

Regulation 61-32

Wholesale Bottled Water, Soft Drink, and Ice Manufacturing

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SECTION I. PURPOSE

This regulation sets forth minimum health standards, procedures, and practices to ensure that wholesale BOTTLED WATER, SOFT DRINKS, and ICE are manufactured in South Carolina in a safe and wholesome manner.

SECTION II. SCOPE

This regulation shall apply to all PERSONS who manufacture or distribute wholesale BOTTLED WATER, SOFT DRINKS, or ICE, sold for human consumption in South Carolina.

SECTION III. DEFINITIONS

A. ADEQUATE - substantial compliance with acceptable health standards, procedures, and practices.

B. ADULTERATED or ADULTERATION - BOTTLED WATER, SOFT DRINKS, or ICE are deemed to be ADULTERATED if the product:

1. Bears or contains any poisonous or deleterious substance in a quantity that may render it injurious to health;

2. Bears or contains any added poisonous or deleterious substance for which no state or federal regulation has established a safe tolerance, or in excess of such tolerance if one has been established;

3. Consists, in whole or in part, of any substance unfit for human consumption;

4. Has been produced, processed, prepared, packaged, or held under unsanitary conditions;

5. Is packaged in a container which is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;

6. Has any substance added thereto, or mixed or packaged therewith, so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is; or

7. Is in violation of Section 402 of the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. Section 342).

C. APPROVED - acceptable to the Department based on a determination of conformity with principles, practices, and generally recognized standards that protect public health.

D. APPROVED LABORATORY - a laboratory APPROVED by the Department or certified by the U.S. Environmental Protection Agency (EPA), or certified (accredited) by a third-party organization acceptable to the Department.

E. APPROVED SOURCE - the source of the water used in a plant's operations or a bottled water plant's product water, whether it be from a spring, artesian well, drilled well, public or community water system, or any other source that has been inspected and the water sampled, analyzed, and found of a safe and sanitary quality with or without treatment, and APPROVED by the Department in accordance with Regulation 61-58, State Primary Drinking Water Regulations.

F. ARTESIAN WATER - BOTTLED WATER from a well tapping a confined aquifer in which the water level stands at some height above the top of the aquifer. ARTESIAN WATER may be collected with the assistance of external force to enhance the natural underground pressure. On request, plants shall demonstrate to the Department that the water level stands at some height above the top of the aquifer.

G. 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. 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.”

H. BOTTLING - filling, capping, packaging, or enclosing in CONTAINERS.

I. BOTTLING PLANT - any establishment involved in the manufacturing or packaging of SOFT DRINKS and/or BOTTLED WATERS.

J. BUSINESS DAY - every official work day of the week excluding weekends and state holidays.

K. BULK WATER - source water collected at an APPROVED site remote from the BOTTLING PLANT and transported to the BOTTLING PLANT for further processing and BOTTLING.

L. CODE OF FEDERAL REGULATION (CFR) - a codification of the general and permanent rules and regulations (administrative LAW) published in the Federal Register by the executive departments and agencies of the federal government of the United States. Citations to the CFR in this regulation refer sequentially to the Title, Part, and Section numbers. For example, the citation 21 CFR 117.10 refers to Title 21, Part 117, Section 117.10.

M. CONTAINER - any material used for the packaging of SOFT DRINKS, BOTTLED WATERS, and ICE, whether of glass, plastic, metal, paper, or any combination thereof.

N. DEMINERALIZED WATER - BOTTLED WATER that is produced by distillation, deionization, reverse osmosis, or other suitable process, that meets the definition of PURIFIED WATER in the United States Pharmacopoeia, and is specified by the U. S. Food and Drug Administration (FDA) in 21 CFR 165.110.

O. DEIONIZED WATER - BOTTLED WATER that has been produced by a process of deionization, that meets the definition of PURIFIED WATER in the United States Pharmacopoeia, and is specified by the FDA in 21 CFR 165.110.

P. DEPARTMENT - the South Carolina Department of Health and Environmental Control and its authorized representatives.

Q. DISTILLED WATER - BOTTLED WATER that has been produced by a process of distillation, meets the definition of PURIFIED WATER in the United States Pharmacopoeia, and is specified by FDA in 21 CFR Section 165.110.

R. DRINKING 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.

S. EMPLOYEE - a permit holder, PERSON in charge, PERSON having supervisory or managerial duties, PERSON on the payroll, family member, volunteer, PERSON performing work under a contractual agreement, or any other PERSON working in a BOTTLED WATER, SOFT DRINK, or ICE plant or distribution station.

T. EQUIPMENT - all machinery, utensils, conveyors, CONTAINERS, cases, and other articles used in the manufacturing of BOTTLED WATER, SOFT DRINKS, or ICE.

U. EXCLUSION - prevention of a PERSON from working as an EMPLOYEE in a BOTTLED WATER, SOFT DRINKS, or ICE plant or distribution station, or entering a BOTTLED WATER, SOFT DRINKS, or ICE plant or distribution station as an EMPLOYEE.

V. FDA - United States Food and Drug Administration.

W. FOOD - means FOOD as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act (“FD&C”) and includes raw materials and ingredients.

X. GROUND WATER - water from a subsurface saturated zone that is under a pressure equal to or greater than atmospheric pressure. GROUND WATER must not be under the direct influence of surface water.

Y. ICE - the product, in any form, obtained as a result of freezing water by mechanical or artificial means.

Z. ICE VENDING MACHINES - any self-service machines that act as stand-alone units and may operate without full-time service personnel. These units are activated by the insertion of money; the ICE is bagged automatically or dispensed in bulk to the customer.

AA. IMMINENT HEALTH HAZARD - a significant threat or danger to health that is considered to exist when there is sufficient evidence to show that a product, practice, circumstance, or event creates a situation requiring immediate correction or cessation of operation to prevent illness or injury based on the number of potential illnesses or injuries, and the nature, severity, and duration of the anticipated illness or injury.

BB. LAW - applicable local, state, and federal statutes, regulations, and ordinances.

CC. MANUFACTURED BOTTLED WATER, SOFT DRINKS, AND/OR ICE PRODUCTS DISTRIBUTION STATION - any place or PREMISES, except RETAILERS, where manufactured BOTTLED WATER, SOFT DRINKS, and ICE products are received, stored, and dispensed to RETAILERS (may also be referred to as “Distribution Station”).

DD. MANUFACTURED BOTTLED WATER, SOFT DRINKS, AND/OR ICE PRODUCTS DISTRIBUTOR - any PERSON, except a RETAILER, who receives, stores, and dispenses manufactured BOTTLED WATER, SOFT DRINKS, and ICE products to RETAILERS (may also be referred to as “Distributor”).

EE. MANUFACTURED BOTTLED WATER, SOFT DRINKS, AND/OR ICE PRODUCTS MANUFACTURER - any PERSON, except a RETAILER, who manufactures, processes, or freezes manufactured BOTTLED WATER, SOFT DRINKS, and ICE products for distribution or sale.

FF. MANUFACTURED BOTTLED WATER, SOFT DRINKS, AND/OR ICE PRODUCTS PLANT - any place or PREMISES, except RETAILERS, where manufactured BOTTLED WATER, SOFT DRINKS, and ICE products are manufactured, processed, or frozen for distribution or sale.

GG. MICROORGANISMS - means yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and includes species that are PATHOGENS. The term "undesirable MICROORGANISMS" includes those MICROORGANISMS that are PATHOGENS, that subject FOOD to decomposition, that indicate that FOOD is contaminated with filth, or that otherwise may cause FOOD to be ADULTERATED.

HH. MINERAL WATER - BOTTLED WATER containing not less than 250 parts per million (ppm) total dissolved solids (TDS), coming from a source tapped at one or more boreholes or springs, originating from a geologically and physically protected underground water source. MINERAL WATER is distinguished from other types of water by its constant level and relative proportions of minerals and trace elements at the point of emergence from the source, with consideration given to the cycles of natural fluctuations. No minerals may be added to this water.

II. NATURAL WATER - bottled spring, mineral, artesian, or WELL WATER that is derived from an underground formation or water from surface water that only requires minimal processing, is not derived from a municipal system or public water supply, and is unmodified except for limited treatment (e.g., filtration, ozonation, or equivalent disinfection process).

JJ. PACKAGED ICE - ICE products packaged by APPROVED manufacturers and sold through retail outlets.

KK. PATHOGEN - a microorganism of public health significance.

LL. PERMIT - the document issued by the DEPARTMENT that authorizes a PERSON or entity to operate a BOTTLED WATER, SOFT DRINKS, or ICE plant or distribution station.

MM. PERMIT HOLDER - the entity, such as the owner, the owner's agent, or other PERSON, that possesses a valid PERMIT to operate a BOTTLED WATER, SOFT DRINKS, or ICE plant or distribution station and is legally responsible for its operation.

NN. PERSON - an association, a corporation, individual, partnership, other legal entity, government, or governmental subdivision or agency.

OO. PEST - any objectionable animals or insects including, but not limited to, birds, rodents, flies and larvae.

PP. PURIFIED WATER - BOTTLED WATER produced by distillation, deionization, reverse osmosis, or other suitable process, that meets the definition of PURIFIED WATER in the United States Pharmacopoeia, and is specified by the FDA in 21 CFR 165.110.

QQ. PREMISES -

1. The physical facility, its contents, its land, and any adjacent or bordering contiguous land or property under the control of the PERMIT HOLDER; or

2. The physical facility, its contents, and land or property not described in (a) of this definition if the facilities and contents are under the control of the PERMIT HOLDER and may impact the BOTTLED WATER, SOFT DRINKS, or ICE plant or distribution station personnel, facilities, or operations, and the BOTTLED WATER, SOFT DRINKS, or ICE plant or distribution station is only one component of a larger operation, such as a healthcare facility, hotel, motel, school, recreational camp, or prison.

RR. RESTRICTION - limitation of the activities of an EMPLOYEE so that there is no risk of transmitting a disease that is transmissible through BOTTLED WATER, SOFT DRINKS, or ICE or their ingredients and the EMPLOYEE does not work with exposed BOTTLED WATER, SOFT DRINKS, or ICE or their ingredients, clean EQUIPMENT, utensils, linens, or unwrapped single-service or single-use articles.

SS. RETAIL FOOD ESTABLISHMENT - an establishment that sells FOOD products directly to consumers as its primary function. RETAIL FOOD ESTABLISHMENTS include, but are not limited to, grocery stores, convenience stores, roadside stands, farmers markets, and community supported agriculture (CSA) operations. Any business making FOOD (including a farm business) with at least 50.1 percent in direct to individual consumer FOOD sales satisfies the definition of a RETAIL FOOD ESTABLISHMENT and is exempt from the Bioterrorism Act registration regulations under the 2002 Bioterrorism Act (21 CFR 1.225) as a RETAIL FOOD ESTABLISHMENT. The term “consumers” does not include businesses. A RETAIL FOOD ESTABLISHMENT also includes certain farm-operated businesses selling FOOD directly to consumers as their primary function.

TT. RETAILER - any PERSON who sells, serves, or dispenses at retail manufactured BOTTLED WATER, SOFT DRINKS, or ICE products that have been processed in an APPROVED manufactured BOTTLED WATER, SOFT DRINKS, or ICE products plant.

UU. REMODELED - any enlarging, replacing of floors, walls, or ceilings, or changing in any respect the structure at which a SOFT DRINK, BOTTLED WATER, or ICE plant is housed. This does not apply to repainting or refinishing of floors or walls.

VV. REVERSE OSMOSIS WATER - BOTTLED WATER that is produced by a process of reverse osmosis, that meets the definition of “PURIFIED WATER” in the United States Pharmacopoeia, and is specified by the FDA in 21 CFR 165.110.

WW. RISK - the likelihood that an adverse health effect will occur within a population as a result of a hazard in a FOOD.

XX. SANITIZE - to ADEQUATELY treat cleaned surfaces by a DEPARTMENT -accepted process that is effective in destroying vegetative cells of PATHOGENS, and in substantially reducing numbers of other undesirable MICROORGANISMS, but without adversely affecting the product or its safety for the consumer.

YY. SOFT DRINK - any nonalcoholic, flavored carbonated beverage, including but not limited to soda or soda water, fruit flavored drink, nonalcoholic still beverage, and seltzer or club soda.

ZZ. SPARKLING BOTTLED WATER - BOTTLED WATER that, after treatment and possible replacement of carbon dioxide, contains the same amount of carbon dioxide that it had at the emergence from the source. Manufacturers may add carbonation to previously noncarbonated BOTTLED WATER products and label such water appropriately (e.g. sparkling SPRING WATER).

AAA. SPRING WATER - BOTTLED WATER derived from an underground formation from which water flows naturally to the surface of the earth. SPRING WATER must comply with the FDA standard of identity in 21 CFR 165.110.

BBB. STERILE WATER - BOTTLED WATER that meets the requirements under “Sterility Tests” <71> in the current United States Pharmacopoeia and specified by the FDA in 21 CFR 165.110.

CCC. UNEXPOSED PACKAGED FOOD - packaged FOOD that is not exposed to the environment.

DDD. WELL WATER - BOTTLED WATER from a hole bored, drilled, or otherwise constructed in the ground that taps the water of an aquifer.

Additional definitions related to this regulation are found in 21 CFR 117.3, as amended.

SECTION IV. ADULTERATED OR MISBRANDED BOTTLED WATER, SOFT DRINKS, OR ICE

A. No PERSON within South Carolina, or its jurisdiction, shall produce, provide, sell, offer, or expose for sale or have in possession with intent to sell, any BOTTLED WATER, SOFT DRINKS, or ICE that is ADULTERATED or misbranded. Any BOTTLED WATER, SOFT DRINK, or ICE that may contain any unwholesome substance, or that does not conform to an applicable standard of identity or other requirement specified under Section III for that particular BOTTLED WATER, SOFT DRINK, or ICE product, shall be deemed ADULTERATED and/or misbranded.

B. The DEPARTMENT may place a hold order on any BOTTLED WATER, SOFT DRINKS, or ICE it determines or has reason to believe:

1. originated from an unAPPROVED SOURCE;
2. may be unsafe, unwholesome, ADULTERATED, misbranded, or not honestly presented;
3. is not labeled according to LAW; or
4. is otherwise not in compliance with this regulation.

C. The DEPARTMENT may suspend a PERSON's PERMIT for violating a hold order.

D. The DEPARTMENT may impound, condemn, forbid the sale of, or cause to be removed or destroyed, any FOOD that is determined to be in violation of this regulation, unwholesome, contaminated, ADULTERATED, misbranded, or from an unAPPROVED source.

E. The DEPARTMENT may issue a hold order to a PERMIT HOLDER or to a PERSON who owns or controls the FOOD, as specified above, without prior warning, notice of a hearing, or a hearing on the hold order.

F. The DEPARTMENT may examine BOTTLED WATER, SOFT DRINKS, and ICE as often as necessary to determine freedom from ADULTERATION or misbranding. Under a hold order, BOTTLED WATER, SOFT DRINKS, or ICE shall be suitably stored. No PERSON shall remove or alter a hold order, notice, or tag placed on BOTTLED WATER, SOFT DRINKS, or ICE by the DEPARTMENT. No PERSON shall relabel, repack, reprocess, alter, dispose of, or destroy such BOTTLED WATER, SOFT DRINKS, or ICE, or the CONTAINERS thereof, without permission of the DEPARTMENT, except on order by a court of competent jurisdiction.

G. When BOTTLED WATER, SOFT DRINKS or ICE are found to be ADULTERATED by pesticides, herbicides, or other poisonous substances, the PERSON or entity in possession of the product shall remove the product from the market, disposed of, and sale stopped until analysis provides the product to be free from ADULTERATION.

SECTION V. COMPLIANCE PROCEDURES

A. PERMIT.

1. It shall be unlawful for any PERSON to manufacture or distribute BOTTLED WATER, SOFT DRINKS, and/or ICE products in South Carolina without a valid PERMIT issued by the DEPARTMENT for the specific BOTTLED WATER, SOFT DRINK, or ICE products plant or distribution station. Grocery stores, restaurants, soda fountains, and similar establishments where BOTTLED WATER, SOFT DRINKS, or ICE are served or sold at retail, but not processed, may be exempt from the requirements of this section.

2. Every BOTTLED WATER, SOFT DRINKS, or ICE manufacturer and distributor must obtain and maintain a PERMIT. PERMITs are nontransferable with respect to PERSONs and/or locations.

B. Suspension of PERMIT.

1. The DEPARTMENT may suspend a PERMIT whenever:

- a. it has reason to believe a public health hazard exists;
- b. the PERMIT HOLDER has violated any of the requirements of this regulation;
- c. the PERMIT HOLDER has violated its PERMIT or an order of the DEPARTMENT, including but not limited to a hold order; or
- d. the PERMIT HOLDER has interfered with the DEPARTMENT in the performance of its duties.

A suspension shall remain in effect until the violation has been corrected to the satisfaction of the DEPARTMENT.

2. The DEPARTMENT may without prior warning, notice of a hearing, or hearing suspend a PERMIT to operate a BOTTLED WATER, SOFT DRINK, or ICE plant or distribution station when the DEPARTMENT determines that the operation of the BOTTLED WATER, SOFT DRINK, or ICE plant or distribution station, including but not limited to a willful refusal to permit authorized inspection, constitutes an IMMEDIATE HEALTH HAZARD. Upon summary PERMIT suspension, all manufacturing and distribution operations shall immediately cease. During the process, the PERMIT shall remain suspended unless the IMMEDIATE HEALTH HAZARD has been corrected.

3. Any BOTTLED WATER, SOFT DRINK, or ICE manufacturer or distributor whose PERMIT has been suspended may make written application for the reinstatement of the PERMIT.

4. Within seven (7) business days of receiving the written application, the DEPARTMENT shall make inspections and/or collect samples for analysis to determine whether the conditions cited in the notice of suspension no longer exist. If conditions warrant, the DEPARTMENT may reinstate the PERMIT.

C. Revocation of PERMIT.

1. The DEPARTMENT may revoke a PERMIT for repeated violations of any of the requirements of this regulation, the PERMIT, or an order of the DEPARTMENT, or for interference with the DEPARTMENT or its staff in the performance of duties. Notwithstanding any other provisions of this regulation, the PERMIT may be revoked if the DEPARTMENT is threatened with bodily harm or physical interference in the performance of inspectional duties.

2. The DEPARTMENT may deny a new PERMIT based upon past noncompliance, including previous enforcement, suspension, or revocation history.

3. Any PERSON whose PERMIT is revoked shall not be eligible to apply for re-permitting within one (1) year from the date of revocation. Any PERSON whose PERMIT has previously been revoked and who obtains a subsequent PERMIT and violates the provisions of this regulation, resulting in revocation of the PERMIT for a second time, shall not be granted another PERMIT for a period of five (5) years.

SECTION VI. LABELING

All BOTTLED WATER, SOFT DRINK, and ICE products shall be labeled according to the requirements in 21 CFR Part 101, as amended.

SECTION VII. INSPECTION OF BOTTLED WATER, SOFT DRINK, AND ICE PLANTS AND DISTRIBUTION STATIONS

A. Each BOTTLED WATER, SOFT DRINK, or ICE manufacturer and distributor whose products are intended for consumption within South Carolina shall be inspected by the DEPARTMENT prior to the issuance of a PERMIT.

B. Following the issuance of a PERMIT, the DEPARTMENT shall inspect each BOTTLED WATER, SOFT DRINK, or ICE manufacturer and distributor at a frequency determined by the RISK level assigned to the product(s) being manufactured or distributed or as otherwise deemed necessary by the DEPARTMENT to determine compliance with this regulation.

C. A copy of the inspection report will be provided, either electronically or in paper form, to the PERMIT HOLDER, manager, or other duly authorized representative.

D. Every BOTTLED WATER, SOFT DRINK, or ICE manufacturer and distributor shall, upon request of a DEPARTMENT representative, permit DEPARTMENT access to all parts of the establishment or facilities to determine compliance with the provisions of this regulation. A PERMIT HOLDER, manager, or other duly authorized representative shall furnish the DEPARTMENT, upon request and for official use only, a true statement of the actual quantities of BOTTLED WATER, SOFT DRINK, or ICE product purchased and sold, a list of all sources of such BOTTLED WATER, SOFT DRINK, or ICE products, records of inspections, and records of tests.

E. It is unlawful for any PERSON who, in an official capacity, obtains any information under the provisions of this regulation which is entitled to protection as a trade secret to use such information to his own advantage or to reveal it to any unauthorized PERSON.

SECTION VIII. EXAMINATION OF BOTTLED WATER, SOFT DRINKS, AND ICE

A. Chemical, microbiological, or extraneous material testing procedures shall be used, where necessary, to identify sanitation failures or possible contamination. All FOOD that has become ADULTERATED shall be rejected, or if permissible, treated or processed to eliminate the contamination.

B. BOTTLED WATER manufacturers must perform weekly total coliform monitoring on the finished product of each BOTTLED WATER product type and conduct quarterly rinse/swab tests on BOTTLED WATER CONTAINERS (incoming, as well as those immediately from the washer) and closures. This monitoring and testing must be performed in-house or by an APPROVED LABORATORY as stipulated

in 21 CFR Section 129.80. For microbiological contaminants (total coliform), each BOTTLED WATER manufacturer must analyze a representative sample from a batch or segment of a continuous production run for each BOTTLED WATER product type produced by the plant.

C. Samples of source water shall be taken and analyzed by the BOTTLED WATER plant as often as necessary, but at a minimum frequency of once each year for chemical contaminants and once every four (4) years for radiological contaminants. Facilities that use a public water system for source water may substitute public water system testing results, or certificates showing full compliance with all provisions of the Environmental Protection Agency's National Primary and Secondary Drinking Water Regulations pertaining to chemical contaminants.

D. For chemical, physical, and radiological contaminants, a representative sample from a batch or segment of continuous production run for each type of finished BOTTLED WATER product produced by a water BOTTLING PLANT shall be analyzed annually to ensure that the product(s) complies with current FDA standards.

SECTION IX. BOTTLED WATER, SOFT DRINK, AND ICE PLANTS AND DISTRIBUTION STATIONS

A. Water supply for BOTTLED WATER, SOFT DRINK, and ICE plants and ICE and water vending.

1. The water supply shall be from an APPROVED public water system as defined in R.61-58, State Primary Drinking Water Regulations.

2. The design, operation, and maintenance of water purification systems used to further treat potable water shall be certified as meeting the specifications of the American National Standard Institute/National Sanitation Foundation (ANSI/NSF). All chemicals and products added to the potable water shall meet ANSI/NSF Standard 60. All materials and products installed that come into contact with the potable water shall meet ANSI/NSF Standard 61. The certifying party shall be accredited by the American National Standards Institute. They shall not be operated beyond their rated capacity and shall be maintained in a clean, sanitary condition at all times. This shall include dispensed water and ICE VENDING MACHINES.

3. Potable running water at a suitable temperature, and under pressure as needed, shall be provided in all areas where required for the processing of SOFT DRINKS, BOTTLED WATER, and ICE; for the cleaning of EQUIPMENT, utensils, and CONTAINERS; and for EMPLOYEE sanitary facilities.

4. Carbonated water shall be conveyed in APPROVED stainless steel or equal FOOD-grade piping and not in piping of galvanized iron, lead, zinc, or other deleterious materials.

5. All water storage and cooling tanks shall be of noncorrosive material, properly covered; air vents properly filtered, clean, and free from dust both inside and outside; and the inlet and outlet so arranged as to prevent contamination during filling and emptying.

B. Required rooms.

1. Except as APPROVED by the DEPARTMENT under paragraph B.2 below, each BOTTLED WATER and SOFT DRINK plant shall have a separate room (commonly called a syrup or blend room) or separate area of the filling room for mixing ingredients for BOTTLED WATER or SOFT DRINKS. This room or separate area of the filling room shall be used only for mixing ingredients and storage of mixed batches.

2. Each BOTTLED WATER and SOFT DRINK plant shall have a separate room for filling and sealing CONTAINERS (commonly called a filling or BOTTLING room). This room shall contain only necessary filling, sealing, electronic inspection, coding, and labeling EQUIPMENT. Only the exit end of the bottle washing machine shall open into this room through a tight-fitting wall. If APPROVED by the DEPARTMENT, the mixing of ingredients and storage of mixed batches may be conducted in this room.

3. ICE for human consumption shall be processed and packaged only in rooms used exclusively for processing and packaging ICE for human consumption. ICE for human consumption shall not be processed or packaged on open platforms or on trucks or delivery vehicles, or in any manner which would allow contamination from overhead drip, condensation, dirt, or other contaminants.

C. Transportation of BULK WATER for BOTTLED WATER plants.

1. BULK WATER shall be from a public water system as APPROVED and defined in R.61-58 by the DEPARTMENT.

2. The means and methods of transporting BULK WATER shall be APPROVED by the DEPARTMENT. Bulk tanks, hoses, pumps, and connections used for loading, transporting, and unloading water shall be SANITIZED. Source water for transport shall be treated with an effective disinfectant APPROVED by the DEPARTMENT at an APPROVED concentration prior to being transported.

3. Tank filling and delivery hose connections shall be cleaned and SANITIZED on a regular basis. The tank shall be sealed at all times except when being filled, being cleaned and SANITIZED, and when the water is being unloaded. A record of such cleaning and SANITIZING shall be maintained with the vehicle and shall be available upon request by the DEPARTMENT. Pumps, hoses, connections, and fittings shall be capped and protected from contamination when not in use. The tank manhole shall not be used as a means of filling the tank. To prevent collapse of the tank during delivery of BULK WATER, the manhole may be opened but shall be provided with an air filter to prevent contamination.

4. All surfaces which come into contact with water during storage prior to transport shall be of smooth, impervious, nonabsorbent, corrosion resistant, and nontoxic material such as stainless steel of the American Iron and Steel Institute 300 Series, or equally corrosion resistant, nontoxic material. All water contact surfaces shall be free of substances that may render the water hazardous to health or may adversely affect the flavor, color, turbidity, odor, radiological, microbiological, or chemical quality of the water.

5. BULK WATER transport is intended to move source water from one area to another for the purpose of treatment, packaging, and human consumption. Such water shall not be dispensed directly to consumers from a BULK WATER transport tank or indirectly through some other vending device, unless otherwise APPROVED by the DEPARTMENT. In case of an emergency, such as a DRINKING WATER shortage or outage, or a contaminated water supply, treated water may be dispensed directly from a properly SANITIZED water transport tank.

D. Returnable CONTAINER cleaning.

1. All returnable CONTAINERS shall be ADEQUATELY, mechanically washed and SANITIZED prior to filling. Unless the CONTAINERS are sealed after washing, they shall be washed immediately prior to filling. Hand cleaning of CONTAINERS is prohibited except as a preliminary to subsequent mechanical washing.

2. Metal and glass CONTAINERS.

(a) All metal and glass CONTAINERS shall be exposed to a minimum three percent (3%) alkali solution of which not less than sixty percent (60%) is caustic soda (sodium hydroxide) by an APPROVED automatic mechanical method for a period of not less than five (5) minutes at a temperature of not less than 130°F, or to an equivalent cleaning and sanitizing process APPROVED by the DEPARTMENT.

(b) CONTAINERS shall be rinsed of all caustic soda with potable water.

3. Polycarbonate CONTAINERS.

(a) Polycarbonate CONTAINERS shall be cleaned with APPROVED non-caustic detergents at their required concentrations by an APPROVED mechanical method.

(b) An APPROVED sanitizing rinse consisting of chlorine, bromine, iodine, quaternary ammonia, or ozonated water at the proper APPROVED temperature/time/concentration must follow the cleaning cycle.

4. A permanent record of key operating parameters of the CONTAINER washer should be maintained. These records or logs should include, but are not limited to, wash temperatures, concentrations of cleaners, concentrations of SANITIZERS, lack of carryover of cleaners or caustic in bottles, and maintenance on the washer. Tests on cleaner/SANITIZER concentrations and carryover should be carried out at start-up and regularly thereafter throughout the shift. All maintenance on the washer should be recorded, such as cleaning or aligning spray jets. All records shall be kept on file at least two (2) years for regulatory inspection. Each washer shall be equipped with an indicating thermometer.

E. Single-service CONTAINERS.

1. Single-service CONTAINERS shall be manufactured from FOOD-grade materials that do not impart odors or tastes to the product, nor contaminate the product with MICROORGANISMS, or toxic or injurious substances.

2. Single-service CONTAINERS shall be packaged and stored in a manner APPROVED by the DEPARTMENT prior to filling.

3. Unless otherwise APPROVED by the DEPARTMENT, all single-service CONTAINERS shall be inverted and rinsed with potable water, then treated by filtered compressed air or vacuumed to remove dust prior to filling.

F. Inspection of returnable CONTAINERS.

1. Bottles.

(a) All empty bottles shall be visually inspected immediately after the final rinse of the washing operation for defects, chips, foreign objects, and unclean product contact surfaces as the bottles pass on a conveyor before a well-illuminated background at a speed slow enough for the inspector to achieve high efficiency.

(b) Dirty bottles shall be removed from the production line and either destroyed or rewashed. Defective bottles shall be removed from the production line and destroyed. When inspectors break bottles for cullet, ADEQUATE protection shall be provided for exposed bottles in the immediate area to prevent glass fragments from entering them.

(c) Electronic inspection devices can be used in addition to visual inspection; however, electronic inspection devices shall not be substituted for visual inspection of returnable bottles without the approval of the DEPARTMENT. Inspectors shall have good eyesight, with or without corrective lenses, and shall be rotated to non-inspection work as often as is necessary to maintain high efficiency.

(d) Returnable bottles shall not be used where their condition or design may prevent proper inspection of the contents thereof.

2. Metal canisters.

(a) All metal canisters shall be visually inspected immediately after the final rinse of the washing operation for the presence of foreign objects or unclean product contact surfaces.

(b) Unclean canisters shall be either immediately returned to the washer or removed to the storage area for unclean canisters.

G. CONTAINER closures.

1. CONTAINER closures shall be manufactured from FOOD-grade materials which do not impart odors or tastes to the product, nor contaminate the product with MICROORGANISMS, or toxic or injurious substances.

2. CONTAINER closures shall be received by the BOTTLING PLANT in an undamaged package sealed by the manufacturer.

3. All CONTAINER closures shall be stored in a clean, dry place protected from insects, rodents, dust, splash, or other contamination. Closures which have been touched on the inner side by the operator, as may occur while adjusting EQUIPMENT, shall be discarded.

4. CONTAINER closures not used during the period of processing operations shall be resealed in their original CONTAINER or stored in an APPROVED tightly covered CONTAINER.

5. Only new CONTAINER closures shall be used.

H. Filling and sealing.

1. CONTAINERS shall be filled and sealed with APPROVED mechanical EQUIPMENT. Manual filling and sealing shall be prohibited, except when otherwise APPROVED by the DEPARTMENT for package sizes in which mechanical sealing EQUIPMENT is not yet readily available.

2. Filling EQUIPMENT which fills glass CONTAINERS under pressure should be provided with an ADEQUATE shield to protect against broken glass entering unsealed CONTAINERS. Whenever a glass bottle breaks while being filled or sealed, the machinery involved shall be stopped and all broken glass shall be removed from parts that touch the opening of bottles or contact the product. This shall be performed in such a manner to protect against transferring broken glass into nearby bottles that have exposed openings.

3. No PERSON or his clothing shall come in contact with any portion of the CONTAINER or EQUIPMENT that might result in contamination of the product.

4. The contents of all imperfectly sealed CONTAINERS shall be discarded.

I. SANITATION OF BOTTLED WATER, SOFT DRINK, AND ICE PLANTS AND DISTRIBUTION STATIONS

1. All BOTTLED WATER, SOFT DRINK, and ICE manufacturers and distributors, regardless of exemption status, shall comply with the requirements of 21 CFR Part 117, Subpart A - General Provisions, Subpart B - Current Good Manufacturing Practice, and Subpart F - Requirements Applying to Records That Must Be Established and Maintained, as amended.

2. All BOTTLED WATER, SOFT DRINK, and ICE plants and distribution stations that have been granted a Qualified Facility Exemption by the FDA or that are solely engaged in the storage of refrigerated UNEXPOSED PACKAGED FOODS when temperature controls are necessary to prevent PATHOGEN growth shall comply with the requirements of 21 CFR Part 117, Subpart A - General Provisions, Subpart B - Current Good Manufacturing Practice, Subpart D - Modified Requirements, and Subpart F - Requirements Applying to Records That Must Be Established and Maintained, and be familiar with Subpart E - Withdrawal of a Qualified Facility Exemption, as amended.

3. All BOTTLED WATER, SOFT DRINK, and ICE plants and distribution stations that have not been granted a Qualified Facility Exemption by the FDA shall comply with the requirements of 21 CFR Part 117, Subpart A - General Provisions, Subpart B - Current Good Manufacturing Practice, Subpart C - Hazard Analysis and Risk -Based Preventive Controls, and Subpart F- Requirements Applying to Records That Must Be Established and Maintained, as amended.

4. All BOTTLED WATER, SOFT DRINK, and ICE plants and distribution stations under an FDA order to withdraw their Qualified Facility Exemption are subject to the requirements of 21 CFR Part 117, Subpart E - Withdrawal of a Qualified Facility Exemption, as amended.

5. BOTTLED WATER, SOFT DRINK, and ICE plants and distribution stations that have not been granted a Qualified Facility Exemption by the FDA and have identified a hazard requiring a supply-chain applied control shall comply with the requirements of 21 CFR Part 117, Subpart G - Supply-Chain Program, as amended.

SECTION X. SUBMISSION OF PLANS

Before a SOFT DRINK, BOTTLED WATER, or ICE plant is constructed or extensively REMODELED, or when an existing structure is converted for use as a SOFT DRINK, BOTTLED WATER, or ICE plant, the BOTTLED WATER, SOFT DRINK, or ICE manufacturer must submit properly prepared plans and specifications for such construction, remodeling, or conversion to the DEPARTMENT for review and approval before construction, remodeling, or conversion. The plans and specifications shall indicate the proposed layout, arrangement, mechanical plans, and construction materials of work areas, and the make and model number of proposed fixed EQUIPMENT and facilities.

SECTION XI. RECIPROcity

A. BOTTLED WATER, SOFT DRINKS, and ICE from out of state or outside the United States may be sold in South Carolina only if the DEPARTMENT determines they are manufactured and distributed under provisions substantially equivalent to the requirements of this regulation and ADEQUATELY enforced.

B. Upon receiving from any PERSON, entity, or any regulatory agency outside this state a report of a possible violation of this regulation by a PERMIT HOLDER, the DEPARTMENT may conduct such inspection or investigation as it deems appropriate. Upon receiving information that SOFT DRINKS, BOTTLED WATER, or ICE manufactured outside this state and introduced into this state may have been

manufactured in violation of applicable state or federal LAW, or not in conformance with prevailing and applicable standards and good public health practices, the DEPARTMENT may notify appropriate regulatory authorities located outside this state and request that such authorities take appropriate action.

SECTION XII. OUT-OF-STATE BOTTLED WATER IMPORTS

Due to additional FDA laboratory testing requirements for BOTTLED WATER products, out-of-state water bottlers shall submit the following to the DEPARTMENT: (a) a certification signed by the applicable regulatory agency with jurisdiction over the BOTTLING in the state of origin stating that the plant(s) is permitted or licensed as required, the source water supply meets all EPA public DRINKING WATER requirements, and is operated and maintained in a sanitary manner based on previous plant inspection(s); (b) the name, address, and phone number(s) of all plant(s) manufacturing bottled products for sale in South Carolina; (c) a copy of the latest finished BOTTLED WATER product water analyses (total coliform, inorganic, organic, radiological); and (d) the location(s) where the product(s) may be sampled in South Carolina.

SECTION XIII. RECALL

A. For BOTTLED WATER, SOFT DRINK, and ICE manufacturers and distributors that have not been granted a Qualified Facility Exemption by the FDA, the Recall Plan requirements of 21 CFR 117.139 supersede the requirements of this section.

B. Each SOFT DRINK, BOTTLED WATER, and ICE manufacturer and distributor shall develop and maintain procedures for the notification of regulatory officials, consumer notification, and product recall, and shall implement any said procedure as necessary with respect to any product for which the PERMIT HOLDER or the DEPARTMENT has reason to believe circumstances exist that may adversely affect its safety for the consumer. If the DEPARTMENT determines, based upon representative samples, RISK analysis, information provided by the SOFT DRINK, BOTTLED WATER, or ICE manufacturer or distributor, and/or other information available to the DEPARTMENT, that the circumstances present an IMMEDIATE HEALTH HAZARD and that a form of consumer notice or product recall can effectively avoid or significantly minimize the threat to public health, the DEPARTMENT may order the SOFT DRINK, BOTTLED WATER, or ICE manufacturer and/or distributor to initiate a level of product recall or, if appropriate, issue a form of notification to customers. Each SOFT DRINK, BOTTLED WATER, and ICE manufacturer and distributor shall be responsible for disseminating the notice in a manner designed to inform customers who may be affected by the problem.

SECTION XIV. EQUIPMENT AND FACILITIES IN OPERATION PRIOR TO JULY 1, 2020

A. EQUIPMENT and physical facilities of BOTTLED WATER, SOFT DRINK, and ICE plants and distribution stations in operation prior to July 1, 2020 are deemed in compliance even if they do not meet all construction, EQUIPMENT, and facilities requirements of this regulation if the facilities and EQUIPMENT:

1. are in compliance with the regulatory standards in place for such EQUIPMENT and facilities on January 1, 2020; and
2. are capable of being maintained in a sanitary condition; and
3. are not a public health hazard or nuisance; and

4. are replaced in the normal course of operation with EQUIPMENT and facilities that meet the requirements of this regulation.

B. This section shall not apply to EQUIPMENT installed or construction commenced on or after July 1, 2020.

SECTION XV. PROCEDURE WHEN INFECTION OR HIGH RISK INFECTION IS SUSPECTED

When reasonable cause exists to suspect the possibility of transmission of infection from any PERSON concerned with the handling of BOTTLED WATER, SOFT DRINKS, or ICE products, or their ingredients, the DEPARTMENT is authorized to require any or all of the following measures:

A. The immediate EXCLUSION or RESTRICTION of that PERSON from handling BOTTLED WATER, SOFT DRINKS, and ICE products, or their ingredients;

B. The immediate removal of the BOTTLED WATER, SOFT DRINKS, and ICE products concerned from distribution and use; and/or

C. ADEQUATE medical and bacteriological examination of the PERSON, of their associates, and of their bodily discharges.

SECTION XVI. ENFORCEMENT PROVISIONS

This regulation is issued under the authority of S.C. Code Ann. Sections 44-1-140 and 44-1-150 and shall be enforced by the DEPARTMENT. Any PERSON found to be in violation of this regulation, in non-compliance with an issued PERMIT, or in violation of an order issued by the DEPARTMENT shall be subject to civil monetary penalties, PERMIT suspension, and/or PERMIT revocation. Each day of continued violation shall be a separate offense.

SECTION XVII. SEVERABILITY CLAUSE

Should any section, paragraph, sentence, clause or phrase of this regulation be declared unconstitutional or invalid for any reason, the remainder of said regulations shall not be affected thereby.