, in a manner approved by the state health officer. No cloth filled bags shall be used.

L. [formerly paragraph 6:096] Employees engaged in the preparation of custard or cream-filled bakery products shall not touch the custard or cream filling with their hands after it has been cooked.

M. [formerly paragraph 6:097] No pastry containing a custard or cream filling shall be displayed in any window or show case except those that are refrigerated or chilled to a temperature of 45°F, or below.

N. [formerly paragraph 6:098] Pastries containing custard or cream filling shall not be sold or delivered from vehicles, except where such vehicles are equipped with a refrigerated compartment where the temperature is maintained at 45°F or below; provided, however, that such pastries may be delivered from manufacturers to retail dealers or consumers by special trip without refrigeration when it is possible to complete such delivery within two hours elapsed time.

O. [formerly paragraph 6:099] All bakery products in package form shall be labeled in compliance with the State Food, Drug and Cosmetic Law, as provided for in R.S. 40:608.

P. [formerly paragraph 6:100] Transportation of any bread, pastry or confectionery product for subsequent display or sale is prohibited unless said bread, pastry or confectionery product is wrapped or packaged in such a manner as to protect the product from contamination by dust, dirt, flies and other extraneous material.

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 28:1239 (June 2002), amended LR 38:2792 (November 2012).

§511. Premises
[formerly paragraph 6:101]

A. Building premises, shipping and receiving areas, etc., shall be kept clean, orderly and free of debris, trash and high weeds.

B. [formerly paragraph 6:102] The ground area outside the shipping and receiving doors and other passageways shall be paved and sloped to allow for proper drainage.

C. [formerly paragraph 6:103] The ground area for storage of covered trash cans and/or compactor type trash containers shall be paved and sloped for adequate drainage. A conveniently located hose bib shall be provided for washdown of this area.

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 28:1240 (June 2002).

Chapter 7. Food Storage Warehouse and Food Salvaging Operations

§701. Definitions [formerly paragraph 6:110]

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.

Food Storage Warehouse—as used in these regulations shall mean any establishment that stores, delivers, receives or ships a food product for further distribution.

Salvager—as used in these regulations shall mean any person or firm that stores, receives, ships or delivers food products for the purpose of salvaging them by means of sorting, repacking or any other means after said products have been misbranded and/or adulterated or damaged as described in the Louisiana Food, Drug and Cosmetic Law (R.S. 40:601 et seq.).

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 28:1240 (June 2002).

§703. Permits [formerly paragraph 6:111]

A. Food storage warehouses and food salvaging operations shall obtain permits from the state health officer, in accordance with the provisions of §103 of Chapter 1 of this Part.

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 28:1240 (June 2002).

§705. Building Construction [formerly paragraph 6:112]

A. The storage and/or salvaging of any food intended for sale or distribution to the general public is prohibited in private residences or in buildings having direct opening to private residences. All establishment buildings shall be well lighted and ventilated.

B. [formerly paragraph 6:113] Floors, walls and ceilings shall be constructed in accordance with §313 of Chapter 3 of this Part so as to be easily cleanable.

C. [formerly paragraph 6:114] All insecticides or pesticides used in any room where foods packaged, repackaged, stored or salvaged shall be approved by the state health officer. All insecticides and pesticides shall be used and applied according to label directions specified as required by the United States Environmental Protection Agency or its successor.

D. [formerly paragraph 6:115] Every warehouse and salvaging operation shall be provided with toilet and hand washing facilities for employees as required by LAC 51:XIV.411, titled "Minimum Plumbing Fixtures". Hand washing facilities shall be located convenient to all toilet facilities. Facilities shall be equipped with hot and cold water under pressure, delivered through a mixer faucet. Soap and sanitary towels or air dryer shall be provided at each lavatory. These facilities shall be kept clean. Toilet room doors shall be self-closing.

E. [formerly paragraph 6:116] Buildings shall be constructed and maintained to prevent access to rodents, insects (e.g., roaches), birds and other vermin.

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 28:1240 (June 2002), amended LR 38:2792 (November 2012).

§707. Premises [formerly paragraph 6:117]

A. All grounds on which warehouses and other buildings or structures used in connection with any food storage and/or salvaging are located shall be graded to provide natural drainage, thus preventing accumulation of stagnant water and other material.

B. [formerly paragraph 6:118] No litter, waste or refuse shall be allowed to accumulate in or around the buildings or yards. Waste shall be removed daily or disposed of promptly and in a manner approved by the state health officer. Ground areas designated for waste storage shall be paved, sloped for drainage and be provided with washdown facilities.

C. [formerly paragraph 6:119] Weeds and grass shall be kept cut to eliminate rodent and vermin harborage. Mud and dust shall be controlled on the premises.

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 28:1240 (June 2002).

§709. Water Supply [formerly paragraph 6:120]

A. The potable water supply shall meet requirements of Chapter 6, entitled "Water Supply and Distribution," of the LSPC. Such water supply shall not be cross-connected to any other supply.

B. [formerly paragraph 6:121] Drinking fountains shall be provided as required by LAC 51:XIV.411, entitled "Minimum Plumbing Fixtures." Drinking fountains shall meet specifications as described in Part XVII, §107.B of this Code and meet with the approval of the state health officer.

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 28:1240 (June 2002), amended LR 38:2792 (November 2012).

§711. Employee Health
[formerly paragraph 6:122]

A. The requirements of Part I, §117, Part II, §§501-503.C 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 28:1241 (June 2002).

§713. Operational Requirements
[formerly paragraph 6:123]

A. [formerly paragraph 6:124] It shall be the responsibility of management to develop and maintain in employees an interest of "good housekeeping" and encourage personal cleanliness.

B. [formerly paragraph 6:125] All incoming foods shall be examined for defilement, infestation or damage. A morgue area shall be provided for the placement of damaged commodities. Defiled or infested commodities shall be disposed of immediately.

C. [formerly paragraph 6:126] Foods shall be stored at least 18" from walls or other obstructions to permit inspection and cleaning. Foods shall also be stored at least 6 inches above the floor level. Pallets and shelving shall be kept clean.

D. [formerly paragraph 6:127] Stock shall be rotated on a "first in, first out" basis.

E. [formerly paragraph 6:128] Hazardous chemicals shall not be used or stored near foods.

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 28:1241 (June 2002).

§715. Salvaged Food Package Labeling Requirements
[formerly paragraph 6:129]

A. The label of any food that has been salvaged as defined in §701 of this Part of this Code, shall comply with the requirements of R.S. 40:608 and the following provisions.

1. [formerly paragraph 6:129-1] The term *salvaged* shall appear on the principal display panel in the case of any food packaged in a firm container (box, carton or can) and either on the principal display panel or upon a firmly attached tag in the case of any food packaged in a soft container (bag or sack). The "principal display panel" is that panel of a product label bearing the product name and quantity of contents statement. The labeling requirements shall only apply to the individual immediate container in which the food is packaged for retail or institutional sale and shall only apply to the food containers actually requiring salvage activities. The term *salvaged* shall be conspicuous and of easily legible bold face print or type in distinct contrast to other matter on the label.

2. [formerly paragraph 6:129-2] In the event the salvager is other than an agent for the original manufacturer, packer, or distributor, the name and business address of the salvager shall appear in the manner and location prescribed in §715.A.1 of this Part and shall include the city, state and zip 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 28:1241 (June 2002).

§717. Salvaged Food Bulk Placard Requirements
[formerly paragraph 6:130]

A. If in bulk display form for wholesale or retail sale (rather than package form), any food that has been salvaged, shall be conspicuously and prominently displayed immediately adjacent to such bulk display. Such placard shall be in easily legible bold face print or type of such color contrast that it may be easily read and shall contain the statements required by §715 of this Part 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 28:1241 (June 2002).

§719. Salvaged Food Labeling Responsibility
[formerly paragraph 6:131]

A. The responsibility for the salvage labeling required by §§715-717 of this Part shall be that of:

1. [formerly paragraph 6:131-1] the person selling or offering to sell such food at wholesale or retail (if in bulk display form);

2. [formerly paragraph 6:131-2] the person selling or offering to sell at retail or for institutional use (if salvaged within the state of Louisiana); or

3. [formerly paragraph 6:131-3] the first person selling or offering to sell such food at wholesale or retail within the state of Louisiana (if salvaged outside of the state of Louisiana).

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 28:1241 (June 2002).

Chapter 9. Processing and Bottling of Bottled Drinking Water

§901. Definitions
[formerly paragraph 6:132]

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.

Approved Source—when used in reference to a plant's product water or operations water means that the source of

the water and the water therefrom, whether it be from a spring, artesian well, drilled well, municipal water supply, or any other source, shall have been inspected and the water sampled, analyzed and found to be of a safe and sanitary quality by the state health officer in accordance with the applicable laws and regulations of the government agency or agencies having jurisdiction. The presence, in the plant, of current certificates or notifications of approval from the government agency or agencies having jurisdiction shall constitute approval of the source and the water supply.

Bottled Water—water that is intended for human consumption and that is sealed in bottles or other containers with no added ingredients except that it may optionally contain safe and suitable antimicrobial agents. Fluoride may be optionally added within the limitations established in 21 CFR §165.110(b)(4)(ii). Bottled water may be used as an ingredient in beverages (e.g., diluted juices, flavored bottled waters). It does not include those food ingredients that are declared in ingredient labeling as "water," "carbonated water," "disinfected water," "filtered water," "seltzer water," "soda water," "sparkling water," and "tonic water." The processing and bottling of bottled water shall comply with regulations specified in this Section of this Chapter.

Lot—a collection of primary containers or unit packages of any same size, type, and style produced under conditions as nearly uniform as possible and designated by a common container code or marking.

Multi-Service-Containers—containers intended for use more than one time.

Nontoxic Materials—materials for product water contact surfaces utilized in the transporting, processing, storing, and packaging of bottled drinking water, which are free of substances which may render the water injurious to health or which may adversely affect the flavor, color, odor, or bacteriological quality of the water.

Operations Water—water which is delivered under pressure to a plant for container washing, hand washing, plant and equipment cleanup and for other sanitary purposes.

Primary Container—the immediate container in which the product water is packaged.

Product Water—processed water used by a plant for bottled drinking water.

Shipping Case—a container in which one or more primary containers of the product are held.

Single-Service-Container—a container intended for one time usage only.

Unit Package—a standard commercial package of bottled drinking water, which may consist of one or more containers.

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 28:1241 (June 2002).

§903. Bottled Drinking Water Permits [formerly paragraph 6:132-1]

A. Processors and bottlers of bottled drinking water shall obtain permits from the state health officer, in accordance with the provisions of Chapter 1 of this Part.

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 28:1242 (June 2002).

§905. Bottled Water for Emergencies [formerly paragraph 6:132-2]

A. Bottled water processed and packaged strictly for the purpose of providing a source of potable drinking water in anticipation of, or during, an emergency such as the aftermath of disasters from severe storms, hurricanes, floods, etc., shall comply with the provisions of this Section of this Chapter unless otherwise specified.

B. [formerly paragraph 6:132-3] Bottled water for emergencies from outside of state. Bottlers, processors, distributors, or dealers of bottled water processed and packaged outside of this state strictly for the purpose of providing a source of potable drinking water in anticipation of, or during, an emergency such as the aftermath of disasters from severe storms, hurricanes, floods, etc., shall show evidence to the state health officer, or his/her duly authorized representative, of compliance with the requirements for processing, packing, and distribution of bottled water in that state, county, or local authority having jurisdiction.

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 28:1242 (June 2002).

§907. Water Bottling Plant Construction and Design [formerly paragraph 6:133-1]

A. The bottling room shall be separated from other plant operations or storage areas by tight walls, ceilings, and self-closing doors to protect against contamination. Conveyor openings shall not exceed the size required to permit passage of containers.

B. [formerly paragraph 6:133-2] If processing operations are conducted in other than a sealed system under pressure, protection shall be provided to preclude contamination of the water and the system.

C. [formerly paragraph 6:133-3] Ventilation shall be provided in accordance with §313.A.4 of this Part and shall minimize condensation in processing rooms, bottling rooms, and container washing and sanitizing areas.

D. [formerly paragraph 6:133-4] The washing and sanitizing of containers for bottled drinking water shall be performed in an enclosed room. The washing and sanitizing operation shall be positioned within the room so as to

minimize any possible post-sanitizing contamination of the containers before they enter the bottling room.

E. [formerly paragraph 6:133-5] Rooms in which product water is handled, processed, or held or in which containers, utensils, or equipment are washed or held shall not open directly into any room for domestic household purposes.

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 28:1242 (June 2002).

§909. Product and Operation Water Supplies; Sanitary Facilities [formerly paragraph 6:134]

A. Each plant shall provide sanitary facilities including, but not limited to, the following.

1. [formerly paragraph 6:134-1] Product Water and Operations Water

a. [formerly paragraph 6:134-1 (1)] Product Water. The product water supply shall be from an approved source and comply with Chapter 9 of this Part entitled "Processing and Bottling of Bottled Drinking Water."

b. [formerly paragraph 6:134-1 (2)] Operations Water. If different from the product water supply, the operations water supply shall be obtained from an approved source properly located, protected, and operated and shall be easily accessible, adequate, and of a safe, sanitary quality which shall be in conformance at all times with the applicable laws and regulations of the government agency or agencies having jurisdiction.

c. [formerly paragraph 6:134-1 (3)] Product Water and Operations Water from Approved Sources

i. Water samples shall be taken from approved sources by the plant at a minimum frequency of twice each year with an interval between samples of not less than five months nor more than seven months to assure that the supply is in conformance with the applicable standards, laws, and regulations of the government agency or agencies having jurisdiction. The sampling and analysis shall be by plant personnel trained in sampling and analysis of water samples. Records of both government agency approval of the water source and the sampling and analysis performed by the plant shall be maintained on file at the plant.

ii. Test and sample methods shall be approved by government agency or agencies having jurisdiction over the approval of the water source, and shall be consistent with the minimum requirements set forth in Part XII of this Code.

iii. Analysis of the samples may be performed for the plant by commercial laboratories.

2. [formerly paragraph 6:134-2] Air under Pressure. Whenever air under pressure is directed at product water or a product water contact surface, it shall be free of oil, dust, rust, excessive moisture, and extraneous materials; shall not affect the bacteriological quality of the water; and shall not adversely affect the flavor, color, or odor of the water.

3. [formerly paragraph 6:134-3] Locker and Lunchrooms. When employee locker and lunchrooms are provided, they shall be separate from plant operations and storage areas and shall be equipped with self-closing doors. The rooms shall be maintained in a clean and sanitary condition and refuse containers shall be provided. Packaging or wrapping material or other processing supplies shall not be stored in locker or lunchrooms.

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 28:1242 (June 2002).

§911. Cleaning and Sanitizing [formerly paragraph 6:135-1]

A. The product water contact surfaces of all multi-service containers, utensils, pipes, and equipment used in the transportation, processing, handling, and storage of product water shall be cleaned and sanitized. All product water contact surfaces shall be inspected by plant personnel as often as necessary to maintain the sanitary condition of such surfaces and to assure they are kept free of scale, evidence of oxidation, and other residue. The presence of any unsanitary condition, scale, residue, or oxidation shall be immediately remedied by cleaning and sanitizing of that product water contact surface prior to use.

1. [formerly paragraph 6:135-2] After sanitizing all multi-service containers, utensils, and disassembled piping and equipment shall be transported and stored in such a manner as to assure drainage and shall be protected from contamination.

2. [formerly paragraph 6:135-3] Single-service containers and caps or seals shall be purchased and stored in sanitary closures and kept clean therein in a clean, dry place until used. Prior to use they shall be examined, and as necessary, washed, rinsed, and sanitized and shall be handled in a sanitary manner.

3. [formerly paragraph 6:135-4] Filling, capping, closing, sealing and packaging of containers shall be done in a sanitary manner so as to preclude contamination of the bottled drinking water. For example, hand filling and capping of containers shall be prohibited. Mechanical equipment shall be provided for this purpose.

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 28:1243 (June 2002).

§913. Suitability of Equipment and Procedures [formerly paragraph 6:136-1(1)]

A. All plant equipment and utensils shall be suitable for their intended use. This includes all collection and storage tanks, piping, fittings, connections, bottle washers, fillers, cappers, and other equipment which may be used to store, handle, process, package, or transport product water.

B. [formerly paragraph 6:136-1 (2)] All product water contact surfaces shall be constructed of nontoxic and nonabsorbent material which can be cleaned and sanitized and is in compliance with Chapter 11 of this Part—Soft Drink Manufacturing.

C. [formerly paragraph 6:136-2] Design. Storage tanks shall be of the type that can be closed to exclude all foreign matter and shall be vented.

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 28:1243 (June 2002).

§915. Product Water Treatment Process [formerly paragraph 6:137-1(A)]

A. All treatment of product water by distillation, ion-exchanging filtration, ultraviolet treatment, reverse osmosis, carbonation, mineral addition, or any other process shall be effective in accomplishing its intended purpose and in accordance with R.S. 40:607(3) of the State Food, Drug and Cosmetic Law. All such processes shall be performed in and by equipment and with substances which will not adulterate the bottled product. A record of the type and date of physical inspections of such equipment, conditions found, and performance and effectiveness of such equipment, shall be maintained by the plant. Product water samples shall be taken after processing and prior to bottling by the plant and analyzed as often as is necessary to assure uniformity and effectiveness of the processes performed by the plant. The methods of analysis shall be those approved by the government agency or agencies having jurisdiction.

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 28:1243 (June 2002).

§917. Treatment Process of Product Water for Emergencies [formerly paragraph 6:137-1(B)]

A. Product water intended for bottling for use during emergencies shall contain a minimum of 0.2 ppm free chlorine residual prior to bottling or, shall be treated as specified in §915 of this Chapter.

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 28:1244 (June 2002).

§919. Multi-Service Containers [formerly paragraph 6:137-2(1)]

A. Multi-service primary containers shall be cleaned, sanitized, and inspected just prior to being filled, capped, and sealed. Containers found to be unsanitary or defective by the inspection shall be reprocessed or discarded. All multi-service primary containers shall be washed, rinsed, and sanitized by mechanical washers or by any other method giving sanitary results. Mechanical washers shall be inspected as often as is necessary to assure dependable performance. Records of physical maintenance, inspections and conditions found, and performance of the mechanical washer shall be maintained by the plant.

B. [formerly paragraph 6:137-2(2)] Multi-service shipping cases shall be maintained in such condition as to assure they will not contaminate the primary container or the product water. Dry or wet cleaning procedures shall be performed as often as necessary to maintain the cases in a sanitary condition.

C. [formerly paragraph 6:137-2(3)] Bottled water that is processed and packaged exclusively for emergency use shall include the following labeling information in addition to any other required labeling information.

1. [formerly paragraph 6:137-2(3)(a)] Bottled water for emergencies may be named "Bottled Water" or "Drinking Water" followed immediately by "for Emergency Use Only, Not for Re-Sale."

2. [formerly paragraph 6:137-2(3)(b)] Each unit container shall include a "Use by date" with the date not to exceed 60 days from the date of bottling.

3. [formerly paragraph 6:137-2(3)(c)] The information required in §919.C.1-2 shall be of the same print size and style.

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 28:1244 (June 2002).

§921. Cleaning and Sanitizing Solutions [formerly paragraph 6:137-3]

A. Cleaning and sanitizing solutions utilized by the plant shall be sampled and tested by the plant as often as is necessary to assure dependable performance in the cleaning and sanitizing operations. Records of these tests shall be maintained by the 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 28:1244 (June 2002).

§923. Sanitizing Operations [formerly paragraph 6:137-4]

A. All product water contact surfaces shall be sanitized by chemical means, circulation of live steam or hot water. The plant should maintain a record of the intensity of the sanitizing agent and the time duration that the agent was in contact with the surface being sanitized. The following times and intensity shall be considered a minimum:

1. [formerly paragraph 6:137-4(1)] live steam in enclosed system: at least 170°F for at least 15 minutes or at least 200°F for at least five minutes;

2. [formerly paragraph 6:137-4(2)] hot water in enclosed system: At least 170°F for at least 15 minutes or at least 200°F for at least five minutes;

3. [formerly paragraph 6:137-4(3)] chemical sanitizers shall be equivalent in bactericidal action to a two-minute exposure of 50 parts per million of available chlorine at or above 57°F when used as an immersion or circulating solution. Chemical sanitizers applied as a spray or fog shall have as a minimum 100 parts per million of available chlorine at or above 57°F or its equivalent in bactericidal action;

4. [formerly paragraph 6:137-4 (4)] 0.1 part per million ozone water solution in an enclosed system for at least five minutes;

5. [formerly paragraph 6:137-4 (5)] when containers are sanitized using a substance other than one provided for in 21 CFR 178.1010 of the Code of Federal Regulations, such substance shall be removed from the surface of the container by a rinsing procedure. The final rinse, prior to filling the container with product water, shall be performed with a disinfected water rinse free of pathogenic bacteria or by an additional sanitizing procedure equivalent in bactericidal action to that required in §923.A.3.

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 28:1244 (June 2002).

§925. Production Code; Unit Package [formerly paragraph 6:137-5]

A. Each unit package from a batch or segment of a continuous production run of bottled drinking water shall be identified by a production code. The production code shall identify a particular batch or segment of a continuous production run and the day produced. The plant shall record and maintain information as to the kind of product, volume produced, date produced, lot code use, and the distribution of the finished product to wholesale and retail outlets.

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 28:1244 (June 2002).

§927. Filling, Capping, or Sealing; Container Testing Requirements [formerly paragraph 6:137-6]

A. During the process of filling, capping or sealing either single-service or mufti-service containers, the performance of the filler, capper or sealer shall be monitored and the filled containers, visually or electronically inspected to assure they are sound, properly capped or sealed, and coded and labeled. Containers which are not satisfactory shall be reprocessed or rejected. Only nontoxic containers and closures shall be used. All containers and closures shall be sampled and inspected to ascertain that they are free from contamination. At least once each three months, a bacteriological swab and/or rinse count should be made from at least four containers and closures selected just prior to filling and sealing. No more than one of the four samples may exceed more than one bacteria per milliliter of capacity or one colony per square centimeter of surface area. All samples shall be free of coliform organisms. The procedure and apparatus for these bacteriological tests shall be in conformance with those recognized by the government agency or agencies having jurisdiction. Tests shall be performed either by plant personnel trained in sampling and analysis of water samples or by a commercial laboratory.

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 28:1244 (June 2002).

§929. Product Testing Requirements [formerly paragraph 6:137-7]

A. To assure that the plant's production of bottled drinking water is in compliance with the State Food Drug and Cosmetic Law (R.S. 40:601 et seq.) and this code, the plant shall:

1. [formerly paragraph 6:137-7 (1)] for bacteriological purposes take and analyze at least once a week a sample from a batch or segment of a continuous production run for each type of bottled drinking water produced during a day's production. The samples shall consist of primary containers of product or unit packages of product;

2. [formerly paragraph 6:137-7 (2)] for chemical, physical, and radiological purposes, take and analyze at least semi-annually a representative sampling from a batch or segment of a continuous production run for each type of bottled drinking water produced during a day's production. The representative sample shall consist of primary containers of product or unit packages of product;

3. [formerly paragraph 6:137-7 (3)] analyze such samples by methods approved by the government agency or agencies having jurisdiction. The plant shall maintain records of date of sampling, type of product sampled, production code, and results of the analysis.

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 28:1245 (June 2002).

§931. Record Retention [formerly paragraph 6:137-8]

A. All records required by 21 CFR 129.1, 21 CFR 129.20, 21 CFR 129.35, 21 CFR 129.37, 21 CFR 129.40, and 21 CFR 129.80 of the Code of Federal Regulations shall be maintained at the plant for not less than two years. Plants shall also retain, on file at the plant, current certificates or notifications of approval issued by the state health officer and other government agencies, (if any) approving the plant's source and supply of product water and operations water. All required documents shall be available for official review at reasonable times.

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 28:1245 (June 2002).

Chapter 11. Soft Drink Manufacturing

§1101. Definitions [formerly paragraph 6:138]

A. The definitions and interpretations contained in the State Food, Drug and Cosmetic Law (R.S. 40:601 et seq.) are applicable to the following words and terms. 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.

Adequate—that which is needed to accomplish the intended purpose in keeping with good public health practice.

Plant—the building or buildings or part thereof, used for or in connection with the manufacturing, processing, labeling or holding of human food.

Sanitize—see §101 of Chapter 1 of this Part.

Soft Drink—the class of non-alcoholic beverages usually, but not necessarily, made by absorbing carbon dioxide in potable water. The amount of carbon dioxide used is not less than that which will be absorbed by the beverage at a pressure of one atmosphere and at a temperature of 60°F. It either contains no alcohol or only such alcohol, not in excess of 0.5 percent by weight of the finished beverage as is contributed by the flavoring ingredient used. Soft drinks may contain any safe and suitable optional ingredients, including natural and artificial flavors as provided for in the food additives statutes—21 USC 409 and/or the Code of Federal Regulations 21 CFR 170.

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 28:1245 (June 2002).

§1103. Location and Use of Building [formerly paragraph 6:139]

A. The building, or portion thereof, employed for the manufacture of soft drinks shall be used for no other purpose, and shall be so located as to be protected from objectionable surroundings, such as hazardous waste dumps, dusty conditions, rodent harborage areas, sanitary landfills, poorly drained areas, etc.

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 28:1245 (June 2002).

§1105. Plans Review [formerly paragraph 6:140]

A. Plans for new establishments shall be submitted to the state health officer for approval before construction.

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 28:1245 (June 2002).

§1107. Walls and Ceilings [formerly paragraph 6:141]

A. Walls and ceilings in the syrup and bottling rooms shall be of hard, sound materials with smooth, easily cleaned surfaces of a light color.

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 28:1246 (June 2002).

§1109. Lighting and Ventilation [formerly paragraph 6:142]

A. All rooms shall be lighted to a minimum standard of 40 foot-candles.

B. Good and sufficient ventilation to insure a healthful and as nearly as practicable, a comfortable atmosphere shall be provided and maintained, by natural or mechanical means at all times during working hours. When the amount of atmospheric contaminants exceeds the limits fixed hereunder, exhaust ventilation shall be provided to reduce the amount of atmospheric contaminants to within the limits fixed.

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 28:1246 (June 2002).

§1111. Insect, Pest and Vermin Control [formerly paragraph 6:143]

A. All openings to the outer air shall be screened or otherwise protected where necessary against entrance of insects and vermin. The syrup room shall be especially protected against insects and vermin.

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 28:1246 (June 2002).

§1113. Syrup Room Requirements [formerly paragraph 6:144]

A. The syrup room shall be completely enclosed, well ventilated and lighted. Sinks shall be provided and shall have hot and cold running water delivered through a mixer faucet. Syrup rooms shall be protected against vermin, flies, dirt and dust and constructed as to be easily cleaned and sanitized.

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 28:1246 (June 2002).

§1115. Potable Water Supply; Not Cross Connected to Product Water Used for Bottling [formerly paragraph 6:145]

A. Running water of potable quality shall be easily accessible to all parts of the plant. Provision shall be made for prompt removal and proper disposal of waste water and sewage. If a separate water supply is used for any purpose in the plant, there shall be no connection between that supply and the potable supply used for manufacturing.

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 28:1246 (June 2002).

§1117. Toilet and Lavatory Facilities [formerly paragraph 6:146]

A. Toilet and lavatory facilities shall be provided as required in LAC 51:XIV.411, and shall be maintained in a clean and sanitary condition. Toilet and washroom fixtures shall be so constructed and so operated as to prevent backflow or back-siphonage as defined in LAC 51:XIV.203.A and LAC 51:XIV.609.G.2, from such fixtures into the water supply. Toilet rooms shall have no direct connection with rooms used for manufacturing or bottling and shall have self-closing doors. Additional lavatory/lavatories shall be conveniently located in the syrup room and other food processing and handling areas. Facilities shall be equipped with hot and cold water under pressure, delivered through a mixer faucet. Soap and sanitary towels or air dryer shall be provided at each lavatory.

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 28:1246 (June 2002), amended LR 38:2792 (November 2012).

§1119. Multi-Use Container Washing and Handling [formerly paragraph 6:147]

A. Every plant manufacturing bottled beverages shall be equipped with suitable mechanical bottle washing apparatus and with approved machines for carbonation, filling and crowning so that these operations can be performed as to prevent any part of the operator or his clothing from coming in contact with those surfaces of the bottles which come in contact with the beverage. Bottle washing machines shall be so constructed and operated as to prevent back-siphonage, or return-flow, into the water supply lines.

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 28:1246 (June 2002).

§1121. Conveyors and Cases [formerly paragraph 6:148]

A. Conveyors and cases shall be maintained in a clean and 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 28:1246 (June 2002).

§1123. Syrup Making and Mixing Equipment [formerly paragraph 6:149]

A. All vats, jars, mixing and storage tanks, pipe lines, filters and other apparatus employed in the preparation of syrups, shall be of sanitary construction and lined with materials resistant to the action of syrup ingredients.

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 28:1246 (June 2002).

§1125. Water Treatment Equipment [formerly paragraph 6:150]

A. Electrical or chemical coagulation devices and filters employed for clarification of water shall be of types approved by the state health officer, shall not be operated beyond their rated capacity and shall be maintained in a clean and sanitary condition at all times.

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 28:1246 (June 2002).

§1127. Miscellaneous Testing Equipment [formerly paragraph 6:151]

A. Every plant manufacturing bottled carbonated beverages shall be provided with thermometers, acid and sugar hydrometers, gas volume testers, and apparatus for ascertaining the alkalinity and causticity of the soaker solution employed in bottle washing.

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 28:1247 (June 2002).

§1129. Good Manufacturing Practices; Processes and Controls [formerly paragraph 6:152]

A. All operations in the receiving, inspection, transporting, packing, segregating, preparing, processing and storing of food shall be conducted in accordance with good sanitation principles. Overall sanitation of the plant shall be under the supervision of an individual assigned responsibility for this function. All precautions shall be taken to assure that production procedures do not contribute contamination such as filth, harmful chemicals, undesirable microorganisms or any other objectionable material to the

processed product. Examples of production procedures which contribute to contamination are poorly maintained bottle washers, lack of sanitizing equipment and poor employee sanitary practices. Quality control records shall be maintained on all tests and analyses done on processed products.

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 28:1247 (June 2002).

§1131. Plant Layout [formerly paragraph 6:153]

A. Where practicable, the operations of bottle washing and filling, compounding and mixing of syrups, and shipping, shall be performed in separate rooms. Where this is not feasible, the various operations shall be located in the available space in such a manner so that operations do not interfere with one another, and do not lead to product 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 28:1247 (June 2002).

§1133. Bottle Washing; Mechanical Cleaning and Sterilizing; Hand Washing of Bottles Prohibited [formerly paragraph 6:154]

A. Hand bottle washing, except as a preliminary to subsequent mechanical washing, is prohibited. All bottles shall be thoroughly cleaned and sterilized, according to the provisions of state law governing containers (R.S. 40:681 et seq.), immediately before filling, by means of an automatic mechanical washing machine.

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 28:1247 (June 2002).

§1135. Preparation of Syrups [formerly paragraph 6:155]

A. Syrups shall be prepared in a clean manner, and every precaution shall be taken against contamination or absorption of deleterious substances (such as, but not limited to, mold, yeast, bacteria, insects, cleaning agent residues, toxic substances such as caustic soda, pesticide residues, etc.), during preparation and subsequent 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 28:1247 (June 2002).

§1137. Filling and Crowning [formerly paragraph 6:156]

A. Manual filling or crowning is prohibited. Bottles shall be filled and capped with automatic machinery, and the operator or his clothes shall not come in contact with any portion of the bottle or machinery which might result in contamination of the product.

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 28:1247 (June 2002).

§1139. Storage of Crowns [formerly paragraph 6:157]

A. Crowns shall be stored in dust proof containers.

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 28:1247 (June 2002).

§1141. Preparation and Storage of Colors [formerly paragraph 6:158]

A. All non-alcoholic colors shall be prepared in small batches, sterilized immediately before use and stored so as protected against dust.

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 28:1247 (June 2002).

§1143. Finished Product Storage [formerly paragraph 6:159]

A. The finished products shall be stored in such a manner as not to interfere with the sanitation of the bottling room.

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 28:1247 (June 2002).

§1145. Refuse and Rubbish [formerly paragraph 6:160]

A. Bottle cases shall be kept free of broken bottles, garbage, litter or other materials which may harbor insects or rodents and other refuse.

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 28:1247 (June 2002).

§1147. Cleaning and Sanitizing of Apparatus [formerly paragraph 6:161]

A. All pipe lines, apparatus and containers employed in the manufacturing processes shall be thoroughly washed, cleaned and sanitized at four-hour intervals, so as to be maintained at all times in a clean and sanitary condition. Steam, hot water, chlorine or other equally efficient agents are permissible for sanitizing.

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.

2. [formerly paragraph 6:193-2] Hospitals, clinics and public health agencies which maintain establishments in conformance with any applicable state laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs, other than human blood products, upon prescription of practitioners, licensed by law to administer such drug for patients under the care of such practitioners in the course of their professional practice; practitioners who are licensed by law to prescribe or administer drugs and who manufacture, prepare, propagate, compound or process drugs solely for use in the course of their professional practice; and manufacturers of harmless inactive ingredients which are excipients, colorings, flavoring, emulsifiers, lubricants, preservatives or solvents that become components of drugs.

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).

§1509. Examination, Condemnation and Destruction of Unwholesome or Adulterated Drugs [formerly paragraph 6:194]

A. Samples of drugs and drug components may be taken and submitted to a state approved laboratory by the state health officer for examination as often as he deems necessary for the detection of unwholesomeness or adulteration. The state health officer may condemn and forbid the sale of, or cause to be removed or destroyed, any drug which he deems unwholesome or adulterated.

AUTHORITY NOTE: Promulgated in accordance with the provisions of §258(B) of Title 36, and Chapters 1 and 4 of Title 40 of the Louisiana Revised Statutes of 1950. See in particular, R.S. 40:4(A)(1)(a) and 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).

§1511. Personnel [formerly paragraph 6:195]

A. The personnel responsible for directing the manufacture and control of the drug shall be adequate in number, and in education, training and experience, or combination thereof, to assure that the drug has the safety, identity, strength, quality and purity that it purports to possess. All personnel shall have capabilities commensurate with their assigned functions, a thorough understanding of the manufacturing and control functions they perform and adequate information concerning the reason for application of pertinent provisions of this Part to their respective functions.

B. [formerly paragraph 6:196] Any person shown at any time (either by medical examination or supervisory observation) to have an apparent illness or open lesion that may adversely affect the safety or quality of drugs, shall be excluded from direct contact with drug products until the condition is corrected. All employees shall be instructed to report to supervisory personnel any condition that may have an adverse affect on drug products.

AUTHORITY NOTE: Promulgated in accordance with the provisions of §258(B) of Title 36, and Chapters 1 and 4 of Title 40 of the Louisiana Revised Statutes of 1950. See in particular, R.S. 40:4(A)(1)(a) and 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).

§1513. Building Construction [formerly paragraph 6:197]

A. Buildings shall be maintained in a clean and orderly manner and shall be of a size and construction to comply with the requirements of §§107-109 of this Part, and of Part XIV (Plumbing) of this code.

AUTHORITY NOTE: Promulgated in accordance with the provisions of §258(B) of Title 36, and Chapters 1 and 4 of Title 40 of the Louisiana Revised Statutes of 1950. See in particular, R.S. 40:4(A)(1)(a) and R.S. 40:601 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1252 (June 2002).

§1515. Building Requirements [formerly paragraph 6:198-1]

A. [formerly paragraph 6:198-1] Buildings shall provide space for:

1. [formerly paragraph 6:198-1 (1)] orderly placement of equipment and materials to minimize the possibility of contamination;

2. [formerly paragraph 6:198-1 (2)] the receipt, storage and withholding from use of components pending sampling, identification and testing prior to release by the materials approval unit for manufacturing or packaging;

3. [formerly paragraph 6:198-1 (3)] the holding of rejected components prior to distribution to preclude the possibility of their use in manufacturing or packaging procedures for which they are unsuitable;

4. [formerly paragraph 6:198-1 (4)] the storage of components, containers, packing materials and labeling;

5. [formerly paragraph 6:198-1 (5)] any manufacturing and processing operation performed;

6. [formerly paragraph 6:198-1 (6)] any packing or labeling operation;

7. [formerly paragraph 6:198-1 (7)] storage of finished product;

8. [formerly paragraph 6:198-1 (8)] control and production laboratory operations.

B. [formerly paragraph 6:198-2] Provide lighting and ventilation as per §313.A.3 and 4 of this Part, and screening, and when necessary for the intended production or control purposes (for example, the production of sterile products or to prevent antibiotic pollution) provide facilities for positive air pressure, microbiological, dust and temperature controls to:

1. [formerly paragraph 6:198-2 (1)] minimize contamination of products by extraneous adulterants,

including cross contamination of one product with dust particles of ingredients arising from the manufacture, storage or handling of another product;

2. [formerly paragraph 6:198-2 (2)] provide for storage of drug components, in-process materials, and finished drugs in conformance with stability information as derived under §1705.A and B of this Code;

3. [formerly paragraph 6:198-2 (3)] minimize dissemination of microorganisms from one area to another;

4. [formerly paragraph 6:198-2 (4)] provide locker facilities for employee clothing and belongings. Provide washing facilities equipped with hot and cold water under pressure, delivered through a mixing faucet. Soap and sanitary towels or air dryer shall be provided at each lavatory.

C. [formerly paragraph 6:198-3] Provide a supply of potable water [LAC 51:XII (Water Supplies)] under conditions of positive pressure in a plumbing system designed in accord with the LSPC and free of defects that could cause or contribute to contamination of any drug. Drains shall be a minimum of 4 inches, and where connected directly to a sewer, shall be equipped with properly vented fixture traps to prevent sewer gas entry into any occupied space.

D. [formerly paragraph 6:198-4] Provide suitable housing and space for the care of all laboratory animals.

E. [formerly paragraph 6:198-5] Provide for safe and sanitary disposal of sewage, trash and other refuse within and from the building and immediate premises.

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 28:1252 (June 2002), amended LR 38:2792 (November 2012).

§1517. Equipment [formerly paragraph 6:199]

A. Equipment used for the manufacture, processing, packing, labeling, holding, testing or control of drugs shall be maintained in a clean and orderly manner and shall be of suitable design, size, construction and location to facilitate cleaning, maintenance and operation of its intended purpose. The equipment shall:

1. [formerly paragraph 6:199-1] be constructed so that all surfaces that come into contact with a drug product shall not be reactive, additive or absorptive so as to alter the safety, identity strength, quality or purity of the drug or its components beyond established requirements;

2. [formerly paragraph 6:199-2] be constructed so that any substance required for operation of the equipment, such as lubricant or coolants, do not contact drug products so as to alter the safety, identity, strength, quality or purity of the drug or its components beyond the established requirements;

3. [formerly paragraph 6:199-3] be constructed and installed to facilitate adjustment, disassembly, cleaning and maintenance to assure the reliability of control procedure's uniformity of production and exclusion from the drugs of contamination from previous and current operations that might affect the safety, identity, strength, quality or purity of the drug or its components beyond established requirements;

4. [formerly paragraph 6:199-4] be of suitable type, size and accuracy for any testing, measuring, mixing, weighing or other processing of storage operations. The regulations in this Part permit the use of precision automatic, mechanical or electronic equipment in the production and control of drugs when inspection and checking procedures are used to assure proper performance.

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 28:1252 (June 2002).

§1519. Product Production and Quality Control [formerly paragraph 6:200]

A. Production and control procedures shall include all reasonable precautions including the following to assure that the drugs produced have the safety, identity, quality, strength and purity they purport to possess:

1. [formerly paragraph 6:201-1] each significant step in the process, such as selection, weighing and measuring during the various stages of the processing and determination of the finished yield shall be performed by a competent and responsible individual and checked by a second competent and responsible individual; or if such steps in the processing are controlled by precision automatic, mechanical or electronic equipment, their performance is checked. The written record of the significant steps in the process shall be performed by a person having requisite abilities; such identifications shall be recorded immediately following the completion of such steps;

2. [formerly paragraph 6:201-2] all containers, lines and equipment used during the production of a batch of drugs shall be properly identified at all times to accurately and completely indicate their contents, and when necessary, the stage of processing of the batch;

3. [formerly paragraph 6:201-3] to minimize contamination and prevent mix-ups, equipment, utensils and containers shall be thoroughly cleaned or sanitized and stored and have previous batch identification removed or obliterated between batches at intervals while production operations are continuing;

4. [formerly paragraph 6:201-4] precautions shall be taken to minimize microbiological and other contamination in the production of drugs purporting to be sterile, or which by virtue of their intended use should be free from objectionable microorganisms, such as the known common pathogens and others which might affect stability, color or taste;

5. [formerly paragraph 6:201-5] procedures shall be established to minimize the hazard to any drugs while being

manufactured or stored. Such procedures shall meet with the approval of the state health officer;

6. [formerly paragraph 6:201-6] to assure the uniformity and integrity of products, there shall be in-process controls, such as checking the weights and disintegration times of tablets, the adequacy of mixing, the homogeneity of suspensions and the clarity of solutions. In-process sampling shall be done at intervals;

7. [formerly paragraph 6:201-7] representative samples of all dosage form drugs shall be tested to determine their conformance with the specifications of the product before distribution;

8. [formerly paragraph 6:201-8] review and approval of all production and control records, including packing and labeling, shall be made prior to the release for distribution of a batch, and records maintained to show this review. A thorough investigation of the failure of a batch to meet any of its specifications shall be undertaken whether or not the batch has been distributed. The investigation shall extend to other batches of the same drug and other drugs that may have been associated with a problem found with that batch. A written record of the investigation shall be made and shall include the conclusion and follow-up;

9. [formerly paragraph 6:201-9] returned goods shall be identified as such and held. If the conditions under which returned goods have been held, stored or shipped prior to or during their return, or the condition of the product, its container, carton or labeling as a result of storage or shipping cast doubt on the safety, identity, strength, quality or purity of the drug, the returned goods shall be destroyed or subjected to examination or testing to assure the material meets all original standards or specifications before being returned to stock for warehouse distribution or repacking. If the product is neither destroyed nor returned to store, it may be reprocessed provided the final product meets all of its standards and specifications. Records of returned goods shall be maintained and shall indicate the quantity returned, date and actual disposition of the product. If the reason for returned goods implicates associated batches, an appropriate investigation shall be made in accordance with the requirements of §1519.A.8 of this Part;

10. [formerly paragraph 6:201-10] use of asbestos-containing or other fiber releasing filters:

a. [formerly paragraph 6:201-10 (1)] filter used in the manufacture, process or packing of components of drug products for parenteral injections in humans shall not release fibers into such products. No asbestos-containing or other fiber-releasing filter may be used in the manufacture, process or packaging of such products unless it is not possible to manufacture that drug product or component without the use of such a filter. Filtration, as needed shall be through a non-fiber-releasing filter. This filter shall be defined as a non-asbestos filter that after the pretreatment such as washing or flushing, will not continue to release fibers into the drug product or component that is being filtered. A fiber is defined as any particle with length at least three times greater than its width;

b. [formerly paragraph 6:201-10 (2)] if the use of a fiber-releasing filter is required, an additional non-fiber releasing filter or maximum pore size of 0.22 microns (0.45 microns if the manufacturing conditions so dictate) shall subsequently be used to reduce the content of any asbestos-form particle in the drug product or component.

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 28:1252 (June 2002).

§1521. Components
[formerly paragraph 6:202]

A. All components and other materials used in the manufacture, processing and packing of drug products, and materials necessary for building and equipment maintenance, shall upon receipt be stored and handled in a safe, sanitary and orderly manner to assure safety, purity and strength. Precautions shall be taken to prevent mix-ups and cross-contamination affecting drugs and drug products. Components shall be held from use until they have been identified, sampled and tested for conformance to established specifications and are released by a material approval unit. Controls of components shall include the following.

1. [formerly paragraph 6:202-1] Each container of component shall be examined visually for damage or contamination prior to use, including examination for breakage of seals, when indicated.

2. [formerly paragraph 6:202-2] Samples shall be taken from component containers from each lot and shall be subjected to one or more tests to establish their specific identity.

3. [formerly paragraph 6:202-3] Samples of components liable to contamination with filth, insect infestation or other extraneous contaminants shall be appropriately examined.

4. [formerly paragraph 6:202-4] Samples of components liable to microbiological contamination shall be subjected to microbiological test prior to use. Such components shall not contain microorganisms that are objectionable in view of their intended use.

5. [formerly paragraph 6:202-5] Samples of all components intended for use as active ingredients shall be tested to determine their strength in order to assure conformance with specifications approved by the state health officer.

6. [formerly paragraph 6:202-6] Components which have previously been approved shall be identified and retested as necessary to assure that they continue to meet specifications:

a. [formerly paragraph 6:202-6 (1)] Components which have been approved shall be handled and stored to guard against contamination or being contaminated by other drugs or components.

b. [formerly paragraph 6:202-6 (2)] Components which have been approved shall be rotated in such a manner that the oldest stock is used first.

c. [formerly paragraph 6:202-6 (3)] Rejected components shall be identified and held to preclude their use in manufacturing or processing procedures for which they are unsuitable.

7. [formerly paragraph 6:202-7] Records shall be maintained for at least two years after distribution has been completed, or one year after the drug's expiration date, whichever is longer. Such records shall include:

a. [formerly paragraph 6:202-7 (1)] the identity and quantity of the component, the name of the supplier, the supplier's lot number and the date of receipt;

b. [formerly paragraph 6:202-7 (2)] examinations and tests performed, and rejected components and their disposition;

c. [formerly paragraph 6:202-7 (3)] an individual inventory and record for each component used in each batch of drug manufactured or processed.

8. [formerly paragraph 6:202-8] An identified reserve sample of all active ingredients consisting of at least twice the quantity necessary for all required tests, except those for sterility and determination of pyrogens, shall be retained for at least two years after distribution of the last drug lot incorporating the component has been completed, or one year after the expiration date of this last drug lot, whichever is longer.

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 28:1253 (June 2002).

§1523. Product Containers and Their Components [formerly paragraph 6:203]

A. Specifications, test methods, cleaning procedures and when indicated, sterilization procedures shall be used to assure that containers, closures and other component parts of drug packages are suitable for their intended use. Containers for parenteral drugs, drug products or drug components shall be cleansed with water which has been filtered through a non-fiber releasing filter. Product containers and their components shall not be reactive, additive or absorptive so as to alter the safety, strength, identity, quality or purity of the drug or its components beyond the official or established requirements, and shall provide protection against external factors that can cause the deterioration or contamination of the drug.

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 28:1254 (June 2002).

§1525. Laboratory Controls [formerly paragraph 6:204]

A. Laboratory controls shall include the establishment of scientifically sound specifications, standards and test procedures to assure that the components, in-processed drugs and finished products conform to standards of identity, strength, quality and purity. Laboratory controls shall include requirements listed in §§1525.A.1-10:

1. [formerly paragraph 6:205-1] the establishment of master records containing specifications for the acceptance of each lot of components, product containers and their components used in drug production and packaging and a description of the sampling and testing procedures used for them. Such records shall also contain provisions for retesting of drug components, product containers and their components which are subject to deterioration;

2. [formerly paragraph 6:205-2] a reserve sample of all active ingredients as required by §1521;

3. [formerly paragraph 6:205-3] the establishment of master records containing specifications and a description of sampling procedures for in-process drug preparations;

4. [formerly paragraph 6:205-4] the establishment of master records containing a description of sampling procedures and appropriate specifications for the finished drug product;

5. [formerly paragraph 6:205-5] provisions for checking the identity and strength of a drug product for all active ingredients and for assuring:

a. [formerly paragraph 6:205-5 (1)] sterility of drugs purported to be sterile; and freedom from objectionable microorganisms (such as the known common pathogens and others which might affect safety, strength and purity) for those drugs which should be so by virtue of their intended use;

b. [formerly paragraph 6:205-5 (2)] the absence of pyrogens for those drugs purporting to be pyrogen-free;

c [formerly paragraph 6:205-5 (3)] minimal contamination of ophthalmic ointment by foreign particles and harsh or abrasive substances;

d. [formerly paragraph 6:205-5 (4)] that the drug release pattern of sustained-release products is tested by laboratory methods to assure conformance to release specifications;

6. [formerly paragraph 6:205-6] provisions for auditing the reliability, accuracy, precision and performance of laboratory instruments and test procedures;

7. [formerly paragraph 6:205-7] an identified reserve sample of the finished product (stored in the same immediate container-closure system in which the drug is marketed) consisting of at least twice the quantity necessary to perform all the necessary tests, except those for sterility and determination of the absence of pyrogens, shall be stored under conditions consistent with product labeling, and shall be retained for at least two years after distribution has been

completed or one year after the expiration date, whichever is longer;

8. [formerly paragraph 6:205-8] provisions for retaining complete records of all laboratory data relating to each batch or lot of drug to which they apply. Such records shall be retained for at least two years after distribution has been completed or one year after the drug's expiration date, whichever is longer;

9. [formerly paragraph 6:205-9] provisions that animals shall be maintained and controlled in a manner that assures suitability for their intended use. They shall be identified and records maintained to determine the history of use;

10. [formerly paragraph 6:205-10] provisions that firms which manufacture non-penicillin products (including certifiable antibiotic products) on the same premises or use the same equipment as that used for manufacturing penicillin products, or that operate under any circumstances that may be regarded as conducive to contamination of other drugs by penicillin, shall test such non-penicillin products. Such products shall not be marketed if intended for use in man and the product is contaminated with an amount of penicillin equivalent to 0.05 units or more of penicillin "G" per maximum single dose recommended in the labeling of a drug intended for oral use.

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 28:1254 (June 2002).

§1527. Stability [formerly paragraph 6:206]

A. There shall be assurance of the stability of the finished drug products. This stability shall be:

1. [formerly paragraph 6:206-1] determined by reliable, specific test methods;

2. [formerly paragraph 6:206-2] determined on products in the same container closure system in which they are marketed;

3. [formerly paragraph 6:206-3] determined on any dry drug product that is to be reconstituted at the time of dispensing (as directed in its labeling) as well as on the reconstituted product;

4. [formerly paragraph 6:206-4] recorded and maintained in such a manner that the stability data may be utilized in establishing product expiration dates.

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 28:1255 (June 2002).

§1529. Expiration Dating [formerly paragraph 6:207]

A. To assure that the drug product liable to deterioration meets appropriate standards of identity, strength, quality and purity at the time of use, the label of all such drugs shall have suitable expiration dates which relate to the stability test performed on the product.

1. [formerly paragraph 6:207-1] Expiration dates appearing on the drug product label shall be justified by readily available data from stability studies such as described in §1527.

2. [formerly paragraph 6:207-2] Expiration dates shall be related to storage conditions stated on the labeling wherever the expiration date appears.

3. [formerly paragraph 6:207-3] When the drug is marketed in the dry state for use in preparing a liquid product, the label shall bear expiration date and information for the reconstituted product as well as an expiration date for the product.

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 28:1255 (June 2002).

§1531. Packaging and Labeling [formerly paragraph 6:208]

A. Packaging and labeling operations shall be controlled to assure that only those products that have met the standards and specifications in their master production and control records shall be distributed; to prevent mix-ups between drugs during filling, packaging and labeling operations to assure that correct labels and labeling are employed for the drug and to identify the finished product with a lot or control number that permits determination of the history of the manufacture and control of the batch. An hour, day or shift code is appropriate as a lot or control number for drug products manufactured or processed in continuous production equipment. Packaging and labeling operations shall:

1. [formerly paragraph 6:208-1] be separated (physically or spatially) from operations on other drugs in a manner so as to avoid mix-ups and minimize cross-contamination. Two or more packaging or labeling operations having drugs, containers or labeling similar in appearance shall not be in process simultaneously on adjacent or nearby lines unless these operations are separated physically or spatially;

2. [formerly paragraph 6:208-2] provide for an inspection of the facilities prior to use to assure that all drugs and previously used products and labeling materials have been removed;

3. [formerly paragraph 6:208-3] include the following labeling controls:

a. [formerly paragraph 6:208-3 (1)] the holding of labels and package labeling upon receipt pending review and proofing against an approved final copy to assure that they are accurate regarding identity, and content before release to inventory;

b. [formerly paragraph 6:208-3 (2)] the maintenance and storage of each type of label and package labeling representing different products, strength, dosage forms or quantity of contents in such a manner as to prevent mix-ups and provide identification;

c. [formerly paragraph 6:208-3 (3)] a system for assuring that only current labels and package labeling are retained and that stocks of obsolete package labeling are destroyed;

d. [formerly paragraph 6:208-3 (4)] restriction of access to labels and package labeling to authorized personnel;

e. [formerly paragraph 6:208-3 (5)] avoidance of gang printing of cut labels, cartons or inserts when the labels, cartons or inserts are for different products or different strengths of the same products or are of the same size and have identical or similar format and/or color schemes. If gang printing is employed, packaging and labeling operation shall provide for added control procedures. These added controls should consider sheet layout, stacking, cutting and handling during and after printing;

4. [formerly paragraph 6:208-4] provide for strict control of the package labeling issued for use with the drug. Such issue shall be carefully checked by a competent individual for identity and conformity to the labeling specified in the batch production. Said individual shall reconcile any discrepancy between the quantity of the drug finished and the quantities of labels issued;

5. [formerly paragraph 6:208-5] provide for examination or laboratory testing of samples of finished product after packaging and labeling to safeguard against any errors in the finished operation and to prevent distribution of any batch until all tests have been 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 28:1255 (June 2002).

§1533. Records and Reports [formerly paragraph 6:209-1]

A. To assure uniformity from batch to batch, a master production and control record for each drug product and each batch size of drug product shall be independently checked, reconciled, dated and signed or initialed by a second. The master production and control record shall include:

1. [formerly paragraph 6:209-1 (1)] the name of the product, description of the dosage form and a specimen of the copy of each label and all other labeling associated with the retail or bulk unit, including copies of such labeling signed or initialized and dated by the person or persons responsible for the approval of such labeling;

2. [formerly paragraph 6:209-1 (2)] the name and weight or measure of each active ingredient per dosage unit, or per unit of weight or measure of the finished drug, and statement of the total weight or measure of any dosage unit;

3.a. [formerly paragraph 6:209-1 (3)] a complete list of ingredients designated by names or codes to indicate any special quality characteristic;

b. an accurate statement of the weight or measure of each ingredient, regardless of whether it appears in the finished product. Reasonable variations may be permitted in the amount of components necessary in the preparation in dosage form, provided that provisions for such variations are included in the master production and control record;

c. a statement of theoretical weight or measure at various stages of processing and a statement of theoretical yield;

4. [formerly paragraph 6:209-1 (4)] a description of the containers, closures and packaging and finishing materials;

5. [formerly paragraph 6:209-1 (5)] manufacturing and control instructions, procedures and specifications, special notations and precautions to be followed.

B. The batch production and control record shall be prepared for each batch of drug produced and shall include complete information relating to the production and control of each batch. These records shall be retained for at least two years after the batch distribution is complete or at least one year after the batch expiration date, whichever is longer. These records shall identify the specific labeling and lot or control numbers used on the batch, and shall be readily available during such retention period. The batch record shall include:

1. [formerly paragraph 6:209-2 (1)] an accurate reproduction of the master formula record checked, dated and signed or initialed by a person responsible for the approval of this record;

2. [formerly paragraph 6:209-2 (2)] a record of each step in the manufacturing, processing, packaging, labeling, testing and controlling of the batch, including dates, individual major equipment and lines employed, specific identification of each batch of components used, weights and measures of components and products used in the course of processing, in-process and laboratory control results and identification and checking each significant step in the operation;

3. [formerly paragraph 6: 209-2 (3)] a batch number that identifies all the production and control documents relating to the history of the batch and all lot and control numbers associated with the batch;

4. [formerly paragraph 6:209-2 (4)] a record of any investigation made according to §1533.A.

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 28:1256 (June 2002).

§1535. Distribution Records
[formerly paragraph 6:209-3]

A. Finished goods warehouse control and distribution procedures shall include a system by which the distribution of each lot of drug can be readily determined to facilitate its recall if necessary. Records within the system shall contain the name and address of the consignee, date and quantity shipped and lot or control number of the drug. They shall be kept for two years after the batch has been completed or one year after the expiration of the drugs, whichever is longer.

B. [formerly paragraph 6:209-4] To assure the quality of the product, finished goods warehouse control shall also include a system whereby the oldest stock is distributed first whenever possible.

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 28:1256 (June 2002).

§1537. Complaint Files
[formerly paragraph 6:210]

A. Records shall be maintained of all written and oral complaints regarding each product. An investigation of each complaint shall be made in accordance with Part I of this Code. The record of each investigation shall be maintained for at least two years after the distribution of the drug has been completed or one year after the expiration date, whichever is longer.

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 28:1256 (June 2002).

Chapter 17. Drug Distributors, Drug Wholesalers and Drug Storage Warehouses

§1701. Definitions
[formerly paragraph 6:211]

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.

Drug Wholesaler or Drug Distributor—any person or establishment that distributes drugs other than to the ultimate consumer.

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 28:1257 (June 2002).

§1703. Permits
[formerly paragraph 6:212]

A. No person shall operate as a drug wholesaler, drug distributor or operate a drug warehouse within the state of Louisiana without first applying for, paying required fee and obtaining a permit to operate issued by the state health officer. Operating without such permit is a violation of this Code.

B. Every establishment regulated by this Part shall have displayed at all times 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 28:1257 (June 2002).

§1705. Buildings
[formerly paragraph 6:213]

A. All buildings shall be maintained in a clean and orderly manner approved by the state health officer and shall be large enough and constructed and located in a way to facilitate cleaning and maintenance of good storage conditions of drugs and drug products.

B. [formerly paragraph 6:214] All buildings shall be well lighted and ventilated.

C. [formerly paragraph 6:215] All floors, walls, ceilings, tables and other fixtures shall be constructed of such materials that they may be readily cleaned.

D. [formerly paragraph 6:216] All buildings shall be free of flies, rats, mice and other vermin. All insecticides and pesticides used shall be approved by the state health officer.

E. [formerly paragraph 6:217] All buildings shall provide locker facilities for employee clothing and belongings. Provide washing facilities equipped with hot and cold water under pressure, delivered through a mixing faucet. Soap and sanitary towels or air dryer shall be provided at each lavatory.

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 28:1257 (June 2002).

§1707. Premises
[formerly paragraph 6:218]

A. All grounds where buildings are located shall be properly graded to provide a natural drainage, thus preventing an accumulation of stagnant water and other material.

B. [formerly paragraph 6:219] No litter, waste or refuse shall be allowed to accumulate in and around the building or yards. Waste shall be removed and disposed of in an approved manner.

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 28:1257 (June 2002).

§1709. Water Supply
[formerly paragraph 6:220]

A. An ample supply of potable water (Part XII) under pressure shall be provided on the premises for drinking, cleaning, washing or other purposes. Such water supply shall not be connected to any other 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 28:1257 (June 2002).

§1711. Records
[formerly paragraph 6:221]

A. Readily retrievable records shall be maintained which will show the disposition of all prescription items. Such records shall be retained for two years.

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 28:1257 (June 2002).