Regulations on Good Hygiene Practice for Food

MOHW Food No. 1031301901 promulgated, November 7, 2014

Chapter 1 General Provisions

Article 1 This Regulation is prescribed in accordance with Paragraph 4 of Article 8 of the Act Governing Food Safety and Sanitation (hereinafter referred to as "Act").

Article 2 The scope of this Regulation is applicable to food businesses in paragraph 7 of Article 3 of the Act. In addition to meeting the requirements established herein, the architecture and equipment of a food factory shall meet the Establishment Standards of Construction andEquipment.

Article 3 The following terms as used in this Regulation are defined as follows:

1. Materials Raw and Packaging Material: This refers to include raw materials and packaging material.
2. Raw Materials: This refers to the constituents in the edible part of a finished product, including the main raw material, ingredient, and food additives.
3. Main Raw Material: This refers to the major component of material in the finished product.
4. Ingredient: This refer to the minor component of material in the finished product besides the main raw materials and food additives.
5. Interior packaging material: This refers to food container such as a bottle, can, box, or bag that comes in direct contact with

food and packing material such as aluminum foil, film, paper, and waxed paper that wraps or covers food directly.

6. Exterior packaging material: This refers to the packaging material that is not come in direct contact with food, such as a label, carton box, binder, etc.
7. Food operation site: This refers to the place where food is processed at all stages, treatment of materials raw and packaging material, manufacturing, preparation, processing, compounding packaging and storing.
8. Harmful microorganisms: This refers to microorganisms that are capable of causing food quality deterioration or having public health significance.
9. Food Contact Surface: This refers to a surface that comes into contact with food directly or indirectly.
   (1) Direct contact surface: This refers to a surface of equipment that comes into contact with food directly.
   (2) Indirect contact surface: This refers to a surface of overflowing liquid or steam under normal operations that will come into contact with food or the surface that contacts food directly.
10. Water activity: This refers to an indication of the free moisture in a food, and is the quotient of the water vapor pressure of the food divided by the vapor pressure of pure water at the same temperature.
11. Partition: This refers to the tangible or intangible isolation measure adopted at a food operation site based on criteria such as site, time or air flow.

12. Food plant: This refers to food manufacturer who has factory license.

Article 4 The site and the environment of food businesses shall meet the requirements of the Good Hygiene Management Guidelines for the site and the environment in Table 1.

Article 5 Food practitioners, equipment and utensils, cleaning and disinfection, waste treatment, edible deep-fry oil, and sanitation managers of food businesses shall meet the requirements of the Good Hygiene Management Guidelines in Table 2.

Article 6 Warehouse control of food businesses shall meet the following requirements:

1. Warehouses for materials raw and packaging material, semi-finished products and finished products shall be set up separately or be adequately partition from one another and be given sufficient room to facilitate transport.
2. Items inside the warehouse shall be classified and placed on pallets, shelves or other effective measures shall be adopted. The items may not be placed directly on the floor and shall be kept clean and well ventilated.
3. Warehouse operations shall be based on the principle of first in and first out and be precisely recorded.
4. When it is necessary to control the temperature or humidity during storage, the control method and criteria shall be established and precisely recorded.
5. The warehouse shall be periodically inspected with precise records kept. Any abnormality shall be handled immediately

to ensure the quality and sanitation status of materials raw and packaging material, semi-finished products, and finished products.

6. For items or packaging materials likely to contaminate materials raw and packaging material, semi-finished products, or finished products, there should be measures to prevent against cross contamination. When prevention against cross contamination is impossible, they may not be kept together with materials raw and packaging material, semi-finished products, or finished products.

Article 7 Transport control of food businesses shall meet the following requirements:

1. Transport vehicles shall be checked for their equipment and be kept clean and sanitary prior to carrying foods.
2. When products are to stack up, they shall be kept steady with air circulation maintained.
3. Before carrying low-temperature foods, transport vehicles shall be checked to ensure that foods in the trunks are kept at a valid low temperature.
4. During transport, foods shall be kept away from direct sun exposure, rain, drastic temperature or humidity changes, collision, and puddles inside the vehicle.
5. For items or packaging materials likely to contaminate materials raw and packaging material, semi-finished products, or finished products, there should be measures to prevent against cross contamination. When prevention against cross contamination is impossible, they may not be

transported together with materials raw and packaging material, semi-finished products, or finished products.

Article 8 The product complaint and recall control of food businesses shall meet the following requirements:

1. Management of product complaints shall be recorded.
2. Product recall and subsequent management shall be recorded.

Chapter 2 Food Manufacturers

Article 9 Process management and quality control in the food manufacturers shall meet the requirements in the Process Management and Quality Control Guidelines in Table 3.

Article 10 Inspection and measuring control in the food manufacturers shall meet the following requirements:

1. Food manufacturers with their own inspection sites shall be equipped with sufficient room and inspection equipment to facilitate performance of quality control and sanitation management-related inspection. When it is considered necessary, a publicly credible research or inspection agency institution shall be authorized to perform inspection.
2. Food manufacturers with their own microbiological inspection sites shall adequately separate the sites with other inspection sites in a tangible manner.
3. Precision of measuring devices or recorders used in measurement, control, or recording operations shall be calibrated periodically.
4. There shall be effective control measures against biological,

physical, and chemical contaminant sources that might occur during inspection.

5. When simplified inspection methods are adopted, they shall be verified against those required by the competent authority or established in laws and regulations periodically and be recorded.

Article 11 Food manufacturers shall establish recycling management plans with regard to product recall and enforce the plans accordingly.

Article 12 Related records, documents, and electronic files or databases created by food manufacturers in accordance with the requirements herein shall be kept for at least five years.

Chapter 3 Food Plant

Article 13 Food plant shall establish related standard operating procedures and keep records of related treatments in accordance with the requirements in Article 4 to the preceding article.

Article 14 Configuration and space at a food operation site shall meet the following requirements:

1. Sites of different operating natures shall be set up separately or be partition from one another effectively and remain clean.
2. There shall be sufficient room to place operating equipment and food utensils, food containers, and packaging, set up sanitary facilities, and store materials raw and packaging material.

Article 15 Food process management and quality control shall meet the

following requirements:

1. Test status of materials raw and packaging material, semi-finished products, and finished products in a process shall be adequately indicated and managed.
2. There should be reasonable criteria for the establishment of an expiry date for a finished product. When it is considered necessary, a durability test shall be performed.
3. There shall be a reserved sample of finished products to be kept until expiry date.
4. There shall be process management and quality control records.

Chapter 4 Food Logistics Industry

Article 16 The food logistics industry shall establish standard operating procedures for logistics control that contain the information in Article 7 and the following requirements:

1. Operation sites for different materials raw and packaging material, semi-finished products and finished products shall be set up separately or be adequate partition and be given sufficient room to facilitate transport.
2. Items shall be classified and placed on pallets and shelves or other effective measures shall be adopted. Items may not be placed directly on the floor and shall be kept clean.
3. Operations shall be based on the principle of First in and First out and be precisely recorded.
4. When it is necessary to control the temperature or humidity during operations, the control method and criteria

shall be established and precisely recorded.

5. The storage process shall be periodically inspected and precisely recorded. Any abnormality shall be handled immediately to ensure the quality and sanitation status of materials raw and packaging material, semi-finished products, and finished products.
6. Before loading and unloading low-temperature foods, the temperature of the foods shall be inspected and recorded.
7. The handling, loading, and unloading of low-temperature foods shall take place at a temperature below 15°C and conducted quickly.
8. Logistics operations shall be based on the product storage temperature requirement established by food manufacturers.

Chapter 5 Food Retailers

Article 17 Food dealers shall meet the following requirements:

1. Facilities and sites for selling and storing foods or food additives shall be kept clean and be equipped with measures to effectively guard against invasion by pests.
2. Foods or food additives shall be kept properly and piled neatly to avoid contamination and spoilage.
3. For hot holding of foods, they should be maintained above 60°C of the core temperature.
4. Items inside warehouses shall be classified and placed on pallets and shelves or other effective measures shall be adopted; they may not be placed directly on the floor and

shall be kept well ventilated.

5. There shall be sanitation managers to take charge of food sanitation management on site.
6. Sale and storage operations shall be based on the principle of First in and First out.
7. When control over the temperature and humidity is required for sale and storage operations, related control methods and criteria shall be established and enforced accordingly.
8. Labels or storage status of products shall be periodically inspected during sale and storage operations. Any abnormality shall be handled immediately to ensure quality and sanitation of foods or food additives.
9. For items or packaging materials likely to contaminate materials raw and packaging material, semi-finished products, or finished products, there should be measures to prevent against cross contamination. When prevention against cross contamination is impossible, they may not be kept together with material raw and packaging material, semi-finished products, or finished products.
10. Illumination shall be provided so that sale site shall be no less than 200 lux or above and the light source may not change the natural color of the food.

When food retailers are wholesalers, they shall establish related standard operating procedures and keep records of related treatments in accordance with the requirements in Articles 4 to 8.

Article 18 For food retailers that sell and store frozen or refrigerated foods, besides the requirements in the preceding articles, the following requirements shall also be met:

1. Retailers may not change the food storage temperature originally set by manufacturers.
2. Frozen foods shall be contained in intact sealed basic packaging. Frozen (Refrigerated) foods may not be fixated with metal nails or rubber bands or other similar materials. Foods with broken packaging may not be sold.
3. Frozen foods shall be stored and sold separately from refrigerated ones.
4. When stored or displayed inside a freezer or refrigerator, frozen (refrigerated) foods may not be loaded higher than the maximum line.

Article 19 For food retailers that sell and store bakery product, besides the requirements in the Article 17, the following requirements shall also be met:

1. Bakery product to be sold but without packaging shall be kept in clean containers and displayed in their respective categories. There shall also be measures and equipment available to prevent against contamination and clean tongs and baskets (trays) available for customers to select and carry the products.
2. Cakes or pies with cream, pudding, jelly, fruits or filling that are prone to deteriorate or be spoiled as their ornaments or stuffing shall be kept in refrigerators at a temperature below 7°C.

Article 20 For food retailers that sell poultry, livestock and aquatic products, besides the requirements in the Article 17, the following requirements shall also be met:

1. Tables used to display poultry, livestock, and aquatic products shall be made of water impermeable and corrosion-resistant materials and shall meet requirements of sanitation standards for food utensils, food containers, and packaging.
2. There shall be adequate washing and drainage facilities at the sale site.
3. Work tables, chopping boards, or knives shall be kept tidy and clean. There shall be separate knives or chopping boards for raw edible fish or fish and meat products that can be consumed without being heated.
4. Meat grinders and slicers, among others, shall be kept clean and free of contamination.
5. Fresh aquatic products shall be kept in water tanks and treated with running tap water and prevented from contaminating finished products to be sold.
6. There shall be adequate temperature and time control for the storage, display, and sale of poultry, livestock, and aquatic products.
7. There shall be freezers (refrigerators) or related facilities for frozen (refrigerated) poultry, livestock, and aquatic products.
8. When poultry, livestock, and aquatic products are to be stored, displayed, or sold in ice, the ice shall meet the

Drinking Water Quality Standart.

Article 21 For stands or small retailers that also sell foods, competent authority in the municipality, county, or county-level city may apply requirements herein depending on the actual situation.

Chapter 6 Food Service Businesses

Article 22 Operation sites of the food services shall meet the following requirements:

1. There shall be sufficient running tap water and dishware rinsing and sterilizing facilities that are capable of rinsing, flushing, and effective disinfection in one at the rinsing site. The height of the faucet shall be above the maximum water level in the tank to avoid reflux and contamination. When there is no sufficient running tap water, disposable dishware shall be provided.
2. Oil interceptor in the kitchen shall be cleaned and kept clean frequently.
3. There shall be adequate treatment measures available for oil fume to prevent its contamination.
4. There shall be measures in the kitchen to keep air pressure and room temperature at an adequate level.
5. When no seats are set, the food service shall have effective partition between their sale counter and preparing, processing, and operating sites.

Article 23 The food service shall adopt one of the following sterilization methods:

1. Boiling sterilization: Towels and cloths shall be boiled for

more than five minutes and dishware for more than one minute at 100°C.

2. Steam sterilization: Towels and cloths shall be heated for more than ten minutes and dishware for more than two minutes with steam at 100°C.
3. Hot water sterilization: Dishware shall be heated for more than two minutes in hot water at a temperature above 80°C.
4. Chlorine sterilization: Dishware et al. shall be soaked in the solution containing less than two hundred-millionth of chlorine in total for more than two minutes.
5. Dry heat sterilization: Dishware et al. shall be heated for more than 30 minutes with dry heat at a temperature above 110°C.
6. Other effective sterilization methods approved by the central health competent authority.

Article 24 The ratio of cooking practitioners holding a culinary technician certificate and bakery technician certificate in a food service business shall meet the requirements of the Regulations on Placement and Management of Food Businesses Employment of Professionals with Vocational or Technical Certification in Food Businesses.

The culinary technician certificate holders indicated in the preceding paragraph shall be enrolled in a food service -related association or union in the municipality, county, or county-level city where they work and local competent authority shall authorize an approved association or union to

present them with a chef certificate.

The association or union issuing the certificate of cook in the preceding paragraph shall receive guidance from the competent authority in the municipality, county, or county-level city. Failure to abide by guidance or violation against any agreement on the authorization, the competent authority in the municipality, county, or county-level city may terminate the authorization.

The certificate of cook is effective for four years and may be extended upon expiration. Each extension shall involve four years. Extension applicants shall attend sanitation workshops organized by competent authorities at all levels or associations or unions, senior high schools and higher level schools, or other food service-related institutions that are approved at least eight hours a year while the certificate is effective.

The requirement in Paragraph 1 shall be enforced at one year after this Regulation is promulgated.

Article 25 Ratios of cooking practitioners holding a Chinese culinary technician certificate for the food service dealing with Chinese food service within one year after this Regulation is promulgated are as follows:

1. Restaurants in tourism hotels: 80%.
2. Food service that contract with schools: 70%.
3. Box meal businesses supplying schools: 70%.
4. Restaurants organizing banquets: 70%.
5. Catering businesses: 70%.

6. Central kitchen-based food service: 60%.
7. Food service contractors: 60%.
8. Self service cafeterias: 50%.

Article 26 Sanitation management of food service shall meet the following requirements:

1. Equipment and utensils used during preparation shall be operated and maintained to prevent against contaminating foods. When it is considered necessary, different colors shall be used to indicate equipment and utensils for different purposes.
2. Bamboo or wooden chopsticks or other disposable dining ware shall be discarded right after use. For sites where people share a table of food, spoons, chopsticks, forks, and knives, among other dishware for dividing the food shall be provided.
3. The provided dishware shall be kept clean, without residual fat, starch, protein, or detergent. When it is considered necessary, pathogenic microorganism test shall be performed.
4. Cross contamination shall be avoided during preparation.
5. An adequate temperature shall be maintained for the storage and supply of prepared meals. When storing foods and dishware, there shall be sanitary facilities available to prevent against dust and pests.
6. Sanitation and safety of to-go ready-to-serve meals shall be ensured.
7. Machines and utensils used in the preparation of foods shall

be kept clean.

8. When raw foods are supplied, preparation, processing, and operation shall be done in an exclusive operating zone.
9. Culture sites of fresh aquatic products shall be effectively partition from the preparation site.
10. Inbound supplies and personnel access to the kitchen shall be adequately controlled during the preparation period.

Article 27 Catering businesses shall meet the following requirements:

1. The cooking site and the supplied foods shall be kept away from direct sun exposure, rain, or contact with pollutants and there shall be shelters, freezing (refrigerating) equipment or facilities.
2. Cooking utensils and dishware shall be kept clean.
3. Preparation of foods shall meet the principles of being fresh, clean, quick, heated, and refrigerated and cross contamination shall be avoided.
4. To organize a catering event serving more than 200 people, filing with the local health authorities in the municipality, county, or county-level city directly or through the direct association or union for reference should be done at three days in advance. Contents filed for reference shall include the sponsor, the undertaker, the location, the number of participants, and the menu.

Article 28 Food service contractors shall meet the requirements of Articles 24 and 26. Before accepting a contract, they shall file with the local health authorities directly or through their direct association or union for reference; contents filed for

reference shall include the sponsor, the undertaker, the location, and the number of people to be served.

Chapter 7 Food Additive Businesses

Article 29 The acceptance, storage, and management of food additives shall meet the following requirements:

1. The acceptance procedure and tracing and tracking system shall be established for the acceptance of food additives or raw materials and information such as the source, content, and quantity shall be recorded.
2. Materials raw and packaging material, semi-finished products or finished products shall be kept in different places. When it is considered necessary, they may be kept in the freezer (refrigerator) and separated from other materials or items not to be used in foods in a tangible way.
3. Warehouse management shall follow the principle of First in and First out.

Article 30 The operation sites for food additives shall meet the following requirements:

1. Manufacturing areas or process steps for food additives and chemical raw materials or chemical products shall be separated.
2. When there is concern of hazardous substance leaks as a result of the use of solvents or powder or dust explosions during the manufacturing process, preventive facilities or equipment shall be in place.

Article 31 Equipment, utensils, containers, and packaging used while food additives are being manufactured shall meet the following requirements:

1. They shall be easy to clean, disinfect, and inspect.
2. They shall meet the requirements of the sanitation standards for food utensils, food containers and packaging.
3. Mixture with lubricant, metal chips, sewage, or other possible polluting substances in the food additives shall be prevented.

Article 32 The process and quality management of food additives shall meet the following requirements:

1. Process and quality control procedures shall be established and completely recorded.
2. The finished products shall meet the Standards for Specification, Scope, Application and Limitation of Food Additives and be completely packaged and labeled. Where each batch of finished products is sold to shall be recorded.

Chapter 8 Low-Acid and Acidified Canned Food Manufacturers

Article 33 The production and processing management of low-acid and acidified canned foods manufactures shall comply with the stipulation of production and processing guidelines in Table 4.

Article 34 The sterilization equipment and method adopted by low-acid and acidified canned foods manufactures shall comply with the stipulation of sterilization equipment and method guidelines in Table 5.

Article 35 Staff of low-acid and acidified canned foods manufactures shall comply with the following stipulation:

1. Canned foods manufacturing plants shall have supervisors of thermal process, as well as sterilizer operators, container closure inspectors, and closing machine operators.
2. The supervisors of thermal process, inspectors and operators for the low-acid metal cans shall be qualified in the training program held by the institutions approved by the central competent authority, and they shall be certified. Other personnel in the forgoing clause shall be trained.

Article 36 Sealing control over containers used in the low-acid and acidified canned foods manufactures shall comply with the stipulation of container sealing control guidelines in Table 6.

Chapter 9 Vacuum Packaged Ready-to-eat Food Manufacturers

Article 37 A vacuum packaged ready-to-eat food is a product that is degassed and sealed within a hermetically sealed container and can be instantly edible after being unsealed, with no need to be processed by any cooking step. The manufacturing of vacuum packaged ready-to-eat foods that can be kept and sold at an ambient temperature shall conform the following stipulations:

1. Vacuum packaged ready-to-eat foods that conform the following stipulations may be kept and sold at room temperature:

(1) water activity $\leqq$ 0.85.

(2) pH value ≧ 9.0.

(3) Commercially sterilized products.

(4) Acid foods (natural or normal pH value equal to 4.6 or below).

(5) Fermented foods (when the pH of the food is reduced to 4.6 or less by the growth of acid producing microorganisms; or salt concentration ≧ 10%).

(6) Carbonated beverages.

(7) Any other condition that can inhibit Clostridium botulinum at room temperature.

2. Products with the first, second, fourth, fifth conditions of above mentioned shall be stored and sold in accordance with their labeling. The proprietors shall reserve related test reports or certification documents proved by the laboratories accredited by the central competent authority for reference. The third conditions of above mentioned shall conform the stipulations in Chapter 8.

Article 38 The manufacturing of vacuum packaged ready-to-eat foods sold and stored in cold storage shall conform the following stipulations:

1. As for *Vacuum*-Packed ready-to-eat foods with water activity above 0.85 that require cold storage, all the processes for storing, transporting and selling them shall be undertaken in the status of cold storage at 7^{o}C.
2. *Shelf life of Vacuum*-Packed ready-to-eat foods in cold Storage:

If such a product does not meet any of the following conditions, its shelf life shall be within ten days. The proprietors shall reserve related test reports or certification documents proved by the laboratories accredited by the central competent authority, for reference.

(1) Added with Nitrite or Nitrate
(2) Water Activity $\leqq$ 0.94
(3) pH value $\leqq$ 4.6
(4) Salt Concentration $>$ 3.5% (only applicable to smoked and fermented products)
(5) Any other condition that can inhibit *Clostridium botulinum*.

Article 39 The manufacturing of Vacuum-Packed ready-to-eat foods require frozen storage, all the processes for storing, transporting and selling them shall be undertaken in the status of cold storage at -18^{o}C.

Chapter 10 Plastic Food Utensils, Food Containers or Packaging Manufacturers

Article 40 The development and design of products shall meet the following requirements:

1. The end use environment and conditions for the products shall be established.
2. Appropriate raw materials shall be selected in accordance with the settings in the preceding subparagraph.
3. There shall be records for reference with regard to the development and design data.

Article 41 The storage of raw materials and products shall meet the

following requirements:

1. There shall be storage space exclusively for or with the possibility of being partition from other areas for plastic raw materials.
2. Cross contamination shall be avoided in the storage space.
3. There shall be complete records of inbound and outbound plastic raw materials; contents of the records shall include the date and the quantity.
4. Businesses shall keep sanitation and safety data provided by the plastic raw materials suppliers.

Article 42 The manufacturing site shall meet the following requirements:

1. Cross contamination shall be avoided while the flow is being planned.
2. The mixing area, processing area, and packaging area shall be separated from one another in a tangible way and contamination by powder, dust and oil fume shall be prevented.
3. Equipment used in and the process involved in processing, packaging, and transport shall be kept clean.

Article 43 Production and manufacturing shall meet the following requirements:

1. Manufacturing shall take place following the recommended processing conditions provided by plastic raw materials suppliers and be recorded on a daily basis. The same shall apply when there are changes to the recommended conditions.
2. Contact with the floor shall be avoided from manufacturing

to packaging. When it is considered necessary, appropriate devices shall be used as containers or carriers during the process.

3. In printing operations, transfer or attachment of ink to the surface that comes in contact with food shall be avoided. When there is concern of ink invading or being extruded to get in contact with foods, colorants allowed in accordance with the Standards for Specification, Scope, Application and Limitation of Food Additives shall be used.

Article 44 Sanitation management of plastic food utensils, food containers or packaging shall meet the following requirements:

1. Transmission, packaging, or transport sites shall be separated in a tangible way and contamination by other substances or microorganisms shall be avoided.
2. Quality control shall be exercised during packaging of finished products.
3. Labeling, testing, removal off shelves, recall, and post-recall disposition and documentation of finished products shall meet the requirements of the Act and applicable laws and regulations.

Article 45 Records of plastic food utensils, food containers or packaging created in accordance with these Regulations shall be kept at least for more than three years after the batch of finished products expires.

Chapter 11 Supplementary Provisions

Article 46 Unless the enforcement date is specified otherwise, these

Regulations shall be enforced on the date of promulgation.

Table 1 Good Hygiene Management Guidelines for the Site and the Environment of Food Businesses

1. The site shall meet the following requirements:

   (1) The floors shall be cleaned and kept clean to reduce dust and dirt.

   (2) The drainage system shall be cleaned frequently and kept clear to prevent odors.

   (3) Poultry, livestock, and pets shall be controlled with adequate measures in place.

2. Buildings and facilities shall meet the following requirements:

   (1) Walls, columns, and floors shall be kept clean and free of deposit, erosion, and puddles.

   (2) Floor plates or ceiling shall be kept clean and free of fungi, peeling, dust, contamination, and dew.

   (3) Exits/entrances, windows, doors, vents, and other pathways shall be kept clean and provided with equipment to prevent pests from entering .

   (4) The drainage system shall be kept fully clear and free of offensive odors. The drainage ditches shall be taken effective measures to prevent solid wastes from flowing and pests from entering.

   (5) Illumination shall be provided so that there shall be no less than 100 lux or above, 200 lux is recommended for work surfaces or preparation stations. Light sources shall not change the natural color of the food. Lighting equipment shall be kept clean.

   (6) There shall be favorable ventilation and no undesirable odors; the vents shall be kept clean.

   (7) The exteriors of piping shall be kept clean.

   (8) For sites where different cleanliness requirements apply, they shall

be effectively partition and managed and there shall be sufficient room to facilitate transport.

(9) There shall be effective prevention and control measures against pests at sites other than those mentioned in Subparagraphs 3 and 4 to prevent against discovery of pests or traces of their presence.

(10) Reservoirs (water towers and tanks) shall be kept clean and cleaned at least once a year with records available.

3. Freezers and refrigerators shall meet the following requirements:

(1) Temperature of frozen foods shall remain below -18°C. Temperature of refrigerated foods shall remain above the freezing point below 7°C. Drastic temperature changes shall be avoided.

(2) Defrosting shall take place from time to time in the freezers and refrigerators. Freezers and refrigerators shall be kept clean.

(3) Freezers and refrigerators shall be equipped with visible temperature indicators. Records shall be done automatically or periodically .

4. The employee dormitory, cafeteria, lounge, test site, or research lab, if available, shall meet the following requirements:

(1) Shall be separated from the food operation site and be well ventilated and illuminated, with facilities to prevent against invasion by pests or contamination by harmful microorganisms in place.

(2) Shall frequently be kept clean and someone shall be assigned to take charge.

5. The restrooms shall meet the following requirements:

(1) The site where the restrooms are located shall be prevented from contaminating the water source.

(2) Shall not open toward the food operation site unless there are buffer facilities and effective control in place to prevent against contamination as a result of the air flow.

(3) Shall be kept clean and free of offensive odors.

(4) There shall be a sign that says "wash your hands after using the restroom" in the readily visible place.

6. Water supply facilities shall meet the following requirements:

(1) Water and ice that come in direct contact with foods and for cleaning food equipment and tools shall meet the Drinking Water Quality Standards**.**

(2) There shall be sufficient water volume and water supply facilities.

(3) When underground water is used, the source shall be at least 15 meters away from contamination sources such as the septic tank and sites where waste is accumulated.

(4) Reservoirs (water towers and tanks) shall be kept clean and located at least 3 meters away from contamination sources such as contaminated sites and septic tanks.

(5) The pipelines for drinking and non-drinking water shall be completed separated from each other; the water outlets shall be clearly indicated.

7. Hand washing facilities at operation sites shall meet the following requirements:

(1) Instructions for simple and easy-to-understand hand wash shall be available and readily visible.

(2) Hand washing and drying equipment shall be set up at an appropriate site in sufficient quantities.

(3) There shall be facilities such as running tap water, detergents,

hand dryers, or paper towels available. When it is considered necessary, appropriate disinfection facilities shall be set up.

(4) Hand washing and disinfection facilities shall be designed in a way to prevent against re-contamination of the washed hand while in use.

8. When there is a changing room, the room shall be separated from the food operation site. Workers shall also have their closets to facilitate storage of personal clothes.

Table 2 Good Hygiene Management Guidelines for Food Businesses

1. Food practitioners shall meet the following requirements:
   (1) New food practitioners shall complete a health examination at a medical institution before they can be hired; the employer shall provide at least one health examination a year.
   (2) New food practitioner shall receive adequate educational training so that they are capable of meeting production, sanitation, and quality management requirements; in-service practitioners shall receive periodical food safety, sanitation, and quality management educational training with records in place.
   (3) When diagnosed by a doctor with Hepatitis A, hand dermatitis, rash, pus, trauma, tuberculosis, typhoid, or other disease likely to result in food contamination, food practitioners shall inform the person in charge at site and may not engage themselves in tasks that involve contact with foods during the affected period.
   (4) When working at a food operation site , food practitioners shall wear clean overalls, hats, and shoes to prevent against falling hair, dandruff, and foreign substances into the foods and shall wear a mask when it is considered necessary. Practitioners that come in direct contact with foods at work may not have long nails, apply nail polish, or wear accessories and may not let the cosmetics and drugs that they apply to their skin contaminate foods or surfaces that come in contact with food.
   (5) Food practitioners shall keep their hands clean at all times and wash and/or disinfect their hands following correct steps after they use the restroom or their hands are contaminated before they enter the food operation site. If they spit, wipe their nose, or are

engaged in any behavior that might contaminate their hands while at work, they shall clean their hands immediately before they continue working.

(6) Food practitioners may not smoke, chew betel nuts, chew gum, drink or eat or engage themselves in other acts that might contaminate foods.

(7) Food practitioners shall wear disinfected clean water impermeable gloves or thoroughly wash and disinfect their hands when preparing directly with hands ready-to-eat foods that do not require heating.

(8) Personal clothes of food practitioners shall be placed at the changing location and may not be brought inside the food operation site.

(9) Access by non-food practitioners shall be adequately controlled; before accessing a food operation site, sanitation requirements in the preceding eight subparagraphs shall be met.

(10) While they are providing service, food practitioners shall attend sanitation workshops or training sessions organized by the competent health authority or a related institution, school, or legal entity it approves or authorizes.

2. Cleaning and sanitation of equipment and utensils shall meet the following requirements:

(1) Surfaces that come in contact with foods shall be kept smooth without dents or cracks and remain clean.

(2) Cleanness of equipment and utensils shall be ensured prior to use in manufacturing, processing, preparing, or packaging (carrying) foods and shall be washed and cleaned after use; recontamination

shall be avoided for washed and disinfected equipment and utensils.

(3) Contamination of foods, surfaces that come in contact with food, and packaging (carrying) materials by detergents or disinfectants shall be prevented during washing and disinfection of equipment and utensils.

3. Management of chemicals and tools used during cleaning and disinfection shall meet the following requirements:

(1) Environmental agents used to prevent against pests shall meet requirements of the Environmental Agents Control Act and its applicable laws and regulations and be specifically labeled and kept at a fixed location; they may not contaminate foods or surfaces that come in contact with food and there shall be a designated person to take exclusive charge of keeping them and recording the their usage.

(2) Detergents, disinfectants, and toxic chemicals shall meet the requirements of related competent authorities and be specifically labeled and kept at a fixed location; there shall also be a designated person to take exclusive charge of keeping them and recording the their usage.

(3) At a food operation site, unless it is required to maintain the sanitation, no agents may be kept and used.

(4) For toxic chemicals, there shall be clear indication of their toxicity, usage, and management in case of emergency.

(5) Cleaning, washing, and disinfectant tools and machines shall be kept well at their exclusive location.

4. Waste treatment shall meet the following requirements:

(1) There may not be waste freely piled up inside a food operation site and its surroundings to help prevent against growth of pests.

(2) Waste shall be cleared and processed in accordance with the Waste Disposal Act and its applicable laws and regulations. There may not be offensive odors or harmful (toxic) gas leaks at the location where waste is placed; this is meant to help prevent against growth of pests or health hazards.

(3) Containers of waste that may be used repeatedly shall be washed and cleaned immediately after they are cleared of waste. Machines and equipment used to treat waste shall be washed and cleaned as soon as they discontinue operation; this is meant to help against growth of pests.

(4) For waste such as chemical drugs, radioactive substances, harmful microorganisms, spoiled items, or expired or recalled products that are likely to endanger human health and food safety and sanitation, there shall be exclusive storage facilities available.

5. Edible deep-fry oil with the content of total polar compounds exceeding 25% and above may not be used again and shall be completely replaced by new oil.
6. Food businesses shall assign sanitation managers who will keep daily sanitation management records of the building, facilities, and sanitation management; contents to be kept in the records shall include sanitation tasks established herein.
7. For sanitation managers at food plants, their name is recommended to be published at a readily visible location in the workplace.

Table 3 Process Management and Quality Control Guidelines for Food Manufacturers

1. Materials raw and packaging material used shall meet requirements of the Act and its applicable laws and regulations and have related data or records for tracing their sources.
2. Inbound materials raw and packaging material shall go through the acceptance procedure; those failing acceptance shall be clearly labeled and handled properly to avoid misuse.
3. Contamination of semi-finished products or finished products shall be prevented for materials raw and packaging material in temporary storage; when temperature and humidity control is required, there shall be control methods and criteria in place and records shall be kept. When thawing frozen raw materials, quality deterioration shall be prevented.
4. The use of raw materials shall be based on the principle of first in and firs out and shall take place within the shelf life.
5. When there is concern of contamination by pesticide, heavy metals, or other toxins, the safety or content shall be ensured to meet requirements of the Act and other applicable laws and regulations.
6. There shall be exclusive shelves for storage of food additives and a designated person to take charge of their management; a roster shall also be established to register types, approval numbers, inbound quantities, use volume, and inventory of food additives.
7. The food manufacturing process shall be planned in accordance with sanitation and safety principles.
8. The operation, use, and maintenance of equipment, utensils and containers used for foods during the manufacturing process shall

fulfill sanitation and safety principles.

9. Foods may not come in direct contact with floors during the manufacturing process.
10. Effective measures shall be adopted during the manufacturing process of foods in order to prevent against adulturation of metals or other foreign substances in foods.
11. When tap water is not used in the manufacturing of foods, a designated person shall be assigned to perform daily available residual chlorine and pH value tests and record the results.
12. When it is necessary to control the temperature, humidity, pH value, water activity, pressure, flow rate, or time while foods are being manufactured, related control methods and criteria shall be established and records shall be kept.
13. The use of food additives shall meet the Standards for Specification, Scope, Application and Limitation of Food Additives. There shall be repeated inspection procedures established for weighing and feeding and records shall be kept.
14. Foods shall be packaged in a way that spoilage or contamination may be prevented during transport and sale.
15. Utensils, containers and packaging that may not be recycled shall be prohibited from repeated use. Utensils, containers and packaging that may be recycled shall be cleaned and disinfected in an appropriate way. When it is considered necessary, they shall go through effective sterilization.
16. Each batch of finished products shall only be shipped after their quality assurance is confirmed. For products confirmed to be disqualified, there shall be appropriate handling procedures in place.

17. In case of abnormality with the manufacturing process and quality control, corrective and preventive measures shall be established against recurrence and records shall be kept.
18. When finished products are packaged foods, there shall be clear indication of the ingredients.
19. For the sale of each batch of finished products, there shall be related documents or records available.

Table 4 Productions and Processing Management Guidelines for Low-Acid and Acidified Canned Foods Manufactures

1. Terminology:

(1) *Canned food* means the food sealed in a hermetically sealed container, which has been subject to commercial sterility either before or after the sealing and that can be stored long-term at room temperature.

(2) *Low-acid canned food* means any food with a final equilibrium pH greater than 4.6 and a water activity (aw) greater than 0.85, which is packed in a hermetically-sealed container and has undergone commercial sterility before or after the packaging.

(3) *Acidified canned food* means any low-acid or acidified food to which acid and (or) acid food are added, so that the finished equilibrium pH value is less than or equal to 4.6 and the water activity greater than 0.85.

(4) *Hermetically sealed container* means a container that is designed and intended to be secure against the entry of microorganisms, including containers made of metal, glass, retort pouch, plastic and laminated composite materials, as well as other containers conforming to the above mentioned condition.

(5) *Commercial sterility* means the thermal process that reaches such a degree to ensure microorganisms not allowed to reproduce in the food under non-refrigerated conditions of storage and distribution and products are free of viable microorganisms (including spores) of public health significance. Commercial sterility of equipment and containers used for aseptic processing and packaging of food means the condition achieved by application of heat, chemical sterilant(s), or other appropriate treatment that renders the equipment and

containers free of viable microorganisms having public health significance, as well as microorganisms of non-health significance, capable of reproducing in the food under non-refrigerated conditions of storage and distribution.

(6) *Come-up time* means the time which elapses between the introduction of steam into the closed retort and the time when the retort reaches the required processing temperature.

(7) *Critical factor* means any property, characteristic, condition, aspect, or other parameter, variation of which may affect the scheduled process and the attainment of commercial sterility.

(8) *Initial temperature* means the average temperature of the contents of the coldest container to be processed at the time the thermal processing cycle begins.

(9) *Sterilization Value (F_0)* is the time in minutes that provide total lethal effects to destruction of microorganisms or spores in equivalent to a reference temperature of 250 F (121.1) and with a z = 18 F.

(10) *Scheduled process* means the process selected by the processor as adequate under the conditions of manufacture for given product to achieve commercial sterility.

2. Product preparation:

(1) Before using raw materials and ingredients susceptible to microbiological contamination, the processor shall ensure that those materials and ingredients are suitable for use in processing canned food.

(2) The containers used for canned foods shall conform to the following stipulations:

A. Incoming cans shall have certificate accompanying all lots received or appropriately sampled and inspected to check their quality and cleanliness.

B. The storage place shall maintain sanitary and avoid contamination. During the process of warehousing, if temperature or humidity control is necessary, control methods and standards shall be enacted while records shall be taken accordingly.

C. Before the containers are utilized, appropriate methods shall be applied to maintain cleanliness.

D. During the processes of transportation, moving, filling and sealing, container damage shall be avoided, while the invasion of any outside inclusion shall be prevented.

(3) As for the manufacturing, processing and packaging of acidified canned foods, after sterilization process, the finished equilibrium pH level shall be maintained at 4.6 or below. The operation shall in accordance with scheduled process in point 3. Also, proper controls shall be undertaken to make the equilibrium pH value of the products no greater than 4.6.

(4) Blanching of raw materials shall conform to the following stipulations:

A. Blanching by heat shall be effected by heating the food to the required temperature and time, then either rapidly cooling the food or passing it to subsequent processing without delay.

B. The blanching equipment shall be cleaned. When using hot water,

hot water shall be replenished often while drainage shall be done to prevent contaminating the blanching water.

C. Water used in the cleaning and cooling of the raw materials shall meet the Drinking Water Quality Standard.

(5) The filling of product into containers shall be controlled so as to ensure that filling weight in accordance with scheduled process in point 3.

(6) The exhausting after filling for the removal of air shall be controlled so as to meet the conditions specified in scheduled process. An exhaust box, if applied, shall be washed, cleaned and maintained regularly.

(7) Critical factors related to product preparation shall be carefully controlled to ensure that their limits in accordance with scheduled process.

3. Establishment of scheduled processes:

(1) Scheduled process for low-acid and acidified canned food shall be established by an institution having expert knowledge of thermal processes and their equipment. The institution shall be approved by the central competent authority.

(2) The type, range, and combination of variations encountered in commercial production shall be adequately provided for in establishing the scheduled process. Critical factors shall be specified in the scheduled process.

(3) The sterilization value (F_0) shall be determined according to the chosen scheduled process. Complete records covering all aspects of the establishment of the process shall be retained and prepared for future reference.

(4) The sterilization value (F_0) for low-acid canned food determined according to scheduled process shall be not less than 3.0.

4. Controls of thermal process operation:

(1) Scheduled process for each product and container size being packed shall either be posted in a conspicuous place near the processing equipment or be made readily available to the retort operator.

(2) A system for product traffic control in the retort room shall be established to prevent unretorted product from bypassing the retort process.

(3) Sterilization process shall be controlled to conform at least to the scheduled process.

(4) Timing device used in sterilizer operation shall be accurate and easy to read. Pocket or wrist watches are not considered satisfactory for timing process.

(5) The sterilizer operator shall record sterilizer operation information in sterilizer operation report at the time it is observed and sign on temperature recorder chart every day. The two records shall be cross-checked with each other.

(6) Sterilizer operation report and temperature recording chart shall be reviewed and signed by supervisor of thermal process within one week after the production. QC supervisor or production supervisor shall check records of closure and sign on it.

(7) Copies of all records of sterilization process and closure shall be kept for at least five years.

5. Whenever process is less than the scheduled process or when the equilibrium pH of acidified canned food is greater than 4.6 or when critical factors are out of control as checked from records, this batch

of product shall take one of the following measures to handle the situation:

(1) This batch of product shall fully reprocess in accordance with scheduled process under Subparagraph 1 of point 3 and keep full records of the reprocessing conditions.

(2) If deviations, such as the control of scheduled process, venting or control points, are found during sterilization process, the sterilization shall extend the process time. If deviations are found immediately after sterilization process, the products shall be fully reprocessed. If deviations are found after a while from sterilization process, the products shall be either fully reprocessed or destroyed, unless it is verified that they are free of viable microorganisms (including spores) of public health significance.

Table 5 Guidelines for Sterilization Equipment and Procedures for Low Acid and Acidified Canned Foods Manufactures

1. Terminology:
   (1) *Aseptic processing and packaging* means the filling of a commercially sterilized and cooled product into pre-sterilized containers, followed by hermetical sealing in a sterile environment.
   (2) *Incubation test* means the test that holding sample(s) at a specified temperature for a specified period of time for the purpose of permitting or stimulating the growth of microorganisms.
2. Equipment and procedures for pressure processing in steam in still retorts:
   (1) Indicating mercury-in-glass thermometer:
      A. Each retort shall be equipped with at least one mercury-in-glass thermometer whose divisions are easily readable to 0.5°C, with a length of at least 178 mm (7 inches), and whose temperature range does not exceed 55°C.
      B. Before installation, thermometer shall be calibrated by the institution approved by the competent authority. After installation, it shall be calibrated at least once every year. The calibration institution shall keep calibration records.
      C. Each thermometer shall have a tag, seal, or other means of identity that includes the date on which it was last tested for accuracy.
      D. Thermometer that has a divided mercury column or that cannot be adjusted to the standard shall be repaired or replaced before further use of the retort.
      E. Thermometer shall be installed where they can be accurately and easily read.
      F. Bulbs of indicating thermometers shall be installed either within the retort shell or in external wells attached to the retort. External wells or pipes shall be connected to the retort through at least a 19mm (3/4-inch) diameter opening and equipped with a 1.6mm (1/16-inch) or larger bleeder opening so located as to provide a full flow of steam past the length of the thermometer bulb. The bleeders for external wells shall emit steam continuously during the entire processing period.

G. During the sterilization process, the mercury-in-glass thermometer shall be the reference instrument for indicating the process temperature, which can NOT be substituted by the recorded temperature on the automatic temperature-recording device.

(2) Temperature-recording device:

A. Each still retort shall equip with an accurate temperature-recording device. Graduations on the temperature-recording devices shall not exceed 1°C within a range of 5°C of the process temperature. Each chart shall have a working scale of not more than 25 °C per 25 mm (1 inch) within a range of 10°C of the process temperature.

B. The recorded temperature shall be adjusted to agree as nearly as possible with, but to be in no event higher than, the known accurate mercury-in-glass thermometer during the sterilization process.

C. A means of preventing unauthorized changes in adjustment shall be provided. A lock, or a notice from management posted at or near the recording device which provides a warning that only authorized persons are permitted to make adjustments, is a satisfactory means for preventing unauthorized changes.

D. The temperature-recorder bulb shall be installed either within the retort shell or in a well attached to the shell. Each temperature-recorder bulb well shall have a 1.6 mm (1/16-inch) or larger bleeder.

E. Air-operated temperature controllers shall have adequate filter systems to ensure a supply of clean and dry air.

(3) Pressure gauge:

A. Each retort shall be equipped with a pressure gauge of which the dial diameter shall not be smaller than 114 mm (4 and 1/2 inch), with the range of reading from zero to 3.5 kg/cm^2. The meter shall be able to indicate a reading of 0.1 kg/cm^2.

B. It shall be calibrated at least once every year.

C. Pressure gauges shall be connected with circular bends.

D. Pressure shall NOT be used for the only basis for sterilization process.

(4) Steam controller:

A. Each retort shall be equipped with a steam controller.
B. If no automatic steam controller is installed, manual operation is adopted instead; records shall be taken during the process of sterilization operation, in order to ensure the compliance of sterilization process requirement.

(5) Steam Inlet:
A. The smallest nominal pipe size of the pipes (e.g. steam inlet pipe, pipe valve, junction, etc.) in the Steam inlet shall not be smaller than 25 mm (1 inch), and the internal diameter of the pipes shall not be smaller than 26 mm (with an accumulation cross-sectional area =530 mm^2), as shown in the specifications in Table 1.

Table 1: Reference data about pipe diameter, aperture, and hole quantity

Pipe diameter Nominal	Outside diameter **(mm)**	Diameter of pipe wall **(mm)**	Inside diameter **(mm)**	Cross sectional area **(mm^2)**	Quantity of Surface Holes			
					Aperture of 3.2 mm (1/8 inch)	Aperture of 4.8 mm (3/16 inch)	Aperture of 5.6 mm (7/32 inch)	Aperture of 6.4 mm (1/4 inch)
1 inch	34.0	2.0	30.0	706.86	134~178	60~79	44~58	34~44
		2.5	29.0	60.52	125~166	56~74	41~54	32~41
		3.0	28.0	615.75	117~155	52~69	39~50	30~33
		3.5	27.0	572.56	109~144	49~64	38~47	29~36
		4.0	26.0	530.93	101~133	45~59	33~43	26~33
1.25 inches	42.7	2.0	38.7	1176.23	223~296	100~132	73~96	56~74
		2.5	37.7	1116.23	212~281	95~125	70~92	53~70
		3.0	36.7	1057.84	200~266	90~113	66~87	51~66
		3.5	35.7	1000.98	190~252	85~112	62~82	48~63
		4.0	34.7	945.63	179~233	80~106	59~77	45~59
1.5 inches	48.6	2.0	44.6	1562.23	296~393	132~175	97~128	74~98
		2.5	43.7	1493.01	283~376	126~167	93~123	71~94
		3.0	42.6	1425.31	270~359	121~160	89~117	68~85

		3.5	41.6	1359.13	257~342	115~152	85~112	65~85
		4.0	40.6	1294.82	245~326	110~145	81~106	62~31

B. The steam inlet to vertical retort shall be installed at the center of the bottom portion of retort.

C. If the length of a horizontal retort is within 9 m (30 feet), the steam inlet shall be installed at the center of the retort bottom (shown as Figure 1). If the length of a retort exceeds 9 m (30 feet), two or more steam inlets shall be installed. The installation of such steam inlet shall enable even heat distribution in retort.

(6) Steam spreaders and spreader holes:

A. Steam spreaders are continuations of the steam inlet line inside the retort. The internal diameter of steam spreader shall not be greater than that of steam inlet piping. Please refer to the illustration in Figure 1.

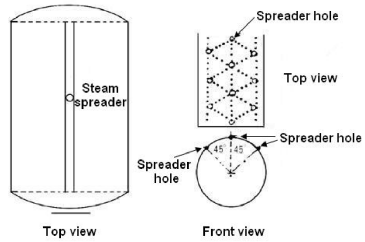

Figure 1: Installation of steam inlet and steam spreaders.

B. Horizontal still retorts shall be equipped with steam spreaders that extend the length of the retort. For steam spreaders along the bottom of the retort, the perforations shall be along the top 90 degrees of this pipe, that is, within 45 degrees on either side of the top center. Each row has approximately the same quantity of spreader holes. The aperture spacing shall be equal. The two neighboring rows of the spreader hole shall not be arranged side by side; they shall be staggered with each other in equidistant intervals, as shown in Figure 2.

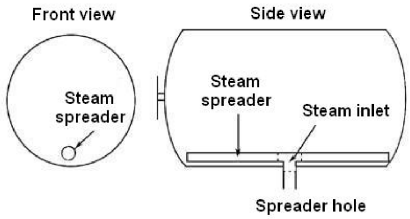

Figure 2: Installation of steam spreaders.

C. In vertical still retorts, the steam spreaders, if used, shall be perforated along the center line of the pipe facing the interior of the retort or along the sides of the pipe.

D. The number of perforations shall be such that the total cross-sectional area of the perforations is equal to 1.5 to 2 times the cross-sectional area of the smallest restriction in the steam inlet line, as shown in the specifications in Table 1.

(7) Bleeders

A. Bleeders, except those for thermometer wells, shall be 3.2 mm (1/8 inch) or larger.

B. It shall be fully open during the entire process, including exhaust, come-up-time, and sterilization.

C. For horizontal still retorts, bleeders shall be located within approximately 20 cm (8 inches) of the outermost locations of containers at each end along the top of the retort; additional bleeders shall be located not more than 240 cm (8 feet) apart along the top.

D. For vertical still retorts, bleeder shall be installed on the retort lid.

E. Bleeders may be installed at positions other than those specified above, as long as there is evidence in the form of heat distribution data that they accomplish adequate removal of air and circulation of steam within the retort.

F. All bleeders shall be arranged so that the operator can check that they are functioning properly.

(8) Vents:

A. Vents shall be installed in such a way that air is removed from the retort before timing of the process is started.

B. Vents shall be controlled by a gate valve or plug cock valve. However, where a retort manifold connects several vent pipes from a single still retort, it should be controlled by a gate valve,

which shall be fully open during the venting period.

C. The vents of a horizontal retort shall be installed on the top portion of the retort, while the vents of a vertical retort on the retort lid.
D. The length of the vent shall not exceed 46cm (1.5 feet). If the length of the vent exceeds 46 cm, the excessive part of the vent shall be extended to the connecting-vent whose pipe diameter is larger than that of the vent. Also, a device for draining condensed water shall be installed at the bottom of the connecting vent.
E. Vents shall not be connected directly to a closed drain pipes or overflow pipe.
F. The retort manifold shall be of a size that the cross-sectional area of the pipe is larger than the total cross-sectional area of all connecting vents.
G. The manifold header shall not be controlled by a valve and shall be of a size that the cross-sectional area is at least equal to the total cross-sectional area of all connecting retort manifold pipes from all retorts venting simultaneously.
H. A manifold header connecting vents or manifolds from several still retorts shall lead to the atmosphere, and avoid bending and exhaust stagnation.
I. Timing of the process shall not begin until the retort has been properly vented and the process temperature has been reached.
J. Some typical installations and operating procedures reflecting the requirements of this section for venting still retorts are given as follows.

   Venting horizontal retorts

   I. Venting through multiple 25 mm (1 inch) vents discharging directly to atmosphere (Figure 3):
      i. Specifications: One 1-inch vent for every 5 feet of retort length, equipped with a gate or plug cock valve and discharging to atmosphere; end vents not more than 76 cm (2.5 feet) from ends of retort.
      ii. Venting method: Vent valves shall be wide open for at least 5 minutes and to at least 108°C or at least 7 minutes and to at least 105°C.

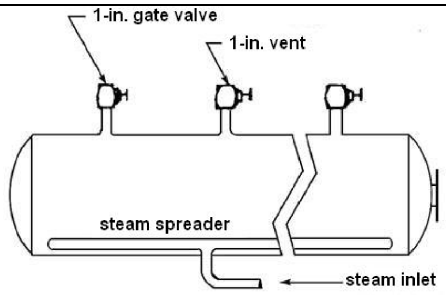

Figure 3: Installation of the vents.

II. Venting through multiple 25 mm (1 inch) vents discharging through a manifold to atmosphere (Figure 4):
   i. Specifications: One 1-inch vent for every 152 cm (5 feet) of retort length; and vents not over 76 cm (2.5 feet) from ends of retort: Size of manifold--for retorts less than 457 cm (15 feet) in length, 64 mm (2.5 inches); for retorts 457 cm (15 feet) and over in length, 76 mm (3inches).
   ii. Venting method: Manifold vent gate or plug cock valve shall be fully open for at least 6 minutes and to at least 108°C, or for at least 8 minutes and to at least 105°C.

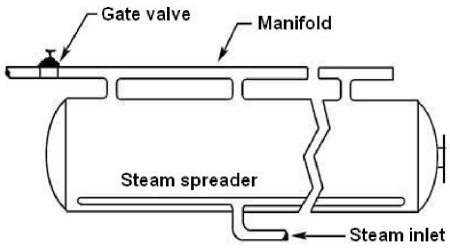

Figure 4: Installation of the vents.

III. Venting through water spreaders (Figure 5):
   i. Size of vent and vent valve: For retorts less than 457 cm (15 feet) in length, 50 mm (2 inches); for retorts 457 cm (15 feet) and over in length, 64 mm (2.5 inches).
   ii. Size of water spreader: For retorts less than 457 cm (15 feet) in length, 38 mm (1.5 inches); for retorts 457 cm (15 feet) and over in length, 50mm (2 inches). The number of holes shall be such that their total cross-sectional area is approximately equal to the cross-sectional area of the vent pipe inlet.
   iii. Venting method: Water spreader vent gate or plug cock valve shall be fully open for at least 5 minutes and to at least 108°C, or for at least 7 minutes and to at least 105°C.

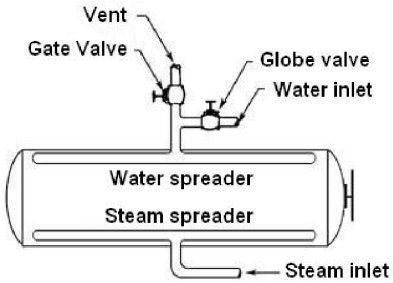

Figure 5: Installation of the vents.

IV. Venting through a single 64 mm (2.5 inches) top vent (for retorts not exceeding 457 cm (15 feet) in length) (Figure 6):

i. Specifications: A 64 mm (2.5 inches) vent equipped with a 64 mm (2.5 inches) gate or plug cock valve and located within 61cm (2 feet) of the center of the retort.

ii. Venting method: Vent gate or plug cock valve shall be wide open for at least 4 minutes and to at least 105°C.

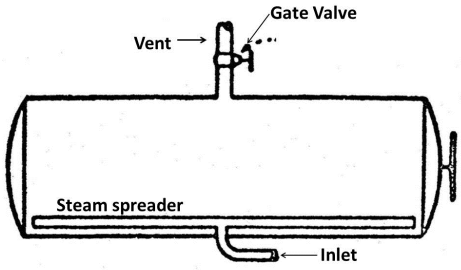

Figure 6: Installation of the vents.

Venting vertical retorts

I. Venting through a 38 mm (1.5 inches) overflow (Figure 7):

i. Specifications: A 38 mm (1.5 inches) overflow pipe equipped with a 38 mm (1.5 inches) gate or plug cock valve and with not more than 183 cm (6 feet) of 38 mm (1.5 inches) pipe beyond the valve before break to the atmosphere or to a manifold header.

ii. Venting method: Vent gate or plug cock valve shall be wide open for at least 4 minutes and to at least 104°C, or for at least 5 minutes and to at least 102°C.

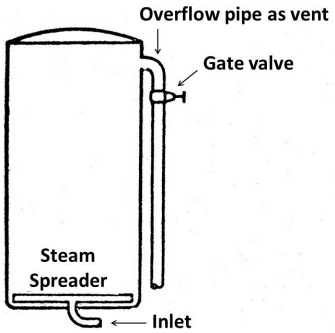

Figure 7: Installation of the vents.

II. Venting through a single 1-inch side or top vent (Figure 8):

i. Specifications: A 25 mm (1 inch) vent in lid or top side, equipped with a 1-inch gate or plug cock valve and discharging directly into the atmosphere

ii. Venting method: Vent gate or plug cock valve shall be wide open for at least 5 minutes and to at least 110°C, or for at least 7 minutes and to at least 105°C .

Figure 8: Installation of the vents.

III. Other installations and operating procedures that deviate from the above specifications may be used if there is evidence in the form of heat distribution data, which shall be kept on file, indicating that they accomplish adequate venting of air.

(9) Stacking equipment:

It shall be made of metal strips, perforated metal sheets or other suitable materials. The perforations of stacking equipment shall be approximately the equivalent of 25 mm (1 inch) holes on 50 mm (2 inches) centers. Also, the total cross-sectional area of holes is not

smaller than 36% of the sheet area. If dividers are used between the layers of containers, they shall be perforated as above.

(10) Crate supports:

A. Baffle plates shall not be used in the bottom of still retorts.

B. A bottom crate support shall be used in vertical still retorts.

(11) Safety valve:

A. Each retort shall have a safety valve.

B. Its aperture shall not be smaller than the diameter of a steam inlet pipe, and it shall be inspected regularly.

(12) The steam pressure from the main steam pipe for use in sterilizing retort shall remain more than 6 kg/cm^2.

(13) Cooling method

A. When performing the cooling in a retort, water shall enter via the top water jet pipe of a horizontal retort, via top water jet ring for a vertical retort. As for the water jet pipe on a horizontal retort, it shall have more than 3 rows of water jet holes to spray water downward (when the 3 rows of water jet holes are being used, the central one row will be vertical and downward, while the remaining two rows will form a 45 degree angle to it).

B. The water inlet pipe shall be installed with a globe valve or ball valve. No gate valve shall be used here.

C. The pipe diameter of the drainage pipe shall not be smaller than pipe diameter of the water inlet.

D. As for the air pipe for air pressuring and cooling, the situation regarding its pipe valve is the same as that of the water inlet pipe.

E. As for the cooling water for finished products after sterilization, the cooling water shall be chlorinated, whose outlet shall be detected to have at least 0.2 ppm of effective residual chlorine.

(14) Controls on the critical factors in sterilization:

Critical factors specified in the scheduled process shall be measured and recorded on the processing record at intervals of sufficient frequency to ensure that the factors are within the limits specified in the scheduled process.

A. Heat distribution, including venting, come-up time, and final process temperature etc., shall be tested by the institution having the expertise regarding heat sterilization of low-acid canned foods, and which has been approved by the central competent

authority.

B. When maximum fill-in or drained weight is specified in the scheduled process, it shall be measured and recorded at intervals of sufficient frequency to ensure that the weight of the product does not exceed the maximum for the given container size specified in the scheduled process.

C. The operation of sterilization shall be controlled and recorded at intervals of sufficient frequency to comply with scheduled process, including, but not limited to, vacuum, head space, viscosity etc. when as specified in the scheduled process.

(15) Incubation test:

Incubation tests shall be conducted on a reasonable product samples from each code; records of the test results shall be maintained.

3. Equipment and procedures for pressure processing in water in still retorts:

(1) Indicating mercury-in-glass thermometer:

A. Each retort shall be equipped with at least one mercury-in-glass thermometer whose divisions are easily readable to 5°C, with a length of at least 178 mm (7 inches), and whose temperature range does not exceed 55°C.

B. Before installation, thermometer shall be calibrated by the institution approved by the central competent authority. After installation, it shall be calibrated at least once every year. The calibration institution shall keep calibration record.

C. Each thermometer shall have a tag, seal, or other means of identity that includes the date on which it was last tested for accuracy.

D. A thermometer that has a divided mercury column or that cannot be adjusted to the standard shall be repaired or replaced before further use of the retort.

E. Thermometers shall be installed where they can be accurately and easily read.

F. During the process of sterilization, the mercury thermometer--not the recorder chart--shall be the reference instrument for indicating the processing temperature, which can NOT be substituted by the recorded temperature on the automatic

temperature-recording device.

G. In both vertical and horizontal retorts, this thermometer bulbs shall extend directly into the water a minimum of at least 50 cm (2 inches).

H. On horizontal retorts, this entry shall be made in the side at the center.

(2) Temperature-recording device:

A. Each still retort shall have an accurate temperature-recording device. Graduations on the temperature-recording devices shall not exceed 1°C within a range of 5°C of the processing temperature. Each chart shall have a working scale of not more than 25 °C per 25 mm (1 inch) within a range of 10°C of the processing temperature.

B. The temperature chart shall be adjusted to agree as nearly as possible with, but to be in no event higher than, the known accurate mercury-in-glass thermometer during the process time.

C. A means of preventing unauthorized changes in adjustment shall be provided. A lock, or a notice from management posted at or near the recording device which provides a warning that only authorized persons are permitted to make adjustments, is a satisfactory means for preventing unauthorized changes.

D. The recorder may be combined with the steam controller and may be a recording-controlling instrument. The recording-thermometer bulb shall be located adjacent to the bulb of the mercury-in-glass thermometer, except in the case of a vertical retort equipped with a combination recorder-controller.

E. In such vertical retorts, the temperature recorder-control bulb shall be located at the bottom of the retort below the lowest crate rest in such a position that the steam does not strike it directly.

F. In horizontal retorts, the temperature recorder-control bulb shall be located between the water surface and the horizontal plane passing through the center of the retort so that there is no opportunity for direct steam impingement on the control bulb.

G. Air-operated temperature controllers shall have adequate filter systems to ensure a supply of clean and dry air.

(3) Pressure gauge and pressure control device:

A. Each retort shall be equipped with a pressure gage of which the dial diameter shall not be smaller than 114 mm (4 and 1/2 inch), with the range of reading from zero to 3.5 kg/cm^2. The meter shall be able to indicate a reading of 0.1 kg/cm^2.
B. It shall be calibrated at least once every year.
C. Pressure gages shall be connected with circular bends.
D. Pressure shall NOT be used for the only basis for sterilization process.
E. Each retort shall have an adjustable pressure relief or control valve of a capacity sufficient to prevent an undesired increase in retort pressure when the water valve is wide open and shall be installed in the overflow line.

(4) Steam controller:
A. Each retort shall be equipped with a steam controller.
B. If no automatic steam controller is installed, manual operation is adopted instead, records shall be taken during the process of sterilization operation, in order to ensure the compliance of sterilization process requirement.

(5) Steam introduction:
A. Steam shall be distributed in the bottom of the retort in a manner adequate to provide uniform heat distribution throughout the retort.
B. In vertical retorts, uniform steam distribution can be achieved by any of several methods.
C. In horizontal retorts, the steam distributor shall run the length of the bottom of the retort with perforations distributed uniformly along the upper part of the pipe.

(6) Crate supports:
A bottom crate support shall be used in vertical still retorts. Centering guides shall be installed so as to ensure that there is about a 4 cm (1 1/2-inch) clearance between the side wall of the crate and the retort wall.

(7) Drain valve:
A non-clogging, water-tight valve shall be used. Screens shall be installed over all drain openings.

(8) Water level indicator:
A. There shall be a means of determining the water level in the

retort during operation, e.g., by using a glass-plate water gauge, water level gauge, etc.

B. Water shall cover the top layer of containers during the entire come-up-time and processing periods and shall cover the top layer of containers during the cooling periods.

C. The operator shall check and record the water level at intervals sufficient to ensure its adequacy.

(9) Air supply and controls:

A. In both horizontal and vertical still retorts for pressure processing in water, a means shall be provided for introducing compressed air at the proper pressure and rate. It shall be introduced into the steam line at a point between the retort and the steam control valve at the bottom of the retort.

B. If no automatic pressure control unit is installed, the pressure shall be controlled manually, in order to be in accordance with scheduled process.

C. A check valve shall be provided in the air supply line to prevent water from entering the air supply system.

(10) Water circulation:

A. When a water circulating system is used for heat distribution, it shall be installed in such a manner that water will be drawn from the bottom of the retort through a suction manifold and discharged through a spreader which extends the length of the top of the retort. The holes in the water spreader shall be uniformly distributed and shall have an aggregate area not greater than the cross-section area of the outlet line from the pump.

B. The suction outlets shall be protected with non-clogging screens to keep debris from entering the circulating system.

C. The pump shall be equipped with a pilot light or other signaling device to warn the operator when it is not running, and with a bleeder to remove air when starting operations.

(11) Retort headspace:

The headspace necessary to control the air pressure shall be maintained between the water level and the top of the retort shell.

(12) Cooling water supply:

A. In vertical retorts the cooling water shall be introduced at the top of the retort between the water and container levels.

B. In horizontal retorts the cooling water shall be introduced into the suction side of the pump. A check valve shall be included in the cooling water line.

(13) Controls on the critical factors:

Critical factors specified in the scheduled process shall be measured and recorded on the processing record at intervals of sufficient frequency to ensure that the factors are within the limits specified in the scheduled process.

A. Heat distribution, including venting, come-up time, and process temperature etc., shall be tested by the institution having the expertise regarding heat sterility of low-acid canned foods, and which has been approved by the central competent authority.

B. When maximum fill-in or drained weight is specified in the scheduled process, it shall be measured and recorded at intervals of sufficient frequency to ensure that the weight of the product does not exceed the maximum for the given container size specified in the scheduled process.

C. The operation of sterilization shall be controlled and recorded at intervals of sufficient frequency to comply with scheduled process, including, but not limited to, vacuum, head space, viscosity etc. when as specified in the scheduled process.

(14) Incubation test:

Incubation tests shall be conducted on a reasonable product samples from each code; records of the test results shall be maintained.

4. Equipment and procedures for pressure processing in steam in discontinuous agitating retorts:

(1) Indicating mercury-in-glass thermometer:

A. Each retort shall be equipped with at least one mercury-in-glass thermometer whose divisions are easily readable to 0.5°C, with a length of at least 178mm (7 inches), and whose temperature range does not exceed 55°C.

B. Before installation, thermometer shall be calibrated by the institution approved by the competent authority. After installation, it shall be calibrated at least once every year. The calibration institution shall keep calibration record.

C. Each thermometer shall have a tag, seal, or other means of

identity that includes the date on which it was last tested for accuracy.

D. A thermometer that has a divided mercury column or that cannot be adjusted to the standard shall be repaired or replaced before further use of the retort.

E. Thermometers shall be installed where they can be accurately and easily read.

F. During the process of sterilization, the mercury thermometer--not the recorder chart--shall be the reference instrument for indicating the processing temperature, which can NOT be substituted by the recorded temperature on the automatic temperature-recording device.

(2) Temperature-recording device:

A. Each still retort shall have an accurate temperature-recording device. Graduations on the temperature-recording devices shall not exceed 1°C within a range of 5°C of the processing temperature. Each recording chart shall have a working scale of not more than 25 °C per 25 mm (1 inch) within a range of 10°C of the processing temperature.

B. The recorded temperature shall be adjusted to agree as nearly as possible with, but to be in no event higher than, the known accurate mercury-in-glass thermometer during the process time.

C. A means of preventing unauthorized changes in adjustment shall be provided. A lock, or a notice from management posted at or near the recording device which provides a warning that only authorized persons are permitted to make adjustments, is a satisfactory means for preventing unauthorized changes.

(3) Pressure gauge and pressure control device:

A. Each retort shall be equipped with a pressure gauge of which the dial diameter shall not be smaller than 114 mm (4 and 1/2 inch), with the range of reading from zero to 3.5 kg/cm^2. The meter shall be able to indicate a reading of 0.1 kg/cm^2.

B. It shall be calibrated at least once every year.

C. Pressure gauges shall be connected with circular bends.

D. Pressure shall NOT be used for the only basis for sterilization process.

(4) Steam controller:

A. Each retort shall be equipped with a steam controller.
B. If no automatic steam controller is installed, manual operation is adopted instead; records shall be taken during the process of sterilization operation, in order to ensure the compliance of sterilization process requirement.

(5) Bleeders
A. Bleeders, except those for thermometer wells, shall be 3.2 mm (1/8 inch) or larger.
B. It shall be wide open during the entire process, including exhaust, come-up-time, and sterilization.
C. For horizontal still retorts, bleeders shall be located within approximately 20 cm (8 inches) of the outermost locations of containers at each end along the top of the retort; additional bleeders shall be located not more than 240 cm (8 feet) apart along the top.

(6) Venting and condensate removal:
A. The air in each retort shall be removed before processing is started.
B. At the time steam is turned on, the drain shall be opened for a time sufficient to remove steam condensate from the retort, and provision shall be made for continuing drainage of condensate during the retort operation.

(7) Retort speed timing:
A. The rotational speed of the retort shall be specified in the scheduled process.
B. The rotational speed as well as the process time shall be recorded for each retort process.
C. A means of preventing unauthorized speed changes on retorts shall be provided. A lock, or a notice from management posted at or near the speed adjustment device that provides a warning that only authorized persons are permitted to make adjustments, is a satisfactory means of preventing unauthorized changes.

(8) Controls on the critical factors in sterilization:
Critical factors specified in the scheduled process shall be measured and recorded on the processing report at intervals of sufficient frequency to ensure that the factors are within the limits specified in the scheduled process.

A. Heat distribution, including venting, come-up time, and process temperature etc., shall be tested by the institution having the expertise regarding heat sterilization of low-acid canned foods, and which has been approved by the central competent authority.

B. When maximum fill-in or drained weight is specified in the scheduled process, it shall be measured and recorded at intervals of sufficient frequency to ensure that the weight of the product does not exceed the maximum for the given container size specified in the scheduled process.

C. The operation of sterilization shall be controlled and recorded at intervals of sufficient frequency to comply with scheduled process, including, but not limited to, vacuum, head space, viscosity etc. when as specified in the scheduled process.

D. Items such as retort speed, minimum headspace (or the maximum fill-in), viscosity, and can arrangement, shall be set up as critical factors.

(9) Incubation test:

Incubation tests shall be conducted on reasonable product samples from each code; records of the test results shall be maintained.

5. Equipment and procedures for pressure processing in water in discontinuous agitating retorts:

(1) Indicating mercury-in-glass thermometer:

A. Each retort shall be equipped with at least one mercury-in-glass thermometer whose divisions are easily readable to 0.5°C, with a length of at least 178 mm (7 inches), and whose temperature range does not exceed 55°C.

B. Before installation, thermometer shall be calibrated by the institution approved by the competent authority. After installation, it shall be calibrated at least once every year. The calibration institution shall keep calibration record.

C. Each thermometer shall have a tag, seal, or other means of identity that includes the date on which it was last tested for accuracy.

D. A thermometer that has a divided mercury column or that cannot be adjusted to the standard shall be repaired or replaced before further use of the retort.

E. Thermometers shall be installed where they can be accurately and

easily read.

F. During the process of sterilization, the mercury thermometer--not the recorder chart--shall be the reference instrument for indicating the processing temperature, which can NOT be substituted by the recorded temperature on the automatic temperature-recording device.

G. Bulbs of indicating thermometers shall be installed either within the retort shell or in external wells attached to the retort.

(2) Temperature-recording device:

A. Each retort shall have an accurate temperature-recording device. Graduations on the temperature-recording devices shall not exceed 1°C within a range of 5°C of the processing temperature. Each recording chart shall have a working scale of not more than 25 °C per 25 mm (1 inch) within a range of 10°C of the processing temperature.

B. The recorded temperature shall be adjusted to agree as nearly as possible with, but to be in no event higher than, the known accurate mercury-in-glass thermometer during the process time.

C. A means of preventing unauthorized changes in adjustment shall be provided. A lock, or a notice from management posted at or near the recording device which provides a warning that only authorized persons are permitted to make adjustments, is a satisfactory means for preventing unauthorized changes.

D. The temperature-recorder bulb shall be installed either within the retort shell or in a well attached to the shell.

(3) Pressure gauge and pressure control device:

A. Each retort shall be equipped with a pressure gage of which the dial diameter shall not be smaller than 114 mm (4 and 1/2 inch), with the range of reading from zero to 3.5 kg/cm^2. The meter shall be able to indicate a reading of 0.1 kg/cm^2.

B. It shall be calibrated at least once every year.

C. Pressure gages shall be connected with circular bends.

D. Pressure shall NOT be used for the only basis for sterilization process.

(4) Steam controller:

A. Each retort shall be equipped with a steam controller.

B. If no automatic steam controller is installed, manual operation is

adopted instead; records shall be taken during the process of sterilization operation, in order to ensure the compliance of sterilization process requirement.

(5) Air supply and control:

A. In both horizontal and vertical retorts for pressure processing in water, a means shall be provided for introducing compressed air at the proper pressure and rate. It shall be introduced into the steam line at a point between the retort and the steam control valve at the bottom of the retort.

B. If no automatic pressure control unit is installed, the pressure shall be controlled manually, in order to be in accordance with scheduled process.

(6) Retort speed timing:

A. The rotational speed of the retort shall be specified in the scheduled process.

B. The rotational speed as well as the process time shall be recorded for each retort process.

C. A means of preventing unauthorized speed changes on retorts shall be provided. A lock, or a notice from management posted at or near the speed adjustment device that provides a warning that only authorized persons are permitted to make adjustments, is a satisfactory means of preventing unauthorized changes.

(7) Controls on the critical factors in sterilization:

Critical factors specified in the scheduled process shall be measured and recorded on the processing record at intervals of sufficient frequency to ensure that the factors are within the limits specified in the scheduled process.

A. Heat distribution, including venting, come-up time, and process temperature etc., shall be tested by the institution having the expertise regarding heat sterilization of low-acid canned foods, and which has been approved by the central competent authority.

B. When maximum fill-in or drained weight is specified in the scheduled process, it shall be measured and recorded at intervals of sufficient frequency to ensure that the weight of the product does not exceed the maximum for the given container size specified in the scheduled process.

C. The operation of sterilization shall be controlled and recorded at

intervals of sufficient frequency to comply with scheduled process, including, but not limited to, vacuum, head space, viscosity etc. when as specified in the scheduled process.

D. Items such as retort speed, minimum headspace (or the maximum fill-in), viscosity, and can arrangement, shall be set up as critical factors.

(8) Incubation test:

Incubation tests shall be conducted on reasonable product samples from each code; records of the test results shall be maintained.

6. Aseptic processing and packaging systems:

(1) Product sterilizer:

A. Equipment

I. Temperature-indicating device

i. Each product sterilizer shall be equipped with at least one temperature indicating device e.g. mercury-in-glass thermometer, or equivalent thermocouple-recorder, etc.

ii. If a mercury-in-glass thermometer is applied, it shall conform to:

(i) Its divisions are easily readable to 0.5°C, with a length of at least 178mm (7 inches), and whose temperature range does not exceed 55°C.

(ii) Before installation, thermometer shall be calibrated by the institution approved by the central competent authority. After installation, it shall be calibrated at least once every year. The calibration institution shall keep calibration record.

(iii) Each thermometer shall have a tag, seal, or other means of identity that includes the date on which it was last tested for accuracy.

(iv) A thermometer that has a divided mercury column or that cannot be adjusted to the standard shall be repaired or replaced before further use of the retort.

(v) Thermometers shall be installed where they can be accurately and easily read.

iii. If a mercury thermometer is not applied,

(i) As for sterility temperature, it shall be based on the temperature indicated on the temperature indication

device.

(ii) The temperature sensing part shall be at the place between the outlet of the holding tube and the inlet of the cooling tube, in which it is able to sense the product temperature directly.

II. Temperature-recording device:

i. There shall be an accurate temperature recording device on each product sterilizer. Temperature-recording devices shall have graduations that do not exceed 1°C within a range of 5°C of the processing temperature. Each recording chart shall have a working scale of not more than 25°C per 25 mm (1 inch) within a range of 10°C of the processing temperature.

ii. The temperature sensing part shall be at the place between the outlet of the holding tube and the inlet of the cooling tube, in which it is able to sense the product temperature directly.

iii. The temperature chart shall be adjusted to agree as nearly as possible with, but to be in no event higher than, the known accurate mercury-in-glass thermometer during the process time.

iv. A means of preventing unauthorized changes in adjustment shall be provided. A lock, or a notice from management posted
at or near the recording device which provides a warning that only authorized persons are permitted to make adjustments, is a satisfactory means for preventing unauthorized changes.

III. Temperature recorder-controller:

i. There shall be an accurate temperature recording control device in order to ensure the product is maintained at the required sterilization temperature.

ii. Air-operated temperature controllers shall have adequate filter systems to ensure a supply of clean, dry air.

IV. Product-to-product regenerators:

It shall be designed, operated, and controlled so that the pressure of the sterilized product in the regenerator is

greater than the pressure of any unsterilized product in the regenerator.

V. Metering pump:
   i. A metering pump shall be located upstream from the holding tube and shall be operated to maintain the required rate of product flow.
   ii. A means of preventing unauthorized speed changes shall be provided. A lock, or a notice from management posted at or near the speed-adjusting device that provides a warning that only authorized persons are permitted to make adjustments, is a satisfactory means of preventing unauthorized changes.

VI. Product holding tube:
   i. The product-sterilizing holding tube shall be designed to give continuous holding of every particle of food for at least the minimum holding time specified in the scheduled process.
   ii. Such time shall conform to the set sterilization time.
   iii. The holding tube shall be designed so that no portion of the tube between the product inlet and the product outlet can be heated, and avoid any situation that may affect the product temperature within the tube.

VII. Flow-diversion systems:
   Controls and/or warning systems shall be designed and installed with necessary sensors and actuators to operate whenever the sterilizing temperature in the holding tube or pressure differential in the product regenerator drops below specified limits.

VIII. Equipment downstream from the holding tube:
   Product coolers, aseptic surge tanks, or any other equipment downstream from the holding tube, with rotating or reciprocating shafts, valve stems, instrument connections, or other such points, are subject to potential entry of microorganisms into the product. Such locations in the system shall be equipped with steam seals or other effective barriers at the potential access points. Appropriate means shall be provided to permit the operator to monitor the

performance of the seals or barriers during operations.

B. Operation

I. Pre-sterilization:

Startup:

Before the start of aseptic processing operations the product sterilizer and all product-contact surfaces downstream shall be brought to a condition of commercial sterility, which shall also be recorded on proper devices for verification.

II. Temperature drop in product-sterilizing holding tube:

i. When product temperature in the holding tube drops below the temperature specified in the scheduled process, product flow shall be diverted away from the filler or aseptic surge tank by means of a flow-diversion system.

ii. If for any reason product subjected to a temperature drop below the scheduled process is filled into containers, the product shall be segregated from product that received the scheduled process. The products shall be either fully reprocessed or destroyed, unless it is verified that they are free of viable microorganisms or spores of public health significance.

iii. If product holding tube and any further system portions affected shall be returned to a condition of commercial sterility before product flow is resumed to the filler or to the aseptic surge tank.

III. Loss of proper pressures in the regenerator:

i. When a regenerator is used, the product may lose sterility whenever the pressure of sterilized product in the regenerator is less than 0.07 kg/cm^2 greater than the pressure of unsterilized product in the regenerator. In this case, product flow shall be diverted away from the filler or aseptic surge tank by means of the flow-diversion system.

ii. If for any reason the product is filled into containers, the product shall be segregated from product that received the scheduled process and shall be reprocessed or destroyed.

iii. Product flow to the filler or to the aseptic surge tank shall not be resumed until the cause of the improper pressure relationships in the regenerator has been corrected and the

affected system(s) has been returned to a condition of commercial sterility.

IV. Loss of sterile air pressure or other protection level in the aseptic surge tank:

i. When an aseptic surge tank is used, conditions of commercial sterility may be lost when the sterile air overpressure or other means of protection drops below the scheduled process. The potentially contaminated product in the tank shall be removed.

ii. Product flow to and/or from the aseptic surge tank shall not be resumed until the aseptic surge tank has been returned to a condition of commercial sterility.

V. Sterilization records:

i. Readings at the following points shall be observed and recorded at the start of aseptic packaging operations and at intervals of sufficient frequency to ensure that these values are as specified in the scheduled process. The measurements and recordings shall be made at intervals not to exceed 1 hour.

ii. Temperature-indicating device and temperature recorder in holding tube outlet.

iii. Differential pressure recorder-controller, if a product-to-product regenerator is used.

iv. Product flow rate as established by the metering pump or as determined by filling and closing rates.

v. If an aseptic surge tank is used, sterile air pressure or other protection means.

vi. Inspections on steam seals or other blocking devices for preventing microbial invasion in the equipment and piping.

(2) Container sterilizing, filling, and closing operation:

A. Equipment

I. Recording device:

The container and closure sterilization system and product filling and closing system shall be instrumented to demonstrate that the required sterilization is being accomplished continuously. Automatic recording devices shall be used to record, when applicable, the sterilization

media flow rates, temperature, concentration, or other factors. When a batch system is used for container sterilization, the sterilization conditions shall be recorded.

II. Timing method:

i. A method(s) shall be used either to give the retention time of containers, and closures if applicable, in the sterilizing environment specified in the scheduled process, or to control the sterilization cycle at the rate specified in the scheduled process.

ii. A means of preventing unauthorized speed changes must be provided. A lock, or a notice from management posted at or near the speed adjusting device that provides a warning that only authorized persons are permitted to make adjustments, is a satisfactory means of preventing unauthorized changes.

B. Operation

I. Startup:

Before the start of packaging operations, both the container and closure sterilizing system and the product filling and closing system shall be brought to a condition of commercial sterility.

II. Loss of sterility:

i. A system shall be provided to stop packaging operations, or alternatively to ensure segregation of any product packaged when the packaging conditions fall below scheduled processes. Compliance with this requirement may be accomplished by diverting product away from the filler or aseptic storage tank.

ii. In the event product is packaged under conditions below those specified in the scheduled process, all such product shall be segregated from normal products.

iii. In the event of loss of sterility, the system(s) shall be returned to a condition of commercial sterility before resuming packaging operations.

III. Records of container filling and sterilization:

i. Observations and measurements of operating conditions shall be made and recorded at intervals of sufficient

frequency; such measurements shall include the sterilization media flow rates, sterilization temperatures, the container sterilization conditions and closure rates.

ii. The measurements and recordings shall be made at intervals not to exceed 1 hour.

(3) Incubation test:
Incubation tests shall be conducted on reasonable product samples from each code; records of the test results shall be maintained.

(4) Critical factors:
Critical factors specified in the scheduled process shall be measured and recorded on the processing record at interval of sufficient frequency.

7. As for the sterilizer for other types of low-acid canned foods, the Practice shall be followed accordingly. Also, to achieve the purpose of commercial sterility, sterilizer shall be tested by the institution having the expertise of heat sterilization of low-acid canned foods, which has been approved by the central competent authority.

Table 6 Container Sealing and Control Guideline for Low-Acid and Acidified Canned Foods Manufactures

1. Sealing (capping) of containers shall conform the following stipulations:
   (1) The visual examination on the appearance of metal cans shall be undertaken by qualified personnel who have received training in Seamer Operation Technique or Seaming QC as indicated in Article 35 Subparagraph 2. Such measurements and recordings shall be taken and recorded at intervals not to exceed one hour.
   (2) No following defects shall appear in cans; cutover, cut seam, sharp seam, false seam, jump-over, vees and lips.
   (3) Teardown examinations for double-seam cans shall be performed by a qualified container closure inspector as indicated in Article 35 Subparagraph 2. Such measurements shall be made and recorded at the start working and additional inspections shall be made at intervals not to exceed 4 hours.
   (4) The inspection items in the above mentioned shall include: seam width and thickness, countersink, cover hook, body hook; overlap length or overlap percent, and wrinkles. The seam quality and inspection method shall comply with Chinese National Standard, Rounded Mattel Cans for Foods.
   (5) The cap of glass bottle shall not have the defects of incomplete sealing in the appearance inspection, such as improper torque or loose caps.
   (6) As for the appearance inspection on the seal of a retort pouch, the defects causing bag leaking, such as a pin hole, uneven seal, inclusion residual at the seal, or incomplete seal, etc. The QC and inspection methods shall conform to related Standards for Foods Contained in Retort Pouches and the Retort Pouch Inspection Method for Packaged Foods in accordance with Chinese National Standard.
   (7) For containers other than metal can, glass containers and retort pouch, appropriate detailed inspections and tests shall be conducted by qualified personnel at intervals of sufficient frequency to ensure proper closing machine performance and consistently reliable hermetic seal production. Records of such tests shall be maintained.

2. When cans after cooling are handled on belt conveyors, the conveyors shall be so constructed as to minimize the conveyors to contact the portion of double seam. All worn and frayed belting, can retarders, cushions, etc. shall be replaced with new nonporous material. All tracks and belts that come into contact with the can seams shall be kept clean thoroughly.