



Montana Department of Public Health and Human Services
Food and Consumer Safety Section

CIRCULAR FCS 2-2019

MONTANA STANDARDS FOR WHOLESALE FOOD ESTABLISHMENTS

Rev. 12.10.18

Preface

This circular of regulations is adopted in compliance with 50-57-103 (2), MCA that requires wholesale food establishment rules to be consistent with retail food establishment rules to the extent feasible.

The circular was adopted by reference in Administrative Rules Montana, Title 37, Chapter 110, Subchapter 3.

This circular is primarily based on the 2013 federal Food and Drug Administration model “Food Code,” which is also the main source document for Montana’s retail food rules. However, this circular has been customized to the needs specific to Montana and wholesale food processors and warehouses. This includes emerging issues, such a mobile units and rise of specialized food processors. The most recent major change to the wholesale food regulation was on November 4, 1973, which was subsequently subjected to minor changes on November 11, 1994.

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Commonly Abbreviated Terms

Term	Meaning
CCF	Condition Control Food, which is equivalent to TCS and PHF.
CFPM	Certified Food Protection Manager
^P	Priority inspection item, formerly known as a critical item.
^{Pf}	Priority foundation inspection item, formerly known as a non-critical item.
PAR	Product Assessment Required, or process authority letter.
pH	Numeric acidity or alkalinity level of a food ingredient or product.
PHF	Potential Hazardous Food, which is equivalent to TCS and PHF.

PIC	Person In Charge.
TCS	Time/Temperature Control for Safety Food, which is equivalent to PHF and CCF.

CHAPTER 1 DEFINITIONS

1-201.10 DEFINITIONS. (1)(a) "**Accredited program**" means a food protection manager certification program that has been evaluated and listed by an accrediting agency as conforming to national standards for organizations that certify individuals.

(b) "accredited program" refers to the certification process and is a designation based upon an independent evaluation of factors such as the sponsor's mission; organizational structure; staff resources; revenue sources; policies; public information regarding program scope, eligibility requirements, re-certification, discipline and grievance procedures; and test development and administration.

(c) "accredited program" does not refer to training functions or educational programs.

(2) "**Additive**" means the same as color additive or food additive as determined in 50-31-103 (5) and (16), MCA.

(3) "**Adulterated**" means the same as stated in the Montana Food, Drug, and Cosmetic Act, 50-31-202, MCA.

(4) "**Approved**" means acceptable to the health regulatory authority based on its determination of conformity with principles, practices, and generally recognized standards that protect public health as to conformance with appropriate standards and good public health practice.

(5)(a) "**Asymptomatic**" means without obvious symptoms; not showing or producing indications of a disease or other medical condition, such as an individual infected with a pathogen, but not exhibiting or producing any signs or symptoms of vomiting, diarrhea, or jaundice.

(b) "asymptomatic" includes not showing symptoms because symptoms have resolved or subsided, or because symptoms never manifested.

(6) "**Balut**" means an embryo inside a fertile egg that has been incubated for a period sufficient for the embryo to reach a specific stage of development after which it is removed from incubation before hatching.

(7) "**Beverage**" means a liquid for drinking, including water.

(8) "**Bottled drinking water**" means water that is sealed in bottles, packages, or other containers and offered for sale for human consumption, including bottled mineral water.

(9) "**Casing**" means a tubular container for sausage products made of either natural or artificial (synthetic) material.

(10) "**Certificate of free sale**" means an official document completed and issued by the department or local health authority attesting that a specific food product regulated under this subchapter, manufactured, distributed, and provided to the public, is labeled in conformance with applicable food law and rule, and attests to the satisfactory results of the most recent inspection of the manufacturer or distributor of the product.

(11) "**Certification number**" means a unique combination of letters and numbers assigned by a shellfish control authority to a molluscan shellfish dealer according to the provisions of the National Shellfish Sanitation Program.

(12) **"Certified Food Protection Manager"** (CFPM) means an individual who operates a food establishment or manages a food establishment who has successfully completed a test through an accredited program required in 2-102.12 (1) of this rule.

(13) **"CFR"** means Code of Federal Regulations. Citations in this rule to the CFR refer sequentially to the Title, Part, and Section numbers, such as 40 CFR 180.194 refers to Title 40, Part 180, Section 194.

(14) **"CIP"** means: (a) cleaned in place by the circulation or flowing by mechanical means through a piping system of a detergent solution, water rinse, and sanitizing solution onto or over equipment surfaces that require cleaning, such as the method used, in part, to clean and sanitize a frozen dessert machine.

(b) "CIP" does not mean the cleaning of equipment such as band saws, slicers, or mixers that are subjected to in-place manual cleaning without the use of a CIP system.

(15) **"Comingle"** means: (a) to combine shellstock harvested on different days or from different growing areas as identified on the tag or label, or;

(b) to combine shucked shellfish from containers with different container rules or different shucking dates.

(16) **"Comminuted"** means: (a) reduced in size by methods including chopping, flaking, grinding, or mincing.

(b) "comminuted" includes fish or meat products that are reduced in size and restructured or reformulated such as gefilte fish, gyros, ground beef, and sausage; and a mixture of 2 or more types of meat that have been reduced in size and combined, such as sausages made from 2 or more meats.

(17) **"Conditional employee"** means a potential food employee to whom a job offer is made, conditional on responses to subsequent medical questions or examinations designed to identify potential food employees who may be suffering from a disease that can be transmitted through food and done in compliance with Title 1 of the Americans with Disabilities Act of 1990.

(18) **"Confirmed disease outbreak"** means a foodborne disease outbreak in which laboratory analysis of appropriate specimens identifies a causative agent and epidemiological analysis implicates the food as the source of the illness.

(19) **"Consumer"** means a person who is a member of the public, takes possession of food, is not functioning in the capacity of a wholesale or retail food establishment operator, and does not offer the food for resale.

(20) **"Core item"** means (a) a provision in this rule that is not designated as a priority item or a priority foundation item.

(b) "core item" includes an item that usually relates to general sanitation, operational controls, sanitation standard operating procedures (SSOPs), facilities or structures, equipment design, or general maintenance.

(21) **"Corrosion-resistant material"** means a material that maintains acceptable surface cleanability characteristics under prolonged influence of the food to be contacted, the normal use of cleaning compounds and sanitizing solutions, and other conditions of the use environment.

(22) **"Counter-mounted equipment"** means equipment that is not portable and is designed to be mounted off the floor on a table, counter, or shelf.

(23) **"Critical control point"** means a point or procedure in a specific food system where loss of control may result in an unacceptable health risk.

(24) **"Critical limit"** means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to minimize the risk that the identified food safety hazard may occur.

(25) **"Cut leafy greens"** means fresh leafy greens whose leaves have been cut, shredded, sliced, chopped, or torn. The term "leafy greens" includes iceberg lettuce, romaine lettuce, leaf lettuce, butter lettuce, baby leaf lettuce (i.e., immature lettuce or leafy greens), escarole, endive, spring mix, spinach, cabbage, kale, arugula and chard. The term "leafy greens" does not include herbs such as cilantro or parsley.

(26) **"Dealer"** means a person who is authorized by a shellfish control authority for the activities of shellstock shipper, shucker-packer, repacker, reshipper, or depuration processor of molluscan shellfish according to the provisions of the National Shellfish Sanitation Program.

(27) **"Department"** means the Montana Department of Public Health and Human Services as defined in 50-57-102(2), MCA.

(28) **"Drinking water"** means: (a) water that meets criteria as specified in 40 CFR Part 141 National Primary Drinking Water Regulations;

(b) "drinking water" is traditionally known as "potable water;" and

(c) "drinking water" includes the term "water" except where the term used connotes that the water is not potable, such as "boiler water," "mop water," "rainwater," "wastewater," and "nondrinking" water.

(29) **"Dry storage area"** means a room or area designated for the storage of packaged or containerized bulk food that is not potentially hazardous food and dry goods such as single-service items.

(30) **"Easily cleanable"** means: (a) a characteristic of a surface that:

(i) allows effective removal of soil by normal cleaning methods;

(ii) is dependent on the material, design, construction, and installation of the surface; and

(iii) varies with the likelihood of the surface's role in introducing pathogenic or toxigenic agents or other contaminants into food based on the surface's approved placement, purpose, and use.

(b) "easily cleanable" includes a tiered application of the criteria that qualify the surface as easily cleanable as specified in (a) of this definition to different situations in which varying degrees of cleanability are required such as:

(i) the appropriateness of stainless steel for a food preparation surface as opposed to the lack of need for stainless steel to be used for floors or for tables used for worker restrooms; or

(ii) the need for a different degree of cleanability for a utilitarian attachment or accessory in the kitchen as opposed to a decorative attachment or accessory in the visitor reception area.

(31) **"Easily movable"** means: (a) portable; mounted on casters, gliders, or rollers; or provided with a mechanical means to safely tilt a unit of equipment for cleaning; and

(b) having no utility connection, a utility connection that disconnects quickly, or a flexible utility connection line of sufficient length to allow the equipment to be moved for cleaning of the equipment and adjacent area.

(32) **"Egg"** means: (a) the shell egg of avian species such as chicken, duck, goose, guinea, quail, ratites or turkey.

(b) "egg" does not include: a balut; the egg of reptile species such as alligator; or an egg product.

(33) **"Egg Product"** means: (a) all, or a portion of, the contents found inside eggs separated from the shell and pasteurized in a food processing establishment, with or without added ingredients, intended for human consumption, such as dried, frozen or liquid eggs; and

(b) "egg product" does not include food which contains eggs only in a relatively small proportion such as cake mixes.

(34) **"Employee"** means the legal licensee, person-in-charge, food employee, person having supervisory or management duties, person on the payroll, family member, volunteer, person performing work under contractual agreement, or other person working in a food establishment. Employee includes any person working in a food processing establishment who transports food or food containers; who engages in food preparation, cutting, wrapping, or service; or who comes in contact with any food utensils or equipment.

(35) **"EPA"** means the U.S. Environmental Protection Agency.

(36) **"Equipment"** means: (a) an article that is used in the operation of a food establishment such as a freezer, grinder, hood, ice maker, meat block, mixer, oven, reach-in refrigerator, scale, sink, slicer, stove, table, temperature measuring device for ambient air, vending machine, or warewashing machine; and

(b) "equipment" does not include apparatuses used for handling or storing large quantities of packaged foods that are received from a supplier in a cased or overwrapped lot, such as hand trucks, forklifts, dollies, pallets, racks, and skids.

(37) **"Exclude"** means to prevent a person from working as an employee in a food establishment or entering a food establishment as an employee.

(38) **"FDA"** means the U.S. Food and Drug Administration.

(39) **"Fish"** means: (a) fresh or saltwater finfish, crustaceans and other forms of aquatic life (including alligator, frog, aquatic turtle, jellyfish, sea cucumber, and sea urchin and the roe of such animals) other than birds or mammals, and all mollusks, if such animal life is intended for human consumption; and

(b) "fish" includes an edible human food product derived in whole or in part from fish, including fish that have been processed in any manner.

(40) **"Food"** means a raw, cooked, or processed edible substance, ice, beverage, or ingredient used or intended for use or for sale in whole or in part for human consumption, or chewing gum.

(41) **"Foodborne disease outbreak"** means the occurrence of two or more cases of a similar illness resulting from the ingestion of a common food.

(42) **"Food contact surfaces"** means: (a) a surface of equipment or a utensil with which food normally comes into contact; or

(b) a surface of equipment or a utensil from which food may drain, drip, or splash:

(i) into a food, or

(ii) onto a surface normally in contact with food.

(43) **"Food employee"** means an individual working with unpackaged food, food equipment or utensils, or food-contact surface.

(44) **"Food establishment"** means: (a) any and all licensable establishments stated in Title 50, chapter 57, MCA;

(b) The term does not include retail food establishments or cottage food operations that sell or serve exclusively, and only to consumers stated in Title 50, chapter 50, MCA.

(45) **"General use pesticide"** means a pesticide that is not classified by EPA for restricted use as specified in 40 CFR 152.175 "Pesticides classified for restricted use."

(46) **"Grade A standards"** means the requirements of the United States Public Health Service/FDA "Grade A Pasteurized Milk Ordinance" with which certain fluid and dry milk and milk products comply.

(47) **"HACCP plan"** means a written document that delineates the formal procedures for following the hazard analysis and critical control point principles developed by The National Advisory Committee on Microbiological Criteria for Foods.

(48) **"Handwashing sink"** means: (a) a lavatory, a basin or vessel for washing, a wash basin, or a plumbing fixture especially placed for use in personal hygiene and designed for the washing of the hands; and

(b) "handwashing sink" includes an automatic handwashing facility.

(49) **"Hazard"** means a biological, chemical, or physical property that may cause an unacceptable consumer health risk.

(50) **"Health practitioner"** means a physician licensed to practice medicine, or if allowed by law, a nurse practitioner, physician assistant, or similar medical professional.

(51) **"Hermetically sealed container"** means a container that is designed and intended to be secure against the entry of microorganisms and, in the case of low acid canned foods, to maintain the commercial sterility of its contents after processing.

(52) **"Highly susceptible population"** means persons who are more likely than other people in the general population to experience foodborne disease because they are:

(a) immunocompromised; preschool age children, or older adults; and

(b) obtaining food at a facility that provides services such as custodial care, health care, or assisted living, such as a child or adult day care center, kidney dialysis center, hospital or nursing home, or nutritional or socialization services such as a senior center.

(53) **"Imminent health hazard"** means a significant threat or danger to health that is considered to exist when there is evidence sufficient to show that a product, practice, circumstance, or event creates a situation that requires immediate correction or cessation of operation to prevent injury based on:

(a) the number of potential injuries, and

(b) the nature, severity, and duration of the anticipated injury.

(54) **"Injected"** means manipulating meat to which a solution has been introduced into its interior by processes that are referred to as "injecting," "pump marinating," or "stitch pumping."

(55) **"Juice"** means: (a) the aqueous liquid expressed or extracted from one or more fruits or vegetables, purées of the edible portions of one or more fruits or vegetables, or any concentrates of such liquid or purée; and

(b) "Juice" does not include, for purposes of HACCP, liquids, purées, or concentrates that are not used as beverages or ingredients of beverages.

(56) **"Kitchenware"** means food preparation and storage utensils.

(57) **"Law"** means applicable local, state, and federal statutes, regulations, and ordinances.

(58) **"Legal licensee"** means the entity that:

(a) is legally responsible for the operation of the food establishment such as the owner, owner's agent, or other person; and

(b) possesses a valid license to operate a food establishment.

(59) **"License"** means the document issued by the regulatory authority that authorizes a person to operate a food establishment.

(60) **"License subtype"** means one or more of the following food establishment activities:

- (a) Acidified foods;
- (b) Alcohol products;
- (c) Dietary supplements;
- (d) Fishery products;
- (e) High-acid canned foods;
- (f) Juice products;
- (g) Low-acid canned foods;
- (h) Mobile establishment;
- (i) Other high-risk processing or packaging;
- (j) Other low-risk processing or packaging;
- (k) Water bottler;
- (l) Wild mushrooms;
- (m) Wild plants.

(61) **"License type"** means a food establishment at a fixed (non-mobile or permanent) location, or mobile food establishment.

(62) **"Linens"** means fabric items such as cloth hampers, cloth napkins, table cloths, wiping cloths, and work garments including cloth gloves.

(63) **"Lot"** means that amount of a food product produced or harvested during a period of time indicated by a specific code.

(64) **"Major food allergen"** means: (a) milk, egg, fish (such as bass, flounder, cod, and including crustacean shellfish such as crab, lobster, or shrimp), tree nuts (almonds, pecans, or walnuts), wheat, peanuts, and soybeans; or

(b) a food ingredient that contains protein derived from a food, as specified (a) of this definition; and

(c) "major food allergen" does not include:

(i) any highly refined oil derived from a food specified in (a) of this definition and any ingredient derived from such highly refined oil; or

(ii) any ingredient that is exempt under the petition or notification process specified in the Food Allergen Labeling and Consumer Protection Act of 2004 (Public Law 108-282).

(65) **"Meat"** means the flesh of animals used as food including the dressed flesh of cattle, swine, sheep, or goats and other edible animals, except fish, poultry, and wild game animals as determined in 81-9-230, 87-4-702, and 87-6-106(1), MCA.

(66) **"Mechanically tenderized"** means: (a) manipulating meat with deep penetration by processes which may be referred to as "blade tenderizing," "jaccarding," "pinning," "needling," or using blades, pins, needles or any mechanical device; and

(b) "mechanically tenderized" does not include processes by which solutions are injected into meat.

(67) **"mg/L"** means milligrams per liter, which is the metric equivalent of parts per million (ppm), and cubic centimeters (cm³).

(68) **"Misbranded"** means the use of any written, printed, or graphic matter upon or accompanying food or containers of food which violates 50-31-203, MCA, the Montana Food, Drug and Cosmetic Act.

(69) **"Mobile food establishment"** means:

(a) a food establishment transport vehicle or movable warehouse operating outside the normal operation of a regulated food carrier where food is provided from a motor vehicle, non-motorized cart, movable vehicle such as a trailer, or boat that has the ability to periodically or continuously change locations, and may or may not necessarily require a servicing area to accommodate the unit for cleaning, inspection, and maintenance, as specified in 5-402.14, 6-101.11, and 6-202.18; and

(b) mobile food establishment does not include transport vehicles holding food that are engaged in their usual course of business as a regulated carrier, or a motor vehicle used solely to transport or deliver food by a motorized carrier regulated by the state or federal government, or any and all mobile retail food establishments regulated under Title 50, Chapter 50, MCA.

(70) **"Molluscan shellfish"** means any edible species of fresh or frozen oysters, clams, mussels, and scallops or edible portions thereof, except when the scallop product consists only of the shucked adductor muscle.

(71) **"Non-continuous cooking"** means: (a) the cooking of food in a food establishment using a process in which the initial heating of the food is intentionally halted so that it may be cooled and held for complete cooking at a later time prior to sale or service; and

(b) "non-continuous cooking" does not include cooking procedures that only involve temporarily interrupting or slowing an otherwise continuous cooking process.

(72) **"Packaged"** means: (a) bottled, canned, cartoned, bagged, or wrapped, whether packaged in a food establishment or a food processing establishment.

(b) "Packaged" does not include wrapped or placed in a carry-out container to protect the food during service or delivery to the firm, consumer, by a food employee, or upon consumer request.

(73) **"Person"** means an individual, partnership, corporation, and association, or other legal entity, government, or governmental subdivision or agency.

(74) **"Person-in-charge"** means the individual present at a food establishment who is responsible for the operation at the time of inspection.

(75) **"Personal care items"** means: (a) items or substances that may be poisonous, toxic, or a source of contamination and are used to maintain or enhance a person's health, hygiene, or appearance.

(b) "personal care items" include items such as medicines; first aid supplies; and other items such as cosmetics, and toiletries such as toothpaste and mouthwash.

(76) **"pH"** means the symbol for the negative logarithm of the hydrogen ion concentration, which is a measure of the degree of acidity or alkalinity of a solution. Values of pH level between 0 and 7 indicate acidity, and values between 7 and 14 indicate alkalinity. The pH value for pure distilled water is 7, which is considered neutral.

(77) **"Physical facilities"** means the structure and interior surfaces of a food establishment including accessories such as soap and towel dispensers and attachments such as light fixtures and heating or air conditioning system vents.

(78) **"Plumbing fixture"** means a receptacle or device that:

(a) is permanently or temporarily connected to the water distribution system of the premises and demands a supply of water from the system; or

(b) discharges used water, waste materials, or sewage directly or indirectly to the drainage system of the premises.

(79) **"Plumbing system"** means the water supply and distribution pipes; plumbing fixtures and traps; soil, waste, and vent pipes; sanitary and storm sewers and building drains, including their respective connections, devices, and appurtenances within the premises; and water-treating equipment.

(80) **"Poisonous or toxic materials"** means substances that are not intended for ingestion and are included in 4 categories:

(a) cleaners and sanitizers, which include cleaning and sanitizing agents and agents such as caustics, acids, drying agents, polishes, and other chemicals;

(b) pesticides, except sanitizers, which include substances such as insecticides and rodenticides;

(c) substances necessary for the operation and maintenance of the establishment such as nonfood grade lubricants and personal care items that may be deleterious to health; and

(d) substances that are not necessary for the operation and maintenance of the establishment and are on the premises for retail sale, such as petroleum products and paints.

(81) **"Potentially hazardous food"** means: (a)(i) the same as time/temperature for safety food (TCS), and condition control food (CCF), and is abbreviated as PHF.

(ii) food in which control of the conditions is critical in maintaining the safety of the food, such as time, temperature, acidity, and water activity during processing, packaging, storage or holding.

(b) PHF, CCF, and TCS also mean a food that requires time and temperature control to limit pathogenic microorganism growth or toxin formation for safety purposes.

(c) potentially hazardous food includes:

(i) an animal food that is raw or heat-treated; a plant food that is heat treated or consists of raw seed sprouts, cut melons, cut leafy greens, cut tomatoes or mixtures of cut tomatoes that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation, or garlic-in-oil mixtures that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation; and

(ii) except as specified in (d)(iv) of this definition, a food that because of the interaction of its Aw and pH values is designated as Product Assessment Required (PAR) in Table 1 or Table 2 of this definition:

Table 1: Acidity and water activity interaction for spore control in packaged and heat-treated foods

Aw value	pH: 4.6 or less	pH: > 4.6 - 5.6	pH: >5.6
≤0.92	Non-PHF	Non-PHF	Non-PHF
>0.92 - 0.95	Non-PHF	Non-PHF	PAR
>0.95	Non-PHF	PAR	PAR

PHF means potentially hazardous food

PAR means product assessment required (process authority evaluation)

Table 2: Acidity and water activity interaction for spore and vegetative cell control in unpackaged and heat-treated or non-heat-treated foods

Aw value	pH: <4.2	pH: 4.2 - 4.6	pH: >4.6 - 5.0	pH: >5.0
<0.88	Non-PHF	Non-PHF	Non-PHF	Non-PHF
0.88 - 0.90	Non-PHF	Non-PHF	Non-PHF	PAR
>0.90 - 0.92	Non-PHF	Non-PHF	PAR	PAR
> 0.92	Non-PHF	PAR	PAR	PAR

PHF means potentially hazardous food

PAR means product assessment required (process authority evaluation)

(d) "Potentially hazardous food" does not include:

(i) an air-cooled hard-boiled egg with shell intact, or an egg with shell intact that is not hard-boiled, but has been pasteurized to destroy all viable *Salmonellae*;

(ii) a food in an unopened hermetically sealed container that is commercially processed to achieve and maintain commercial sterility under conditions of non-refrigerated storage and distribution;

(iii) a food that because of its pH or Aw value, or interaction of Aw and pH values, is designated as a non-CCF food in Table 1 or Table 2 of this definition;

(iv) A food that is designated as Product Assessment Required (PA) in Table 1 or Table 2 of this definition and has undergone a product assessment showing that the growth or toxin formation of pathogenic microorganisms that are reasonably likely to occur in that food is precluded due to:

(A) intrinsic factors including added or natural characteristics of the food such as preservatives, antimicrobials, humectants, acidulants, or nutrients,

(B) extrinsic factors including environmental or operational factors that affect the food such as packaging, modified atmosphere such as reduced oxygen packaging, shelf life and use, or temperature range of storage and use, or

(C) a combination of intrinsic and extrinsic factors; or

(v) a food that does not support the growth or toxin formation of pathogenic microorganisms in accordance with (d)(i) through (d)(iv) of this definition even though the food may contain a pathogenic microorganism or chemical or physical contaminant at a level sufficient to cause illness or injury.

(82) "**Poultry**" means: (a) any domesticated bird (chickens, turkeys, ducks, geese, guineas, ratites, or squabs), whether live or dead, as defined in 9 CFR 381.1 Poultry Products Inspection Regulations Definitions, Poultry; and

(b) any migratory waterfowl or game bird, pheasant, partridge, quail, grouse, or pigeon, whether live or dead, as defined in 9 CFR 362.1 Voluntary Poultry Inspection Regulations, Definitions.

(83) "**Premises**" means: (a) the physical facility, its contents, and the contiguous land or property under the control of the legal licensee; or

(b) the physical facility, its contents, and the land or property not described in (a) of this definition if its facilities and contents are under the control of the legal licensee and may impact food establishment personnel, facilities, or operations, and a food establishment is only one component of a larger operation such as a health care facility, hotel, motel, school, recreational camp, or prison.

(84) "**Primal cut**" means a basic major cut into which carcasses and sides of meat are separated, such as a beef round, pork loin, lamb flank, or veal breast.

(85) "**Priority item**" means: (a) a provision in this rule whose application contributes directly to the elimination, prevention or reduction to an acceptable level, hazards associated with foodborne illness or injury and there is no other provision that more directly controls the hazard.

(b) "priority item" includes items with a quantifiable measure to show control of hazards such as cooking, reheating, cooling, handwashing; and

(c) "priority item" is an item denoted in this rule by the uppercase letter symbol, "P."

(86) "**Priority foundation item**" means: (a) a provision in this rule whose application supports, facilitates or enables one or more priority items.

(b) "priority foundation item" includes an item that requires the purposeful incorporation of specific actions, equipment or procedures by industry management to attain control of risk factors that contribute to foodborne illness or injury such as personnel training, infrastructure or necessary equipment, HACCP plans, documentation or record keeping, and labeling; and

(c) "priority foundation item" is an item that is denoted in this rule by the upper and lowercase letter symbol, "Pf."

(87) **"Processing"** means the same as "preparation" of food through one or more methods including: assembling, baking, bottling, brewing, canning, coating, cooking, cutting, dicing, distilling, drying, extracting, fermenting, freezing, grinding, heating, infusing, mixing, packaging, reheating, repackaging, pickling, slicing, smoking, stuffing, or other food treatment or food preservation method.

(88) **"Public water system"** has the meaning stated in 40 CFR Part 141 National Primary Drinking Water Regulations.

(89) **"Ratite"** means a flightless bird such as an emu, ostrich, or rhea.

(90) **"Ready-to-eat food"** means: (a) food that:

(i) is in a form that is edible without additional preparation to achieve food safety, as specified in 3-401.11 (1), 3-401.12, and 3-402.11.

(b) "ready-to-eat food" includes:

(i) raw animal food that is cooked as specified in 3-401.11 and 3-401.12, or frozen as specified in 3-402.11;

(ii) raw fruits and vegetables that are washed as specified in 3-302.15;

(iii) fruits and vegetables that are cooked for hot holding, as specified in 3-401.13;

(iv) all potentially hazardous food that is cooked to the temperature and time required for the specific food in 3-401 of this rule and cooled as specified in 3-501.14;

(v) plant food for which further washing, cooking, or other processing is not required for food safety, and from which rinds, peels, husks, or shells, if naturally present are removed;

(vi) substances derived from plants such as spices, seasonings, and sugar;

(vii) A bakery item such as bread, cakes, pies, fillings, or icing for which further cooking is not required for food safety;

(viii) the following products that are produced in accordance with USDA guidelines and that have received a lethality treatment for pathogens: dry, fermented sausages, such as dry salami or pepperoni; salt-cured meat and poultry products, such as prosciutto ham, country cured ham, and Parma ham; and dried meat and poultry products, such as jerky or beef sticks; and

(ix) foods manufactured as specified in 21 CFR Part 113, Thermally Processed Low-acid Foods Packaged in Hermetically Sealed Containers.

(91) **"Reduced oxygen packaging"** means: (a)(i) the reduction of the amount of oxygen in a package by removing oxygen; displacing oxygen and replacing it with another gas or combination of gases; or otherwise controlling the oxygen content to a level below that normally found in the atmosphere (approximately 21% at sea level); and

(ii) a process as specified in (a)(i) of this definition that involves a food for which the hazards *Clostridium botulinum* or *Listeria monocytogenes* require control in the final packaged form.

(b) "reduced oxygen packaging" includes, but is not limited to:

(i) vacuum packaging, in which air is removed from a package of food and the package is hermetically sealed so that a vacuum remains inside the package;

(ii) modified atmosphere packaging, in which the atmosphere of a package

of food is modified so that its composition is different from air but the atmosphere may change over time due to the permeability of the packaging material or the respiration of the food. Modified atmosphere packaging includes reduction in the proportion of oxygen, total replacement of oxygen, or an increase in the proportion of other gases such as carbon dioxide or nitrogen;

(iii) controlled atmosphere packaging, in which the atmosphere of a package of food is modified so that until the package is opened, its composition is different from air, and continuous control of that atmosphere is maintained, such as by using oxygen scavengers or a combination of total replacement of oxygen, non-respiring food, and impermeable packaging material;

(iv) cook-chill packaging, in which cooked food is hot filled into impermeable bags which have the air expelled and are then sealed or crimped closed. The bagged food is rapidly chilled and refrigerated at temperatures that inhibit the growth of psychrotrophic pathogens; or

(v) sous vide packaging, in which raw or partially cooked food is vacuum packaged in an impermeable bag, cooked in the bag, rapidly chilled, and refrigerated at temperatures that inhibit the growth of psychrotrophic pathogens.

(92) "**Refuse**" means solid waste not carried by water through the sewage system.

(93) "**Regulatory authority**" means the local, state, or federal enforcement body or authorized representative having jurisdiction over the food establishment.

(94) "**Reminder**" means a written statement concerning the health risk of consuming animal foods raw, undercooked, or without otherwise being processed to eliminate pathogens.

(95) "**Re-service**" means the transfer of food that is unused and returned by a consumer after being served or sold and in the possession of the consumer, to another person.

(96) "**Restrict**" means to limit the activities of a food employee so that there is no risk of transmitting a disease that is transmissible through food and the food employee does not work with exposed food, clean equipment, utensils, linens, or unwrapped single-service or single-use articles.

(97) "**Restricted egg**" means any check, dirty egg, incubator reject, inedible, leaker, or loss as defined in 9 CFR Part 590.

(98) "**Restricted use pesticide**" means a pesticide product that contains the active ingredients specified in 40 CFR 152.175 Pesticides classified for restricted use, and that is limited to use by or under the direct supervision of a certified applicator.

(99) "**Risk**" means the likelihood that an adverse health effect will occur within a population as a result of a hazard in a food.

(100) "**Safe material**" means: (a) an article manufactured from or composed of materials that may not reasonably be expected to result, directly or indirectly, in their becoming a component or otherwise affecting the characteristics of any food;

(b) an additive that is used as specified in § 409 of the federal Food, Drug, and Cosmetic Act (21 U.S.C. § 348); or

(c) other materials that are not additives and that are used in conformity with applicable regulations of the Food and Drug Administration.

(101) "**Sanitize**" means the application of cumulative heat or chemicals on cleaned food-contact surface that, when evaluated for efficacy, is sufficient to yield a reduction of 5 logs, which is equal to a 99.999% reduction of representative disease microorganisms of public health importance.

(102) "**Sealed**" means free of cracks or other openings which license entry or passage of moisture.

(103) "**Service animal**" means an animal such as a guide dog, signal dog, or other animal individually trained to provide assistance to an individual with a disability.

(104) "**Service base**" means an operating base location to which a mobile food establishment or transportation vehicle returns regularly for such things as vehicle and equipment cleaning, discharging liquid or solid wastes, refilling water tanks and ice bins, and boarding food.

(105) "**Sewage**" means liquid waste containing animal or vegetable matter in suspension or solution and may include liquids containing chemicals in solution.

(106) "**Shellfish control authority**" means a state, federal, foreign, tribal, or other government entity legally responsible for administering a program that includes certification of molluscan shellfish harvesters and dealers for interstate commerce.

(107) "**Shellstock**" means raw, in-shell molluscan shellfish.

(108) "**Shiga toxin-producing Escherichia coli**" (STEC) means any E. coli capable of producing shiga toxins (also called verocytotoxins). STEC infections can be asymptomatic or may result in a spectrum of illness ranging from mild non-bloody diarrhea, to hemorrhagic colitis (i.e., bloody diarrhea), to hemolytic uremic syndrome (HUS - a type of kidney failure). Examples of serotypes of STEC include: E. coli O157:H7; E. coli O157:NM; E. coli O26:H11; E. coli O145:NM; E. coli O103:H2; and E. coli O111:NM. STEC are sometimes referred to as VTEC (verocytotoxigenic E. coli) or as EHEC (enterohemorrhagic E. coli). EHEC are a subset of STEC which can cause hemorrhagic colitis or HUS.

(109) "**Shucked shellfish**" means molluscan shellfish that have one or both shells removed.

(110) "**Single-service articles**" means tableware, carry-out utensils, and other items such as bags, containers, placemats, stirrers, straws, toothpicks, and wrappers that are designed and constructed for one time, one person use after which they are intended for discard

(111) "**Single-use articles**" means: (a) utensils and bulk food containers designed and constructed to be used once and discarded.

(b) "single-use articles" includes items such as wax paper, butcher paper, plastic wrap, formed aluminum food containers, jars, plastic tubs or buckets, bread wrappers, pickle barrels, ketchup bottles, and number 10 cans which do not meet the materials, durability, strength, and cleanability specifications in 4-101.11, 4-201.11, and 4-202.11 for multiuse utensils.

(112) "**Slacking**" means the process of moderating the temperature of a food such as allowing a food to gradually increase from a temperature of -23°C (-10°F) to -4°C (25°F) in preparation for deep-fat frying or to facilitate even heat penetration during the cooking of previously block-frozen food such as shrimp.

(113) "**Smooth**" means: (a) A food-contact surface having a surface free of pits and inclusions with a cleanability equal to or exceeding that of (100 grit) number 3 stainless steel;

(b) a nonfood-contact surface of equipment having a surface equal to that of commercial grade hot-rolled steel free of visible scale; and

(c) a floor, wall, or ceiling having an even or level surface with no roughness or projections that render it difficult to clean.

(114) **"Tableware"** means eating, drinking, and serving utensils for table use such as flatware including forks, knives, and spoons; hollowware including bowls, cups, serving dishes, and tumblers; and plates.

(115) **"Temperature measuring device"** means a thermometer, thermocouple, thermistor, or other device that indicates the temperature of food, air, or water.

(116) **"Time/Temperature Control for Safety Food"** means the same as condition control food and potentially hazardous food.

(117) **"USDA"** means the U.S. Department of Agriculture.

(118) **"Utensil"** means a food-contact implement or container used in the storage, preparation, transportation, dispensing, sale, or service of food, such as kitchenware or tableware that is multiuse, single-service, or single-use; gloves used in contact with food; temperature sensing probes of food temperature measuring devices; and probe-type price or identification tags used in contact with food.

(119) **"Variance"** means a written document issued by the regulatory authority that authorizes a modification or waiver of one or more requirements of this rule if, in the opinion of the regulatory authority, a health hazard or nuisance will not result from the modification or waiver.

(120) **"Warewashing"** means the cleaning and sanitizing of utensils and food-contact surfaces of equipment.

(121) **"Water activity"** means a measure of the free moisture in a food, calculated by the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature, indicated by the symbol (A_w), and is often not necessarily synonymous with the moisture content of a food.

(122) **"Whole-muscle, intact beef"** means whole muscle beef that is not injected, mechanically tenderized, reconstructed, or scored and marinated, from which beef steaks may be cut.

(123) **"Wild"** means food not grown in a cultivated manner, or raised in domesticated fashion.

(124) **"Wild game animal"** means game animal as defined in 87-6-101(12), MCA and game fish as defined in 87-6-101(13), MCA.

CHAPTER 2 MANAGEMENT AND PERSONNEL

2-101.11 FOOD SAFETY ASSIGNMENT. (1) Except as specified in (2), the legal licensee must be the person in charge, or must designate a person in charge, and must ensure that a person in charge is present at the food establishment during all hours of operation. ^{Pf}

(2) In a single food establishment with two or more separately licensed establishments that are the responsibility of the same legal licensee, and that are located on the same premises, the legal licensee may, during specific time periods when food is not being processed, packaged, or served, designate a single person in charge who is present on the premises during all hours of operation, and who is responsible for each separately licensed food establishment on the premises. ^{Pf}

2-102.11 DEMONSTRATION. Based on the risks inherent to the food operation, during inspections and upon request the person in charge must demonstrate to the regulatory authority knowledge of foodborne disease prevention, application of the Hazard Analysis of Critical

Control Point principles, and the requirements of this rule. The person in charge must demonstrate this knowledge by:

- (1) Complying with this rule by having no violations of priority items during the current inspection; ^{Pf}
- (2) Being a certified food protection manager who has shown proficiency of required information through passing a test that is part of an accredited program; ^{Pf} or
- (3) Responding correctly to the inspector's questions as they relate to the specific food operation. The areas of knowledge include:
 - (a) describing the relationship between the prevention of foodborne disease and the personal hygiene of a food employee; ^{Pf}
 - (b) explaining the responsibility of the person in charge for preventing the transmission of foodborne disease by a food employee who has a disease or medical condition that may cause foodborne disease; ^{Pf}
 - (c) describing the symptoms associated with the diseases that are transmissible through food; ^{Pf}
 - (d) explaining the significance of the relationship between maintaining the time and temperature of potentially hazardous food and the prevention of foodborne illness; ^{Pf}
 - (e) explaining the hazards involved in the consumption of raw or undercooked meat, poultry, eggs, and fish; ^{Pf}
 - (f) stating the required food temperatures and times for safe cooking of potentially hazardous food including meat, poultry, eggs, and fish; ^{Pf}
 - (g) stating the required temperatures and times for the safe refrigerated storage, hot holding, cooling, and reheating of potentially hazardous food; ^{Pf}
 - (h) describing the relationship between the prevention of foodborne illness and the management and control of the following:
 - (i) cross contamination; ^{Pf}
 - (ii) hand contact with ready-to-eat foods; ^{Pf}
 - (iii) handwashing; ^{Pf} and
 - (iv) maintaining the food establishment in a clean condition and in good repair; ^{Pf}
 - (i) describing foods identified as major food allergens and the symptoms that a major food allergen could cause in a sensitive individual who has an allergic reaction. ^{Pf}
 - (j) explaining the relationship between food safety and providing equipment that is:
 - (i) sufficient in number and capacity; ^{Pf} and
 - (ii) properly designed, constructed, located, installed, operated, maintained, and cleaned; ^{Pf}
 - (k) explaining correct procedures for cleaning and sanitizing utensils and food-contact surfaces of equipment; ^{Pf}
 - (l) identifying the source of water used and measures taken to ensure that it remains protected from contamination such as providing protection from backflow and precluding the creation of cross connections; ^{Pf}
 - (m) identifying poisonous or toxic materials in the food establishment and the procedures necessary to ensure that they are safely stored, dispensed, used, and disposed of according to law; ^{Pf}
 - (n) identifying critical control points in the operation from purchasing through sale or service that when not controlled may contribute to the transmission of foodborne illness and explaining steps taken to ensure that the points are controlled in accordance with the requirements of this rule; ^{Pf}
 - (o) explaining the details of how the person in charge and food employees comply with the HACCP plan if a plan is required by the law, this rule, or an agreement between the regulatory authority and the food establishment; ^{Pf}
 - (p) explaining the responsibilities, rights, and authorities assigned by this rule to the:

- (i) food employee, ^{Pf}
- (ii) conditional employee, ^{Pf}
- (iii) person in charge, ^{Pf}
- (iv) regulatory authority; ^{Pf} and
- (q) explaining how the person in charge, food employees, and conditional employees comply with reporting responsibilities and exclusion or restriction of food employees. ^{Pf}

2-102.12 CERTIFIED MANAGER REQUIRED. (1) At least one employee that has supervisory and management responsibility and the authority to direct and control food preparation and service must be a Certified Food Protection Manager who has shown proficiency of required information through passing a test that is part of an accredited program.

(2) This section does not apply to food establishments:

- (a) deemed by the regulatory authority to pose minimal risk of causing, or contributing to, foodborne illness based on the nature of the operation and extent of food preparation; or
- (b) "Category A" and "Category B" establishments described in rule.

(3)(a) A one-year, phase-in period will apply to affected establishments to have a Certified Food Protection Manager, and the one-year period will begin from the date new rules are adopted.

(b) After the one-year, phase-in period, new legal licensees required to have a Certified Food Protection Manager must have a Certified Food Protection Manager within 90 days of issuance of a new license.

(c) After the one-year, phase-in period, existing legal licensees required to have a Certified Food Protection Manager must have a Certified Food Protection Manager within 45 days of losing their Certified Food Protection Manager.

2-102.20 MANAGER CERTIFICATION. (1) A person in charge who demonstrates knowledge by being a food protection manager that is certified by a food protection manager certification program that is evaluated and listed by a Conference for Food Protection-recognized accrediting agency as conforming to the Conference for Food Protection standards for accreditation of food protection manager certification programs is deemed to comply with 2-102.11(2).

(2) A food establishment that has an employee that is certified by a food protection manager certification program that is evaluated and listed by a Conference for Food Protection recognized accrediting agency as conforming to the Conference for Food Protection standards for accreditation of food protection manager certification programs is deemed to comply with 2-102.12.

2-103.11 PERSON IN CHARGE. The person in charge must ensure that:

(1) Food establishment operations are not conducted in a private home or room that is also used as living or sleeping quarters as specified in 6-202.111. Living quarters must be completely separated from the approved food activities; ^{Pf}

(2) Persons unnecessary to the food establishment operation are not allowed in the food preparation, food storage, or warewashing areas, except that brief visits and tours may be authorized by the person in charge if steps are taken to ensure that exposed food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles are protected from contamination; ^{Pf}

(3) Employees and other persons such as delivery and maintenance persons and pesticide applicators entering the food preparation, food storage, and warewashing areas comply with this rule; ^{Pf}

(4) employees are effectively cleaning their hands, by routinely monitoring the employees' handwashing; ^{Pf}

(5) Employees are visibly observing foods as they are received to determine that they are from approved sources, delivered at the required temperatures, protected from contamination, unadulterated, and accurately presented, by routinely monitoring the employees' observations and periodically evaluating foods upon their receipt; ^{Pf}

(6) Employees are verifying that foods delivered to the food establishment during non-operating hours are from approved sources and are placed into appropriate storage locations such that they are maintained at the required temperatures, protected from contamination, unadulterated, and accurately presented; ^{Pf}

(7) Employees are properly cooking potentially hazardous food, being particularly careful in cooking those foods known to cause severe foodborne illness and death, such as eggs and comminuted meats, through daily oversight of the employees' routine monitoring of the cooking temperatures using appropriate temperature measuring devices properly scaled and calibrated as specified in 4-203.11 and 4-502.11(2); ^{Pf}

(8) Employees are using proper methods to rapidly cool potentially hazardous foods that are not held hot or are not for consumption within 4 hours, through daily oversight of the employees' routine monitoring of food temperatures during cooling; ^{Pf}

(9) Employees are properly sanitizing cleaned multiuse equipment and utensils before they are reused, through routine monitoring of solution temperature and exposure time for hot water sanitizing, and chemical concentration, pH, temperature, and exposure time for chemical sanitizing; ^{Pf}

(10) Except when approval is obtained from the regulatory authority as specified in 3-301.11(5), employees are preventing cross-contamination of ready-to-eat food with bare hands by properly using suitable utensils such as deli-tissue, spatulas, tongs, single-use gloves, or dispensing equipment; ^{Pf}

(11) Employees are properly trained in food safety, including food allergy awareness, as it relates to their assigned duties; ^{Pf}

(12) Food employees and conditional employees are informed in a verifiable manner of their responsibility to report in accordance with law, to the person in charge, information about their health and activities as they relate to diseases that are transmissible through food, as specified in 2-201.11(1); ^{Pf} and

(13) Written procedures and plans, where specified by this rule and as developed by the food establishment, are maintained and implemented as required. ^{Pf}

2-201.11 RESPONSIBILITY (1) The legal licensee must require food employees and conditional employees to report to the person in charge information about their health and activities as they relate to diseases that are transmissible through food. A food employee or conditional employee must report the information in a manner that allows the person in charge to reduce the risk of foodborne disease transmission, including providing necessary additional information, such as the date of onset of symptoms and an illness, or of a diagnosis without symptoms, if the food employee or conditional employee:

(a) has any of the following symptoms:

(i) vomiting, ^P

(ii) diarrhea, ^P

(iii) jaundice, ^P

(iv) sore throat with fever, ^P or

(v) a lesion containing pus such as a boil or infected wound that is open or draining and

is:

(A) on the hands or wrists, unless an impermeable cover such as a finger cot or stall protects the lesion and a single-use glove is worn over the impermeable cover, ^P

(B) on exposed portions of the arms, unless the lesion is protected by an impermeable cover, ^P or

(C) on other parts of the body, unless the lesion is covered by a dry, durable, tight-fitting bandage; ^P

(b) has an illness diagnosed by a health practitioner due to:

(i) Norovirus, ^P

(ii) Hepatitis A virus, ^P

(iii) Shigella spp., ^P

(iv) shiga toxin-producing Escherichia coli, ^P

(v) Salmonella typhi; ^P or

(vi) non-typhoidal Salmonella; ^P

(c) had a previous illness, diagnosed by a health practitioner, within the past 3 months due to Salmonella typhi, without having received antibiotic therapy, as determined by a health practitioner; ^P

(d) has been exposed to, or is the suspected source of, a confirmed disease outbreak, because the food employee or conditional employee consumed or processed food implicated in the outbreak, or consumed food at an event processed by a person who is infected or ill with:

(i) Norovirus within the past 48 hours of the last exposure, ^P

(ii) shiga toxin-producing Escherichia coli or Shigella spp., within the past 3 days of the last exposure, ^P

(iii) Salmonella typhi within the past 14 days of the last exposure, ^P or

(iv) Hepatitis A virus within the past 30 days of the last exposure; ^P or

(e) has been exposed by attending or working in a setting where there is a confirmed disease outbreak, or living in the same household as, and has knowledge about, an individual who works or attends a setting where there is a confirmed disease outbreak, or living in the same household as, and has knowledge about, an individual diagnosed with an illness caused by:

(i) Norovirus within the past 48 hours of the last exposure, ^P

(ii) shiga toxin-producing Escherichia coli or Shigella spp. within the past 3 days of the last exposure, ^P

(iii) Salmonella typhi within the past 14 days of the last exposure, ^P or

(iv) Hepatitis A virus within the past 30 days of the last exposure. ^P

(2) The person in charge must notify the regulatory authority when a food employee is:

(a) jaundiced, ^{Pf} or

(b) diagnosed with an illness due to a pathogen as specified under paragraph (1)(b).^{Pf}

(3) The person in charge must ensure that a conditional employee:

(a) who exhibits or reports a symptom, or who reports a diagnosed illness as specified under paragraphs (1)(a)-(1)(c), is prohibited from becoming a food employee until the conditional employee meets the criteria for the specific symptoms or diagnosed illness as specified in 2-201.13; ^P and

(b) who will work as a food employee in a food establishment that serves as a highly susceptible population and reports a history of exposure as specified under paragraphs (1)(d)-(1)(e), is prohibited from becoming a food employee until the conditional employee meets the criteria as specified in 2-201.13(9). ^P

(4) The person in charge must ensure that a food employee who exhibits or reports a symptom, or who reports a diagnosed illness or a history of exposure as specified under paragraphs (1)(a)-(1)(e) is:

(a) excluded as specified in 2-201.12 (1)-(3), and subparagraphs (4)(a), (5)(a), (6)(a), (7) or (8)(a) and in compliance with the provisions specified in 2-201.13 (1)-(8); ^P or

(b) restricted as specified in 2-201.12 (4)(b), (5)(b), (6)(b), and (8)(b), or 2-201.12(9)-(10) and in compliance with the provisions specified in 2-201.13(4)-(10). ^P

(5) A food employee or conditional employee must report to the person in charge the information as specified in (1). ^{Pf}

- (6) A food employee must:
- (a) comply with an exclusion as specified in 2-201.12(1)–(3) and 2-201.12(4)(a), (5)(a), (6)(a), (7), or (8)(a) and with the provisions specified in 2-201.13(1)–(8);^P or
 - (b) comply with a restriction as specified in 2-201.12(4)(b), (5)(b), (6)(b), (7), (8)(b), or 2-201.12(8)–(10) and comply with the provisions specified in 2-201.13(4)–(10).^P
- (7) Specific communicable disease control measures outlined in this section will be followed, unless more stringent rules are provided in ARM 37.114.501, in such case, the more stringent control applies.

2-201.12 EXCLUSIONS AND RESTRICTIONS. The person in charge must exclude or restrict a food employee from a food establishment in accordance with the following:

- (1) Except when the symptom is from a noninfectious condition, exclude a food employee if the food employee is:
- (a) symptomatic with vomiting or diarrhea;^P or
 - (b) symptomatic with vomiting or diarrhea and diagnosed with an infection from Norovirus, Shigella spp., non-typhoidal Salmonella, or shiga toxin-producing E. coli.^P
- (2) Exclude a food employee who is:
- (a) jaundiced and the onset of jaundice occurred within the last 7 calendar days, unless the food employee provides to the person in charge written medical documentation from a health practitioner specifying that the jaundice is not caused by Hepatitis A virus or other fecal-orally transmitted infection;^P
 - (b) diagnosed with an infection from Hepatitis A virus within 14 calendar days from the onset of any illness symptoms, or within 7 calendar days of the onset of jaundice;^P or
 - (c) diagnosed with an infection from Hepatitis A virus without developing symptoms.^P
- (3) Exclude a food employee who is diagnosed with an infection from Salmonella typhi, or reports a previous infection with Salmonella typhi within the past 3 months as specified in 2-201.11(1)(c).^P
- (4) If a food employee is diagnosed with an infection from Norovirus and is asymptomatic:
- (a) exclude the food employee who works in a food establishment serving a highly susceptible population;^P or
 - (b) restrict the food employee who works in a food establishment not serving a highly susceptible population.^P
- (5) If a food employee is diagnosed with an infection from Shigella spp. and is asymptomatic:
- (a) exclude the food employee who works in a food establishment serving a highly susceptible population;^P or
 - (b) restrict the food employee who works in a food establishment not serving a highly susceptible population.^P
- (6) If a food employee is diagnosed with an infection from shiga toxin-producing E. coli, and is asymptomatic:
- (a) exclude the food employee who works in a food establishment serving a highly susceptible population;^P or
 - (b) restrict the food employee who works in a food establishment not serving a highly susceptible population.^P
- (7) If a food employee is diagnosed with an infection from non-typhoidal Salmonella and is asymptomatic, restrict the food employee who works in a food establishment serving a highly susceptible population or in a food establishment not serving a highly susceptible population.^P
- (8) If a food employee is ill with symptoms of acute onset of sore throat with fever:
- (a) exclude the food employee who works in a food establishment serving a highly susceptible population;^P or

(b) restrict the food employee who works in a food establishment not serving a highly susceptible population. ^P

(9) If a food employee is infected with a skin lesion containing pus such as a boil or infected wound that is open or draining and not properly covered as specified in 2-201.11(1)(a)(v), restrict the food employee. ^P

(10) If a food employee is exposed to a foodborne pathogen as specified in 2-201.11(1)(d)(i)-(iv) or 2-201.11(1)(e)(i)-(iv), restrict the food employee who works in a food establishment serving a highly susceptible population. ^P

2-201.13 REMOVAL, ADJUSTMENT, RETENTION. The person in charge must adhere to the following conditions when removing, adjusting, or retaining the exclusion or restriction of a food employee:

(1) Except when a food employee is diagnosed with an infection from Hepatitis A virus or Salmonella typhi:

(a) reinstate a food employee who was excluded as specified in 2-201.12(1)(a) if the food employee:

(i) is asymptomatic for at least 24 hours; ^P or

(ii) provides to the person in charge written medical documentation from a health practitioner that states the symptom is from a noninfectious condition. ^P

(b) if a food employee was diagnosed with an infection from Norovirus and excluded as specified in 2-201.12(1)(b):

(i) restrict the food employee, who is asymptomatic for at least 24 hours and works in a food establishment not serving a highly susceptible population, until the conditions for reinstatement as specified under paragraphs (4)(a)-(b) are met; ^P or

(ii) retain the exclusion for the food employee, who is asymptomatic for at least 24 hours and works in a food establishment that serves a highly susceptible population, until the conditions for reinstatement as specified under paragraphs (4)(a)-(b) are met. ^P

(c) if a food employee was diagnosed with an infection from Shigella spp. and excluded as specified in 2-201.12(1)(b):

(i) restrict the food employee, who is asymptomatic for at least 24 hours and works in a food establishment not serving a highly susceptible population, until the conditions for reinstatement as specified in (5)(a)-(b) are met; ^P or

(ii) retain the exclusion for the food employee, who is asymptomatic for at least 24 hours and works in a food establishment that serves a highly susceptible population, until the conditions for reinstatement as specified in (5)(a)-(b), or (5)(a) and (3)(a) are met. ^P

(d) if a food employee was diagnosed with an infection from shiga-toxin-producing Escherichia coli and excluded as specified in 2-201.12(1)(b):

(i) restrict the food employee, who is asymptomatic for at least 24 hours and works in a food establishment not serving a highly susceptible population, until the conditions for reinstatement as specified in (6)(a) or (b) are met; ^P or

(ii) retain the exclusion for the food employee, who is asymptomatic for at least 24 hours and works in a food establishment that serves a highly susceptible population, until the conditions for reinstatement as specified in (6)(a) or (b) are met. ^P

(e) if a food employee was diagnosed with an infection from non-typhoidal Salmonella and excluded as specified in 2-201.12(1)(b):

(i) restrict the food employee, who is asymptomatic for at least 30 days until conditions for reinstatement as specified in (7)(a) or (b) are met; ^P or

(ii) retain the exclusion for the food employee who is symptomatic, until conditions for reinstatement as specified in (7)(a) or (7)(b) are met. ^P

(2) Reinstate a food employee who was excluded as specified in 2-201.12(2) if the person in charge obtains approval from the regulatory authority and one of the following conditions is met;

(a) the food employee has been jaundiced for more than 7 calendar days; ^P

(b) the anicteric food employee has been symptomatic with symptoms other than jaundice for more than 14 calendar days; ^P or

(c) the food employee provides to the person in charge written medical documentation from a health practitioner stating that the food employee is free of a Hepatitis A virus infection. ^P

(3) Reinstate a food employee who was excluded as specified in 2-201.12(3) if:

(a) the person in charge obtains approval from the regulatory authority; ^P and

(b) the food employee provides to the person in charge written medical documentation from a health practitioner that states the food employee is free from S. typhi infection. ^P

(4) Reinstate a food employee who was excluded as specified in 2-201.12(1)(b) or (4)(a) or who was restricted in 2-201.12(4)(b) if the person in charge obtains approval from the regulatory authority and one of the following conditions is met:

(a) the excluded or restricted food employee provides to the person in charge written medical documentation from a health practitioner stating that the food employee is free of a Norovirus infection; ^P

(b) the food employee was excluded or restricted after symptoms of vomiting or diarrhea resolved, and more than 48 hours have passed since the food employee became asymptomatic; ^P or

(c) the food employee was excluded or restricted and did not develop symptoms and more than 48 hours have passed since the food employee was diagnosed. ^P

(5) Reinstate a food employee who was excluded as specified in 2-201.12(1)(b) or (5)(a) or who was restricted in 2-201.12(5)(b) if the person in charge obtains approval from the regulatory authority and one of the following conditions is met:

(a) the excluded or restricted food employee provides to the person in charge written medical documentation from a health practitioner stating that the food employee is free of a Shigella spp. infection based on test results showing 2 consecutive negative stool specimen cultures that are taken:

(i) not earlier than 48 hours after discontinuance of antibiotics, ^P and

(ii) at least 24 hours apart; ^P

(b) the food employee was excluded or restricted after symptoms of vomiting or diarrhea resolved, and more than 7 calendar days have passed since the food employee became asymptomatic; ^P or

(c) the food employee was excluded or restricted and did not develop symptoms and more than 7 calendar days have passed since the food employee was diagnosed. ^P

(6) Reinstate a food employee who was excluded or restricted as specified in 2-201.12(1)(b) or (6)(a) or who was restricted in 2-201.12(6)(b) if the person in charge obtains approval from the regulatory authority and one of the following conditions is met:

(a) the excluded or restricted food employee provides to the person in charge written medical documentation from a health practitioner stating that the food employee is free of an infection from shiga-toxin producing Escherichia coli based on test results that show 2 consecutive negative stool specimen cultures that are taken:

(i) not earlier than 48 hours after discontinuance of antibiotics; ^P and

(ii) at least 24 hours apart; ^P

(b) the food employee was excluded or restricted after symptoms of vomiting or diarrhea resolved and more than 7 calendar days have passed since the food employee became asymptomatic; ^P or

(c) the food employee was excluded or restricted and did not develop symptoms and more than 7 days have passed since the food employee was diagnosed. ^P

(7) Reinstate a food employee who was excluded as specified in 2-201.12(1)(b) or who was restricted as specified in 2-201.12(7) if the person in charge obtains approval from the regulatory authority, ^P, and one of the following conditions is met:

(a) the excluded or restricted food employee provides to the person in charge written medical documentation from a health practitioner stating that the food employee is free of a non-typhoidal Salmonella infection based on test results showing 2 consecutive negative stool specimen cultures that are taken;

(i) not earlier than 48 hours after discontinuance of antibiotics, ^P and

(ii) at least 24 hours apart; ^P

(b) the food employee was restricted after symptoms of vomiting or diarrhea resolved, and more than 30 days have passed since the food employee became asymptomatic; ^P or

(c) the food employee was excluded or restricted and did not develop symptoms and more than 30 days have passed since the food employee was diagnosed. ^P

(8) Reinstate a food employee who was excluded or restricted as specified in 2-201.12(8)(a) or (8)(b) if the food employee provides to the person in charge written medical documentation from a health practitioner stating that the food employee meets one of the following conditions:

(a) has received antibiotic therapy for Streptococcus pyogenes infection for more than 24 hours; ^P

(b) has at least one negative throat specimen culture for Streptococcus pyogenes infection; ^P or

(c) is otherwise determined by a health practitioner to be free of a Streptococcus pyogenes infection. ^P

(9) Reinstate a food employee who was restricted as specified in 2-201.12(9) if the skin, infected wound, cut, or pustular boil is properly covered with one of the following:

(a) an impermeable cover such as a finger cot or stall and a single-use glove over the impermeable cover if the infected wound or pustular boil is on the hand, finger, or wrist; ^P

(b) an impermeable cover on the arm if the infected wound or pustular boil is on the arm; ^P or

(c) a dry, durable, tight-fitting bandage if the infected wound or pustular boil is on another part of the body. ^P

(10) Reinstate a food employee who was restricted as specified in 2-201.12(10) and was exposed to one of the following pathogens as specified in 2-201.11(1)(d)(i)-(vi) or 2-201.11(1)(e)(i)-(iv):

(a) Norovirus and one of the following conditions is met:

(i) more than 48 hours have passed since the last day the food employee was potentially exposed; ^P or

(ii) more than 48 hours have passed since the food employee's household contact became asymptomatic. ^P

(b) Shigella spp. or shiga toxin-producing Escherichia coli and one of the following conditions is met:

(i) more than 3 calendar days have passed since the last day the food employee was potentially exposed; ^P or

(ii) more than 3 calendar days have passed since the food employee's household contact became asymptomatic. ^P

(c) S. typhi and one of the following conditions is met:

(i) more than 14 calendar days have passed since the last day the food employee was potentially exposed; ^P or

(ii) more than 14 calendar days have passed since the food employee's household contact became asymptomatic. ^P

(d) Hepatitis A virus and one of the following conditions is

met:

- (i) the food employee is immune to Hepatitis A virus infection because of a prior illness from Hepatitis A; ^P
- (ii) the food employee is immune to Hepatitis A virus infection because of vaccination against Hepatitis A; ^P
- (iii) the food employee is immune to Hepatitis A virus infection because of IgG administration; ^P
- (iv) more than 30 calendar days have passed since the last day the food employee was potentially exposed; ^P
- (v) more than 30 calendar days have passed since the food employee's household contact became jaundiced; ^P or
- (vi) the food employee does not use an alternative procedure that allows bare hand contact with ready-to-eat food until at least 30 days after the potential exposure, as specified in paragraphs (10)(d)(iv) and (v), and the food employee receives additional training about:
 - (A) Hepatitis A symptoms and preventing the transmission of infection, ^P
 - (B) proper handwashing procedures, ^P and
 - (C) protecting ready-to-eat food from contamination introduced by barehand contact. ^P

2-301.11 CLEAN CONDITION. (1) Food employees must keep their hands and exposed portions of their arms clean when handling exposed food. ^P

2-301.12 CLEANING PROCEDURE. (1) Except as specified in (4), food employees must clean their hands and exposed portions of their arms, including surrogate prosthetic devices for hands or arms for at least 20 seconds, using a cleaning compound in a handwashing sink that is equipped as specified in 5-202.12 and 6-301 of this rule regarding handwashing facilities. ^P

(2) food employees must use the following cleaning procedure in the order stated to clean their hands and exposed portions of their arms, including surrogate prosthetic devices for hands and arms:

- (a) rinse under clean, flowing warm water; ^P
- (b) apply an amount of cleaning compound recommended by the cleaning compound manufacturer; ^P
- (c) rub together vigorously for at least 10 to 15 seconds while:
 - (i) paying particular attention to removing soil from underneath the fingernails during the cleaning procedure, ^P and
 - (ii) creating friction on the surfaces of the hands and arms or surrogate prosthetic devices for hands and arms, finger tips, and areas between the fingers; ^P
- (d) thoroughly rinse under clean, flowing warm water; ^P and
- (e) immediately follow the cleaning procedure with thorough drying using a method as specified in 6-301.12. ^P

(3) to avoid re-contaminating their hands or surrogate prosthetic devices, food employees may use disposable paper towels or similar clean barriers when touching surfaces such as manually operated faucet handles on a handwashing sink or the handle of a restroom door.

(4) if approved and capable of removing the types of soils encountered in the food operations involved, an automatic handwashing facility may be used by food employees to clean their hands or surrogate prosthetic devices.

2-301.14 WHEN TO WASH. (1) Food employees must clean their hands and exposed portions of their arms as specified in 2-301.12 immediately before engaging in food preparation including working with exposed food, clean equipment and utensils, and unwrapped single-service and single-use articles. ^P and:

- (a) after touching bare human body parts other than clean hands and clean, exposed portions of arms; ^P
- (b) after using the toilet room; ^P
- (c) after caring for or handling service animals or aquatic animals as specified in 2-403.11(2); ^P
- (d) except as specified in 2-401.11(2), after coughing, sneezing, using a handkerchief or disposable tissue, using tobacco, eating, or drinking; ^P
- (e) after handling soiled equipment or utensils; ^P
- (f) during food preparation, as often as necessary to remove soil and contamination and to prevent cross contamination when changing tasks; ^P
- (g) when switching between working with raw food and working with ready-to-eat food; ^P
- (h) before donning gloves to initiate a task that involves working with food; ^P and
- (i) after engaging in other activities that contaminate the hands. ^P

2-301.15 WHERE TO WASH. (1)(a) Food employees must clean their hands in a handwashing sink or approved automatic handwashing facility. ^{Pf}

(b) Food employees shall not clean their hands in a sink used for food preparation or warewashing, or in a service sink, or a curbed cleaning facility used for the disposal of mop water and similar liquid waste, or using the spray arm of a warewashing machine. ^{Pf}

2-301.16 HAND ANTISEPTICS. A hand antiseptic used as a topical application, a hand antiseptic solution used as a hand dip, or a hand antiseptic soap must:

- (1) Comply with one of the following:
 - (a) be an approved drug that is listed in the FDA publication approved drug products with therapeutic equivalence evaluations as an approved drug based on safety and effectiveness; ^{Pf} or
 - (b) have active antimicrobial ingredients that are listed in the FDA monograph for over-the-counter health-care antiseptic drug products as an antiseptic handwash, ^{Pf} and
 - (2) Consist only of components which the intended use of each complies with one of the following:
 - (a) a threshold of regulation exemption under 21 CFR 170.39 - Threshold of Regulation for Substances Used in Food-contact Articles; ^{Pf} or
 - (b) 21 CFR Part 178 - indirect food additives: adjuvants, production aids, and sanitizers as regulated for use as a food additive with conditions of safe use, ^{Pf} or
 - (c) a determination of Generally Recognized as Safe (GRAS). Partial listings of substances with food uses that are GRAS may be found in 21 CFR Part 182 – Substances Generally Recognized as Safe, 21 CFR Part 184 - Direct Food Substances Affirmed as Generally Recognized as Safe, or 21 CFR Part 186 – Indirect Food Substances Affirmed as Generally Recognized as Safe For Use In Contact with Food, and in FDA’s inventory of GRAS notices, ^{Pf} or
 - (d) a prior sanction listed under 21 CFR Part 181 – Prior Sanctioned Food Ingredients, ^{Pf}
- or
- (e) a food contact notification that is effective, ^{Pf} and
- (3) Be applied only to hands that are cleaned as specified in 2-301.12. ^{Pf}
 - (4) If a hand antiseptic or a hand antiseptic solution used as a hand dip does not meet the criteria specified in (1)(b), use must be:
 - (a) followed by thorough hand rinsing in clean water beforehand contact with food or by the use of gloves; ^{Pf} or
 - (b) limited to situations that involve no direct contact with food by the bare hands. ^{Pf}
 - (5) A hand antiseptic solution used as a hand dip must be maintained clean and at a strength equivalent to at least 100 mg/L chlorine. ^{Pf}

2-302.11 FINGERNAILS (1) Food employees must keep their fingernails trimmed, filed, and maintained so the edges and surfaces are cleanable and not rough. ^{Pf}

(2) Unless wearing intact gloves in good repair, a food employee may not wear fingernail polish or artificial fingernails when working with exposed food. ^{Pf}

2-303.11 JEWELRY (1) Except for a plain ring such as a wedding band, while preparing food, food employees may not wear jewelry including medical information jewelry on their arms and hands.

2-304.11 CLOTHING (1) Food employees must wear clean outer clothing to prevent contamination of food, equipment, utensils, linens, and single-service and single-use articles, and the clothing should be light colored.

2-401.11 EATING, DRINKING, TOBACCO (1) Except as specified in (2), an employee must eat, drink, use any form of tobacco, or simulated tobacco products only in designated areas where the contamination of exposed food; clean equipment, utensils, and linens; unwrapped single-service and single-use articles; or other items needing protection cannot result.

(2) A food employee may drink from a closed beverage container if the container is handled to prevent contamination of:

(a) the employee's hands;

(b) the container; and

(c) exposed food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles.

2-401.12 EYES, NOSE, MOUTH (1) Food employees experiencing persistent sneezing, coughing, or a runny nose that causes discharges from the eyes, nose, or mouth may not work with exposed food; clean equipment, utensils, and linens; or unwrapped single-service or single-use articles.

2-402.11 HAIR RESTRAINTS (1) Except as provided in (2), food employees must wear hair restraints such as hats, hair coverings or nets, beard restraints, and clothing that covers body hair, that are designed and worn to effectively keep their hair from contacting exposed food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles.

(2) This section does not apply to food employees such as counter staff who only serve beverages and wrapped or packaged foods, hostesses, and wait staff if they present a minimal risk of contaminating exposed food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles.

2-403.11 ANIMALS (1) Except as specified in (2), food employees may not care for or handle animals that may be present such as patrol dogs, service animals, or pets that are allowed as specified in 6-501.115(2)(b)(d). ^{Pf}

(2) Food employees with service animals may handle or care for their service animals and food employees may handle or care for fish in aquariums or molluscan shellfish or crustacea in display tanks if they wash their hands as specified in 2-301.12 and 2-301.14(1)(c).

2-501.11 VOMIT, DIARRHEA (1) A food establishment must have procedures for employees to follow when responding to vomiting or diarrheal events that involve the discharge of vomitus or fecal matter onto surfaces in the food establishment. the procedures must address the specific actions employees must take to minimize the spread of contamination and the exposure of employees, consumers, food, and surfaces to vomitus or fecal matter. ^{Pf}

CHAPTER 3 FOOD

3-101.11 UNADULTERATED, NOT MISBRANDED (1) Food must be safe, unadulterated, and, as specified in 3-601.12, honestly presented, and not misbranded. ^P

3-201.11 FOOD SOURCES (1) Food must be obtained from sources that comply with law. ^P

(2) Food processed in a private home may not be used or offered for human consumption in a food establishment. ^P

(3) Packaged food must be labeled as specified in law, including ARM 37.110.101(1), 21 CFR 101 Food Labeling, 9 CFR 317 Labeling, Marking Devices, and Containers, and 9 CFR 381 subpart N Labeling and Containers, and as specified in 3-202.17 and 3-202.18. ^{Pf}

(4) Fish, other than those specified in 3-402.11(2), that are intended for consumption in raw or undercooked form may be offered for sale or service if they are obtained from a supplier that freezes the fish as specified in 3-402.11; or if they are frozen on the premises as specified in 3-402.11 and records are retained as specified in 3-402.12.

(5) Eggs that have not been specifically treated to destroy all viable Salmonellae must be labeled to include safe handling instructions as specified in law, including 21 CFR 101.17(h).

3-201.12 HERMETICALLY SEALED CONTAINERS (1) Food in a hermetically sealed container must be obtained from a food processing and packaging plant that is regulated by the food regulatory agency that has jurisdiction over the plant. ^P

3-201.13 MILK AND MILK PRODUCTS (1) Fluid milk and milk products must be obtained from sources that comply with Grade A standards as specified in law. ^P

3-201.14 FISH (1) Fish that are received for sale or service must be:

(a) commercially and legally caught or harvested; ^P or

(b) approved for sale or service. ^P

(2) Molluscan shellfish that are recreationally caught may not be received for sale or service. ^P

3-201.15 MOLLUSCAN SHELLFISH (1) Molluscan shellfish must be obtained from sources according to law and the requirements specified in the U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, National Shellfish Sanitation program guide for the control of molluscan shellfish. ^P

(2) Molluscan shellfish received in interstate commerce must be from sources that are listed in the interstate certified shellfish shippers list. ^P

3-201.16 WILD MUSHROOMS AND WILD PLANTS (1) License: persons engaged in warehousing or processing of wild mushrooms or wild plants for distribution to retail food establishments, or other persons involved in providing food directly to consumers must procure an annual license from the department.

(2) Harvesting: wild mushrooms or wild plants harvested in Montana under this rule from any public or private land must be obtained in full compliance with law;

(a) state land: wild mushrooms or wild plants harvested in excess of the personal harvest allowance for commercial purposes from any state public land must receive and keep for inspection or investigation purposes written harvest permission from the Montana Department of Natural Resources, Conservation Trust Land Management Division;

(b) federal land: wild mushrooms or wild plants harvested in excess of the personal harvest allowance for commercial purposes from any federal public land must receive and keep for inspection or investigation purposes a Commercial Use Permit from the United States Forest Service; and

(c) tribal land: wild mushrooms or wild plants harvested in excess of the personal harvest allowance for commercial purposes from any tribal land must receive and keep for inspection or investigation purposes written documentation of harvest permission from the appropriate tribal authority.

(3) Approved list: only the following wild mushrooms may be offered to retailers, or other persons engaged in providing food directly to the consumer:

- (a) black trumpet mushroom (yet unnamed Montana species similar to the *Craterellus fallax* group);
- (b) chanterelle mushroom (*Cantharellus cibarius* variety *roseocanus*, and *C. subalbidus*);
- (c) clustered blue chanterelle mushroom (*Polyozellus multiplex*)
- (d) comb tooth mushroom (*Hericium corraloides*, formerly known as *Hericium ramosum*, and *H. erinaceus*);
- (e) king bolete mushroom (*Boletus edulis*);
- (f) lobster mushroom (*Hypomyces lactifluorum*)
- (g) morel mushrooms (*Morchella* species, including, but not limited to: black morel [*Morchella elata* group], and yellow morel [*Morchella americana*, formerly known as *esculenta*]);
- (h) orange-latex milky mushroom, saffron milk camp (*Lactarius deliciosus* group)
- (i) oyster mushroom (*Pleurotus pulmonarius*, and *P. populinus*)
- (j) sweet tooth mushroom (*Hydnum repandum* formerly *Dentinum repandum*, and *H. umbilicatum*);
- (k) trumpet chanterelle mushroom (*Craterellus tubaeformis*, formerly known as *Cantharellus tubaeformis*); and
- (l) white matsutake mushroom (*Tricholoma magnivelare*, formerly known as *Armillaria ponderosa* and *Tricholoma ponderosum*).

(4) Harvest log: each and every wild mushroom or wild plants lot will be documented on a harvest log to include the following information:

- (a) year and day of harvest;
- (b) scientific name (Latin binomial) of the wild mushrooms or wild plants identifying the genus and species of the food;
- (c) common name of the wild mushrooms or wild plants;
- (d) usual name of any and all wild plant parts to be used in food or dietary supplements (e.g., bark, bulb, flower, fruit, leaf, needle, stem, root, etc.).
- (e) county name in which the wild mushrooms or wild plants were harvested;
- (f) approximate quantity of wild mushrooms or wild plants harvested for each lot;
- (g) written documentation that the area in which the wild mushroom or wild plant lot was harvested was not subjected to the application of any wildland fire chemicals (retardants, foams, or water enhancers) listed by the United States Forest Service within 90 days of the date of harvest;
- (h) written documentation that the area in which the wild mushroom or wild plant lot was harvested was not subjected to the application of any manufactured chemical containing hydrazine within 30 days of the date of harvest;
- (i) full legal name, job title, current address, and current telephone number of the individual who identified the wild mushrooms or wild plants; and
- (j) name of the legal licensee.

(5) Package labeling: (a) wild mushrooms or wild plants packaged as individual consumer commodities, or contained as bulk food items must comply with applicable labeling requirements of ARM 37.110.101(1)(j), and labeled or disclosed with the following additional information for the retailer, or other persons involved in providing food directly to consumers:

- (b)(i) scientific name (Latin binomial) of the wild mushroom or wild plants with the genus and species clearly marked on the package or container; and
- (ii) common name of the wild mushroom or wild plants clearly marked on the package or container.

(6)(a) Training: the legal licensee must create and keep for inspection and investigation purposes written documentation that the legal licensee has determined the mushroom or plant identifier is qualified through academic coursework and field coursework, or field experience to

correctly identify edible Montana wild mushrooms or wild plants and poisonous Montana wild mushrooms or wild plants. The documentation must also comply with (4)(h); and

(b) The local regulatory authority may create a wild mushroom or wild plant identification training regulation that is specific to:

- (i) wild mushroom species listed in (3) that are also within their jurisdiction; and
- (ii) wild edible plant species that are within their jurisdiction.

3-201.17 WILD GAME ANIMALS (1) Wild game animals used as food must comply with applicable sections of 81-9-230, 87-4-702, and 87-6-106(1), MCA.

3-202.11 FOOD TRANSPORT (1)(a) Except as specified in (2), refrigerated, potentially hazardous food must be at a temperature of 5°C (41°F) or below when received, and during transport. ^P

(b) except as approved by the regulatory authority, potentially hazardous food must be transported from a food wholesaler in Montana under mechanical refrigeration. ^P

(2)(a) If a temperature other than 5°C (41°F) for a potentially hazardous food is specified in law governing its distribution, such as laws governing milk and molluscan shellfish, or fish products, the food may be received at the specified temperature.

(b) Unfrozen fish transported in packaging or containers that are not reduced or modified in oxygen content that are from a food wholesaler in Montana must be held at or below 4.4°C (40°F) at all times for control of histamine production in scombroid toxin-forming fish species, such as but not limited to: tuna, bluefish, and mahi mahi.

(3) Raw eggs must be received in refrigerated equipment that maintains an ambient air temperature of 7°C (45°F) or less. ^P

(4) Potentially hazardous food that is cooked to a temperature and for a time specified under this rule must be at a temperature of 57°C (135°F) or above during transport and receiving. ^P

(5) A food that is labeled frozen and shipped frozen by a food processing establishment must be received frozen. ^{Pf}

(6) Upon receipt, potentially hazardous food must be free of evidence of previous temperature abuse. ^{Pf}

(7) Receiving: upon receiving food transported to the food establishment, food employees will examine the food cargo holding unit of the transport vehicle to ensure the cargo holding unit is in adequate condition to protect food from contamination. Primary and secondary cardboard boxes, paper boxes, plastic boxes, paper wraps, plastic wraps, plastic bags, paper bags, and similar foodgrade material containing food, and exposed to weather elements during transport are not adequate protection from possible sources of contamination. ^P

(8) Shipping: upon shipping food transported from the food establishment, food employees will examine the food cargo holding unit of the transport vehicle to ensure the cargo holding unit is in adequate condition to protect food from contamination. Primary and secondary cardboard boxes, paper boxes, plastic boxes, paper wraps, plastic wraps, plastic bags, paper bags, and similar foodgrade material containing food, and exposed to weather elements during transport are not adequate protection from possible sources of contamination. ^P

3-202.12 ADDITIVES (1) Food may not contain unapproved food additives or additives that exceed amounts specified in 21 CFR Parts 170-180 relating to food additives, Generally Recognized As Safe or prior sanctioned substances that exceed amounts specified in 21 CFR Parts 181-186, substances that exceed amounts specified in 9 CFR 424.21(b) – Food Ingredients and Sources of Radiation, or pesticide residues that exceed provisions specified in 40 CFR Part 180 - Tolerances for Pesticides Chemicals in Food, and Exceptions. ^P

3-202.13 EGGS (1) Eggs must be received clean and sound and may not exceed the restricted egg tolerances for U.S. Consumer Grade B as specified in United States Standards, Grades, and Weight classes for Shell Eggs, AMS 56.200 et seq., administered by the Agricultural Marketing Service of USDA. ^P

3-202.14 PASTEURIZATION (1) Egg products must be obtained pasteurized. ^P

(2) Fluid and dry milk and milk products must:

(a) be obtained pasteurized; ^P and

(b) comply with grade a standards as specified in law. ^P

(3) Frozen milk products, such as ice cream, must be obtained pasteurized as specified in 21 CFR Part 135 - Frozen Desserts. ^P

(4) Cheese must be obtained pasteurized unless alternative procedures to pasteurization are specified in the CFR, such as 21 CFR Part 133 - Cheeses and related Cheese Products, for Curing Certain Cheese Varieties. ^P

3-202.15 PACKAGE INTEGRITY (1) Food packages must be in good condition and protect the integrity of the contents so that the food is not exposed to adulteration or potential contaminants. ^{Pf}

3-202.16 ICE FOR COOLING (1) Ice used as a cooling medium must be made from drinking water. ^P

3-202.17 SHUCKED SHELLFISH (1) Raw shucked shellfish must be obtained in nonreturnable packages which bear a legible label that identifies the: ^{Pf}

(a) name, address, and certification number of the shucker, packer or re-packer of the molluscan shellfish; ^{Pf} and

(b) the "Sell by" or "Best if used by" date for packages with a capacity of less than 1.89 L (one half-gallon) or the date shucked for packages with a capacity of 1.89 L (one half-gallon), or more. ^{Pf}

(2) A package of raw shucked shellfish that does not bear a label or which bears a label which does not contain all the information as specified in (1) must be subject to a hold order, as allowed by law, or seizure and destruction in accordance with 21 CFR Subpart D – Specific Administrative Decisions Regarding Interstate Shipments, Section 1240.60(d) Molluscan shellfish.

3-202.18 SHELLSTOCK IDENTIFICATION (1) Shellstock must be obtained in containers bearing legible source identification tags or labels that are affixed by the harvester or dealer that depurates, ships, or re-ships the shellstock, as specified in the National Shellfish Sanitation program guide for the control of molluscan shellfish, and that list: ^{Pf}

(a) except as specified in (3), on the harvester's tag or label, the following information in the following order: ^{Pf}

(i) the harvester's identification number that is assigned by the shellfish control authority, ^{Pf}

(ii) the date of harvesting, ^{Pf}

(iii) the most precise identification of the harvest location or aquaculture site that is practicable based on the system of harvest area designations that is in use by the shellfish control authority and including the abbreviation of the name of the state or country in which the shellfish are harvested, ^{Pf}

(iv) the type and quantity of shellfish, ^{Pf} and

(v) the following statement in bold, capitalized type: "This tag is required to be attached until container is empty or retagged and thereafter kept on file for 90 days"; ^{Pf} and

(b) except as specified in (4), on each dealer's tag or label, the following information in the following order: ^{Pf}

(i) the dealer's name and address, and the certification number assigned by the shellfish control authority, ^{Pf}

(ii) the original shipper's certification number including the abbreviation of the name of the state or country in which the shellfish are harvested, ^{Pf}

(c) the same information as specified for a harvester's tag in (1)(a)(ii)-(iv), ^{Pf} and

(d) the following statement in bold, capitalized type: "This tag is required to be attached until container is empty and thereafter kept on file for 90 days." ^{Pf}

(2) A container of shellstock that does not bear a tag or label or that bears a tag or label that does not contain all the information as specified in (1) must be subject to a hold order, as allowed by law, or seizure and destruction in accordance with 21 CFR Subpart D - Specific Administrative Decisions Regarding Interstate Shipments, Section 1240.60 (d).

(3) If a place is provided on the harvester's tag or label for a dealer's name, address, and certification number, the dealer's information must be listed first.

(4) If the harvester's tag or label is designed to accommodate each dealer's identification as specified in (1)(b)(i)(ii), individual dealer tags or labels need not be provided.

3-202.19 RECEIVING SHELLSTOCK (1) When received by a food establishment, shellstock must be reasonably free of mud, dead shellfish, and shellfish with broken shells. Dead shellfish or shellstock with badly broken shells must be discarded.

3-202.110 PRE-PACKAGED JUICE (1)(a) Pre-packaged juice must be obtained from a processor with a HACCP system as specified in 21 CFR Part 120 Hazard Analysis of Critical Control Points (HACCP) systems; ^{Pf} and

(b) pre-packaged juice must be obtained pasteurized or otherwise treated to attain a 5-log reduction of the most resistant microorganism of public health significance, as specified in 21 CFR 120.24 Process Controls. ^P

(2) Packaged and bulk juice manufacturers must comply with 3-404.11(3)(a).

3-203.11 MOLLUSCAN SHELLFISH, ORIGINAL CONTAINER (1) Except as specified in (2), molluscan shellfish may not be removed from the container in which they are received other than immediately before sale or preparation for service.

(2) For display purposes, shellstock may be removed from the container in which they are received, displayed on drained ice, or held in a display container if:

(a) the source of the shellstock on display is identified as specified in 3-202.18 and recorded as specified in 3-203.12; and

(b) the shellstock are protected from contamination.

3-203.12 SHELLSTOCK IDENTIFICATION MAINTENANCE (1) Except as specified in (3)(b) of, shellstock tags or labels must remain attached to the container in which the shellstock are received until the container is empty. ^{Pf}

(2) The date when the last shellstock from the container is sold or served must be recorded on the tag or label. ^{Pf}

(3) The identity of the source of shellstock that are sold or served must be maintained by retaining shellstock tags or labels for 90 calendar days from the date that is recorded on the tag or label, as specified in 2, by: ^{Pf}

(a) using an approved record keeping system that keeps the tags or labels in chronological order correlated to the date that is recorded on the tag or label, as specified in 2; ^{Pf} and

(b) if shellstock are removed from its tagged or labeled container:

(i) preserving source identification by using a record keeping system as specified in (3)(a), ^{Pf} and

(ii) ensuring that shellstock from one tagged or labeled container are not commingled with shellstock from another container with different certification numbers; different harvest

dates; or different growing areas as identified on the tag or label before being ordered by the consumer. ^{Pf}

3-301.11 PREVENTING CONTAMINATION FROM HANDS (1) Food employees must wash their hands as specified in 2-301.12.

(2) Except when washing fruits and vegetables as specified in 3-302.15 or as specified in (4) and (5), food employees may not contact exposed, ready-to-eat food with their bare hands and must use suitable utensils such as deli tissue, spatulas, tongs, single-use gloves, or dispensing equipment. ^P

(3) Food employees must minimize bare hand and arm contact with exposed food that is not in a ready-to-eat form. ^{Pf}

(4) Paragraph (2) does not apply to a food employee that contacts exposed, ready-to-eat food with bare hands at the time the ready-to-eat food is being added as an ingredient to a food that:

(a) contains a raw animal food and is to be cooked in the food establishment to heat all parts of the food to the minimum temperatures specified in 3-401.11 and 3-401.12; or

(b) does not contain a raw animal food, but is to be cooked in the food establishment to heat all parts of the food to a temperature of at least 63°C (145°F).

(5) Food employees not serving a highly susceptible population may contact exposed, ready-to-eat food with their bare hands if:

(a) the legal licensee obtains prior approval from the regulatory authority;

(b) written procedures are maintained in the food establishment and made available to the regulatory authority upon request that include:

(i) for each bare-hand contact procedure, a listing of the specific ready-to-eat foods that are touched by bare hands; and

(ii) diagrams and other information showing that handwashing facilities, installed, located, equipped, and maintained as specified in 5-203.11, 5-204.11, 5-205.11, 6-301.11, 6-301.12, and 6-301.14, are in an easily accessible location and in close proximity to the work station where the bare hand contact procedure is conducted;

(c) a written employee health policy is in place that details how the food establishment complies with 2-201.11, 2-201.12, and 2-201.13 including:

(i) documentation that food employees and conditional employees acknowledge that they are informed to report information about their health and activities as they relate to gastrointestinal symptoms and diseases that are transmittable through food as specified in 2-201.11(1),

(ii) documentation that food employees and conditional employees acknowledge their responsibilities as specified in 2-201.11(5) and (6), and

(iii) documentation that the person in charge acknowledges the responsibilities as specified in 2-201.11(2)-(4), 2-201.12, and 2-201.13;

(iv) documentation that food employees acknowledge that they have received training in:

(A) the risks of contacting the specific ready-to-eat foods with bare hands,

(B) proper handwashing as specified in 2-301.12,

(C) when to wash their hands as specified in 2-301.14,

(D) where to wash their hands as specified in 2-301.15,

(E) proper fingernail maintenance as specified in 2-302.11,

(F) prohibition of jewelry as specified in 2-303.11, and

(G) good hygienic practices as specified in 2-401.11 and 2-401.12;

(d) documentation that hands are washed before food preparation and as necessary to prevent cross contamination by food employees as specified in 2-301.11, 2-301.12, 2-301.14, and 2-301.15 during all hours of operation when the specific ready-to-eat foods are processed;

(e) documentation that food employees contacting ready-to-eat food with bare hands use two or more of the following control measures to provide additional safeguards to hazards associated with bare hand contact:

- (i) double handwashing,
- (ii) nail brushes,
- (iii) a hand antiseptic after handwashing as specified in 2-301.16,
- (iv) incentive programs such as paid sick leave that assist or encourage food employees not to work when they are ill, or
- (v) other control measures approved by the regulatory authority; and
- (vi) documentation that corrective action is taken when (5)(a)–(f) are not followed.

3-301.12 TASTING (1) A food employee may not use a utensil more than once without cleaning and sanitizing between uses when tasting food that is to be sold or served. ^P

3-302.11 CROSS CONTAMINATION (1) Food must be protected from cross contamination by:

(a) except as provided in (1)(a)(iii), separating raw animal foods during storage, preparation, holding, and display from:

- (i) raw ready-to-eat food including other raw animal food such as fish for sushi or molluscan shellfish, or other raw ready-to-eat food such as fruits and vegetables, ^P and
- (ii) cooked ready-to-eat food; ^P
- (iii) frozen, commercially processed and packaged raw animal food may be stored or displayed with or above frozen, commercially processed and packaged, ready-to-eat food.

(b) except when combined as ingredients, separating types of raw animal foods from each other such as beef, fish, lamb, pork, and poultry during storage, preparation, holding, and display by:

- (i) using separate equipment for each type, ^P or
 - (ii) arranging each type of food in equipment so that cross contamination of one type with another is prevented, ^P and
 - (iii) preparing each type of food at different times or in separate areas; ^P
- (c) cleaning equipment and utensils as specified in 4-602.11(1) and sanitizing as specified in 4-703.11;
- (d) except as specified in 3-501.15(2)(b) and in (2), storing the food in packages, covered containers, or wrappings;
- (e) cleaning hermetically sealed containers of food of visible soil before opening;
- (f) protecting food containers that are received packaged together in a case or overwrap from cuts when the case or overwrap is opened;
- (g) storing damaged, spoiled, or recalled food being held in the food establishment as specified in 6-404.11; and
- (h) separating fruits and vegetables, before they are washed as specified in 3-302.15 from ready-to-eat food.

(2) Paragraph (1)(d) does not apply to:

- (a) whole, uncut, raw fruits and vegetables and nuts in the shell, that require peeling or hulling before consumption;
- (b) primal cuts, quarters, or sides of raw meat or slab bacon that are hung on clean, sanitized hooks or placed on clean, sanitized racks;
- (c) whole, uncut, processed meats such as country hams, and smoked or cured sausages that are placed on clean, sanitized racks;
- (d) food being cooled as specified in 3-501.15(2)(b); or
- (e) shellstock.

3-302.110 CROSS CONTACT (1) Food must be protected from cross-contact contamination by separating major allergen foods, which are milk, eggs, peanuts, tree nuts, fish shellfish, wheat, and soybeans.

(2) Equipment and utensils not exclusively dedicated to process a single type of major allergen food must be thoroughly cleaned between uses to sufficiently reduce the presence of any major allergen, with the intent of elimination of the major allergen. If processing a major allergen, operators are strongly urged to dedicate equipment and utensils to that single purpose.

3-302.12 FOOD STORAGE IDENTIFICATION (1) Except for containers holding food that can be readily and unmistakably recognized such as dry pasta, working containers holding food or food ingredients that are removed from their original packages for use in the food establishment, such as cooking oils, flour, herbs, potato flakes, salt, spices, and sugar must be identified with the common name of the food.

3-302.13 PASTEURIZED EGGS (1) Pasteurized eggs or egg products must be substituted for raw eggs in the preparation of foods such as Caesar salad, hollandaise or béarnaise sauce, mayonnaise, meringue, eggnog, ice cream, and egg-fortified beverages that are not cooked as specified in 3-401.11(1)(a)-(b);^P

3-302.14 UNAPPROVED ADDITIVES (1) Food must be protected from contamination that may result from the addition of, as specified in 3-202.12:

(a) unsafe or unapproved food or color additives;^P and

(b) unsafe or unapproved levels of approved food and color additives.^P

(2) A food employee may not:

(a) apply sulfiting agents to fresh fruits and vegetables intended for raw consumption or to a food considered to be a good source of vitamin B1;^P or

(b) except for grapes, serve or sell food specified in (2)(a) that is treated with sulfiting agents before receipt by the food establishment.^P

3-302.15 WASHING FRUITS AND VEGETABLES (1) Except as specified in (2) and except for whole, raw fruits and vegetables that are intended for washing by the consumer before consumption, raw fruits and vegetables must be thoroughly washed in water to remove soil and other contaminants before being cut, combined with other ingredients, cooked, served, or offered for human consumption in ready-to-eat form.

(2) Fruits and vegetables may be washed by using chemicals as specified in 7-204.12.

(3) Devices used for on-site generation of chemicals meeting the requirements specified in 21 CFR 173.315, chemicals used in the washing or to assist in the peeling of fruits and vegetables, for the washing of raw, whole fruits and vegetables must be used in accordance with the manufacturer's instructions.^{Pf}

3-303.11 COOLANT ICE RESTRICTED (1) After use as a medium for cooling the exterior surfaces of food such as melons or fish, packaged foods such as canned beverages, or cooling coils and tubes of equipment, ice may not be used as food.^P

3-303.12 FOOD IN CONTACT WITH WATER OR ICE (1) Packaged food may not be stored in direct contact with ice or water if the food is subject to the entry of water because of the nature of its packaging, wrapping, or container or its positioning in the ice or water

(2) Except as specified in (3) and (4), unpackaged food may not be stored in direct contact with undrained ice.

(3) Whole, raw fruits or vegetables; cut, raw vegetables such as celery or carrot sticks or cut potatoes; and tofu may be immersed in ice or water.

(4) Raw poultry and raw fish that are shipped or received immersed in ice in shipping containers may remain in that condition while in transport, storage awaiting preparation, display, service, or sale.

3-304.11 FOOD CONTACT WITH EQUIPMENT AND UTENSILS (1) Food must only contact surfaces of:

- (a) Equipment and utensils that are cleaned as specified under part 4-6 of this rule and sanitized as specified under part 4-7 of this rule; ^P
- (b) single-service and single-use articles; ^P or
- (c) linens, such as cloth napkins, as specified in 3-304.13 that are laundered as specified under part 4-8 of this rule. ^P

3-304.12 UTENSILS IN-USE, BETWEEN-USE (1) During pauses in food preparation or dispensing, food preparation and dispensing utensils must be stored:

- (a) except as specified in (1)(b), in the food with their handles above the top of the food and the container;
- (b) in food that is not CCF, with their handles above the top of the food within containers or equipment that can be closed, such as bins of sugar, flour, or cinnamon;
- (c) on a clean portion of the food preparation table or cooking equipment only if the in-use utensil and the food-contact surface of the food preparation table or cooking equipment are cleaned and sanitized at a frequency specified in 4-602.11 and 4-702.11;
- (d) in flowing water of sufficient velocity to flush particulates to the drain, if used with moist food such as ice cream or mashed potatoes;
- (e) in a clean, protected location if the utensils, such as ice scoops, are used only with a food that is not potentially hazardous food; or
- (f) in a container of water if the water is maintained at a temperature of at least 57°C (135°F) and the container is cleaned at a frequency specified in 4-602.11(4)(g).

3-304.13 LINENS AND NAPKINS (1) Linens, such as cloth napkins, may not be used in contact with food unless they are used to line a container for the service or preparation of foods, and the linens and napkins are replaced each time the container is used or reused, and is considered to not pose a hazard by the regulatory authority.

3-304.14 WIPING CLOTHS (1) Cloths in-use for wiping food spills from possibly contaminated containers that occur as food is being prepared must be:

- (a) maintained dry; and
 - (b) used for no other purpose.
- (2) Cloths in-use for wiping counters and other equipment surfaces must be:
- (a) held between uses in a chemical sanitizer solution at a concentration specified in 4-501.114; and
 - (b) laundered daily as specified in 4-802.11(4).
- (3) Cloths in-use for wiping surfaces in contact with raw animal foods must be kept separate from cloths used for other purposes.
- (4) Dry wiping cloths and the chemical sanitizing solutions specified in (2)(a) in which wet wiping cloths are held between uses must be free of food debris and visible soil.
- (5) Containers of chemical sanitizing solutions specified in (2)(a) in which wet wiping cloths are held between uses must be stored off the floor and used in a manner that prevents contamination of food, equipment, utensils, linens, single-service, or single-use articles.
- (6) Single-use disposable sanitizer wipes must be used in accordance with EPA-approved manufacturer's label use instructions.

3-304.15 GLOVE USE (1) If used, single-use gloves must be used for only one task such as working with ready-to-eat food or with raw animal food, used for no other purpose, and discarded when damaged or soiled, or when interruptions occur in the operation. ^P

(2) Except as specified in (3), slash-resistant gloves that are used to protect the hands during operations requiring cutting must be used in direct contact only with food that is

subsequently cooked as specified under part 3-4 of this rule such as frozen food or a primal cut of meat.

(3) Slash-resistant gloves may be used with ready-to-eat food that will not be subsequently cooked if the slash-resistant gloves have a smooth, durable, and non-absorbent outer surface; or if the slash-resistant gloves are covered with a smooth, durable, non-absorbent glove, or a single-use glove.

(4) Cloth gloves may not be used in direct contact with food unless the food is subsequently cooked, such as frozen food or a primal cut of meat.

3-304.17 REFILLING RETURNABLES (1) Empty containers returned to a food establishment for cleaning and refilling with food must be cleaned and refilled in a regulated food processing establishment. ^P

(2) A take-home food container returned to a food establishment may be refilled at a food establishment with food if the food container is:

(a) designed and constructed for reuse and in accordance with these rule requirements; ^P

(b) one that was initially provided by the food establishment to the consumer, either empty or filled with food by the food establishment, for the purpose of being returned for reuse;

(c) returned to the food establishment by the consumer after use;

(d) subject to the following steps before being refilled with food:

(i) cleaned as specified under this rule,

(ii) sanitized as specified under this rule; ^P and

(iii) visually inspected by a food employee to verify that the container, as returned, meets the requirements specified under this rule; ^P and

(3) A take-home food container returned to a food establishment may be refilled at a food establishment with beverage if:

(a) the beverage is not a potentially hazardous food;

(b) 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;

(c) 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;

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

(e) 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 as specified in 4-204.13(1), (2), and (4) that cannot be bypassed by the container owner.

(4) Consumer-owned, personal take-out beverage containers, such as thermally insulated bottles, non-spill coffee cups, and promotional beverage glasses, may be refilled by employees or the consumer if refilling is a contamination-free process as specified in 4-204.13 (1), (2), and (4).

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

3-305.11 FOOD STORAGE (1) Except as specified in (2) and (3), food must be protected from contamination by storing the food:

(a) in a clean, dry location;

(b) where it is not exposed to splash, dust, or other contamination; and

(c) at least 15 cm (6 inches) above the floor.

(2) 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 in 4-204.122.

(3) 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.

3-305.12 FOOD STORAGE, PROHIBITED AREAS (1) Food may not be stored:

- (a) in locker rooms;
- (b) in toilet rooms;
- (c) in dressing rooms;
- (d) in garbage rooms;
- (e) in mechanical rooms;
- (f) under sewer lines that are not shielded to intercept potential drips;
- (g) under leaking water lines, including leaking automatic fire sprinkler heads, or under lines on which water has condensed;
- (h) under open stairwells; or
- (i) under or near other sources of contamination.

3-305.14 FOOD PREPARATION (1) During preparation, unpackaged food must be protected from environmental sources of contamination.

3-306.11 FOOD DISPLAY (1) 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 must be protected from contamination by the use of packaging; counter, service line, display cases, or other effective means. ^P

3-306.14 RETURNED FOOD (1) After being served or sold and previously in possession of a consumer, wholesaler or retailer, food that is unused or returned may not be reused as food or offered as food for human consumption, unless approved by the regulatory authority prior to reuse. ^P

3-307.11 MISCELLANEOUS CONTAMINATION SOURCES (1) Food must be protected from contamination that may result from a factor or source not specified under parts 3-301 through 3-306 of this rule.

3-401.11 COOKING RAW ANIMAL FOODS (1) If made for ready-to-eat products, raw animal foods such as eggs, fish, meat, poultry, and foods containing these raw animal foods, must 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:

- (a) 63°C (145°F) or greater for 15 seconds for fish and whole-muscle meat; ^P
- (b) 68°C (155°F) or greater for 15 seconds for raw eggs, ratites, mechanically tenderized meat, injected meats, and comminuted fish; ^P or
- (c) 74°C (165°F) or above for 15 seconds for poultry, baluts, wild game animals, stuffed fish, stuffed meat, stuffed pasta, stuffed poultry, stuffed ratites, or stuffing containing fish, meat, poultry, or ratites. ^P

3-401.12 MICROWAVE COOKING (1) If made for ready-to-eat products, raw animal foods cooked in a microwave oven must be:

- (a) rotated or stirred throughout or midway during cooking to compensate for uneven distribution of heat;
- (b) covered to retain surface moisture;
- (c) heated to a temperature of at least 74°C (165°F) in all parts of the food; ^P and
- (d) allowed to stand covered for 2 minutes after cooking to obtain temperature equilibrium.

3-401.13 PLANT FOOD TREATMENT (1) With consideration to 3-302.15, fruits and vegetables for use as ingredients in ready-to-eat food products must be properly treated to at least achieve a 5-log reduction in target pathogens, through methods such as heating, acidification, high pressure, irradiation, or other safe methods, unless an alternative process is approved by the regulatory authority prior to product production. ^{Pf}

3-401.14 NON-CONTINUOUS COOKING OF RAW ANIMAL FOODS. If made for ready-to-eat products, raw animal foods that are cooked using a non-continuous cooking process must be:

- (1) Subject to an initial heating process that is no longer than 60 minutes in duration; ^P
- (2) Immediately after initial heating, cooled according to the time and temperature parameters specified for cooked potentially hazardous food in 3-501.14(1); ^P
- (3) After cooling, held frozen or cold, as specified for potentially hazardous food in 3-501.16(1)(b); ^P
- (4) Prior to sale or service, cooked using a process that heats all parts of the food to a temperature and for a time as specified in 3-401.11(1)-(3); ^P
- (5) Cooled according to the time and temperature parameters specified for cooked potentially hazardous food in 3-501.14(1) if not either hot held as specified in 3-501.16(1), served immediately, or held using time as a public health control as specified in 3-501.19 after complete cooking; ^P and
 - (6) Processed and stored according to written procedures that:
 - (a) have obtained prior approval from the regulatory authority; ^{Pf}
 - (b) are maintained in the food establishment and are available to the regulatory authority upon request; ^{Pf}
 - (c) describe how the requirements specified in (1)-(5) are to be monitored and documented by the legal licensee and the corrective actions to be taken if the requirements are not met; ^{Pf}
 - (d) 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 in (4) prior to being offered for sale or service; ^{Pf} and
 - (e) describe how the foods, after initial heating, but prior to cooking as specified in (4), are to be separated from ready-to-eat foods as specified in 3-302.11(1). ^{Pf}

3-402.11 PARASITE DESTRUCTION (1) except as specified in (2), before service or sale in ready-to-eat form, raw, raw-marinated, partially cooked, or marinated-partially cooked fish must be:

- (a) 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
 - (b) 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
 - (c) 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
- (2) paragraph (1) does not apply to:
- (a) molluscan shellfish;
 - (b) a scallop product consisting only of the shucked adductor muscle;
 - (c) tuna of the species *thunnus alalunga*, *thunnus albacares* (yellowfin tuna), *thunnus atlanticus*, *thunnus maccoyii* (bluefin tuna, southern), *thunnus obesus* (bigeye tuna), or *thunnus thynnus* (bluefin tuna, northern); or
 - (d) aquacultured fish, such as salmon, that:
 - (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.

(e) fish eggs that have been removed from the skin and rinsed.

3-402.12 RECORDS, CREATION AND RETENTION (1) except as specified in 3-402.11(2) and in (2) of this section, if raw, raw-marinated, partially cooked, or marinated-partially cooked fish are served or sold in ready-to-eat form, the person in charge must record the freezing temperature and time to which the fish are subjected and must retain the records of the food establishment for 90 calendar days beyond the time of service or sale of the fish. ^{Pf}

(2) 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 in 3-402.11 may substitute for the records specified in (1).

(3) 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 3-402.11(2)(c), a written agreement or statement from the supplier or aquaculturist stipulating that the fish were raised and fed as specified in 3-402.11(2)(c) must 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}

3-403.11 REHEATING FOR HOT HOLDING (1) Except as specified in (2),(3), and (5), potentially hazardous food that is cooked, cooled, and reheated for hot holding for ready-to-eat products must be reheated to enable all parts of the food reach a temperature of at least 74°C (165°F) for 15 seconds. ^P

(2) Except as specified in (3), potentially hazardous food reheated in a microwave oven for hot holding must 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 potentially hazardous food that has been commercially processed and packaged in a food processing establishment that is inspected by the regulatory authority that has jurisdiction over the plant, must be heated to a temperature of at least 57°C (135°F) when being reheated for hot holding. ^P

(4) Reheating for hot holding as specified in (1)-(3) must be done rapidly and the time the food is between 5°C (41°F) and the temperatures specified in (1)-(3) may not exceed 2 hours. ^P

3-404.11 SPECIALIZED PROCESSING (1) Acidified foods are regulated under this rule, and under food standards ARM 37.110.101(1)(p) and (u).

(2) Fish and fishery products are regulated under this rule, and under food standards ARM 37.110.101(1)(y).

(3) (a) Fruit and vegetable juice that are packaged as consumer commodities or as bulk juice are regulated under this rule, and under food standards ARM 37.110.101(1)(x).

(4) Thermally processed low-acid foods in hermetically sealed containers are regulated under this rule, and under food standards ARM 37.110.101(1)(p) and (t).

3-501.11 FROZEN FOOD (1) Stored frozen foods must be maintained in a completely frozen state, especially fish in reduced oxygen packaging.

3-501.12 SLACKING (1) Frozen potentially hazardous food that is slacked to moderate the temperature must be held:

(a) under refrigeration that maintains the food temperature at 5°C (41°F) or less; or

(b) at any temperature if the food remains frozen;

(c) fish in reduced oxygen packaging must be cut open at the time of slacking and held under refrigeration at 3°C (38°F) or less.

3-501.13 THAWING. (1) Potentially hazardous food must be thawed:

(a) under refrigeration that maintains the food temperature at 5°C (41°F) or less; or

(b) completely submerged under flowing water at a water temperature of 21°C (70°F) or below, with sufficient water velocity to agitate and float off loose particles in an overflow, and for a period of time that does not allow thawed portions of ready-to-eat food to rise above 5°C (41°F), or;

(c) for a period of time that does not allow thawed portions of a raw animal food requiring cooking to be above 5°C (41°F), for more than 4 hours, including the time the food is exposed to the flowing water, and the time needed for preparation for cooking, or the time it takes under refrigeration to lower the food temperature to 5°C (41°F);

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

(a) cooked; or

(b) thawed in a microwave oven and immediately transferred to conventional cooking equipment, with no interruption in the process.

(3) Reduced oxygen packaged fish that bears a label indicating that it is to be kept frozen until time of use must be removed from the reduced oxygen environment and held at 3°C (38°F) or less:

(a) prior to its thawing under refrigeration as specified in (1); or

(b) prior to, or immediately upon completion of, its thawing using procedures specified in

(2).

3-501.14 COOLING (1) Cooked potentially hazardous food must be cooled:

(a) within 2 hours from 57°C (135°F) to 21°C (70°F); ^P and 57°C

(b) within a total of 6 hours from 57°C (135°F) to 5°C (41°F) or less; ^P or

(c) within the time and temperature parameters described by the process authority. ^P

(2) Potentially hazardous food must be cooled within 4 hours to 5°C (41°F) or less if processed from ingredients at ambient temperature, such as reconstituted foods and canned tuna. ^P

(3) Except as specified in (4), a potentially hazardous food received in compliance with laws allowing a temperature above 5°C (41°F) during shipment from the supplier as specified in 3-202.11(2), must be cooled within 4 hours to 5°C (41°F) or less. ^P

(4) Raw eggs must be received as specified in 3-202.11(3) and immediately placed in refrigerated equipment that maintains an ambient air temperature of 7°C (45°F) or less. ^P

3-501.15 COOLING METHODS (1) Cooling must be accomplished in accordance with the time and temperature criteria specified in 3-501.14 by using one or more of the following methods based on the type of food being cooled:

(a) placing the food in shallow pans; ^{Pf}

(b) separating the food into smaller or thinner portions; ^{Pf}

(c) using rapid cooling equipment; ^{Pf}

(d) stirring the food in a container placed in an ice water bath; ^{Pf}

(e) using containers that facilitate heat transfer; ^{Pf}

(f) adding ice as an ingredient; ^{Pf} or

(g) other effective methods. ^{Pf}

(2) When placed in cooling or cold holding equipment, food containers in which food is being cooled must be:

(a) arranged in the equipment to provide maximum heat transfer through the container walls; and

(b) loosely covered, or uncovered if protected from overhead contamination as specified in 3-305.11(1)(b), during the cooling period to facilitate heat transfer from the surface of the food.

3-501.16 HOT AND COLD HOLDING (1) Except during preparation, cooking, or cooling, or when time is used as the public health control, and except as specified in (2) and (3), potentially hazardous food must be maintained:

(a) at 57°C (135°F) or above, except that cooked and reheated roasts may be held at a temperature of 54°C (130°F) or above; ^P or

(b) at 5°C (41°F) or less. ^P

(2) Eggs that have not been treated to destroy all viable Salmonellae must be stored in refrigerated equipment that maintains an ambient air temperature of 7°C (45°F) or less. ^P

(3) Potentially hazardous food in a homogenous liquid form may be maintained outside of the temperature control requirements, as specified in (1), while contained within specially designed equipment that complies with the design and construction requirements as specified in 4-204.13(5).

3-501.17 DATE MARKING (1) Except when packaging food using a reduced oxygen packaging method as specified in 3-502.12, and except as specified in (5) and (6), refrigerated, ready-to-eat, potentially hazardous food processed and held in a food establishment for more than 24 hours must be clearly marked to indicate the date or day by which the food must be discarded when held at a temperature of 5°C (41°F) or less for a maximum of 7 days. The day of preparation must be counted as day 1. ^{Pf}

(2) Except as specified in (5)–(7), refrigerated, ready-to-eat potentially hazardous food processed and packaged by a food processing establishment must 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 must be discarded, based on the temperature and time combinations specified in (1) and: ^{Pf}

(a) the day the original container is opened in the food establishment must be counted as day 1; ^{Pf} and

(b) 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}

(3) A refrigerated, ready-to-eat potentially hazardous food ingredient or a portion of a refrigerated, ready-to-eat, potentially hazardous food that is subsequently combined with additional ingredients or portions of food must retain the date marking of the earliest-processed or first prepared ingredient. ^{Pf}

(4) A date marking system that meets the criteria stated in (1) and (2) may include:

(a) using a method approved by the regulatory authority for refrigerated, ready-to-eat potentially hazardous 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;

(b) 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 discarded as specified in (1);

(c) 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 discarded as specified in (2); or

(d) using calendar dates, days of the week, color-coded marks, or other effective marking methods, provided that the marking system is disclosed to the regulatory authority upon request.

(5) Paragraphs (1) and (2) do not apply to shellstock.

(6) Paragraph (2) does not apply to the following foods processed and packaged by a food processing establishment inspected by a regulatory authority:

(a) 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;

(b) 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;

(c) 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;

(d) cultured dairy products as defined in 21 CFR Part 131 milk and cream, such as yogurt, sour cream, and buttermilk;

(e) preserved fish products, such as pickled herring and dried or salted cod, and other acidified fish products defined in 21 CFR Part 114 acidified foods;

(f) shelf stable, dry fermented sausages, such as pepperoni and genoa; and

(g) shelf stable salt-cured products such as prosciutto and parma (ham).

3-501.18 DISPOSITION (1) A food specified in 3-501.17 (1)-(2) must be discarded if it:

(a) exceeds the temperature and time combination specified 3-501.17(1), except time that the product is frozen; ^P

(b) is in a container or package that does not bear a date or day; ^P or

(c) is appropriately marked with a date or day that exceeds a temperature and time combination as specified in 3-501.17(1). ^P

(2) Refrigerated, ready-to-eat, potentially hazardous food processed in a food establishment and dispensed through a vending machine with an automatic shutoff control must be discarded if it exceeds a temperature and time combination as specified in 3-501.17(1). ^P

3-501.19 TIME AS A PUBLIC HEALTH CONTROL (1) Time without temperature control for potentially hazardous may not be used in wholesale food establishments, unless written prior approval is given by both the department and local regulatory authority. ^P

3-502.12 REDUCED OXYGEN PACKAGING (1) Except for foods reviewed and approved in 3-404.11 and in (4) and (5), a food establishment that packages potentially hazardous food, using this section, using a reduced oxygen packaging method must control the growth and toxin formation of *Clostridium botulinum* and the growth of *Listeria monocytogenes*, using at least two control barriers, described in (1)(a)-(e). ^P

(a) Packaged food must be maintained at 5°C (41°F) or less; ^{Pf}

(b) has a water activity of 0.91 or less, ^{Pf}

(c) has a pH of 4.6 or less, ^{Pf}

(d) is a meat or poultry product cured at a food processing establishment 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

(e) is a food with a high level of competing organisms such as raw meat, raw poultry, or raw vegetables; ^{Pf}

(2) Except for (4), consumer commodity package labeling must be prominently and conspicuously marked on the principal display panel in bold type on a contrasting background, with the following instructions: ^{Pf}

(a) "Keep refrigerated;" and

(b) "Use By" date that limits the refrigerated shelf life to no more than 30 calendar days from packaging to consumption, except time the product is maintained frozen, or a written process authority assessment specifies an extended time frame, greater than 30 calendar days for the specific product, whichever occurs first. ^P

(3) A food establishment that packages or repackages cheese from previously pasteurized milk sources using a reduced oxygen packaging method must obtain a process authority letter for assessment of the process and packaging before introduction into commerce.

(a) Prior to introduction into commerce, the operator or license applicant must submit the proposal for packaging or repackaging cheese from previously pasteurized milk sources to the local health authority and department for review and approval.

(b) Cheeses packaged or repackaged under this section are limited to those that meet standards of identify as specified in 21 CFR 133.150 hard cheeses, 21 CFR 133.169 pasteurized process cheese or 21 CFR 133.187 semisoft cheeses because intrinsic factors of these cheeses working together act as a secondary barrier to pathogen growth; ^P

(c) labels on the package principal display panel must have a "sell by" or "use by" date, whichever occurs first; ^{Pf} and

(d) discards the reduced oxygen packaged cheese if it is not sold or provided within 30 calendar days of its packaging. ^{Pf}

(4) Fish placed in reduced oxygen packaging must:

(a) be reviewed and approved in 3-404.11(2);

(b) remain frozen during all times of storage, transport, and display;

(c) consumer commodity package labeling must be prominently and conspicuously marked on the principal display panel in bold type of a contrasting background, with the following instructions:

(i) "Keep Frozen", and

(ii) "Thaw under refrigeration" and/or

(iii) "Remove from packaging before thawing".

(5) A food establishment that packages potentially hazardous food, in the absence of two control barriers, using a cook-chill or sous vide process must:

(a) provide to the regulatory authority prior to implementation, a HACCP plan that contains the information as specified in 8-201.14(2) and (4); ^{Pf}

(b) cooked to heat all parts of the food to a temperature and for a time as specified in 3-401.11(1)-(3); ^P

(c) protected from contamination before and after cooking as specified under Parts 3-3 and 3-4 of this rule; ^P

(d) 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

(e) cooled to 5°C (41°F) in the sealed package or bag as specified in 3-501.14 and: ^P

(i) 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

(ii) held at 5°C (41°F) or less for no more than 7 days, at which time the food must be consumed or discarded; ^P or

(iii) held frozen with no shelf life restriction while frozen until consumed or used. ^P

(f) 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}

(vii) 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}

(viii) labeled with the product name and the date packaged; ^{Pf}

(c) maintain the records required to confirm that cooling and cold holding refrigeration time/temperature parameters are required as part of the HACCP plan:

(i) make such records available to the regulatory authority upon request, ^{Pf}

(ii) hold such records for at least 6 months; ^{Pf}

(d) implement written operational procedures and training program as specified in (2)(e).

^{Pf}

(e) create and keep a HACCP plan for operational procedures that:

(i) prohibit contacting ready-to-eat food with bare hands as specified in 3-301.11(2).^{Pf}

- (ii) identify a designated word area and the method by which: ^{Pf}
 - (A) physical barriers or methods of separation of raw foods and ready-to-eat foods minimize cross contamination. ^{Pf}
 - (B) access to the processing equipment is limited to responsible trained personnel familiar with the potential hazards of the operation. ^{Pf}
 - (C) delineate cleaning and sanitization procedures for food-contact surfaces: ^{Pf} and
- (iii) describes the training program that ensures that the individual responsible for the reduced oxygen packaging operation understands the:
 - (A) concepts required for a safe operation; ^{Pf}
 - (B) equipment and facilities; ^{Pf}
 - (C) procedures specified in 8-201.14(2) and (4) ^{Pf}; and
 - (D) is provided to the regulatory authority prior to implementation as specified in 8-201, 13(2).

3-601.11 STANDARDS OF IDENTITY, COMPOSITION (1) Packaged food must comply with standard of identity requirements in ARM 37.110.101 (1)(ab)-(av), and Definitions and standards of identity or composition 9 CFR Part 319, and general requirements in ARM 37.110.101(1)(aa).

(2) If manufactured in Montana, packaged fish, beef, poultry, pork and other animal tissue and organ products in which 3-601.11(1) is silent regarding minimum standards of identities and composition for finished closed-face sandwiches and fishery products, the finished products must comply with applicable requirements below:

(a) (i) In finished closed-face sandwiches when a single animal species is named in the statement of identity on the commodity label, the characterizing ingredient must constitute not less than 20 percent of the total weight of the finished product.

(ii) In finished closed-face sandwiches when multiple animal species constitute the characterizing ingredients of the product, the combined weight of the characterizing ingredients must not be less than 20 percent of the total weight of the finished product, and the lead animal species named in the statement of identity on the commodity label must be the predominant sub-ingredient, if an animal species is named in the statement of identity.

(b) (i) In finished fishery products for which there is no federal standard of identity, when a single animal species is named in the statement of identity on the commodity label and solid particles comprise the characterizing ingredient must constitute not less than 2 percent of the total weight of the finished product.

(ii) In finished fishery products for which there is no federal standard of identity, when multiple animal species constitute the characterizing ingredients of the product as solid particles, the combined weight of the characterizing ingredients must not be less than 2 percent of the total weight of the finished product, and the lead animal species named in the statement of identity on the commodity label must be the predominant sub-ingredient, if an animal species is named in the statement of identity.

3-601.12 HONESTLY PRESENTED (1) Food must be offered for human consumption in a way that does not mislead or misinform the consumer.

(2) Food or color additives, colored overwraps, or lights may not be used to misrepresent the true appearance, color, or quality of a food.

3-601.13 FOOD SAMPLING (1) As part of an off-site marketing activity, a wholesale food establishment legal licensee may offer free food samples to the public when the following items are met:

(a) the local regulatory authority is provided sufficient notice of the exact location and dates of the marketing activity, and is provided all other relevant information the agency needs to ascertain the food safety of the proposed activity. Sufficient notice is determined by the local regulatory authority, but not in excess of 30 days;

(b) the local regulatory authority has assessed and approved the proposed food sampling activity for compliance with the following items:

(i) the type of food offered for sampling is that for which the establishment has been issued a current and valid license, and may be combined or served with other foods provided in the judgment of the regulatory authority no unusual public health hazards or risks are created engaging in that activity.

(ii) the quantity of food offered as a single sample is in the amount a reasonable person would consider as being a sample;

(iii)(A) with the exception in (1)(b)(iii)(B), food preparation is prohibited at the sampling site when a non-potentially hazardous food is changed into potentially hazardous food;

(B) when hermetically sealed containers are broken that hold potentially hazardous food, the food from the container must be served or discarded within four hours or less;

(iv) samples must be kept in clean, non-absorbent, and covered containers intended by the manufacturer for use with foods;

(v) distribution and processing of samples must only occur in an area or shelter that adequately protects food, equipment, and utensils from wind, rain, dust, and other potential contaminants;

(vi) food samples must be distributed by the legal licensee in a manner that is sanitary, and without the possibility of a consumer touching the remaining samples;

(vii) (A) except for (1)(b)(iii)(B), no bare-hand contact is allowed with exposed ready-to-eat food in which the food could be contaminated by hands;

(B) barehand contact may be allowed if all applicable provisions of 3-301.11(5) are met by the legal licensee;

(viii) potable water may be required for handwashing and sanitizing, if the need is deemed necessary, and is approved by the regulatory agency;

(ix) potentially hazardous food samples must be handled in a manner consistent with other applicable sections of this rule;

(x) utensils, single-service articles, and equipment used at sampling sites must be consistent with other applicable sections of this rule;

(xi) wastewater must be disposed of in a manner acceptable by the regulatory authority;

(xii) handwashing stations must be provided when deemed necessary by the regulatory authority, and is consistent with other applicable sections of this rule;

(xiii) toilet facilities for food workers must be provided when deemed necessary by the regulatory authority, and is consistent with 6-402.11; and

(xiv) all other applicable parts of this rule applies to food sampling sites, including but not limited to: time as a public health control; prohibition of live animals, except for service animals; garbage and refuse; smoking and tobacco use; food storage and transportation; and cross-contamination.

(2) The regulatory authority may inspect the sampling site for compliance with (b)(i)–(xiv), and take any appropriate enforcement action allowed in 50-31-202, et seq., MCA regarding adulteration or misbranding.

3-602.11 FOOD LABELS (1) Food packaged in a food establishment, must be labeled as specified in law, including ARM 37.110.101(1)(j), and 9 CFR Part 317 labeling, marking devices, and containers.

(2) Label information must include:

(a) the common name of the food, or absent a common name, an adequately descriptive identity statement;

(b) if made from two or more ingredients, a list of ingredients and sub-ingredients in descending order of predominance by weight, including a declaration of artificial colors, artificial flavors and chemical preservatives, if contained in the food;

(c) an accurate declaration of the net quantity of contents;
(d) the name and place of business of the manufacturer, packer, or distributor; and
(e) 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. ^{Pf}

(f) except as exempted in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 343), nutrition labeling as specified in 21 CFR 101 - Food Labeling and 9 CFR 317, Subpart B Nutrition Labeling.

(g) for any salmonid fish containing canthaxanthin or astaxanthin 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 or astaxanthin.

(3) Bulk food that is available for customer self-dispensing must be prominently labeled with the following information in plain view:

(a) the manufacturer's or processor's label that was provided with the food; or

(b) a card, sign, or other method of notification that includes the information specified in (2)(a), (2)(b), and (2)(f).

(4) Bulk foods not packaged as individual consumer commodities must convey at least the following information to the retailer:

(a) Common name of the food item;

(b) Net contents of the food;

(c) If more than a single-ingredient food, a listing of all ingredients in order of predominance;

(d) Listing of major food allergens, if present; and

(e) Contact information for the responsible firm.

(5) Honey, or mixtures or blended food or dietary supplements products containing honey, manufactured and packaged as consumer commodities within the state, must provide on the product label of display panel, information panel, or both, a warning notice that is prominent and conspicuous in text letters not less than one-sixteen inch in height, based on a lower-case letter "o", with the following, "WARNING: Do not feed honey to children less than one year in age. Honey has the potential to cause infant botulism." ^{Pf}

(6) Consumer and bulk food commodities packages or packaging, whichever is applicable, that have not been adequately treated for potential pathogen reduction, and are not ready to eat, should be labeled with an advisory warning bearing the following statement in a conspicuous and prominent manner: "WARNING: This product is not ready to eat, and should be cooked or properly prepared before consuming."

3-602.12 OTHER LABEL INFORMATION (1) If required by law, consumer warnings must be provided.

(2) Food establishment or manufacturers' dating on foods may not be concealed or altered.

3-701.11 DISCARDING, RECONDITIONING FOOD (1) A food that is unsafe, adulterated, or not honestly presented as specified in 3-101.11 must be discarded or reconditioned according to an approved procedure. ^P

(2) Food that is not from an approved source as specified in 3-201.11 through 3-201.17 must be discarded. ^P

(3) Ready-to-eat food that may have been contaminated by an employee who has been restricted or excluded as specified in 2-201.12 must be discarded. ^P

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

CHAPTER 4 EQUIPMENT, UTENSILS, LINEN

4-101.11 MATERIALS CHARACTERISTICS. (1) 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 must be:
P

- (a) Safe; P
- (b) Durable, corrosion-resistant, and non-absorbent;
- (c) Sufficient in weight and thickness to withstand repeated warewashing;
- (d) Finished to have a smooth, easily cleanable surface; and
- (e) Resistant to pitting, chipping, crazing, scratching, scoring, distortion, and decomposition.

4-101.12 CAST IRON USE (1) Except as specified in (2) and (3), cast iron may not be used for utensils or food-contact surfaces of equipment.

(2) Cast iron may be used as a surface for cooking.

(3) 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.

4-101.13 LEAD LIMITATIONS (1) Ceramic, china, and crystal utensils, and decorative utensils such as hand painted ceramic or china that are used in contact with food must be lead-free or contain levels of lead not exceeding the limits of the following utensil categories: P

Utensil category	Ceramic article description	Lead amount maximum (mg/L)
Mugs, cups, pitchers	Coffee mugs	0.5
Large hollowware (excluding pitchers)	Bowls ≥ 1.1L (1.16 quarts)	1.0
Small hollowware (excluding cups and mugs)	Bowels < 1.1L (1.16 quarts)	2.0
Tableware flat	Plates, Saucers	3.0

(2) Pewter alloys containing lead in excess of 0.05% may not be used as a food-contact surface. P

(3) Solder and flux containing lead in excess of 0.2% may not be used as a food-contact surface.

4-101.14 COPPER USE (1) Except as specified in (2), 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. P

(2) Copper and copper alloys may be used in contact with beer brewing ingredients that have a pH below 6 in the pre-fermentation and fermentation steps of a beer brewing operation such as a brewery, brewpub, or microbrewery.

4-101.15 GALVANIZED METAL RESTRICTION (1) Galvanized metal may not be used for utensils or food-contact surfaces of equipment that are used in contact with acidic food. P

4-101.16 SPONGE RESTRICTION (1) Sponges may not be used in contact with cleaned and sanitized or in-use food-contact surfaces.

4-101.17 WOOD USE (1) Except as specified in (2)-(4), wood and wood wicker may not be used as a food-contact surface.

(2) Hard maple or an equivalently hard, close-grained wood may be used for:

- (a) cutting boards; cutting blocks; bakers' tables; and utensils such as rolling pins, doughnut dowels, salad bowls, and chopsticks; and

(b) wooden paddles used in confectionery operations for pressure scraping kettles when manually preparing confections at a temperature of 110°C (230°F) or above.

(3) 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.

(4) 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:

(a) untreated wood containers; or

(b) treated wood containers if the containers are treated with a preservative that meets the requirements specified in 21 CFR 178.3800 Preservatives for Wood.

4-101.18 NON-STICK COATINGS USE (1) Multiuse kitchenware such as frying pans, griddles, sauce pans, cookie sheets, and waffle bakers that have a perfluorocarbon resin coating must be used with non-scoring or non-scratching utensils and cleaning aids.

4-101.19 NON-FOOD-CONTACT SURFACES (1) Nonfood-contact surfaces of equipment that are exposed to splash, spillage, or other food soiling or that require frequent cleaning must be constructed of a corrosion-resistant, non-absorbent, and smooth material.

4-102.11 SINGLE USAGE MATERIALS. (1) Materials used to make single-service and single-use articles:

(a) must not allow the migration of deleterious substances, ^P

(b) must not impart colors, odors, or tastes to food;

(c) must be safe, ^P and

(d) must be clean.

4-201.11 EQUIPMENT, UTENSIL DESIGN (1) Equipment and utensils must be designed and constructed to be durable and to retain their characteristic qualities under normal use conditions.

4-201.12 TEMPERATURE MEASURING DEVICES (1) 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

4-202.11 FOOD-CONTACT SURFACES CONSTRUCTION (1) Multiuse food-contact surfaces must be:

(a) smooth, easily cleanable, durable, non-absorbent, foodgrade material(s); ^{Pf}

(b) free of breaks, open seams, cracks, chips, inclusions, pits, and similar imperfections; ^{Pf}

(c) free of sharp internal angles, corners, and crevices; ^{Pf}

(d) finished to have smooth welds and joints; ^{Pf} and

(e) except as specified in (2), 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}

(2) Paragraph (1)(e) does not apply to cooking oil storage tanks, distribution lines for cooking oils, or beverage syrup lines or tubes.

4-202.12 CLEAN-IN-PLACE EQUIPMENT (1) Clean-in-place equipment must meet the characteristics specified in 4-202.11 and must be designed and constructed so that:

(a) cleaning and sanitizing solutions circulate throughout a fixed system and contact all interior food-contact surfaces, ^{Pf} and

(b) the system is self-draining or capable of being completely drained of cleaning and sanitizing solutions.

(2) Clean-in-place equipment that is not designed to be disassembled for cleaning must be designed with inspection access points to ensure that all interior food-contact surfaces throughout the fixed system are being effectively cleaned.

4-202.13 "V" THREADS USE (1) Except for hot oil cooking or filtering equipment, "v" type threads may not be used on food-contact surfaces.

4-202.14 FILTERING EQUIPMENT (1) hot oil filtering equipment must meet the characteristics specified in 4-202.11 or 4-202.12 and must be readily accessible for filter replacement and cleaning of the filter.

4-202.15 CAN OPENERS (1) Cutting or piercing parts of can openers must be readily removable for cleaning and for replacement.

4-202.16 NON-FOOD-CONTACT SURFACES (1) Non-food-contact surfaces must be free of unnecessary ledges, projections, and crevices, and designed and constructed to allow easy cleaning and to facilitate maintenance.

4-202.17 KICK PLATE DESIGN. Kick plates must be designed so that the areas behind them are accessible for inspection and cleaning by being:

(1) Removable by one of the methods specified in 4-202.11(1)(e) or capable of being rotated open; and

(2) Removable or capable of being rotated open without unlocking equipment doors.

4-202.18 VENTILATION HOODS (1) Filters or other grease extracting equipment must be designed to be readily removable for cleaning and replacement if not designed to be cleaned in place.

4-203.11 TEMPERATURE DEVICES ACCURACY (1) Food temperature measuring devices that are scaled only in Celsius or dually scaled in Celsius and Fahrenheit must be accurate to $\pm 1^{\circ}\text{C}$ in the intended range of use. ^{Pf}

(2) Food temperature measuring devices that are scaled only in Fahrenheit must be accurate to $\pm 2^{\circ}\text{F}$ in the intended range of use. ^{Pf}

4-203.12 TEMPERATURE DEVICE FLUIDS (1) Ambient air and water temperature measuring devices that are scaled in Celsius or dually scaled in Celsius and Fahrenheit must be designed to be easily readable and accurate to $\pm 1.5^{\circ}\text{C}$ in the intended range of use. ^{Pf}

(2) Ambient air and water temperature measuring devices that are scaled only in Fahrenheit must be accurate to $\pm 3^{\circ}\text{F}$ in the intended range of use. ^{Pf}

4-203.13 PRESSURE DEVICES, EQUIPMENT (1) Pressure measuring devices that display the pressures in the water supply line for the fresh hot water sanitizing rinse must have increments of 7 kilopascals (1 pound per square inch) or smaller and must be accurate to ± 14 kilopascals (± 2 pounds per square inch) in the range indicated on the manufacturer's data plate.

4-204.11 VENTILATION HOODS (1) Exhaust ventilation hood systems in food preparation and warewashing areas including components such as hoods, fans, guards, and ducting must be designed to prevent grease or condensation from draining or dripping onto food, equipment, utensils, linens, and single-service and single-use articles.

4-204.12 EQUIPMENT OPENINGS, CLOSURES, DEFLECTORS (1) A cover or lid for equipment must overlap the opening and be sloped to drain.

(2) An opening located within the top of a unit of equipment that is designed for use with a cover or lid must be flanged upward at least 5 millimeters (two-tenths of an inch).

(3) Except as specified in (4), fixed piping, temperature measuring devices, rotary shafts, and other parts extending into equipment must be provided with a watertight joint at the point where the item enters the equipment.

(4)(a) If a watertight joint is not provided the piping, temperature measuring devices, rotary shafts, and other parts extending through the openings must be equipped with an apron designed to deflect condensation, drips, and dust from openings into the food; and

(b) the opening must be flanged as specified in (2).

4-204.13 DISPENSING EQUIPMENT. In equipment that dispenses or vends liquid food or ice in unpackaged form:

(1) The delivery tube, chute, orifice, and splash surfaces directly above the container receiving the food must 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;

(2) The delivery tube, chute, and orifice must be protected from manual contact such as by being recessed;

(3) The delivery tube or chute and orifice of equipment used to vend liquid food or ice in unpackaged form to self-service consumers must be 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:

(a) 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

(b) available for self-service during hours when it is not under the full-time supervision of a food employee; and

(4) The dispensing equipment actuating lever or mechanism and filling device of consumer self-service beverage dispensing equipment must be designed to prevent contact with the lip-contact surface of glasses or cups that are refilled.

(5) Dispensing equipment in which potentially hazardous food in a homogenous liquid form is maintained outside of the temperature control requirements as specified in 3-501.16(1) must:

(a) 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

(b) conform to the requirements for this equipment as specified in NSF/ANSI 18-2006-Manual Food and Beverage Dispensing Equipment. ^P

4-204.15 BEARINGS AND GEARS (1) Equipment containing bearings and gears that require lubricants must be designed and constructed so that the lubricant cannot leak, drip, or be forced into food or onto food-contact surfaces.

4-204.16 BEVERAGE TUBING (1) 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.

4-204.17 ICE UNIT DRAINS (1) Liquid waste drain lines may not pass through an ice machine or ice storage bin.

4-204.18 CONDENSER UNIT (1) If a condenser unit is an integral component of equipment, the condenser unit must be separated from the food and food storage space by a dustproof barrier.

4-204.110 MOLLUSCAN SHELLFISH TANKS (1) Except as specified in (2), molluscan shellfish life support system display tanks may not be used to store or display shellfish that are offered for human consumption and must be conspicuously marked so that it is obvious to the consumer that the shellfish are for display only. ^P

(2) Molluscan shellfish life-support system display tanks that are used to store or display shellfish that are offered for human consumption must be operated and maintained in accordance with a variance granted by the regulatory authority as specified in 8-103.10 and a HACCP plan that: ^{Pf}

(a) is submitted by the legal licensee and approved as specified in 8-103.11; ^{Pf} and

(b) 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 in 3-203.12. ^{Pf}

4-204.112 TEMPERATURE MEASURING DEVICES (1) In a mechanically refrigerated or hot food storage unit, the sensor of a temperature measuring device must 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.

(2) Except as specified in (3), cold or hot holding equipment used for potentially hazardous food must be designed to include and must 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.

(3) Paragraph (2) 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 calrod units, heat lamps, cold plates, bain-marie/hot-water bath, steam tables, insulated food transport containers, and salad bars.

(4) Temperature measuring devices must be designed to be easily readable.

(5) Food temperature measuring devices and water temperature measuring devices on warewashing machines must 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}

4-204.113 WAREWASHING DATA PLATE (1) A warewashing machine must 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:

(a) temperatures required for washing, rinsing, and sanitizing;

(b) pressure required for the fresh water sanitizing rinse unless the machine is designed to use only a pumped sanitizing rinse; and

(c) conveyor speed for conveyor machines or cycle time for stationary rack machines.

4-204.114 WAREWASHING INTERNAL COMPONENTS (1) Warewashing machine wash and rinse tanks must be equipped with baffles, curtains, or other means to minimize internal cross-contamination of the solutions in wash and rinse tanks.

4-204.115 WAREWASHING TEMPERATURE DEVICES (1) A warewashing machine must be equipped with a temperature measuring device that indicates the temperature of the water:

(a) in each wash and rinse tank; ^{Pf} and

(b) as the water enters the hot water sanitizing final rinse manifold or in the chemical sanitizing solution tank. ^{Pf}

4-204.116 MANUAL WAREWASHING EQUIPMENT (1) If hot water is used for sanitization in manual warewashing operations, the sanitizing compartment of the sink must be:

(a) designed with an integral heating device that is capable of maintaining water at a temperature not less than 77°C (171°F); ^{Pf} and

(b) provided with a rack or basket to allow complete immersion of equipment and utensils into the hot water. ^{Pf}

4-204.117 WAREWASHING DISPENSING (1) A warewashing machine that is installed after adoption of this rule, must be equipped to:

(a) automatically dispense detergents and sanitizers; ^{Pf} and

(b) 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}

4-204.118 WAREWASHING PRESSURE DEVICE (1) Warewashing machines that provide a fresh hot water sanitizing rinse must 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

(2) If the flow pressure measuring device is upstream of the fresh hot water sanitizing rinse control valve, the device must be mounted in a 6.4 millimeter or one-fourth inch iron pipe size (IPS) valve.

(3) Paragraphs (1) and (2) do not apply to a machine that uses only a pumped or recirculated sanitizing rinse.

4-204.119 WAREWASHING SELF-DRAINING (1) Sinks and drainboards of warewashing sinks and machines must be self-draining.

4-204.120 EQUIPMENT DRAINAGE (1) Equipment compartments that are subject to accumulation of moisture due to conditions such as condensation, food or beverage drip, or water from melting ice must be sloped to an outlet that allows complete draining.

4-204.122 BULK FOOD HANDLING (1) Apparatuses, such as dollies, pallets, racks, and skids used to store and transport large quantities of packaged foods shipped or received in a cased or overwrapped lot, must be designed to be moved by hand or by conveniently available apparatuses such as hand trucks and forklifts.

4-205.10 FOOD EQUIPMENT STANDARDS (1) Unless a variance is granted under 8-103.10, food-contact equipment for use in wholesale food establishments must meet applicable standards of NSF International/American National Standards Institute (ANSI), or its equivalent standards that are from a reputable certification and testing organization. Specifically, food-contact equipment must at least meet applicable sections of NSF/ANSI 2-2014 for food equipment, and NSF/ANSI 51-2014 for food equipment materials. Other NSF/ANSI standards may be applicable, as determined by the regulatory authority.

4-301.11 TEMPERATURE HOLDING CAPACITIES (1) Equipment for cooling and heating food, and holding cold and hot food, must be sufficient in number and capacity to provide food temperatures as specified under this rule. ^{Pf}

4-301.12 SINK COMPARTMENT REQUIREMENTS (1) Except as specified in (3), a sink with at least 3 compartments with adequate drainboards must be provided for manually washing, rinsing, and sanitizing equipment and utensils. ^{Pf}

(2) Sink compartments must be large enough to accommodate immersion of the largest equipment and utensils. If equipment or utensils are too large for the warewashing sink, a warewashing machine or alternative equipment as specified in (3) must be used. ^{Pf}

(3) Alternative manual warewashing equipment may be used when there are special cleaning needs or constraints, and its use is approved. Alternative manual warewashing equipment may include:

- (a) high-pressure detergent sprayers;
- (b) low- or line-pressure spray detergent foamers;
- (c) other task-specific cleaning equipment;
- (d) brushes or other implements;
- (e) 2-compartment sinks as specified in (4) and (5); or
- (f) receptacles that substitute for the compartments of a multi-compartment sink.

(4) Before a 2-compartment sink is used:

(a) the legal licensee must have its use approved; and
(b) the legal licensee must limit the number of kitchenware items cleaned and sanitized in the 2-compartment sink, and must limit warewashing to batch operations for cleaning kitchenware such as between cutting one type of raw meat and another or cleanup at the end of a shift, and must:

(i) make up the cleaning and sanitizing solutions immediately before use and drain them immediately after use, and

(ii) use a detergent-sanitizer to sanitize and apply the detergent-sanitizer in accordance with the manufacturer's label instructions and as specified in 4-501.115, or

(iii) use a hot water sanitization immersion step as specified in 4-603.16(3).

(5) A 2-compartment sink may not be used for warewashing operations where cleaning and sanitizing solutions are used for a continuous or intermittent flow of kitchenware or tableware in an ongoing warewashing process.

(6) A food preparation sink must be provided if food is placed into a sink or sink compartment for the purposes of thawing or cleaning. A food preparation sink must meet the requirements specified in 4-205.10, 5-202.13, and 5-402.11.

4-301.12 FOOD PREPARATION SINK (1) A food preparation sink must be provided if food is placed into a sink or sink compartment for the purposes of thawing or cleaning, and must meet the applicable requirements specified in this rule. ^P

4-301.13 DRAINBOARDS (1) Drainboards, utensil racks, or tables large enough to accommodate all soiled and cleaned items that may accumulate during hours of operation must be provided for necessary utensil holding before cleaning and after sanitizing.

4-301.14 VENTILATION HOODS (1) Ventilation hood systems and devices must be sufficient in number and capacity to prevent grease or condensation from collecting on walls and ceilings.

4-301.15 LAUNDRY FACILITIES (1) Except as specified in (2), if work clothes or linens are laundered on the premises, a mechanical clothes washer and dryer must be provided and used.

(2) If on-premises laundering is limited to wiping cloths intended to be used moist, or wiping cloths are air-dried as specified 4-901.12, a mechanical clothes washer and dryer need not be provided.

4-302.12 FOOD TEMPERATURE DEVICES (1) Food temperature measuring devices must be provided and readily accessible for use in ensuring attainment and maintenance of food temperatures as specified under this rule. ^{Pf}

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

4-302.13 TEMPERATURE DEVICES WAREWASHING (1) In manual warewashing operations, a temperature measuring device must be provided and readily accessible for frequently measuring the washing and sanitizing temperatures. ^{Pf}

(2) In hot water mechanical warewashing operations, an irreversible registering temperature indicator must be provided, and readily accessible for measuring the utensil surface temperature. ^{Pf}

4-302.14 SANITIZING TESTING DEVICES (1) A test kit or other device that accurately measures the concentration in mg/L or parts per million (ppm) of sanitizing solutions must be provided. ^{Pf}

4-401.11 LOCATION OF ITEMS (1) Except as specified in (2), 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:

- (a) in locker rooms;
- (b) in toilet rooms;
- (c) in garbage rooms;
- (d) in mechanical rooms;
- (e) under sewer lines that are not shielded to intercept potential drips;
- (f) under leaking water lines including leaking automatic fire sprinkler heads or under lines on which water has condensed;
- (g) under open stairwells; or
- (h) under other sources of contamination.

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

(3) If a mechanical clothes washer or dryer is provided, it must 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.

4-402.11 INSTALLATION OF EQUIPMENT (1) Equipment that is fixed because it is not easily movable must be installed so that it is:

- (a) spaced to allow access for cleaning along the sides, behind, and above the equipment;
- (b) spaced from adjoining equipment, walls, and ceilings a distance of not more than 1 millimeter or one thirty-second inch; or
- (c) sealed to adjoining equipment or walls, if the equipment is exposed to spillage or seepage.

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

- (a) sealed; or
- (b) elevated on legs as specified under 4-402.12(4).

4-402.12 FIXED EQUIPMENT (1) Except as specified in (2) and (3), floor-mounted equipment that is not easily movable must be sealed to the floor or elevated on legs that provide at least a 15 centimeters (6 inches) clearance between the floor and the equipment.

(2) 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).

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

(4) Except as specified in (5), counter-mounted equipment that is not easily movable must be elevated on legs that provide at least a 10 centimeters (4 inches) clearance between the table and the equipment.

(5) The clearance space between the table and counter-mounted equipment may be:

(a) 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

(b) 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.

4-501.11 EQUIPMENT REPAIR, ADJUSTMENT (1) Equipment must be maintained in a state of repair and condition that meets the requirements specified under this rule.

(2) Equipment components such as doors, seals, hinges, fasteners, and kick plates must be kept intact, tight, and adjusted in accordance with manufacturer's specifications.

(3) Cutting or piercing parts of can openers must be kept sharp to minimize the creation of metal fragments that can contaminate food when the container is opened.

4-501.12 CUTTING SURFACES (1) Surfaces such as cutting blocks and boards that are subject to scratching and scoring must be resurfaced if they can no longer be effectively cleaned and sanitized, or discarded, if they are not capable of being resurfaced.

4-501.13 MICROWAVE OVENS (1) Microwave ovens must meet the safety standards specified in 21 CFR 1030.10 microwave ovens.

4-501.14 WAREWASHING CLEANING, FREQUENCY. (1) 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 in 4-301.13 must be cleaned:

(a) before use;

(b) 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

(c) if used, at least every 24 hours.

4-501.15 WAREWASHING OPERATING INSTRUCTIONS (1) A warewashing machine and its auxiliary components must be operated in accordance with the machine's data plate and other manufacturer's instructions.

(2) A warewashing machine's conveyor speed or automatic cycle times must be maintained accurately timed in accordance with manufacturer's specifications.

4-501.16 WAREWASHING SINK LIMITATION (1) A warewashing sink may not be used for handwashing as specified in 2-301.15.

(2) If a warewashing sink is used to wash wiping cloths, wash produce, or thaw food, the sink must be cleaned as specified under 4-501.14 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 must be sanitized as specified under this subchapter before and after using the sink to wash produce or thaw food.

4-501.17 WAREWASHING CLEANING AGENTS (1) When used for warewashing, the wash compartment of a sink, mechanical warewasher, or wash receptacle of alternative manual warewashing equipment as specified in 4-301.12(3), must 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}

4-501.18 CLEAN WAREWASHING SOLUTIONS (1) The wash, rinse, and sanitize solutions must be maintained clean.

4-501.19 MANUAL WAREWASHING TEMPERATURE (1) The temperature of the wash solution in manual warewashing equipment must be maintained at not less than 43°C (110°F), or the temperature specified on the cleaning agent manufacturer's label instructions. ^{Pf}

4-501.110 MECHANICAL WAREWASHING TEMPERATURE (1) The temperature of the wash solution in spray type warewashers that use hot water to sanitize may not be less than:

- (a) for a stationary rack, single temperature machine, 74°C (165°F); ^{Pf}
- (b) for a stationary rack, dual temperature machine, 66°C (150°F); ^{Pf}
- (c) for a single tank, conveyor, dual temperature machine, 71°C (160°F); ^{Pf} or
- (d) for a multi-tank, conveyor, multi-temperature machine, 66°C (150°F). ^{Pf}

(2) 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}

4-501.111 MANUAL HOT-WATER SANITIZATION (1) If immersion in hot water is used for sanitizing in a manual operation, the temperature of the water must be maintained at 77°C (171°F) or above. ^P

4-501.112 MECHANICAL HOT-WATER SANITIZATION (1) Except as specified in (2), 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}

- (a) for a stationary rack, single temperature machine, 74°C (165°F); ^{Pf} or
- (b) for all other machines, 82°C (180°F). ^{Pf}

(2) The maximum temperature specified in (1), 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.

4-501.113 MECHANICAL WAREWASHING PRESSURE (1) 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, must 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).

4-501.114 WAREWASHING SANITIZATION PARAMETERS. A chemical sanitizer used in a sanitizing solution for a manual or mechanical operation at contact times specified 4-703.11(3) must meet the criteria specified 7-204.11 sanitizers, criteria, must be used in accordance with the EPA-registered label use instructions, ^P and must be used as follows:

(1) A chlorine solution must have a minimum temperature based on the concentration and pH of the solution as listed in the following chart; ^P

Concentration (mg/L)	Min. Temp. ≤ pH 10, °C (°F)	Min. Temp. ≤ pH 8, °C (°F)
25 – 49	49 (120)	49 (120)
50 – 99	38 (100)	24 (75)
100	13 (55)	13 (55)

(2) An iodine solution must have a:

- (a) minimum temperature of 20°C (68°F), ^P
- (b) 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

(c) concentration between 12.5 mg/L and 25 mg/L; ^P

(3) A quaternary ammonium compound solution must:

(a) have a minimum temperature of 24°C (75°F), ^P

(b) have a concentration as specified in 7-204.11, and as indicated by the manufacturer's use directions included in the labeling, ^P and

(c) be used only in water with 500 mg/l hardness or less or in water having a hardness no greater than specified by the EPA-registered label use instructions; ^P

(4) If another solution of a chemical specified in (1)–(3) is used, the legal licensee must demonstrate to the regulatory authority that the solution achieves sanitization and the use of the solution must be approved; ^P

(5) If a chemical sanitizer other than chlorine, iodine, or a quaternary ammonium compound is used, it must be applied in accordance with the EPA-registered label use instructions; ^P and

(6) If a chemical sanitizer is generated by a device located on-site at the food establishment it must be used as specified in (1)–(4) and must be produced by a device that:

(a) complies with regulation as specified in 2(q)(1) and 12 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C § 136 et seq, ^P

(b) complies with 40 CFR 152.500 Requirement for Devices and 40 CFR 156.10 Labeling Requirements, ^P

(c) displays the EPA device manufacturing facility registration number on the device, ^{Pf} and

(d) is operated and maintained in accordance with manufacturer's instructions ^{Pf}.

4-501.115 WAREWASHING DETERGENT-SANITIZERS (1) If a detergent-sanitizer is used to sanitize in a cleaning and sanitizing procedure where there is no distinct water rinse between the washing and sanitizing steps, the agent applied in the sanitizing step must be the same detergent-sanitizer that is used in the washing step.

4-501.116 SANITIZER TESTING (1) Concentration of the sanitizing solution must be accurately determined by using a test kit or other device. ^{Pf}

4-502.11 EQUIPMENT, UTENSIL MAINTENANCE (1) Utensils must be maintained in a state of repair or condition that complies with the requirements specified under this rule, or must be discarded.

(2) Food temperature measuring devices must be calibrated in accordance with manufacturer's specifications as necessary to ensure their accuracy. ^{Pf}

(3) Ambient air temperature, water pressure, and water temperature measuring devices must be maintained in good repair and be accurate within the intended range of use.

4-502.13 SINGLE-USE, SERVICE LIMITATION (1) Single-service and single-use articles may not be reused.

(2) The bulk milk container dispensing tube must be cut on the diagonal leaving no more than one inch protruding from the chilled dispensing head.

4-502.14 SHELL USE LIMITATION (1) Mollusk and crustacea shells may not be used more than once as serving containers.

4-601.11 FOOD, NON-FOOD SURFACES (1) Equipment food-contact surfaces and utensils must be clean to sight and touch. ^{Pf}

(2) The food-contact surfaces of cooking equipment and pans must be kept free of encrusted grease deposits and other soil accumulations.

(3) Non-food-contact surfaces of equipment must be kept free of an accumulation of dust, dirt, food residue, and other debris.

4-602.11 CLEANING FREQUENCY FOR SURFACES (1) Equipment food-contact surfaces and utensils must be cleaned:

(a) except as specified in (2), before each use with a different type of raw animal food such as beef, fish, lamb, pork, or poultry; ^P

(b) each time there is a change from working with raw foods to working with ready-to-eat foods; ^P

(c) between uses of raw fruits and vegetables and with potentially hazardous food; ^P

(d) before using or storing a food temperature measuring device; ^P and

(e) at any time during the operation when contamination may have occurred. ^P

(2) Paragraph (1)(a) does not apply if the food-contact surface or utensil is in contact with a succession of different types of raw meat and poultry each requiring a higher cooking temperature as specified in 3-401.11 than the previous type.

(3) Except as specified in (4), if used with potentially hazardous food, equipment food-contact surfaces and utensils must be cleaned throughout the day at least every 4 hours. ^P

(4) Surfaces of utensils and equipment contacting potentially hazardous food may be cleaned less frequently than every 4 hours if:

(a) in storage, containers of potentially hazardous food and their contents are maintained at temperatures specified under this rule and the containers are cleaned when they are empty;

(b) 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

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

(ii) the cleaning frequency based on the ambient temperature of the refrigerated room or area is documented in the food establishment.

(c) 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 this rule;

(d) 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;

(e) 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

(f) 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.

(5) Except when dry cleaning methods are used as specified under this rule, surfaces of utensils and equipment contacting food that is not potentially hazardous food must be cleaned:

(a) at any time when contamination may have occurred;

(b) 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.

4-602.12 COOKING, BAKING EQUIPMENT (1) The food-contact surfaces of cooking and baking equipment must be cleaned at a frequency necessary to preclude accumulation of excessive soil residues. This section does not apply to hot oil cooking and filtering equipment if it is cleaned as specified in 4-602.11(4)(f).

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

4-602.13 NON-FOOD-CONTACT SURFACES (1) Non-food-contact surfaces of equipment must be cleaned at a frequency necessary to preclude accumulation of soil residues.

4-603.11 DRY CLEANING (1) If used, dry cleaning methods such as brushing, scraping, and vacuuming must contact only surfaces that are soiled with dry food residues that are not potentially hazardous food.

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

4-603.12 PRE-CLEANING (1) Food debris on equipment and utensils must be scraped over a waste disposal unit or garbage receptacle or must be removed in a warewashing machine with a prewash cycle.

(2) If necessary for effective cleaning, utensils and equipment must be pre-flushed, presoaked, or scrubbed with abrasives.

4-603.13 LOADING WAREWASHING MACHINES (1) Soiled items to be cleaned in a warewashing machine must be loaded into racks, trays, or baskets or onto conveyors in a position that:

- (a) exposes the items to the unobstructed spray from all cycles; and
- (b) allows the items to drain.

4-603.14 WET CLEANING (1) Equipment food-contact surfaces and utensils must 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.

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

4-603.15 ALTERNATIVE WAREWASHING. (1) 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 must be done by using alternative manual warewashing equipment as specified in 4-301.12(3) in accordance with the following procedures:

(a) equipment must be disassembled as necessary to allow access of the detergent solution to all parts;

(b) equipment components and utensils must be scrapped or rough cleaned to remove food particle accumulation; and

(c) equipment and utensils must be washed as specified under 4-603.14(1).

4-603.16 RINSING PROCEDURES. Washed utensils and equipment must be rinsed so that abrasives are removed and cleaning chemicals are removed or diluted through the use of water or a detergent-sanitizer solution by using one of the following procedures:

(1) Use of a distinct, separate water rinse after washing and before sanitizing if utilizing:

(a) a 3-compartment sink,

- (b) alternative manual warewashing equipment equivalent to a 3-compartment sink as specified in 4-301.12(3), or
- (c) a 3-step washing, rinsing, and sanitizing procedure in a warewashing system for cip equipment;
 - (2) Use of a detergent-sanitizer as specified under 4-501.115 if utilizing:
 - (a) alternative warewashing equipment as specified in 4-301.12(3) that is approved for use with a detergent-sanitizer, or
 - (b) a warewashing system for clean-in-place equipment;
 - (3) Use of a non-distinct water rinse that is integrated in the hot water sanitization immersion step of a 2-compartment sink operation;
 - (4) If using a warewashing machine that does not recycle the sanitizing solution as specified in (5), or alternative manual warewashing equipment such as sprayers, use of a non-distinct water rinse that is:
 - (a) integrated in the application of the sanitizing solution, and
 - (b) wasted immediately after each application; or
 - (5) If using a warewashing machine that recycles the sanitizing solution for use in the next wash cycle, use of a non-distinct water rinse that is integrated in the application of the sanitizing solution.

4-701.10 SANITIZING OBJECTIVE (1) Equipment food-contact surfaces and utensils must be sanitized to decrease the possible presence of pathogens.

4-702.11 WHEN TO SANITIZE (1) Utensils and food-contact surfaces of equipment must be sanitized before use after cleaning. ^P

4-703.11 HOW TO SANITIZE. After being cleaned, equipment food-contact surfaces and utensils must be sanitized in:

- (1) Hot water manual operations by immersion for at least 30 seconds and as specified in 4-501.111; ^P
- (2) Hot water mechanical operations by being cycled through equipment that is set up as specified in 4-501.15, 4-501.112, and 4-501.113 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 in 4-501.114. Contact times must be consistent with those on EPA-registered label use instructions by providing:
 - (a) except as specified in (3)(b), a contact time of at least 10 seconds for a chlorine solution specified in 4-501.114(1), ^P
 - (b) 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
 - (c) a contact time of at least 30 seconds for other chemical sanitizing solutions, ^P or
 - (d) a contact time used in relationship with a combination of temperature, concentration, and pH that, when evaluated for efficacy, yields a 5-log sanitization level as defined in this rule. ^P

4-801.11 CLEAN LINENS (1) Clean linens must be free from food residues and other soiling matter.

4-802.11 CLOTH USE (1) Linens that do not come in direct contact with food must be laundered between operations if they become wet, sticky, or visibly soiled.

(2) Cloth gloves used as specified in 3-304.15(4) must be laundered before being used with a different type of raw animal food such as beef, fish, lamb, pork or poultry.

(3) Linens that are used as specified in 3-304.13 and cloth napkins must be laundered between each use.

(4) Wet wiping cloths must be laundered daily.

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

4-803.11 SOILED LINENS (1) Soiled linens must be kept in clean, non-absorbent 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.

4-803.12 MECHANICAL WASHING (1) Except as specified in (2), linens must be mechanically washed.

(2) In food establishments in which only wiping cloths are laundered as specified in 4-301.15(2), 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 in 4-501.14.

4-803.13 LAUNDRY FACILITIES (1) Except as specified in (2), laundry facilities on the premises of a food establishment must be used only for the washing and drying of items used in the operation of the establishment.

(2) 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.

4-901.11 AIR-DRYING (1) After cleaning and sanitizing, equipment and utensils must be air-dried or used after adequate draining as specified in 40 CFR 180.940(a) tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (food-contact surface sanitizing solutions), before contact with food; and

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

4-901.12 WIPING CLOTH DRYING (1) Wiping cloths laundered in a food establishment that does not have a mechanical clothes dryer as specified in 4-301.15(2) must 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 in 4-501.114.

4-902.11 LUBRICANTS (1) Lubricants as specified in 7-205.11 must be applied to food-contact surfaces that require lubrication in a manner that does not contaminate food-contact surfaces.

4-902.12 EQUIPMENT REASSEMBLY (1) Equipment must be reassembled in a manner that food-contact surfaces are not contaminated.

4-903.11 ITEM STORAGE (1) Except as specified in (4), cleaned equipment and utensils, laundered linens, and single-service and single-use articles must be stored:

(a) in a clean, dry location;

(b) where they are not exposed to splash, dust, or other contamination; and

(c) at least 15 cm (6 inches) above the floor.

(2) Clean equipment and utensils must be stored as specified in (1) and must be stored:

(a) in a self-draining position that allows air drying; and

(b) covered or inverted.

(3) Single-service and single-use articles must be stored as specified in (1) and must be kept in the original protective package or stored by using other means that afford protection from contamination until used.

(4) 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 in 4-204.122.

4-903.12 STORAGE PROHIBITIONS (1) Except as specified in (2), cleaned and sanitized equipment, utensils, laundered linens, and single-service and single-use articles may not be stored:

- (a) in locker rooms;
- (b) in toilet rooms;
- (c) in garbage rooms;
- (d) in mechanical rooms;
- (e) under sewer lines that are not shielded to intercept potential drips;
- (f) under leaking water lines, including leaking automatic fire sprinkler heads or under lines on which water has condensed;
- (g) under open stairwells; or
- (h) under other sources of contamination.

(2) 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.

4-904.11 TABLEWARE HANDLING (1) Single-service and single-use articles and cleaned and sanitized utensils must be handled, displayed, and dispensed so that contamination of food and lip-contact surfaces is prevented.

4-904.14 RINSING AFTER SANITIZING (1) After being cleaned and sanitized, equipment and utensils must not be rinsed before air drying or use unless the rinse is applied directly from a potable water supply by a warewashing machine that is maintained and operated as specified under applicable sections of this rule, and 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.

CHAPTER 5 WATER, PLUMBING, WASTE

5-101.11.01 PUBLIC WATER SYSTEM (1) Potable water must be obtained from an approved source that is a public water system, unless the potable water system meets all applicable requirements in 5-101.11.02. ^P

5-101.01 NONPUBLIC WATER SYSTEM (1) Potable water not obtained from a source under **5-101.11.01** must be obtained from an approved source that is a nonpublic system meeting requirements of Nonpublic Water Supply Circular FCS 1-2016.

5-101.12 SYSTEM FLUSHING, DISINFECTION (1) A drinking water system must 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

5-101.13 BOTTLED DRINKING WATER (1) Bottled drinking water used or sold in a food establishment must be obtained from approved sources in accordance with 21 CFR Part 129 - Processing and Bottling of Bottled Drinking Water. ^P

(2) Each food manufacturing establishment in Montana where water for human consumption is prepared for sale in bottles or other containers must:

(a) obtain its water from a public water system approved by the water quality division of the Department of Environmental Quality, or, if water is obtained from a separate or independent system, that system must comply with the statutes governing public water supplies,

75-6-101 et seq., MCA, the rules governing public water supplies, ARM 17.38.201 et seq., and the rule governing plans for public water supplies or wastewater systems, ARM 17.38.101.

(b) maintain representative batch sampling records that show laboratory testing results for bacteriological, chemical, physical, and radiological levels, required in 21 CFR Part 129 for bottled drinking water; and

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

5-101.14 ICE AND SNOW LIMITATIONS (1) Natural ice and snow that is from a stream, creek, river, lake, pond, or other surface water location may not be used as food or in food processing.

(2) natural or manufactured ice that does not conform to safe-usage standards must be conspicuously labeled as unsafe or inedible, and may not be used as food or in food processing. If such ice is sold or distributed for refrigeration purposes, the seller or distributor must notify the recipient that it is not safe for human consumption or use in food processing.

5-102.11 WATER STANDARDS. Except as specified in 5-201.12:

(1) water from a public water system must meet 40 CFR Part 141 - National Primary Drinking Water Regulations, and state drinking water quality standards; ^P and

(2) water from a nonpublic water system must meet state drinking water quality standards for public systems. ^P

5-102.12 NON-DRINKING WATER (1) A nondrinking water supply must be used only if its use is approved. ^P

(2) Nondrinking water must be used only for non-culinary purposes such as air conditioning, nonfood equipment cooling, and fire protection. ^P

5-102.14 NONPUBLIC WATER SYSTEM REPORT (1) The most recent sample report for the nonpublic water system must be retained on file in the food establishment, and made available for inspection and investigation purposes.

5-103.11 WATER CAPACITIES (1) The water source and system must be of sufficient capacity to meet the peak water demands of the food establishment. ^{Pf}

(2) Hot water generation and distribution systems must be sufficient to meet the peak hot water demands throughout the food establishment. ^{Pf}

(3) Water storage tank, or tanks, in a mobile food establishment must be of adequate capacity, as required in (1), but no smaller than the following:

(a) a mobile food establishment that serves beverages or food or reheats processed foods must have a water storage tank, or tanks, with a capacity of at least 38 liters (10 gallons) for food employee handwashing;

(b) a food pushcart must have a water storage tank, or tanks, with a minimum capacity of 19 liters (5 gallons) for handwashing; and

(c) a mobile food establishment that processes food or beverages must have a water storage tank, or tanks, with a capacity of at least 151 liters (40 gallons) for handwashing, utensil washing, and sanitizing purposes with the exact capacity to be determined by the department in close cooperation and consultation with the local regulatory authority.

5-103.12 WATER PRESSURE (1) Water under pressure must be provided to all fixtures, equipment, and nonfood equipment that are required to use water except that water supplied as specified in 5-104.12 (1)-(2) to a temporary food establishment or in response to a temporary interruption of a water supply need not be under pressure. ^{Pf}

5-104.11 WATER SYSTEMS. Water must be received from the source through the use of:

- (1) An approved public water main; ^{Pf} or
- (2) One or more of the following that must be constructed, maintained, and operated according to law: ^{Pf}
 - (a) nonpublic water main, water pumps, pipes, hoses, connections, and other appurtenances, ^{Pf}
 - (b) water transport vehicles, ^{Pf} or
 - (c) water containers. ^{Pf}

5-104.12 ALTERNATIVE WATER SUPPLY. Water meeting the requirements specified under applicable sections of this rule must 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:

- (1) A supply of containers of commercially bottled drinking water; ^{Pf}
- (2) One or more closed portable water containers; ^{Pf}
- (3) An enclosed vehicular water tank; ^{Pf}
- (4) An on-premises water storage tank; ^{Pf} or
- (5) Piping, tubing, or hoses connected to an adjacent approved source. ^{Pf}

5-201.11 WATER SYSTEM APPROVED MATERIALS (1) A plumbing system and hoses conveying water must be constructed and repaired with approved materials according to law. ^P

- (2) A water filter must be made of safe materials. ^P

5-202.11 PLUMBING SYSTEM (1) A plumbing system must be designed, constructed, and installed according to law. ^P

- (2) A plumbing fixture such as a handwashing sink, toilet, or urinal must be smooth, durable, and easily cleanable.

5-202.12 HANDWASHING SINK, INSTALLATION (1) A handwashing sink must be equipped to provide water at a temperature of at least 38°C (100°F) through a mixing valve or combination faucet. ^{Pf}

- (2) a steam mixing valve may not be used at a handwashing sink.
- (3) a self-closing, slow-closing, or metering faucet must provide a flow of water for at least 15 seconds without the need to reactivate the faucet.
- (4) an automatic handwashing facility must be installed in accordance with manufacturer's instructions.

5-202.13 PLUMBING AIR GAP (1) An air gap between the water supply inlet and the flood level rim of the plumbing fixture, equipment, or nonfood equipment must be at least twice the diameter of the water supply inlet and may not be less than 25 mm (1 inch). ^P

5-202.14 PLUMBING BACKFLOW STANDARD (1) A backflow or backsiphonage prevention device installed on a water supply system must 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

5-202.15 WATER TREATMENT (1) A water filter, screen, and other water conditioning device installed on water lines must be designed to facilitate disassembly for periodic servicing and cleaning. A water filter element must be of the replaceable type.

5-203.11 HANDWASHING SINKS (1) Except as specified in (2) and (3), at least 1 handwashing sink, a number of handwashing sinks necessary for their convenient use by employees in areas specified in 5-204.11, and not fewer than the number of handwashing sinks required by law must be provided. ^{Pf}

(2) 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.

(3) If, and only if approved, when food exposure is limited and handwashing sinks are not conveniently available, such as in some mobile or temporary food establishments or at some vending machine locations, employees may use chemically treated towelettes for handwashing.

5-203.12 TOILETS AND URINALS (1) At least 1 toilet, and not fewer than the number of toilets required by law must be provided for all food establishments. If authorized by law, and urinals are substituted for toilets, the substitution must be done as specified in law.

5-203.13 SERVICE SINK (1) At least 1 service sink or 1 curbed cleaning facility equipped with a floor drain must 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.

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

(3) Handwashing and warewashing sinks may not be used as service sinks. ^P

5-203.14 REQUIRED BACKFLOW DEVICE. A plumbing system must 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:

(1) Providing an air gap as specified in 5-202.13 ^P; or

(2) Installing an approved backflow prevention device as specified in 5-202.14. ^P

5-203.15 CARBONATOR BACKFLOW PREVENTION (1) If not provided with an air gap as specified under section 5-202.13, 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) must be installed upstream from a carbonating device and downstream from any copper in the water supply line. ^P

(2) 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 paragraph (1) of this section.

5-204.11 HANDWASHING SINK LOCATION. (1) A handwashing sink must be located:

(a) to allow convenient use by employees in food preparation, food dispensing, and warewashing areas; ^{Pf} and

(b) in, or immediately adjacent to, toilet rooms. ^{Pf}

5-204.12 BACKFLOW PREVENTION LOCATION (1) A backflow prevention device must be located so that it may be serviced and maintained.

5-204.13 WATER CONDITIONING LOCATION (1) A water filter, screen, and other water conditioning device installed on water lines must be located to facilitate disassembly for periodic servicing and cleaning.

5-205.11 HANDWASHING SINK USE (1) A handwashing sink must be maintained so that it is accessible at all times for employee use. ^{Pf}

(2) A handwashing sink may not be used for purposes other than handwashing. ^{Pf}

(3) An automatic handwashing facility must be used in accordance with the manufacturer's instructions. ^{Pf}

5-205.12 CROSS CONNECTION PROHIBITION (1) 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

(2) The piping of a nondrinking water system must be durably identified so that it is readily distinguishable from piping that carries drinking water. ^{Pf}

5-205.13 WATER SYSTEM SERVICE (1) A device such as a water treatment device or backflow preventer must 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 must be maintained by the person-in-charge. ^{Pf}

5-205.14 FOGGING DEVICES (1) A reservoir that is used to supply water to a device such as a produce fogger must be:

(a) maintained in accordance with manufacturer's specifications; ^P and
(b) cleaned in accordance with manufacturer's specifications or according to the procedures specified in (2), whichever is more stringent. ^P

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

(a) draining and complete disassembly of the water and aerosol contact parts; ^P
(b) brush-cleaning the reservoir, aerosol tubing, and discharge nozzles with a suitable detergent solution; ^P
(c) flushing the complete system with water to remove the detergent solution and particulate accumulation; ^P and
(d) rinsing by immersing, spraying, or swabbing the reservoir, aerosol tubing, and discharge nozzles with at least 50 mg/L hypochlorite solution. ^P

5-205.15 PLUMBING SYSTEM CONDITION (1) A plumbing system must be:

(a) repaired according to law; ^P and
(b) maintained in good repair.

5-301.11 MOBILE WATER TANK MATERIALS (1) Materials used in the construction of a mobile water tank, mobile food establishment water tank, and appurtenances must be:

(a) safe; ^P
(b) durable, corrosion-resistant, and non-absorbent; and
(c) finished to have a smooth, easily cleanable surface.

5-302.11 MOBILE WATER TANK INSTALLATION (1) A mobile water tank must be:

(a) enclosed from the filling inlet to the discharge outlet; and
(b) sloped to an outlet that allows complete drainage of the tank.

5-302.12 WATER TANK CONSTRUCTION (1) If a water tank is designed with an access port for inspection and cleaning, the opening must be in the top of the tank and:

(a) flanged upward at least 13 mm (one half-inch); and
(b) 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.

(2)(a) Every mobile food establishment must be equipped with a pressurized water storage tank.

(b) The water storage tank, or tanks, in a mobile food establishment must be of adequate capacity, as required in 5-103.11.

5-302.13 WATER TANK CONNECTIONS (1) A fitting with "v" type threads on a water tank inlet or outlet must be allowed only when a hose is permanently attached.

5-302.14 WATER TANK VENTILATION (1) If provided, a water tank vent must terminate in a downward direction and must be covered with:

- (a) 16 mesh to 25.4 mm (16 mesh to 1 inch) screen or equivalent when the vent is in a protected area; or
- (b) a protective filter when the vent is in an area that is not protected from windblown dirt and debris.

5-302.15 WATER TANK DESIGN (1) A water tank and its inlet and outlet must be sloped to drain.

(2) A water tank inlet must be positioned so that it is protected from contaminants such as waste discharge, road dust, oil, or grease.

5-302.16 WATER TANK HOSE (1) A hose used for conveying drinking water from a water tank must be:

- (a) safe; ^P
- (b) durable, corrosion-resistant, and non-absorbent;
- (c) resistant to pitting, chipping, crazing, scratching, scoring, distortion, and decomposition;
- (d) finished with a smooth interior surface; and
- (e) clearly and durably identified as to its use if not permanently attached.

5-303.11 WATER TANK FILTER (1) A filter that does not pass oil or oil vapors must 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

5-303.12 WATER SAFEGUARD (1) A cap and keeper chain, closed cabinet, closed storage tube, or other approved protective cover or device must be provided for a water inlet, outlet, and hose.

5-303.13 MOBILE WATER TANK INLET (1) A mobile food establishment's water tank inlet must be:

- (a) 19.1 mm (three-quarter inch) or less in inner diameter; and
- (b) provided with a hose connection of a size or type that will prevent its use for any other service.

5-304.11 WATER TANK SANITIZING (1) A water tank, pump, and hoses must be flushed and sanitized before being placed in service after construction, repair, modification, and periods of nonuse. ^P

5-304.12 WATER TANK PROTECTION (1) A person must operate a water tank, pump, and hoses so that backflow and other contamination of the water supply are prevented.

5-304.13 WATER TANK COVER (1) If not in use, a water tank and hose inlet and outlet fitting must be protected using a cover or device as specified in 5-303.12.

5-304.14 WATER TANK EQUIPMENT (1) Except as specified in (2), a water tank, pump, and hoses used for conveying drinking water must be used for no other purpose. ^P

(2) 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.

5-401.11 MOBILE SEWAGE TANK (1) A sewage holding tank in a mobile food establishment must be:

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

5-402.10 SEWAGE DRAINAGE SYSTEM (1) Food establishment drainage systems, including grease traps, that convey sewage must be designed and installed as specified in 5-202.11(1).

5-402.11 SEWAGE BACKFLOW PREVENTION (1) Except as specified in (2), (3), and (4), a direct connection must not exist between the sewage system and a drain originating from equipment in which food, portable equipment, or utensils are placed. ^P

(2) Paragraph (1) does not apply to floor drains that originate in refrigerated spaces that are constructed as an integral part of the building.

(3) 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.

(4) If allowed by law, a warewashing sink may have a direct connection.

5-402.12 GREASE TRAP (1) If used, a grease trap must be located to be easily accessible for cleaning.

5-402.13 CONVEYING SEWAGE (1) Sewage must 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

5-402.14 MOBILE SEWAGE DISPOSAL (1) Sewage and other liquid wastes must 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}

5-402.15 WASTEWATER TANK CLEANING (1) A tank for liquid waste retention must be thoroughly flushed and drained in a sanitary manner during the servicing operation.

5-403.11 APPROVED SEWAGE DISPOSAL (1) Sewage must be disposed through an approved facility that is:

(a) a public sewage treatment plant; ^P or

(b) an individual sewage disposal system that is sized, constructed, maintained, and operated according to law. ^P

5-403.12 OTHER LIQUID WASTES (1) Condensate drainage and other non-sewage liquids and rainwater must be drained from point of discharge to disposal according to law.

5-501.10 INDOOR TRASH STORAGE (1) If located within the food establishment, a storage area for refuse, recyclables, and returnables must meet the requirements specified under applicable sections of this rule.

5-501.11 OUTDOOR TRASH SURFACE AREA (1) An outdoor storage surface for refuse, recyclables, and returnables must be constructed of non-absorbent material such as concrete or asphalt and must be smooth, durable, and sloped to drain.

5-501.12 OUTDOOR TRASH ENCLOSURE (1) If used, an outdoor enclosure for refuse, recyclables, and returnables must be constructed of durable and cleanable materials.

(2) If an outdoor enclosure is not used for refuse, recyclables, and returnables, storage must not create a nuisance or health hazard.

5-501.13 TRASH RECEPTACLES (1) Except as specified in (2), receptacles and waste handling units for refuse, recyclables, and returnables and for use with materials containing food residue must be durable, cleanable, insect-and-rodent resistant, leak-proof, and non-absorbent.

(2) Plastic bags and wet strength paper bags may be used to line receptacles for storage inside the food establishment, or within closed outside receptacles.

5-501.15 OUTSIDE TRASH RECEPTACLES (1) Receptacles and waste handling units for refuse, recyclables, and returnables used with materials containing food residue and used

outside the food establishment must be designed and constructed to have tight-fitting lids, doors, or covers.

(2) Receptacles and waste handling units for refuse and recyclables such as an on-site compactor must 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.

5-501.16 TRASH STORAGE (1) An inside storage room and area and outside storage area and enclosure, and receptacles must be of sufficient capacity to hold refuse, recyclables, and returnables that accumulate.

(2) A receptacle must 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.

(3) If disposable towels are used at handwashing lavatories, a waste receptacle must be located at each lavatory or group of adjacent lavatories.

5-501.17 COVERED RECEPTACLE (1) A toilet room used by females must be provided with a covered receptacle for sanitary napkins.

5-501.18 TRASH RECEPTACLE CLEANING (1) Except as specified in (2), suitable cleaning implements and supplies such as high pressure pumps, hot water, steam, and detergent must be provided as necessary for effective cleaning of receptacles and waste handling units for refuse, recyclables, and returnables.

(2) If approved, off-premises-based cleaning services may be used if on-premises cleaning implements and supplies are not provided.

5-501.19 TRASH AREA LOCATION (1) An area designated for refuse, recyclables, returnables, and, except as specified in (2), a redeeming machine for recyclables or returnables must 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.

(2) A redeeming machine may be located in the packaged food storage area or consumer area of a food establishment if food, equipment, utensils, 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.

(3) 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.

5-501.110 TRASH INACCESSIBILITY (1) Refuse, recyclables, and returnables must be stored in receptacles or waste handling units so that they are inaccessible to insects and rodents.

5-501.111 TRASH AREA MAINTENANCE (1) Storage areas, enclosures, and receptacles for refuse, recyclables, and returnables must be maintained in good repair.

5-501.112 OUTSIDE STORAGE PROHIBITIONS (1) Except as specified in (2), refuse receptacles not meeting the requirements specified in 5-501.13(1) such as receptacles that are not rodent-resistant, unprotected plastic bags and paper bags, or baled units that contain materials with food residue may not be stored outside.

(2) 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.

5-501.113 COVERING OTHER RECEPTACLES. Receptacles and waste handling units for refuse, recyclables, and returnables must be kept covered:

- (1) Inside the food establishment if the receptacles and units:
 - (a) contain food residue and are not in continuous use; or
 - (b) after they are filled; and
- (2) With tight-fitting lids or doors if kept outside the food establishment.

5-501.114 RECEPTACLE DRAIN PLUGS (1) Drains in receptacles and waste handling units for refuse, recyclables, and returnables must have drain plugs in place.

5-501.115 TRASH AREA, UNNECESSARY ITEMS (1) A storage area and enclosure for refuse, recyclables, or returnables must be maintained free of unnecessary items, as specified in 6-501.114, and clean.

5-501.116 TRASH RECEPTACLE CLEANING FREQUENCY (1) Receptacles and waste handling units for refuse, recyclables, and returnables must be thoroughly cleaned in a way that does not contaminate food, equipment, utensils, linens, or single-service and single-use articles, and waste water must be disposed of as specified in 5-402.13.

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

5-502.11 TRASH REMOVAL FREQUENCY (1) Refuse, recyclables, and returnables must 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.

5-502.12 RECEPTACLES OR VEHICLES. Refuse, recyclables, and returnables must be removed from the premises by means of:

- (1) Portable receptacles constructed and maintained according to law; or
- (2) A transport vehicle constructed, maintained, and operated according to law.

5-503.11 TRASH DEPOSITION (1) Solid waste not disposed of through the sewage system such as through grinders and pulpers must be recycled or disposed of in an approved public or private community recycling or refuse facility; or solid waste must be disposed of in an individual refuse facility such as a landfill or incinerator which is sized, constructed, maintained, and operated according to law.

CHAPTER 6 PHYSICAL FACILITIES

6-101.11 INDOOR AREA SURFACES (1) Except as specified in (2), materials for indoor floor, wall, and ceiling surfaces under conditions of normal use must be:

(a) smooth, durable, and easily cleanable for areas where food establishment operations are conducted;

(b) closely woven and easily cleanable carpet for carpeted areas; and

(c) non-absorbent 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:

(a) 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 mud; and

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

6-102.11 OUTDOOR AREA SURFACES (1) The outdoor walking and driving areas must 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 must be of weather-resistant materials and must comply with law.

(3) Outdoor storage areas for refuse, recyclables, or returnables must be of materials specified under applicable sections of this rule.

6-201.11 FLOORS, WALLS, CEILINGS CLEANABILITY (1) Except as specified in 6-201.14 and except for anti-slip floor coverings or applications that may be used for safety reasons, floors, floor coverings, walls, wall coverings, and ceilings must be designed, constructed, and installed so they are smooth, durable, non-absorbent, and easily cleanable.

(2) the department highly recommends that flooring in food processing and warewashing areas be light in color whenever possible to facilitate evaluation of cleaning efficacy.

6-201.12 UTILITY LINES (1) Utility service lines and pipes may not be unnecessarily exposed.

(2) Exposed utility service lines and pipes must be installed so they do not obstruct or prevent cleaning of the floors, walls, or ceilings.

(3) Exposed horizontal utility service lines and pipes may not be installed on the floor.

6-201.13 FLOOR, WALL JUNCTURES (1) In food establishments in which cleaning methods other than water flushing are used for cleaning floors, the floor and wall junctures must be covered and closed to no larger than 1 mm (one thirty-second inch).

(2) The floors in food establishments in which water flush cleaning methods are used must be provided with drains and be graded to drain and the floor and wall junctures must be covered and sealed.

6-201.14 CARPETING (1) A floor covering such as carpeting or similar material may not be installed as a floor covering in food processing areas, walk-in refrigerators, warewashing areas, toilet room areas where handwashing lavatories, toilets, and urinals are located, refuse storage rooms, or other areas where the floor is subject to moisture, flushing, or spray cleaning methods.

(2) If carpeting is installed as a floor covering in areas other than those specified in (1), it must be:

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

(b) 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.

6-201.15 OTHER FLOOR COVERINGS (1) Mats and duckboards must be designed to be removable and easily cleanable, and must not be, or have the potential to be a source of contamination of food, or food equipment and utensils.

6-201.16 WALL COVERINGS (1) Wall and ceiling covering materials must be attached so that they are easily cleanable.

(2) Except in areas used only for dry storage, concrete, porous blocks, or bricks used for indoor wall construction must be finished and sealed to provide a smooth, non-absorbent, easily cleanable surface.

6-201.17 WALL, CEILING ATTACHMENTS (1) Attachments to walls and ceilings such as light fixtures, mechanical room ventilation system components, vent covers, wall mounted fans, decorative items, and other attachments must be easily cleanable.

6-201.18 STUDS, JOISTS, RAFTERS (1) Studs, joists, and rafters may not be exposed in areas subject to moisture, and/or accumulation of vapors from grease and oil.

6-202.11 LIGHT SHIELDING (1) Except as specified in (2), light bulbs must 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.

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

(a) the integrity of the packages cannot be affected by broken glass falling onto them; and

(b) the packages are capable of being cleaned of debris from broken bulbs before the packages are opened.

(3) An infrared or other heat lamp must be protected against breakage by a shield surrounding and extending beyond the bulb so that only the face of the bulb is exposed.

6-202.12 AIR SYSTEMS (1) Heating, ventilating, and air conditioning systems must 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.

6-202.13 INSECT CONTROL SYSTEMS (1) Insect control devices that are used to electrocute or stun flying insects must be designed to retain the insect within the device.

(2) Insect control devices must be installed so that:

(a) the devices are not located over a food preparation area; and

(b) 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.

6-202.14 TOILET ROOMS ENCLOSED (1) 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 must be completely enclosed and provided with a tightfitting and self-closing door.

6-202.15 OUTER OPENINGS PROTECTED (1) Except as specified in (2), (3), (4) and (5), outer openings of a food establishment must be protected against the entry of insects and rodents by:

(a) filling or closing holes and other gaps along floors, walls, and ceilings;

(b) closed, tight-fitting windows; and

(c) solid, self-closing, tight-fitting doors.

(2) Paragraph (1) 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.

(3) Exterior doors used as exits need not be self-closing if they are:

(a) solid and tight-fitting;

(b) designated for use only when an emergency exists, by the fire protection authority that has jurisdiction over the food establishment; and

(c) limited-use so they are not used for entrance or exit from the building for purposes other than the designated emergency exit use.

(4) Except as specified in (2) and (5), 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 in (1), the openings must be protected against the entry of insects and rodents by:

(a) 16 mesh to 25.4 mm (16 mesh to 1 inch) screens;

(b) properly designed and installed air curtains to control flying insects; or

(c) other effective means.

(5) Paragraph (4) does not apply if flying insects and other pests are absent due to the location of the establishment, the weather, or other limiting condition.

6-202.16 EXTERIOR PROTECTIVE BARRIER (1) Perimeter walls and roofs of a food establishment must effectively protect the establishment from the weather and the entry of insects, rodents, and other animals.

6-202.18 SERVICE AREAS PROTECTED (1) Except for areas used only for the loading of water or the discharge of sewage and other liquid waste, through the use of a closed system of hoses, servicing areas must be provided with overhead protection.

6-202.19 GRADED OUTDOOR SURFACES (1) Exterior walking and driving surfaces must be graded to drain.

6-202.110 TRASH AREA CONSTRUCTION (1) Outdoor refuse areas must be constructed in accordance with law, and must 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.

6-202.111 PRIVATE QUARTERS PROHIBITION (1) A private home, 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. Living quarters, and driving compartments in mobile units, must be completely separated from the approved food activities.
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6-202.112 ONSITE PRIVATE QUARTERS (1) Living or sleeping quarters located on the premises of a food establishment such as those provided for lodging registration clerks or resident managers must be separated from rooms and areas used for food establishment operations by complete partitioning and solid self-closing doors.

6-301.10 HANDWASHING SINKS MINIMUM (1) Handwashing sinks must be provided as specified in 5-203.11.

6-301.11 HANDWASHING CLEANSER AVAILABILITY (1) Each handwashing sink or group of 2 adjacent handwashing sinks must be provided with a supply of hand cleaning liquid, powder, or bar soap. ^{Pf}

6-301.12 HAND DRYING PROVISION (1) Each handwashing sink or group of adjacent handwashing sinks must be provided with:

(a) individual, disposable towels; ^{Pf}

(b) a continuous towel system that supplies the user with a clean towel; ^{Pf}

(c) a heated-air hand drying device; ^{Pf} or

(d) a hand drying device that employs an air-knife system that delivers high velocity, pressurized air at ambient temperatures. ^{Pf}

6-301.13 HANDWASHING AID RESTRICTIONS (1) 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 in 6-301.11, 6-301.12 and 5-501.16(3).

6-301.14 HANDWASHING SIGNAGE (1) A sign or poster that notifies food employees to wash their hands must be provided at all handwashing sinks used by food employees and must be clearly visible to food employees. Food establishment operators may create and post their own signs or posters for this requirement.

6-301.20 DISPOSABLE TOWEL RECEPTACLE (1) A handwashing sink or group of adjacent handwashing sinks that is provided with disposable towels must be provided with a waste receptacle as specified in 5-501.16(3).

6-302.10 TOILET, URINAL NUMBERS (1) Toilets and urinals must be provided as specified in 5-203.12.

6-302.11 TOILET TISSUE AVAILABILITY (1) An adequate supply of toilet tissue must be available at each toilet. ^{Pf}

6-303.11 LIGHT INTENSITY (1) Light intensity must be:

(a) 10 foot-candles (108 lux) or greater 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;

(b) 20 foot-candles (215 lux) or greater:

(i) inside equipment such as reach-in and under-counter refrigerators; and

(ii) at a distance of 75 cm (30 inches) above the floor in areas used for handwashing, warewashing, and equipment and utensil storage, and in toilet rooms; and

(c) 50 foot-candles (540 lux) or greater at a surface where a food employee is working with food or working with utensils or equipment such as knives, slicers, grinders, or saws where employee safety is a factor.

6-304.11 MECHANICAL VENTILATION (1) If necessary to keep rooms free of excessive heat, steam, condensation, vapors, obnoxious odors, smoke, and fumes, mechanical ventilation of sufficient capacity must be provided.

6-305.11 DRESSING AREAS (1) Dressing rooms or dressing areas must be designated if employees routinely change their clothes in the establishment.

(2) Lockers or other suitable facilities must be provided for the orderly storage of employees' clothing and other possessions.

6-306.10 SERVICE SINK AVAILABILITY (1) A service sink or curbed cleaning facility must be provided as specified in 5-203.13(1).

6-401.10 HANDWASHING SINK LOCATION (1) Handwashing sinks must be conveniently located as specified in 5-204.11.

6-402.11 TOILET ROOMS ACCESSIBILITY (1) Toilet rooms must be conveniently located and accessible to workers during all hours of operation.

6-403.11 EMPLOYEE AREAS (1) Areas designated for employees to eat, drink, and use tobacco must be located so that food, equipment, linens, and single-service and single-use articles are protected from contamination.

(2) Lockers or other suitable facilities must be located in a designated room or area where contamination of food, equipment, utensils, linens, and single-service and single-use articles cannot occur.

6-404.11 PRODUCT SEGREGATION (1) Products that are held by the legal licensee for credit, redemption, or return to the distributor, such as damaged, spoiled, or recalled products, must be segregated and held in designated areas that are separated from food, equipment, utensils, linens, and single-service and single-use articles. ^{Pf}

6-405.10 TRASH AREA DESIGNATION (1) Units, receptacles, and areas designated for storage of refuse and recyclable and returnable containers must be located as specified in 5-501.19.

6-501.11 PHYSICAL FACILITY REPAIR (1) Physical facilities must be maintained in good repair.

6-501.12 FACILITY CLEANING (1) Physical facilities must 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 must be done during periods when the least amount of food is exposed such as after closing.

6-501.13 CLEANING METHODS (1) Except as specified in (2), 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:

(a) without the use of dust-arresting compounds; and

(b) 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.

6-501.14 CLEANING RESTRICTIONS (1) Intake and exhaust air ducts must 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, nuisance, or unlawful discharge.

6-501.15 PREVENTING CLEANING CONTAMINATION (1) 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. ^{Pf}

6-501.16 DRYING MOPS (1) After use, mops must be placed in a position that allows them to air-dry without soiling walls, equipment, or supplies.

6-501.17 ABSORBENT MATERIALS LIMITATION (1) Except as specified in 6-501.13(2), sawdust, wood shavings, granular salt, baked clay, diatomaceous earth, or similar materials may not be used on floors.

6-501.18 CLEANING PLUMBING FIXTURES (1) Plumbing fixtures such as handwashing sinks, toilets, and urinals must be cleaned as often as necessary to keep them clean.

6-501.19 TOILET ROOM DOORS (1) Except during cleaning and maintenance operations, toilet room doors as specified in 6-202.14 must be kept closed.

6-501.110 DRESSING AREA USE (1) Dressing rooms must be used by employees if the employees regularly change their clothes in the establishment.

(2) Lockers or other suitable facilities must be used for the orderly storage of employee clothing and other possessions.

6-501.111 PEST CONTROL (1) The premises must be maintained free of insects, rodents, and other pests. The presence of insects, rodents, and other pests must be controlled to eliminate their presence on the premises by:

(a) routinely inspecting incoming shipments of food and supplies;

(b) routinely inspecting the premises for evidence of pests;

(c) using methods, if pests are found, such as trapping devices or other means of pest control as specified in 7-202.12, 7-206.12, and 7-206.13; ^{Pf} and

(d) eliminating harborage conditions.

6-501.112 REMOVING DEAD PESTS (1) Dead or trapped birds, insects, rodents, and other pests must be removed from control devices and the premises at a frequency that prevents their accumulation, decomposition, or the attraction of pests.

6-501.113 STORING MAINTENANCE TOOLS (1) Maintenance tools such as brooms, mops, vacuum cleaners, and similar items must be:

(a) stored so they do not contaminate food, equipment, utensils, linens, and single-service and single-use articles; and

(b) stored in an orderly manner that facilitates cleaning the area used for storing the maintenance tools.

6-501.114 UNNECESSARY ITEMS (1) The premises must be free of items that are unnecessary to the operation or maintenance of the establishment such as equipment.

6-501.115 PROHIBITING ANIMALS (1) Except as specified in (2) and (3), live animals may not be allowed on the premises of a food establishment. ^{Pf}

(2) Live animals may be allowed in the following situations if the contamination of food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles cannot result:

(a) edible fish or decorative fish in aquariums, shellfish or crustacea on ice or under refrigeration, and shellfish and crustacea in display tank systems;

(b) patrol dogs accompanying police or security officers in offices and dining, sales, and storage areas, and sentry dogs flowing loose in outside fenced areas;

(c) in areas that are not used for food preparation and that are usually open for customers, such as dining and sales areas, service animals that are controlled by the disabled employee or person, if a health or safety hazard will not result from the presence or activities of the service animal; and

(d) pets in the common dining areas of institutional care facilities such as nursing homes, assisted living facilities, group homes, or residential care facilities at times other than during meals if:

(i) effective partitioning and self-closing doors separate the common dining areas from food storage or food preparation areas,

(ii) condiments, equipment, and utensils are stored in enclosed cabinets or removed from the common dining areas when pets are present,

(iii) dining areas including tables, countertops, and similar surfaces are effectively cleaned before the next meal service; and

(iv) 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.

CHAPTER 7 POISONOUS, TOXIC MATERIALS

7-101.11 SUBSTANCE CONTAINER LABEL (1) Containers of poisonous or toxic materials and personal care items must bear a legible manufacturer's label. ^{Pf}

7-102.11 WORKING SUBSTANCE CONTAINERS (1) Working containers used for storing poisonous or toxic materials such as cleaners and sanitizers taken from bulk supplies must be clearly and individually identified with the common name of the material. ^{Pf}

7-201.11 SUBSTANCE STORAGE (1) Poisonous or toxic materials must be stored 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

(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. This paragraph 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

7-202.11 SUBSTANCE RESTRICTION (1) 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, must be allowed in a food establishment. ^{Pf}

(2) Paragraph (1) does not apply to packaged poisonous or toxic materials that are for retail sale.

7-202.12 SUBSTANCE USE (1) Poisonous or toxic materials must be:

- (a) used according to:
 - (i) law and this rule;
 - (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 regulatory authority; and
- (b) 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
 - (A) removing the items; ^P
 - (B) covering the items with impermeable covers; ^P or
 - (C) taking other appropriate preventive actions; ^P and
 - (D) cleaning and sanitizing equipment and utensils after the application. ^P
- (c) a restricted use pesticide must be applied only by an applicator certified as defined in 7 USC § 136(e) of the Federal Insecticide, Fungicide, and Rodenticide Act, or a person under the direct supervision of a certified applicator. ^{Pf}

7-203.11 SUBSTANCE CONTAINER REUSE (1) A container previously used to store poisonous or toxic materials may not be used to store, transport, or dispense food. ^P

7-204.11 SANITIZER CRITERIA (1) Chemical sanitizers, including chemical sanitizing solutions generated on-site, and other chemical antimicrobials applied to food-contact surfaces must:

- (a) 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, or
- (b) meet the requirements as specified in 40 CFR 180.2020 pesticide chemicals not requiring a tolerance or exemption from tolerance-non-food determinations. ^P

7-204.12 PRODUCE CHEMICALS (1) Chemicals, including those generated on-site, used to wash or peel raw, whole fruits and vegetables must:

- (a) be an approved food additive listed for this intended use in 21 CFR Part 173, ^P or
- (b) be Generally Recognized as Safe (GRAS) for this intended use, ^P or
- (c) be the subject of an effective food contact notification for this intended use (only effective for the manufacturer or supplier identified in the notification), ^P and
- (d) meet the requirements in 40 CFR Part 156 Labeling Requirements for Pesticide and devices. ^P

(2) Ozone as an antimicrobial agent used in the treatment, storage, and processing of fruits and vegetables in a food establishment must meet the requirements specified in 21 CFR 173.368 Ozone. ^P

7-204.13 BOILER WATER ADDITIVES (1) Chemicals used as boiler water additives must meet the requirements specified in 21 CFR 173.310 Boiler Water Additives. ^P

7-204.14 DRYING AGENTS. Drying agents used in conjunction with sanitization must:

(1) Contain only components that are listed as one of the following:

(a) Generally Recognized as Safe (GRAS) 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

(b) Generally Recognized as Safe (GRAS) for the intended use as specified in 21 CFR Part 186 - Indirect Food Substances Affirmed as Generally Recognized as Safe, ^P

(c) Generally Recognized as Safe (GRAS) for the intended use as determined by experts qualified in scientific training and experience to evaluate the safety of substances added, directly or indirectly, to food as described in 21 CFR 170.30 eligibility for classification as Generally Recognized as Safe (GRAS), ^P

(d) subject of an effective food contact notification as described in the Federal Food Drug and Cosmetic Act (FFDCA) section 409(h), 21 USC 348 (h), ^P

(e) approved for use as a drying agent under a prior sanction as described in the Federal Food Drug and Cosmetic Act (FFDCA) section 201(s)(4), 21 USC 201(s)(4); ^P

(f) specifically regulated as an indirect food additive for use as a drying agent as specified in 21 CFR Parts 174-178, ^P or

(g) 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

(2) When sanitization is with chemicals, the approval required in (1)(e) or (1)(g) or the regulation as an indirect food additive required in (1)(f), must be specifically for use with chemical sanitizing solutions. ^P

7-205.11 LUBRICANT USE (1) Lubricants must 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

7-206.11 RESTRICTED PESTICIDES (1) Restricted use pesticides specified in 7-202.12(3) must meet the requirements specified in 40 CFR Part 152, Subpart I - Classification of Pesticides. ^P

7-206.12 RODENT BAIT STATIONS (1) Rodent bait must be contained in a covered, tamper-resistant bait station. ^P

7-206.13 PEST POWDERS (1) Except as specified in (2), a tracking powder pesticide may not be used in a food establishment. ^P

(2) 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.

7-207.11 MEDICINE STORAGE (1) 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}

(2) Medicines that are in a food establishment for the employees' use must be labeled as specified in 7-101.11 and located to prevent the contamination of food, equipment, utensils, linens, and single-service and single-use articles. ^P

7-207.12 REFRIGERATED MEDICINE (1) Medicines belonging to employees or to children in a day care center that require refrigeration and are stored in a food refrigerator must be:

- (a) stored in a package or container and kept inside a covered, leak-proof container that is identified as a container for the storage of medicines; ^P and
- (b) located so they are inaccessible to children. ^P

7-208.11 FIRST AID SUPPLIES (1) First aid supplies that are in a food establishment for the employees' use must be:

- (a) labeled as specified in 7-101.11; ^{Pf} and
- (b) 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

7-209.11 PERSONAL ITEMS (1) Except as specified in 7-207.12 and 7-208.11, employees must store their personal care items in facilities as specified in 6-305.11(2).

7-301.11 SUBSTANCE SEPARATION (1) Poisonous or toxic materials must 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
- (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

CHAPTER 8 COMPLIANCE, ENFORCEMENT

8-101.10 REGULATORY AUTHORITY RESPONSIBILITIES (1) The regulatory authority must apply this rule to promote its underlying purpose, which is safeguarding public health and ensuring that food is safe, unadulterated, and honestly presented when offered to the retailer, and ultimately the consumer.

(2) In enforcing the provisions of this rule, the regulatory authority must assess existing facilities or equipment that were in use before the effective date of this rule based on the following considerations:

- (a) whether the facilities or equipment are in good repair and capable of being maintained in a sanitary condition;
- (b) whether food-contact surfaces comply with applicable regulations of this rule;
- (c) whether the capacities of cooling, heating, and holding equipment are sufficient to comply with 4-301.11; and
- (d) the existence of a documented agreement with the legal licensee that the facilities or equipment will be replaced as specified 8-304.11(7).

8-102.10 OTHER HEALTH HAZARDS (1) If necessary to protect against public health hazards or nuisances, the regulatory authority may impose specific requirements in addition to the requirements contained in this rule that are authorized by law, especially in the case of mobile food establishments engaging in high-risk processing or packaging, as determined by the regulatory authority.

(2) The regulatory authority must document the conditions that necessitate the imposition of additional requirements and the underlying public health rationale. The documentation must be provided to the license applicant or legal licensee and a copy must be maintained in the local regulatory authority's file for the food establishment.

8-103.10 VARIANCES (1) The regulatory authority may grant a variance by modifying or waiving the requirements of this rule if in the opinion of the regulatory authority a health hazard or nuisance will not result from the variance. If a variance is granted, the regulatory authority must retain the information specified in 8-103.11 in its records for the food establishment.

(2)(a) Prior to issuing a variance, the local regulatory authority will contact, notify, and consult with the department about any similar variances to determine prior precedence set by other local jurisdictions to help ensure uniform application of the law.

(b) Failure by the local regulatory authority to comply with (2)(a) may result in action by the department allowed by law.

8-103.11 VARIANCE DOCUMENTATION. (1) Before a variance from a requirement of this rule is approved, the information that must be provided by the person requesting the variance and retained in the local regulatory authority's file on the food establishment includes:

(a) A statement of the proposed variance of the rule requirement citing relevant rule section numbers; ^{Pf}

(b) An analysis of the rationale for how the potential public health hazards and nuisances addressed by the relevant rule sections will be alternatively addressed by the proposal; ^{Pf} and

(c) A HACCP plan if required as specified in 8-201.13 that includes the information specified in 8-201.14 as it is relevant to the variance requested. ^{Pf}

8-103.12 VARIANCE, HACCP PROCEDURES. (1) If the regulatory authority grants a variance as specified in 8-103.10, or a HACCP plan is otherwise required as specified in 8-201.13, the legal licensee must:

(a) comply with the HACCP plans and procedures that are submitted as specified under section 8-201.14 and approved as a basis for the modification or waiver; ^P and

(b) maintain and provide to the regulatory authority, upon request, records specified in 8-201.14(4) and (5) that demonstrate that the following are routinely employed;

(i) procedures for monitoring the critical control points, ^{Pf}

(ii) monitoring of the critical control points, ^{Pf}

(iii) verification of the effectiveness of the operation or process, ^{Pf} and

(iv) necessary corrective actions if there is failure at a critical control point. ^{Pf}

8-201.13 HACCP, RECALL, FOOD SAFETY PLANS (1) Wholesale food establishments and their affiliates and subsidiaries that collectively have an average annual income at or greater than \$1 million per year in sales or holding fees of human food, after adjusting for inflation, during the 3-year period preceding the applicable calendar year must create, keep and maintain a food plan in accordance with 21 CFR Part 117, Subpart C.

(2) Before engaging in an activity that requires a HACCP plan, a license applicant or legal licensee must submit to the regulatory authority for approval a properly processed HACCP plan as specified in 8-201.14 and relevant provisions of this rule if:

(a) submission of a HACCP plan is required in applicable parts of 3-404.11;

(b) a variance is required as specified in 4-204.110(2) or 8-103.10; and

(c) the regulatory authority determines that a food preparation or processing method requires a variance based on a plan submittal, an inspectional finding, or a variance request.

(3) Before engaging in reduced oxygen packaging without a variance as specified in 3-502.12, a license applicant or legal licensee must submit a properly processed HACCP plan to the regulatory authority.

8-201.14 HACCP PLAN CONTENTS. (1) For a food establishment that is required in 8-201.13 to have a HACCP plan, the plan and specifications must indicate:

(a) A categorization of the types of potentially hazardous 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 regulatory authority; ^{Pf}

(b) A flow diagram by specific food 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, ^{Pf} and
- (ii) formulations or recipes that delineate methods and procedural control measures that address the food safety concerns involved. ^{Pf}

(2) Food employee and supervisory training plan that addresses the food safety issues of concern; ^{Pf}

(3) A statement of standard operating procedures for the plan under consideration including clearly identifying:

- (a) each critical control point, ^{Pf}
- (b) the critical limits for each critical control point, ^{Pf}
- (c) the method and frequency for monitoring and controlling each critical control point by the food employee designated by the person in charge, ^{Pf}
- (d) 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, ^{Pf}
- (e) action to be taken by the person in charge if the critical limits for each critical control point are not met, ^{Pf} and
- (f) records to be maintained by the person in charge to demonstrate that the HACCP plan is properly operated and managed; ^{Pf} and

(4) Additional scientific data or other information, as required by the regulatory authority, supporting the determination that food safety is not compromised by the proposal. ^{Pf}

8-202.10 TRADE SECRET CONFIDENTIALITY (1) The regulatory authority must treat as confidential in accordance with law, information that meets the criteria specified in 30-14-401 et seq., MCA for a trade secret that is contained on inspection report forms and in the plans and specifications submitted as specified in 8-201.14.

8-304.11 LEGAL LICENSEE RESPONSIBILITIES. (1) Upon acceptance of the license issued by the regulatory authority, the legal licensee in order to retain the license must:

- (a) post the license in a location in the food establishment that is conspicuous to consumers or public;
- (b) comply with the provisions of this rule including the conditions of a granted variance as specified in 8-103.12;
- (c) if a food establishment is required in 8-201.13 to operate under a HACCP plan, comply with the plan as specified in 8-103.12;
- (d) immediately contact the regulatory authority to report an illness of a food employee or conditional employee as specified in 2-201.11(2);
- (e) immediately discontinue operations and notify the regulatory authority if an imminent health hazard may exist as specified in 8-404.11;
- (f) allow representatives of the regulatory authority access to the food establishment as specified in 8-402.15;
- (g) replace existing facilities and equipment specified in 8-101.10 with facilities and equipment that comply with this rule if:
 - (i) the regulatory authority 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,
 - (ii) the regulatory authority directs the replacement of the facilities and equipment because of a change of ownership, or
 - (iii) the facilities and equipment are replaced in the normal course of operation;
- (h) Comply with directives of the regulatory authority including time frames for corrective actions specified in inspection reports, notices, orders, warnings, and other directives issued by

the regulatory authority in regard to the legal licensee's food establishment or in response to community emergencies;

(i) Accept notices issued and served by the regulatory authority according to law; and

(j) Be subject to the administrative, civil, injunctive, and criminal remedies authorized in law for failure to comply with this rule or a directive of the regulatory authority, including time frames for corrective actions specified in inspection reports, notices, orders, warnings, and other directives.

(k) Notify retailers that a copy of the most recent establishment inspection report is available upon request by posting a sign or placard in a location in the food establishment that is conspicuous to customers or by another method acceptable to the regulatory authority.

8-401.20 REGULATORY INSPECTION PRIORITIES (1) Within the parameters specified in 8-401.10, the regulatory authority must prioritize, and conduct more frequent inspections based upon its assessment of a food establishment's history of compliance with this rule and the establishment's potential as a vector of foodborne illness by evaluating:

(a) past performance, for non-conformance with rule or HACCP plan requirements that are priority items or priority foundation items;

(b) past performance, for numerous or repeat violations of rule or HACCP plan requirements that are core items;

(c) past performance, for complaints investigated and found to be valid;

(d) the hazards associated with the particular foods that are processed, stored, or served;

(e) the type of operation, including methods and extent of food storage, preparation, and service;

(f) the number of people served; and

(g) whether the population to be ultimately served is a highly susceptible population, such as but not limited to a school or institution that cares for children or the elderly.

8-402.10 INSPECTOR COMPETENCY (1) An authorized representative of the regulatory authority who inspects a food establishment or conducts plan review for compliance with this rule must have the sanitarian registration, training, knowledge, skills, and ability to adequately perform the required duties.

8-402.11 RELEVANT TRAINING (1) The department and local regulatory authority must provide relevant training as agency resources permit for inspectors to meet requirements of 8-402.10.

8-402.15 INSPECTION ACCESS (1) After the regulatory authority presents official credentials and provides notice of the purpose of, and an intent to conduct, an inspection, the person in charge must allow the regulatory authority to determine if the food establishment is in compliance with this rule by allowing access to the establishment, allowing inspection, and providing information and records specified in this rule and to which the regulatory authority is entitled according to law, during the food establishment's hours of operation and other reasonable times.

8-402.20 ACCESS REFUSAL (1) If a person denies access to the regulatory authority, the regulatory authority must:

(a) inform the person that:

(i) the legal licensee is required to allow access to the regulatory authority as specified in 8-402.15,

(ii) access is a condition of the acceptance and retention of a food establishment license to operate as specified in 8-304.11(6), and

(iii) if access is denied, an order issued by the appropriate authority allowing access, hereinafter referred to as an inspection order, may be obtained according to law; and

(b) make a final request for access.

8-402.30 REFUSAL DOCUMENTATION (1) If after the regulatory authority presents credentials and provides notice as specified in 8-402.15 explains the authority upon which access is requested, and makes a final request for access as specified in 8-402.20, the person in charge continues to refuse access, the regulatory authority must provide details of the denial of access on an inspection report form.

8-402.40 INSPECTION ORDER (1) If denied access to a food establishment for an authorized purpose and after complying with 8-402.20, the regulatory authority may issue, or apply for the issuance of, an inspection order to gain access as provided in law.

8-403.10 INSPECTION DOCUMENTATION. (1) The regulatory authority must document on an inspection report form:

(a) Administrative information about the food establishment's legal identity, street and mailing addresses, type of establishment and operation as specified in 8-302.14(3), inspection date, and other information such as type of water supply and sewage disposal, status of the license, and personnel certificates that may be required; and

(b) Specific factual observations of violative conditions or other deviations from this rule that require correction by the legal licensee 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 rule as specified in 2-102.11,

(ii) failure of food employees, conditional employees, and the person in charge to report a disease or medical condition as specified in 2-201.11(2) and (4),

(iii) non-conformance with priority items or priority foundation items of this rule,

(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 regulatory authority as specified in 8-103.12,

(v) failure of the person in charge to provide records required by the regulatory authority for determining conformance with a HACCP plan as specified in 8-201.14(4)(f), and

(vi) non-conformance with critical limits of a HACCP plan.

8-403.20 CORRECTION NOTICE (1) The regulatory authority must specify on the inspection report form the time frame for correction of violations as specified in 8-404.11, 8-405.11, and 8-406.11.

8-403.30 COMPLETED INSPECTION (1) At the conclusion of an inspection and according to law, the regulatory authority must provide a copy of the completed inspection report and the notice to correct violations to the legal licensee or to the person in charge, and request a signed acknowledgment of receipt.

8-403.40 REFUSAL TO SIGN. (1) The regulatory authority must:

(a) Inform a person who declines to sign an acknowledgment of receipt of inspectional findings as specified in 8-403.30 that:

(i) an acknowledgment of receipt is not an agreement with findings,

(ii) Refusal to sign an acknowledgment of receipt will not affect the legal licensee'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 regulatory authority's historical record for the food establishment; and

(2) Make a final request that the person in charge sign an acknowledgment receipt of inspectional findings.

8-403.50 PUBLIC INFORMATION (1) Except as specified in 8-202.10, the regulatory authority must treat the inspection report as a public document and must make it available for disclosure to a person who requests it as provided in law.

8-404.11 IMMINENT HEALTH HAZARDS (1) Except as specified in (2), a legal licensee must immediately discontinue operations and notify the regulatory authority 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. ^P

(2) A legal licensee need not discontinue operations in an area of an establishment that is unaffected by the imminent health hazard.

8-404.12 RESUMPTION OF OPERATIONS (1) If operations are discontinued as specified in 8-404.11 or otherwise according to law, the legal licensee must obtain approval from the regulatory authority before resuming operations.

8-405.11 PRIORITY CORRECTIONS (1) Except as specified in (2), a license holder must at the time of inspection correct a violation of a priority item or priority foundation item of this rule and implement corrective actions for a HACCP plan provision that is not in compliance with its critical limit. ^{Pf}

(2) Considering the nature of the potential hazard involved and the complexity of the corrective action needed, the regulatory authority may agree to or specify a longer time frame, not to exceed:

(a) 72 hours after the inspection, for the legal licensee to correct violations of a priority item; or

(b) 10 calendar days after the inspection, for the license holder to correct violations of a priority foundation item or HACCP plan deviations.

8-405.20 CORRECTION DOCUMENTATION (1) 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 regulatory authority must enter the violation and information about the corrective action on the inspection report.

(2) as specified in 8-405.11(2), after receiving notification that the legal licensee 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 regulatory authority must verify correction of the violation, document the information on an inspection report, and enter the report in the regulatory authority's records.

8-406.11 CORE CORRECTIONS (1) Except as specified in (2), the legal licensee must correct core items by a date and time agreed to or specified by the regulatory authority but no later than 90 calendar days after the inspection.

(2) The regulatory authority may approve a compliance schedule that extends beyond the time limits specified in (1) if a written schedule of compliance is submitted by the legal licensee and no health hazard exists or will result from allowing an extended schedule for compliance, such as at a change in legal ownership, or at the time of significant remodeling.

8-501.10 REGULATORY AUTHORITY DUE DILIGENCE (1) The regulatory authority must 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 is transmissible 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 acute respiratory infection, by:

(a) securing a confidential medical history of the food employee or conditional employee suspected of transmitting disease or making other investigations as deemed appropriate; and

(b) requiring appropriate medical examinations, including collection of specimens for laboratory analysis, of a suspected food employee or conditional employee.

8-501.20 INVESTIGATION ACTIONS (1) Based on the findings of an investigation related to a food employee or conditional employee who is suspected of being infected or diseased, the regulatory authority may issue an order to the suspected food employee, conditional employee or legal licensee instituting one or more of the following control measures:

(a) restricting the food employee or conditional employee;

(b) excluding the food employee or conditional employee; or

(c) closing the food establishment by summarily suspending a license to operate in accordance with law.

8-501.30 INVESTIGATION ORDERS (1) Based on the findings of the investigation as specified in 8-501.10 and to control disease transmission, the regulatory authority may issue an order of restriction or exclusion to a suspected food employee or the license holder without prior warning, notice of a hearing, or a hearing if the order:

(a) states the reasons for the restriction or exclusion that is ordered;

(b) states the evidence that the food employee or license holder must provide in order to demonstrate that the reasons for the restriction or exclusion are eliminated;

(c) states that the suspected food employee or the legal licensee may request an appeal hearing by submitting a timely request as provided in law; and

(d) provides the name and address of the regulatory authority representative to whom a request for an appeal hearing may be made.

8-501.40 ORDER RELEASE (1) The regulatory authority must release a food employee, or conditional employee from restriction or exclusion according to law and the conditions specified in 2-201.13.