

FSMA PC Human Food	Subpart B - Current Good Manufacturing Practice							
FSMA PC Rule, Subpart B	FSMA Requirement	Company PRP	Company SOP	Monitoring Record	Notes	Status	Assigned To:	Completion Date
§ 117.10 Personnel	The management of the establishment must take reasonable measures and precautions to ensure the following:					Incomplete	(Select Employee)	
	(a) Disease control. Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, must be excluded from any operations which may be expected to result in such contamination until the condition is corrected, unless conditions such as open lesions, boils, and infected wounds are adequately covered (e.g., by an impermeable cover). Personnel must be instructed to report such health conditions to their supervisors.					Incomplete	(Select Employee)	
	(b) Cleanliness. All persons working in direct contact with food, food-contact surfaces, and food-packaging materials must conform to hygienic practices while on duty to the extent necessary to protect against allergen cross-contact and against contamination of food. The methods for maintaining cleanliness include:					Incomplete	(Select Employee)	
	(1) Wearing outer garments suitable to the operation in a manner that protects against allergen cross-contact and against the contamination of food, food-contact surfaces, or food-packaging materials.					Incomplete	(Select Employee)	
	(2) Maintaining adequate personal cleanliness.					Incomplete	(Select Employee)	
	(3) Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate hand-washing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated.					Incomplete	(Select Employee)	
	(4) Removing all unsecured jewelry and other objects that might fall into food, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand. If such hand jewelry cannot be removed, it may be covered by material which can be maintained in an intact, clean, and sanitary condition and which effectively protects against the contamination by these objects of the food, food-contact surfaces, or food-packaging materials.					Incomplete	(Select Employee)	
	(5) Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition.					Incomplete	(Select Employee)	
	(6) Wearing, where appropriate, in an effective manner, hair nets, headbands, caps, beard covers, or other effective hair restraints.					Incomplete	(Select Employee)	
	(7) Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.					Incomplete	(Select Employee)	
	(8) Confining the following to areas other than where food may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, or using tobacco.					Incomplete	(Select Employee)	
	(9) Taking any other necessary precautions to protect against allergen cross-contact and against contamination of food, food-contact surfaces, or food-packaging materials with microorganisms or foreign substances (including perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin).					Incomplete	(Select Employee)	
§ 117.20 Plant and grounds	(a) Grounds. The grounds about a food plant under the control of the operator must be kept in a condition that will protect against the contamination of food. The methods for adequate maintenance of grounds must include:					Incomplete	(Select Employee)	
	(1) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant that may constitute an attractant, breeding place, or harborage for pests.					Incomplete	(Select Employee)	
	(2) Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed.					Incomplete	(Select Employee)	
	(3) Adequately draining areas that may contribute contamination to food by seepage, foot-borne filth, or providing a breeding place for pests					Incomplete	(Select Employee)	
	(4) Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed					Incomplete	(Select Employee)	

	(5) If the plant grounds are bordered by grounds not under the operator's control and not maintained in the manner described in paragraphs (a)(1) through (4) of this section, care must be exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination.					Incomplete	(Select Employee)
	(b) Plant construction and design. The plant must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-production purposes (i.e., manufacturing, processing, packing, and holding). The plant must:					Incomplete	(Select Employee)
	(1) Provide adequate space for such placement of equipment and storage of materials as is necessary for maintenance, sanitary operations, and the production of safe food.					Incomplete	(Select Employee)
	(2) Permit the taking of adequate precautions to reduce the potential for allergen cross-contact and for contamination of food, food-contact surfaces, or food-packaging materials with microorganisms, chemicals, filth, and other extraneous material. The potential for allergen cross-contact and for contamination may be reduced by adequate food safety controls and operating practices or effective design, including the separation of operations in which allergen cross-contact and contamination are likely to occur, by one or more of the following means: location, time, partition, air flow systems, dust control systems, enclosed systems, or other effective means.					Incomplete	(Select Employee)
	(3) Permit the taking of adequate precautions to protect food in installed outdoor bulk vessels by any effective means, including:					Incomplete	(Select Employee)
	(i) Using protective coverings.					Incomplete	(Select Employee)
	(ii) Controlling areas over and around the vessels to eliminate harborage for pests.					Incomplete	(Select Employee)
	(iii) Checking on a regular basis for pests and pest infestation.					Incomplete	(Select Employee)
	(iv) Skimming fermentation vessels, as necessary.					Incomplete	(Select Employee)
	(4) Be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and kept in good repair; that drip or condensate from fixtures, ducts and pipes does not contaminate food, food-contact surfaces, or food-packaging materials; and that aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating food, food-contact surfaces, or food-packaging materials with clothing or personal contact.					Incomplete	(Select Employee)
	(5) Provide adequate lighting in hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where food is examined, manufactured, processed, packed, or held and where equipment or utensils are cleaned; and provide shatter-resistant light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation or otherwise protect against food contamination in case of glass breakage.					Incomplete	(Select Employee)
	(6) Provide adequate ventilation or control equipment to minimize dust, odors and vapors (including steam and noxious fumes) in areas where they may cause allergen cross-contact or contaminate food; and locate and operate fans and other airblowing equipment in a manner that minimizes the potential for allergen cross-contact and for contaminating food, food-packaging materials, and food-contact surfaces.					Incomplete	(Select Employee)
	(7) Provide, where necessary, adequate screening or other protection against pests.					Incomplete	(Select Employee)
§ 117.35 Sanitary operations	(a) General maintenance. Buildings, fixtures, and other physical facilities of the plant must be maintained in a clean and sanitary condition and must be kept in repair adequate to prevent food from becoming adulterated. Cleaning and sanitizing of utensils and equipment must be conducted in a manner that protects against allergen cross-contact and against contamination of food, food-contact surfaces, or food-packaging materials.					Incomplete	(Select Employee)
	(b) Substances used in cleaning and sanitizing; storage of toxic materials.					Incomplete	(Select Employee)

	(1) Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures must be free from undesirable microorganisms and must be safe and adequate under the conditions of use. Compliance with this requirement must be verified by any effective means, including purchase of these substances under a letter of guarantee or certification or examination of these substances for contamination. Only the following toxic materials may be used or stored in a plant where food is processed or exposed:					Incomplete	(Select Employee)
	(i) Those required to maintain clean and sanitary conditions;					Incomplete	(Select Employee)
	(ii) Those necessary for use in laboratory testing procedures;					Incomplete	(Select Employee)
	(iii) Those necessary for plant and equipment maintenance and operation; and					Incomplete	(Select Employee)
	(iv) Those necessary for use in the plant's operations.					Incomplete	(Select Employee)
	(2) Toxic cleaning compounds, sanitizing agents, and pesticide chemicals must be identified, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.					Incomplete	(Select Employee)
	(c) Pest control. Pests must not be allowed in any area of a food plant. Guard, guide, or pest-detecting dogs may be allowed in some areas of a plant if the presence of the dogs is unlikely to result in contamination of food, food-contact surfaces, or food-packaging materials. Effective measures must be taken to exclude pests from the manufacturing, processing, packing, and holding areas and to protect against the contamination of food on the premises by pests. The use of pesticides to control pests in the plant is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials.					Incomplete	(Select Employee)
	(d) Sanitation of food-contact surfaces. All food-contact surfaces, including utensils and food-contact surfaces of equipment, must be cleaned as frequently as necessary to protect against allergen cross-contact and against contamination of food.					Incomplete	(Select Employee)
	(1) Food-contact surfaces used for manufacturing/processing, packing, or holding low-moisture food must be in a clean, dry, sanitary condition before use. When the surfaces are wet-cleaned, they must, when necessary, be sanitized and thoroughly dried before subsequent use.					Incomplete	(Select Employee)
	(2) In wet processing, when cleaning is necessary to protect against allergen cross-contact or the introduction of microorganisms into food, all foodcontact surfaces must be cleaned and sanitized before use and after any interruption during which the foodcontact surfaces may have become contaminated. Where equipment and utensils are used in a continuous production operation, the utensils and food-contact surfaces of the equipment must be cleaned and sanitized as necessary.					Incomplete	(Select Employee)
	(3) Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) must be stored, handled, and disposed of in a manner that protects against allergen cross-contact and against contamination of food, food-contact surfaces, or food-packaging materials.					Incomplete	(Select Employee)
	(e) Sanitation of non-food-contact surfaces. Non-food-contact surfaces of equipment used in the operation of a food plant must be cleaned in a manner and as frequently as necessary to protect against allergen cross-contact and against contamination of food, food-contact surfaces, and food-packaging materials.					Incomplete	(Select Employee)
	(f) Storage and handling of cleaned portable equipment and utensils. Cleaned and sanitized portable equipment with food-contact surfaces and utensils must be stored in a location and manner that protects food-contact surfaces from allergen cross-contact and from contamination.					Incomplete	(Select Employee)
§ 117.37 Sanitary facilities and controls	Each plant must be equipped with adequate sanitary facilities and accommodations including:					Incomplete	(Select Employee)

	(a) Water supply. The water supply must be adequate for the operations intended and must be derived from an adequate source. Any water that contacts food, food-contact surfaces, or food-packaging materials must be safe and of adequate sanitary quality. Running water at a suitable temperature, and under pressure as needed, must be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials, or for employee sanitary facilities.					Incomplete	(Select Employee)	
	(b) Plumbing. Plumbing must be of adequate size and design and adequately installed and maintained to:					Incomplete	(Select Employee)	
	(1) Carry adequate quantities of water to required locations throughout the plant.					Incomplete	(Select Employee)	
	(2) Properly convey sewage and liquid disposable waste from the plant.					Incomplete	(Select Employee)	
	(3) Avoid constituting a source of contamination to food, water supplies, equipment, or utensils or creating an unsanitary condition.					Incomplete	(Select Employee)	
	(4) Provide adequate floor drainage in all areas where floors are subject to floodingtype cleaning or where normal operations release or discharge water or other liquid waste on the floor.					Incomplete	(Select Employee)	
	(5) Provide that there is not backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for food or food manufacturing.					Incomplete	(Select Employee)	
	(c) Sewage disposal. Sewage must be disposed of into an adequate sewerage system or disposed of through other adequate means.					Incomplete	(Select Employee)	
	(d) Toilet facilities. Each plant must provide employees with adequate, readily accessible toilet facilities. Toilet facilities must be kept clean and must not be a potential source of contamination of food, food-contact surfaces, or food-packaging materials.					Incomplete	(Select Employee)	
	(e) Hand-washing facilities. Each plant must provide hand-washing facilities designed to ensure that an employee's hands are not a source of contamination of food, foodcontact surfaces, or food-packaging materials, by providing facilities that are adequate, convenient, and furnish running water at a suitable temperature.					Incomplete	(Select Employee)	
	(f) Rubbish and offal disposal. Rubbish and any offal must be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of food, food-contact surfaces, food-packaging materials, water supplies, and ground surfaces.					Incomplete	(Select Employee)	
§ 117.40 Equipment and utensils	(a)(1) All plant equipment and utensils used in manufacturing, processing, packing, or holding food must be so designed and of such material and workmanship as to be adequately cleanable, and must be adequately maintained to protect against allergen cross-contact and contamination.					Incomplete	(Select Employee)	
	(2) Equipment and utensils must be designed, constructed, and used appropriately to avoid the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants.					Incomplete	(Select Employee)	
	(3) Equipment must be installed so as to facilitate the cleaning and maintenance of the equipment and of adjacent spaces.					Incomplete	(Select Employee)	
	(4) Food-contact surfaces must be corrosion-resistant when in contact with food.					Incomplete	(Select Employee)	
	(5) Food-contact surfaces must be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds, sanitizing agents, and cleaning procedures.					Incomplete	(Select Employee)	
	(6) Food-contact surfaces must be maintained to protect food from allergen cross-contact and from being contaminated by any source, including unlawful indirect food additives.					Incomplete	(Select Employee)	
	(b) Seams on food-contact surfaces must be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms and allergen cross contact.					Incomplete	(Select Employee)	
	(c) Equipment that is in areas where food is manufactured, processed, packed, or held and that does not come into contact with food must be so constructed that it can be kept in a clean and sanitary condition.					Incomplete	(Select Employee)	