

(Rule 1200-23-1-.04, continued)

glove.

- (iv) Cloth gloves may not be used in direct contact with food unless the food is subsequently cooked as required under 1200-23-01-.03(4)(a)-(b) such as frozen food or a primal cut of meat.

6. Using Clean Tableware for Second Portions and Refills.

- (i) Except for refilling a consumer's drinking cup or container without contact between the pouring utensil and the lip-contact area of the drinking cup or container, food employees may not use tableware, including single-service articles, soiled by the consumer, to provide second portions or refills.
- (ii) Except as specified in (iii) of this part, self-service consumers may not be allowed to use soiled tableware, including single-service articles, to obtain additional food from the display and serving equipment.
- (iii) Drinking cups and containers may be reused by self-service consumers if refilling is a contamination-free process as specified under 1200-23-01-.04(2)(d)3(i),(ii) and (iv).

7. Refilling Returnables.

- (i) A take-home food container returned to a food establishment may not be refilled at a food establishment with a time/temperature control for safety food.
- (ii) Except as specified in subpart (iii) of this subpart, a take-home food container refilled with food that is not time/temperature control for safety food shall be cleaned as specified under 1200-23-01-.04(6)(c)7(ii).
- (iii) Personal take-out beverage containers, such as thermally insulated bottles, nonspill coffee cups, and promotional beverage glasses, may be refilled by employees or the consumer if refilling is a contamination-free process as specified under 1200-23-01-.04(2)(d)3(i), (ii) and (iv).

(e) Preventing Contamination from the Premises

1. Food Storage.

- (i) Except as specified in subparts (ii) and (iii) of this part, food shall be protected from contamination by storing the food:
- (I) In a clean, dry location;
- (II) Where it is not exposed to splash, dust, or other contamination;
and
- (III) At least 15 cm (6 inches) above the floor.
- (ii) Food in packages and working containers may be stored less than 15 cm (6 inches) above the floor on case lot handling equipment as specified

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under 1200-23-01-.04(9)(c)1(iv).

- (iii) Pressurized beverage containers, cased food in waterproof containers such as bottles or cans, and milk containers in plastic crates may be stored on a floor that is clean and not exposed to floor moisture.

2. Food Storage, Prohibited Areas. Food may not be stored:

- (i) In locker rooms;
(ii) In toilet rooms;
(iii) In dressing rooms;
(iv) In garbage rooms;
(v) In mechanical rooms;
(vi) Under sewer lines that are not shielded to intercept potential drips;
(vii) Under leaking water lines, including leaking automatic fire sprinkler heads, or under lines on which water has condensed;
(viii) Under open stairwells; or
(ix) Under other sources of contamination.

3. Food Preparation. During preparation, unpackaged food shall be protected from environmental sources of contamination.

(f) Preventing Contamination by Consumers

1. Food Display. Except for nuts in the shell and whole, raw fruits and vegetables that are intended for hulling, peeling, or washing by the consumer before consumption, food on display shall be protected from contamination by the use of packaging; counter, service line, or salad bar food guards; display cases; or other effective means. (P)

2. Condiments, Protection. Condiments shall be protected from contamination by being kept in dispensers that are designed to provide protection, protected food displays provided with the proper utensils, original containers designed for dispensing, or individual packages or portions.

3. Consumer Self-Service Operations.

- (i) Raw, unpackaged animal food, such as beef, lamb, pork, poultry, and fish may not be offered for consumer self-service. This paragraph does not apply to:
- (I) Consumer self-service of ready-to-eat foods at buffets or salad bars that serve foods such as sushi or raw shellfish;
- (II) Ready-to-cook individual portions for immediate cooking and consumption on the premises such as consumer-cooked meats

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or consumer-selected ingredients for Mongolian barbecue; or(III) Raw, frozen, shell-on shrimp, or lobster.(ii) Consumer self-service operations for ready-to-eat foods shall be provided with suitable utensils or effective dispensing methods that protect the food from contamination. (Pf)(iii) Consumer self-service operations such as buffets and salad bars shall be monitored by food employees trained in safe operating procedures. (Pf)

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4. Returned Food and Re-Service of Food.(i) Except as specified in subpart (ii) of this part, after being served or sold and in the possession of a consumer, food that is unused or returned by the consumer may not be offered as food for human consumption. (P)(ii) Except as specified under 1200-23-01-.03(8)(g), a container of food that is not time/temperature control for safety food may be re-served from one consumer to another if:(I) The food is dispensed so that it is protected from contamination and the container is closed between uses, such as a narrow-neck bottle containing catsup, steak sauce, or wine; or(II) The food, such as crackers, salt, or pepper, is in an unopened original package and is maintained in sound condition.5. Preventing Contamination from Other Sources - Miscellaneous Sources of Contamination: Food shall be protected from contamination that may result from a factor or source not specified under 1200-23-01-.03(3)(a)-(f).(4) Destruction of Organisms of Public Health Concern(a) Cooking1. Raw Animal Foods.(i) Except as specified under subparts (ii),(iii) and (iv) of this part, raw animal foods such as eggs, fish, meat, poultry, and foods containing these raw animal foods, shall be cooked to heat all parts of the food to a temperature and for a time that complies with one of the following methods based on the food that is being cooked:(I) 63°C (145°F) or above for 15 seconds for: (P)I. Raw eggs that are broken and prepared in response to a consumer's order and for immediate service, (P) andII. Except as specified under items (i)(II) and (i)(III) and subparts (ii), and (iii) of this part, fish and meat including game animals commercially raised for food as specified under 1200-23-01-.03(2)(a)7(i) and game animals under

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a voluntary inspection program as specified under 1200-23-01-.03(2)(a)7(ii); (P)

- (II) 68°C (155°F) for 15 seconds or the temperature specified in the following chart that corresponds to the holding time for ratites, mechanically tenderized, and injected meats; the following if they are comminuted: fish, meat, game animals commercially raised for food as specified under 1200-23-01-.03(2)(a)7(i), and game animals under a voluntary inspection program as specified under 1200-23-01-.03(2)(a)7(i)(II) and raw eggs that are not prepared as specified under 1(i)(I) of this subparagraph: (P) or

<u>Minimum</u>	
<u>Temperature</u>	<u>Time</u>
<u>°C (°F)</u>	
63 (145)	3 minutes
66 (150)	1 minute
70 (158)	< 1 second (instantaneous)

<u>Oven Type</u>	<u>Oven Temperature Based on Roast Weight</u>	
	<u>Less than 4.5 kg (10lbs)</u>	<u>4.5 kg (10 lbs) or More</u>
<u>Still Dry</u>	<u>177°C (350°F) or more</u>	<u>121°C (250°F) or more</u>
<u>Convection</u>	<u>163°C (325°F) or more</u>	<u>121°C (250°F) or more</u>
<u>High Humidity¹</u>	<u>121°C (250°F) or less</u>	<u>121°C (250°F) or less</u>

¹Relative humidity greater than 90% for at least 1 hour as measured in the cooking chamber or exit of the oven; or in a moisture-impermeable bag that provides 100% humidity.

- (III) 74°C (165°F) or above for 15 seconds for poultry, baluts, wild game animals as specified under 1200-23-01-.03(2) (a) 7 (iii) and (iv), stuffed fish, stuffed meat, stuffed pasta, stuffed poultry, stuffed ratites, or stuffing containing fish, meat, poultry, or ratites. (P)

- (ii) Whole meat roasts including beef, corned beef, lamb, pork, and cured pork roasts such as ham shall be cooked:

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- (I) In an oven that is preheated to the temperature specified for the roast's weight in the following chart and that is held at that temperature: (P); and
- (II) As specified in the following chart, to heat all parts of the food to a temperature and for the holding time that corresponds to that temperature: (P)

<u>Temperature °C (°F)</u>	<u>Time¹ in Minutes</u>	<u>Temperature °C (°F)</u>	<u>Time¹ in Seconds</u>
54.4 (130)	112	63.9 (147)	134
55.0 (131)	89	65.0 (149)	85
56.1 (133)	56	66.1 (151)	54
57.2 (135)	36	67.2 (153)	34
57.8 (136)	28	68.3 (155)	22
58.9 (138)	18	69.4 (157)	14
60.0 (140)	12	70.0 (158)	0
61.1 (142)	8		
62.2 (144)	5		
62.8 (145)	4		

¹Holding time may include postoven heat rise.

- (iii) A raw or undercooked whole-muscle, intact beef steak may be served or offered for sale in a ready-to-eat form if:
 - (I) The food establishment serves a population that is not a highly susceptible population.
 - (II) The steak is labeled to indicate that it meets the definition of "whole-muscle, intact beef" as specified under 1200-23-01-.03(2)(a)1(v), and
 - (III) The steak is cooked on both the top and bottom to a surface temperature of 63°C (145°F) or above and a cooked color change is achieved on all external surfaces.
- (iv) A raw animal food such as raw egg, raw fish, raw-marinated fish, raw molluscan shellfish, or steak tartare; or a partially cooked food such as lightly cooked fish, soft cooked eggs, or rare meat other than whole-muscle, intact beef steaks as specified in (iii) of this part, may be served or offered for sale upon consumer request or selection in a ready-to-eat form if:
 - (I) As specified under 1200-23-01-.03(8)(c)1 and 2, the food establishment serves a population that is not a highly susceptible population;
 - (II) The food, if served or offered for service by consumer selection

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- from a children's menu, does not contain comminuted; (Pf) and
- (III) The consumer is informed as specified under 1200-23-01-.03(6)(c) that to ensure its safety, the food should be cooked as specified under subparts (i) or (ii) of this part; or
- (IV) The department grants a variance from (i) or (ii) of this part as specified in 1200-23-01-.08(1)(d)1 based on a HACCP plan that:
- I. Is submitted by the permit holder and approved as specified under 1200-23-01-.08(1)(d)2,
 - II. Documents scientific data or other information showing that a lesser time and temperature regimen results in a safe food, and
 - III. Verifies that equipment and procedures for food preparation and training of food employees at the food establishment meet the conditions of the variance.
2. Microwave Cooking. Raw animal foods cooked in a microwave oven shall be:
- (i) Rotated or stirred throughout or midway during cooking to compensate for uneven distribution of heat;
 - (ii) Covered to retain surface moisture;
 - (iii) Heated to a temperature of at least 74°C (165°F) in all parts of the food; and
 - (iv) Allowed to stand covered for 2 minutes after cooking to obtain temperature equilibrium.
3. Plant Food Cooking for Hot Holding. Fruits and vegetables cooked for hot holding shall be cooked to a temperature of 57°C (135°F). (Pf)
4. Non-Continuous Cooking of Raw Animal Foods. Raw animal foods cooked using a non-continuous cooking process shall be:
- (i) Subject to an initial heating process that is no longer than sixty minutes in duration; (P)
 - (ii) Immediately after initial heating, cooled according to the time and temperature parameters specified for cooked time /temperature control for safety food under 1200-23-01-.03(5)(a)4; (P)
 - (iii) After cooling, held frozen or cold, as specified for time/temperature control for safety food under 1200-23-01-.03(5)(a)6(i); (P)
 - (iv) Prior to sale or service, cooked using a process that heats all parts of the food to a temperature of at least 74°C (165°F) for 15 seconds; (P)
 - (v) Cooled according to the time and temperature parameters specified for cooked time /temperature control for safety food under 1200-23-01-

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.03(5)(a)4 if not either hot held as specified under 1200-23-01-.03(5)(a)6, served immediately, or held using time as a public health control as specified under 1200-23-01-.03(5)(a)9 after complete cooking; (P) and Prepared and stored according to written procedures that:

- (I) Have obtained prior approval from the department; (Pf)
- (II) Are maintained in the food establishment and are available to the department upon request; (Pf)
- (III) Describe how the requirements specified under (i)-(v) of this part are to be monitored and documented by the permit holder and the corrective actions to be taken if the requirements are not met; (Pf)
- (IV) Describe how the foods, after initial heating, but prior to complete cooking, are to be marked or otherwise identified as foods that must be cooked as specified under subpart (iv) of this part prior to being offered for sale or service; (Pf) and
- (V) Describe how the foods, after initial heating but prior to cooking as specified under subpart (iv) of this part, are to be separated from ready-to-eat foods as specified under 1200-23-01-.03(5)(c). (Pf)

(b) Freezing1. Parasite Destruction.

- (i) Except as specified in (ii) of this part, before service or sale in ready-to-eat form, raw, raw-marinated, partially cooked, or marinated-partially cooked fish shall be:
 - (I) Frozen and stored at a temperature of 20°C (4°F) or below for a minimum of 168 hours (7 days) in a freezer; (P)
 - (II) Frozen at 35°C (31°F) or below until solid and stored at 35°C (31°F) or below for a minimum of 15 hours; (P) or
 - (III) Frozen at 35°C (31°F) or below until solid and stored at 20°C (4°F) or below for a minimum of 24 hours. (P)
- (ii) Subpart (i) of this part does not apply to:
 - (I) Molluscan shellfish;
 - (II) Tuna of the species *Thunnus alalunga*, *Thunnus albacares* (Yellowfin tuna), *Thunnus atlanticus*, *Thunnus maccoyii* (Bluefin tuna, Southern), *Thunnus obesus* (Bigeye tuna), Scallops consisting only of the shucked abductor muscle, or *Thunnus thynnus* (Bluefin tuna, Northern); or
 - (III) Aquacultured fish, such as salmon, that:

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- I. If raised in open water, are raised in net-pens, or
- II. Are raised in land-based operations such as ponds or tanks, and
- III. Are fed formulated feed, such as pellets, that contains no live parasites infective to the aquacultured fish.
- (IV) Fish eggs that have been removed from the skein and rinsed.

2. Records, Creation and Retention.

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- (i) Except as specified in 1200-23-01-.03(4)(b)1(ii) and (ii) of this part, if raw, raw-marinated, partially cooked, or marinated-partially cooked fish are served or sold in ready-to-eat form, the person-in-charge shall record the freezing temperature and time to which the fish are subjected and shall retain the records of the food establishment for 90 calendar days beyond the time of service or sale of the fish. (Pf)
- (ii) If the fish are frozen by a supplier, a written agreement or statement from the supplier stipulating that the fish supplied are frozen to a temperature and for a time specified under 1200-23-01-.03(4)(b)1 may substitute for the records specified under subpart (i) of this part.
- (iii) If raw, raw-marinated, partially cooked, or marinated-partially cooked fish are served or sold in ready-to-eat form, and the fish are raised and fed as specified in 1200-23-01-.03(4)(b)1(ii)(III), a written agreement or statement from the supplier or aquaculturist stipulating that the fish were raised and fed as specified in 1200-23-01-.03(4)(b)1(ii)(III) shall be obtained by the person in charge and retained in the records of the food establishment for 90 calendar days beyond the time of service or sale of the fish. (Pf)

3. Preparation for Immediate Service. Cooked and refrigerated food that is prepared for immediate service in response to an individual consumer order, such as a roast beef sandwich au jus, may be served at any temperature.

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(c) Reheating for Hot Holding.

- 1. Except as specified under parts 2, 3 and 5 of this subparagraph, time/temperature control for safety food) that is cooked, cooled, and reheated for hot holding shall be reheated so that all parts of the food reach a temperature of at least 74°C (165°F) for 15 seconds. (P)
- 2. Except as specified under part 3 of this subparagraph, time/temperature control for safety food reheated in a microwave oven for hot holding shall be reheated so that all parts of the food reach a temperature of at least 74°C (165°F) and the food is rotated or stirred, covered, and allowed to stand covered for 2 minutes after reheating. (P)
- 3. Ready-to-eat taken from a commercially processed, hermetically-sealed container, or from an intact package from a food processing plant that is inspected by the food department that has jurisdiction over the plant, shall be heated to a temperature of at least 57°C (135°F) for hot holding. (P)

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4. Reheating for hot holding as specified under parts 1. through 3. of this subparagraph shall be completed within 2 hours and the time the food is between 5°C (41°F) or 7°C (45°F) and the temperatures specified under 1 through 3 of this subparagraph may not exceed 2 hours. (P)

5. Remaining unsliced portions of meat roasts that are cooked as specified under 1200-23-01-.03(4)(a)1(ii) may be reheated for hot holding using the oven parameters and minimum time and temperature conditions specified under 1200-23-01-.03(4)(a)1(ii).

(d) Treating Juice. Juice packaged in a food establishment shall be:

1. Treated under a HACCP PLAN as specified in 1200-23-01-.08(2)(d) to attain a 5-log reduction, which is equal to a 99.999% reduction, of the most resistant microorganism of public health significance; (P) or

2. Labeled, if not treated to yield a 5-log reduction of the most resistant microorganism of public health significance: (Pf)

(i) As specified under 1200-23-01-.03(6)(b), (Pf) and

(ii) As specified in 21 CFR § 101.17(g) Food labeling, warning, notice, and safe handling statements, juices that have not been specifically processed to prevent, reduce, or eliminate the presence of pathogens with the following, "WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems." (Pf)

(5) Limitation of Growth of Organisms of Public Health Concern.

(a) Temperature and Time Control.

1. Frozen Food. Stored frozen foods shall be maintained frozen.

2. Time/Temperature Control for Safety Food, Slacking. Frozen time/temperature control for safety food that is slacked to moderate the temperature shall be held:

(i) Under refrigeration that maintains the food temperature at 5°C (41°F) or less.

(ii) At any temperature if the food remains frozen.

3. Thawing. Except as specified in subpart (iv) of this part, time/temperature control for safety food shall be thawed:

(i) Under refrigeration that maintains the food temperature at 5°C (41°F) or less°.

(ii) Completely submerged under running water:

(I) At a water temperature of 21°C (70°F) or below.

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(II) With sufficient water velocity to agitate and float off loose particles in an overflow.

(III) Such that for ready-to-eat food, the temperature of thawed portions do not rise above 5°C (41°F), and

(IV) Such that for raw animal food requiring cooking as specified under 1200-23-01-.03(4)(a)1(i) or (ii), thawed portions are not above 5°C (41°F), for more than 4 hours including:

I. The time the food is exposed to the running water and the time needed for preparation for cooking, or

II. The time it takes under refrigeration to lower the food temperature to 5°C (41°F);

(iii) As part of a cooking process if the food that is frozen is:

(I) Cooked as specified under 1200-23-01-.03(4)(a)1(i) or (ii) or under 1200-23-01-.03(4)(a)2(i), or

(II) Thawed in a microwave oven and immediately transferred to conventional cooking equipment, with no interruption in the process; or

(iv) Using any procedure if a portion of frozen ready-to-eat food is thawed and prepared for immediate service in response to an individual consumer's order.

4. Cooling.

(i) Cooked time/temperature control for safety food shall be cooled:

1. Within 2 hours from 57°C (135°F) to 21°C (70°F); (P) and

2. Within a total of 6 hours from 57°C (135°F) to 5°C (41°F) or less. (P)

(ii) Time/temperature control for safety food shall be cooled within 4 hours to 5°C (41°F) or less, if prepared from ingredients at ambient temperature such as reconstituted foods and canned tuna. (P)

(iii) Except as specified under subpart (iv) of this part, a time/temperature control for safety food received in compliance with laws allowing a temperature above 5°C (41°F) during shipment from the supplier as specified under 1200-23-01-.03(2)(b)1(ii), shall be cooled within 4 hours to 5°C (41°F) or less. (P)

(iv) Raw eggs shall be received as specified under 1200-23-01-.03(2)(b)3 and immediately placed in refrigerated equipment that maintains an ambient air temperature of 5°C (41°F) or less. (P)

5. Cooling Methods.

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- (i) Cooling shall be accomplished in accordance with the time and temperature criteria specified under 1200-23-01-.03(5)(a)4 by using one or more of the following methods based on the type of food being cooled:
 - (I) Placing the food in shallow pans; (Pf)
 - (II) Separating the food into smaller or thinner portions; (Pf)
 - (III) Using rapid cooling equipment; (Pf)
 - (IV) Stirring the food in a container placed in an ice water bath; (Pf)
 - (V) Using containers that facilitate heat transfer; (Pf)
 - (VI) Adding ice as an ingredient; (Pf) or
 - (VII) Other effective methods. (Pf)
- (ii) When placed in cooling or cold holding equipment, food containers in which food is being cooled shall be:
 - (I) Arranged in the equipment to provide maximum heat transfer through the container walls; and
 - (II) Loosely covered, or uncovered if protected from overhead contamination as specified under 1200-23-01.03(3)(e)1(i)(I), during the cooling period to facilitate heat transfer from the surface of the food.

6. Time/Temperature Control for Safety Food, Hot and Cold Holding.

- (i) Except during preparation, cooking, or cooling, or when time is used as the public health control as specified under 1200-23-01-.03(5)(a)9, and except as specified under (ii) and in (iii) of this part, time/temperature control for safety food shall be maintained at 57°C (135°F) or above, except that roasts cooked to a temperature and for a time specified under 1200-23-01-.03(4)(a)1(ii) or reheated as specified in 1200-23-01-.03(4)(c)5 may be held at a temperature of 54°C (130°F) or above. (P)
- (ii) Eggs that have not been treated to destroy all viable Salmonellae shall be stored in refrigerated equipment that maintains an ambient air temperature of 5°C (41°F) or less. (P)
- (iii) Time/temperature control for safety food in a homogenous liquid form may be maintained outside of the temperature control requirements, as specified under (i) of this part, while contained within specially designed equipment that complies with the design and construction requirements as specified under 1200-23-01-.04(2)(d)3(v).

7. Ready-to-Eat, Time/Temperature Control for Safety Food Date Marking

- (i) Except when packaging food using a reduced oxygen packing method as specified under 1200-23-01-.03(5)(c), and except as specified in subpart (v) of this part, refrigerated, ready-to-eat, time/temperature control for

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safety food prepared and held in a food establishment for more than 24 hours shall be marked to indicate the date or day by which the food shall be consumed on the premises, sold, or discarded, based on the temperature and time combination of 5°C (41°F) or less for a maximum of 7 days. The day of preparation shall be counted as day 1. (Pf)

- (ii) Except as specified in (v) - (vi) of this part, refrigerated, ready-to-eat, time/temperature control for safety food prepared and packaged by a food processing plant shall be clearly marked, at the time the original container is opened in a food establishment and if the food is held for more than 24 hours, to indicate the date or day by which the food shall be consumed on the premises, sold, or discarded, based on the temperature and time combinations specified in (i) of this part and: (Pf)

 - (I) The day the original container is opened in the food establishment shall be counted as day 1; (Pf) and
 - (II) The day or date marked by the food establishment may not exceed a manufacturer's use-by date if the manufacturer determined the use-by date based on food safety. (Pf)
- (iii) A refrigerated, ready-to-eat, time/temperature control for safety food ingredient or a portion of a refrigerated, ready-to-eat, time/temperature control for safety food that is subsequently combined with additional ingredients or portions of food shall retain the date marking of the earliest-prepared or first-prepared ingredient. (Pf)
- (iv) A date marking system that meets the criteria stated in subparts (i) and (ii) of this part may include:

 - (I) Using a method approved by the department for refrigerated, ready-to-eat time/temperature control for safety food that is frequently rewrapped, such as lunchmeat or a roast, or for which date marking is impractical, such as soft serve mix or milk in a dispensing machine;
 - (II) Marking the date or day of preparation, with a procedure to discard the food on or before the last date or day by which the food must be consumed on the premises, sold, or discarded as specified under subpart (i) of this part;
 - (III) Marking the date or day the original container is opened in a food establishment, with a procedure to discard the food on or before the last date or day by which the food must be consumed on the premises, sold, or discarded as specified under subpart (ii) of this part; or
 - (IV) Using calendar dates, days of the week, color-coded marks, or other effective marking methods, provided that the marking system is disclosed to the department upon request.
- (v) Subparts (i) and (ii) of this part do not apply to individual meal portions served or repackaged for sale from a bulk container upon a consumer's request.

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- (vi) Subpart (ii) of this part does not apply to the following foods prepared and packaged by a food processing plant inspected by a department:
- (I) Deli salads, such as ham salad, seafood salad, chicken salad, egg salad, pasta salad, potato salad, and macaroni salad, manufactured in accordance with 21 CFR Part 110 Current good manufacturing practice in manufacturing, packing, or holding human food;
 - (II) Hard cheeses containing not more than 39% moisture as defined in 21 CFR Part 133 Cheeses and related cheese products, such as cheddar, gruyere, parmesan and reggiano, and romano;
 - (III) Semi-soft cheeses containing more than 39% moisture, but not more than 50% moisture, as defined in 21 CFR Part 133 Cheeses and related cheese products, such as blue, edam, gorgonzola, gouda, and monterey jack;
 - (IV) Cultured dairy products as defined in 21 CFR Part 131 Milk and cream, such as yogurt, sour cream, and buttermilk;
 - (V) Preserved fish products, such as pickled herring and dried or salted cod, and other acidified fish products as defined in 21 CFR Part 114 Acidified foods;
 - (VI) Shelf stable, dry fermented sausages, such as pepperoni and Genoa salami that are not labeled "Keep Refrigerated" as specified in 9 CFR Part 317 Labeling, marking devices, and containers, and which retain the original casing on the product; and
 - (VII) Shelf stable salt-cured products such as prosciutto and Parma (ham) that are not labeled "Keep Refrigerated" as specified in 9 CFR Part 317 Labeling, marking devices, and containers.

8. Ready-to-Eat, time/temperature control for safety food, Disposition.

- (i) A food specified in 1200-23-01-.03(5)(a)7(i) or (ii) shall be discarded if it:
- (I) Exceeds the temperature and time combination specified in 1200-23-01-.03(5)(a)7(i), except time that the product is frozen; (P)
 - (II) Is in a container or package that does not bear a date or day; (P)
or
 - (III) Is appropriately marked with a date or day that exceeds a temperature and time combination as specified in 1200-23-01-.03(5)(a)7(i). (P)
- (ii) Refrigerated, ready-to-eat, potentially hazardous foods time/temperature control for safety food prepared in a food establishment and dispensed through a vending machine with an automatic shutoff control shall be

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discarded if it exceeds a temperature and time combination as specified in 1200-23-01-.03(5)(a)7(i).

9. Time as a Public Health Control.

- (i) Except as specified under subpart (iv) of this part, if time without temperature control is used as the public health control for a working supply of time/temperature control for safety food before cooking, or for ready-to-eat time/temperature control for safety food that is displayed or held for sale or service:

 - (I) Written procedures shall be prepared in advance, maintained in the food establishment and made available to the department upon request that specify: (Pf)

 - I. Methods of compliance with items (ii)(I)-(IV) or (iii)(I)-(V) of this part; (Pf) and
 - II. Methods of compliance with 1200-23-01-.03(5)(a)4 for food that is prepared, cooked, and refrigerated before time is used as a public health control. (Pf)
- (ii) If time without temperature control is used as the public health control up to a maximum of 4 hours:

 - (I) The food shall have an initial temperature of 5°C (41°F) or less when removed from cold holding temperature control, or 57°C (135°F) or greater when removed from hot holding temperature control; (P)
 - (II) The food shall be marked or otherwise identified to indicate the time that is 4 hours past the point in time when the food is removed from temperature control; (Pf)
 - (III) The food shall be cooked and served, served at any temperature if ready-to-eat, or discarded, within 4 hours from the point in time when the food is removed from temperature control; (P) and
 - (IV) The food in unmarked containers or packages, or marked to exceed a 4-hour limit shall be discarded. (P)
- (iii) If time without temperature control is used as the public health control up to a maximum of 6 hours:

 - (I) The food shall have an initial temperature of 5°C (41°F) or less when removed from temperature control and the food temperature may not exceed 21°C (70°F) within a maximum time period of 6 hours; (P)
 - (II) The food shall be monitored to ensure the warmest portion of the food does not exceed 21°C (70°F) during the 6 hour period, unless an ambient air temperature is maintained that ensures the food does not exceed 21°C (70°F) during the 6-hour holding period; (Pf)

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- (III) The food shall be marked or otherwise identified to indicate: (Pf)
 - I. The time when the food is removed from 5°C (41°F) or less cold holding temperature control. (Pf) and
 - II. The time that is 6 hours past the point in time when the food is removed from cold holding temperature control; (Pf)
- (IV) The food shall be:
 - I. Discarded if the temperature of the food exceeds 21°C (70°F), (P) or
 - II. Cooked and served, served at any temperature if ready-to-eat, or discarded within a maximum of 6 hours from the point in time when the food is removed from 5°C (41°F) or less cold holding temperature control; (P) and
- (V) The food in unmarked containers or packages, or marked with a time that exceeds the 6-hour limit shall be discarded. (P)
- (iv) A food establishment that serves a highly susceptible population may not use time as specified under subparts (i), (ii) or (iii) of this part as the public health control for raw eggs.
- (b) Specialized Processing Methods: Variance Requirement. A food establishment shall obtain a variance from the department as specified in 1200-23-01-.08(1)(d)1 and under 1200-23-01-.08(1)(d)2 before: (Pf)
 - 1. Smoking food as a method of food preservation rather than as a method of flavor enhancement; (Pf)
 - 2. Curing food; (Pf)
 - 3. Using food additives or adding components such as vinegar: (Pf)
 - (i) As a method of food preservation rather than as a method of flavor enhancement. (Pf) or
 - (ii) To render a food so that it is not time/temperature control of safety food; (Pf)
 - 4. Packaging food using a reduced oxygen packing method except where the growth of and toxin formation by Clostridium botulinum and the growth of Listeria monocytogenes are controlled as specified under 1200-23-01-.03(5)(c); (Pf)
 - 5. Operating a molluscan shellfish life-support system display tank used to store or display shellfish that are offered for human consumption; (Pf)
 - 6. Custom processing animals that are for personal use as food and not for sale or service in a food establishment; (Pf)

(Rule 1200-23-1-.04, continued)

7. Preparing food by another method that is determined by the department to require a variance; (Pf)or

8. Sprouting seeds or beans. (Pf)

(c) Clostridium botulinum and Listeria monocytogenes Controls. - Reduced Oxygen Packaging Without a Variance, Criteria.

1. Except for a food establishment that obtains a variance as specified under 1200-23-01-.03(5)(b)4, a food establishment that packages time/temperature control for safety food using a reduced oxygen packaging method shall control the growth and toxin formation of Clostridium botulinum and the growth of Listeria monocytogenes. (P)

2. A food establishment that packages time/temperature control for safety food using a reduced oxygen method shall have a HACCP plan that contains the information specified under 1200-23-01-.08(2)(d)4 and that: (Pf)

(i) Identifies the food to be packaged; (Pf)

(ii) Except as specified under parts 3. – 5. of this subparagraph, requires that the packaged food shall be maintained at 5°C (41°F) or less and meet at least one of the following criteria: (Pf)

(I) Has an A_w of 0.91 or less. (Pf)

(II) Has a P_h of 4.6 or less. (Pf)

(III) Is a meat or poultry product cured at a food processing plant regulated by the USDA using substances specified in 9 CFR § 424.21, Use of food ingredients and sources of radiation, and is received in an intact package. (Pf)or

(IV) Is a food with a high level of competing organisms such as raw meat, raw poultry, or raw vegetables; (Pf)

(iii) Describes how the package shall be prominently and conspicuously labeled on the principal display panel in bold type on a contrasting background, with instructions to: (Pf)

(I) Maintain the food at 5°C (41°F) or below. (Pf) and

(II) Discard the food if within 14 calendar days of its packaging it is not served for on-premises consumption, or consumed if served or sold for off-premises consumption; (Pf)

(iv) Limits the refrigerated shelf life to no more than 14 calendar days from packing to consumption, except the time the product is maintained frozen, or the original manufacturer's "sell by" or "use by" date, whichever occurs first; (P)

(v) Includes operational procedures that:

(I) Prohibit contacting ready-to-eat food with bare hands as

(Rule 1200-23-1-.04, continued)

- specified under 1200-23-01-.03(3)(a)1(ii), (Pf)
- (II) Identify a designated work area and the method by which: (Pf)
- I. Physical barriers or methods of separation of raw foods and ready-to-eat foods minimize cross contamination, (Pf) and
- II. Access to the processing equipment is limited to responsible trained personnel familiar with the potential hazards of the operation, (Pf) and
- III. Delineate cleaning and sanitation procedures for food-contact surfaces; (Pf) and
- (vi) Describes the training program that ensures that the individual responsible for the reduced oxygen packaging operation understands the: (Pf)
- (I) Concepts required for a safe operation, (Pf)
- (II) Equipment and facilities, (Pf) and
- (III) Procedures specified under subpart 2(v) of this part and 1200-23-01-.08(2)(d)4. (Pf)
3. Except for fish that is frozen before, during, and after packaging, a food establishment may not package fish using a reduced oxygen packaging method. (P)
4. Except as specified under part 3 of this subparagraph, a food establishment that packages food using a cook-chill or sous vide process shall:
- (i) Implement a HACCP plan that contains the information as specified under 1200-23-01-.08(2)(d)4; (Pf)
- (ii) Ensure the food is:
- (I) Prepared and consumed on the premises, or prepared and consumed off the premises but within the same business entity with no distribution or sale of the packaged product to another business entity or the consumer. (Pf)
- (II) Cooked to heat all parts of the food to a temperature and for a time as specified under 1200-23-01-.03(4)(a)1, (Pf)
- (III) Protected from contamination before and after cooking as specified under 1200-23-01-.03(3)-(5), (P)
- (IV) Placed in a package with an oxygen barrier and sealed before cooking, or placed in a package and sealed immediately after cooking and before reaching a temperature below 57°C (135°F). (P)

(Rule 1200-23-1-.04, continued)

- (V) Cooled to 5°C (41°F) in the sealed package or bag as specified under 1200-23-01-.03(5)(a)4 and subsequently; (P)
 - (VI) Cooled to 1°C (34°F) within 48 hours of reaching 5°C (41°F) and held at that temperature until consumed or discarded within 30 days after the date of packaging; (P)
 - (VII) Cooled to 1°C (34°F) within 48 hours of reaching 5°C (41°F), removed from refrigeration equipment that maintains a 1°C (34°F) food temperature and then held at 5°C (41°F) or less for no more than 72 hours, at which time the food must be consumed or discarded; (P)
 - (VIII) Cooled to 3°C (38°F) or less within 24 hours of reaching 5°C (41°F) and held there for no more than 72 hours from packaging, at which time the food must be consumed or discarded; (P) or
 - (IX) Held frozen with no shelf life restriction while frozen until consumed or used. (P)
 - (X) Held in a refrigeration unit that is equipped with an electronic system that continuously monitors time and temperature and is visually examined for proper operation twice daily. (Pf)
 - (XI) If transported off-site to a satellite location of the same business entity, equipped with verifiable electronic monitoring devices to ensure that times and temperatures are monitored during transportation, (Pf) and
- (iii) Maintain the records required to confirm that cooling and cold holding refrigeration time/temperature parameters are required as part of the HACCP plan and:
- (I) Make such records available to the department upon request (Pf); and
 - (II) Hold such records for at least 6 months; (Pf) and
- (iv) Implement written operational procedures as specified under subpart 2(v) of this subparagraph and a training program as specified under subpart 2(vi) of this subparagraph.
5. A food establishment that packages cheese using a reduced oxygen packaging method shall:
- (i) Limit the cheeses packaged to those that are commercially manufactured in a food processing plant with no ingredients added in the food establishment and that meet the Standards of Identity as specified in 21 CFR § 133.150 Hard cheeses, 21 CFR § 133.169 Pasteurized process cheese or 21 CFR § 133.187 Semisoft cheeses; (P)
 - (ii) Have a HACCP plan that contains the information specified under 1200-23-01-.08(2)(d)4 and as specified under subparts 2(i), 2(v) and 2(vi) and item (2)(iii)(I) of this subparagraph; (Pf)

(Rule 1200-23-1-.04, continued)

- (iii) Labels the package on the principal display panel with a "use by" date that does not exceed 30 days from its packaging or the original manufacturer's "sell by" or "use by" date, whichever occurs first; (Pf) and
- (iv) Discards the reduced oxygen packaged cheese if it is not sold for off-premises consumption or consumed within 30 calendar days of its packaging. (Pf)

(6) Food Identity, Presentation, and On-Premises Labeling

(a) Accurate Representation.

1. Standards of Identity. Packaged food shall comply with standard of identity requirements in 21 CFR Parts 131-169 and 9 CFR Part 319 Definitions and standards of identity or composition, and the general requirements in 21 CFR Part 130 – Food Standards: General and 9 CFR Part 319 Subpart A – General Provisions.
2. Honestly Presented.
 - (i) Food shall be offered for human consumption in a way that does not mislead or misinform the consumer.
 - (ii) Food or color additives, colored overwraps, or lights may not be used to misrepresent the true appearance, color, or quality of a food.

(b) Labeling.

1. Food packaged in a food establishment, shall be labeled as specified in law, including 21 CFR Part 101 - Food labeling, and 9 CFR Part 317 Labeling, marking devices, and containers.
2. Label information shall include:
 - (i) The common name of the food, or absent a common name, an adequately descriptive identity statement;
 - (ii) If made from two or more ingredients, a list of ingredients in descending order of predominance by weight, including a declaration of artificial color or flavor and chemical preservatives, if contained in the food;
 - (iii) An accurate declaration of the quantity of contents;
 - (iv) The name and place of business of the manufacturer, packer, or distributor; and
 - (v) The name of the food source for each major food allergen contained in the food unless the food source is already part of the common or usual name of the respective ingredient (Effective January 1, 2006). (Pf)
 - (vi) Except as exempted in the Federal Food, Drug, and Cosmetic Act § 403(Q)(3) - (5), nutrition labeling as specified in 21 CFR Part 101 - Food Labeling and 9 CFR Part 317 Subpart B Nutrition Labeling.

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- (vii) For any salmonid fish containing canthaxanthin as a color additive, the labeling of the bulk fish container, including a list of ingredients, displayed on the retail container or by other written means, such as a counter card, that discloses the use of canthaxanthin.
3. Bulk food that is available for consumer self-dispensing shall be prominently labeled with the following information in plain view of the consumer:
- (i) The manufacturer's or processor's label that was provided with the food;
or
 - (ii) A card, sign, or other method of notification that includes the information specified under subparts 2(i), (ii), and (v) of this part.
4. Bulk, unpackaged foods such as bakery products and unpackaged foods that are portioned to consumer specification need not be labeled if:
- (i) A health, nutrient content, or other claim is not made;
 - (ii) There are no state or local laws requiring labeling; and
 - (iii) The food is manufactured or prepared on the premises of the food establishment or at another food establishment or a food processing plant that is owned by the same person and is regulated by the food regulatory agency that has jurisdiction.
5. Other Forms of Information.
- (i) If required by law, consumer warnings shall be provided.
 - (ii) Food establishment or manufacturers' dating information on foods may not be concealed or altered.
- (c) Consumer Advisory - Consumption of Animal Foods that are Raw, Undercooked, or Not Otherwise Processed to Eliminate Pathogens.
1. Except as specified in 1200-23-01-.03(4)(a)1(iii) and 1200-23-01-.03(4)(a)1(iv)(IV) and under 1200-23-01-.03(8)(c), if an animal food such as beef, eggs, fish, lamb, milk, pork, poultry, or shellfish is served or sold raw, undercooked, or without otherwise being processed to eliminate pathogens, either in ready-to-eat form or as an ingredient in another ready-to-eat food, the permit holder shall inform consumers of the significantly increased risk of consuming such foods by way of a disclosure and reminder, as specified in parts 2 and 3 of this subparagraph using brochures, deli case or menu advisories, label statements, table tents, placards, or other effective written means. (Pf)
2. Disclosure shall include:
- (i) A description of the animal-derived foods, such as "oysters on the half shell (raw oysters)," "raw-egg Caesar salad," and "hamburgers (can be cooked to order)"; (Pf) or
 - (ii) Identification of the animal-derived foods by asterisking them to a

(Rule 1200-23-1-.04, continued)

footnote that states that the items are served raw or undercooked, or contain (or may contain) raw or undercooked ingredients. (Pf)

3. Reminder shall include asterisking the animal-derived foods requiring disclosure to a footnote that states:

(i) Regarding the safety of these items, written information is available upon request; (Pf)

(ii) Consuming raw or undercooked meats, poultry, seafood, shellfish, or eggs may increase your risk of foodborne illness; (Pf) or

(iii) Consuming raw or undercooked meats, poultry, seafood, shellfish, or eggs may increase your risk of foodborne illness, especially if you have certain medical conditions. (Pf)

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(7) Contaminated Food - Disposition. Discarding or Reconditioning Unsafe, Adulterated, or Contaminated Food.

(a) A food that is unsafe, adulterated, or not honestly presented as specified under 1200-23-01-.03(1) shall be discarded or reconditioned according to an approved procedure. (P)

(b) Food that is not from an approved source as specified under 1200-23-01-.03(2)(a) – (c) shall be discarded. (P)

(c) Ready-to-eat food that may have been contaminated by an employee who has been restricted or excluded as specified under 1200-23-01-.02(2)(b) shall be discarded. (P)

(d) Food that is contaminated by food employees, consumers, or other persons through contact with their hands, bodily discharges, such as nasal or oral discharges, or other means shall be discarded. (P)

(8) Special Requirements for Highly Susceptible Populations - Pasteurized Foods, Prohibited Re-Service, and Prohibited Food. In a food establishment that serves a highly susceptible population:

(a) The following criteria apply to juice:

1. For the purposes of this paragraph only, children who are age 9 or less and receive food in a school, day care setting, or similar facility that provides custodial care are included as highly susceptible populations;

2. Prepackaged juice or a prepackaged beverage containing juice, that bears a warning label as specified in 21 CFR § 101.17(g) Food labeling, warning, notice, and safe handling statements, juices that have not been specifically processed to prevent, reduce, or eliminate the presence of pathogens, or a packaged juice or beverage containing juice, that bears a warning label as specified under 1200-23-01-.03(4)(d)2 may not be served or offered for sale; (P) and

3. Unpackaged juice that is prepared on the premises for service or sale in a ready-to-eat form shall be processed under a HACCP plan that contains the information specified under 1200-23-01-.08(2)(d) and as specified in 21 CFR Part 120 – Hazard Analysis and Critical Control Point (HACCP) Systems, Subpart B Pathogen Reduction, § 120.24 Process controls. (P)

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- (b) Pasteurized eggs or egg products shall be substituted for raw eggs in the preparation of: (P)
1. Foods such as Caesar salad, hollandaise or Béarnaise sauce, mayonnaise, meringue, eggnog, ice cream, and egg-fortified beverages. (P) and
 2. Except as specified in (f) of this paragraph, recipes in which more than one egg is broken and the eggs are combined. (P)
- (c) The following foods may not be served or offered for sale in a ready-to-eat form: (P)
1. Raw animal foods such as raw fish, raw-marinated fish, raw molluscan shellfish, and steak tartare. (P)
 2. A partially cooked animal food such as lightly cooked fish, rare meat, soft-cooked eggs that are made from raw eggs, and meringue. (P) and
 3. Raw seed sprouts. (P)
- (d) Food employees may not contact ready-to-eat food as specified under 1200-23-01-.03(3)(a)1.(ii) and (iv). (P)
- (e) Time only, as the public health control as specified under 1200-23-01-.03(5)(a)9(iv), may not be used for raw eggs.
- (f) Subparagraph (b)2 of this paragraph does not apply if:
1. The raw eggs are combined immediately before cooking for one consumer's serving at a single meal, cooked as specified under 1200-23-01-.03(4)(a)1(i)(I), and served immediately, such as an omelet, soufflé, or scrambled eggs. (P)
 2. The raw eggs are combined as an ingredient immediately before baking and the eggs are thoroughly cooked to a ready-to-eat form, such as a cake, muffin, or bread; or
 3. The preparation of the food is conducted under a HACCP plan that:
 - (i) Identifies the food to be prepared.
 - (ii) Prohibits contacting ready-to-eat food with bare hands.
 - (iii) Includes specifications and practices that ensure:
 - (I) Salmonella Enteritidis growth is controlled before and after cooking, and
 - (II) Salmonella Enteritidis is destroyed by cooking the eggs according to the temperature and time specified in 1200-23-01-.03(4)(a)1(i)(II).
 - (iv) Contains the information specified under 1200-23-01-.08(2)(d)4 including procedures that:

(Rule 1200-23-1-.04, continued)

- (I) Control cross contamination of ready-to-eat food with raw eggs, and
- (II) Delineate cleaning and sanitization procedures for food-contact surfaces, and
- (v) Describes the training program that ensures that the food employee responsible for the preparation of the food understands the procedures to be used.
- (g) Except as specified in subparagraph (h) of this paragraph, food may be re-served as specified under 1200-23-01-.03(3)(f)4(ii)(I) and (II).
- (h) Food may not be re-served under the following conditions:
 - 1. Any food served to patients or clients who are under contact precautions in medical isolation or quarantine, or protective environment isolation may not be re-served to others outside.
 - 2. Packages of food from any patients, clients, or other consumers should not be re-served to persons in protective environment isolation.

Authority: T.C.A. §§ 68-14-701 through 68-14-726.

1200-23-01-.04 Equipment, Utensils, and Linens(1) Materials for Construction and Repair(a) Multiuse1. Characteristics

- (i) Materials that are used in the construction of utensils and food-contact surfaces of equipment may not allow the migration of deleterious substances or impart colors, odors, or tastes to food and under normal use conditions shall be: (P)
 - (I) Safe; (P)
 - (II) Durable, corrosion-resistant, and nonabsorbent;
 - (III) Sufficient in weight and thickness to withstand repeated warewashing;
 - (IV) Finished to have a smooth, easily cleanable surface; and
 - (V) Resistant to pitting, chipping, crazing, scratching, scoring, distortion and decomposition.
- (ii) Cast Iron, Use Limitation.
 - (I) Except as specified in items (II) and (III) of this subpart, cast iron may not be used for utensils or food-contact surfaces of equipment.

(Rule 1200-23-1-.04, continued)

- (II) Cast iron may be used as a surface for cooking.
- (III) Cast iron may be used in utensils for serving food if the utensils are used only as part of an uninterrupted process from cooking through service.

(iii) Lead, Use Limitation.

- (I) Ceramic, china, and crystal utensils, and decorative utensils such as hand painted ceramic or china that are used in contact with food shall be lead-free or contain levels of lead not exceeding the limits of the following utensil categories (P)

Utensil Category	Ceramic Article Description	Maximum Lead Mg/L
Beverage Mugs, Cups, Pitchers	Coffee Mugs	0.5
Large Hollowware (excluding pitchers)	Bowls > 1.1 Liter (1.16 Quart)	1
Small Hollowware (excluding cups & mugs)	Bowls < 1.1 Liter (1.16 Quart)	2.0
Flat Tableware	Plates, Saucers	3.0

- (II) Pewter alloys containing lead in excess of 0.05% may not be used as a food-contact surface. (P)
 - (III) Solder and flux containing lead in excess of 0.2% may not be used as a food-contact surface.
- (iv) Copper, Use Limitation.
- (I) Except as specified in item (II) of this subpart, copper and copper alloys such as brass may not be used in contact with a food that has a pH below 6 such as vinegar, fruit juice, or wine or for a fitting or tubing installed between a backflow prevention device and a carbonator.
 - (II) Copper and copper alloys may be used in contact with beer brewing ingredients that have a pH below 6 in the prefermentation and fermentation steps of a beer brewing operation such as a brewpub or microbrewery.
- (v) Galvanized Metal, Use Limitation. Galvanized metal may not be used for utensils or food-contact surfaces of equipment that are used in contact with acidic food.
- (vi) Sponges, Use Limitation. Sponges may not be used in contact with cleaned and sanitized or in-use food-contact surfaces.
- (vii) Wood, Use Limitation.

(Rule 1200-23-1-.04, continued)

- (I) Except as specified in items (II), (III) and (IV) of this subpart, wood and wood wicker may not be used as a food-contact surface.
 - (II) Hard maple or an equivalently hard, close-grained wood may be used for:
 - I. Cutting boards; cutting blocks; bakers' tables; and utensils such as rolling pins, doughnut dowels, salad bowls, and chopsticks; and
 - II. Wooden paddles used in confectionery operations for pressure scraping kettles when manually preparing confections at a temperature of 110°C (230°F) or above.
 - (III) Whole, uncut, raw fruits and vegetables, and nuts in the shell may be kept in the wood shipping containers in which they were received, until the fruits, vegetables, or nuts are used.
 - (IV) If the nature of the food requires removal of rinds, peels, husks, or shells before consumption, the whole, uncut, raw food may be kept in:
 - I. Untreated wood containers; or
 - II. Treated wood containers if the containers are treated with a preservative that meets the requirements specified in 21 CFR § 178.3800 Preservatives for wood.
 - (viii) Nonstick Coatings, Use Limitation. Multiuse kitchenware such as frying pans, griddles, sauce pans, cookie sheets, and waffle bakers that have a perfluorocarbon resin coating shall be used with nonscoring or nonscratching utensils and cleaning aids.
 - (ix) Nonfood-Contact Surfaces. Nonfood-contact surfaces of equipment that are exposed to splash, spillage, or other food soiling or that require frequent cleaning shall be constructed of a corrosion-resistant, nonabsorbent, and smooth material.
- (b) Single Service and Single-Use.
- 1. Characteristics. Materials that are used to make single-service and single-use articles:
 - (i) May not:
 - (I) Allow the migration of deleterious substances, (P) or
 - (II) Impart colors, odors, or tastes to food; and
 - (ii) Shall be:
 - (I) Safe, (P) and

(Rule 1200-23-1-.04, continued)

(II) Clean.

(2) Design and Construction

(a) Durability and Strength

1. Equipment and Utensils. Equipment and Utensils shall be designed and constructed to be durable and to retain their characteristic qualities under normal use conditions.
2. Food temperature measuring devices may not have sensors or stems constructed of glass, except that thermometers with glass sensors or stems that are encased in a shatterproof coating such as candy thermometers may be used.
(P)

(b) Cleanability

1. Food-Contact Surfaces.

(i) Multiuse food-contact surfaces shall be:

- (I) Smooth; (Pf)
- (II) Free of breaks, open seams, cracks, chips, inclusions, pits, and similar imperfections; (Pf)
- (III) Free of sharp internal angles, corners, and crevices; (Pf)
- (IV) Finished to have smooth welds and joints; (Pf) and
- (V) Except as specified in subpart (ii) of this part, accessible for cleaning and inspection by one of the following methods:
 - I. Without being disassembled; (Pf)
 - II. By disassembling without the use of tools; (Pf) or
 - III. By easy disassembling with the use of handheld tools commonly available to maintenance and cleaning personnel such as screwdrivers, pliers, open-end wrenches, and Allen wrenches. (Pf)

(ii) Item (i)(V) of this part does not apply to cooking oil storage tanks, distribution lines for cooking oils, or beverage syrup lines or tubes.

2. CIP Equipment.

- (i) CIP equipment shall meet the characteristics specified under 1200-23-01-.04(2)(a) and shall be designed and constructed so that:
 - (I) Cleaning and sanitizing solutions circulate throughout a fixed system and contact all interior food-contact surfaces; (Pf) and

(Rule 1200-23-1-.04, continued)

- (ii) Ambient air and water temperature measuring devices that are scaled only in Fahrenheit shall be accurate to $\pm 3^{\circ}\text{f}$ in the intended range of use. (Pf)
- 3. Pressure Measuring Devices, Mechanical Warewashing Equipment. - Pressure measuring devices that display the pressures in the water supply line for the fresh hot water sanitizing rinse shall have increments of 7 kilopascals (1 pound per square inch) or smaller and shall be accurate to ± 14 kilopascals (± 2 pounds per square inch) in the range indicated on the manufacturer's data plate.
- (d) Functionality
 - 1. Ventilation Hood Systems, Drip Prevention. - Exhaust ventilation hood systems in food preparation and warewashing areas including components such as hoods, fans, guards, and ducting shall be designed to prevent grease or condensation from draining or dripping onto food, equipment, utensils, linens, and single-service and single-use articles.
 - 2. Equipment Openings, Closures and Deflectors.
 - (i) A cover or lid for equipment shall overlap the opening and be sloped to drain.
 - (ii) An opening located within the top of a unit of equipment that is designed for use with a cover or lid shall be flanged upward at least 5 millimeters (two-tenths of an inch).
 - (iii) Except as specified under subpart (iv) of this part, fixed piping, temperature measuring devices, rotary shafts, and other parts extending into equipment shall be provided with a watertight joint at the point where the item enters the equipment.
 - (iv) If a watertight joint is not provided:
 - (I) The piping, temperature measuring devices, rotary shafts, and other parts extending through the openings shall be equipped with an apron designed to deflect condensation, drips, and dust from openings into the food; and
 - (II) The opening shall be flanged as specified under (ii) of this part.
 - 3. Dispensing Equipment, Protection of Food. - In equipment that dispenses or vends liquid food or ice in unpackaged form:
 - (i) The delivery tube, chute, orifice, and splash surfaces directly above the container receiving the food shall be designed in a manner, such as with barriers, baffles, or drip aprons, so that drips from condensation and splash are diverted from the opening of the container receiving the food;
 - (ii) The delivery tube, chute, and orifice shall be protected from manual contact such as by being recessed;
 - (iii) The delivery tube or chute and orifice of equipment used to vend liquid food or ice in unpackaged form to self-service consumers shall be

(Rule 1200-23-1-.04, continued)

designed so that the delivery tube or chute and orifice are protected from dust, insects, rodents, and other contamination by a self-closing door if the equipment is:

- (I) Located in an outside area that does not otherwise afford the protection of an enclosure against the rain, windblown debris, insects, rodents, and other contaminants that are present in the environment, or
 - (II) Available for self-service during hours when it is not under the full-time supervision of a food employee; and
- (iv) The dispensing equipment actuating lever or mechanism and filling device of consumer self-service beverage dispensing equipment shall be designed to prevent contact with the lip-contact surface of glasses or cups that are refilled.
- (v) Dispensing equipment in which time/temperature control for safety food in a homogenous liquid form is maintained outside of the temperature control requirements as specified under 1200-23-01-.03(5)(a)6 shall:
- (I) be specifically designed and equipped to maintain the commercial sterility of aseptically packaged food in a homogenous liquid form for a specified duration from the time of opening the packaging within the equipment; (P) and
 - (II) conform to the requirements for this equipment as specified in NSF/ANSI 18-2006- Manual Food and Beverage Dispensing Equipment. (P)
4. Bearings and Gear Boxes, Leakproof - Equipment containing bearings and gears that require lubricants shall be designed and constructed so that the lubricant cannot leak, drip, or be forced into food or onto food-contact surfaces.
5. Beverage Tubing, Separation. - Except for cold plates that are constructed integrally with an ice storage bin, beverage tubing and cold-plate beverage cooling devices may not be installed in contact with stored ice.
6. Ice Units, Separation of Drains. - Liquid waste drain lines may not pass through an ice machine or ice storage bin.
7. Condenser Unit, Separation. - If a condenser unit is an integral component of equipment, the condenser unit shall be separated from the food and food storage space by a dustproof barrier.
8. Molluscan Shellfish Tanks.
- (i) Except as specified under subpart (ii) of this part, molluscan shellfish life support system display tanks may not be used to store or display shellfish that are offered for human consumption and shall be conspicuously marked so that it is obvious to the consumer that the shellfish are for display only. (P)

(Rule 1200-23-1-.04, continued)

- (ii) Molluscan shellfish life-support system display tanks that are used to store or display shellfish that are offered for human consumption shall be operated and maintained in accordance with a variance granted by the department as specified in 1200-23-01-.08(1)(d)1 and a HACCP plan that: (Pf)
 - (I) Is submitted by the permit holder and approved as specified under 1200-23-01-.08(2); (Pf) and
 - (II) Ensures that:
 - I. Water used with fish other than molluscan shellfish does not flow into the molluscan tank, (Pf)
 - II. The safety and quality of the shellfish as they were received are not compromised by the use of the tank, (Pf) and
 - III. The identity of the source of the shellstock is retained as specified under 1200-23-01-.03(2)(c)1. (Pf)

9. Temperature Measuring Devices.

- (i) In a mechanically refrigerated or hot food storage unit, the sensor of a temperature measuring device shall be located to measure the air temperature or a simulated product temperature in the warmest part of a mechanically refrigerated unit and in the coolest part of a hot food storage unit.
 - (ii) Except as specified in (iii) of this part, cold or hot holding equipment used for time/temperature control for safety food shall be designed to include and shall be equipped with at least one integral or permanently affixed temperature measuring device that is located to allow easy viewing of the device's temperature display.
 - (iii) Subpart (ii) of this part does not apply to equipment for which the placement of a temperature measuring device is not a practical means for measuring the ambient air surrounding the food because of the design, type, and use of the equipment, such as calor units, heat lamps, cold plates, bainmaries, steam tables, insulated food transport containers, and salad bars.
 - (iv) Temperature measuring devices shall be designed to be easily readable.
 - (v) Food temperature measuring devices and water temperature measuring devices on warewashing machines shall have a numerical scale, printed record, or digital readout in increments no greater than 1°C or 2°F in the intended range of use. (Pf)
10. Warewashing Machines, Data Plate Operating Specifications - A warewashing machine shall be provided with an easily accessible and readable data plate affixed to the machine by the manufacturer that indicates the machine's design and operation specifications including the:

(Rule 1200-23-1-.04, continued)

- (i) Temperatures required for washing, rinsing, and sanitizing;
 - (ii) Pressure required for the fresh water sanitizing rinse unless the machine is designed to use only a pumped sanitizing rinse; and
 - (iii) Conveyor speed for conveyor machines or cycle time for stationary rack machines.
11. Warewashing Machines, Internal Baffles. - Warewashing machine wash and rinse tanks shall be equipped with baffles, curtains, or other means to minimize internal cross contamination of the solutions in wash and rinse tanks.
12. Warewashing Machines, Temperature Measuring Devices. - A warewashing machine shall be equipped with a temperature measuring device that indicates the temperature of the water:
- (i) In each wash and rinse tank; (Pf) and
 - (ii) As the water enters the hot water sanitizing final rinse manifold or in the chemical sanitizing solution tank. (Pf)
13. Manual Warewashing Equipment, Heaters and Baskets. - If hot water is used for sanitation in manual warewashing operations, the sanitizing compartment of the sink shall be:
- (i) Designed with an integral heating device that is capable of maintaining water at a temperature not less than 77°C (171°F); (Pf) and
 - (ii) Provided with a rack or basket to allow complete immersion of equipment and utensils into the hot water. (Pf)
14. Warewashing Machines, Automatic Dispensing of Detergents and Sanitizers. - A warewashing machine that is installed after adoption of these regulations, shall be equipped to:
- (i) Automatically dispense detergents and sanitizers; (Pf) and
 - (ii) Incorporate a visual means to verify that detergents and sanitizers are delivered or a visual or audible alarm to signal if the detergents and sanitizers are not delivered to the respective washing and sanitizing cycles. (Pf)
15. Warewashing Machine Flow Pressure Device.
- (i) Warewashing machines that provide a fresh hot water sanitizing rinse shall be equipped with a pressure gauge or similar device such as a transducer that measures and displays the water pressure in the supply line immediately before entering the warewashing machine; and
 - (ii) If the flow pressure measuring device is upstream of the fresh hot water sanitizing rinse control valve, the device shall be mounted in a 6.4 millimeter or one-fourth inch Iron Pipe Size (IPS) valve.

(Rule 1200-23-1-.04, continued)

(iii) Subparts (i) and (ii) of this part do not apply to a machine that uses only a pumped or recirculated sanitizing rinse.

16. Warewashing Sinks and Drainboards, Self-Draining. - Warewashing sinks and drainboards of warewashing sinks and machines shall be self-draining.

17. Equipment Compartments, Drainage. - Equipment compartments that are subject to accumulation of moisture due to conditions such as condensation, food or beverage drip, or water from melting ice shall be sloped to an outlet that allows complete draining.

18. Case Lot Handling Apparatuses, Movability. - Apparatuses, such as dollies, pallets, racks, and skids used to store and transport large quantities of packaged foods received from a supplier in a cased or overwrapped lot, shall be designed to be moved by hand or by conveniently available apparatuses such as hand trucks and forklifts.

(e) Acceptability

1. Food equipment that is certified or classified for sanitation by an American National Standards Institute (ANSI)-accredited certification program is deemed to comply with 1200-23-01-.04.

(3) Numbers and Capacities

(a) Equipment

1. Cooling, Heating, and Holding Capacities. - Equipment for cooling and heating food, and holding cold and hot food, shall be sufficient in number and capacity to provide food temperatures as specified under 1200-23-01-.03. (Pf)

2. Manual Warewashing, Sink Compartment Requirements.

(i) A sink with at least 3 compartments shall be provided for manually washing, rinsing, and sanitizing equipment and utensils. (Pf)

(ii) Sink compartments shall be large enough to accommodate immersion of the largest equipment and utensils. (Pf)

3. Drainboards. - Drainboards, utensil racks, or tables large enough to accommodate all soiled and cleaned items that may accumulate during hours of operation shall be provided for necessary utensil holding before cleaning and after sanitizing.

4. Ventilation Hood Systems, Adequacy. - Ventilation hood systems and devices shall prevent grease or condensation from collecting on equipment, walls, and ceilings.

5. Clothes Washers and Dryers.

(i) Except as specified in (ii) of this part, if work clothes or linens are laundered on the premises, a mechanical clothes washer and dryer shall be provided and used.

(Rule 1200-23-1-.04, continued)

(ii) If on-premises laundering is limited to wiping cloths intended to be used moist, or wiping cloths are air-dried as specified under 1200-23-01-.04(9)(a), a mechanical clothes washer and dryer need not be provided.

(b) Utensils, Temperature Measuring Devices, and Testing Devices.

1. Utensils, Consumer Self-Service. - A food dispensing utensil shall be available for each container displayed at a consumer self-service unit such as a buffet or salad bar. (Pf)

2. Food Temperature Measuring Devices.

(i) Food temperature measuring devices shall be provided and readily accessible for use in ensuring attainment and maintenance of food temperatures as specified under 1200-23-01-.03. (Pf)

(ii) A temperature measuring device with a suitable small-diameter probe that is designed to measure the temperature of thin masses shall be provided and readily accessible to accurately measure the temperature in thin foods such as meat patties and fish filets. (Pf)

3. Temperature Measuring Devices, Manual Warewashing. - In manual warewashing operations, a temperature measuring device shall be provided and readily accessible for frequently measuring the washing and sanitizing temperatures.

4. Sanitizing Solutions, Testing Devices. - A test kit or other device that accurately measures the concentration in mg/L of sanitizing solutions shall be provided. (Pf)

(4) Location and Installation

(a) Location

1. Equipment, Clothes Washers and Dryers, and Storage Cabinets, Contamination Prevention.

(i) Except as specified in subpart (ii) of this part, equipment, a cabinet used for the storage of food, or a cabinet that is used to store cleaned and sanitized equipment, utensils, laundered linens, and single-service and single-use articles may not be located:

(I) In locker rooms;

(II) In toilet rooms;

(III) In garbage rooms;

(IV) In mechanical rooms;

(V) Under sewer lines that are not shielded to intercept potential drips;

(Rule 1200-23-1-.04, continued)

(VI) Under leaking water lines including leaking automatic fire sprinkler heads or under lines on which water has condensed;

(VII) Under open stairwells; or

(VIII) Under other sources of contamination.

(ii) A storage cabinet used for linens or single-service or single-use articles may be stored in a locker room.

(iii) If a mechanical clothes washer or dryer is provided, it shall be located so that the washer or dryer is protected from contamination and only where there is no exposed food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles.

(b) Installation

1. Fixed Equipment, Spacing or Sealing.

(i) Equipment that is fixed because it is not easily movable shall be installed so that it is:

(I) Spaced to allow access for cleaning along the sides, behind, and above the equipment;

(II) Spaced from adjoining equipment, walls, and ceilings a distance of not more than 1 millimeter or one thirty-second inch; or

(III) Sealed to adjoining equipment or walls, if the equipment is exposed to spillage or seepage.

(ii) Counter-mounted equipment that is not easily movable shall be installed to allow cleaning of the equipment and areas underneath and around the equipment by being:

(I) Sealed; or

(II) Elevated on legs as specified under 1200-23-01-.04(4)(b)2(iv).

2. Fixed Equipment, Elevation or Sealing.

(i) Except as specified in subparts (ii) and (iii) of this part, floor-mounted equipment that is not easily movable shall be sealed to the floor or elevated on legs that provide at least a 15 centimeter (6 inch) clearance between the floor and the equipment.

(ii) If no part of the floor under the floor-mounted equipment is more than 15 centimeters (6 inches) from the point of cleaning access, the clearance space may be only 10 centimeters (4 inches).

(iii) This section does not apply to display shelving units, display refrigeration units, and display freezer units located in the consumer shopping areas of a retail food store, if the floor under the units is maintained clean.

(Rule 1200-23-1-.04, continued)

- (iv) Except as specified in (v) of this part, counter-mounted equipment that is not easily movable shall be elevated on legs that provide at least a 10 centimeter (4 inch) clearance between the table and the equipment.
- (v) The clearance space between the table and counter-mounted equipment may be:
 - (I) 7.5 centimeters (3 inches) if the horizontal distance of the table top under the equipment is no more than 50 centimeters (20 inches) from the point of access for cleaning; or
 - (II) 5 centimeters (2 inches) if the horizontal distance of the table top under the equipment is no more than 7.5 centimeters (3 inches) from the point of access for cleaning.

(5) Maintenance and Operation

(a) Equipment

1. Good Repair and Proper Adjustment.

- (i) Equipment shall be maintained in a state of repair and condition that meets the requirements specified under 1200-23-01-.04(1) and 1200-23-01-.04(2)
- (ii) Equipment components such as doors, seals, hinges, fasteners, and kick plates shall be kept intact, tight, and adjusted in accordance with manufacturer's specifications.
- (iii) Cutting or piercing parts of can openers shall be kept sharp to minimize the creation of metal fragments that can contaminate food when the container is opened.

2. Cutting Surfaces. - Surfaces such as cutting blocks and boards that are subject to scratching and scoring shall be resurfaced if they can no longer be effectively cleaned and sanitized, or discarded if they are not capable of being resurfaced.

3. Microwave Ovens. - Microwave ovens shall meet the safety standards specified in 21CFR § 1030.10 Microwave ovens.

4. Warewashing Equipment, Cleaning Frequency. - A warewashing machine; the compartments of sinks, basins, or other receptacles used for washing and rinsing equipment, utensils, or raw foods, or laundering wiping cloths; and drainboards or other equipment used to substitute for drainboards as specified under 1200-23-01-.04(3)(a)3. shall be cleaned:

- (i) Before use;
- (ii) Throughout the day at a frequency necessary to prevent recontamination of equipment and utensils and to ensure that the equipment performs its intended function; and
- (iii) If used, at least every 24 hours.

(Rule 1200-23-1-.04, continued)

5. Warewashing Machines, Manufacturers' Operating Instructions.

- (i) A warewashing machine and its auxiliary components shall be operated in accordance with the machine's data plate and other manufacturer's instructions.
- (ii) A warewashing machine's conveyor speed or automatic cycle times shall be maintained accurately timed in accordance with manufacturer's specifications.

6. Warewashing Sinks, Use Limitation.

- (i) A warewashing sink may not be used for handwashing as specified under 1200-23-01-.02(3)(d).
- (ii) If a warewashing sink is used to wash wiping cloths, wash produce, or thaw food, the sink shall be cleaned as specified under 1200-23-01-.04(5)(a)4 before and after each time it is used to wash wiping cloths or wash produce or thaw food. Sinks used to wash or thaw food shall be sanitized as specified under 1200-23-01-.04(7) before and after using the sink to wash produce or thaw food.

7. Warewashing Equipment, Cleaning Agents. - When used for warewashing, the wash compartment of a sink, mechanical warewasher, or wash receptacle of alternative manual warewashing equipment as specified in 1200-23-01-.04(3)(a)2 shall contain a wash solution of soap, detergent, acid cleaner, alkaline cleaner, degreaser, abrasive cleaner, or other cleaning agent according to the cleaning agent manufacturer's label instructions. (Pf)

8. Warewashing Equipment, Clean Solutions. - The wash, rinse, and sanitize solutions shall be maintained clean.

9. Manual Warewashing Equipment, Wash Solution Temperature. - The temperature of the wash solution in manual warewashing equipment shall be maintained at not less than 43°C (110°F) or the temperature specified on the cleaning agent manufacturer's label instructions. (Pf)

10. Mechanical Warewashing Equipment, Wash Solution Temperature.

- (i) The temperature of the wash solution in spray type warewashers that use hot water to sanitize may not be less than:

(I) For a stationary rack, single temperature machine, 74°C (165°F); (Pf) Formatted: Indent: Left: 1.97", Hanging: 0.53"

(II) For a stationary rack, dual temperature machine, 66°C (150°F); (Pf) Formatted: Indent: Left: 1.97", Hanging: 0.53"

(III) For a single tank, conveyor, dual temperature machine, 71°C (160°F); (Pf) or

(IV) For a multitank, conveyor, multitemperature machine, 66°C (150°F); (Pf) Formatted: Indent: Left: 1.97", Hanging: 0.53"

(Rule 1200-23-1-.04, continued)

(ii) The temperature of the wash solution in spray-type warewashers that use chemicals to sanitize may not be less than 49°C (120°F). (Pf)

11. Manual Warewashing Equipment, Hot Water Sanitization Temperatures. - If immersion in hot water is used for sanitizing in a manual operation, the temperature of the water shall be maintained at 77°C (171°F) or above. (P)

12. Mechanical Warewashing Equipment, Hot Water Sanitization Temperatures.

(i) Except as specified in subpart (ii) of this part, in a mechanical operation, the temperature of the fresh hot water sanitizing rinse as it enters the manifold may not be more than 90°C (194°F), or less than: (Pf)

(I) For a stationary rack, single temperature machine, 74°C (165°F); (Pf) or

(II) For all other machines, 82°C (180°F). (Pf)

(ii) The maximum temperature specified under subpart (i) of this part, does not apply to the high pressure and temperature systems with wand-type, hand-held, spraying devices used for the in-place cleaning and sanitizing of equipment such as meat saws.

13. Mechanical Warewashing Equipment, Sanitization Pressure. - The flow pressure of the fresh hot water sanitizing rinse in a warewashing machine, as measured in the water line immediately downstream or upstream from the fresh hot water sanitizing rinse control valve, shall be within the range specified on the machine manufacturer's data plate and may not be less than 35 kilopascals (5 pounds per square inch) or more than 200 kilopascals (30 pounds per square inch).

14. Manual and Mechanical Warewashing Equipment, Chemical Sanitization - Temperature, pH, Concentration, and Hardness. - A chemical sanitizer used in a sanitizing solution for a manual or mechanical operation at contact times specified under 1200-23-01-.04(7)(c) shall meet the criteria specified under 1200-23-01-.07(2)(d)1 Sanitizers, Criteria, shall be used in accordance with the EPA-registered label use instructions, and shall be used as follows (P):

(i) A chlorine solution shall have a minimum temperature based on the concentration and pH of the solution as listed in the following chart:(P)

<u>Concentration Range</u>	<u>Minimum Temperature</u>	
<u>mg/L</u>	<u>pH 10 or less</u>	<u>pH 8 or less</u>
	<u>°C (°F)</u>	<u>°C (°F)</u>
<u>25 -49</u>	<u>49 (120)</u>	<u>49 (120)</u>
<u>50 -99</u>	<u>38 (100)</u>	<u>24 (75)</u>
<u>100</u>	<u>13 (55)</u>	<u>13 (55)</u>

(ii) An iodine solution shall have a:

(I) Minimum temperature of 20°C (68°F). (P)

(II) A pH of 5.0 or less or a pH no higher than the level for which the manufacturer specifies the solution is effective. (P) and

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(Rule 1200-23-1-.04, continued)

3. Single-Service and Single-Use Articles, Use Limitation.
 - (i) Single-service and single-use articles may not be reused.
 - (ii) The bulk milk container dispensing tube shall be cut on the diagonal leaving no more than one inch protruding from the chilled dispensing head.
4. Shells, Use Limitation. - Mollusk and crustacean shells may not be used more than once as serving containers.

(6) Cleaning of Equipment and Utensils

(a) Objective

1. Equipment, Food-Contact Surfaces, Nonfood-Contact Surfaces, and Utensils.
 - (i) Equipment food-contact surfaces and utensils shall be clean to sight and touch. (Pf)
 - (ii) The food-contact surfaces of cooking equipment and pans shall be kept free of encrusted grease deposits and other soil accumulations.
 - (iii) Nonfood-contact surfaces of equipment shall be kept free of an accumulation of dust, dirt, food residue, and other debris.

(b) Frequency

1. Equipment Food-Contact Surfaces and Utensils.
 - (i) Equipment food-contact surfaces and utensils shall be cleaned:
 - (I) Except as specified in (ii) of this part, before each use with a different type of raw animal food such as beef, fish, lamb, pork, or poultry; (P)
 - (II) Each time there is a change from working with raw foods to working with ready-to-eat foods; (P)
 - (III) Between uses with raw fruits and vegetables and with time/temperature control for safety food; (P)
 - (IV) Before using or storing a food temperature measuring device; (P) and
 - (V) At any time during the operation when contamination may have occurred. (P)
 - (ii) Item (i)(I) of this part does not apply if the food-contact surface or utensil is in contact with a succession of different raw animal foods each requiring a higher cooking temperature as specified under 1200-23-01-.03(4)(a)1 than the previous food, such as preparing raw fish followed by cutting raw poultry on the same cutting board.

(Rule 1200-23-1-.04, continued)

(iii) Except as specified in subpart (iv) of this part, if used with time/temperature control for safety food, equipment food-contact surfaces and utensils shall be cleaned throughout the day at least every 4 hours. (P)

(iv) Surfaces of utensils and equipment contacting time/temperature control for safety food may be cleaned less frequently than every 4 hours if:

(I) In storage, containers of time/temperature control for safety food and their contents are maintained at temperatures specified under 1200-23-01-.03 and the containers are cleaned when they are empty;

(II) Utensils and equipment are used to prepare food in a refrigerated room or area that is maintained at one of the temperatures in the following chart and:

I. The utensils and equipment are cleaned at the frequency in the following chart that corresponds to the temperature; and

<u>Temperature</u>	<u>Cleaning Frequency</u>
<u>5.0°C (41°F) or less</u>	<u>24 hours</u>
<u>>5.0°C - 7.2°C (>41°F - 45°F)</u>	<u>20 hours</u>
<u>>7.2°C - 10.0°C (>45°F - 50°F)</u>	<u>16 hours</u>
<u>>10.0°C - 12.8°C (>50°F - 55°F)</u>	<u>10 hours</u>

II. The cleaning frequency based on the ambient temperature of the refrigerated room or area is documented in the food establishment.

(III) Containers in serving situations such as salad bars, delis, and cafeteria lines hold ready-to-eat time/temperature control for safety food that is maintained at the temperatures specified under 1200-23-01-.03, are intermittently combined with additional supplies of the same food that is at the required temperature, and the containers are cleaned at least every 24 hours;

(IV) Temperature measuring devices are maintained in contact with food, such as when left in a container of deli food or in a roast, held at temperatures specified under 1200-23-01-.03;

(Rule 1200-23-1-.04, continued)

(V) Equipment is used for storage of packaged or unpackaged food such as a reach-in refrigerator and the equipment is cleaned at a frequency necessary to preclude accumulation of soil residues;

(VI) The cleaning schedule is approved based on consideration of:

I. Characteristics of the equipment and its use,

II. The type of food involved,

III. The amount of food residue accumulation, and

IV. The temperature at which the food is maintained during the operation and the potential for the rapid and progressive multiplication of pathogenic or toxigenic microorganisms that are capable of causing foodborne disease, or

(VII) In-use utensils are intermittently stored in a container of water in which the water is maintained at 57°C (135°F) or more and the utensils and container are cleaned at least every 24 hours or at a frequency necessary to preclude accumulation of soil residues.

(v) Except when dry cleaning methods are used as specified under 1200-23-01-.04(6)(c)1, surfaces of utensils and equipment contacting food that is not time/temperature control for safety food shall be cleaned:

(I) At any time when contamination may have occurred;

(II) At least every 24 hours for iced tea dispensers and consumer self-service utensils such as tongs, scoops, or ladles;

(III) Before restocking consumer self-service equipment and utensils such as condiment dispensers and display containers; and

(IV) In equipment such as ice bins and beverage dispensing nozzles and enclosed components of equipment such as ice makers, cooking oil storage tanks and distribution lines, beverage and syrup dispensing lines or tubes, coffee bean grinders, and water vending equipment:

I. At a frequency specified by the manufacturer, or

II. Absent manufacturer specifications, at a frequency necessary to preclude accumulation of soil or mold.

2. Cooking and Baking Equipment.

(i) The food-contact surfaces of cooking and baking equipment shall be cleaned at least every 24 hours. This section does not apply to hot oil cooking and filtering equipment if it is cleaned as specified in 1200-23-01-.04(6)(b)1(iv)(VI).

(Rule 1200-23-1-.04, continued)

(ii) The cavities and door seals of microwave ovens shall be cleaned at least every 24 hours by using the manufacturer's recommended cleaning procedure.

3. Nonfood-Contact Surfaces. - Nonfood-contact surfaces of equipment shall be cleaned at a frequency necessary to preclude accumulation of soil residues

(c) Methods

1. Dry Cleaning.

(i) If used, dry cleaning methods such as brushing, scraping, and vacuuming shall contact only surfaces that are soiled with dry food residues that are not time/temperature control for safety food.

(ii) Cleaning equipment used in dry cleaning food-contact surfaces may not be used for any other purpose

2. Precleaning.

(i) Food debris on equipment and utensils shall be scrapped over a waste disposal unit or garbage receptacle or shall be removed in a warewashing machine with a prewash cycle.

(ii) If necessary for effective cleaning, utensils and equipment shall be preflushed, presoaked, or scrubbed with abrasives.

3. Loading of Soiled Items, Warewashing Machines. - Soiled items to be cleaned in a warewashing machine shall be loaded into racks, trays, or baskets or onto conveyors in a position that:

(i) Exposes the items to the unobstructed spray from all cycles; and

(ii) Allows the items to drain.

4. Wet Cleaning.

(i) Equipment, food-contact surfaces and utensils shall be effectively washed to remove or completely loosen soils by using the manual or mechanical means necessary such as the application of detergents containing wetting agents and emulsifiers; acid, alkaline, or abrasive cleaners; hot water; brushes; scouring pads; high-pressure sprays; or ultrasonic devices.

(ii) The washing procedures selected shall be based on the type and purpose of the equipment or utensil, and on the type of soil to be removed.

5. Washing, Procedures for Alternative Manual Warewashing Equipment. - If washing in sink compartments or a warewashing machine is impractical such as when the equipment is fixed or the utensils are too large, washing shall be done in accordance with the following procedures:

(Rule 1200-23-1-.04, continued)

- (i) Equipment shall be disassembled as necessary to allow access of the detergent solution to all parts;
- (ii) Equipment components and utensils shall be scrapped or rough cleaned to remove food particle accumulation; and
- (iii) Equipment and utensils shall be washed as specified under 1200-23-01-.04(6)(c)4(i).

6. Rinsing Procedures. - Washed utensils and equipment shall be rinsed so that abrasives are removed and cleaning chemicals are removed or diluted through use of a distinct, separate water rinse after washing and before sanitizing.

7. Returnables, Cleaning for Refilling.

(i) Except as specified in subparts (ii) and (iii), returned empty containers intended for cleaning and refilling with food shall be cleaned and refilled in a regulated food processing plant. (P)

(ii) A food-specific container for beverages may be refilled at a food establishment if:

(I) Only a beverage that is not a time/temperature control for safety food is used as specified under 1200-23-01-.03(3)(d)7.

(II) The design of the container and of the rinsing equipment and the nature of the beverage, when considered together, allow effective cleaning at home or in the food establishment;

(III) Facilities for rinsing before refilling returned containers with fresh, hot water that is under pressure and not recirculated are provided as part of the dispensing system;

(IV) The consumer-owned container returned to the food establishment for refilling is refilled for sale or service only to the same consumer; and

(V) The container is refilled by:

I. An employee of the food establishment, or

II. The owner of the container if the beverage system includes a contamination-free transfer process that cannot be by-passed by the container owner.

(iii) Consumer-owned containers that are not food-specific may be filled at a water vending machine or system.

(7) Sanitization of Equipment and Utensils

(a) Objective. - Food-Contact Surfaces and Utensils. - Equipment, food-contact surfaces and utensils shall be sanitized.

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(Rule 1200-23-1-.04, continued)

- (b) Frequency - Before Use After Cleaning. - Utensils and food-contact surfaces of equipment shall be sanitized before use after cleaning. (P)
- (c) Methods - Hot Water and Chemical. - After being cleaned, equipment, food-contact surfaces and utensils shall be sanitized in:
1. Hot water manual operations by immersion for at least 30 seconds and as specified under 1200-23-01-.04(5)(a)11.; (P)
 2. Hot water mechanical operations by being cycled through equipment that is set up as specified under 1200-23-01-.04(5)(a)5, 1200-23-01-.04(5)(a)12, and 1200-23-01-.04(5)(a)13. and achieving a utensil surface temperature of 71°C (160°F) as measured by an irreversible registering temperature indicator; (P) or
 3. Chemical manual or mechanical operations, including the application of sanitizing chemicals by immersion, manual swabbing, brushing, or pressure spraying methods, using a solution as specified under 1200-23-01-.04(5)(a)14. Contact times shall be consistent with those on EPA-registered label use instructions by providing:
 - (i) Except as specified under part (c)2. of this subparagraph, a contact time of at least 10 seconds for a chlorine solution specified under 1200-23-01-.04(5)(a)14(i).; (P)
 - (ii) A contact time of at least 7 seconds for a chlorine solution of 50 mg/L that has a pH of 10 or less and a temperature of at least 38°C (100°F) or a pH of 8 or less and a temperature of at least 24°C (75°F).; (P)
 - (iii) A contact time of at least 30 seconds for other chemical sanitizing solutions.; (P) or
 - (iv) A contact time used in relationship with a combination of temperature, concentration, and pH that, when evaluated for efficacy, yields sanitization as defined in 1200-23-01-.01.; (P)

(8) Laundering.

- (a) Objective. --Clean Linens. - Clean linens shall be free from food residues and other soiling matter.
- (b) Frequency - Specifications.
1. Linens that do not come in direct contact with food shall be laundered between operations if they become wet, sticky, or visibly soiled.
 2. Cloth gloves used as specified in 1200-23-01-.03(3)(d)5 shall be laundered before being used with a different type of raw animal food such as beef, fish, lamb, pork or poultry.
 3. Linens and cloth napkins that are used as specified under 1200-23-01-.03(3)(d)3 and cloth napkins shall be laundered between each use.
 4. Wet wiping cloths shall be laundered daily.

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(Rule 1200-23-1-.04, continued)

5. Dry wiping cloths shall be laundered as necessary to prevent contamination of food and clean serving utensils.

(c) Methods.

1. Storage of Soiled Linens. - Soiled linens shall be kept in clean, nonabsorbent receptacles or clean, washable laundry bags and stored and transported to prevent contamination of food, clean equipment, clean utensils, and single-service and single-use articles.

2. Mechanical Washing.

- (i) Except as specified in (ii) of this part, linens shall be mechanically washed.

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- (ii) In food establishments in which only wiping cloths are laundered as specified in 1200-23-01-.04(3)(a)5(ii) the wiping cloths may be laundered in a mechanical washer, sink designated only for laundering wiping cloths, or a warewashing or food preparation sink that is cleaned as specified under 1200-23-01-.04(5)(a)14.

3. Use of Laundry Facilities

- (i) Except as specified in subpart (ii) of this part, laundry facilities on the premises of a food establishment shall be used only for the washing and drying of items used in the operation of the establishment.

- (ii) Separate laundry facilities located on the premises for the purpose of general laundering such as for institutions providing boarding and lodging may also be used for laundering food establishment items.

(9) Protection of Clean Items

(a) Drying.

1. Equipment and Utensils, Air-Drying Required. - After cleaning and sanitizing, equipment and utensils:

- (i) Shall be air-dried or used after adequate draining as specified in the first paragraph of 40 CFR § 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (food-contact surface sanitizing solutions), before contact with food; and

- (ii) May not be cloth dried except that utensils that have been air-dried may be polished with cloths that are maintained clean and dry.

2. Wiping Cloths, Air-Drying Locations. Wiping cloths laundered in a food establishment that does not have a mechanical clothes dryer as specified in 1200-23-01-.04(3)(a)5(ii) shall be air-dried in a location and in a manner that prevents contamination of food, equipment, utensils, linens, and single-service and single-use articles and the wiping cloths. This section does not apply if wiping cloths are stored after laundering in a sanitizing solution as specified under 1200-23-01-.04(5)(a)14.

(Rule 1200-23-1-.04, continued)

(b) Lubricating and Reassembling. —

1. Food-Contact Surfaces. Lubricants as specified under 1200-23-01-.07(2)(e) shall be applied to food-contact surfaces that require lubrication in a manner that does not contaminate food-contact surfaces.
2. Equipment. Equipment shall be reassembled so that food-contact surfaces are not contaminated.

(c) Storing

1. Equipment, Utensils, Linens, and Single-Service and Single-Use Articles.
 - (i) Except as specified in subpart (iv) of this part, cleaned equipment and utensils, laundered linens, and single-service and single-use articles shall be stored:
 - (I) In a clean, dry location;
 - (II) Where they are not exposed to splash, dust, or other contamination; and
 - (III) At least 15 cm (6 inches) above the floor.
 - (ii) Clean equipment and utensils shall be stored as specified under (i) of this part and shall be stored:
 - (I) In a self-draining position that allows air drying; and
 - (II) Covered or inverted.
 - (iii) Single-service and single-use articles shall be stored as specified under (i) of this part and shall be kept in the original protective package or stored by using other means that afford protection from contamination until used.
 - (iv) Items that are kept in closed packages may be stored less than 15 cm (6 inches) above the floor on dollies, pallets, racks, and skids that are designed as specified under 1200-23-01-.04(2)(d)18.
2. Prohibitions.
 - (i) Except as specified in subpart (ii) of this part, cleaned and sanitized equipment, utensils, laundered linens, and single-service and single-use articles may not be stored:
 - (I) In locker rooms;
 - (II) In toilet rooms;
 - (III) In garbage rooms;
 - (IV) In mechanical rooms;

(Rule 1200-23-1-.04, continued)

(V) Under sewer lines that are not shielded to intercept potential drips;

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(VI) Under leaking water lines including leaking automatic fire sprinkler heads or under lines on which water has condensed;

(VII) Under open stairwells; or

(VIII) Under other sources of contamination.

(ii) Laundered linens and single-service and single-use articles that are packaged or in a facility such as a cabinet may be stored in a locker room.

(d) Preventing Contamination

1. Kitchenware and Tableware.

(i) Single-service and single-use articles and cleaned and sanitized utensils shall be handled, displayed, and dispensed so that contamination of food- and lip-contact surfaces is prevented.

(ii) Knives, forks, and spoons that are not prewrapped shall be presented so that only the handles are touched by employees and by consumers if consumer self-service is provided.

(iii) Except as specified under subpart (ii) of this part, single-service articles that are intended for food- or lip-contact shall be furnished for consumer self-service with the original individual wrapper intact or from an approved dispenser.

2. Soiled and Clean Tableware. Soiled tableware shall be removed from consumer eating and drinking areas and handled so that clean tableware is not contaminated.

3. Preset Tableware.

(i) Except as specified in subpart (ii) of this part, tableware that is preset shall be protected from contamination by being wrapped, covered, or inverted.

(ii) Preset tableware may be exposed if:

(I) Unused settings are removed when a consumer is seated; or

(II) Settings not removed when a consumer is seated are cleaned and sanitized before further use.

4. Rinsing Equipment and Utensils after Cleaning and Sanitizing. After being cleaned and sanitized, equipment and utensils shall not be rinsed before air drying or use unless:

(i) The rinse is applied directly from a potable water supply by a warewashing machine that is maintained and operated as specified

(Rule 1200-23-1-.04, continued)

under 1200-23-01-.04(2)(d) and 1200-23-01-.04(5); and

- (ii) The rinse is applied only after the equipment and utensils have been sanitized by the application of hot water or by the application of a chemical sanitizer solution whose EPA-registered label use instructions call for rinsing off the sanitizer after it is applied in a commercial warewashing machine.

Authority: T.C.A. §§ 68-14-701 through 68-14-726.

Rule 1200-23-01-.05 Water, Plumbing, and Waste.

(1) Water

(a) Source

1. Approved System. - Drinking water shall be obtained from an approved source that is:
 - (i) A public water system; (P) or
 - (ii) A nonpublic water system that is constructed, maintained, and operated according to law. (P)
2. System Flushing and Disinfection. A drinking water system shall be flushed and disinfected before being placed in service after construction, repair, or modification and after an emergency situation, such as a flood, that may introduce contaminants to the system. (P)
3. Bottled Drinking Water. Bottled drinking water used or sold in a food establishment shall be obtained from approved sources in accordance with 21 CFR Part 129 - Processing and Bottling of Bottled drinking water. (P)

(b) Quality

1. Standards. Except as specified under 1200-23-01-.05(1)(b)2:
 - (i) Water from a public water system shall meet 40 CFR Part 141 - National Primary Drinking Water Regulations and state drinking water quality standards; and (P)
 - (ii) Water from a nonpublic water system shall meet state drinking water quality standards. (P)
2. Nondrinking Water.
 - (i) A nondrinking water supply shall be used only if its use is approved (P).
 - (ii) Nondrinking water shall be used only for nonculinary purposes such as air conditioning, nonfood equipment cooling, and fire protection. (P)
3. Sampling. Except when used as specified under 1200-23-01-.05(1)(b)2, water from a nonpublic water system shall be sampled and tested at least annually and as required by state water quality regulations. (Pf)

(Rule 1200-23-1-.04, continued)

4. Sample Report. The most recent sample report for the nonpublic water system shall be retained on file in the food establishment or the report shall be maintained as specified by state water quality regulations.

(c) Quantity and Availability

1. Capacity.

- (i) The water source and system shall be of sufficient capacity to meet the peak water demands of the food establishment. (Pf)
- (ii) Hot water generation and distribution systems shall be sufficient to meet the peak hot water demands throughout the food establishment. (Pf)

2. Pressure. Water under pressure shall be provided to all fixtures, equipment, and nonfood equipment that are required to use water except that water supplied as specified under 1200-23-01-.05(1)(d)2(i) and (ii) to a temporary food establishment or in response to a temporary interruption of a water supply need not be under pressure. (Pf)

(d) Distribution, Delivery, and Retention

1. System. Water shall be received from the source through the use of:

- (i) An approved public water main (Pf); or
- (ii) One or more of the following that shall be constructed, maintained, and operated according to law: (Pf)
- (I) Nonpublic water main, water pumps, pipes, hoses, connections, and other appurtenances, (Pf)
- (II) Water transport vehicles, (Pf) or
- (III) Water containers. (Pf)

2. Alternative Water Supply. Water meeting the requirements specified under 1200-23-01-.05(1)(a), 1200-23-01-.05(1)(b), and 1200-23-01-.05(1)(c) shall be made available for a mobile facility, for a temporary food establishment without a permanent water supply, and for a food establishment with a temporary interruption of its water supply through:

- (i) A supply of containers of commercially bottled drinking water; (Pf)
- (ii) One or more closed portable water containers; (Pf)
- (iii) An enclosed vehicular water tank; (Pf)
- (iv) An on-premises water storage tank; or (Pf)
- (v) Piping, tubing, or hoses connected to an adjacent approved source. (Pf)

(2) Plumbing System

(Rule 1200-23-1-.04, continued)

(a) Materials - Approved.

1. A plumbing system and hoses conveying water shall be constructed and repaired with approved materials according to law. (P)
2. A water filter shall be made of safe materials. (P)

(b) Design, Construction, and Installation.

1. Approved System and Cleanable Fixtures.
 - (i) A plumbing system shall be designed, constructed, and installed according to law. (P)
 - (ii) A plumbing fixture such as a handwashing sink, toilet, or urinal shall be easily cleanable.
2. Handwashing Sink, Installation.
 - (i) A handwashing sink shall be equipped to provide water at a temperature of at least 38°C (100°F) through a mixing valve or combination faucet. (Pf)
 - (ii) A steam-mixing valve may not be used at a handwashing sink.
 - (iii) A self-closing, slow-closing, or metering faucet shall provide a flow of water for at least 15 seconds without the need to reactivate the faucet.
 - (iv) An automatic handwashing facility shall be installed in accordance with manufacturer's instructions.
3. Backflow Prevention, Air Gap. An air gap between the water supply inlet and the flood level rim of the plumbing fixture equipment, or nonfood equipment shall be at least twice the diameter of the water supply inlet and may not be less than 25 mm (1 inch). (P)
4. Backflow Prevention Device, Design Standard. A backflow or backsiphonage prevention device installed on a water supply system shall meet American Society of Sanitary Engineering (A.S.S.E.) standards for construction, installation, maintenance, inspection, and testing for that specific application and type of device. (P)
5. Conditioning Device, Design. A water filter, screen, and other water conditioning device installed on water lines shall be designed to facilitate disassembly for periodic servicing and cleaning. A water filter element shall be of the replaceable type.

(c) Numbers and Capacities

1. Handwashing Sinks.
 - (i) Except as specified in subpart (ii) of this part, at least 1 handwashing sink, a number of handwashing sinks necessary for their convenient use

(Rule 1200-23-1-.04, continued)

by employees in areas specified under 1200-23-01-.05(2)(d)1, and not fewer than the number of handwashing sinks required by law shall be provided. (Pf)

(ii) If approved and capable of removing the types of soils encountered in the food operations involved, automatic handwashing facilities may be substituted for handwashing sinks in a food establishment that has at least 1 handwashing sink.

2. Toilets and Urinals. At least 1 toilet and not fewer than the toilets required by law shall be provided. If the food service establishment has more than 16 seats, two restrooms must be available. If authorized by law and urinals are substituted for toilets, the substitution shall be done as specified in law.

3. Service Sink.

(i) At least 1 service sink or 1 curbed cleaning facility equipped with a floor drain shall be provided and conveniently located for the cleaning of mops or similar wet floor cleaning tools and for the disposal of mop water and similar liquid waste.

(ii) Toilets and urinals may not be used as a service sink for the disposal of mop water and similar liquid waste.

4. Backflow Prevention Device, When Required. A plumbing system shall be installed to preclude backflow of a solid, liquid, or gas contaminant into the water supply system at each point of use at the food establishment, including on a hose bibb if a hose is attached or on a hose bibb if a hose is not attached and backflow prevention is required by law, by:

(i) Providing an air gap as specified under 1200-23-01-.05(2)(b)3; (P) or

(ii) Installing an approved backflow prevention device as specified under 1200-23-01-.05(2)(b)4. (P)

5. Backflow Prevention Device, Carbonator.

(i) If not provided with an air gap as specified under 1200-23-01-.05(2)(b)3, a dual check valve with an intermediate vent preceded by a screen of not less than 100 mesh to 25.4 mm (100 mesh to 1 inch) shall be installed upstream from a carbonating device and downstream from any copper in the water supply line.

(ii) A dual check valve attached to the carbonator need not be of the vented type if an air gap or vented backflow prevention device has been otherwise provided as specified under subpart (i) of this part.

(d) Location and Placement:

1. Handwashing sinks shall be located:

(i) To allow convenient use by employees in food preparation, food dispensing, and warewashing areas; (Pf) and

(Rule 1200-23-1-.04, continued)

(ii) In, or immediately adjacent to, toilet rooms. (Pf)

2. Backflow Prevention Device, Location. A backflow prevention device shall be located so that it may be serviced and maintained.

3. Conditioning Device, Location. A water filter, screen, and other water conditioning device installed on water lines shall be located to facilitate disassembly for periodic servicing and cleaning.

(e) Operation and Maintenance

1. Using a Handwashing Sink.

(i) A handwashing sink shall be maintained so that it is accessible at all times for employee use. (Pf)

(ii) A handwashing sink may not be used for purposes other than handwashing. (Pf)

(iii) An automatic handwashing facility shall be used in accordance with manufacturer's instructions. (Pf)

2. Prohibiting a Cross Connection.

(i) A person may not create a cross connection by connecting a pipe or conduit between the drinking water system and a nondrinking water system or a water system of unknown quality. (P)

(ii) The piping of a nondrinking water system shall be durably identified so that it is readily distinguishable from piping that carries drinking water. (Pf)

3. Scheduling Inspection and Service for a Water System Device. A device such as a water treatment device or backflow preventer shall be scheduled for inspection and service, in accordance with manufacturer's instructions and as necessary to prevent device failure based on local water conditions, and records demonstrating inspection and service shall be maintained by the person in charge. (Pf)

4. Water Reservoir of Fogging Devices, Cleaning.

(i) A reservoir that is used to supply water to a device such as a produce fogger shall be:

(I) Maintained in accordance with manufacturer's specifications; (P)
and

(II) Cleaned in accordance with manufacturer's specifications or according to the procedures specified under subpart (ii) of this part, whichever is more stringent. (P)

(ii) Cleaning procedures shall include at least the following steps and shall be conducted at least once a week:

(Rule 1200-23-1-.04, continued)

- (I) Draining and complete disassembly of the water and aerosol contact parts; (P)
- (II) Brush-cleaning the reservoir, aerosol tubing, and discharge nozzles with a suitable detergent solution; (P)
- (III) Flushing the complete system with water to remove the detergent solution and particulate accumulation; (P) and
- (IV) Rinsing by immersing, spraying, or swabbing the reservoir, aerosol tubing, and discharge nozzles with at least 50 MG/L hypochlorite solution. (P)

5. System Maintained in Good Repair. A plumbing system shall be:

- (i) Repaired according to law; (P) and
- (ii) Maintained in good repair. (P)

(3) Mobile Water Tanks and Mobile Food Establishment Water Tanks.

(a) Materials that are used in the construction of a mobile water tank, mobile food establishment water tank, and appurtenances shall be:

- 1. Safe; (P)
- 2. Durable, corrosion-resistant, and nonabsorbent; and
- 3. Finished to have a smooth, easily cleanable surface.

(b) Design and Construction.

1. Enclosed System, Sloped to Drain. A mobile water tank shall be:

- (i) Enclosed from the filling inlet to the discharge outlet; and
- (ii) Sloped to an outlet that allows complete drainage of the tank.

2. Inspection and Cleaning Port, Protected and Secured. If a water tank is designed with an access port for inspection and cleaning, the opening shall be in the top of the tank and:

- (i) Flanged upward at least 13 mm (one-half inch); and
- (ii) Equipped with a port cover assembly that is:
 - (I) Provided with a gasket and a device for securing the cover in place, and
 - (II) Flanged to overlap the opening and sloped to drain.

3. "V" Type Threads, Use Limitation. A fitting with "V" type threads on a water tank inlet or outlet shall be allowed only when a hose is permanently attached.

(Rule 1200-23-1-.04, continued)

4. Tank Vent, Protected. If provided, a water tank vent shall terminate in a downward direction and shall be covered with:
 - (i) 16 mesh to 25.4 mm (16 mesh to 1 inch) screen or equivalent when the vent is in a protected area; or
 - (ii) A protective filter when the vent is in an area that is not protected from windblown dirt and debris.
5. Inlet and Outlet, Sloped to Drain.
 - (i) A water tank and its inlet and outlet shall be sloped to drain.
 - (ii) A water tank inlet shall be positioned so that it is protected from contaminants such as waste discharge, road dust, oil, or grease.
6. Hose, Construction and Identification. A hose used for conveying drinking water from a water tank shall be:
 - (i) Safe; (P)
 - (ii) Durable, corrosion-resistant, and nonabsorbent;
 - (iii) Resistant to pitting, chipping, crazing, scratching, scoring, distortion, and decomposition;
 - (iv) Finished with a smooth interior surface; and
 - (v) Clearly and durably identified as to its use if not permanently attached.

(c) Number and Capacities

1. Filter, Compressed Air. A filter that does not pass oil or oil vapors shall be installed in the air supply line between the compressor and drinking water system when compressed air is used to pressurize the water tank system. (P)
2. Protective Cover or Device. A cap and keeper chain, closed cabinet, closed storage tube, or other approved protective cover or device shall be provided for a water inlet, outlet, and hose.
3. Mobile Food Establishment Tank Inlet. A mobile food establishment's water tank inlet shall be:
 - (i) 19.1 mm (three-fourths inch) in inner diameter or less; and
 - (ii) Provided with a hose connection of a size or type that will prevent its use for any other service.

(d) Operation and Maintenance.

1. System Flushing and Sanitization. A water tank, pump, and hoses shall be flushed and sanitized before being placed in service after construction, repair, modification, and periods of nonuse. (P)

(Rule 1200-23-1-.04, continued)

2. Using a Pump and Hoses, Backflow Prevention. A person shall operate a water tank, pump, and hoses so that backflow and other contamination of the water supply are prevented.
3. Protecting Inlet, Outlet, and Hose Fitting. If not in use, a water tank and hose inlet and outlet fitting shall be protected using a cover or device as specified under 1200-23-01-.05(3)(c)2.
4. Tank, Pump, and Hoses, Dedication.
 - (i) Except as specified in subpart (ii) of this part, a water tank, pump, and hoses used for conveying drinking water shall be used for no other purpose.
 - (ii) Water tanks, pumps, and hoses approved for liquid foods may be used for conveying drinking water if they are cleaned and sanitized before they are used to convey water.

(4) Sewage, Other Liquid Waste, and Rainwater.

- (a) Mobile Holding Tank, Capacity and Drainage. A sewage holding tank in a mobile food establishment shall be:

1. Sized 15 percent larger in capacity than the water supply tank; and
2. Sloped to a drain that is 25 mm (1 inch) in inner diameter or greater, equipped with a shut-off valve.

(b) Retention Drainage and Delivery.

1. Establishment Drainage System. Food establishment drainage systems, including grease traps, that convey sewage shall be designed and installed as specified under 1200-23-01-.05(2)(b).
2. Backflow Prevention.
 - (i) Except as specified in subparts (ii), (iii), and (iv) of this part, a direct connection may not exist between the sewage system and a drain originating from equipment in which food, portable equipment, or utensils are placed.
 - (ii) Subpart (i) of this part does not apply to floor drains that originate in refrigerated spaces that are constructed as an integral part of the building.
 - (iii) If allowed by law, a warewashing machine may have a direct connection between its waste outlet and a floor drain when the machine is located within 1.5 m (5 feet) of a trapped floor drain and the machine outlet is connected to the inlet side of a properly vented floor drain trap.
 - (iv) If allowed by law, a warewashing or culinary sink may have a direct connection.
3. Grease Trap. If used, a grease trap shall be located to be easily accessible for

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(Rule 1200-23-1-.04, continued)

cleaning.

4. Conveying Sewage. Sewage shall be conveyed to the point of disposal through an approved sanitary sewage system or other system, including use of sewage transport vehicles, waste retention tanks, pumps, pipes, hoses, and connections that are constructed, maintained, and operated according to law. (P)
5. Removing Mobile Food Establishment Wastes. Sewage and other liquid wastes shall be removed from a mobile food establishment at an approved waste servicing area or by a sewage transport vehicle in such a way that a public health hazard or nuisance is not created. (Pf)
6. Flushing a Waste Retention Tank. A tank for liquid waste retention shall be thoroughly flushed and drained in a sanitary manner during the servicing operation.

(c) Approved Sewage Disposal System.

1. Sewage shall be disposed through an approved facility that is:
 - (i) A public sewage treatment plant; (P) or
 - (ii) An individual sewage disposal system that is sized, constructed, maintained, and operated according to law. (P)
2. Other Liquid Wastes and Rainwater. Condensate drainage and other nonsewage liquids and rainwater shall be drained from point of discharge to disposal according to law.

(5) Refuse, Recyclables, and Returnables.

(a) Facilities on the Premises.

1. Indoor Storage Area. If located within the food establishment, a storage area for refuse, recyclables, and returnables shall meet the requirements specified under 1200-23-01-.06(1)(a)1, 1200-23-01-.06(2)(a)1, 1200-23-01-.06(2)(a)8, 1200-23-01-.06(2)(b)5, and 1200-23-01-.06(2)(b)6.
2. Outdoor Storage Surface. An outdoor storage surface for refuse, recyclables, and returnables shall be constructed of nonabsorbent material such as concrete or asphalt and shall be smooth, durable, and sloped to drain.
3. Outdoor Enclosure. If used, an outdoor enclosure for refuse, recyclables, and returnables shall be constructed of durable and cleanable materials.
4. Receptacles.
 - (i) Except as specified in subpart (ii) of this part, receptacles and waste handling units for refuse, recyclables, and returnables and for use with materials containing food residue shall be durable, cleanable, insect- and rodent-resistant, leakproof, and nonabsorbent.
 - (ii) Plastic bags and wet strength paper bags may be used to line receptacles for storage inside the food establishment, or within closed

(Rule 1200-23-1-.04, continued)

outside receptacles.

5. Outside Receptacles.

- (i) Receptacles and waste handling units for refuse, recyclables, and returnables used with materials containing food residue and used outside the food establishment shall be designed and constructed to have tight-fitting lids, doors, or covers.
- (ii) Receptacles and waste handling units for refuse and recyclables such as an on-site compactor shall be installed so that accumulation of debris and insect and rodent attraction and harborage are minimized and effective cleaning is facilitated around and, if the unit is not installed flush with the base pad, under the unit.

6. Storage Areas, Rooms, and Receptacles, Capacity and Availability.

- (i) An inside storage room and area and outside storage area and enclosure, and receptacles shall be of sufficient capacity to hold refuse, recyclables, and returnables that accumulate.
- (ii) A receptacle shall be provided in each area of the food establishment or premises where refuse is generated or commonly discarded, or where recyclables or returnables are placed.
- (iii) If disposable towels are used at handwashing lavatories, a waste receptacle shall be located at each lavatory or group of adjacent lavatories.

7. Toilet Room Receptacle, Covered. A toilet room used by females shall be provided with a covered receptacle for sanitary napkins.

8. Cleaning Implements and Supplies.

- (i) Except as specified in subpart (ii) of this part, suitable cleaning implements and supplies such as high pressure pumps, hot water, steam, and detergent shall be provided as necessary for effective cleaning of receptacles and waste handling units for refuse, recyclables, and returnables.
- (ii) If approved, off-premises-based cleaning services may be used if on-premises cleaning implements and supplies are not provided.

9. Storage Areas, Redeeming Machines, Receptacles and Waste Handling Units, Location.

- (i) An area designated for refuse, recyclables, returnables, and, except as specified in (ii) of this part, a redeeming machine for recyclables or returnables shall be located so that it is separate from food, equipment, utensils, linens, and single-service and single-use articles and a public health hazard or nuisance is not created.
- (ii) A redeeming machine may be located in the packaged food storage area or consumer area of a food establishment if food, equipment, utensils,

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(Rule 1200-23-1-.04, continued)

- linens, and single-service and single-use articles are not subject to contamination from the machines and a public health hazard or nuisance is not created.
- (iii) The location of receptacles and waste handling units for refuse, recyclables, and returnables may not create a public health hazard or nuisance or interfere with the cleaning of adjacent space.
10. Storing Refuse, Recyclables, and Returnables. Refuse, recyclables, and returnables shall be stored in receptacles or waste handling units so that they are inaccessible to insects and rodents.
11. Areas, Enclosures, and Receptacles, Good Repair. Storage areas, enclosures, and receptacles for refuse, recyclables, and returnables shall be maintained in good repair.
12. Outside Storage Prohibitions.
- (i) Except as specified in subpart (ii) of this part, refuse receptacles not meeting the requirements specified under 1200-23-01-.05(5)(a)4(i) such as receptacles that are not rodent-resistant, that consist of unprotected plastic bags and paper bags, or baled units that contain materials with food residue, may not be stored outside.
- (ii) Cardboard or other packaging material that does not contain food residues and that is awaiting regularly scheduled delivery to a recycling or disposal site may be stored outside without being in a covered receptacle if it is stored so that it does not create a rodent harborage problem.
13. Covering Receptacles. Receptacles and waste handling units for refuse, recyclables, and returnables shall be kept covered:
- (i) Inside the food establishment if the receptacles and units:
- (I) Contain food residue and are not in continuous use; or
- (II) After they are filled; and
- (ii) With tight-fitting lids or doors if kept outside the food establishment.
14. Using Drain Plugs. Drains in receptacles and waste handling units for refuse, recyclables, and returnables shall have drain plugs in place.
15. Maintaining Refuse Areas and Enclosures. A storage area and enclosure for refuse, recyclables, or returnables shall be maintained free of unnecessary items, as specified under 1200-23-01-.06(5)(n), and clean.
16. Cleaning Receptacles.
- (i) Receptacles and waste handling units for refuse, recyclables, and returnables shall be thoroughly cleaned in a way that does not contaminate food, equipment, utensils, linens, or single-service and single-use articles, and waste water shall be disposed of as specified

(Rule 1200-23-1-.04, continued)

under 1200-23-01-.05(4)(b)4.

- (ii) Soiled receptacles and waste handling units for refuse, recyclables, and returnables shall be cleaned at a frequency necessary to prevent them from developing a buildup of soil or becoming attractants for insects and rodents.

(b) Removal.

- 1. Frequency. Refuse, recyclables, and returnables shall be removed from the premises at a frequency that will minimize the development of objectionable odors and other conditions that attract or harbor insects and rodents.

- 2. Receptacles or Vehicles. Refuse, recyclables, and returnables shall be removed from the premises by way of:

- (i) Portable receptacles that are constructed and maintained according to law; or
- (ii) A transport vehicle that is constructed, maintained, and operated according to law.

- (c) Facilities for Disposal and Recycling, Community or Individual Facility. Solid waste not disposed of through the sewage system such as through grinders and pulpers shall be recycled or disposed of in an approved public or private community recycling or refuse facility; or solid waste shall be disposed of in an individual refuse facility such as a landfill or incinerator which is sized, constructed, maintained, and operated according to law.

Authority: T.C.A. §§ 68-14-701 through 68-14-726.

1200-23-01-.06 Physical Facilities.

(1) Materials for Construction and Repair.

(a) Indoor Areas. Surface Characteristics

- 1. Except as specified in part 2. of this subparagraph, materials for indoor floor, wall, and ceiling surfaces under conditions of normal use shall be:

- (i) Smooth, durable, and easily cleanable for areas where food establishment operations are conducted;
- (ii) Closely woven and easily cleanable carpet for carpeted areas; and
- (iii) Nonabsorbent for areas subject to moisture such as food preparation areas, walk-in refrigerators, warewashing areas, toilet rooms, mobile food establishment servicing areas, and areas subject to flushing or spray cleaning methods.

- 2. In a temporary food establishment:

- (i) If graded to drain, a floor may be concrete, machine-laid asphalt, or dirt or gravel if it is covered with mats, removable platforms, duckboards, or other approved materials that are effectively treated to control dust and

(Rule 1200-23-1-.04, continued)

mud; and

- (ii) Walls and ceilings may be constructed of a material that protects the interior from the weather and windblown dust and debris.

(b) Outdoor Areas. Surface Characteristics.

1. The outdoor walking and driving areas shall be surfaced with concrete, asphalt, or gravel or other materials that have been effectively treated to minimize dust, facilitate maintenance, and prevent muddy conditions.
2. Exterior surfaces of buildings and mobile food establishments shall be of weather-resistant materials and shall comply with law.
3. Outdoor storage areas for refuse, recyclables, or returnables shall be of materials specified under 1200-23-01-.05(5)(a)2 and 1200-23-01-.05(5)(a)3.

(2) Design, Construction, and Installation.

(a) Cleanability.

1. Floors, Walls, and Ceilings. Except as specified under part 4. of this subparagraph and except for antislip floor coverings or applications that may be used for safety reasons, floors, floor coverings, walls, wall coverings, and ceilings shall be designed, constructed, and installed so they are smooth and easily cleanable.
2. Floors, Walls, and Ceilings, Utility Lines.
 - (i) Utility service lines and pipes may not be unnecessarily exposed.
 - (ii) Exposed utility service lines and pipes shall be installed so they do not obstruct or prevent cleaning of the floors, walls, or ceilings.
 - (iii) Exposed horizontal utility service lines and pipes may not be installed on the floor.
3. Floor and Wall Junctures, Coved, and Enclosed or Sealed.
 - (i) In food establishments in which cleaning methods other than water flushing are used for cleaning floors, the floor and wall junctures shall be coved and closed to no larger than 1 mm (one thirty-second inch).
 - (ii) The floors in food establishments in which water flush cleaning methods are used shall be provided with drains and be graded to drain, and the floor and wall junctures shall be coved and sealed.
4. Floor Carpeting, Restrictions, and Installation.
 - (i) A floor covering such as carpeting or similar material may not be installed as a floor covering in food preparation areas, walk-in refrigerators, warewashing areas, toilet room areas where handwashing lavatories, toilets, and urinals are located, refuse storage rooms, or other

(Rule 1200-23-1-.04, continued)

areas where the floor is subject to moisture, flushing, or spray cleaning methods.

(ii) If carpeting is installed as a floor covering in areas other than those specified under subpart (i) of this part, it shall be:

(I) Securely attached to the floor with a durable mastic, by using a stretch and tack method, or by another method; and

(II) Installed tightly against the wall under the coving or installed away from the wall with a space between the carpet and the wall and with the edges of the carpet secured by metal stripping or some other means.

5. Floor Covering, Mats and Duckboards. Mats and duckboards shall be designed to be removable and easily cleanable.

6. Wall and Ceiling Coverings and Coatings.

(i) Wall and ceiling covering materials shall be attached so that they are easily cleanable.

(ii) Except in areas used only for dry storage, concrete, porous blocks, or bricks used for indoor wall construction shall be finished and sealed to provide a smooth, nonabsorbent, easily cleanable surface.

7. Walls and Ceilings, Attachments.

(i) Except as specified in subpart (ii) of this part, attachments to walls and ceilings such as light fixtures, mechanical room ventilation system components, vent covers, wall mounted fans, decorative items, and other attachments shall be easily cleanable.

(ii) In a consumer area, wall and ceiling surfaces and decorative items and attachments that are provided for ambiance need not meet this requirement if they are kept clean.

8. Walls and Ceilings, Studs, Joists, and Rafters. Except for temporary food establishments, studs, joists, and rafters may not be exposed in areas subject to moisture.

(b) Functionality.

1. Light Bulbs, Protective Shielding.

(i) Except as specified in subpart (ii) of this part, light bulbs shall be shielded, coated, or otherwise shatter-resistant in areas where there is exposed food, clean equipment, utensils, and linens; or unwrapped single-service and single-use articles.

(ii) Shielded, coated, or otherwise shatter-resistant bulbs need not be used in areas used only for storing food in unopened packages, if:

(I) The integrity of the packages cannot be affected by broken glass

(Rule 1200-23-1-.04, continued)

- falling onto them; and
- (II) The packages are capable of being cleaned of debris from broken bulbs before the packages are opened.
- (iii) An infrared or other heat lamp shall be protected against breakage by a shield surrounding and extending beyond the bulb so that only the face of the bulb is exposed.
2. Heating, Ventilating, Air Conditioning System Vents. Heating, ventilating, and air conditioning systems shall be designed and installed so that make-up air intake and exhaust vents do not cause contamination of food, food-contact surfaces, equipment, or utensils.
3. Insect Control Devices, Design and Installation.
- (i) Insect control devices that are used to electrocute or stun flying insects shall be designed to retain the insect within the device.
- (ii) Insect control devices shall be installed so that:
- (I) The devices are not located over a food preparation area; and
- (II) Dead insects and insect fragments are prevented from being impelled onto or falling on exposed food, clean equipment, utensils, and linens, and unwrapped single-service and single-use articles.
4. Toilet Rooms, Enclosed. Except where a toilet room is located outside a food establishment and does not open directly into the food establishment such as a toilet room that is provided by the management of a shopping mall, a toilet room located on the premises shall be completely enclosed and provided with a tight-fitting and self-closing door.
5. Outer Openings, Protected.
- (i) Except as specified in subparts (ii), (iii), (iv) and (v) of this part, outer openings of a food establishment shall be protected against the entry of insects and rodents by:
- (I) Filling or closing holes and other gaps along floors, walls, and ceilings;
- (II) Closed, tight-fitting windows; and
- (III) Solid, self-closing, tight-fitting doors.
- (ii) Subpart (i) of this part does not apply if a food establishment opens into a larger structure, such as a mall, airport, or office building, or into an attached structure, such as a porch, and the outer openings from the larger or attached structure are protected against the entry of insects and rodents.
- (iii) Exterior doors used as exits need not be self-closing if they are:

(Rule 1200-23-1-.04, continued)

- (I) Solid and tight-fitting;
 - (II) Designated for use only when an emergency exists, by the fire protection authority that has jurisdiction over the food establishment; and
 - (III) Limited-use so they are not used for entrance or exit from the building for purposes other than the designated emergency exit use.
 - (iv) Except as specified in subparts (ii) and (v) of this part, if the windows or doors of a food establishment, or of a larger structure within which a food establishment is located, are kept open for ventilation or other purposes or a temporary food establishment is not provided with windows and doors as specified under subpart (i) of this part, the openings shall be protected against the entry of insects and rodents by:
 - (I) 16 mesh to 25.4 mm (16 mesh to 1 inch) screens;
 - (II) Properly designed and installed air curtains to control flying insects; or
 - (III) Other effective means.
 - (v) Subpart (iv) of this part does not apply if flying insects and other pests are absent due to the location of the establishment, the weather, or other limiting condition.
6. Exterior Walls and Roofs, Protective Barrier. Perimeter walls and roofs of a food establishment shall effectively protect the establishment from the weather and the entry of insects, rodents, and other animals.
7. Outdoor Walking and Driving Surfaces, Graded to Drain. Exterior walking and driving surfaces shall be graded to drain.
8. Outdoor Refuse Areas, Curbed and Graded to Drain. Outdoor refuse areas shall be constructed in accordance with law and shall be curbed and graded to drain to collect and dispose of liquid waste that results from the refuse and from cleaning the area and waste receptacles.
9. Private Homes and Living or Sleeping Quarters, Use Prohibition. A private home, except as provided by T.C.A. § 53-8-117, a room used as living or sleeping quarters, or an area directly opening into a room used as living or sleeping quarters may not be used for conducting food establishment operations.
10. Living or Sleeping Quarters, Separation. Living or sleeping quarters located on the premises of a food establishment such as those provided for lodging registration clerks or resident managers shall be separated from rooms and areas used for food establishments operations by complete partitioning and solid self-closing doors.

(3) Number and Capacities.

(Rule 1200-23-1-.04, continued)

(a) Handwashing Sinks

1. Handwashing sinks shall be provided as specified under 1200-23-01-.05(2)(c)1.
2. Handwashing Cleanser, Availability. Each handwashing sink or group of 2 adjacent handwashing sinks shall be provided with a supply of hand cleaning liquid, powder, or bar soap.
3. Hand Drying Provision. Each handwashing sink or group of adjacent handwashing sinks shall be provided with:
 - (i) Individual, disposable towels;
 - (ii) A continuous towel system that supplies the user with a clean towel; or
 - (iii) A heated-air hand drying device; or
 - (iv) A hand drying device that employs an air-knife system that delivers high velocity, pressurized air at ambient temperatures.
4. Handwashing Aids and Devices, Use Restrictions. A sink used for food preparation or utensil washing, or a service sink or curbed cleaning facility used for the disposal of mop water or similar wastes, may not be provided with the handwashing aids and devices required for a handwashing sink as specified under 1200-23-01-.06(3)(a)2 and 1200-23-01-.06(3)(a)3 and 1200-23-01-.05(5)(a)6.
5. Handwashing Signage. A sign or poster that notifies food employees to wash their hands shall be provided at all handwashing sinks used by food employees and shall be clearly visible to food employees.
6. Disposable Towels, Waste Receptacle. A handwashing sink or group of adjacent handwashing sinks that is provided with disposable towels shall be provided with a waste receptacle as specified under 1200-23-01-.05(5)(a)6.

(b) Toilets and Urinals.

1. Toilets and urinals shall be provided as specified under 1200-23-01-.05(2)(c)2.
2. A supply of toilet tissue shall be available at each toilet. (Pf)

(c) Lighting. The light intensity shall be:

1. At least 108 lux (10 foot candles) at a distance of 75 cm (30 inches) above the floor, in walk-in refrigeration units and dry food storage areas and in other areas and rooms during periods of cleaning;
2. At least 215 lux (20 foot candles):
 - (i) At a surface where food is provided for consumer self-service such as buffets and salad bars or where fresh produce or packaged foods are sold or offered for consumption,
 - (ii) Inside equipment such as reach-in and under-counter refrigerators; and

(Rule 1200-23-1-.04, continued)

(b) Cleaning, Frequency and Restrictions.

1. Physical facilities shall be cleaned as often as necessary to keep them clean.
2. Except for cleaning that is necessary due to a spill or other accident, cleaning shall be done during periods when the least amount of food is exposed such as after closing.

(c) Cleaning Floors, Dustless Methods.

1. Except as specified in part 2. of this subparagraph, only dustless methods of cleaning shall be used, such as wet cleaning, vacuum cleaning, mopping with treated dust mops, or sweeping using a broom and dust-arresting compounds.
2. Spills or drippage on floors that occur between normal floor cleaning times may be cleaned:
 - (i) Without the use of dust-arresting compounds; and
 - (ii) In the case of liquid spills or drippage, with the use of a small amount of absorbent compound such as sawdust or diatomaceous earth applied immediately before spot cleaning.

(d) Cleaning Ventilation Systems, Nuisance and Discharge Prohibition.

1. Intake and exhaust air ducts shall be cleaned and filters changed so they are not a source of contamination by dust, dirt, and other materials.
2. If vented to the outside, ventilation systems may not create a public health hazard or nuisance or unlawful discharge.

(e) Cleaning Maintenance Tools, Preventing Contamination. Food preparation sinks, handwashing sinks, and warewashing equipment may not be used for the cleaning of maintenance tools, the preparation or holding of maintenance materials, or the disposal of mop water and similar liquid wastes.

(f) Drying Mops. After use, mops shall be placed in a position that allows them to air-dry without soiling walls, equipment, or supplies.

(g) Absorbent Materials on Floors, Use Limitation. Except as specified in 1200-23-01-.06(5)(c)2, sawdust, wood shavings, granular salt, baked clay, diatomaceous earth, or similar materials may not be used on floors.

(h) Cleaning of Plumbing Fixtures. Plumbing fixtures such as handwashing sinks, toilets, and urinals shall be cleaned as often as necessary to keep them clean.

(i) Closing Toilet Room Doors. Except during cleaning and maintenance operations, toilet room doors as specified under 1200-23-01-.06(2)(b)4 shall be kept closed.

(j) Using Dressing Rooms and Lockers.

1. Dressing rooms shall be used by employees if the employees regularly change their clothes in the establishment.

(Rule 1200-23-1-.04, continued)

2. Lockers or other suitable facilities shall be used for the orderly storage of employee clothing and other possessions.
- (k) Controlling Pests. The premises shall be maintained free of insects, rodents, and other pests. The presence of insects, rodents, and other pests shall be controlled to eliminate their presence on the premises by:
1. Routinely inspecting incoming shipments of food and supplies;
 2. Routinely inspecting the premises for evidence of pests;
 3. Using methods, if pests are found, such as trapping devices or other means of pest control as specified under 1200-23-01-.07(2)(b)2 and 1200-23-01-.07(2)(f); and
 4. Eliminating harborage conditions.
- (l) Removing Dead or Trapped Birds, Insects, Rodents, and Other Pests. Dead or trapped birds, insects, rodents, and other pests shall be removed from control devices and the premises at a frequency that prevents their accumulation, decomposition, or the attraction of pests.
- (m) Storing Maintenance Tools. Maintenance tools such as brooms, mops, vacuum cleaners, and similar items shall be:
1. Stored so they do not contaminate food, equipment, utensils, linens, and single-service and single-use; and
 2. Stored in an orderly manner that facilitates cleaning the area used for storing the maintenance tools.
- (n) Maintaining Premises, Unnecessary Items and Litter. The premises shall be free of:
1. Items that are unnecessary to the operation or maintenance of the establishment such as equipment that is nonfunctional or no longer used; and
 2. Litter.
- (o) Prohibiting Animals.
1. Except as specified in parts 2. and 3. of this subparagraph, live animals may not be allowed on the premises of a food establishment.
 2. Live animals are allowed in the following situations if the owner or operator does not permit animals to physically contact food, serving dishes, utensils, tableware, linens, unwrapped single-service and single-use articles or other food service items that may result in contamination of food or food-contact surfaces and does not permit animals to physically contact employees engaged in the preparation or handling of food:
 - (i) Fish or crustacea in aquariums or display tanks;
 - (ii) Patrol dogs accompanying police or security officers in offices and

(Rule 1200-23-1-.04, continued)

dining, sales, and storage areas; and sentry dogs in outside fenced areas;

(iii) Service animals accompanying persons with disabilities in areas that are not used for food preparation;

(iv) Dogs (Canis lupus familiaris) and cats (Felis catus) in outdoor dining areas; provided that dogs and cats are physically restrained, and do not pass through any indoor areas of the food establishment. Except for service animals described in subpart (iii) of this part, nothing in this Chapter prohibits a food establishment from prohibiting dogs and cats in outdoor dining areas; and

(v) In areas that are not used for food preparation, storage, sales, display, or dining, in which there are caged animals or animals that are similarly confined, such as in a variety store that sells pets or a tourist park that displays animals.

3. Live or dead fish bait may be stored if contamination of food, clean equipment, utensils, and linens, and unwrapped single-service and single-use articles cannot result.

(p) Dogs in outdoor Dining Areas

Notwithstanding subparagraph (o) of this paragraph, where a county or municipality has passed an ordinance or resolution under T.C.A. § 6-54-135 authorizing individual restaurants to permit dogs in outdoor dining areas and to charge permit holders a reasonable permit fee, dogs other than service dogs may be permitted in outside areas of a food establishment, provided, however:

1. Except as provided in subparagraph (o), no dog shall be present in the interior of any restaurant or in any area where food is prepared;

2. The food establishment shall have the right to refuse to serve the owner of a dog if the owner fails to exercise reasonable control over the dog or the pet dog is otherwise behaving in a manner that compromises or threatens to compromise the health or safety of any person present in the food establishment;

3. The person in charge shall not permit dogs to physically contact food, serving dishes, utensils, tableware, linens, unwrapped single-service and single-use articles or other food service items that may result in contamination of food or food-contact surfaces and shall not permit animals to physically contact employees engaged in the preparation or handling of food;

4. The person in charge shall instruct employees and patrons that dogs shall not be allowed to come into contact with serving dishes, utensils, tableware, linens, paper products or any other items involved in food service operations;

5. Patrons shall keep their dogs on a leash at all times and keep their dogs under reasonable control;

6. Dogs shall not be allowed on tables, chairs or other furnishings;

7. The person in charge shall ensure that any accidents involving dog waste are

(Rule 1200-23-1-.04, continued)

cleaned immediately and the area sanitized with an approved product. A kit with the appropriate materials for this purpose shall be kept near the designated outdoor area.

8. The permit holder shall post a sign or signs reminding employees and patrons of the applicable rules on the premises in a manner and in such place(s) as determined by the local permitting authority; and
9. Pet dogs shall not be permitted to travel through indoor or nondesignated portions of the food establishment, and ingress and egress to the designated outdoor portions of the food establishment shall not require entrance into nor passage through any indoor area of the food establishment.

Authority: T.C.A. §§ 6-54-135, 53-8-117, and 68-14-701 through 68-14-726.

1200-23-01-.07 Poisonous or Toxic Materials.

(1) Labeling and Identification.

- (a) Original Containers. Containers of poisonous or toxic materials and personal care items shall bear a legible manufacturer's label. Only those pesticides that have been registered with the EPA and with the Department shall be used. If the manufacturer's label is missing from a pesticide container, the container shall be identified with the manufacturer's product brand name, percentage of each active ingredient, and EPA registration number. (Pf)
- (b) Working containers used for storing poisonous or toxic materials such as cleaners and sanitizers taken from bulk supplies shall be clearly and individually identified with the common name of the material. (Pf)

(2) Operational Supplies and Applications.

- (a) Storage. Poisonous or toxic materials shall be stored so they cannot contaminate food, equipment, utensils, linens, and single-service and single-use articles by:
 1. Separating the poisonous or toxic materials by spacing or partitioning; (P) and
 2. Locating the poisonous or toxic materials in an area that is not above food, equipment, utensils, linens, and single-service or single-use articles. This part does not apply to equipment and utensil cleaners and sanitizers that are stored in warewashing areas for availability and convenience if the materials are stored to prevent contamination of food, equipment, utensils, linens, and single-service and single-use articles. (P)
- (b) Presence and Use.
 1. Restriction.
 - (i) Only those poisonous or toxic materials that are required for the operation and maintenance of a food establishment, such as for the cleaning and sanitizing of equipment and utensils and the control of insects and rodents, shall be allowed in a food establishment.
 - (ii) Subpart (i) of this part does not apply to packaged poisonous or toxic

(Rule 1200-23-1-.04, continued)

materials that are for retail sale.

2. Conditions of Use. Poisonous or toxic materials shall be:

(i) Used according to:

(I) Law and this Chapter,

(II) Manufacturer's use directions included in labeling, and, for a pesticide, manufacturer's label instructions that state that use is allowed in a food establishment, (P)

(III) The conditions of certification, if certification is required, for use of the pest control materials, (P) and

(IV) Additional conditions that may be established by the department; and

(ii) Applied so that:

(I) A hazard to employees or other persons is not constituted, (P) and

(II) Contamination including toxic residues due to drip, drain, fog, splash or spray on food, equipment, utensils, linens, and single-service and single-use articles is prevented, and for a restricted use pesticide, this is achieved by: (P)

I. Removing the items, (P)

II. Covering the items with impermeable covers, (P) or

III. Taking other appropriate preventive actions, (P) and

IV. Cleaning and sanitizing equipment and utensils after the application. (P)

(iii) A general use or restricted use pesticide shall be applied only by an applicator certified as defined in 7 USC § 136(e), Certified Applicator, of the Federal Insecticide, Fungicide, and Rodenticide Act and Tennessee Rule Chapter 0080-06-16 Regulations Governing Use of Restricted Use Pesticides. (Pf)

(c) Container Prohibitions. Poisonous or Toxic Material Containers. A container previously used to store poisonous or toxic materials may not be used to store, transport, or dispense food. Sanitizing solutions shall not be stored in or dispensed from containers previously containing other poisonous or toxic materials. (P)

(d) Chemicals

1. Sanitizers, Criteria. Chemical sanitizers and other chemical antimicrobials applied to food-contact surfaces shall meet the requirements specified in 40 CFR § 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (food-contact surface sanitizing solutions). (P)

(Rule 1200-23-1-.04, continued)

2. Chemicals for Washing, Treatment, Storage and Processing Fruits and Vegetables, Criteria.
 - (i) Chemicals used to wash or peel raw, whole fruits and vegetables shall meet the requirements specified in 21 CFR § 173.315 Chemicals used in washing or to assist in the peeling of fruits and vegetables. (P)
 - (ii) Ozone as an antimicrobial agent used in the treatment, storage, and processing of fruits and vegetables in a food establishment shall meet the requirements specified in 21 CFR § 173.368 Ozone.
3. Boiler Water Additives, Criteria. Chemicals used as boiler water additives shall meet the requirements specified in 21 CFR § 173.310 Boiler water additives. (P)
4. Drying Agents, Criteria. Drying agents used in conjunction with sanitization shall:
 - (i) Contain only components that are listed as one of the following:
 - (I) Generally recognized as safe for use in food as specified in 21 CFR Part 182 - Substances Generally Recognized as Safe, or 21 CFR Part 184 - Direct Food Substances Affirmed as Generally Recognized as Safe, (P)
 - (II) Generally recognized as safe for the intended use as specified in 21 CFR Part 186 - Indirect Food Substances Affirmed as Generally Recognized as Safe, (P)
 - (III) Approved for use as a drying agent under a prior sanction specified in 21 CFR Part 181 - Prior-Sanctioned Food Ingredients, (P)
 - (IV) Specifically regulated as an indirect food additive for use as a drying agent as specified in 21 CFR Parts 175 through 178, (P) or
 - (V) Approved for use as a drying agent under the threshold of regulation process established by 21 CFR § 170.39 Threshold of regulation for substances used in food-contact articles; (P) and
 - (ii) When sanitization is with chemicals, the approval required under (i)(III) or (i)(V) of this part or the regulation as an indirect food additive required under (i)(IV) of this part, shall be specifically for use with chemical sanitizing solutions. (P)
- (e) Lubricants shall meet the requirements specified in 21 CFR § 178.3570 Lubricants with incidental food contact, if they are used on food-contact surfaces, on bearings and gears located on or within food-contact surfaces, or on bearings and gears that are located so that lubricants may leak, drip, or be forced into food or onto food-contact surfaces. (P)
- (f) Pesticides.
 1. Restricted use pesticides specified under 1200-23-01-.07(2)(b)2(iii) shall meet the requirements specified in 40 CFR Part 152 Subpart I - Classification of

(Rule 1200-23-1-.04, continued)

Pesticides. (P)

2. Rodent Bait Stations. Rodent bait shall be placed outside and contained in a covered, tamper-resistant bait station. (P)

3. Tracking Powders, Pest Control and Monitoring.

(i) Except as specified in (ii) of this part, a tracking powder pesticide may not be used in a food establishment. (P)

(ii) If used, a nontoxic tracking powder such as talcum or flour may not contaminate food, equipment, utensils, linens, and single-service and single-use articles.

(g) Medicines.

1. Restriction and Storage.

(i) Except for medicines that are stored or displayed for retail sale, only those medicines that are necessary for the health of employees shall be allowed in a food establishment. (Pf)

(ii) Medicines that are in a food establishment for the employees' use shall be labeled as specified under 1200-23-01-.07(1) and located to prevent the contamination of food, equipment, utensils, linens, and single-service and single-use articles. (P)

2. Refrigerated Medicines, Storage. Medicines belonging to employees or to children in a day care center that require refrigeration and are stored in a food refrigerator shall be:

(i) Stored in a package or container and kept inside a covered, leakproof container that is identified as a container for the storage of medicines; (P) and

(ii) Located so they are inaccessible to children. (P)

(h) First Aid Supplies that are in a food establishment for the employees' use shall be:

1. Labeled as specified under 1200-23-01-.07(1); (Pf) and

2. Stored in a kit or a container that is located to prevent the contamination of food, equipment, utensils, and linens, and single-service and single-use articles. (P)

(i) Other Personal Care Items. Except as specified under 1200-23-01-.07(2)(g)2, employees shall store their personal care items in facilities as specified under 1200-23-01-.06(3)(e)2.

(3) Stock and Retail Sale.

Poisonous or toxic materials shall be stored and displayed for retail sale so they cannot contaminate food, equipment, utensils, linens, and single-service and single-use articles by:

(a) Separating the poisonous or toxic materials by spacing or partitioning; (P) and

(Rule 1200-23-1-.04, continued)

- (b) Locating the poisonous or toxic materials in an area that is not above food, equipment, utensils, linens, and single-service or single-use articles. (P)

Authority: T.C.A. §§ 68-14-701 through 68-14-726.

1200-23-01-.08 Compliance and Enforcement

(1) Applicability

- (a) Public Health Protection – The department shall apply this code to promote its purpose of safeguarding public health and ensuring that food is safe, unadulterated and honestly presented when it is offered to the consumer.

- (b) In enforcing the provisions of this Chapter, the department shall assess existing facilities or equipment that were in use before the effective date of this Chapter based on the following considerations:

1. Whether the facilities or equipment are in good repair and capable of being maintained in a sanitary condition;
2. Whether food-contact surfaces comply with 1200-23-01-.04(1)(a);
3. Whether the capacities of cooling, heating, and holding equipment are sufficient to comply with 1200-23-01-.04(3)(a)1; and
4. The existence of a documented agreement with the permit holder that the facilities or equipment will be replaced as specified under 1200-23-01-.08(3)(i)6.

(c) Preventing Health Hazards, Provision for Conditions Not Addressed.

1. If necessary to protect against public health hazards or nuisances, the department may impose specific requirements in addition to the requirements contained in this Chapter that are authorized by law.
2. The department shall document the conditions that necessitate the imposition of additional requirements and the underlying public health rationale. The documentation shall be provided to the permit applicant or permit holder and a copy shall be maintained in the department's file for the food establishment.

(d) Variances

1. Modifications and Waivers. The department may grant a variance by modifying or waiving the requirements of this Chapter if in the opinion of the department a health hazard or nuisance will not result from the variance. If a variance is granted, the department shall retain the information specified under part 2. of this subparagraph in its records for the food establishment. Variance requests shall be submitted to a committee including a food scientist and representatives from industry and state and local public health agencies appointed by the department.
2. Documentation of Proposed Variance and Justification. Before a variance from a requirement of this Chapter is approved, the information that shall be provided by the person requesting the variance and retained in the department's file on the food establishment includes:

(Rule 1200-23-1-.04, continued)

- (i) A statement of the proposed variance of the Chapter requirement citing relevant Chapter section numbers;
 - (ii) An analysis of the rationale for how the potential public health hazards and nuisances addressed by the relevant Chapter sections will be alternatively addressed by the proposal; and
 - (iii) A HACCP plan if required as specified under 1200-23-01-.08(2)(c) that includes the information specified under 1200-23-01-.08(2)(d) as it is relevant to the variance requested.
3. Conformance with Approved Procedures. If the department grants a variance as specified in 1200-23-01-.08(1)(d), or a HACCP plan is otherwise required as specified under 1200-23-01-.08(2)(c), the permit holder shall:
- (i) Comply with the HACCP plans and procedures that are submitted as specified under 1200-23-01-.08(2)(d) and approved as a basis for the modification or waiver; (P) and
 - (ii) Maintain and provide to the department, upon request, records specified under 1200-23-01-.08(2)(d)4 that demonstrate that the following are routinely employed:
 - (I) Procedures for monitoring the critical control points,
 - (II) Monitoring of the critical control points,
 - (III) Verification of the effectiveness of the operation or process, and
 - (IV) Necessary corrective actions if there is failure at a critical control point.

(2) Plan Submission and Approval

- (a) When Plans Are Required. Plans drawn to scale for food establishments shall be submitted for review and approval to the department. A permit applicant or permit holder shall submit to the department properly prepared plans and specifications for review and approval before:
- 1. The construction of a food establishment;
 - 2. The conversion of an existing structure for use as a food establishment; or
 - 3. The remodeling of a food establishment or a change of type of food establishment or food operation as specified under 1200-23-01-.08(3)(e)3 if the department determines that plans and specifications are necessary to ensure compliance with this Chapter.
- (b) Contents of the Plans and Specifications. The plans and specifications for a food establishment, including a food establishment specified under 1200-23-01-.08(2)(c), shall include, as required by the department based on the type of operation, type of food preparation, and foods prepared, the following information to demonstrate conformance with Chapter provisions:

(Rule 1200-23-1-.04, continued)

1. Intended menu and plans to be reviewed;
2. Anticipated volume of food to be stored, prepared, and sold or served;
3. Proposed layout, mechanical schematics, construction materials, and finish schedules;
4. Proposed equipment types, manufacturers, model numbers, locations, dimensions, performance capacities, and installation specifications;
5. Evidence that standard procedures that ensure compliance with the requirements of this Chapter are developed or are being developed; and
6. Other information that may be required by the department for the proper review of the proposed construction, conversion or modification, and procedures for operating a food establishment.

(c) When a HACCP Plan is Required.

1. Before engaging in an activity that requires a HACCP plan, a permit applicant or permit holder shall submit to the department for approval a properly prepared HACCP plan as specified under 1200-23-01-.08(2)(d) and the relevant provisions of this Chapter if:
 - (i) Submission of a HACCP PLAN is required according to law;
 - (ii) A variance is required as specified under 1200-23-01-.03(4)(a)1(iv), 1200-23-01-.03(5)(b), or 1200-23-01-.04(2)(d)8(ii);
 - (iii) The department determines that a food preparation or processing method requires a variance based on a plan submittal specified under 1200-23-01-.08(2)(b), an inspectional finding, or a variance request.
2. A permit applicant or permit holder shall have a properly prepared HACCP plan as specified under 1200-23-01-.03(5)(c).

(d) Contents of a HACCP Plan. For a food establishment that is required under 1200-23-01-.08(2)(c) to have a HACCP plan, the plan and specifications shall indicate:

1. A categorization of the types of time/temperature control for safety foods that are specified in the menu such as soups and sauces, salads, and bulk, solid foods such as meat roasts, or of other foods that are specified by the department;
2. A flow diagram by specific or category type identifying critical control points and providing information on the following:
 - (i) Ingredients, materials, and equipment used in the preparation of that food, and
 - (ii) Formulations or recipes that delineate methods and procedural control measures that address the food safety concerns involved;
3. Food employee and supervisory training plan that addresses the food safety

(Rule 1200-23-1-.04, continued)

issues of concern:

4. A statement of standard operating procedures for the plan under consideration including clearly identifying:
 - (i) Each critical control point,
 - (ii) The critical limits for each critical control points,
 - (iii) The method and frequency for monitoring and controlling each critical control point by the food employee designated by the person in charge,
 - (iv) The method and frequency for the person in charge to routinely verify that the food employee is following standard operating procedures and monitoring critical control points,
 - (v) Action to be taken by the person in charge if the critical limits for each critical control point are not met,
 - (vi) Records to be maintained by the person in charge to demonstrate that the HACCP Plan is properly operated and managed; and
 - (vii) Additional scientific data or other information, as required by the department, supporting the determination that food safety is not compromised by the proposal.

(e) Trade Secrets. The department shall treat as confidential in accordance with law information that meets the criteria specified in law for a trade secret which is contained on inspection report forms and in the plans and specifications submitted under subparagraphs (a) and (b) of this rule.

(f) Preoperational Inspections. The department may conduct one or more preoperational inspections to verify that the food establishment is constructed and equipped in accordance with the approved plans and approved modifications of those plans, has established standard operating procedures as specified under part (2)(b)5. of this paragraph, and is in compliance with law and this Chapter.

(3) Permit to Operate

(a) Prerequisite for Operation. A person may not operate a food establishment without a valid permit to operate issued by the department.

(b) Submission 15 Calendar Days Before Proposed Opening. An applicant shall submit an application for a permit at least 15 calendar days before the date planned for opening a food establishment or the expiration date of the current permit for an existing facility.

(c) Form of Submission. A person desiring to operate a food establishment shall submit to the department a written application for a permit on a form provided by the department.

(d) To qualify for a permit, an applicant shall:

1. Be an owner of the food establishment or an officer of the legal ownership;
2. Comply with the requirements of this Chapter;

(Rule 1200-23-1-.04, continued)

3. As specified under 1200-23-01-.08(4)(b), agree to allow access to the food establishment and to provide required information; and

4. Pay the applicable permit fees at the time the application is submitted.

(e) Contents of the Application. The application shall include:

1. The name, mailing address, telephone number, and signature of the person applying for the permit and the name, mailing address, and location of the food establishment;

2. Information specifying whether the food establishment is owned by an association, corporation, individual, partnership, or other legal entity;

3. A statement specifying whether the food establishment:

(i) Is mobile or stationary and temporary or permanent, and

(ii) Is an operation that includes one or more of the following:

(I) Prepares, offers for sale, or serves time/temperature control for safety food:

I. Only to order upon a consumer's request,

II. In advance in quantities based on projected consumer demand and discards food that is not sold or served at an approved frequency, or

III. Using time as the public health control as specified under 1200-23-01-.03(5)(a)9.

(II) Prepares time/temperature control for safety food in advance using a food preparation method that involves two or more steps which may include combining time/temperature control for safety food ingredients; cooking; cooling; reheating; hot or cold holding; freezing; or thawing;

(III) Prepares food as specified under item 3(ii)(II) of this subparagraph for delivery to and consumption at a location off the premises of the food establishment where it is prepared;

(IV) Prepares food as specified under item 3(ii)(II) of this subparagraph for service to a highly susceptible population;

(V) Prepares only food that is not time/temperature control for safety food, or

(VI) Does not prepare, but offers for sale only prepackaged food that is not time/temperature control for safety food;

4. The name, title, address, and telephone number of the person directly responsible for the food establishment;

(Rule 1200-23-1-.04, continued)

5. The name, title, address and telephone number of the person who functions as the immediate supervisor of the person specified under 4 of this subparagraph such as the zone, district or regional supervisor;
 6. The names, titles, and addresses of the persons comprising the legal ownership as specified under 2 of this subparagraph including the owners and officers;
 7. A statement signed by the applicant that attests to the accuracy of the information provided in the application; and
 8. Other information required by the department.
- (f) New, Converted, or Remodeled Establishments. For food establishments that are required to submit plans as specified under 1200-23-01-.08(2)(a), the department shall issue a permit to the applicant after:
1. A properly completed application is submitted;
 2. The required fee is submitted;
 3. The required plans, specifications, and information are reviewed and approved; and
 4. A preoperational inspection as specified in 1200-23-01-.08(2)(f) shows that the establishment is built or remodeled in accordance with the approved plans and specifications and that the establishment is in compliance with this Chapter.
- (g) Existing Establishments and Change of Ownership. As applicable, the department may issue a permit to a new owner of an existing food establishment after an application is submitted, reviewed, and approved, and an inspection shows that the establishment is in compliance with this Chapter.
- (h) Denial of Application for Permit, Notice. If an application for a permit to operate is denied, the department shall provide the applicant with a notice that includes:
1. The specific reasons and Chapter citations for the permit denial;
 2. The actions, if any, that the applicant must take to qualify for a permit; and
 3. Advisement of the applicant's right of appeal and the process and time frames for appeal that are provided in law.
- (i) Responsibilities of the Permit Holder. Upon acceptance of the permit issued by the department, the permit holder in order to retain the permit shall:
1. Comply with the provisions of this Chapter including the conditions of a granted variance as specified under 1200-23-01-.08(1)(d)3, and approved plans as specified under 1200-23-01-.08(2)(b);
 2. If a food establishment is required under 1200-23-01-.08(2)(c) to operate under a HACCP Plan, comply with the plan as specified under 1200-23-01-.08(1)(d)3;

(Rule 1200-23-1-.04, continued)

3. Immediately contact the department to report an illness of a food employee or conditional employee as specified under 1200-23-01-.02(2)(a)2;
 4. Immediately discontinue operations and notify the department if an imminent health hazard may exist as specified under 1200-23-01-.08(4)(d);
 5. Allow representatives of the department access to the food establishment as specified under 1200-23-01-.08(4)(b);
 6. Replace existing facilities and equipment specified in 1200-23-01-.08(1)(b) with facilities and equipment that comply with this Chapter if:
 - (i) The department directs the replacement because the facilities and equipment constitute a public health hazard or nuisance or no longer comply with the criteria upon which the facilities and equipment were accepted; or
 - (ii) The department directs the replacement of the facilities and equipment because of a change of ownership.
 7. Comply with directives of the department including time frames for corrective actions specified in inspection reports, notices, orders, warnings, and other directives issued by the department in regard to the permit holder's food establishment or in response to community emergencies;
 8. Accept notices issued and served by the department according to law;
 9. Be subject to the administrative, civil, injunctive, and criminal remedies authorized in law for failure to comply with this Chapter or a directive of the department, including time frames for corrective actions specified in inspection reports, notices, orders, warnings, and other directives;
 10. Post the permit in a conspicuous manner as designated by the inspector at the time of inspection, and ensure that no person except an authorized representative of the department shall modify, remove, cover or otherwise make the permit less conspicuous; and
 11. In the event of a lost, misplaced or destroyed permit, immediately apply for a duplicate and forward the fee with the application for a duplicate permit.
- (i) A permit may not be transferred from one person to another person, from one food establishment to another, or from one type of operation to another if the food operation changes from the type of operation specified in the application as specified under 1200-23-01-.08(3)(e)3.

(4) Inspection and Correction of Violations(a) Frequency.

1. Establishing Inspection Interval. Except as specified in parts 2 and 4 of this subparagraph, the department may inspect a food establishment at least once every 6 months.
2. The department may increase the interval between inspections beyond six

(Rule 1200-23-1-.04, continued)

months if:

- (i) The food establishment is fully operating under an approved and validated HACCP plan as specified under 1200-23-01-.08(2)(d) and 1200-23-01-.08(1)(d) 3(i) and (ii);
 - (ii) The food establishment is assigned a less frequent inspection frequency based on a written risk-based inspection schedule that is being uniformly applied throughout the jurisdiction; or
 - (iii) The establishment's operation involves only coffee service and other unpackaged or prepackaged food that is not time/temperature control for safety food such as carbonated beverages and snack food such as chips, nuts, popcorn, and pretzels.
3. The department may periodically inspect throughout its permit period a temporary food establishment that prepares, sells, or services unpackaged time/temperature control for safety food and that has improvised rather than permanent facilities or equipment for accomplishing functions such as handwashing, food preparation and protection, food temperature control, warewashing, providing drinking water, waste retention and disposal, and insect and rodent control; or
4. Performance- and Risk-Based. – Within the parameters specified in (4)(a) –(c) of this paragraph, the department shall prioritize and conduct more frequent inspections based upon its assessment of a food establishment's history of compliance with this chapter and the establishment's potential as a vector of foodborne illness by evaluating:
- (i) Past performance, for nonconformance with this chapter or HACCP plan requirements that are priority items or priority foundation items;
 - (ii) Past performance, for numerous or repeat violations of this chapter or HACCP plan requirements that are core items;
 - (iii) Past performance, for complaints investigated and found to be valid;
 - (iv) The hazards associated with the particular foods that are prepared, stored, or served;
 - (v) The type of operation including the methods and extent of food storage, preparation, and service;
 - (vi) The number of people served; and
 - (vii) Whether the population served is a highly susceptible population.

(b) Access

1. Allowed at Reasonable Times after Due Notice. After the department presents official credentials and provides notice of the purpose of, and an intent to conduct, an inspection, the person in charge shall allow the department to determine if the food establishment is in compliance with this chapter by allowing access to the establishment, allowing inspection, and providing information and

(Rule 1200-23-1-.04, continued)

records specified in this chapter and to which the department is entitled according to law, during the food establishment's hours of operation and other reasonable times.

2. Refusal, Notification of Right to Access, and Final Request for Access. If a person denies access to the department, the department shall inform the person that:
 - (i) The permit holder shall allow access to the department as specified under 1200-23-01-.08(4)(b)1.
 - (ii) Access is a condition of the acceptance and retention of a food establishment permit to operate as specified under 1200-23-01-.08(3)(i)5.
 - (iii) If access is denied, an administrative warrant may be obtained according to law, and
 - (iv) A final request for access will be made.
3. Refusal, Reporting. If after the department presents credentials and provides notice as specified under 1200-23-01-.08(4)(b)1, explains the authority upon which access is requested, and makes a final request for access as specified in 1200-23-01-.08(4)(b)2, the person in charge continues to refuse access, the department shall provide details of the denial of access on an inspection report form.
4. Administrative Warrant to Gain Access: If denied access to a food establishment for an authorized purpose, and after complying with 1200-23-01-.08(4)(b)1 - 1200-23-01-.08(4)(b)3, the department may issue an administrative warrant to gain access.

(c) Report of Findings.

1. Documenting Information and Observations. The department shall document on an inspection report form:
 - (i) Administrative information about the food establishment's legal identity, street and mailing addresses, type of establishment and operation as specified under 1200-23-01-.08(3)(e)3, inspection date, and other information such as type of water supply and sewage disposal, status of the permit, and personnel certificates that may be required; and
 - (ii) Specific factual observations of violative conditions or other deviations from this Chapter that require correction by the permit holder including:
 - (I) Failure of the person in charge to demonstrate the knowledge of foodborne illness prevention, application of HACCP principles, and the requirements of this Chapter as specified under 1200-23-01-.02(1)(b).
 - (II) Failure of food employees, conditional employees, and the person in charge to report a disease or medical condition as specified under 1200-23-01-.02(2)(a).

(Rule 1200-23-1-.04, continued)

- (III) Nonconformance with priority items or priority foundation items of this Chapter.
 - (IV) Failure of the appropriate food employees to demonstrate their knowledge of, and ability to perform in accordance with, the procedural, monitoring, verification, and corrective action practices required by the department as specified under 1200-23-01-.08(1)(d)3.
 - (V) Failure of the person in charge to provide records required by the department for determining conformance with a HACCP plan as specified under 1200-23-01-.08(2)(d)4(vi), and
 - (VI) Nonconformance with critical limits of a HACCP plan.
2. Specifying Time Frame for Corrections. The department shall specify on the inspection report form the time frame for correction of the violations as specified under 1200-23-01-.08(4)(e) and 1200-23-01-.08(4)(f)1.
3. Issuance of Report, Acknowledgment of Receipt and Posting. At the conclusion of the inspection:
- (i) The department shall provide a copy of the completed inspection report and any notice to correct violations to the permit holder or to the person in charge, and request a signed acknowledgment of receipt; and
 - (ii) The permit holder shall post the most recent completed report in a conspicuous location on the premises.
4. Refusal to Sign Acknowledgment. The department shall:
- (i) Inform a person who declines to sign an acknowledgment of receipt of inspectional findings as specified in 1200-23-01-.08(4)(c)3 that:
 - (I) An acknowledgment of receipt is not an agreement with findings.
 - (II) Refusal to sign an acknowledgment of receipt will not affect the permit holder's obligation to correct the violations noted in the inspection report within the time frames specified; and
 - (III) A refusal to sign an acknowledgment of receipt is noted in the inspection report and conveyed to the department's historical record for the food establishment; and
 - (ii) Make a final request that the person in charge or permit holder sign an acknowledgment of receipt of inspectional findings.
5. Public Information. Except as specified in 1200-23-01-.08(2)(e) the department shall treat the inspection report as a public document and shall make it available for disclosure to a person who requests it as provided by law.
- (d) Imminent Health Hazard

(Rule 1200-23-1-.04, continued)

1. Ceasing Operations and Reporting.

- (i) Except as specified in (ii) of this part, a permit holder shall immediately discontinue operations and notify the department if an imminent health hazard may exist because of an emergency such as a fire, flood, extended interruption of electrical or water service, sewage backup, misuse of poisonous or toxic materials, onset of an apparent foodborne illness outbreak, gross insanitary occurrence or condition, or other circumstance that may endanger public health.
- (ii) A permit holder need not discontinue operations in an area of an establishment that is unaffected by the imminent health hazard.
- (iii) Upon declaration of an imminent health hazard by the Commissioner, the permit holder shall immediately cease operations until authorized to reopen.

2. Resumption of Operations. If operations are discontinued as specified under 1200-23-01-08(4)(e)1 or otherwise according to law, the permit holder shall obtain approval from the department before resuming operations.

(e) Violation of Priority Item or Priority Foundation Item. —

1. Timely Correction.

- (i) Except as specified in subpart (ii) of this part, a permit holder shall at the time of inspection correct a violation of a priority item or priority foundation item of this Chapter and implement corrective actions for a HACCP plan provision that is not in compliance with its critical limit.
- (ii) Considering the nature of the potential hazard involved and the complexity of the corrective action needed, the department may agree to or specify a longer time frame, not to exceed 10 calendar days after the inspection, for the permit holder to correct violations of a priority item or priority foundation item or HACCP plan deviations.

2. Verification and Documentation of Correction.

- (i) After observing at the time of inspection a correction of a violation of a priority item or priority foundation item or a HACCP plan deviation, the department shall enter the violation and information about the corrective action on the inspection report.
- (ii) As specified under 1200-23-01-08(4)(e)1(ii), after receiving notification that the permit holder has corrected a violation of a priority item or priority foundation item or HACCP plan deviation, or at the end of the specified period of time, the department may verify correction of the violation.

(f) Core Violation

- 1. Except as specified in part 2. of this subparagraph, the permit holder shall correct core items by a date and time agreed to or specified by the department but no later than 90 calendar days after the inspection.

(Rule 1200-23-1-.04, continued)

2. The department may approve a compliance schedule that extends beyond the time limits specified under part 1. of this subparagraph if a written schedule of compliance is submitted by the permit holder and no health hazard exists or will result from allowing an extended schedule for compliance.

(g) Temporary Food Establishments – Time Frame for Correction. In the case of a temporary food establishment pursuant to 1200-23-01-.01(114), all violations shall be corrected within twenty four (24) hours. If violations are not corrected within twenty four (24) hours, the establishment shall immediately cease food service operation until authorized to resume by the department.

(5) Prevention of Foodborne Disease Transmission by Employees

(a) Obtaining Information: Personal History of Illness, Medical Examination and Specimen Analysis. The Department shall act when it has reasonable cause to believe that a food employee or conditional employee has possibly transmitted disease; may be infected with a disease in a communicable form that may be transmitted through food; may be a carrier of infectious agents that cause a disease that is transmissible through food; or is affected with a boil, an infected wound or an acute respiratory infection by:

1. Securing a confidential medical history of the food employee or conditional employee suspected of transmitting disease or making other investigations as deemed appropriate; and

2. Requiring appropriate medical examinations, including collection of specimens for laboratory analysis, of a suspected food employee or conditional employee.

(b) Restriction or Exclusion of Food Employee or Summary Suspension of Permit. Based on the findings of an investigation related to a food employee or conditional employee who is suspected of being infected or diseased, the Department may issue an order to the suspected food employee, conditional employee or permit holder instituting one or more of the following control measures:

1. Restricting the food employee or conditional employee;

2. Excluding the food employee or conditional employee;

3. Closing the food establishment by summarily suspending a permit to operate in accordance with the law.

(c) Restriction or Exclusion Order: Warning or Hearing Not Required; Information Required in Order. Based on the findings of an investigation and to control disease transmission, the department may issue a summary order of restriction or exclusion to a suspected food employee or the permit holder without prior warning, a notice of hearing or a hearing if the order:

1. States the reasons for the restriction or exclusion;

2. States the evidence that the food employee or permit holder shall provide in order to demonstrate that the reasons for the restriction or exclusion are eliminated;

3. States that the suspected food employee or permit holder may request an appeal

(Rule 1200-23-1-.04, continued)

hearing by submitting a timely request within seven business days of the issuance of the order; and

4. Provides the name and address of the department representative to whom a request for appeal hearing may be made.

(d) Removal of Exclusions and Restrictions. The department shall release a food employee or conditional employee from restriction or exclusion upon a showing that the employee meets the conditions for reinstatement under Rule 1200-23-01-.02(2)(c).

(6) Reviews Following Inspection

(a) The inspection report shall state that failure to comply with any time limits specified by the department for correction may result in cessation of operation.

(b) The citation of a violation of a priority item may be reviewed, upon receipt of a written request submitted to the department within ten (10) calendar days following the date of the inspection report. If the tenth (10th) day falls on a weekend or state holiday, the first work day following shall be treated as the tenth (10th) day. The request for review shall identify the priority item(s) being reviewed. The final determination on the review shall be made by the Commissioner of Health or the Commissioner's designee in writing and within a reasonable time after receipt of the request for a review.

(c) The citation of a violation of a priority foundation item may also be reviewed upon the receipt of a written request submitted to the department within ten (10) calendar days following the date of the inspection report. If the tenth (10th) falls on a weekend or state holiday, the first work day following shall be treated as the tenth (10th) day. The request for review shall identify the priority foundation item(s) being reviewed. The decision of the department shall be final and made in writing within a reasonable time after receipt of the request for a review.

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(d) In the event of an order of cessation of operation based upon the reviewed critical item(s), a request for a hearing may be made in writing to the Commissioner of Health received within ten (10) calendar days of the decision of the department. Except as otherwise provided by law, no action shall be taken regarding a closure on the critical item(s) under review or subject to a hearing pending the outcome of the hearing which shall be held pursuant to the Uniform Administrative Procedures Act.

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(7) Permit Revocation

(a) After providing an opportunity for a hearing, the Commissioner of Health or his duly authorized representative may revoke a permit for serious or repeated violations of requirements of this part or for interference with the department or its duly authorized representative in the performance of his duty.

(b) Prior to revocation, the department shall notify, in writing, the permittee of the specific reason(s) for which the permit is to be revoked, and that the permit shall be revoked at the end of ten (10) days following service of such notice, unless a written request for a hearing is filed with the department within such ten-day period. If no request for hearing is filed within the ten-day period, the revocation of the permit becomes final.

(8) Whenever a facility is required under this section to cease operations, it shall not resume operations until it is shown on re-inspection that conditions responsible for the order to cease operations no longer exist. Opportunity for re-inspection shall be offered within a reasonable time.

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Widow/Orphan control

(Rule 1200-23-1-.04, continued)

Authority: T.C.A. §§ 68-14-701 through 68-14-726.

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* If a roll-call vote was necessary, the vote by the Agency on these rulemaking hearing rules was as follows:

Board Member	Aye	No	Abstain	Absent	Signature (if required)
N/A					

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Bureau of Communicable and Environmental Diseases and Emergency Preparedness, Division of General Environmental Health (board/commission/ other authority) on 10/28/2014 (mm/dd/yyyy), and is in compliance with the provisions of T.C.A. § 4-5-222.

I further certify the following:

Notice of Rulemaking Hearing filed with the Department of State on: 09/05/14

Rulemaking Hearing(s) Conducted on: (add more dates). 10/28/14



Date: 2/10/2015

Signature: Mary Kennedy

Name of Officer: Mary Kennedy

Deputy General Counsel

Title of Officer: Department of Health

Subscribed and sworn to before me on: 2/10/2015

Notary Public Signature: Mark Ingram

My commission expires on: My Commission Expires: July 6, 2015

All rulemaking hearing rules provided for herein have been examined by the Attorney General and Reporter of the State of Tennessee and are approved as to legality pursuant to the provisions of the Administrative Procedures Act, Tennessee Code Annotated, Title 4, Chapter 5.

Herbert H. Slatery III
Herbert H. Slatery III
Attorney General and Reporter

4/15/2015

Date

Department of State Use Only

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PUBLICATIONS

Filed with the Department of State on: 4/17/15

Effective on: 7/16/15

Tre Hargett

Tre Hargett
Secretary of State

G.O.C. STAFF RULE ABSTRACT

<u>BOARD:</u>	Tennessee Medical Laboratory Board
<u>SUBJECT:</u>	Rules Governing Medical Laboratories
<u>STATUTORY AUTHORITY:</u>	Tennessee Code Annotated, Sections 68-29-105 and 69-29-138
<u>EFFECTIVE DATES:</u>	June 30, 2015 through June 30, 2016
<u>FISCAL IMPACT:</u>	None
<u>STAFF RULE ABSTRACT:</u>	The rule establishes a special regulation for laboratories that perform advanced esoteric applied toxicological, forensic, or biochemical analysis utilizing emerging technology, whereby persons who accept specimens, perform analytical testing, or report test results for such laboratories are not required to be licensed as a technologist, technician, laboratory trainee, or special analyst. Persons who analyze or report laboratory results will be required to possess at least a baccalaureate degree in the appropriate sciences. The exemption from licensure for certain laboratory personnel is required by Tennessee Code Annotated, Section 69-29-138.

Public Hearing Comments

One copy of a document containing responses to comments made at the public hearing must accompany the filing pursuant to T.C.A. § 4-5-222. Agencies shall include only their responses to public hearing comments, which can be summarized. No letters of inquiry from parties questioning the rule will be accepted. When no comments are received at the public hearing, the agency need only draft a memorandum stating such and include it with the Rulemaking Hearing Rule filing. Minutes of the meeting will not be accepted. Transcripts are not acceptable.

There were no public comments, either written or oral.

Regulatory Flexibility Addendum

Pursuant to T.C.A. §§ 4-5-401 through 4-5-404, prior to initiating the rule making process as described in T.C.A. § 4-5-202(a)(3) and T.C.A. § 4-5-202(a), all agencies shall conduct a review of whether a proposed rule or rule affects small businesses.

(1) The extent to which the rule or rules may overlap, duplicate, or conflict with other federal, state, and local governmental rules.

These proposed rule amendments do not overlap, duplicate, or conflict with other federal, state, or local governmental rules. Upon passage of these proposed rule amendments, there will be two separate licensure categories for medical laboratories, which is necessary in order to separately regulate a facility which is not required to employ licensed personnel.

(2) Clarity, conciseness, and lack of ambiguity in the rule or rules.

These proposed rule amendments exhibit clarity, conciseness, and lack of ambiguity.

(3) The establishment of flexible compliance and/or reporting requirements for small businesses.

These proposed rule amendments do not create flexible compliance and/or reporting requirements for small businesses. The purpose of these rule amendments is to regulate medical laboratories utilizing unlicensed personnel, as well as what tests are performed in order to comply with the Medical Laboratory Act requirements.

(4) The establishment of friendly schedules or deadlines for compliance and/or reporting requirements for small businesses.

These proposed rule amendments do not establish reporting requirements.

(5) The consolidation or simplification of compliance or reporting requirements for small businesses.

All medical laboratories are required to be licensed regardless of business size, and these proposed rule amendments and additions do not complicate the compliance or reporting requirements. The purpose of a separate license for laboratories utilizing individuals who are not licensed medical laboratory personnel is to regulate tests non-licensed personnel are performing by creating a separate licensure category.

(6) The establishment of performance standards for small businesses as opposed to design or operational standards required in the proposed rule.

These proposed rule amendments do not establish performance, design, or operational standards.

(7) The unnecessary creation of entry barriers or other effects that stifle entrepreneurial activity, curb innovation, or increase costs.

These proposed rule amendments do not create unnecessary barriers or stifle entrepreneurial activity or innovation. The statutory change encourages medical laboratories participating in leading edge technology to be located in Tennessee.

STATEMENT OF ECONOMIC IMPACT TO SMALL BUSINESSES

Name of Board, Committee or Council: *Medical Laboratory Board*

- 1. Type or types of small business and an identification and estimate of the number of small businesses subject to the proposed rule that would bear the cost of, and/or directly benefit from the proposed rule:**

These proposed rule amendments will only affect medical laboratories performing esoteric testing that utilize unlicensed personnel, and at this time, the number of laboratories intending to pursue such licensure is unknown. If an esoteric laboratory chooses to employ licensed personnel, these proposed rule amendments would not affect that lab.

- 2. Projected reporting, recordkeeping and other administrative costs required for compliance with the proposed rule, including the type of professional skills necessary for preparation of the report or record:**

These proposed rule amendments do not affect the reporting requirements or other administrative costs for compliance. Although the licensure application and annual renewal fees are \$1,000.00, this cost is the same for all medical laboratories.

- 3. Statement of the probable effect on impacted small businesses and consumers:**

These proposed rule amendments should not have a specific effect on small businesses. The proposed rule amendments create a new category of medical laboratory license; however, there has always been a requirement that the facility be licensed regardless of the size of the lab or business.

- 4. Description of any less burdensome, less intrusive or less costly alternative methods of achieving the purpose and/or objectives of the proposed rule that may exist, and to what extent, such alternative means might be less burdensome to small business:**

These proposed rule amendments are not burdensome or intrusive. Although these rules will require a medical laboratory engaged in esoteric testing to apply for a license at a cost of \$1,000.00, the proposed rule amendments are required to effectively regulate exceptions created by Public Chapter No. 213. The application and renewal costs are the same for each type of medical laboratory, whether or not the lab is engaged in esoteric testing.

- 5. Comparison of the proposed rule with any federal or state counterparts:**

Federal: The United States Code Annotated requires medical laboratories to be certified. See 42 U.S.C.A. § 263a. Medical laboratories licensed under these proposed rules amendments are still required to be federally certified, just as all medical laboratories in Tennessee.

State: In order to operate a medical laboratory in Tennessee, the lab is required to obtain a license from the Board pursuant to T.C.A. § 68-29-111. These proposed rule amendments require medical laboratories engaged in esoteric testing be licensed under a separate licensure category from a typical medical laboratory due to the difference in requirements for personnel. However, the process for labs engaged in esoteric testing is identical to any other lab obtaining licensure; the procedures for obtaining such license are found at Tenn. Comp. R. & Regs.1200-06-03-.02.

States such as Kentucky and Maryland also require medical laboratories to require a state level license. However, this is not true for all states. Arizona, for example, defines medical laboratory as one certified by the United States Department of Health and Human Services. A.R.S. § 36-451.

Not all states require personnel in medical laboratories to obtain state licensure. Instead of totally removing licensure requirements for medical laboratory

personnel, Public Chapter No. 213 creates an exception for personnel engaged in certain types of testing not be required to obtain a state license. In order to ensure medical laboratories not engaged in esoteric testing described in Public Chapter No. 213 are utilizing licensed personnel, two separate facility licensure categories are necessary to enforce this new exception.

6. Analysis of the effect of the possible exemption of small businesses from all or any part of the requirements contained in the proposed rule.

These proposed rule amendments do not provide exemptions. All medical laboratories are required to be licensed, and the proposed rule amendments simply add a licensure category.

Impact on Local Governments

Pursuant to T.C.A. §§ 4-5-220 and 4-5-228 “any rule proposed to be promulgated shall state in a simple declarative sentence, without additional comments on the merits of the policy of the rules or regulation, whether the rule or regulation may have a projected impact on local governments.” (See Public Chapter Number 1070 (<http://state.tn.us/sos/acts/106/pub/pc1070.pdf>) of the 2010 Session of the General Assembly)

The proposed rule amendments should not have a financial impact on local governments.

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Sequence Number: 04-02-15
Rule ID(s): 5923
File Date: 4/1/15
Effective Date: 6/30/15

Rulemaking Hearing Rule(s) Filing Form

Rulemaking Hearing Rules are rules filed after and as a result of a rulemaking hearing. T.C.A. § 4-5-205

Agency/Board/Commission: Department of Health
Division: Tennessee Medical Laboratory Board
Contact Person: Mollie Gass
Address: 665 Mainstream Drive, Nashville, Tennessee
Zip: 37234
Phone: (615) 741-1611
Email: Mollie.Gass@tn.gov

Revision Type (check all that apply):

- Amendment
- New
- Repeal

Rule(s) Revised (ALL chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. Please enter only ONE Rule Number/Rule Title per row)

Chapter Number	Chapter Title
1200-06-03	General Rules Governing Medical Laboratories
Rule Number	Rule Title
	Table of Contents
1200-06-03-.22	Special Regulations Regarding Laboratories Licensed Under T.C.A. § 68-29-138

**RULES
OF
TENNESSEE MEDICAL LABORATORY BOARD**

**CHAPTER 1200-06-03
GENERAL RULES GOVERNING MEDICAL LABORATORIES**

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1200-06-03-.01	Definitions	1200-06-03-.12	Reportable Diseases
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1200-06-03-.04	Inspections - Reports	1200-06-03-.15	Special Regulations for ASTC, Blood Donor Centers, and Plasmapheresis Centers
1200-06-03-.05	Licensure Discipline, Civil Penalties, Assessment of Costs, and Subpoenas	1200-06-03-.16	Alternate Site Testing
1200-06-03-.06	Minimum Standards	1200-06-03-.17	Waived Testing
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1200-06-03-.08	Patient Test Management	1200-06-03-.19	Preparatory Portions of Laboratory Tests
1200-06-03-.09	Quality Control	1200-06-03-.20	Advertising
1200-06-03-.10	Performance Improvement Program	1200-06-03-.21	Renewal of Laboratory License
		1200-06-03-.22	Special Regulations Regarding Laboratories Licensed Under T.C.A. § 68-29-138.
1200-06-03-.11	Facilities, Safety, Infectious and Hazardous Waste Disposal		

1200-06-03-.01 DEFINITIONS. As used in this chapter of Rules the following terms and acronyms shall have the following meanings ascribed to them:

- (1) ASTC - Ambulatory Surgical Treatment Center, specifically any institution, place or building devoted primarily to the maintenance and operation of a facility for the performance of surgical procedures or any facility in which a medical or surgical procedure is utilized to terminate a pregnancy and is licensed by the Tennessee Board for Licensing Health Care Facilities under Rule 1200-8-10.
- (2) Anatomic laboratory - Any medical laboratory performing only the biophysical examination of specimens pertaining to the clinical specialty of pathology, to include histopathology, oral pathology, and cytopathology. The examination of these specimens taken from the human body are performed to obtain information for diagnosis, prophylaxis, or treatment or where any examination, determination or test is made of any sample used as a basis for health advice, or where any sample is collected for the purpose of transfusion or processing of blood or blood fractions, or the training of medical laboratory personnel. Compliance with Rule 1200-6-1-.20 is required to be the director of an anatomic laboratory.
- (3) Authorized person - A physician or intern or resident in an American Medical Association approved training program or a duly licensed optometrist or a duly licensed dentist or a duly licensed chiropractic physician or other health care professional legally permitted to submit to a medical laboratory a written request for tests appropriate to that professional's practice or a law enforcement officer acting in accordance with T.C.A. § 55-10-406.
- (4) Board - The Tennessee Medical Laboratory Board.
- (5) CLIA - The Clinical Laboratory Improvement Amendments as found in 42 CFR 493.
- (6) CLSI - The Clinical Laboratory and Standards Institute.

(Rule 1200-06-03-.21, continued)

2. Paper Renewals - For laboratories or collection stations that have not renewed their license online via the Internet, a renewal application form will be mailed to each laboratory and collection station licensed by the Board at least sixty (60) days prior to the expiration date to the last address provided to the Board. Failure to receive such notification does not relieve the laboratory or collection station from the responsibility of meeting all requirements for renewal.
- (3) To be eligible for renewal, a laboratory or collection station must submit to the Division of Health Related Boards on or before the expiration date all of the following:
1. A completed renewal application form, signed by the owner and director of the medical laboratory or public official responsible for the operation of a city or county medical laboratory or institution that contains a medical laboratory; and
 2. In alphabetical order, a roster of all personnel currently employed in the laboratory, the classification/category in which the employee functions and is licensed, license number, expiration date and social security number. This shall include all medical laboratory directors, consultants, supervisors and testing personnel; and
 3. The renewal and state regulatory fees as provided in Rule 1200-06-03-.02.
- (4) All laboratories performing tests must file a separate renewal application for each laboratory address.
- (5) Laboratories within a hospital that are located in contiguous buildings on the same campus and under common direction may file a single renewal application or multiple renewal applications for the laboratory sites within the same physical location or street address.
- (6) Laboratories and collection stations which submit a signed renewal form or letter that is found to be untrue may be subject to disciplinary action as provided in Rule 1200-06-03-.05.
- (7) Laboratories and collection stations which fail to comply with the renewal rules or notification received by them concerning failure to timely renew shall have their licenses processed pursuant to rule 1200-10-01-.10.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-29-105, 68-29-113, and 68-29-126. **Administrative History:** Original rule filed April 17, 2007; effective July 1, 2007.

Rule 1200-06-03-.22 Special Regulations Regarding Laboratories Licensed Under T.C.A. § 68-29-138.

(1) Medical laboratories performing advanced esoteric applied toxicological, forensic, or biochemical analysis utilizing emerging technology shall be licensed.

(a) Licensing procedures set out in Rule 1200-06-03-.02 shall be met.

(b) Laboratories licensed under T.C.A. § 68-29-138(a) are subject to all provisions of the Medical Laboratory Act except for the provisions of the Medical Laboratory Act and rules promulgated under the Act that require persons who accept specimens for laboratory examination and perform analytical testing or report the results of a laboratory examination to be licensed as a technologist, technician, laboratory trainee, or special analyst.

1. To be eligible for the licensed personnel exemption, a medical laboratory must obtain a license pursuant to T.C.A. § 68-29-138. This license shall be unique and in addition

(Rule 1200-06-03-.21, continued)

to other licenses for laboratories located in contiguous buildings on the same campus that do not fall within the exemption.

- (c) The application for licensure under this exemption shall require a specific testing menu.
- (2) Laboratories licensed under this rule shall be subject to on-site surveys by the Department. The survey shall include inspection of the following: laboratories, tools therein, and educational requirements of personnel defined in T.C.A. § 68-29-138(c).
- (3) Only medical laboratories engaged in advanced esoteric applied toxicological, forensic, or biochemical laboratory analysis utilizing emerging technologies shall be given an exemption defined in subparagraph (1)(b).
- (a) Definition: advanced esoteric applied toxicological, forensic, or biochemical laboratory analysis is narrowly focused analysis that takes place within independent laboratories.
- (b) Emerging technologies include, but are not limited to, chromatographic and non-chromatographic techniques coupled with mass spectrometer based detector systems and molecular diagnostic techniques.
- (4) Personnel in laboratories licensed under T.C.A. § 68-29-138 shall not be required to complete the procedures for personnel licensure as provided in Rule 1200-06-01-.05. However, personnel who analyze or report laboratory results shall possess a baccalaureate or advanced degree in the appropriate sciences with at least sixteen (16) semester hours of chemistry and/or biological science courses.
- (a) Licensed personnel shall be allowed to perform tasks for which they are appropriately licensed and trained in laboratories exempt from hiring licensed personnel.
- (b) Determining the appropriate sciences for baccalaureate or advanced degree for unlicensed personnel shall be left to the medical director of the laboratory.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-29-103, 68-29-104, 68-29-105, 68-29-111, 68-29-113, 68-29-114, 68-29-115, and 68-29-138.

* If a roll-call vote was necessary, the vote by the Agency on these rulemaking hearing rules was as follows:

Board Member	Aye	No	Abstain	Absent	Signature (if required)
Cheryl K. Arnott, CT	X				
Tereyo M. Cox, MT	X				
Mark A. Calarco, DO	X				
Kathleen Kenwright, MT		X			
Stephanie Dolsen, MT	X				
Patti J. Walton, MT	X				
Carla M. Davis, MD	X				
Jason S. Nolan, M.D.	X				
Jerry L. Miller, MD	X				
Royce E. Joyner, M.D.	X				
Vacant					
Vacant					
Vacant					

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Tennessee Medical Laboratory Board (board/commission/ other authority) on 07/18/2014 (mm/dd/yyyy), and is in compliance with the provisions of T.C.A. § 4-5-222.

I further certify the following:

Notice of Rulemaking Hearing filed with the Department of State on: 04/07/14 (mm/dd/yy)

Rulemaking Hearing(s) Conducted on: (add more dates). 07/18/2014 (mm/dd/yy)

Date: 3/24/15

Signature: Mollie X. Gass

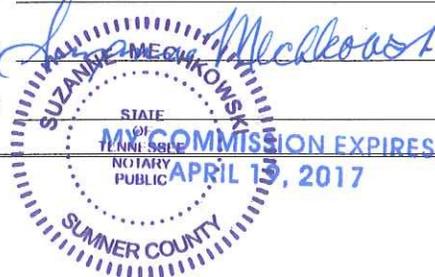
Name of Officer: Mollie Gass
Assistant General Counsel

Title of Officer: Department of Health

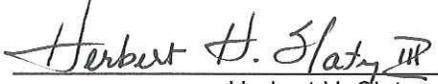
Subscribed and sworn to before me on: 3-24-15

Notary Public Signature: Suzanne Meko

My commission expires on: _____



All proposed rules provided for herein have been examined by the Attorney General and Reporter of the State of Tennessee and are approved as to legality pursuant to the provisions of the Administrative Procedures Act, Tennessee Code Annotated, Title 4, Chapter 5.



Herbert H. Slatery III
Attorney General and Reporter
3/30/2015

Date

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Filed with the Department of State on: 4/1/15

Effective on: 4/30/15



Tre Hargett
Secretary of State

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