Good Manufacturing Practices Part 117 Online Course

GMP Requirements: What You Can Do and How to Monitor

Table of Contents

Module 1: GMP Regulation & Training

GMP Requirement - Subpart A §117.4

Qualifications of individuals who manufacture, process, pack, or hold food. (a) Applicability (1) The management of an establishment must ensure that all individuals who manufacture, process, pack, or hold food subject to subparts B and F of this part are qualified to perform their assigned duties.

GMP Requirement - Subpart A §117.4

Qualifications of all individuals engaged in manufacturing, processing, packing, or holding food. Each individual engaged in manufacturing, processing, packing, or holding food (including temporary and seasonal personnel) or in the supervision thereof must:

(b)(1) Be a qualified individual as that term is defined in § 117.3—i.e., have the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties; and

(b)(2) Receive training in the principles of food hygiene and food safety, including the importance of employee health and personal hygiene, as appropriate to the food, the facility and the individual's assigned duties.

(c) Additional qualifications of supervisory personnel. Responsibility for ensuring compliance by individuals with the requirements of this part must be clearly assigned to supervisory personnel who have the education, training, or experience (or a combination thereof) necessary to supervise the production of clean and safe food.

GMP Requirement - §117.4(b)(1)

Each individual (including temporary and seasonal personnel) must be a qualified individual as that term is defined in §117.3 -i.e., have the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack or hold clean food as appropriate to the individual's assigned duties.

GMP Requirement - §117.4(b)(2)

Receive training in the principles of food hygiene and food safety, including the importance of employee health and personal hygiene, as appropriate to the food, the facility, and the individual's assigned duties.

GMP Requirement - §117.4(c)

Additional qualifications of supervisory personnel. Responsibility for ensuring compliance by individuals with the requirements of this part must be clearly assigned to supervisory personnel who have the education, training, or experience (or a combination thereof) necessary to supervise the production of clean and safe food.

GMP Requirement - §117.4(d)

Records. Records that document training required by paragraph (b)(2) of this section must be established and maintained.

GMP Requirement - Subpart F §117.305

General requirements applying to records. Records must:

(a) Be kept as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records;

(b) Contain the actual values and observations obtained during monitoring and, as appropriate, during verification activities;

(c) Be accurate, indelible, and legible;

(d) Be created concurrently with performance of the activity documented;

(e) Be as detailed as necessary to provide history of work performed; and

(f) Include:

(1) Information adequate to identify the plant or facility (e.g., the name, and when necessary, the location of the plant or facility);

(2) The date and, when appropriate, the time of the activity documented;

(3) The signature or initials of the person performing the activity; and

(4) Where appropriate, the identity of the product and the lot code, if any.

(g) Records that are established or maintained to satisfy the requirements of this part and that meet the definition of electronic records in §11.3(b)(6) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this part, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11 of this chapter.

Module 3: Personnel: Health & Hygiene

GMP Requirement - §117.10

Personnel – The management of the establishment must take reasonable measures and precautions to ensure the following:

GMP Requirement - §117.10(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.

What You Can Do

Develop Company Policies and Procedures

Develop company policies and procedures that describe the symptoms, illnesses, or conditions that employees must report to their supervisor. Policies should identify what action will be taken to prevent food contamination, such as reassigning employees to tasks that do not involve food handling or taking sick leave. Procedures should describe how the firm will determine that the employees' conditions have been resolved and they can resume their normal work activities.

Train Supervisors or Managers

Train supervisors or managers to ensure that they understand company policies and procedures and can recognize symptoms or signs of illness that could represent a potential risk for food contamination, and develop and maintain records of these training activities.

Train Employees

Train employees to ensure that they understand company policies and procedures and the symptoms or conditions that must be reported and their potential impact on food safety, and develop and maintain records of these training activities.

Monitor Employees

Monitor employees and their behavior daily to ensure that employees who are ill or who have open sores or wounds do not contaminate food.

How to Monitor

Supervisors should monitor employee health conditions daily. Although the current GMP does not require monitoring records, you may want to keep a record of the results of your observations for your own use. If any actions are necessary to correct problems, these actions should also be noted on a written record. Records must also be kept to demonstrate that all employees have been properly trained.

GMP Requirement - §117.10(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.

GMP Requirement - §117.10(b)(1)

All personnel must wear 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.

GMP Requirement - §117.10(b)(2)

All personnel must maintain adequate personal cleanliness.

GMP Requirement - §117.10(b)(4)

All personnel must remove all unsecured jewelry and other objects that might fall into food, equipment, or containers, and remove 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.

GMP Requirement - §117.10(b)(6)

All personnel must wear, where appropriate, in an effective manner, hair nets, headbands, caps, beard covers, or other effective hair restraints.

GMP Requirement - §117.10(b)(7)

All personnel must not store clothing or other personal belongings in areas where food is exposed or where equipment or utensils are washed.

GMP Requirement - §117.10(b)(8)

All personnel must confine 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.

GMP Requirement - §117.10(b)(9)

All personnel must take 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.

What You Can Do

To meet GMP requirements for employee cleanliness and hygiene your company needs to:

Develop Company Policies and Procedures for:

1. **The garments or other body coverings and shoes** that will be worn in areas where food is handled, stored or processed including aprons, sleeve protectors and shoes that will be provided by the company. How workers should use lockers or other facilities away from food handling areas to store street clothes, coats, shoes or other items. Which items are to be laundered or maintained by the company, and what employees are required to do.
2. **The hair and beard or moustache restraints** that are required for workers in each area of the plant and what employees need to do to meet this requirement.
3. **Company standards for personal cleanliness, wearing jewelry, and the use of cosmetics, skin care products or medicines.**
4. **Company policies that prohibit eating, drinking or smoking** in any food handling, storage or processing area. If necessary, specific instructions should be provided to employees describing where these activities can take place if they are allowed during break or other periods away from work areas.
5. **Company restrictions for personal items** that can be brought into work areas.

Train All Employees

Train all employees to ensure that they understand all company policies related to cleanliness, personal hygiene, attire, and personal activities. Most firms provide employees with a handbook to make sure that they understand what is expected of them. Training programs can be used to further explain the handbook and help employees understand why these policies and procedures are necessary. Develop and maintain required records for these training activities.

Monitor Employees Routinely

Monitor employees routinely during the day to make sure that they meet requirements for cleanliness, hygiene, attire, and proper practices.

How to Monitor

Supervisors should observe all employees at the beginning of the shift and periodically throughout the day as necessary to make sure that they are:

- clean, and practicing good hygiene;
- wearing appropriate outer garments;
- not wearing jewelry or other prohibited items;
- wearing appropriate hair and beard restraints;
- not bringing personal items into work areas;
- not smoking, eating, or drinking in work areas; and
- not using personal care products that could contaminate food.

If problems are observed, employees should be required to correct their attire or behavior before they start to work. Supervisors should be trained to make sure that they understand what is acceptable and how to work with employees to correct problems.

It may be useful to develop a simple checklist that covers all of the personal hygiene requirements that should be monitored on a daily basis. Although the current GMP does not require monitoring records, you may want to keep a record of the results of your observations for your own use. Records must also be kept of employee training for both supervisors and for other employees to demonstrate that they understand these requirements and have been informed about company policies.

GMP Requirement - §117.10(b)(3)

All personnel must wash their hands thoroughly (and sanitize 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.

What You Can Do

Anyone who works in food plant will need to wash their hands many times each day. To meet the hand washing requirements of the GMP you need to:

Evaluate the Location of Hand Washing Facilities

Evaluate the location of hand washing facilities or stations to ensure that it is convenient for employees to wash their hands at all times when it is necessary.

Develop Company Policies

Develop company policies that describe when, where and how all employees must wash their hands throughout the workday.

Train All Employees

Train all employees to make sure that they understand why hand washing is important and when, where and how to wash their hands properly. Develop and maintain required records of all training activities.

Monitor Hand Wash Stations

Monitor hand wash stations daily to make sure that they are working and are properly equipped with hot and cold running water, soap, and disposable towels.

Monitor Employee Hand Washing Practices

Monitor employee hand washing practices routinely to make sure that all employees follow company policies on how and when hands must be washed.

How to Monitor

Supervisors should monitor employee hand washing practices daily to ensure that expected practices are followed. Hand wash facilities should also be monitored daily to be sure that they are operating properly and have the proper supplies including soap, disposable towels, and other items that are needed. Although the current GMP does not require monitoring records, you may want to keep a record of the results of your observations for your own use. If any actions are necessary to correct problems, these actions should also be noted on a written record. Records must also be kept to demonstrate that all employees have been properly trained.

GMP Requirement - §117.10(b)(5)

All personnel must maintain gloves, if they are used in food handling, in an intact, clean, and sanitary condition.

What You Can Do

To meet the GMP requirement that gloves be maintained in an intact, clean and sanitary condition and should be made of impermeable material you need to:

Determine if There Are Any State or Local Regulations

Determine if there are any state or local regulations related to the use of gloves when handling food, and adjust procedures or policies as necessary to meet these requirements.

Evaluate the Type of Gloves

Evaluate the type of gloves that are used to make sure that they are impermeable, durable for their intended use, can be cleaned and sanitized, and do not create employee skin allergy or other problems.

Evaluate Company Procedures or Policies

Evaluate company procedures or policies that describe when and where employees will wear gloves and hand washing and sanitizing procedures that must be followed before and after employees put on their gloves. Make and implement any changes that are necessary.

Monitor Employees

Monitor employees daily to make sure that they are using gloves properly and following hand washing and glove sanitizing procedures.

Monitor Glove Sanitizing Solutions

Monitor glove sanitizing solutions daily to make sure that the proper sanitizer concentration is used.

How to Monitor

Supervisors should monitor employees daily to ensure that expected glove use and practices are followed. Hand sanitizing stations or dips should also be monitored daily to be sure that they are clean and have the proper sanitizer concentration. Although the current GMP does not require monitoring records, you may want to keep a record of the results of your observations for your own use. If any actions are necessary to correct problems, these actions should also be noted on a written record. Records must be kept to demonstrate that all employees have been properly trained to perform their assigned duties.

Module 4: Plant Grounds & Pest Control

GMP Requirement - §117.20(a)

Grounds – The grounds about a food plant under the control of the operator must be kept in good condition that will protect against the contamination of food.

GMP Requirement - §117.20(a)(5)

If the plant grounds are bordered by grounds not under the operators control and not maintained in the manner described in paragraphs (a)(1) through (a)(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.

GMP Requirement - §117.20(a)(1)

To adequately maintain grounds, you must properly store equipment, remove litter and waste, and cut weeds or grass within the immediate vicinity of the plant that may constitute an attractant, breeding place, or harborage for pests.

What You Can Do

To meet the GMP requirement to keep the outside of your facility in good condition and to cut weeds and grass and remove litter and waste that could serve as an attractant, breeding place, or harborage for pests you need to:

Conduct Maintenance Tasks Regularly

Conduct maintenance tasks regularly such as mowing the grass, remove weeds, trimming or maintaining shrubbery or any ornamental plants or trees, and removing any trash, equipment or other debris.

Monitor

Monitor the condition of all areas outside your building routinely.

How to Monitor

You should monitor the conditions outside your plant on a regular basis. Depending on the time of year, you may want to monitor outside conditions every other week to make sure you are complying with the GMP's and not providing water, food and shelter for pests. The conditions you find will determine how often you need to monitor. If you find a problem, you should check more often until the problem is solved.

Although the current GMP does not require monitoring records, you may want to keep a record of the results of your observations for your own use. If any corrections to problems that you observe need to take place, those corrections could also be part of your monitoring record.

GMP Requirement- §117.20(a)(2)

To adequately maintain grounds, you must maintain roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed.

GMP Requirement - §117.20(a)(3)

To adequately maintain grounds, you must drain areas that may contribute contamination to food by seepage, foot-borne filth, or provide a breeding place for pests.

What You Can Do

To meet the GMP requirements to maintain roads, yards and parking lots and adequate drainage to minimize contamination and eliminate breeding places or attractants for pests you need to:

Evaluate

Evaluate the condition of your roads and parking lots to make sure that there is adequate drainage and that water, dust or other sources of contamination are not present.

Maintain

Maintain the condition of roads and parking lots routinely and after unusual rainfall, snow or other events that could create drainage or other problems.

Monitor

Monitor the condition of roads and parking lots routinely.

How to Monitor

It's a good idea to routinely check the condition of roads and parking lots and look for standing water during the check of conditions outside the plant every other week that was suggested in the previous section. You should also monitor conditions after unusual weather events with large amounts of rain or snow.

Although the current GMP does not require monitoring records, you may want to keep a record of the results of your observations for your own use. If any actions are necessary to correct problems, these actions should also be noted on the written record.

GMP Requirement - §117.20(b)(7)

The plant must provide, where necessary, **adequate screening or other protection against pests.**

GMP Requirement - §117.20(b)(3)

The plant must permit the taking of adequate precautions to protect food in installed outdoor bulk vessels by any effective means including:

(i) – Using protective coverings.

(ii) – Controlling areas over and around the vessels to eliminate harborage for pests.

(iii) – Checking on a regular basis for pests and pest infestation.

(iv) – Skimming fermentation vessels, as necessary.

What You Can Do

To comply with this GMP requirement you need to:

Cover Outdoor Fermentation Vessels

Cover outdoor fermentation vessels and implement control strategies to eliminate pests that might be attracted to them.

Monitor Outdoor Fermentation Vessels Routinely

Monitor outdoor fermentation vessels routinely to make sure that pest control measures are effective and the food is protected from contamination.

How to Monitor

Outdoor fermentation vessels should be part of routine monitoring of conditions outside the plant facility as described in Module 4. Although the current GMP does not require monitoring records, you may want to keep a record of the results of your observations for your own use. If actions are needed to correct problems they should also be included on a record.

GMP Requirement - §117.35(c)

Pest Control.

Pests must not be allowed in any area of a food plant. Guard, guide, or pestdetecting dogs may be allowed in some areas of the plant if the presence of the dogs is unlikely to result in contamination of the 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.

What You Can Do

To meet the GMP requirements to provide adequate screening or other protection against pests, to exclude or prevent their entry into the facility, and to eliminate any pests that may find their way into the facility you need to:

Check the Entire Facility and Make Necessary Repairs

Check the entire facility and make necessary repairs to seal all openings, cracks or other places where pests may be harbored or gain entry into the building including:

- Any openings ¼ inch or greater;
- Openings or seals around windows, doors, vents, pipes, or electrical or other utility wires or conduits;
- Screens on or around windows, doors, fans, or vents;
- Drains; and
- Floor, wall or ceiling joints, seams, holes or other damaged areas that could harbor pests or allow them to enter.

Evaluate the Facility

Evaluate the facility to determine what types of pests including insects, rodents, birds or other animals are likely to be attracted to or find entry into the building.

Develop an Effective Pest Control Program

This program should identify what active measures will be taken such as using bait, traps, electrocution, ound repellants or other devices to prevent entry and eliminate any insects, rodents, birds or other pests identified as a potential problem in your evaluation that may gain entry into the plant.

Implement an Effective Pest Control Program

Determine who will be responsible for pest control measures and how and when these tasks will be completed. Some firms may use an outside company to control pests, and responsibilities and expected results should be identified. Other firms may conduct pest control tasks themselves. In either case, procedures must be used to make sure that poisonous or toxic chemicals do not contaminate food handling or storage areas, and that these chemicals are used in compliance with all regulations.

Monitor the Food Processing Facility Daily

Monitor the food processing facility daily before work activities begin to make sure that no pests are present in food handling or storage areas. This monitoring should also include looking for any signs of pest infestation such as droppings, rub or chew marks, fur, feathers or other signs.

Monitor All Active Pest Control Devices

Monitor all active pest control devices to make sure that they are working properly and stored, cleaned, or discarded properly so that they are not a source of contamination.

How to Monitor Pest Control Measures

All active pest control measures, whether conducted by people from your company or by an outside pest control company, should be monitored on a routine basis to make sure that the program is working.

At a minimum, someone should monitor all areas where food will be handled or stored on a daily basis to ensure that no pests are present in these areas, and that all food and ingredients are protected from contamination by pests.

Since most pests are active at night, it is unlikely that you will see many during the day. For this reason, you should also look for signs that rodents, insects or other pests are living near or in your plant. Rodent signs include such things as gnawed packages or containers, droppings, or rub marks along walls. For insects, you will need to search for droppings, insect nests, or trails from nests to sources of food and water. For birds or other animals, look for droppings, feathers, fur or other signs that these pests are present.

You should determine how often you will monitor the outside and inside conditions for your plant. How often you monitor will depend on the conditions you find. For example, if you find signs of pest infestation you may want to monitor more frequently until those conditions are corrected. When the conditions meet the requirements of the GMPs, you may be able to monitor less frequently.

Although the current GMP does not require monitoring records, you may want to keep a record of the results of your observations for your own use. If any actions are necessary to correct problems, these actions should also be noted on the written record.

Module 5: Plant Construction & Design

GMP Requirement - §117.20(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).

GMP Requirement - §117.20(b)(4)

The plant must be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept in good repair.

What You Can Do

To meet the GMP requirement that floors, walls and ceilings be in good repair and kept adequately clean to prevent contamination of food, food contact surfaces or packaging materials you need to:

Evaluate

Evaluate the materials and the condition of all floors, walls and ceilings.

Repair or Replace

Repair or replace any areas that are not made of suitable materials, which are damaged, or are otherwise unable to be kept clean and sanitary.

Monitor

Monitor the condition of floors, walls and ceilings routinely so that damaged or unsuitable conditions can be repaired before contamination occurs.

How to Monitor

Conduct a visual inspection of the condition of all areas of the plant daily. Although the current GMP does not require monitoring records, you may want to keep a record of the results of your observations for your own use. If any actions are necessary to correct problems, these actions should also be noted on the written record.

GMP Requirement - §117.20(b)(4)

The plant must be constructed in a manner that drip or condensate from fixtures, ducts and pipes **does not contaminate food, food-contact surfaces or food packaging materials.**

GMP Requirement - §117.20(b)(6)

The plant must 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 air-blowing equipment in a manner that minimizes the potential for allergen cross-contact and for contaminating food, food packaging materials, and food-contact surfaces.**

What You Can Do

To meet the two related GMP requirements to provide adequate ventilation and to prevent dripping water and condensation from contaminating food, food-contact surfaces, and packaging materials you need to:

Evaluate the Environmental Conditions in Your Plant

The capacity and operation of the ventilation or HVAC system should be evaluated. Conditions such as humidity, steam or other vapors, and the location of overhead pipes, fixtures or other items that could collect condensation and drip onto food or food contact surfaces should be evaluated.

Evaluate How Fans or Air Blowing Equipment are Used

Evaluate how fans or air blowing equipment are used in the facility and make sure that they do not contaminate food, food-contact surfaces, or packaging materials.

Repair, Modify or Upgrade the Ventilation or HVAC System

Repair, modify or upgrade the ventilation or HVAC system as necessary to maintain the proper conditions in the plant facilities.

Implement Controls

Implement controls as necessary to prevent dripping water or condensation from contaminating food or food contact surfaces.

Conduct Routine Maintenance of the Ventilation or HVAC System

Conduct routine maintenance of the ventilation or HVAC system as necessary to make sure that it is operating properly.

Monitor the Environmental Conditions in the Plant

Monitor the environmental conditions in the plant routinely to make sure that ventilation or HVAC systems are operating properly and contamination from condensate or dripping water is prevented.

How to Monitor

At least monthly, take a walk through your facility. Using your sense of sight and smell, check for condensate, steam, dirty fans and odors. If you operate a HVAC system check the condition of the system, and follow the manufacturer's directions for its maintenance.

Although the current GMP does not require monitoring records, you may want to keep a record of the results of your observations for your own use. You should also keep records of the periodic maintenance that you conduct on the HVAC system.

GMP Regulation - §117.20(b)(5)

The plant must provide adequate lighting in hand-washing areas, dressing and locker rooms, 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 protect against food contamination in case of glass breakage.

What You Can Do

To meet the GMP requirement to provide adequate lighting and to protect food from contamination by glass from light bulbs or other fixtures you need to:

Check the Light Bulbs or Fixtures to Make Sure That There is Adequate Light

Check the light bulbs or fixtures to make sure that there is adequate light in hand washing areas, dressing or locker rooms, toilet rooms, and all areas where food is examined processed or stored, or where equipment and utensils are cleaned.

Check the Light Bulbs or Fixtures to Make Sure That They are Properly Shielded

Check the light bulbs or fixtures to make sure that they are properly shielded or made of shatter resistant materials in all areas where food is examined processed or stored, or where equipment and utensils are cleaned.

Repair, Replace or Modify Any Light Fixtures

Repair, replace or modify any light fixtures that do not provide adequate light or are not adequately shielded or made of shatter resistant material.

Develop a Procedure to Inspect Deliveries

Develop a procedure to inspect deliveries of replacement light bulbs, fixtures, or safety shields to make sure that they meet safety requirements.

Monitor Light Bulbs and Fixtures Routinely

Monitor light bulbs and fixtures routinely to make sure that they provide adequate light and are properly shielded or made of shatter resistant materials.

How to Monitor

A routine daily visual inspection of light sources in all areas of the plant should be made. Check that all replacements meet the requirements set for proper shielding or bulb type. Although the current GMP does not require monitoring records, you may want to keep a record of the results of your observations for your own use. If any actions are necessary to correct problems, these actions should also be noted on the written record.

GMP Requirement - §117.20(b)(4)

The plant and its facilities must be constructed in such a manner 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.

What You Can Do

To meet the GMP requirement to provide adequate aisles or working spaces between equipment and walls that are unobstructed to permit employees to do their work and prevent contamination of food, food-contact surfaces, and packaging materials you need to:

Evaluate

Evaluate the layout and placement of equipment, processing lines, and workstations to make sure that aisles and workspaces are adequate and unobstructed and designed to prevent contamination.

Relocate, Move, or Otherwise Modify

Relocate, move, or otherwise modify placement of equipment, processing lines, or workstations so that adequate space is provided for employees to perform their duties and contamination is prevented.

Monitor

Monitor routinely all areas where food, food contact surfaces and packaging materials are used to make sure that adequate, unobstructed space is provided.

How to Monitor

Periodically observe the activities conducted in all areas of the plant at several different times of the day and monitor the impact of any changes that are made. Although the current GMP does not require monitoring records, you may want to keep a record of the results of your observations for your own use. If any actions are necessary to correct problems, these actions should also be noted on the written record.

GMP Requirement - §117.20(b)(2)

The plant must 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.

What You Can Do

To meet the GMP requirement to protect food from contamination during mechanical manufacturing steps you need to:

Evaluate Your Operations

Evaluate your operations to determine if adequate precautions are in place to prevent allergen cross-contact and contamination of food, food-contact surfaces and packaging materials. Determine if it is necessary to separate specific production activities by location, time, or using enclosed systems or dust control measures.

Develop Preventive Procedures

Develop preventive procedures as necessary using a schedule for activities, dedicated areas or other controls to prevent contamination and allergen cross-contact.

Train Employees

Train employees to make sure that they understand what must be done at the manufacturing steps that they are involved in to prevent food contamination.

Routinely Monitor Activities at Each Processing Step

Routinely monitor activities at each processing step to make sure that proper practices are followed and mistakes are immediately corrected.

How to Monitor

Supervisors should routinely monitor all activities conducted in the plant to determine that they are conducted in the proper location and at the proper time to make sure that food, food-contact surfaces, and packaging material are protected from contamination and allergen cross-contact. Supervisors should make sure that all employees understand what they must do to prevent contamination and allergen cross-contact, and participate in or conduct training as necessary. Although the current GMP does not require monitoring records, you may want to keep a record of the results of your observations for your own use. If any corrections are necessary to correct problems, those actions should also be noted on a written record.

GMP Requirement - §117.20(a)(4)

Systems for waste treatment and disposal must be operated in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed.

GMP Requirement - §117.37(f)

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.

What You Can Do

To meet the GMP requirement to operate waste treatment and disposal systems in an adequate manner to minimize contamination and eliminate breeding places or attractants for pests you need to:

Evaluate

Evaluate your system for handling, storing and discarding food waste and other garbage to make sure that it minimizes the potential for contamination and does not attract pests.

Maintain, Clean and Sanitize

Maintain, clean and sanitize waste receptacles, dumpsters and other elements of your waste system to minimize odor and eliminate breeding places or attractants for pests.

Monitor

Monitor your waste disposal, handling and storage system including food waste containers and storage areas, dumpsters and other areas on a routine basis.

How to Monitor

You should monitor your waste control system often to ensure that containers, dumpsters or other waste receptacles have been handled, stored, and emptied in a way to avoid attracting pests. Ideally you would monitor this at least once a day, the best possible time might be at the end of the processing day.

Although the current GMP does not require monitoring records, you may want to keep a record of the results of your observations for your own use. Any corrections to problems that arise should also be written on a monitoring record.

Module 6: Sanitary Facilities: Water, Plumbing & Toilets

GMP Requirement - §117.37(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.

GMP Requirement - §117.37(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.

GMP Requirement - §117.37(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.**

GMP Requirement - §117.37(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.

What You Can Do

To meet the GMP requirements related to the source and safety of water and the need to have an adequate supply at the proper temperature and locations you need to do the following.

Determine the Source

Determine the source of your water and verify its safety.

Routinely Check

If your water is from a public drinking water system you need to:

- Routinely check the water temperature at all locations where hot water is needed; and
- Routinely check the water pressure at all locations where water is needed.

If you use water from a well or other private source you need to:

- Obtain the necessary permits or approval to use the well water or other private water supply from local health authorities;
- Conduct required testing and keep records of test results to demonstrate that the water you are using meets current safety standards;
- Routinely check the water temperature at all locations where hot water is needed; and
- Routinely check the water pressure at all locations where water is needed.

How to Monitor

Monitoring can be accomplished by having a current bill or statement from the municipal supplier showing you are one of their customers as well as annual water test results. For a private well, most public health authorities will require that your water be tested at least twice a year to confirm its safety. A copy of the test results should be kept at your processing facility. You should also inspect the wellhead routinely for cracks or other sources of contamination.

In addition, supervisors or other managers should check periodically to make sure that there is enough water at suitable temperatures in those areas where it is needed for the work to be done that day.

Records of monitoring the source and safety should be kept and updated at least once a year. If you are using a private well for your water source, a copy of all the test results required by your local health authority can be used as your monitoring record. Periodic checks of the water temperatures where hot water is needed should be done, and the results could be recorded on a routine sanitation monitoring record.

If you encounter any problems with the source, test results, quantity, or temperature of the water you will need to correct the problem. For example, if you receive test results from a water sample that showed high coliform counts in your well water, your correction might be to stop processing and resample immediately. If the resample was satisfactory and meets your local health authority's requirements, processing could resume. This correction would be recorded on a sanitation monitoring record.

Although the current GMP does not require monitoring records, you may want to keep a record of the results of your observations for your own use.

GMP Requirement - §117.37(b)

Plumbing – Plumbing must be of adequate size and design and adequately installed and maintained to:

(1) Carry adequate quantities of water to required location throughout the plant.

(2) Properly convey sewage and liquid disposable waste from the plant.

(3) Avoid constituting a source of contamination to food, water supplies, equipment or utensils or creating an unsanitary condition.

(4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water of other liquid waste on the floor.

(5) Provide that there is not backflow from, or cross-connection between, piping systems that discharge wastewater or sewage and piping systems that carry water for food or food manufacturing.

GMP Requirement - §117.37(b)(1)

Plumbing must be of adequate size and design and adequately installed and maintained to **carry adequate quantities of water to required locations throughout the plant.**

GMP Requirement - §117.37(b)(2)

Plumbing must be of adequate size and design and adequately installed and maintained to **properly convey sewage and liquid disposable waste from the plant.**

GMP Requirement - §117.37(b)(3)

Plumbing must be of adequate size and design and adequately installed and maintained to **avoid constituting a source of contamination to food, water supplies, equipment or utensils or creating an unsanitary condition.**

GMP Requirement - §117.37(b)(4)

Plumbing must be of adequate size and design and adequately installed and maintained to **provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.**

GMP Requirement - §117.37(b)(5)

Plumbing must be of adequate size and design and adequately installed and maintained to **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.**

What You Can Do

To meet the GMP requirements for your plant's plumbing system for delivering potable water, disposing of liquid waste, providing adequate floor drainage, and preventing backflow conditions you need to:

Evaluate Existing Plumbing System

Evaluate existing plumbing system for delivering potable water to make sure that it meets all relevant plumbing codes for proper design and capacity.

Evaluate Liquid Waste Disposal Plumbing

Evaluate liquid waste disposal plumbing to make sure that it meets all design requirements for proper disposal of liquid, processing and human waste, and has an adequate capacity.

Evaluate the Condition, Design and Location of Floors and Floor Drains

Evaluate the condition, design and location of floors and floor drains, and maintain them properly to make sure that they are not a source of contamination.

Install Backflow Prevention Systems or Devices

Install backflow prevention systems or devices at all locations where it is necessary such as faucets to prevent cross-connections, backflow or back-siphonage that could contaminate the potable water supply.

Conduct Periodic Maintenance

Conduct periodic maintenance of plumbing and waste disposal systems and testing of back flow prevention devices consistent with manufacturer recommendations.

Monitor

Monitor the condition and performance of the plumbing, hoses and seals at water junctions, waste disposal systems and backflow prevention systems.

How to Monitor

Daily checks should be made to make sure that floors are draining properly and that there are no puddles of water on the floor that could be a source of contamination. Hoses and other equipment attached to water lines should be checked to make sure that they have appropriate backflow prevention devices and that hoses are not submerged in sinks, lying on the floor, or in contact with water or other material that could contaminate them

Although the current GMP does not require monitoring records, you may want to keep a record of the results of your observations for your own use. If any actions are necessary to correct problems, these actions should also be noted on the written record. Records should also be kept to demonstrate that backflow prevention devices have been maintained and tested according to manufacturer recommendations.

GMP Requirement - §117.37(c)

Sewage must be disposed of into an adequate sewerage system or disposed of through other adequate means.

What You Can Do

To meet the GMP requirements for proper disposal of sewage you need to:

Evaluate Your System for Sewage Disposal

Evaluate your system for sewage disposal to determine that it meets local regulations or codes, has an adequate capacity, and meets requirements set by your public sewage receiver or set by local authorities for septic or other private systems.

Conduct Routine Maintenance

Conduct routine maintenance as necessary to make sure your system is working properly.

Develop a Plan to Respond to Unusual Events

Develop a plan to respond to unusual events such as sewer backups, flooding or other occurrences. Make sure that the plan describes the steps that must be taken to correct the problem and prevent contamination of the facility, food or food-contact surfaces.

Monitor the Sewage System Routinely

Monitor the sewage system routinely to make sure that it is working properly and that problems are immediately corrected.

How to Monitor

Conditions should be monitored daily to be sure that the system is working properly and no problems have developed. Although the current GMP does not require monitoring records, you may want to keep a record of the results of your observations for your own use. If any actions are necessary to correct problems, these actions should also be noted on the written record.

GMP Requirement - §117.37(d)

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.

GMP Requirement - §117.37(e)

Each plant must provide hand washing facilities designed to ensure that an employee's hands are not a source of contamination of food, food-contact surfaces, or food packaging materials, by providing facilities that are adequate, convenient, and furnish running water at a suitable temperature.

What You Can Do

To meet the GMP requirements to provide adequate, accessible toilet and hand washing facilities that operate properly and are maintained in sanitary condition at all times to protect food and food handling areas from contamination you need to:

Evaluate the Number and Location of Existing Toilet and Hand Washing Facilities

Evaluate the number and location of existing toilet and hand washing facilities to make sure that you meet existing requirements and that they are easily accessible and will not contaminate food or food handling areas.

Evaluate the Design of Each Toilet Facility

Evaluate the design of each toilet facility to make sure that:

- Doors are tight fitting and self-closing;
- Ventilation is adequate and designed to prevent airborne contamination; and
- All facilities are equipped for proper hand washing including adequate sinks, hot water, hand drying, and waste disposal.

Monitor Toilet and Hand Washing Facilities Routinely

Monitor toilet and hand washing facilities routinely to make sure that they are operating properly, and that they are properly equipped.

How to Monitor

Toilet and hand washing facilities should be checked daily prior to processing and periodically during the day if necessary after employees have used the facility. You should visually monitor that the facilities are in good repair, clean, and that they are adequately supplied. If during your monitoring you encounter a problem, you should correct it and record the correction. For example if one of the toilets has a leak in the seal where it is attached to the drain pipe, it should be taken out of use and fixed before it can be put back in use. Although the current GMP does not require monitoring records, you may want to keep a record of the results of your observations for your own use, along with a description of any corrections that are needed.

Module 7: Sanitary Operations: Cleaning & Sanitizing

GMP Requirement - §117.35(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.

GMP Requirement - §117.35(b)(1)

Substances used in cleaning and sanitizing. 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.

What You Can Do

To meet the GMP requirements to use safe and effective cleaning and sanitizing agents that are free from harmful microorganisms you need to:

Evaluate

Evaluate all cleaning and sanitizing agents used in your facility to determine if they are approved for use in food establishments.

Obtain Written Documentation

Obtain written documentation from the manufacturer or supplier of your cleaning and sanitizing chemicals to verify that these products meet current regulations and are approved for use in food establishments.

Check Your Procedures

Check your procedures to verify that they are consistent with manufacturer recommendations and label directions for the proper use of all cleaning and sanitizing products including test kits to verify sanitizer concentration.

Monitor Chemical Deliveries

Monitor chemical deliveries to verify that the proper products are received, that the proper documentation is on file, and that the instructions for use have not changed.

How to Monitor

Keep appropriate records from your supplier to show that the cleaning and sanitizing chemicals that you use are approved and adequate when used properly. Monitor cleaning and sanitation procedures daily to be sure that they are conducted properly. Use test strips to confirm that you have the appropriate sanitizer concentration each time that sanitizing solutions are prepared. Although the current GMP does not require monitoring records, you may want to keep a record of the results of your observations for your own use. If any corrections are necessary to correct problems, those actions should also be noted on a written record.

GMP Requirement - §117.35(b)

Use and Storage of Toxic Materials – Only the following toxic materials may be used or stored in a plant where food is processed or exposed:

(i) Those required to maintain clean and sanitary conditions;

(ii) Those necessary for use in laboratory testing procedures;

(iii) Those necessary for plant and equipment maintenance and operation; and

(iv) Those necessary for use in the plant's operations.

GMP Requirement - §117.35(b)(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.

GMP Requirement - §117.35(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.

GMP Requirement - §117.35(d)(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.

GMP Requirement - §117.35(d)(2)

In wet processing, when cleaning is necessary to protect against allergen cross-contact or the introduction of microorganisms into food, **all food-contact surfaces must be cleaned and sanitized before use and after any interruption during which the food-contact 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.**

GMP Requirement - §117.35(e)

Non-food-contact surfaces of equipment used in operation of a food plant **must be cleaned in a manner and as frequently as necessary** to protect against allergen cross-contact and against the contamination of food, food-contact surfaces, and food packaging materials.

GMP Requirement - §117.35(f)

Storage and handling of cleaned portable equipment and utensils. **Cleaned and sanitized portable equipment with foodcontact surfaces and utensils must be stored in a location and manner that protects food-contact surfaces from allergen cross-contact and from contamination.**

GMP Requirement - §117.35(d)(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.**

What You Can Do

To meet the general GMP requirements for cleaning and sanitizing food-contact surfaces, equipment, utensils, and non-food-contact surfaces in the plant environment as necessary you need to:

Develop Sanitation Procedures

Develop sanitation procedures for equipment, utensils, containers, processing areas, and all other plant facilities as necessary. These procedures must be effective but the GMP does not currently require that they be written down.

A complete sanitation procedure should describe:

- What areas of your facility and what equipment and utensils need to be cleaned and sanitized.
- How each item or area will be cleaned and sanitized including:
  - The chemical cleaning and sanitizing products to be used.
  - Instructions on how to prepare cleaning and sanitizing solutions properly and test or verify their concentration.
  - Instructions on how to apply these solutions.
  - The cleaning tools to be used for each task.
  - Instructions for each of the steps in the procedure and their proper order or sequence.
  - Instructions for proper storage of cleaned equipment.
- When each cleaning and sanitizing task will be done.
- Who will conduct each task.

Different types of procedures may be needed. For example, some operations may need one procedure for cleaning and sanitizing the tables, walls and floors for their entire plant at the end of the day. Other firms may need one procedure for the area of the plant that handles raw products, and a different procedure for the area of the plant where finished products are packaged. You may also need different procedures for different pieces of equipment that are cleaned and sanitized in place, and for portable items and utensils that are cleaned and sanitized in a three-compartment sink. Specific procedures may also be needed to prevent allergen cross-contact.

Implement

Implement each of the cleaning and sanitation procedures that are needed. Implementation includes purchasing the necessary chemicals and equipment to complete all tasks, placing these items in the proper location, and storing them properly.

Train Employees

Train employees who have cleaning and sanitizing responsibilities to make sure that they understand what tasks must be completed and how to conduct them properly.

Monitor

Monitor cleaning and sanitizing activities to make sure that they are conducted properly and consistently. Monitoring could include testing to verify that the procedures developed are effective.

How to Monitor

Cleaning and sanitizing activities should be routinely checked to be sure that they are conducted properly and at the proper time as described in your sanitation procedure. This may include monitoring the proper use of detergents and cleaning aids, sanitizers, and cleaning and sanitizing procedures. Additional periodic checks using monitoring tools for cleanliness and/or tests for specific types of bacteria or food allergens should be conducted as needed or required by regulations for certain types of food products. Although the current GMP does not require monitoring records, you may want to keep a record of the results of your observations for your own use. If any corrections are necessary to correct problems, those actions should also be noted on a written record.

Module 8: Equipment & Utensils

GMP Requirements - General Requirements for Equipment and Utensils:

§117.40(a)(1) - All plant equipment and utensils used in manufacturing, processing, packing and 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.**

§117.40(a)(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.

§117.40(a)(3) - Equipment must be installed so as to facilitate the cleaning and maintenance of the equipment and of adjacent spaces.

GMP Requirements for Food-Contact Surfaces

§117.40(a)(4) - Food-contact surfaces shall be corrosion-resistant when in contact with food.

§117.40(a)(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.

§117.40(a)(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.

§117.40(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.

GMP Requirement for Non-Food-Contact Surfaces

§117.40(c) - Equipment that is in areas where food is manufactured, processed, packed or held and **that does not come in contact with food must be so constructed that it can be kept in a clean and sanitary condition.**

What You Can Do

To meet the GMP requirements for the proper design and construction of equipment, utensils and food-contact surfaces you need to:

Develop a Checklist for Evaluating All New Equipment and Utensils

Develop a checklist for evaluating all new equipment and utensils before they are purchased that answers the following questions:

- Are there food or worker safety standards that the equipment, utensil or food-contact surface must meet? If so, does it meet those standards?
- What material is the equipment or utensil made of? Is this material the best choice for the task while balancing cost, ease of maintenance and durability requirements?
- Is the equipment, utensil or food-contact surface designed and constructed properly to prevent food from being contaminated when it is used?
- Can the equipment be easily taken apart and cleaned and sanitized?

Develop a Checklist to Evaluate Existing Equipment

Develop a checklist to evaluate existing equipment to detect signs of corrosion, pitting, scarring, cracking or other deterioration that could harbor harmful bacteria and be difficult to clean and sanitize.

Develop Procedures for Fixing, Removing or Discarding Equipment

Develop procedures for fixing, removing or discarding equipment that is damaged and cannot be kept clean and sanitary.

Monitor All Deliveries

Monitor all deliveries of new or used equipment to make sure that it meets company requirements.

Monitor the Condition of All Existing Equipment

Monitor the condition of all existing equipment, utensils or food-contact surfaces periodically to make sure that they are suitable for use and will not contaminate food.

How to Monitor

Managers should determine that company procedures have been followed before new equipment or utensils are purchased and used or installed in food processing, handling or storage areas. Supervisors or other individuals should periodically (weekly or monthly) inspect equipment and utensils to make sure that unacceptable items are removed and discarded or refurbished. Equipment or surfaces that have been resurfaced, sanded, welded or repaired would need to be cleaned and sanitized before they are used. Supervisors should also monitor cleaning and sanitizing procedures to make sure that equipment or utensils do not become a source of contamination

Although the current GMP does not require monitoring records, you may want to keep a record of the results of your observations for your own use. If any corrections are necessary to correct problems, those actions should also be noted on the written record.

GMP Requirement - §117.40(a)(3)

Equipment must be installed so as to facilitate the cleaning and maintenance of the equipment and of adjacent spaces.

GMP Requirement - §117.40(d)

Holding, conveying and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, **must be of a design and construction that enables them to be maintained in an appropriate clean and sanitary condition.**

What You Can Do

To meet the GMP requirements for the proper design, installation and maintenance of equipment, holding, conveying, and manufacturing systems you need to:

Develop a Checklist for Evaluating All New Processing Lines or Systems Including Conveyors and Holding Units

Develop a checklist for evaluating all new processing lines or systems including conveyors and holding units before they are purchased that answers the following questions:

- Are there food or worker safety standards that the system must meet? If so, does it meet those standards?
- What material is the equipment in the system made of? Is this material the best choice for the task while balancing cost, ease of maintenance and durability requirements?
- Is the system designed and constructed properly to prevent food from being contaminated when it is used?
- Can the system be easily taken apart and cleaned and sanitized?

Develop a Checklist for Evaluating Existing Processing Systems and Conveyances

Develop a checklist for evaluating existing processing systems and conveyances to detect signs of corrosion, pitting, scarring, cracking or other deterioration that could harbor harmful bacteria and be difficult to clean and sanitize.

Develop Procedures

Develop procedures for fixing, removing or discarding equipment that is damaged and cannot be kept clean and sanitary.

Monitor the Condition of All Existing Processing Systems and Conveyances Periodically

Monitor the condition of all existing processing systems and conveyances periodically to make sure that they are suitable for use and will not contaminate food.

How to Monitor

The same monitoring that was described earlier for equipment should be applied to conveyances and processing systems. Management should have a procedure in place to make sure that new equipment is evaluated before it is purchased and installed. Supervisors or other individuals should periodically (weekly or monthly) inspect conveyors and other systems to make sure that unacceptable components are removed and discarded or refurbished. Supervisors should also monitor cleaning and sanitizing procedures to make sure that equipment or utensils do not become a source of contamination. Although the current GMP does not require monitoring records, you may want to keep a record of the results of your observations for your own use. If any corrections are necessary to correct problems, those actions should also be noted on the written record.

GMP Requirement - §117.40(e)

Each freezer and cold storage compartment used to store and hold food that is capable of supporting the growth of microorganisms **must be fitted with an indicating thermometer, temperature-measuring device,** or temperature-recording device so installed as to show the temperature accurately within the compartment.

What You Can Do

To meet the GMP requirement to monitor the temperature of freezer and cold storage units with an accurate device and the GMP recommendation to use an appropriate control or alert system you need to:

Install an Indicating Thermometer or Other Temperature-sensing or Recording Device

Install an indicating thermometer or other temperature-sensing or recording device that meets appropriate standards for use with food products and is accurate to ±3°F (2°C) in all refrigeration and freezer units.

Consider Installing an Automatic Control System

Consider installing an automatic control system to regulate temperature of freezer and refrigeration units or an alarm system to alert managers when units are outside the desired temperature range.

Monitor the Temperature of All Refrigeration and Freezer Units Routinely

Monitor the temperature of all refrigeration and freezer units routinely with visual observations in addition to any automatic measurements that are made.

How to Monitor

A designated person should be assigned to check all refrigeration or freezer units routinely to make sure tha they have appropriate temperature-measuring devices that are working properly. The actual temperature of each unit should be checked and recorded as necessary to make sure that all food that could support the growth of harmful bacteria or microorganisms is kept below 40°F (5°C). If the temperature is too high, the problem should be identified, fixed, and the unit adjusted until the proper temperature is achieved. It may be necessary to move the contents of the unit to another unit that is working properly or to ice the product or take other measures to make sure that the food is not exposed to an elevated temperature for an extended period of time. Although the current GMP does not require monitoring records, you may want to keep a record of the results of your observations for your own use. If any corrections are necessary to correct problems, those actions should also be noted on a written record.

GMP Requirement - §117.40(f)

Instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food **must be accurate and precise and adequately maintained, and adequate in number for their designated uses.**

What You Can Do

To meet the GMP requirements for the proper use, maintenance, and calibration of thermometers and other instruments for measuring conditions in food such as pH or water activity you need to:

Determine What Monitoring Devices

Determine what monitoring devices are needed for your operation, such as thermometers or pH meters.

Purchase Monitoring Devices that Meet Current Standards

Purchase monitoring devices that meet current standards for use in food processing.

Maintain, Check the Accuracy Routinely, and Calibrate as Necessary All Monitoring Devices

Maintain, check the accuracy routinely, and calibrate as necessary all monitoring devices as recommended by the manufacturer of the device.

Train Employees

Train employees to use monitoring devices correctly.

Monitor

Monitor the way that these devices are used, maintained, stored, and calibrated.

How to Monitor

Supervisors should check on a daily or weekly basis to make sure that all thermometers or other measuring devices are working properly and are being used properly. Instrument calibration should be conducted periodically as suggested by the manufacturer, or if it is suspected that the instrument in not working properly. Although the current GMP does not require monitoring records, you may want to keep a record of the results of your observations, routine checks, and periodic calibration results for your own use. If any corrections are necessary to correct problems, those actions should also be noted on the written record.

GMP Requirement - §117.40(g)

Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment **must be treated in such a way that the food is not contaminated** with unlawful indirect food additives.

What You Can Do

To meet the GMP requirement to protect food from contamination by compressed air or other gases you need to:

Determine

Determine what (if any) equipment or systems in your operation use compressed air or other gases.

Evaluate Your Suppliers and Any Equipment

Evaluate your suppliers and any equipment that uses compressed air systems or gases to determine that they meet all current standards and regulations and do not contain any harmful substances or microorganisms that could contaminate food or food-contact surfaces.

Conduct Maintenance

Conduct maintenance of compressed air or gas systems as recommended by the supplier or manufacturer.

Monitor

Monitor compressed air or gas systems to make sure that they are operating properly, are being used properly, and have been maintained as recommended by the manufacturer.

How to Monitor

Supervisory personnel should evaluate all shipments of compressed gases or compressed air equipment to verify that it meets company specifications when they are received. Supervisors should check to make sure that all systems that used compressed air or other gases are working properly and are being used properly on a regular basis. Supervisors should also check to make sure that routine maintenance of compressed air or gas systems is conducted as recommended by the manufacturer. Although the current GMP does not require monitoring records, you may want to keep a record of the results of your observations for your own use. If any corrections are necessary, those actions should also be noted on the written record.

Module 9: Plant Operations & Raw Materials

GMP Requirement - §117.80(a)(1)

All operations in the manufacturing, processing, packing, and holding of food (including operations directed to receiving, inspecting, transporting and segregating) **must be conducted in accordance with adequate sanitation principles.**

GMP Requirement - §117.80(a)(2)

Appropriate quality control operations must be employed to ensure that food is suitable for human consumption and that food packaging materials are safe and suitable.

GMP Requirement §117.80(3)

Overall sanitation of the plant must be under the supervision of one or more competent individuals **assigned responsibility for this function.**

GMP Requirement - §117.80(a)(4)

Adequate precautions must be taken to ensure that production procedures do not contribute to allergen cross-contact and to contamination from any source.

GMP Requirement - §117.80(a)(5)

Chemical, microbial or extraneous testing procedures must be used where necessary to identify sanitation failures or possible allergen cross-contact and food contamination.

GMP Requirement - §117.80(a)(6)

All food that has become contaminated to the extent that it is adulterated must be rejected, or if appropriate, treated or processed to eliminate the contamination.

What You Can Do

To meet GMP requirements that outline the general sanitation and quality control responsibilities that firms who receive, process or store food must meet to prevent food contamination you need to:

Identify What Reasonable Precautions are Necessary

Identify what reasonable precautions are necessary at each step of your operation to prevent food contamination.

Develop and Implement a Quality Control System

Develop and implement a quality control system that describes what precautions and sanitation controls must be followed at each step of the operation to prevent food contamination.

Assign One or More Qualified Individuals to Supervise

Assign one or more qualified individuals to supervise quality control and plant sanitation activities.

Routinely Monitor Plant Activities

Routinely monitor plant activities to identify sanitation failures or incidents that could contaminate food products. For small operations this monitoring could be done by a single individual who has the responsibility to make sure that all daily activities are conducted properly, that food is protected from contamination, and that proper procedures are followed. For complex operations, a team of people may be responsible for monitoring activities, and each person should understand their individual responsibility and their relationship to the firm's overall quality control program.

Develop Testing Procedures

Develop testing procedures that will be used to identify when contamination events or sanitation failures have occurred. These procedures should describe how products will be evaluated, and how decisions will be made about the affected products' disposition.

Reject or Destroy Contaminated Food or Reprocess it

Reject or destroy contaminated food or reprocess it if possible to eliminate contamination. Reprocessing is an option only if a pre-determined validated process is used that has been scientifically shown to be effective in eliminating the contamination.

How to Monitor

Individuals who have responsibility to ensure that all reasonable precautions are taken to make sure that food is not contaminated should conduct the monitoring activities assigned to them as described in the firm's quality control and sanitation procedures. Although the current GMP does not require monitoring records, you may want to keep a record of the results of your observations for your own use. If problems are detected, they should be corrected at the time that they are observed, and the actions that are taken should also be recorded. Records should be kept of contamination events, test results, and the disposition (reject, destroy or reprocess) of the affected products.

GMP Requirement - §117.80(b)(1)

Raw materials and other ingredients must be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food.

Raw materials and other ingredients must be stored under conditions that will protect against allergen cross-contact and against contamination and minimize deterioration.

Raw materials must be washed or cleaned as necessary to remove soil or other contamination. Water used for washing, rinsing, or conveying food must be safe and of adequate sanitary quality. Water may be reused for washing, rinsing or conveying food if it does not cause allergen cross-contact or increase the level of contamination of the food.

What You Can Do

To meet the general GMP requirements for inspecting and storing raw foods and ingredients, you need to:

Develop

Develop consistent procedures for receiving food or ingredients that describe how they will be evaluated, separated, and cleaned if necessary, and then stored.

Inspect

Inspect every delivery to make sure that all items are clean and suitable for use as food.

Separate
Separate any contaminated items and filthy or damaged containers from those that are acceptable. Identify and separate foods that contain allergens from those that do not to prevent allergen cross-contact.

Reject
Reject food or containers that are spoiled, contaminated with filth, or otherwise unsuitable for food, and properly dispose them in a sanitary manner.

Wash
Wash items as necessary if they are acceptable for use, and then repack for storage.

Water
Water used for washing must be potable and not lead to allergen cross-contact.

Store
Store all food and ingredients in containers or in ways that will adequately protect them from contamination from other foods or the plant environment, and from allergen cross-contact.

Monitor and Clean and Sanitize
Monitor and clean and sanitize mechanical systems including conveyors to make sure that they do not contaminate food or lead to allergen cross-contact.

Monitor and inspect
Monitor and inspect every delivery of food, ingredients, or packaging materials.

How to Monitor

A supervisor or other employee, who has been trained or has adequate experience, must be assigned to inspect and evaluate any food or ingredients when they are received. These individuals will be responsible for making sure that unacceptable items are separated from acceptable ones and properly disposed. They will also monitor any washing or cleaning of food or ingredients, and make sure that all items are stored properly to protect them from contamination. Although the current GMP does not require monitoring records, you may want to keep a record of the results of your observations for your own use. If any corrections are necessary to fix problems, those actions should also be noted on an appropriate record.

GMP Requirement - §117.80(b)(2)

Raw materials and other ingredients must either not contain levels of microorganisms that may render the food injurious to the health of humans, or they must be pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated.

What You Can Do

To meet the general GMP requirements to minimize harmful microorganisms you need to:

Determine
Determine what types of bacteria or other microorganisms are likely to be a concern for your products, and what practices may be needed to minimize or prevent contamination with these microorganisms.

Communicate
Communicate with your suppliers and inspect them if necessary to make sure that they understand what practices are expected and what types of guarantees you need in order to meet this GMP requirement.

Test and Resolve Problems

Test and resolve problems. It may be prudent to conduct periodic tests of raw foods and ingredients to verify that pathogens of concern in your food products are not present at high levels. If problems are detected, it may be necessary to work with suppliers and conduct additional tests until acceptable practices are implemented to correct the problem.

Develop a Validated Pasteurization Process if Necessary.

Develop a validated pasteurization process if necessary. This option will be used to eliminate or reduce harmful microorganisms, and supervisors must monitor the process to demonstrate that the conditions identified in the validation study have been met.

Monitor

Monitor your suppliers and all food and ingredients at receipt to make sure that necessary guarantees have been provided and all necessary steps have been taken to minimize microbial contamination.

How to Monitor

Individuals who are responsible for receiving products should monitor where the products are coming from and determine if your firm has approved this supplier or that appropriate guarantees or certificates have been provided. Samples should be taken as necessary for testing to verify that acceptable preventive practices are being followed. Supplier guarantees or certificates should be kept on file. Although the current GMP does not require monitoring records, you may want to keep a record of the results of your observations for your own use. If products are rejected or discarded, those actions should also be noted on the record. Monitoring records for any pasteurization procedure should be kept on an appropriate processing record.

GMP Requirement - §117.80(b)(3)

Raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins must comply with current Food and Drug Administration regulations for poisonous or deleterious substances before these materials or ingredients are incorporated into finished food.

What You Can Do

To meet this GMP requirement for aflatoxin and other toxins you need to:

Determine

Determine which raw food or ingredients that you handle may be susceptible to contamination with aflatoxin or other natural toxins.

Communicate

Communicate with your suppliers to make sure that they understand what practices are expected and the guarantees needed to meet this GMP requirement.

Test and Resolve Problems

It may be prudent to conduct periodic tests of raw foods and ingredients to verify that toxins like aflatoxin that may be a concern in your food products are not present at unacceptable levels. If problems are detected it may be necessary to work with suppliers and conduct additional tests until acceptable practices are implemented to correct the problem.

Monitor

Monitor your suppliers and any products that might be susceptible to contamination by aflatoxin or marine toxins to make sure that necessary guarantees have been provided and all necessary steps have been taken to minimize contamination.

How to Monitor

Individuals who are responsible for receiving products should monitor where the products are coming from and determine if your firm has approved this supplier or if the appropriate guarantees or certificates have been provided. Samples should be taken as necessary for testing to verify that acceptable preventative practices are being followed. Supplier guarantees or certificates should be kept on file. Although the current GMP does not require monitoring records, you may want to keep a record of the results of your observations for your own use. If products are rejected or discarded those actions should also be noted on a record.

GMP Requirement - §117.80(b)(4)

Raw materials, other ingredients and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material **must comply with applicable Food and Drug Administration regulations for natural or unavoidable defects** if a manufacturer wishes to use the materials in manufacturing food.

GMP Requirement - §117.80(b)(5)

Raw materials, other ingredients, and rework, must be held in bulk, or in containers designed and constructed so as **to protect against allergen cross-contact and against contamination and must be held at such temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated.** Material scheduled for rework shall be identified as such.

GMP Requirement - §117.80(b)(7)

Liquid or dry raw materials and other ingredients received and stored in bulk form **must be held in a manner that protects against allergen cross-contact and against contamination.**

What You Can Do

To comply with the GMP requirement for proper food and ingredient storage you need to:

Determine

Determine what conditions are required to properly store all of the raw food and ingredients that you receive, store and process.

Label

Label food or ingredients that will be reworked or reprocessed, and separate and store them properly.

Monitor Storage Conditions

Monitor storage conditions to make sure that all perishable foods are stored in containers or storage units at the proper temperature, and that dried foods are stored at the proper humidity. Assign responsibility for the routine monitoring of food storage conditions.

How to Monitor

A manager or supervisor will check all food storage areas at least once per day to determine that all food, ingredients and rework is properly labeled and stored. Although the current GMP does not require monitoring records, you may want to keep a record of the results of your observations for your own use. If corrections are necessary to fix problems, those actions should also be noted on a written record.

GMP Requirement - §117.80(b)(6)

Frozen raw materials and other ingredients must be kept frozen. If thawing is required prior to use, it must be done in a manner that prevents the raw materials and other ingredients from becoming adulterated.

What You Can Do

To meet the GMP requirement for storing and thawing frozen foods properly you need to:

Inspect

Inspect all frozen food when it is received to make sure that it is frozen. Frozen products should not show signs of unintentional thawing and refreezing.

Store

Store frozen food in a freezer that will keep it frozen.

Monitor Frozen Storage Conditions

Monitor frozen storage conditions to make sure that all food is protected from contamination and kept at the proper temperature.

Develop Procedures to Thaw

Develop procedures to thaw frozen foods properly to prevent the growth of harmful microorganisms.

Monitor

Monitor thawing procedures, and make sure that foods are not contaminated during thawing.

How to Monitor

Assign responsibility for inspecting frozen foods when they are received and for routinely monitoring frozen storage equipment and temperatures. Monitor thawing to ensure that proper procedures are used and food temperature does not exceed suggested limits to prevent the growth of harmful bacteria or other microorganisms. Although the current GMP does not require monitoring records, you may want to keep a record of the results of your observations for your own use. If any corrections are necessary to fix problems, those actions should also be noted on a written record.

GMP Requirement - §117.80(b)(8)

Raw materials and other ingredients that are food allergens, and rework that contains food allergens must be identified and held in a manner that prevents allergen cross-contact.

What You Can Do

To meet the general GMP requirements for raw materials and ingredients to identify food allergens and prevent allergen cross-contact you need to:

Determine

Determine which raw materials or ingredients are a food allergen or contain a food allergen, and make sure that they are labeled to identify them as a food allergen at receipt and during manufacturing, processing, packing and holding.

Develop Procedures to Prevent Allergen Cross-contact

Develop procedures to prevent allergen cross-contact for raw materials and ingredients. These procedures could include moving and storing allergenic foods in sealed containers, having dedicated equipment, containers and utensils, separating processing operations by location or time, and using adequate cleaning and sanitizing procedures at the proper time.

Train employees

Train employees to ensure that they understand which raw materials or ingredients are or contain a food allergen. Train employees to ensure that they understand what procedures must be followed to prevent allergen cross-contact.

Monitor the Receipt of Raw Materials and Ingredients

Monitor the receipt of raw materials and ingredients to be sure that allergens are properly identified and labeled. Correct mistakes as they are identified.

Monitor the Procedures

Monitor the procedures that are used to prevent allergen cross-contact during manufacturing, processing, packing and holding operations. Correct mistakes at the time that they are identified.

How to Monitor

Individuals who are responsible for receiving products should identify which products are food allergens and that they are properly labeled. Supervisors should monitor all areas of the plant where allergenic foods are stored, handled or processed to ensure that they are properly identified. Supervisors should also monitor the processing or packing of allergenic foods to ensure that proper procedures are followed to prevent allergen cross-contact. Although the current GMP does not require monitoring records, you may want to keep a record of the results of your observations for your own use. If products are rejected or discarded, those actions should also be noted on the record. Monitoring records for any pasteurization procedure should be kept on an appropriate processing record.

Module 10: Manufacturing Operations: Process Controls

GMP Requirement - §117.80(c)(1)

Equipment and utensils and food containers must be maintained in an adequate condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment must be taken apart for thorough cleaning.

GMP Requirement - §117.80(c)(7)

Equipment, containers, and utensils used to convey, hold, or store raw materials and other ingredients, work-in-process, rework or other food **must be constructed, handled and maintained in a manner that protects against allergen cross-contact and against contamination.**

What You Can Do

To meet the GMP requirement for the proper construction, maintenance and sanitation of equipment, containers and utensils used for food, ingredients, work-in-process, or rework in your manufacturing operations you need to:

Develop and Implement Procedures

Develop and implement procedures to prevent food products from being contaminated by equipment, utensils and containers. These procedures should include how and when these items will be cleaned and sanitized between uses, color-coding strategies, or other steps to prevent cooked or ready-to-eat foods from being contaminated by raw food, ingredients or other contamination sources and to prevent allergen crosscontact.

Train Employees

Train employees to make sure that they understand cleaning, sanitation, color-coding and other procedures for equipment, utensils and containers.

Routinely Monitor How Equipment, Utensils and Containers are Used

Routinely monitor how equipment, utensils and containers are used to make sure that proper practices to prevent contamination and allergen crosscontact are followed and mistakes are immediately corrected.

How to Monitor

Supervisors should be assigned responsibility to routinely monitor how equipment, containers and utensils are used to ensure that all reasonable precautions to prevent cross-contamination and allergen cross-contact are taken. Although the current GMP does not require monitoring records, you may want to keep a record of the results of your observations for your own use. If any corrections are necessary to fix problems, those actions should also be noted on a written record.

GMP Requirement - §117.80(c)(2)

All food manufacturing, processing, packing and holding must be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, allergen cross-contact, contamination of food, and deterioration of food.

GMP Requirement - §117.80(c)(3)

Food that can support the rapid growth of undesirable microorganisms must be held at temperatures that will prevent the food from becoming adulterated during manufacturing, processing, packing and holding.

GMP Requirement - §117.80(c)(5)

Work-in-process and rework must be handled in a manner that protects against allergen cross-contact, contamination, and growth of undesirable microorganisms.

What You Can Do

To comply with the three GMP requirements that require food processors to have controls in place to prevent microbial growth and allergen cross-contact for food, ingredients, work-in-process, and rework during manufacturing operations you need to:

Determine

Determine the factors that could affect the growth of microorganisms in all food products, ingredients, work-in-process and rework.

Develop

Develop procedures to control the conditions that are necessary to prevent or minimize the potential for the growth of microorganisms in all food, ingredients, work-in-process and rework. These procedures must make sure that target levels for temperature, time, pH, or water activity (a_w) are consistently maintained during manufacturing, processing, packing or holding.

Identify

Identify all food products or ingredients that contain allergens and develop manufacturing, processing, packing and holding procedures to prevent allergen cross-contact.

Monitor

Monitor the conditions at key steps in the manufacturing process that are necessary to reach target levels for the conditions that are necessary to prevent the growth of harmful microorganisms, and to prevent allergen cross-contact.

How to Monitor

Supervisors or other trained individuals should be assigned responsibility for routine monitoring of the conditions and procedures necessary to prevent microbial growth and allergen cross-contact during manufacturing, processing, packing and holding operations. Key processing steps may need to be monitored to ensure that the conditions necessary to prevent or minimize microbial growth or to prevent allergen cross-contact have been maintained during manufacturing operations. Although the current GMP does not require monitoring records, you may want to keep a record of the results of your observations for your own use. If any corrections are necessary to fix problems, those actions should also be noted on a written record.

GMP Requirement - §117.80(c)(4)

Measures such as sterilizing, irradiating, pasteurizing, cooking, freezing, refrigerating, controlling pH or controlling aw that are taken to destroy or prevent the growth of undesirable microorganisms must be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated.

What You Can Do

To comply with the GMP requirement to have an adequate process in place to destroy undesirable microorganisms or to prevent their growth during manufacturing operations you need to:

Evaluate
Evaluate the processes you use to destroy microorganisms or prevent their growth in the food you manufacture. Determine what factors affect the growth of microorganisms of concern in your products.

Develop
Develop processing procedures to control physical factors that destroy, prevent, or minimize the potential for the growth of microorganisms. These procedures must make sure that target levels for temperature and time, pH, or aw are consistently reached in the manufacturing process.

Establish a Validated Process When Necessary
Establish a validated process when necessary with a food safety expert that describes the conditions, such as minimum or maximum time and temperature limits, water activity, pH, or salt levels, necessary for you unique food product and process.

Monitor
Monitor the steps in the process that are necessary to reach target levels for one or more of the factors identified in the validated process.

How to Monitor

Supervisors or other trained individuals should be assigned responsibility for routine monitoring of each specific manufacturing process. Specific processing steps will need to be monitored to ensure that the basic conditions determined in a validated study have been achieved to destroy or prevent the growth of microorganisms. Although the current GMP does not require monitoring records, you may want to keep a record of the results of your observations for your own use. If any corrections are necessary to fix problems, those actions should also be noted on an appropriate written record.

GMP Requirement - §117.80(c)(6)

Effective measures must be taken to protect finished food from allergen cross-contact and from contamination by raw materials, other ingredients, or refuse. When raw materials, other ingredients or refuse are unprotected, they shall not be handled simultaneously in a receiving, loading or shipping area if that handling could result in allergen cross-contact or contaminated food. Food transported by conveyor must be protected against allergen crosscontact and against contamination as necessary.

What You Can Do

To meet the GMP requirement to protect finished food products from crosscontamination and allergen cross-contact by raw material, ingredients, refuse, or the plant environment you need to:

Develop and Implement Procedures that Prevent Direct Cross-contamination
Develop and implement procedures that prevent direct cross-contamination of finished, cooked, or ready-to-eat food products by raw products, garbage, equipment, utensils, containers, conveyors, and employees.

Develop and Implement Procedures that Prevent Allergen Cross-contact
Develop and implement procedures that prevent allergen cross-contact between food or ingredients, equipment, utensils and food packaging materials that contain food allergens and food, ingredients, equipment, utensils and food packaging materials that do not contain allergens.

Develop and Implement Procedures to Minimize the Spread of Contamination

Develop and implement procedures to minimize the spread of contamination or prevent allergen cross-contact when people, equipment and utensils move from one area of the plant to another. These procedures could include hand washing, changing outer garment and gloves, foam barriers for footwear and wheels of equipment, cleaning and sanitation of equipment prior to movement, and other strategies.

Train Employees

Train employees to make sure that they understand company procedures that must be followed to prevent cross-contamination and allergen cross-contact.

Routinely Monitor Plant Conditions

Routinely monitor plant conditions and activities to identify when conditions develop that could lead to contamination and to make sure that they are immediately corrected.

How to Monitor

Supervisors should routinely monitor all areas where food is manufactured, processed, packed or held to ensure that all reasonable precautions to prevent crosscontamination are taken. Although the current GMP does not require monitoring records, you may want to keep a record of the results of your observations for your own use. If any corrections are necessary to fix problems, those actions should also be noted on a written record.

GMP Requirement - §117.80(c)(8)

Adequate measures must be taken to protect against the inclusion of metal or other extraneous material in food.

What You Can Do

To meet the requirements of the GMP regulation to prevent food from being contaminated with metal or similar extraneous objects you need to:

Evaluate All of the Food and Ingredients

Evaluate all of the food and ingredients that you handle and determine if any of them are likely to be contaminated with metal or other extraneous material.

Evaluate Your Processing Operation

Evaluate your processing operation and determine if any of the processing activities or equipment used is likely to contaminate food or ingredients with metal or other extraneous material.

Implement Procedures

Implement procedures to either remove metal, use a metal detector, or use another appropriate detection device to screen any ingredients or finished food products that your evaluation has determined could be subject to contamination with metal or other extraneous material.

Routinely Monitor

Routinely monitor the operation of metal detectors or other detection systems to assure they are in proper working condition and calibrated. Removal devices such as screens or sieves should be maintained to prevent metal contamination.

How to Monitor

Managers or supervisors should evaluate all sources of food and ingredients and all processing steps of their operation to determine if contamination with metal or other extraneous material is likely. If detection or removal systems are necessary, supervisors should monitor their operation daily to make sure that they are operating properly. Although the current GMP does not require monitoring records, you may want to keep a record of the results of your observations for your own use. If actions are taken to correct problems, these actions should also be included in a written record.

GMP Requirement - §117.80(c)(10)

Steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming must be performed so as to protect food against allergen cross-contact and against contamination. Food must be protected from contaminants that may drip, drain, or be drawn into the food.

What You Can Do

To meet the GMP requirement to protect food from contamination during mechanical manufacturing steps you need to:

Evaluate Each Step of Your Operation

Evaluate each step of your operation where food is processed, and make sure that all food and food-contact surfaces used at that step are protected from contamination.

Develop Preventive Procedures

Develop preventive procedures and a schedule for activities like cleaning and sanitizing to prevent food contamination at all processing steps.

Train Employees

Train employees to make sure that they understand what must be done at the manufacturing steps that they are involved in to prevent food contamination.

Routinely Monitor Activities at Each Processing Step

Routinely monitor activities at each processing step to make sure that proper practices are followed and mistakes are immediately corrected.

How to Monitor

Supervisors should routinely monitor every processing step and all of the necessary cleaning and sanitizing activities to make sure that food and food-contact surfaces are protected from contamination. Although the current GMP does not require monitoring records, you may want to keep a record of the results of your observations for your own use. If any corrections are necessary to correct problems, those actions should also be noted on a written record.

GMP Requirement - §117.80(c)(11)

Heat blanching, when required in the preparation of food capable of supporting microbial growth, must be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent manufacturing without delay. Growth and contamination by thermophilic microorganisms must be minimized by the use of adequate operating temperatures and by periodic cleaning and sanitizing as necessary.

What You Can Do

To meet the GMP requirement for blanching you need to:

Develop

Develop a procedure that specifies the minimum temperature and time for blanching and how all food products will be rapidly chilled after blanching to prevent the growth of harmful bacteria or other microorganisms

Maintain, Clean, and Sanitize

Maintain, clean, and sanitize blanching equipment.

Use Water

Use water that is safe and sanitary (potable).

Monitor

Monitor the blanching process to determine that the proper temperature was reached, held for the proper amount of time, and then cooled to the target temperature within the required amount of time.

How to Monitor

The temperature and time of the blanching and cooling process should be routinely checked throughout the day or as necessary. Cleaning and sanitizing procedures for blanching equipment should also be monitored and checked as necessary. Although the current GMP does not require monitoring records, you may want to keep a record of the results of your observations for your own use. Monitoring observations for the cleaning and sanitizing equipment should be included in the sanitation record. If corrections are needed to fix problems, those actions should be noted on a written record.

GMP Requirement - §117.80(c)(12)

Batters, breading, sauces, gravies, dressings, dipping solutions and other similar preparations that are held and used repeatedly over time must be treated or maintained in such a manner that they are protected against allergen cross-contact and against contamination, and minimizing the potential for the growth of undesirable microorganisms.

What You Can Do

If you use or produce batters, breading, sauces, gravies, or dressing, to comply with this GMP requirement you need to:

Develop and Implement Controls

Develop and implement controls to prevent these foods from being contaminated and to prevent the growth of harmful bacteria like Staph during processing and storage. Time and temperature controls should minimize the amount of time that these foods are exposed to temperatures above 50°F (10°C).

Establish a Validated Process

Establish a validated process based on a scientific study by a food safety expert, if heat is used to kill harmful bacteria like Staph. The process controls developed by the study should comply with USDA guidance for meat and poultry products or FDA guidance for seafood products.

Discard

Discard any product that is exposed to unacceptable conditions.

Monitor

Monitor all manufacturing or storage steps for these foods to make sure that time and temperature control limits established in the validation study are met.

How to Monitor

Production employees should be trained to monitor the process to make sure that time and temperature limits are not exceeded or that target levels identified in your validated process are reached. Supervisors should routinely check these monitoring results to make sure that the proper conditions have been met before product is released into the marketplace. Supervisors should also monitor conditions to make sure that workers or the plant environment do not contaminate these foods. Although the current GMP does not require monitoring records, you may want to keep a record of the results of your observations for your own use. If corrections are needed to correct problems, those actions should also be noted on a written record.

GMP Requirement - §117.80(c)(13)

Filling, assembling, packaging and other operations must be performed in a way that food is protected from allergen crosscontact, contamination and growth of undesirable microorganisms.

What You Can Do

To meet GMP requirements to prevent contamination during filling, assembling, and packaging you need to:

Evaluate the Containers and Food Packaging Materials

Evaluate the containers and food packaging materials that you use to determine that they are safe and suitable for your food products.

Identify those Places in Your Finished Product Packaging Operation

Identify those places in your finished product packaging operation where food, containers, or packaging materials may be susceptible to airborne or other contamination.

Implement Procedures to Prevent Contamination and Food Allergen Cross-contact

Implement procedures to prevent contamination and food allergen cross-contact and to clean and sanitize packaging equipment, containers or areas to prevent food contamination.

Routinely Monitor Packaging Activities

Routinely monitor packaging activities to make sure that proper practices are followed and mistakes are immediately corrected.

How to Monitor

Supervisors should routinely monitor the area where finished food products are filled or packaged to make sure that food and packaging materials are protected from contamination. Cleaning and sanitizing activities should also be monitored to make sure that food and food-contact surfaces are protected from contamination. Although the current GMP does not require monitoring records, you may want to keep a record of the results of your observations for your own use. If any corrections are necessary to correct problems, those actions should also be noted in a written record.

GMP Requirement - §117.80(c)(14)

Food such as dry mixes, nuts, intermediate moisture food, and dehydrated food, **that relies on the control of water activity (a_w) for preventing the growth of undesirable microorganisms must be processed to and maintained at a safe moisture level.**

What You Can Do

If you use or produce dry, dehydrated or semi-moist foods that depend on the control of water activity to maintain safety, to comply with this GMP requirement you need to:

Evaluate Dry Foods

Evaluate dry foods when they are received to determine that they are packaged correctly and/or have been produced and shipped in a way that has not allowed them to absorb enough moisture to enable harmful bacteria or other microorganisms to grow.

Store

Store acceptable food and ingredients in packages, or containers that will prevent them from absorbing moisture during storage.

Package

Package finished food products as necessary to maintain the proper water activity.

Establish a Validated Process

Establish a validated process if you manufacture or produce dry, dehydrated or semi-moist foods that rely on a low water activity to prevent the growth of bacteria or other microorganisms that could cause foodborne illness. This can be done by having a validation study done by a food safety expert.

Monitor

Monitor the processing variables for each batch to determine that they have reached the target levels identified in your validated process. These variables may include conditions such as air temperature, air flow, humidity, and time. Alternatively, processors could control the soluble solids to water ratio in the finished product.

How to Monitor

Production employees should be trained to monitor the steps in your process that are necessary to make sure all products meet the target levels identified in your validation study. This could include monitoring the conditions established in your validated process for each batch of product that is produced or monitor periodically in a continuous operation. Supervisors should routinely check these monitoring results to make sure that critical conditions have been met before product is released into the marketplace. Although the current GMP does not require monitoring records, you may want to keep a record of the results of your observations for your own use. If corrections are needed to fix problems or products need to be re-processed, these actions should also be noted on a written record.

GMP Requirement - §117.80(c)(15)

Food, such as, **acid and acidified food,** that relies principally on the control of pH for preventing the growth of undesirable microorganisms **must be monitored and maintained at a pH of 4.6 or below.**

What You Can Do

To comply with the GMP requirements for acid or acidified foods you need to:

Determine

Determine which foods or ingredients, if any, that you receive, store or process depend on the control of acidity or pH to ensure safety.

Establish a Validated Process

Establish a validated process if you manufacture or produce acidified, pickled, or fermented foods that rely on a pH of 4.6 or below to prevent the growth of bacteria or other microorganisms that could cause foodborne illness. A validation study must be conducted by a food safety expert to determine the processing variables necessary to reach the target pH. These variables include the type, amount and concentration of the acid ingredient to be added to a pre-determined amount of product of the appropriate thickness or size, and the amount of time and temperature needed to reach a pH of 4.6 or below in the finished product.

Monitor

Monitor each of the variables identified in the validation study for each batch. Alternatively, the pH of each batch of food produced could be directly measured using a standard procedure.

How to Monitor

Production employees should be trained to monitor the process to ensure that they meet target levels identified in your validation study for each batch or periodically as necessary in a continuous operation. Supervisors should routinely check these monitoring results to make sure that critical conditions have been met before product is released into the marketplace. Although the current GMP does not require monitoring records, you may want to keep a record of the results of your observations for your own use. If corrections are needed to fix problems or products need to be re-processed, those actions should also be noted on a written record.

GMP Requirement - §117.80(c)(16)

When ice is used in contact with food, it **must be made from water that is safe** and of adequate sanitary quality in accordance with §117.37(a), and **must be used only if it has been manufactured in accordance with current good manufacturing practices** as outlined in this part.

What You Can Do

To comply with the GMP requirement for the proper use of ice you need to:

Select

Select ice making equipment that is designed to be easily cleaned and sanitized.

Connect

Connect ice making equipment to the potable water supply with appropriate backflow prevention devices

Maintain

Maintain all ice making equipment and equipment or utensils used to store, transfer, or transport ice in a clean and sanitary condition.

Discard

Discard ice that has been exposed to contamination from raw food products, the plant environment, or employees.

Monitor

Monitor ice making equipment routinely to make sure that it is installed and operating properly and is clean and sanitized.

How to Monitor

The condition and cleanliness of ice makers and equipment used to store or transport ice should be routinely monitored. Although the current GMP does not require monitoring records, you may want to keep a record of the results of your observations for your own use. If corrections are necessary to fix problems, those actions should also be noted on a written record.

Module 11: Warehousing, Food Disposition & Defects

GMP Requirement §117.80(c)(9)

Food, raw materials, and other ingredients that are adulterated:

(i) Must be disposed of in a manner that protects against the contamination of other food; or

(ii) If the adulterated food is capable of being reconditioned, it must be:

(A) Reconditioned (if appropriate) using a method that has proven to be effective; or

(B) Reconditioned (if appropriate) and reexamined and subsequently found not to be adulterated within the meaning of the Federal Food, Drug and Cosmetic Act before being incorporated into other food.

What You Can Do

To meet the GMP requirements for proper disposal or reconditioning of contaminated food you need to:

Develop an Evaluation Plan

Develop an evaluation plan that describes how your company will determine if food has been adulterated, and how you will determine whether it must be disposed of or can be reconditioned. This plan should be based on current federal, state or local regulations and include procedures for contacting regulatory agencies if necessary

Develop a Disposal Plan

Develop a disposal plan that describes how adulterated food will be disposed of properly.

Develop a Reconditioning Plan

Develop a reconditioning plan consistent with current regulations that describes how adulterated food that meets pre-determined conditions will be reconditioned or diverted to acceptable non-food or non-feed uses.

Monitor and Keep Records

Monitor and keep records of evaluation results and the final disposition of all food that was disposed or reconditioned.

How to Monitor

Assign the responsibility for evaluating contaminated food and determining its final disposition to one or more individuals who have the skills and experience necessary to make sure that adulterated food is not sold or distributed. Supervisors should monitor and keep records that document that adulterated products were properly disposed, reconditioned, or diverted to a non-food or non-feed use that is consistent with all regulatory requirements. Although the current GMP does not require monitoring records, you may want to keep a record of the results of your observations for your own use.

GMP Requirement - §117.93

Storage and transportation of food must be under conditions that will protect against allergen cross-contact and against biological, chemical (including radiological) and physical, contamination of food as well as against deterioration of the food and the container.

What You Can Do

To meet the GMP requirements for warehousing and distribution and the proper storage and transportation of finished food products you need to:

Identify What Reasonable Precautions are Needed

Identify what reasonable precautions are needed to protect food from contamination and to prevent spoilage at those steps in your operation where food is stored or transported.

Use the Proper Equipment and Implement Procedures

Use the proper equipment and implement procedures to protect food from contamination and make sure that proper conditions are maintained to prevent food spoilage or deterioration during storage and transportation.

Monitor Storage and Transportation Conditions

Monitor storage and transportation conditions to make sure that food is protected from contamination and the proper conditions to prevent deterioration are maintained.

How to Monitor

Supervisors or managers should routinely monitor all storage areas to make sure that food is protected from contamination and stored properly to prevent deterioration. Supervisors and drivers should routinely monitor transportation conditions to make sure that food is protected from contamination and that proper conditions are maintained to protect food from deterioration. Although the current GMP does not require monitoring records, you may want to keep a record of the results of your observations for your own use. If actions are taken to correct problems, these actions should also be included in a written record.

GMP Requirement §117.95(a)

Human food by-products held for distribution as animal food without additional manufacturing or processing by the human food processor, as identified in §507.12 of this chapter, must be held under conditions that will protect against contamination, including the following:

(1) **Containers and equipment used to convey or hold** human food by-products for use as animal food before distribution **must be designed, constructed of appropriate material, cleaned as necessary, and maintained** to protect against the contamination of human food by-products for use as animal food.

(2) Human food by-products for use as animal food held for distribution **must be held in a way to protect against contamination from sources such as trash.**

(3) **During holding,** human food by-products for use as animal food **must be accurately identified.**

GMP Requirement §117.95(b)

Labeling that identifies the by-product by the common or usual name must be affixed to or accompany food products for use as animal food when distributed.

GMP Requirement §117.95(c)

Shipping containers (e.g., totes, drums and tubs) and bulk vehicles used to distribute human food by-products for use as animal food **must be examined prior to use** to protect against contamination of the human food by-products from the container or vehicle when the facility is responsible for transporting the human food by-products itself or arranges with a third party to transport the by-products.

What You Can Do

To meet the GMP requirements for holding and distributing human food by-products for use as animal food you need to:

Identify What Human Food By-products Will be Held and Distributed for Use as Animal Food

Identify what human food by-products will be held and distributed for use as animal food and develop procedures to use appropriate containers and equipment for these by-products and store them properly.

Develop and Implement Procedures

Develop and implement procedures to ensure that all human food byproducts that will be used for animal food are properly labeled.

Develop and Implement Procedures to Examine Any Shipping Containers

Develop and implement procedures to examine any shipping containers or bulk vessels that will be used to transport human food products for use as animal foods prior to their use.

Monitor

Monitor the condition of equipment, containers, labeling procedures and procedures to examine bulk shipping containers prior to use to ensure that the proper conditions to prevent contamination are maintained.

How to Monitor

Supervisors or managers should routinely monitor the diversion of any human food byproducts that will be used for animal food. Appropriate equipment, containers and bulk shipping containers should be examined to ensure that they are appropriate for storage or distribution of by-products. Monitoring should also ensure that all by-products are appropriately labeled. Although the current GMP does not require monitoring records, you may want to keep a record of the results of your observations for your own use. If actions are taken to correct problems, these actions should also be included in a written record.

GMP Requirement - §117.110(a)

The manufacturer, processor, packer and holder of food must at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible.

GMP Requirement - §117.110(b)

The mixing of a food containing defects that render that food adulterated with another lot of food is not permitted and renders the final food adulterated, regardless of the defect level of the final food. For examples of defect action levels that may render food adulterated, see the Defect Levels Handbook at www.fda.gov/pchfrule and at www.fda.gov

What You Can Do

To comply with the GMP requirement for unavoidable defects in food you need to:

Determine

Determine if there are any defect action levels for the food or ingredients that you manufacture, process, pack or hold.

Communicate

Communicate the defect action levels that must not be exceeded to your suppliers to make sure that they are aware of them and they meet these standards.

Evaluate

Evaluate all food and ingredients when they are received to be sure that defect action levels are not exceeded. Company procedures should be developed to describe visual inspection or testing procedures.

Test and Resolve Problems

Food or ingredients that need further evaluation should be separated until test results confirm that it is acceptable for use. Unacceptable products must be rejected, returned to suppliers, or properly discarded.

Monitor

Monitor your suppliers and the food or ingredients that you receive to make sure that all necessary steps have been taken to meet any applicable defect action levels.

How to Monitor

The receiving manager should check each shipment of raw food or ingredients to determine that it is from a company recognized supplier. Inspect raw material or ingredients visually or by testing if necessary using an appropriate sampling plan to determine that acceptable defect levels are not likely to have been exceeded. Recognized supplier lists should be kept on file. Although the current GMP does not require monitoring records, you may want to keep a record of the results of your observations for your own use. If products are rejected or discarded those actions should be noted on a record.