

## *chapter four*

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# *GMPs and HACCP prerequisite programs*

### *4.1 Introduction*

This chapter deals with practices commonly used to address food safety and sanitary conditions in the food industry, and particularly in food processing establishments. Many of these food safety and sanitary practices have been mandated by government food laws and regulations that prohibit the adulteration of foods. Many food safety practices are good manufacturing practices (GMPs) that have been mandated by government agencies on the basis of scientific knowledge relating to known health hazards in foods, and the need to prevent unacceptable levels of these hazards or to eliminate them from foods. In addition, some mandatory GMPs address food quality and fitness of food for human use. Some other GMPs are not mandatory but recommended practices, advisory practices, or common food industry practices; these serve as guidance for achieving food safety and food quality. In this chapter, no distinction is made between mandatory practices and recommended or advisory practices; the reader should refer to the written text of food laws and regulations for information on mandatory practices.

### *4.2 GMPs and government regulations*

Traditionally, the food industry, and particularly the food processing sector, has relied on the use of GMPs in its efforts to ensure the safety of processed foods. Most of these GMPs are used by many national governments worldwide for monitoring the safety of consumer foods and for inspection of establishments that process, package, handle, and store foods. A good example of GMPs that are part of government regulations at the national level is the “*Current Good Manufacturing Practice In Manufacturing, Packing, Or Holding Human Food*” of the U.S. Code of Federal Regulations (CFR), Title 21, Part 110. The *Current Good Manufacturing Practice* can be considered the minimum criteria for the monitoring and inspection of food processing establishments

by the U.S. *Food and Drug Administration* (FDA). The GMP criteria are addressed in the following *Subparts: General Provisions, Buildings and Facilities, Equipment, Production and Process Controls, and Defect Action Levels*; the specific topics addressed in each of these *Subparts* are listed in [Table 4.1](#). In many situations in the food industry, GMPs are documented as Standard Operating Procedures (SOPs); for example, some food regulations in the U.S. require that certain food companies establish Sanitation standard operating procedures (SSOPs) to address some aspects of food safety.

In addition to GMPs that have been developed by national governments, food safety practices have been developed for use at the international level for the purposes of facilitating fairness in global food trade, and for the protection of health of consumers around the world. The recognized practices relating to food safety are described in the “*Recommended International Code of Practice, General Principles of Food Hygiene*” of the *Codex Alimentarius Commission, Food and Agricultural Organization/World Health Organization* (FAO/WHO) *Food Standards Programme*. These practices are covered in the following Sections of this standard: *Primary Production; Establishment: Design And Facilities; Control of Operation; Establishment: Maintenance And Sanitation; Establishment: Personal Hygiene; Transportation; Product Information and Consumer Awareness; and Training*. The specific topics addressed in each of these Sections are listed in Table 4.1. The GMP requirements of many national governments are compatible with the food safety practices described in this *Codex Alimentarius* standard.

### 4.3 GMPs as business practice in the food industry

In addition to their use for purposes of government regulations and international trade, GMPs are commonly used as part of business practices in the food industry. GMPs have been used very widely as the basis for developing and establishing food safety programs within food processing establishments. In many cases, and particularly in large- and medium-sized establishments, food manufacturers have developed food safety programs that substantially exceed the GMP requirements of governments. The objective of these programs is to meet government requirements as well as customer requirements, and to achieve competitive advantage in securing business with potential customers. Many food companies use GMP criteria as an important consideration in the selection of their suppliers of raw materials, ingredients, packaging materials, and services.

It is common practice for food manufacturers to assess and evaluate their GMP-based food safety programs for effectiveness using internal GMP audits or food safety audits. In addition, some food companies evaluate the effectiveness of the GMP-based food safety programs of their suppliers, using either second-party food safety audits or independent, third-party food safety audits. The outcome of these evaluations can have a major influence on a company’s decision to purchase from a supplier or to enter into a customer-supplier relationship.

**Table 4.1** Topics Covered By GMPs And HACCP Prerequisite Programs

Current Good Manufacturing Practices in Manufacturing, Packing, Or Holding Human Food, U.S. Code of Federal Regulations, Title 21 CFR Part 110	
<i>Subpart A-General Provisions</i>	<i>Subpart C-Equipment</i>
– Definitions	– Equipment and utensils
– Current good manufacturing practice	<i>Subpart E-Production and Process Controls</i>
– Personnel	– Process and controls
– Exclusions	– Warehousing and distribution
<i>Subpart B-Buildings and Facilities</i>	<i>Subpart G-Defect Action Levels</i>
– Plants and grounds	– Natural or unavoidable defects in food for human use that present no health hazard
– Sanitary operations	
– Sanitary facilities and controls	
Examples of Common Prerequisite Programs for HACCP systems, U.S. National Advisory Committee on Microbiological Criteria for Foods (NACMCF, 1997)	
– Facilities	– Receiving, storage, and shipping
– Supplier control	– Traceability and recall
– Specifications	– Pest control
– Production Equipment	– Others: quality assurance procedures; labeling; standard operating procedures for sanitation, processes, product formulations, and recipes; glass control; employee food and ingredient-handling practices
– Cleaning and Sanitation	
– Personal hygiene	
– Training	
– Chemical control	
Recommended International Code of Practice, General Principles of Food Hygiene, Codex Alimentarius Commission (1997)	
<i>Establishment: Design and Facilities</i>	<i>Establishment: Personal Hygiene</i>
– Location	– Health status
– Premises and rooms	– Illness and injuries
– Equipment	– Personal cleanliness
– Facilities	– Personal behavior
	– Visitors
<i>Control of Operations</i>	<i>Transportation</i>
– Control of food hazards	– General
– Key aspects of hygiene control system	– Requirements
– Incoming materials requirements	– Use and maintenance
– Packaging	
– Water	<i>Product Information and Consumer Awareness</i>
– Management and supervision	– Lot identification
– Documentation and records	– Product information
– Recall procedures	– Labelling
– Incoming materials requirements	– Consumer education

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**Table 4.1** Topics Covered By GMPs And HACCP Prerequisite Programs

Current Good Manufacturing Practices in Manufacturing, Packing, Or Holding Human Food, U.S. Code of Federal Regulations, Title 21 CFR Part 110	
<i>Establishment: Maintenance and Sanitation</i>	
– Maintenance and cleaning	<i>Training</i>
– Cleaning programs	– Awareness and responsibilities
– Pest control systems	– Training programs
– Waste management	– Instruction and supervision
– Monitoring effectiveness	– Refresher training

Sources: *J. Food Prot.* 61, 9, 1998, 1246–1259; and the Food and Agriculture Organization of the United Nations, codex Alimentarius, 1997 *Basic Texts on Food Hygiene*, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Program, Rome.

#### 4.4 GMPs and HACCP prerequisite programs

With the use of the hazard analysis critical control point (HACCP) system to address food safety in food processing, GMPs have become part of the very basic requirements that must be in place before an effective HACCP system can be implemented. Consequently, the traditional GMPs, along with some additional requirements, are now universally regarded as *Prerequisite Programs* for the implementation of an HACCP system. In the U.S., the mandatory HACCP systems for certain food industry sectors have SSOPs as part of the prerequisite programs.

The emergence of the HACCP system for achieving food safety has reinforced the importance of GMPs to the extent that the prerequisite programs are considered as the necessary foundation on which an effective HACCP system is built. In a functional HACCP system at a food establishment, the GMPs are part of the HACCP prerequisite programs that address all food safety considerations that are not included as a part of the HACCP plan(s), as well as all unsanitary and undesirable but nonhazardous contaminants. Together, the HACCP prerequisite programs and the HACCP plan(s) at a food establishment form the “*House of Product Safety*” (ASQ Food, Drug, and Cosmetic Division, 2002).

#### 4.5 Activities covered by GMPs and HACCP prerequisite programs

When GMP programs or HACCP prerequisite programs are developed and implemented at a food plant, they should cover the basic controls required for raw materials, ingredients, packaging materials and products, and for the plant’s facilities, employees, equipment, operations, and environment that influence the safety of a food. Many of the GMPs and prerequisite program activities are directed at ensuring that the necessary conditions exist for the prevention of potential contamination and cross-contamination of food.

The activities addressed by HACCP prerequisite programs have been well documented by various organizations, food companies, and government regulatory agencies; GMPs are a substantial part of these prerequisite programs. However, a standardized framework for HACCP prerequisite programs has not been developed in the same way as the formal HACCP system, with its recognized set of seven principles. Consequently, the actual framework for designing HACCP prerequisite programs tends to vary from one country to another and from one food industry sector to another. However, of greater importance is the fact that the topics the prerequisite programs cover and the activities they address are essentially very similar. This point is best illustrated by the following examples:

- In the U.S. Department of Agriculture (USDA)/Food Safety and Inspection Services (FSIS) mandatory *Pathogen Reduction: HACCP* inspection program for the meat and poultry sector, HACCP prerequisite programs are covered in sections on *Establishment's grounds and facilities, Equipment and utensils, Sanitary operations, Employee hygiene, Tagging unsanitary equipment, utensils, rooms or compartments* and mandatory *Sanitation standard operating procedures (SSOPs)*.
- In the FDA's *Seafood HACCP Final Rule*, HACCP prerequisite programs are addressed by mandatory *Current good manufacturing practice* (Table 4.1) and *Sanitation control procedures*, consisting of recommended *Sanitation SOP* and mandatory *Sanitation monitoring*.
- In the FDA's *Juice HACCP Final Rule*, HACCP prerequisite programs are addressed by mandatory *Current good manufacturing practice* (Table 4.1) and mandatory *Sanitation standard operating procedures*.
- The NACMCF's *Hazard Analysis and Critical Control Point Principles and Application Guidelines* in 1997, recognized the following as *Examples of Common Prerequisite Programs: Facilities, Supplier Control, Specifications, Production Equipment, Cleaning and Sanitation, Personal Hygiene, Training, Chemical Control, Receiving, Storage, and Shipping, Traceability and Recall, Pest Control*. (Table 4.1)
- In Canada, *Agriculture and Agri-Foods Canada Food Safety Enhancement Program (FSEP)*, HACCP prerequisite programs are covered by the following: *Premises, Transportation and Storage, Sanitation, Equipment, Personnel Training, Recall Program and Records*
- At the international level, the *Codex Alimentarius Commission's Recommended International Code of Practice General Principles of Food Hygiene* can be considered as the HACCP prerequisite programs.

For purposes of comparison, Table 4.1 lists the activities that are recognized as *Current good manufacturing practice* (Title 21 CFR Part 110) and as HACCP prerequisite programs, including the activities covered by the *Codex Alimentarius Commission's General Principles of Food Hygiene*.

#### 4.6 GMPs, HACCP prerequisite programs, HACCP systems, and quality systems

Food plants that operate with HACCP systems will have the required prerequisite programs that include GMPs and in some industry sectors in the U.S., also include SSOPs. In food processing plants that do not have HACCP systems, the GMPs remain the essential practices for addressing food safety. In these situations, it is more appropriate for the HACCP prerequisite programs to be used instead of the basic GMPs. The prerequisite programs provide more comprehensive coverage of the requirements relating to conditions and activities in a food plant than will the GMPs. In food plants that do not operate with HACCP systems but have implemented the *ISO 9001 Quality management systems* standard, as a minimum the GMPs should be part of the applicable regulatory requirements of the standard.

Within the requirements of the *ISO 9001:2000* standard, there are specific sections that address activities that can be related to activities covered by some of the HACCP prerequisite programs. This is evidence of compatibility between the quality management system requirements and HACCP prerequisite programs. In addition to the use of the *ISO 9001* standard by some food companies, many other food companies have developed their own companywide quality systems that include the activities covered in the HACCP prerequisite programs.

From the discussion in the preceding paragraph, and on the basis of the food safety and quality activities that are used in their operations, food plants can be identified within one of the following categories:

- Food plants which operate only with the mandatory GMPs required by government regulations, and other food safety and quality practices required by customers.
- Food plants that operate with HACCP systems required by government regulations or by customers, and quality practices required by government and customers. The HACCP prerequisite programs include GMPs.
- Food plants that operate with voluntary HACCP systems and quality practices required by government and customers. The HACCP prerequisite programs include the GMPs
- Food plants that operate with quality systems such as *ISO 9001:2000* or other nonregistered quality systems which address quality practices required by government and customers. As a minimum, GMPs should be integrated into the quality systems.
- Food plants which operate with quality systems and mandatory or voluntary HACCP systems. The HACCP prerequisite programs include the GMPs.

## 4.7 Development and implementation of GMPs and HACCP prerequisite programs

All food plants need to develop and implement a program of GMPs to address food safety requirements. Food plants that develop and implement HACCP systems to address food safety also need to develop and implement the HACCP prerequisite programs. In the U.S., food plants identified within some food industry sectors, such as the meat and poultry sector, the juice processing sector, and the seafood sector, are required to operate with HACCP systems that include specific mandatory prerequisite programs that contain SSOPs. It is the responsibility of a food plant's senior management to develop, implement and maintain the appropriate food safety program, whether it is a GMP-based program or a complete HACCP system. The food plant's employees who are responsible for the food safety program must be familiar with the government regulatory requirements that apply to the operations at the plant.

The activities for GMPs or the HACCP prerequisite programs that are developed at a food plant should be documented as SOPs. In addition, where monitoring, inspection, or testing is carried out as part of the programs, records should be kept as evidence that these activities are actually performed. The documents and records that are used in these programs should be controlled in the same manner as documents and records are controlled in a quality system. The prerequisite programs should be developed as an integrated set of activities that address food safety requirements not specifically addressed by HACCP plans ([Chapter 5](#)).

In general, many of the activities which are included in GMPs program or in the HACCP prerequisite programs should be quite similar for most food plants, regardless of the type of processing that is carried out. Therefore, it is possible to compile a generic list of topics which address the entire range of activities in a particular prerequisite program or a particular category of GMPs. However, certain specific activities in this generic list might not be applicable to certain food plants; this depends on the specific type of processing that takes place in a particular food plant. In addition, in certain situations it is possible that a particular activity in a prerequisite program can be considered as a critical control point (CCP, [Chapter 5](#)) in an HACCP plan for a product at a particular food plant.

The following sections describe the activities of a set of generic HACCP prerequisite programs; they include the prerequisite programs recognized by the NACMCF (1997), and also address the activities covered in the various sections of the *Codex Alimentarius General Principles of Food Hygiene* standard. In addition, the prerequisite programs that are described in the following sections include the GMP activities required by food regulations, and should, therefore, be applicable to food plants that operate without HACCP systems; consequently, these sections are titled as HACCP prerequisite programs.



## 4.8 HACCP prerequisite program premises and facilities

This prerequisite program addresses the requirements for the location, design, construction, and maintenance of buildings that are used for food processing. It covers the grounds, all exterior and interior structures of buildings, and all facilities and essential services required in food processing establishments. Many sections of this prerequisite program need to be considered during the design and construction stages of a food plant. Engineering, design, and construction requirements and guidelines for food plants have been developed by some government agencies.

The general conditions in a food plant, including the state of repairs, maintenance, and cleanliness of all structures and facilities, are critical in order to achieve the sanitary requirements for food processing. The primary considerations are that the building, its grounds, structures, and facilities are not a source of contamination or cross-contamination of food, there is protection from entry of pests into the building, and clean and sanitary conditions can be maintained.

This prerequisite program includes the GMP items addressed in the sections on *Plants and grounds* and *Sanitary facilities and controls* of *Subpart B-Buildings and Facilities* of the *Current Good Manufacturing Practices* (Table 4.1), and in *Establishment: Design and Facilities* of the *General Principles of Food Hygiene* (Table 4.1). Table 4.2 provides a list of the topics which are covered by this prerequisite program.

*Relationship to ISO 9001:2000:* The requirements of 6.3 *Infrastructure* address the topics covered by this prerequisite program.

### 4.8.1 Location

The buildings in which food is processed or stored should not be located in close proximity to sites that are sources of environmental pollutants, pest infestations, smoke or dust, to areas that accumulate wastes or stagnant water, or have industrial, agricultural or other activities which are potential sources of food contamination. If any of these undesirable conditions exist, there should be adequate safeguard to protect against any potential contamination or pest infestation.

### 4.8.2 Grounds

The grounds of buildings in which food is processed or stored should be adequately sloped and drained to prevent stagnant water, be free of waste and debris, be controlled for dust, and be adequately maintained to protect against becoming a source of contamination or pest infestation. In order to protect from pests, maintenance of the grounds should address grass and lawns, hedges, shrubs, trees, receptacles for storage of garbage, and any structures located on the grounds. In particular, the perimeter of the building exterior should be well maintained to prevent breeding or attraction of pests.



**Table 4.2** Topics Covered by Prerequisite Program  
*Premises and Facilities*

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Location
Grounds
Building exterior
Building interior
– Design and layout
– Structures
– Glass
– Corners and joints
– Floors
– Windows and doors
– Lighting
– Ventilation
– Drains
– Pipes and hoses
Access to premises
Employee facilities
– Hand-washing stations
– Washrooms and change-rooms
– Lunchrooms and break-rooms
Cleaning and sanitizing facilities
Storage facilities
Waste collection/storage facilities
Water/steam/ice
– Supply
– Quality

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Parking lots and roadways should be maintained so that they are not sources of dust and airborne contaminants that can enter the building.

### 4.8.3 *Building exterior*

The design, construction and maintenance of exterior walls and roofs of buildings, should prevent the entry of sources of contamination and pests, and leakage of water into the building. Exterior walls should be free of cracks that could be breeding sites for pests. Openings for exhaust fans and air intake ducts, and exterior drainpipes should be adequately screened and protected to prevent entry of pests. The loading and unloading areas of the building, and all exterior doors and windows should be adequately protected to prevent entry of pests. The location of exterior lighting should not attract insects into the building.

### 4.8.4 *Building interior*

- *Design and layout:* The design and layout of the building interior and the location of all structures, equipment, services, and facilities should permit movement of personnel and equipment, flow of air,

materials and products, movement of waste and garbage, and storage of materials and products, in a manner that prevents contamination and cross-contamination of materials and products. There should be designated areas for processing, for packaging, for raw materials storage and preparation, and for finished product storage. Processing activities that are potential sources of cross-contamination should be located in areas that are separated from other processing activities. The layout of the building should provide adequate workspace for plant employees to perform their tasks satisfactorily, and adequate space for cleaning of all structures. The location of equipment should be such that it is accessible for regular cleaning and maintenance.

- *Structures:* The design and construction of all building structures such as floors, walls, ceilings, overhead structures, windows, doors, and stairs, and all utilities and service structures such as ducts, pipes and drains should meet all requirements for construction of food plants. The materials used for construction and finishing of these structures should not be sources of contamination and should be durable, impervious, smooth and easily cleaned and maintained. The materials used for construction of walls and floors should withstand the routine plant operating conditions and the routine cleaning and sanitizing conditions.
- *Glass:* Glass or glass-like materials such as breakable plastic in food plants can be sources of physical hazards and should not be used in processing areas where there is a likelihood of breakage that will result in contamination of product. If these materials must be used, they must be adequately protected from breakage. Overhead light bulbs should be protected from breakage if they are a potential source of contamination. The control of glass and glass-like materials in a food plant should be addressed in a glass policy that should cover instructions for dealing with breakage of glass, and the control of glass and glass-like materials in items such as clocks, lights, gauges, containers and glassware.
- *Corners and joints:* Corners and joints in all structures should be designed to prevent accumulation of contaminants and to facilitate cleaning; they should be free of cracks and openings. The junctions between walls and floors should be designed to facilitate cleaning. Joints on walls, floors, and ceilings should be sealed and should be easily cleaned.
- *Floors:* The surface of floors should be even, but with the appropriate slope for waste-water and other liquids to be drained at the designated outlets. Floor surfaces should be impervious, durable and free of cracks to facilitate cleaning.

- *Windows and doors:* Windows on exterior walls should be sealed or fitted with screens to prevent entry of pests. Exterior doors should be self-closing, should always be kept closed, and should be without gaps or openings when closed, to prevent entry of pests. Exterior doors should be kept closed to prevent unauthorized access into the building.
- *Lighting:* The building interior should be equipped with adequate light and lighting facilities to permit employees to carry out their designated tasks in areas where processing, handling, storage, testing, inspection and cleaning activities take place. Adequate lighting should also be provided in hand-washing areas, change-rooms, locker rooms and toilet rooms.
- *Ventilation:* There should be adequate ventilation and air exchange throughout the building to prevent airborne contamination, condensation on any structure or equipment, and accumulation of dust. High humidity should be avoided to prevent mold growth and some types of insects. The direction of air-flow should not result in contamination or cross-contamination of foods. In addition, fans and other air-blowing equipment should be operated in a manner that does not result in contamination. Air filters and dust collectors should be cleaned, maintained and replaced so that they are effective and do not become sources of contamination.
- *Drainage and sewage systems:* The drainage and sewage systems should be designed to prevent cross-connection of sewage with other wastes from the plant in order to avoid any potential for contamination. Drains should be adequately sloped to ensure there is no accumulation of wastewater or other liquids. The location of drains and drain traps should permit ready access for cleaning. The design and maintenance of the drainage system should prevent backflow of wastewater into the building.
- *Pipes and hoses:* Water pipes should be free of condensation. Insulated pipes should be well maintained and should be free of condensation drips and mold growth. Water taps, faucets, and hose connections should be free of leaks and water drips. Hose reels should be provided for storage of water hoses when not in use.

#### 4.8.5 Access to premises

The entrances and exits of a food plant should be controlled to prevent access by unauthorized personnel. Exterior doors should not open from the outside of the building. Food plant employees should use only the designated entrances and exits. Receiving and shipping locations should not be used by employees as entrances or exits. Access of visitors into food plants should be controlled.

#### 4.8.6 *Employee facilities*

- *Hand-washing:* There should be accessible hand-washing stations at the appropriate locations, with potable running water at a suitable temperature, soap or other hand-cleaning and sanitizing materials, sanitary hand-drying equipment or supplies for employees to wash and dry hands as required. The water control devices at the hand-washing stations should be designed to protect against recontamination of washed hands. If disposable towel is used for hand-drying, a covered garbage receptacle should be provided for used towels. There should be easily understandable signs posted at hand-washing stations to remind employees to wash hands.
- *Washrooms and toilet rooms:* Washrooms and toilet rooms in particular, should be separated from and should not open directly into food storage, handling and processing areas. Washrooms should be equipped with the required hand-washing facilities, covered garbage receptacles, and easily understandable signs to serve as reminders to employees.
- *Change-rooms:* Change-rooms should be available for employees to change from their personal external clothing into designated work uniform and footwear. Change-rooms should be equipped with lockers or suitable storage racks for employees to store clothing, footwear and other personal items, with receptacles for dirty work clothes, and covered garbage receptacles. The design and location of lockers and storage racks in change-rooms should facilitate cleaning.
- *Lunchrooms and break-rooms:* There should be designated lunchrooms and break-rooms for employees. Lunchrooms should be equipped with appropriate appliances and food storage facilities for employees' food and with covered garbage receptacles. If smoking is permitted in lunchrooms and break-rooms, it should be restricted to designated areas and ashtrays should be provided.

#### 4.8.7 *Cleaning and sanitizing facilities*

Potable running water at the required temperatures and pressures should be available for all cleaning and sanitizing activities. The required equipment and tools for cleaning and sanitizing should be available. Equipment and tools used for cleaning of food-contact surfaces, food processing equipment and utensils should be appropriately identified and stored so that they are separate from those used for cleaning of building structures such as floors and walls. There should be designated areas for cleaning of cleaning equipment and tools and for their storage when they are not in use.

#### 4.8.8 Storage facilities

There should be adequate and appropriate facilities such as warehouse, storage rooms, silos, tanks, vats, bins, or other containers, for the storage of raw materials, ingredients, packaging materials, products to be reworked or recycled, semi-finished products, finished products, cleaning materials and nonfood chemicals. These storage facilities should be designed to ensure that there is no contamination, cross-contamination, or pest infestation of raw materials, ingredients, packaging materials, and semi-finished and finished products during storage. There should be separate storage facilities to segregate food materials from nonfood chemicals.

There should also be appropriate storage facilities for idle food processing equipment and for tools, materials, and spare parts used for repair and maintenance of equipment.

#### 4.8.9 Waste collection and storage facilities

There should be designated containers with covers, if necessary, for collection of waste and garbage and for their temporary storage until disposal. These containers should be properly identified, and be made of durable, impervious material and maintained in a sanitary condition. There should be no leakage from waste containers. Waste collection containers located on the grounds outside of the building should be maintained so that they are not sources of contamination or pest infestation.

#### 4.8.10 Water

- *Water supply:* There should be an adequate supply of potable water, at the desired temperatures and pressures, for use in processing operations and for cleaning. There should be facilities to ensure that temperature and pressure requirements for water can be achieved.
- *Water quality:* Only potable water should be used in all food plant processing and cleaning operations. The water quality should conform to the guidelines for potable water based on microbiological, chemical, and physical specifications of applicable government agencies. Water should be tested periodically to determine if it complies with these specifications; the records of water quality test results should be maintained.

If water treatment facilities are located on the premises, they should be adequately monitored and maintained; records should be kept for water treatment activities. Water treatment processes that are designed for re-circulated water should have the required controls with the appropriate records to demonstrate compliance to the re-circulated water quality specifications.

Only approved chemicals should be used for treatment of water used in food plants. Containers with chemicals for water treatment should be identified with labels, and their conditions and location of storage should prevent any potential contamination of food or food contact surfaces.

#### 4.8.11 *Ice and steam*

Ice for use in food plants should be made from potable water and should be handled and stored to protect from contamination. Steam that comes into contact with food or food contact surfaces should be generated from potable water. Only approved chemicals should be used in boilers which generate steam for these purposes; these chemicals should be controlled in a similar manner as described for water treatment chemicals.

### 4.9 *HACCP prerequisite program personnel training, hygiene and practices*

This prerequisite program addresses the requirements for employees of food plants; some of the requirements are also applicable to visitors to food plants as well as any other personnel who are not employees at a food plant, but carry out some type of work on the premises or facilities. The requirements for personnel at food plants can be conveniently classified under the sections, *Personnel training*, *Personal hygiene*, and *Personnel practices*.

Employees in a food plant play a critical role in ensuring the safety of foods produced at the plant. In addition, employees should not contribute to or be a source of contamination or cross-contamination of foods. In this prerequisite program, the primary considerations are to ensure that both temporary and permanent employees have the required education and training, are adequately supervised, and follow their required work-related tasks, personal hygiene requirements and acceptable personnel practices during their work.

This prerequisite program covers the items included in the section on personnel in *Subpart A—General Provisions of the Current Good Manufacturing Practice (Table 4.1)* and in *Section VII—Establishment: Personal Hygiene* and *Section X—Training of the General Principles of Food Hygiene (Table 4.1)*. [Table 4.3](#) lists the topics covered by this prerequisite program.

*Relationship to ISO 9001:* The requirements of 6.2 *Human resources* address the topics covered by this prerequisite program.

#### 4.9.1 *Personnel training*

- *Food safety training:* All food plant employees, including temporary employees, should be trained in the basic food safety principles and practices that are required to prevent contamination and cross-contamination of foods. This training should cover hygienic food handling practices, personal hygiene requirements, and the dangers

**Table 4.3** Topics Covered by Prerequisite Program  
*Personnel Training, Hygiene, Practices*

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Personnel training
– Food safety training
– Technical training
– Training records
Personal practices
– Personal hygiene
– Hand washing
– Eating and smoking
– Garment and work-wear
– Personal items
Illness and injuries
Visitors and noncompany personnel
– Controlled access to premises
– Personal practices

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associated with poor personal hygiene and unsanitary personnel practices in a food plant. In addition, personnel who have the responsibility to monitor the adequacy of food safety practices of food plants should have the necessary training and experience to recognize and identify food hazards and situations that have the potential to lead to contamination or cross-contamination of foods. This includes the training of supervisory personnel to recognize injuries or infectious illnesses among plant employees. The food safety training needs of employees in food plants should be reviewed periodically, and if necessary, additional training or refresher training should be provided. Whenever food safety training is provided to employees, there should be an evaluation to determine that the training is understood and could be put into practice by the employees.

- *Technical training:* Employees whose tasks involve operation, maintenance, and cleaning of food processing equipment, and sanitation and cleaning activities should be provided with the relevant technical training that is required to carry out their specific tasks so that all food safety requirements are met. The technical training needs of employees should be reviewed periodically, and if necessary, additional or refresher technical training should be provided. Technical training should also include on-the-job training and evaluation to ensure that employees understand the training and perform their tasks based on the training.
- *Training records:* Records should be kept as evidence that the relevant food safety training or technical training was provided to employees, and that they were evaluated after completion of the training. In addition, there should be records to show that the training needs of employees are reviewed periodically.



#### 4.9.2 Personnel practices

- *Personal hygiene:* In order to protect against contamination of products, food plant employees are required to maintain satisfactory personal grooming and cleanliness and to practice good personal hygiene habits during all food handling operations. This includes general cleanliness of clothing and body, including hair and fingernails. Employees should refrain from placing fingers in mouth, nose or ears, and from eating, chewing, spitting, and smoking during food handling operations, and avoid coughing and sneezing over unprotected products, food-contact surfaces, or food processing equipment.
- *Hand-washing:* In order to protect hands from being a source of contamination of products, food plant employees should wash, sanitize if necessary, and dry their hands at the designated hand-washing stations when their hands become dirty. Employees should wash hands before start of work, when re-entering their work area, after a visit to the toilet, after coughing or sneezing into their hands, or after handling raw materials, equipment, waste or waste containers, or after any other situation that will cause the hands to become dirty and be a source of contamination or cross-contamination.
- *Eating, drinking and smoking:* Employees should eat, drink, and if permitted, smoke only in the designated lunchrooms and break-rooms or other authorized areas. Employees' food or drink should be kept in the designated areas and should not be taken into their work areas. Drinking of water should be done at the designated water fountains. Employees should not take their medication into their work areas.
- *Garments and work-wear:* Employees should wear the uniforms or outer garments provided for their work. Uniforms and garments should be clean at the start of work and should be changed when they become dirty or according to the required change frequency. If gloves are required to be worn during work, they should always be clean and sanitary, and should be changed if they become torn. Hair and beard restraints should be worn to completely cover hair and beard.
- *Personal items:* Employees should not wear jewelry, hairpins, wrist-watches or other personal items such as false eyelashes, false fingernails and nail polish during food handling operations. In addition, during work, employees should refrain from keeping in their possession any personal items which could be a potential source of contamination.

### 4.9.3 Illness and injuries

Food plant employees with certain illnesses or injuries should be excluded from food handling activities; these illnesses include jaundice, diarrhea, vomiting, fever, sore throat with fever, open or infected skin lesions (e.g., boils, cuts, burns), discharges from the eyes, ears or nose, or any disease that can be transmitted through food. Employees should inform their supervisors if they suffer from any of these health conditions. In addition, supervisory personnel in food plants should constantly monitor food-handling employees for these injuries and illnesses.

### 4.9.4 Visitors and noncompany personnel

- *Controlled access to premises:* The access of visitors and noncompany personnel to a food plant should be controlled to avoid any potential source of contamination from these individuals. This control should apply to family members of employees, noncompany personnel working on the premises, suppliers, customers, government inspectors, auditors, and individuals from educational and other institutions on organized visits and plant tours.
- *Personal practices:* Visitors and noncompany personnel who are permitted entry into the food processing and handling areas of the food plant should be required to follow the same personal practices of the regular employees of a food plant. These include practices relating to personal hygiene, hand-washing, eating, drinking, smoking, outer garments, personal items and illnesses and injuries.

## 4.10 HACCP prerequisite program sanitation and cleaning

This prerequisite program covers all ongoing and periodic activities and operations that are directed at maintaining the environment, facilities, structures, and equipment in a food plant under sanitary conditions at all times. The design, construction, and layout considerations that relate to sanitation and cleaning are covered in the prerequisite program *Premises and Facilities*. It is quite common for the term sanitation alone to include house-keeping, cleaning and sanitizing; however, the distinction should be made between cleaning and sanitizing. In general, cleaning activities cover the removal of dust, dirt, debris, accumulated raw materials, ingredients or product, and any chemical residues, from utensils, food processing equipment, and structures. Sanitizing activities cover the use of a chemical agent or a specific technique to kill microorganisms present on equipment, utensils and structures.

The maintenance of sanitary conditions in a food plant, including clean and sanitary environment, structures, facilities, and equipment is essential

to ensure that food is produced under sanitary conditions, to prevent contamination from these sources and to prevent breeding of pests. Food processing operations in a food plant should only commence after all the required cleaning and sanitizing activities have been completed. In this prerequisite program, the primary considerations are the activities for maintaining sanitary conditions by means of a sanitation program, and ongoing monitoring of the sanitary conditions during all operations at a food plant.

Sanitation standard operation procedures (SSOPs), a prerequisite program, covers some of the items included in the section on *Sanitary operations* in the *Current Good Manufacturing Practices* (Table 4.1) and in *Establishment: Maintenance and Sanitation* of the *General Principles of Food Hygiene* (Table 4.1). Table 4.4 lists the topics that are covered under this prerequisite program.

*Relationship to ISO 9001:* The requirements of 6.4 *Work environment* address the topics covered by this prerequisite program.

#### 4.10.1 Sanitation and cleaning program

There should be a written program for cleaning and sanitizing of the structures, facilities, and equipment in a food plant. This written program should identify each structure, facility, and equipment to be cleaned and sanitized. For each of these, the program should include detailed cleaning and sanitizing procedures, the cleaning and sanitizing chemicals to be used and their concentrations or dilutions, removal of residues of cleaning and sanitizing chemicals, the cleaning tools to be used, the frequency of cleaning and sanitizing, and the personnel responsible for cleaning specific equipment or structures. Each aspect of the cleaning and sanitation program should be monitored to ensure that the program is followed. There should be some verification to determine the effectiveness of the program. Sanitation records should be kept for the activities that are required, including the monitoring and verification of the sanitation program.

**Table 4.4** Topics Covered by Prerequisite Program  
*Sanitation and Cleaning*

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Sanitation and cleaning program
Equipment cleaning and sanitizing
– Cleaned-in-place (CIP) equipment
– Cleaned-out-of-place (COP) equipment
– Utensils and food contact surfaces
Master cleaning schedule
– Daily housekeeping
– Establishment cleaning
Cleaning and sanitizing chemicals
Cleaning tools and equipment
Cleaning area
Cleaning and sanitizing personnel
Effectiveness of cleaning and sanitizing
Sanitation and cleaning records

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### 4.10.2 Equipment cleaning and sanitizing

There should be a program for cleaning of all equipment, including all food processing and food handling equipment, as well as food storage equipment such as storage tanks, refrigerators, and freezers. For each type of equipment there should be a schedule for cleaning and sanitizing, along with any specific cleaning instructions.

- *Cleaned-in-Place (CIP) Equipment:* In some food processing operations, certain equipment cannot be easily disassembled for cleaning between successive production runs, although this equipment should be cleaned at the end of each use. These types of equipment are considered CIP equipment. There should be written procedures for cleaning and sanitizing of each type of CIP equipment.
- *Cleaned-out-of-Place (COP) Equipment:* Certain food processing equipment should be disassembled for cleaning after each use or periodically, these are considered COP equipment. There should be instructions for disassembly and reassembly of COP equipment, in addition to instructions for their cleaning and sanitizing.
- *Utensils and food contact services:* All utensils used for handling food, including all containers, trays, pans and dollies, and all food contact surfaces should be cleaned and sanitized as it becomes necessary. These should be protected from contamination if they are stored after cleaning.

### 4.10.3 Master cleaning schedule

- *Daily housekeeping:* A program of daily cleaning should be in place to ensure that equipment and work areas are maintained in a clean state during routine daily operations so as to prevent contamination of products. This may require that equipment, utensils, food contact services, work area and floors be cleaned periodically during daily operations. Clean up of leaks and spills of all types of materials and products should be done as soon as possible, or immediately if they are potential sources of contamination or pest infestation. There should be monitoring and verification of this daily housekeeping program.
- *Establishment cleaning:* In addition to the daily housekeeping, a comprehensive program should be in place to ensure that every aspect of the establishment is subject to periodic cleaning to eliminate the potential for contamination. This program should cover all facility structures, including lunch rooms, appliances, vending machines, break-rooms, change-rooms, and toilet rooms, ceilings and overhead structures such as pipes and ducts, walls and floors of all structures, windows and doors, and all equipment. The frequency and type of cleaning should be specified for each facility or structure. There should be monitoring and verification of this cleaning program for the establishment.

#### *4.10.4 Cleaning and sanitizing chemicals*

All chemical compounds used for cleaning and sanitizing should be approved as safe for use in food establishments, and on food-contact surfaces in particular, by an appropriate government regulatory agency. The manufacturer's guidelines and directions for use of these chemicals must be followed to ensure the effectiveness of the cleaning and sanitizing, and to remove or prevent potential contamination. The chemicals themselves must not be a source of contamination.

All packages and containers, including intermediate containers with chemical compounds used for cleaning and sanitizing, must be clearly identified by labeling, and must be stored separately from food materials and products.

#### *4.10.5 Cleaning tools and equipment*

All tools and equipment (e.g., brushes, dustpans, brooms, mops, trays, carts) used for cleaning should also be subjected to appropriate cleaning and storage. Broken or damaged tools should not be used. Tools used for cleaning food processing, storage and handling equipment should not be used for other cleaning, should not be stored on the floor, and should be identified and stored separately from tools used for other cleaning. In addition, tools used for cleaning of toilets and toilet rooms should be identified and not be used for cleaning of food processing, handling and storage areas.

#### *4.10.6 Cleaning area*

There should be designated location and facility for cleaning of cleaning tools and equipment. This area or facility, as well as all sinks and washbasins and surrounding areas, should be kept clean and sanitary. Wash-water should be removed and drained immediately to prevent the potential for contamination.

#### *4.10.7 Cleaning and sanitizing personnel*

Personnel who are assigned cleaning and sanitizing tasks should be trained in the safe use of the cleaning and sanitizing chemicals and the proper handling, identification and storage of these chemicals. They should be provided with the directions for use, including the appropriate usage concentration or dilution for food-contact surfaces, and instructions for removal of residues of these chemicals from these surfaces.

#### *4.10.8 Effectiveness of cleaning and sanitizing*

The effectiveness of the cleaning and sanitizing activities for removal of contamination should be verified. This should be done by microbiological swab tests, by visual inspection of cleaned equipment and areas, and by observing employees who carry out the cleaning and sanitizing activities.

In addition, there should be no unacceptable residues of cleaning and sanitizing chemicals on food-contact surfaces.

#### 4.10.9 Sanitation and cleaning records

As part of the establishment's cleaning and sanitation program, records should be kept as evidence that the activities in the program are performed according to the required instructions and frequency, and that the program is monitored routinely and verified for its effectiveness.

### 4.11 HACCP prerequisite program pest control

This prerequisite program covers the specific activities that are directed at controlling, preventing and excluding the occurrence of pests, particularly rodents, insects and birds, from a food plant. Pet animals such as cats and dogs should not be allowed to enter food plants. The prerequisite program *Premises and facilities* includes certain preventive measures for pest control; these relate to the building structures, as well as the internal environment and the external surroundings. Pest control measures are also part of the prerequisite programs *Sanitation and cleaning* and *Transportation, receiving, storage, and shipping*.

The pest control program includes the specific activities directed at detecting pests and pest activity, both within a food plant and its immediate exterior, preventing pests from entering the building, eliminating pests from the building and the immediate surroundings, and monitoring of the pest control program for its effectiveness. In addition, the program includes control of the use and storage of chemicals or other materials used for pest control to prevent contamination of product.

This prerequisite program is included in the section on *Sanitary operations* in *Subpart B—Buildings and Facilities* in the *Current Good Manufacturing Practices* (Table 4.1) and in *Pest control systems* in *Establishment: Maintenance and Sanitation* of the *General Principles of Food Hygiene* (Table 4.1). Table 4.5 lists the topics which are covered under the prerequisite program Pest Control.

*Relationship to ISO 9001:* The requirements of 6.4 *Work environment* address the topics covered by this prerequisite program.

#### 4.11.1 Pest control program

There should be a formal, documented pest control program that is maintained for the establishment. This program should cover all of the preventive measures that are taken to exclude and eliminate pests, the various pest-control devices and pest-control chemicals that are used, the monitoring of pest activity, and compliance with government regulations on use of pesticides and pest control devices. It is common for food companies to engage the services of external pest control contractors to undertake some of the required pest-control activities.

**Table 4.5** Topics Covered by Prerequisite Program  
*Pest Control*

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Pest control program
– Pest control devices
– Monitoring and maintenance of devices
Pest control personnel
Pest control chemicals
Monitoring for effectiveness
Pest control records

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- *Pest-control devices:* The establishment's pest control program should include outside bait stations for rodent control, nettings, bait stations or mechanical traps for birds, inside devices such as mechanical traps, glue-boards for rodents, and insect light traps for flying insects. These devices should be located at appropriate positions where they are most effective for removing pests from the building. Outside devices should be located so as to prevent entry of pests into the building. There should be an updated diagram or map to show the actual locations of all pest control devices both inside and outside the building.
- *Monitoring and maintenance of devices:* The pest control devices should be monitored at an established frequency for any pest activity and for the status of the devices. If this monitoring shows unusual pest activity, the appropriate follow-up action should be undertaken immediately. In addition, if the pest control device has lost its effectiveness, it should be serviced. A written report of this monitoring and maintenance should be kept.

#### 4.11.2 *Pest control personnel*

The personnel responsible for placement, monitoring and maintenance of the pest control devices, and for handling and use of pesticides, should have the required qualification and training, including food safety training. If an external pest control company is contracted by a food plant to carry out the activities of the pest control program, it should be required to provide evidence that it has the appropriate license or certification from the appropriate government agency.

#### 4.11.3 *Pest control chemicals*

Only chemicals approved as pesticides by the appropriate regulatory agency should be used for pest control in a food plant. "Restricted Use" pesticides should only be used with the required supervision and "General Use" pesticides should only be used by personnel with the required training. Every effort should be made to prevent the likelihood of contamination of food and food contact surfaces with pesticides. All pesticides and all pesticide



application equipment must be clearly identified with labels and stored in a protected, locked area far removed from food processing areas and storage areas for raw materials, ingredients, packaging materials, cleaning materials and products.

#### 4.11.4 *Monitoring for effectiveness*

The pest control program should be monitored for effectiveness on a continuous basis. Whenever there is evidence of pests or pest activity at the pest control devices or at any location in a food plant, the source of the pest should be identified and eliminated as soon as possible. In addition, the pest control program should be reviewed to determine that the preventive aspects of the program are effective.

#### 4.11.5 *Pest control records*

A food plant should maintain records as part of its pest control program. These should include the reports of the scheduled monitoring of pest control devices along with evidence of pests and pest activity and records relating the use of any pesticide for pest control within the plant.

### 4.12 *HACCP prerequisite program equipment*

This prerequisite program covers activities directed at design, construction, installation, performance, maintenance, and use of equipment in a food plant. It also includes the calibration of equipment used for monitoring and measuring parameters at any point in a process of detection, elimination, control, or prevention of food safety hazards, and for measuring product characteristics that are indicators of the safety of a product. The cleaning and sanitation of equipment is covered under the prerequisite program *Sanitation and cleaning*. Equipment used for storage of materials and products is covered under the prerequisite program *Transportation, receiving, storage, and shipping*.

The particular types of equipment that are used in a food plant depend on the specific type of products that are processed. The performance of equipment should ensure that the safety or quality specifications of a food can be achieved. In this prerequisite program, the primary considerations are to ensure that the equipment are capable of processing products that meet the safety and quality requirements, while at the same time the equipment must not be a source of contamination of the product.

This prerequisite program covers the items addressed in *Subpart C—Equipment* of the *Current Good Manufacturing Practices (Part 110, Title 21, CFR)* and in *4.3 Equipment* in *Establishment: Design and Facilities* of the *General Principles of Food Hygiene (Codex Alimentarius Commission)*. [Table 4.6](#) lists the topics which are covered by this prerequisite program.

**Table 4.6** Topics Covered by Prerequisite Program  
*Equipment*

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Processing equipment
– Design and installation
– Food-contact surfaces
– Installation
– Maintenance program
– Maintenance personnel
Handling equipment
Storage equipment
Monitoring and monitoring equipment
– Calibration

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*Relationship to ISO 9001:* The requirements of sections 6.3 *Infrastructure*, 7.5.1 *Control of production and service provision*, and 7.6 *Control of monitoring and measuring devices* address the topics covered by this prerequisite program.

#### 4.12.1 *Processing equipment*

- *Design and construction:* All equipment should be suitably designed and constructed to ensure that the specific requirements of the process can be achieved and the required maintenance, inspection, and cleaning can be readily undertaken. In addition, during the operation and use of equipment, there should be no contamination of product from the equipment itself, and there should be no unacceptable accumulation of any material (e.g., dust, metal fragments, oil, water, product) that is likely to be a source of contamination. In some food processing operations, a government regulatory agency specifies the design and construction requirements of the equipment that are used.
- *Food-contact surfaces:* The food-contact surfaces of equipment should be made of nontoxic material and should not be corroded or damaged in any way during normal operations, or when in contact with raw materials, products, and cleaning materials. The seams on food contact surfaces should be smooth so as to prevent accumulation of product and to facilitate cleaning and sanitizing.
- *Installation:* All processing equipment should be installed in a manner that will facilitate its operation, and the cleaning and maintenance of both the equipment and its immediate surroundings. After any equipment has been installed, it should be inspected and approved for use before it is put into regular operation. This inspection and approval should confirm that the equipment is capable of performing the intended operation and that the equipment is not a source of contamination.