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Series

Good Manufacturing Practices (GMP) Audit Standard

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INTRODUCTION

This document is designed to give guidance to Specialty Crops Inspection Division personnel of the United States Department of Agriculture (USDA).

Compliance with the Agricultural Marketing Service (AMS) guidelines does not excuse failure to comply with the Food, Drug, and Cosmetic Act or any other applicable Federal or State laws or regulations. SCI Division of the Specialty Crops Programs (SC), AMS is responsible for grading/inspecting, audits and standardization programs of fresh and/or processed fruits and vegetables and related products. The legal authority for grading, auditing and standardization activities are the Agricultural Marketing Acts of 1936 and 1946, as amended.

Applicants may obtain inspections and audits of any fresh and/or processed fruit and vegetable and related products for which they have a financial interest. The inspection service is voluntary and self-supporting, and is offered on a fee-for-service basis.

GUIDE FOR ELECTRONIC USAGE

The AIM system of instructional manuals is available electronically in Adobe Acrobat Portable Document Format (PDF) at the following intranet address:

<https://usdagcc.sharepoint.com/sites/ams/AMS-SCI/SitePages/Home.aspx>.

When accessed electronically, AIM materials have hyperlinks and hypertext (visible as underlined [blue text](#)) available to the PDF user. Clicking on a hyperlink takes the reader to a web site with information relating to the subject. Hypertext links the reader to a different page within the current manual, or a different manual, with information relating to the subject. For example, the hypertext in the Table of Contents allows a reader to go directly to the section of interest in the manual by clicking on the section title.

PDF offers a variety of tools depending on the Adobe version the reader has. The newer the version, the more tools available. PDF documents are easily searchable for content within a document or within multiple documents. To learn about the variety of PDF search options:

- Click on the “Help” tab on the top of any page in Adobe Acrobat,
- Then click on the “Adobe Acrobat Help” bar,
- Type the word “Search” in the “Search” box, and click on the “Search” button,
- A series of options will become available,
- Click on the “Access Search Features” link and follow the instructions for the type of search you are interested in.

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HOW TO USE THIS STANDARD

The GMP Audit Standard is intended to be used as the core element of a Plant Systems Audit (PSA) Program audit. The standard includes the requirements of the [Current GMP regulation 21 CFR 117](#), other requirements such as the [Bioterrorism Act of 2002](#), and expectations of the [Global Food Safety Initiative \(GFSI\) Technical Equivalence Requirements Part III CII – Section 3: Good Industry Practice Requirements](#).

This issue of the United States Department of Agriculture’s GMP Audit Standard, along with the other standards and manuals still in development, supersede the previous materials describing the Plant Systems Audit Program.

The standard includes the following columns:

- Requirement – a statement of the expectation for compliance to the audit standard.
- Reference – the text from the cited source of the requirement.
- Citation – the location of the cited source within the referenced document.
- Auditor Guidance – a brief description of how the auditor will find evidence to verify compliance. Additional guidance is in the PSA Program Auditor Manual.
- Documentation – an indication of the required type of documentation.
 - Policy – This indicates a need for a documented policy (high-level guidance that describes general goals and acceptable procedures) or procedure (specified way to carry out an activity or process). This documentation should also identify the established forms that will be used to show implementation.
 - Record - a document stating results achieved or providing evidence of activities performed. Examples of records include checklists, bills of lading, process charts, certificates of assurance, and analytical test results.

For instructions on its use, including the associated checklist and the rating system used for the audit outcome, please see the PSA Program Auditor Manual. Additional information on the Program can be found on the AMS website at <https://www.ams.usda.gov/services/auditing/plant-audits>.

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GOOD MANUFACTURING PRACTICES AUDIT STANDARD

1.1 Regulatory

Req. No.	Requirement	Reference	Citation	Auditor Guidance	Documentation
1.1.1	The facility shall have a Food and Drug Administration (FDA) registration number.	The Food and Drug Administration (FDA) requires domestic and foreign facilities that manufacture/process, pack, or hold food for human or animal consumption in the United States to register with FDA.	Bioterrorism Act of 2002	Request to see a copy of the facility’s registration with FDA. This is renewed every other year. Verify location information is correct and registration is current. Do not document the facility number in your audit/notes. Record the expiration date.	Record
1.1.2	The facility must establish a documented traceability system which enables identification of food which is received and to where it is eventually shipped, either in its original state or as part of a finished product.	People who “manufacture, process, pack, transport, distribute, receive, hold, or import food” in the United States, as well as foreign food transporters in the United States, are required to maintain records to identify the previous sources and subsequent recipients of the food. Exclusions include: farms, restaurants, food processed for personal consumption, and outer food packaging. Direct to consumer distributors are not required to keep records of the people to whom they sell. Food transfers within a company are not subject to recordkeeping. Also excluded are food samples used for quality assurance, research or analysis purposes that are not consumed. Required records for food received and released must include: previous/subsequent source (including full contact details), description of food (brand name and	Bioterrorism Act of 2002	Verify that there is a documented traceability program and review practices for effectiveness. Are records established showing previous sources and subsequent receivers of food? Do the records include previous/subsequent source (including full contact details), description of food (brand name and variety), date received/released, lot or code number (if relevant), quantity and packaging?	Policy, Record

Req. No.	Requirement	Reference	Citation	Auditor Guidance	Documentation
		<p>variety), date received/released, lot or code number (if relevant), quantity and packaging. When food is released, records additionally must include information "reasonably available" identifying specific sources of each ingredient to each lot of finished product. In cases where food processors commingle ingredients such as flour from different suppliers, FDA accepts that manufacturers may not be able to identify 1 specific source.</p> <p>Records must be retained for 6 mo to 2 y depending on food type.</p> <p>Any person engaged in the business of supplying a covered commodity to a retailer, directly or indirectly, must maintain records to establish and identify the immediate previous source (if applicable) and immediate subsequent recipient of the product.</p> <p>Such records must identify the product unique to that transaction by means of a lot number or other unique identifier, for a period of 1 year from the date of the transaction.</p>			
1.1.3	The operation has performed a "mock recall" that was proven to be effective. This exercise must be performed at least annually.			Ask to see the record of a mock recall performed in the last 12 months.	Record

1.2 Food Safety Plan

Req. No.	Requirement	Reference	Citation	Auditor Guidance	Documentation
1.2.1	<p>The facility must have a food safety plan which is documented and implemented.</p> <p>The plan must include, at a minimum, all documented policies and procedures identified as requirements in this audit standard, in addition to any regulatory requirements.</p>			<p>Verify that a policy has been developed and implemented. Confirm employee understanding via interview.</p>	Policy
1.2.2	<p>Implementation and oversight of the food safety plan must be under the supervision of one or more competent individuals assigned responsibility for this function.</p>			<p>Verify that responsibility for the management of the food safety plan is assigned to someone who has had appropriate food safety training and/or knowledge based on work experience.</p>	Policy
1.2.3	<p>The facility must document, implement, and record daily, weekly, and/or monthly site inspections as necessary to verify implementation of their food safety plan controls and policies associated with housekeeping, cleaning and sanitation, and maintenance.</p>	<p><i>A programme of site inspections / checks shall be established, implemented and maintained to ensure the site environment and processing equipment are maintained in a suitable condition to ensure food safety, as applicable to the activity of the site.</i></p>	<p><i>GFSI, GMP 10</i></p>	<p>Identify the daily, weekly, and monthly inspections that have been established and review the recent records of the inspections.</p>	Policy, Record

1.3 Personnel Qualifications and Training

Req. No.	Requirement	Reference	Citation	Auditor Guidance	Documentation
1.3.1	<p>All personnel who manufacture, process, pack, or hold food must be qualified to perform their assigned duties.</p> <p>Qualifications must be documented.</p>	<p>The management of an establishment must ensure that all individuals who manufacture, process, pack, or hold food are qualified to perform their assigned duties. Each individual engaged in manufacturing, processing, packing, or holding food (including temporary and seasonal personnel) or in the supervision thereof must:</p>	<p>21 CFR 117.4 (a) and (b)</p>	<p>Ask to see job descriptions and qualifications for specific jobs in the facility (A quality control technician job will require different qualifications than a maintenance technician job). Verify that appropriate food safety training requirements are indicated.</p>	<p>Policy, Record</p>
1.3.1.1	<p>Each individual must be, or be under the supervision of, a qualified individual.</p>	<p>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</p>	<p>(1)</p>	<p>Review the personnel who are designated as supervisors. Ask employees who their supervisors are. In 1.3.2, you will verify the training and qualifications of the supervisors. If someone isn’t being directly supervised, see if their training and qualifications would establish them as a qualified individual.</p>	<p>Record</p>
1.3.1.2	<p>Each individual must receive training on the principles of food hygiene and food safety, as appropriate to their role and responsibilities. Training must be provided when first hired, with a minimum of an annual refreshers.</p>	<p>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.</p>	<p>(2)</p>	<p>Verify that the company has a documented policy for the training of all employees on the principles of food safety, appropriate to their position. Review food safety training records of a random selection of employees, including administrative, management, and processing staff. Record training dates and subject</p>	<p>Policy, Record</p>

Req. No.	Requirement	Reference	Citation	Auditor Guidance	Documentation
				material. Training, at a minimum, should be a new hire/promotion, and as an annual refresher.	
1.3.2	Supervisory personnel must be assigned the responsibility for personnel compliance with food safety and food hygiene policies and procedures, and have the education, training, or experience (or a combination thereof) necessary to supervise the production of clean and safe food.	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.	(c)	Verify education, training, or experience of supervisors' specific job duties by reviewing training records. Ask to see any certificates from courses such as HACCP, SQF, etc.	Record
1.3.3	Records of training must be established and maintained.	Records. Records that document training required by paragraph (b)(2) of this section must be established and maintained.	(d)	Verify that food safety training records are maintained for all employees and that they are available for review.	Record

1.4 Personnel Hygiene

Req. No.	Requirement	Reference	Citation	Auditor Guidance	Documentation
1.4.1	<p>There shall be a documented personnel hygiene policy that is effectively implemented, with all personnel and visitors following the policy.</p> <p>The written policy must include the following elements:</p>	<p>The management of the establishment must take reasonable measures and precautions to ensure the following: Cleanliness. All persons working in direct contact with food, food-contact surfaces, and food-packaging materials must conform to hygienic practices while on duty to the extent necessary to protect against allergen cross-contact and against contamination of food. The methods for maintaining cleanliness include:</p>	<p>21 CFR 117.10 (b)</p>	<p>Verify that the facility has a policy for personnel hygiene, and that both employees and visitors are required to comply with it. Did they communicate the policy to you when you arrive at the plant? This could also be communicated via email prior to the audit.</p>	<p>Policy</p>
1.4.1.1	<p>The basics of personal hygiene</p>	<p>Maintaining a dequate personal cleanliness.</p>	<p>(2)</p>	<p>Note whether the policy includes basics about employee cleanliness. Verify implementation by observation.</p>	
1.4.1.2	<p>Clothing and footwear</p>	<p>Wearing outer garments suitable to the operation in a manner that protects against allergen cross-contact and against the contamination of food, food contact surfaces, or food-packaging materials.</p>	<p>(1)</p>	<p>Is there a policy about changing outer garments when leaving an allergen zone? Observe if employees are following the facility policies to prevent cross contamination. What is the facility policy for footwear? (Plant specific shoes, shoe coverings etc.)</p>	
1.4.1.3	<p>Uniforms (if used) - must include requirements for proper use and maintenance.</p>			<p>If uniforms are used in the facility, verify that there is an established uniform policy. Does it include a provision for cleaning them (professionally laundered or laundered at home)? Good practices include</p>	

Req. No.	Requirement	Reference	Citation	Auditor Guidance	Documentation
				no buttons (snap closure) and no pockets, or nothing kept in pockets, above the waist. Observe if uniforms are clean.	
1.4.1.4	Gloves (if used) - must include a requirement that they be maintained in an intact, clean, and sanitary condition.	Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition.	(5)	If gloves are used in the facility, ensure there is an established policy for how they are used. Observe that employees are changing soiled gloves prior to handling food or touching food contact surfaces. How are gloves stored? Are employees using torn or damaged gloves?	
1.4.1.5	Handwashing (in an adequate handwashing facility) before starting work, after each absence from the workstation, and at any other time when the hands may have become soiled or contaminated.	Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate handwashing facility before starting work, after each absence from the workstation, and at any other time when the hands may have become soiled or contaminated.	(3)	Observe that employees are washing hands starting a shift or returning from a break. Interview employees about handwashing for training retention. (The condition of the handwashing station will be covered at requirement 1.7.5.)	
1.4.1.6	Removal of unsecured jewelry and other objects that might fall into food, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand.	Removing all unsecured jewelry and other objects that might fall into food, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand. If such hand jewelry cannot be removed, it may be covered by material which can be maintained in an intact, clean, and sanitary condition and which effectively protects against the contamination by these objects of the food, food-contact surfaces, or food-packaging materials.	(4)	Are the employees wearing any jewelry which might pose a food safety risk? Are they following the established policy?	

Req. No.	Requirement	Reference	Citation	Auditor Guidance	Documentation
1.4.1.7	Fingernails (absence of polish; neatly trimmed)			Verify by observation that the employees are following the facility's established policy.	
1.4.1.8	Hair restraints	Wearing, where appropriate, in an effective manner, hair nets, headbands, caps, beard covers, or other effective hair restraints.	(6)	Verify by observation that hair restraints are being worn properly, according to the facility's established policy.	
1.4.1.9	Storage of clothing and personal belongings	Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.	(7)	Verify there is an area, located away from where food is exposed, for employees to store their personal items. The policy should indicate requirements for appropriate cell phone usage. Observe if employees are in compliance.	
1.4.1.10	Eating, drinking, and smoking	Confining the following to areas other than where food may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, or using tobacco.	(8)	Verify there is a designated area away from food handling areas, for eating and drinking and that smoking/tobacco/gum use is not permitted where food is exposed. Observe if food or beverages are in areas where food is exposed.	
1.4.1.11	Precautions to protect against allergen cross-contact with respect to personnel hygiene issues.	Taking any other necessary precautions to protect against allergen cross-contact and against contamination of food, food-contact surfaces, or food packaging materials with microorganisms or foreign substances (including perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin).	(9)	Observe employees for personal hygiene issues that could result in allergen cross-contact, such as perspiration, wearing excessive cosmetic materials, hair, tobacco products, chemicals, and medicinal products applied to the skin. Are outer garments (smocks or aprons) being removed before breaks?	

Req. No.	Requirement	Reference	Citation	Auditor Guidance	Documentation
1.4.1.12	Control of blood or bodily fluids. The procedure shall specify the procedures for containment and elimination of blood or bodily fluids, and the cleaning and sanitation of surfaces that are affected.			Review the policy and observe the operation for evidence of compliance. Has training been provided and, if specified in the policy, is there a cleanup kit available?	
1.4.2	<p>There shall be a documented policy for control of employee illness.</p> <p>The written policy shall:</p>	<p>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.</p>	(a)	Verify that a policy has been developed, implemented, and shared with both employees and visitors. Confirm employee understanding via interview.	Policy
1.4.2.1	Include a requirement for employees to inform management if they are sick or have been infected with a food borne illness.			Ask employees about their understanding of the company's policy on working while ill. Do they understand the need to report illness to their supervisor?	
1.4.2.2	Restrict personnel that are ill from production areas until an assessment of illness takes place to determine what tasks they can perform.			Interview a supervisor to find out if they understand the need to prevent employees who are ill from working in the processing area.	

Req. No.	Requirement	Reference	Citation	Auditor Guidance	Documentation
1.4.2.3	Require a dequate covering of such conditions as open lesions, boils, and infected wounds.			Verify by observation that any employees with open lesions, boils or infected wounds are using a dequate coverings to protect and cover the affected areas.	

1.5 Supply Chain

Req. No.	Requirement	Reference	Citation	Auditor Guidance	Documentation
1.5.1	The facility must document and implement procedures for receiving raw materials and other ingredients, ensuring that raw materials and other ingredients meet established food safety requirements.	<i>Appropriate procedures for the reception of purchased materials shall be established, implemented and maintained to assure that only materials that meet food safety requirements are accepted.</i>	<i>GFSI, GMP 14</i>	Verify that a policy has been developed and implemented. Confirm employee understanding via interview.	Policy, Record

1.6 Processes and Controls

Req. No.	Requirement	Reference	Citation	Auditor Guidance	Documentation
1.6.1	General		21 CFR 117.80 (a)		
1.6.1.1	All facility operations must be conducted in accordance with adequate sanitation principles.	All operations in the manufacturing, processing, packing, and holding of food (including operations directed to receiving, inspecting, transporting, and segregating)	(1)	Observe conditions in the facility to verify that the facility has implemented practices for cleaning and	

Req. No.	Requirement	Reference	Citation	Auditor Guidance	Documentation
		must be conducted in accordance with a dequate sanitation principles.		sanitizing (as appropriate) the facility, transportation containers, and equipment.	
1.6.1.2	Quality control measures must be established and implemented to ensure that food and food-packaging materials are safe and suitable for intended use.	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.	(2)	Verify that necessary quality control procedures are in place. Observe that food is inspected prior to use to ensure it is safe for human consumption. Are the packaging materials nontoxic?	
1.6.1.3	Sanitation of the plant must be under the supervision of one or more competent individuals assigned responsibility for this function.	Overall sanitation of the plant must be under the supervision of one or more competent individuals assigned responsibility for this function.	(3)	Interview employees who perform sanitation duties, if they are available at the time of the audit, and ask them to confirm the name of their supervisor. Interview supervisor and ask about their experience and training (if not available, verify by observing established training or certification records).	
	Training received:			Record training of the person responsible for sanitation and pre-op inspections.	Record
1.6.1.4	Adequate precautions must be taken to ensure that production procedures do not contribute to allergen cross-contact and to contamination from any source. If color coding is used to identify equipment for various purposes, the system shall be effectively implemented.	Adequate precautions must be taken to ensure that production procedures do not contribute to allergen cross-contact and to contamination from any source.	(4)	Observe the handling of ingredients and finished products to verify the risk of product contamination. If a color-coding system is implemented, observe whether employees are following the system. Is production scheduled to run allergen products after non-	

Req. No.	Requirement	Reference	Citation	Auditor Guidance	Documentation
				<p>a llergen products? Is there a complete clean-up and sanitation after running a llergen products?</p>	
1.6.1.5	<p>Documented testing procedures shall be used where necessary to identify sanitation failures or possible a llergen cross-contact and food contamination.</p>	<p>Chemical, microbial, or extraneous-material testing procedures must be used where necessary to identify sanitation failures or possible a llergen cross-contact and food contamination.</p>	(5)	<p>Observe if metal detectors (if used) are working properly. Interview employees to verify implementation and corrective actions. If microbial swabbing is used, review records to verify implementation and corrective actions. If the facility uses test kits for a llergens, review those results.</p>	Policy, Record
1.6.1.6	<p>Food that has become contaminated to the extent that it is a adulterated must be rejected, or if appropriate, treated or processed to eliminate the contamination.</p>	<p>All food that has become contaminated to the extent that it is a adulterated must be rejected, or if appropriate, treated or processed to eliminate the contamination.</p>	(6)	<p>Observe if contaminated/adulterated food is clearly identified. Verify that there is a procedure in place if the contaminated food can be reprocessed to eliminate the contamination. Also verify that there is a procedure in place to handle the contaminated product if it cannot be reprocessed.</p> <p>These procedures should include the disposition of food that have come into contact with blood or other bodily fluids.</p>	
1.6.2	Raw Ingredients		(b)		
1.6.2.1	<p>There is a system in place for the proper inspection, handling,</p>	<p>Raw materials and other ingredients must be inspected and segregated or otherwise handled as necessary to ascertain that they</p>	(1)	<p>Verify by observation that all raw materials are inspected and safe for human</p>	

Req. No.	Requirement	Reference	Citation	Auditor Guidance	Documentation
	segregation, and storage of raw materials.	are clean and suitable for processing into food and must be stored under conditions that will protect against allergen cross-contact and against contamination and minimize deterioration.		consumption. Observe that any unsafe food is segregated and labeled as such. Verify the food is stored under proper sanitary and environmental conditions. Verify by observation if foods classified as allergens are labeled and stored properly (segregated or stored below non-allergen food).	
1.6.2.2	Raw materials must be washed or cleaned as necessary to remove soil or other contamination.	Raw materials must be washed or cleaned as necessary to remove soil or other contamination.		Verify by observation that the company is following their established procedures.	
1.6.2.3	Water used for washing, rinsing, or conveying food must be safe and of adequate sanitary quality. If recirculated or reused, the water must be used in a way to prevent allergen cross-contact or an increase in the level of contamination of the food. If the water is treated, treatment must be monitored to verify adequate pH, temperature, and/or chemical control.	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.		<p>Verify that there is a plan for the appropriate use of water throughout the facility and that it is of adequate quality for its use.</p> <p>If water is reused, how often is the recirculated water changed or tested?</p> <p>If the water is treated, interview and ask how it is monitored. Ask to see the testing records. Controls may include pH, temperature, and the addition of chemicals.</p> <p>Verify that any chemicals used are appropriate for their use.</p>	Record

Req. No.	Requirement	Reference	Citation	Auditor Guidance	Documentation
1.6.2.4	<p>The facility must identify raw materials and/or ingredients that need pasteurization or other treatment prior to processing to prevent possible contamination from pathogenic microorganisms and implement the necessary treatments.</p> <p>These treatment procedures must be documented.</p>	<p>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.</p>	(2)	<p>Verify if the facility has identified any ingredients that require pasteurization or heat treatment or testing for microorganisms. Review pasteurization charts/heat treatment records/lab results.</p>	Policy, Record
1.6.2.5	<p>The facility must identify raw materials and/or ingredients that are susceptible to contamination with aflatoxin or other natural toxins and implement steps to ensure compliance with FDA regulations for poisonous or deleterious substances.</p> <p>Control measures must be documented.</p>	<p>Raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins must comply with FDA regulations for poisonous or deleterious substances before these raw materials or other ingredients are incorporated into finished food.</p>	(3)	<p>Review raw ingredients to verify appropriate controls for mycotoxins and poisonous substances. Ask the facility how they are mitigating any identified risks. Verify implementation of the control measures.</p>	Policy, record
1.6.2.6	<p>The facility must identify raw materials and/or ingredients that pose a risk for contamination with pests, undesirable microorganisms, or extraneous material and implement steps to ensure compliance with FDA regulations for natural or unavoidable defects.</p>	<p>Raw materials, other ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material must comply with applicable FDA regulations for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing food.</p>	(4)	<p>Review raw ingredients to verify expected controls are in place. Ask the facility how they are mitigating any identified risks.</p> <p>Prior to the audit, visit the FDA regulatory site to familiarize yourself with the controls for the stated ingredients or products.</p>	Policy, record

Req. No.	Requirement	Reference	Citation	Auditor Guidance	Documentation
	Control measures must be documented.			https://www.fda.gov/food/ingredients-additives-gras-packaging-guidance-documents-regulatory-information/food-defect-levels-handbook	
1.6.2.7	<p>Raw materials, other ingredients, and rework must be:</p> <ul style="list-style-type: none"> - held in bulk or in containers designed and constructed to protect against allergen cross-contact and against contamination. - held at appropriate temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated. - identified for rework, if scheduled for this purpose. 	<p>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 must be identified as such.</p> <p>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.</p>	(5) and (7)	<p>Are best storage practices used to prevent allergen cross contact of raw materials and ingredients? Are ingredients and rework stored in containers that will protect it from contamination and in the correct environment?</p> <p>Observe if rework product is labeled as such.</p>	
1.6.2.8	<p>Frozen raw materials and other ingredients shall be kept frozen.</p> <p>Temperature of the freezer(s):</p> <p>If product is thawed prior to use, it must be done in a manner that prevents the raw materials and other ingredients from becoming adulterated.</p>	<p>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.</p>	(6)	<p>Verify by observation that products that are to be stored as frozen are frozen. Check the freezer temperature and record it. Verify that the temperature is being checked and recorded daily.</p> <p>Observe any product that is being thawed to make certain that it cannot be contaminated (is it covered properly, are</p>	Record

Req. No.	Requirement	Reference	Citation	Auditor Guidance	Documentation
				they thawing it inside or outside on the dock?). Verify that the plant has a procedure for thawing products.	
1.6.3	Allergens				
1.6.3.1	There shall be documented procedures in place for management to identify all allergenic materials (nine major allergens are peanuts, tree nuts, eggs or egg products, milk or dairy products, crustaceans, fin fish, soy and wheat, and sesame seeds; food chemical sensitivities include sulfites and/or food colorings) present in the facility.			Verify that the plant has identified all allergenic materials present in the facility as well as chemical sensitive materials.	Policy
	Identified types of allergens/chemicals:			List the allergens that have been identified by the facility.	
1.6.3.2	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.	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.	21 CFR 117.80, (b) (8)	If the facility has identified any allergens, verify that the facility has policies and procedures in place for handling allergenic products. Verify by observation that allergen containing foods are labeled as containing allergens and the type of allergen. Verify that food products are stored by segregating allergenic from non-allergenic products (for example, on separate pallets, on shelves below non-allergen foods, etc.).	Policy

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Req. No.	Requirement	Reference	Citation	Auditor Guidance	Documentation
1.6.4	Operations	Manufacturing operations	21 CFR 117.80, (c)		
1.6.4.1	Equipment and utensils and food containers must be maintained in an adequate condition through appropriate cleaning and sanitizing, as necessary. Equipment must be taken apart for thorough cleaning, if necessary.	Equipment and utensils and food containers must be maintained in an adequate condition through appropriate cleaning and sanitizing, as necessary. In so far as necessary, equipment must be taken apart for thorough cleaning.	(1)	Verify that there are procedures in place for cleaning and sanitizing each piece of equipment. Observe that all food contact surfaces and equipment are maintained, clean, and free from food residue or soil. Any equipment that must be dismantled and hand cleaned shall be cleaned in this manner. Observe how the equipment should be cleaned (Cleaned in place (CIP), cleaned out of place (COP), or hand cleaned).	
1.6.4.2	Manufacturing, processing, packing, and holding shall be conducted to minimize the potential for the growth of microorganisms, allergen cross-contact, contamination of food, and deterioration of food.	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.	(2)	Verify by observation during the walk-thru of the facility. Observe staff working or processes underway to identify if there are any practices that are introducing risks of product contamination or deterioration.	
1.6.4.3	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.	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.	(3)	Observe that the food is stored under proper storage conditions (frozen, refrigerated, ambient). Verify that the storage areas are temperature controlled, if required for food safety. Are there temperature recording charts? Are there	Record

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				thermometers in the storage areas? Are temperatures monitored and recorded daily?	
1.6.4.4	Measures such as sterilizing, irradiating, pasteurizing, cooking, freezing, refrigerating, controlling pH, or controlling Aw, that are necessary to destroy or prevent the growth of undesirable microorganisms, must be identified, implemented, and documented.	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.	(4)	Observe what methods are used. As you walk through, observe temperature/pH/other control levels for the process. Review the established policy and records to verify adequate implementation.	Policy, Record
	The identified measures are:			List the processes that are being used.	
1.6.4.5	The facility's product flow and work areas for work-in-process (WIP) and rework provides protection against comingling, allergen cross-contact, contamination, and growth of undesirable microorganisms.	Work-in-process and rework must be handled in a manner that protects against allergen cross-contact, contamination, and growth of undesirable microorganisms.	(5)	Observe if WIP and rework are handled and stored under appropriate conditions for the food product and to prevent comingling of production stages. Observe that the product is not exposed to the environment (open, torn packages). Are there adequate protections for the product?	
1.6.4.6	Effective measures shall be taken to protect finished food from allergen cross-contact and from contamination by raw materials, other ingredients, or refuse. Raw materials, other ingredients, or refuse that are unprotected must not be handled simultaneously in a receiving, loading, or shipping area if that handling could	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 must 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	(6)	Verify by observation. Are finished food products, including raw fruit and vegetables, being handled simultaneously in a receiving or shipping area which may contribute to cross contamination of the finished product? Is iced product dripping on product stored below?	

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	result in allergen cross-contact or contaminated food. Food transported by conveyor must be protected against allergen cross-contact and against contamination as necessary.	protected against allergen cross-contact and against contamination as necessary.			
1.6.4.7	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 during manufacturing, processing, packing, and holding in a manner that protects against allergen cross-contact and against contamination.	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 during manufacturing, processing, packing, and holding in a manner that protects against allergen cross-contact and against contamination.	(7)	Verify by observation. Are equipment, utensils, containers, and conveyors clean? Are they constructed of materials acceptable for food contact? Are they maintained in good condition and stored appropriately?	
1.6.4.8	The facility must take adequate measures to protect against the inclusion of metal or other extraneous material in food.	Adequate measures must be taken to protect against the inclusion of metal or other extraneous material in food.	(8)	Ask if the facility takes any steps for preventing metal and extraneous material in food. Observe if there are metal detectors, filters, or screens in use. If no risks have been identified, this may be marked as N/A.	
1.6.4.9	If the facility identifies food, raw materials, and other ingredients as adulterated, they must dispose of the material in a manner that protects against the contamination of other food; or, if appropriate,	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	(9)	Verify by observation that adulterated food is labeled as such. Verify the facility has procedures for disposing of the adulterated food. If the food is to be reconditioned, verify the method and that the	Record

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	recondition the material so that it meets process and regulatory requirements.	ii) If the a adulterated food is capable of being reconditioned, it must be: A. Reconditioned (if appropriate) using a method that has been proven to be effective; or B. Reconditioned (if appropriate) and reexamined and subsequently found not to be a adulterated within the meaning of the Federal Food, Drug, and Cosmetic Act before being incorporated into other food.		method used meets the regulatory requirements for that food. Ask to see production records for the reconditioning of the food to verify that they are meeting the requirements.	
1.6.4.10	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.	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.	(10)	Verify by observation. Does the facility have procedures in place for the different steps in their process to protect food from contamination and allergen cross-contact? Is food protected from contaminants that may drip, drain or be drawn into the food?	
1.6.4.11	If heat blanching is utilized in the preparation of food capable of supporting microbial growth, the process must be documented and implemented.	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	(11)	Review blanching heat-treatment records for the required temperature and hold time for the type of product. Is the product being cooled	Policy, Record

Req. No.	Requirement	Reference	Citation	Auditor Guidance	Documentation
	The blanching equipment must be periodically cleaned and sanitized as necessary.	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 in blanchers must be minimized by the use of adequate operating temperatures and by periodic cleaning and sanitizing as necessary.		rapidly or being processed without delay? Verify that the system is cleaned and sanitized regularly.	
1.6.4.12	If batters, breading, sauces, gravies, dressings, dipping solutions, and other similar preparations are held and used repeatedly over time, they must be treated or maintained in such a manner that they are protected against allergen cross-contact and against contamination, and to minimize the potential for the growth of undesirable microorganisms.	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.	(12)	Verify that holding containers, vats, tubs, etc. are cleaned and sanitized regularly. Have they done a risk assessment for each type of product? Question how they determine when a product that is repeatedly used is no longer safe or of good quality. If products are to be held under specific temperature requirements to minimize microbial growth, verify that it is being done. Observe that storage container lids/coverings are in place.	Policy, Record
1.6.4.13	Filling, assembling, packaging, and other operations must be performed in such a way that the food is protected against allergen cross-contact, contamination, and growth of undesirable microorganisms.	Filling, assembling, packaging, and other operations must be performed in such a way that the food is protected against allergen cross-contact, contamination and growth of undesirable microorganisms.	(13)	Observe the processes to verify GMP's are being followed. Look for such things as covers that are open or missing from filler hoppers, packaging material sitting on the floor, product conveying on dirty/unsanitary conveyor belts. Observe that	Record

Req. No.	Requirement	Reference	Citation	Auditor Guidance	Documentation
				temperature and/or time requirements for filling, assembling, or packaging are being met.	
1.6.4.14	<p>Dry mixes, nuts, intermediate moisture food, and dehydrated food, that rely principally on the control of water activity (Aw) for preventing the growth of undesirable microorganisms, must be processed to, and maintained at a safe Aw level.</p> <p>Controls must be documented.</p>	<p>Food, such as dry mixes, nuts, intermediate moisture food, and dehydrated food, that relies principally on the control of Aw for preventing the growth of undesirable microorganisms must be processed to and maintained at a safe moisture level.</p>	(14)	<p>If products are controlled for Aw, verify that the facility is monitoring Aw of the product. What does the facility do with product that does not meet their requirements? Do they have a microbial monitoring program for monitoring pathogenic bacteria? Review test results. Are products stored in a manner to prevent Aw levels from changing?</p>	Policy, Record
1.6.4.15	<p>Acid and acidified food are monitored and maintained at a pH of 4.6 or below.</p>	<p>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.</p>	(15)	<p>Review pH monitoring records. What is the facility policy for products that do not meet the pH requirement?</p>	Policy, Record
1.6.4.16	<p>Ice that is used (internally produced or externally supplied) in contact with food must be made from water that is safe and of a adequate sanitary quality and manufactured in accordance with current good manufacturing practices.</p>	<p>When ice is used in contact with food, it must be made from water that is safe and of a 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.</p>	(16)	<p>Verify that the water used for ice production is potable (see 1.7.1.1) and stored and handled under sanitary conditions. Verify that the ice machine is on a cleaning and sanitation schedule.</p> <p>If ice is from an outside source, ask for the documented assurances that the ice was potable.</p>	Record

1.7 Defect Action

Req. No.	Requirement	Reference	Citation	Auditor Guidance	Documentation
1.7.1	<p>The facility must determine if defect action levels are established for the food handled or manufactured by the facility.</p> <p>Controls must be documented.</p>		21 CFR 117.110	<p>Review the finished products produced or handled at the facility against the Defect Levels Handbook, https://www.fda.gov/food/ingredients-additives-gras-packaging-guidance-documents-regulatory-information/food-defect-levels-handbook.</p>	Policy
	Identify defect action levels:			Record the defect action levels appropriate for the facility and/or what the facility has identified.	
1.7.2	Quality control operations must be conducted in a way that reduce natural or unavoidable defects to the lowest level currently feasible. The policies must be documented, with records of implementation.	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.	(a)	Observe if appropriate controls have been documented and implemented, based on the FDA Defect Levels Handbook. Some contracts require that the chemical or microbial tests be performed by a laboratory accredited to ISO17025, or a USDA lab. Review a random sample of the associated test or inspection records.	Policy, Record
1.7.3	The facility shall not mix foods containing defects at levels that render that food adulterated with other lots of food.	The mixing of a food containing defects at levels that render that food adulterated with another lot of food is not permitted and renders the final food adulterated,	(b)	Ask the facility how they would handle finished product that exceeds established limits. Any policy for mixing	

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		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, which is accessible at http://www.fda.gov/pchfrule and at http://www.fda.gov .		foods with those that exceed established limits would be unacceptable.	

1.8 Equipment and Utensils (Design, Materials, and Maintenance)

Req. No.	Requirement	Reference	Citation	Auditor Guidance	Documentation
1.8.1	General		21 CFR 117.40 (a)		
1.8.1.1	All plant equipment and utensils used in manufacturing, processing, packing, or holding food must be designed and of such material and workmanship as to be adequately cleanable and must be adequately maintained.	All plant equipment and utensils used in manufacturing, processing, packing, or holding food must be so designed and of such material and workmanship as to be adequately cleanable, and must be adequately maintained to protect against allergen cross-contact and contamination.	(1)	Verify by observation. Are the materials used to manufacture the utensils and equipment acceptable for use in food plants? Is equipment designed to be easily dismantled for cleaning? Is the equipment included in a preventive maintenance program?	
1.8.1.2	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.	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.	(2)	Verify by observation. Look for things such as metal rubbing against metal (possibly in product pumps, grinders, extruders), nuts and bolts in food contact zones, excessive lubrication on conveyor gears/gear boxes/bearings in close contact to or above food or food contact surfaces,	

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				excessive grease on greased fittings for packaging machines, excessive grease on rollers for crimping & sealing cans. Are high pressure washers being used appropriately to prevent contamination from water?	
1.8.1.3	Equipment must be constructed and located so that they are accessible for cleaning, maintenance, and inspection.	Equipment must be installed so as to facilitate the cleaning and maintenance of the equipment and of adjacent spaces.	(3)	Verify by observation that equipment is located so that it can be easily cleaned, inspected, and maintained. Does the location of the equipment prevent adjacent areas being properly cleaned, inspected, and maintained?	
1.8.1.4	Food-contact surfaces must be corrosion-resistant, made of nontoxic materials, and designed to withstand the environment of their intended use and of the cleaning process.	Food-contact surfaces must be corrosion-resistant when in contact with food. 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.	(4) and (5)	Verify by observation. If you are unsure if a contact surface is acceptable for use in a food plant, ask to see documentation that certifies that it is acceptable.	
1.8.1.5	Food-contact surfaces must be maintained to protect food from allergen cross-contact and from being contaminated.	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.	(6)	Verify by observation. Look for scratches, pitting, cavitation in stainless steel that should be polished smooth; cuts, gouges, and tears on conveyor belts; deep cuts, scratches or frayed plastic on plastic utensils, buckets, tubs, totes, etc.	

Req. No.	Requirement	Reference	Citation	Auditor Guidance	Documentation
1.8.2	Seams on food-contact surfaces must be sanitary welds, smoothly bonded and maintained to minimize accumulation of food particles, dirt, and organic matter minimizing the opportunity for microorganism growth and allergen cross-contact.	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.	(b)	Verify by observation. Look for unsanitary welds - cracks and open seams that need to be sealed, skip welds, broken welds, and rough welds that need to be polished smooth.	
1.8.3	Non-food contact equipment located in the processing and packing areas shall be constructed so that it can be maintained, and is in good condition, able to be cleaned.	Equipment that is in areas where food is manufactured, processed, packed, or held and that does not come into contact with food must be so constructed that it can be kept in a clean and sanitary condition.	(c)	Verify by observation that equipment is clean, free from dust accumulation, rust, peeling paint, has smooth cleanable surfaces, etc. This applies to equipment that is non-food contact, as well as currently unused processing equipment.	
1.8.4	Holding, conveying, and manufacturing systems must be of a design and construction that enables them to be maintained, and are in an appropriate clean and sanitary condition.	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.	(d)	Verify by observation. Verify that there are no line extensions or out of reach areas that create a situation in which cleaning is ineffective.	
1.8.5	Freezer and cold storage compartments must be fitted with an indicating thermometer, temperature-measuring device, or temperature recording device.	Each freezer and cold storage compartment used to store and hold food capable of supporting 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.	(e)	Observe that there are thermometers or temperature recording devices in all freezer and cold storage areas.	

Req. No.	Requirement	Reference	Citation	Auditor Guidance	Documentation
1.8.6	Instruments and controls used for measuring, regulating, or recording temperatures, pH, water activity, etc. must be properly maintained, calibrated, and adequate in number for their designated uses.	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.	(f)	Verify that instruments and thermometers have been calibrated. Ask to see the calibration documentation. Verify that the instruments, (such as scales, pH meters, etc.) are checked daily for accuracy and that equipment such as pasteurizers that regulate temperature and time are checked routinely. Ask to see the calibration policy for the plant. Are there preventive maintenance (PM) policies for instruments and have they been implemented? Note that scales used strictly for product weight in the packaging area would not be included in this requirement.	Policy, Record
1.8.7	Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment must be filtered and oil free.	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 food is not contaminated with unlawful indirect food additives.	(g)	Verify that there is a PM plan for changing filters in the air lines and that separators are working correctly. Verify that the sources for other gases such as nitrogen can certify the gas to be clean and dry.	Policy, Record

1.9 Sanitary Facilities and Controls

Req. No.	Requirement	Reference	Citation	Auditor Guidance	Documentation
1.9.1	General	Each plant must be equipped with adequate sanitary facilities and accommodations including:	21 CFR 117.37		
1.9.1.1	The water supply/system must be adequate for the operations intended and must be derived from an adequate source. Private wells must be inspected on an annual basis.	Water supply. The water supply must be adequate for the operations intended and must be derived from an adequate source.	(a)	Document the water source (for example, municipal, well, or other). If well water is the source, verify that the system has been inspected yearly.	Record
1.9.1.1.1	There shall be testing results showing that water used for processing, cleaning, as an ingredient, or by personnel is potable. Water test results issued by: Date of testing:	Any water that contacts food, food-contact surfaces, or food-packaging materials must be safe and of adequate sanitary quality.		Verify that the plant has test results from an accredited laboratory showing that water meets the EPA National Drinking Water Regulations for Microorganisms. Record the issuer and the date of the test report. If the water source is municipal, the report may be from the municipality. Testing must be performed annually, at a minimum. Verify that the water is free of generic <i>E. coli</i> . and total coliforms.	Record
1.9.1.1.2	Running water of suitable temperature and pressure must be available in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-	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.		Verify by observation. Observe if there are steam regulators to control the temperature and pressure transducers to control the water pressure and if they are covered by the PM program.	Record

Req. No.	Requirement	Reference	Citation	Auditor Guidance	Documentation
	packaging materials, or for employee sanitary facilities.			Check that the water temperature at sinks where employees wash their hands is conducive for hand washing and that at hose stations is adequate for its purpose. Is there adequate water pressure? What are water temperature requirements for the processes? Check temperature logs to verify adequate processing or cleaning implementation.	
1.9.2	Plumbing	Plumbing. Plumbing must be of adequate size and design and adequately installed and maintained to:	(b)		
1.9.2.1	Plumbing must be of adequate size and design to handle the water and waste flow for the facility, and not create possible contamination or unsanitary conditions.	Carry adequate quantities of water to required locations throughout the plant. Properly convey sewage and liquid disposable waste from the plant. Avoid constituting a source of contamination to food, water supplies, equipment, or utensils or creating an unsanitary condition.	(1) – (3)	Verify by observation. Are there signs of sewage back-up or odors from drains? Are there water leaks or seepage? Is plumbing adequate to carry water to required locations throughout the plant? Observe if lines are installed over product zones.	
1.9.2.2	Floors, gutters, or drains must have sufficient slope and outlets to drain adequately.	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.	(4)	Observe if floors are properly sloped, if there are a sufficient number of drains, if drain covers are in place, if drains are clogged and if drains are properly trapped.	
1.9.2.3	There shall not be any cross connections between treated and untreated supplies.	Provide that there is not backflow from, or cross-connection between, piping systems that discharge waste water or sewage and	(5)	Verify by observation that water lines are separate from	

Req. No.	Requirement	Reference	Citation	Auditor Guidance	Documentation
		pipng systems that carry water for food or food manufacturing.		sewer lines/wastewater lines and that lines are labeled.	
1.9.2.4	Back flow prevention devices must be installed on all water and steam lines, and periodically certified. Certification by: Date of last certification:		(5)	Verify that the back flow prevention devices have been installed and that they are on an annual PM schedule for certification. Record the name of the company that certified the back flow device and the date of certification on the audit report. This must be performed by a certified individual (in-house) or the local municipality or state.	Record
1.9.3	Sewage must be disposed of into an adequate sewage system or disposed of through other adequate means.	Sewage disposal. Sewage must be disposed of into an adequate sewerage system or disposed of through other adequate means.	(c)	Verify how the sewage is disposed of (city sewer system, plant wastewater system, septic tank, etc.). Observe if there are any obvious issues with the system.	
1.9.4	For toilet facilities that are located in production areas or primarily used by production staff, there must be:	Toilet facilities. Each plant must provide employees with adequate, readily accessible toilet facilities. Toilet facilities must be kept clean and must not be a potential source of contamination of food, food-contact surfaces, or food-packaging materials.	(d)		
1.9.4.1	An adequate, readily accessible, number of units for the facility size/number of employees.			Observation. Verify that OSHA or state mandated requirements are met and that facilities are accessible to employees.	

Req. No.	Requirement	Reference	Citation	Auditor Guidance	Documentation
1.9.4.2	Independent outside ventilation.			Observation. There needs to be a working exhaust fan/system, vented to the outside of the building.	
1.9.4.3	Design so that they do not open directly into food handling areas (i.e., processing, repacking, or reconditioning areas).			Observation.	
1.9.4.4	Self-closing doors or maze-type entrance.			Observation.	
1.9.4.5	Adequate lighting.			Observation.	
1.9.4.6	Sufficient and proper waste receptacles.			Observation. Trash containers should be hands free to eliminate the potential recontamination of clean and sanitized hands. Observe if trash containers are overflowing.	
1.9.4.7	Signs posted indicating the importance of hand washing (multilingual if appropriate).			Observation. Verify signs are posted in all toilet facilities.	
1.9.4.8	Hand-washing facilities with running water at a suitable temperature, soap, and single use towels or forced air hand dryers.			Observation. Hands-free fixtures at sinks and soap dispensers are preferred but not required. Is there a available warm water, antimicrobial soap, and single use towels or air dryers?	
1.9.4.9	Toilet areas that are clean, dry, properly stocked with toilet paper, and of good general appearance.			Observation. Verify that cleaning and sanitizing practices are adequate. Are toilet bowls, sinks, walls, and floors clean? Is housekeeping adequate? Is toilet paper available?	

Req. No.	Requirement	Reference	Citation	Auditor Guidance	Documentation
1.9.4.10	Toilets, sinks, and faucets in good working condition.			Observe by testing one or two of the units to see if they work properly and that there is a dequate water pressure.	
1.9.5	Hand-washing facilities (located in breakroom and production area) shall include running water at a suitable temperature, soap, and single use towels or forced air hand dryers. Signs must be posted indicating the importance of hand washing (multilingual if appropriate).	Hand-washing facilities. Each plant must provide hand-washing facilities designed to ensure that an employee’s hands are not a source of contamination of food, food-contact surfaces, or food-packaging materials, by providing facilities that are a dequate, convenient, and furnish running water at a suitable temperature.	(e)	This requirement applies to hand-washing facilities that <u>are not</u> located in toilet areas. Test that the sinks work properly, have warm water, that forced air hand dryers (if used) work properly. Observe that there is antimicrobial hand soap and single use towels. Is there an a dequate number of facilities and are they convenient? Are hand-washing signs posted and multilingual, if appropriate.	
1.9.6	The capacity of the facility’s rubbish/waste storage must be sufficient for the operation, with dedicated waste containers and timely removal of waste. A policy must be documented.	Rubbish and offal disposal. Rubbish and any offal must be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of food, food-contact surfaces, food-packaging materials, water supplies, and ground surfaces. <i>A procedure shall be established, implemented and maintained for the collection, storage and disposal of waste material, including waste water and drainage.</i>	(f) <i>GFSI, GMP 12.1</i>	Verify that the facility has a documented plan for the containment and removal of waste from the interior of the building(s). Check if there is a map/route to follow to the trash dumpster to eliminate the potential for cross contamination. Observe if trash containers are covered, over-flowing, and if there is food/trash/debris on the floor/ground. Is there a strong odor from the trash that may permeate into the plant or be absorbed into the food? Check	Policy

Req. No.	Requirement	Reference	Citation	Auditor Guidance	Documentation
				the frequency of waste removal.	

1.10 Maintenance and Sanitation

Req. No.	Requirement	Reference	Citation	Auditor Guidance	Documentation
1.10.1	General Maintenance		21 CFR 117.35 (a)		
1.10.1.1	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. After maintenance repairs of equipment associated with food processing or with food contact surfaces, the equipment must be cleaned, sanitized, and inspected. This policy must be documented, and implementation must be recorded.	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.		Observe such things as peeling paint on walls, ceilings, floors, drains, and equipment, dust and debris on ledges, missing/torn screens from doors and windows, cracks/holes in walls, missing/low grout in floor and wall tiles, proper ventilation to eliminate condensation and mold growth, etc. Verify that the plant has a sanitation policy in place for when maintenance or repairs are performed in a food contact zone or on food processing equipment. Steps should be taken to isolate the area to prevent contamination. Inspection by a competent individual must occur and be recorded before the equipment is released for use.	Policy, Record

Req. No.	Requirement	Reference	Citation	Auditor Guidance	Documentation
1.10.1.2	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. The procedure must be documented and there must be records to show completion.	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.		Verify that there are policies for cleaning and sanitizing all equipment and utensils and that it has been implemented. Review recent records of cleaning and sanitization.	Policy, Record
1.10.2	Sanitation Chemicals and Supplies		(b)		
1.10.2.1	Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures must be free from undesirable microorganisms and appropriate for use (documentation must be available for verification).	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.	(1)	Review the cleaning compounds and sanitizing agents used in the plant. Request to see letters of guarantee, certificates of assurance (COA's), labels, or other documentation from the suppliers to verify that they are free of undesirable microbes and are safe for their intended use. Select a random number of containers to examine the label to verify that it is appropriate for its use. Verify that label instructions are being followed for mixing and application.	
1.10.2.2	The chemicals stored at the facility must be appropriate for presence in a plant where food is processed and exposed. Food	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;	(1)	Check the maintenance shop to verify non-food grade and food grade oils and lubricants are stored separately. Verify that lab chemicals and	

Req. No.	Requirement	Reference	Citation	Auditor Guidance	Documentation
	grade lubricants must be used in exposed product zones.	ii) Those necessary for use in laboratory testing procedures; iii) Those necessary for plant and equipment maintenance and operation; and Those necessary for use in the plant's operations.		chemicals needed for use during production or sanitation are kept in an area out of a food contact zone. Are Safety Data Sheets (SDS) available to employees?	
1.10.2.3	There shall be a locked storage area for chemicals with controlled access, and chemicals must be clearly and properly labeled.	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.	(2)	Observe that there is a designated and locked area for chemical storage located in an area away from food packaging material, exposed food, or food contact surfaces. Observe that all containers are properly and clearly labeled. Observe that pesticides are not stored with cleaning and sanitizing agents. Verify controlled access to the secured area.	
1.10.3	Pest Control		(c)		
1.10.3.1	The facility shall document and implement an effective pest control program.	Pests must not be allowed in any area of a food plant. Guard, guide, or pest-detecting dogs may be allowed in some areas of a plant if the presence of the dogs is unlikely to result in contamination of food, food contact surfaces, or food-packaging materials. Effective measures must be taken to exclude pests from the manufacturing, processing, packing, and holding areas and to protect against the contamination of food on the premises by pests.		Verify that the plant has a pest control program. If an outside pest control company is used, request to see the certification of the provider. If the company provides their own pest control, ask to see certification of personnel responsible for pest control. Are there pest control traps, lights, mats, etc. located in the plant or warehouse to prevent pests from infesting the facility?	Policy, Record

Req. No.	Requirement	Reference	Citation	Auditor Guidance	Documentation
1.10.3.1.1	A pest control station map is properly maintained and available.			Verify the facility has a pest control map and the date the pest control map was last updated.	Policy, Record
1.10.3.1.2	Routine maintenance and inspection of pest control devices is documented.			Review the pest control inspection and surveillance results. Document how often the inspections are performed. Are electrical insect killers, blowers or fans working properly?	Policy, Record
1.10.3.1.3	The type, number, and placement of pest control/deterrent devices is adequate and appropriate to prevent infestation.			Observe as you walk through if randomly selected stations are in place as noted on the map. Do you see evidence of infestation? Bait stations <u>must not</u> be used inside the facility. (See 1.13.2.3 for requirements in bulk storage areas.)	
1.10.3.1.4	The facility is free from pest infestation.			Verify by observation if there is evidence of infestation.	
1.10.3.2	The use of pesticides to control pests in the facility must be performed under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food packaging materials.	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.		Verify that there are appropriate measures for the application and storage of pesticides and that the individual responsible for pesticide application is properly trained and certified. Any exposed food or packaging material shall be covered before pesticides are applied, and equipment and utensils shall be thoroughly cleaned and sanitized before	Record

Req. No.	Requirement	Reference	Citation	Auditor Guidance	Documentation
				use after pesticides are applied.	
1.10.4	Sanitation of Food-Contact Surfaces	Sanitation of food-contact surfaces.	(d)		
1.10.4.1	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. The procedure must be documented and there must be records to show completion. Cleaning and sanitation oversight must be assigned to at least one competent staff person.	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.		Verify that there are adequate procedures for cleaning and sanitizing all food contact surfaces used for processing food. Are procedures fully implemented? Review recent records of cleaning and sanitation. Note the responsible party(s) for oversight of cleaning and sanitation, and verify that they have received appropriate training.	Policy, Record
1.10.4.2	For processing, packing, or holding low-moisture food, food contact surfaces must be clean and dry before use. If wet-cleaned, the surfaces must be sanitized and thoroughly dried before use. The procedure must be documented and there must be records to show completion.	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.	(1)	Observe if food contact surfaces are thoroughly dried after cleaning and sanitizing. The use of alcohol-based wipes are acceptable means of sanitizing surfaces. Air drying is a common method for drying surfaces.	Policy, Record
1.10.4.3	In wet processing, 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	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	(2)	Verify that there are policies for cleaning and sanitizing all equipment and utensils. Verify the cleaning schedule in continuous operations is being followed. Observe that food contact surfaces are clean and free of food residue, soil, etc.	Policy, Record

Req. No.	Requirement	Reference	Citation	Auditor Guidance	Documentation
	utensils and food-contact surfaces of the equipment must be cleaned and sanitized as necessary. The procedure must be documented and there must be records to show completion.	production operation, the utensils and food-contact surfaces of the equipment must be cleaned and sanitized as necessary.			
1.10.4.4	Single-service articles 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.	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.	(3)	Verify by observation if single-service products are covered/protected from contamination and adequately stored, and that any used, dirty, or soiled products are disposed, destroyed, or stored and labeled as not for use until they can be properly disposed of.	
1.10.5	Non-food contact surfaces of equipment used in the operation of a food plant must be cleaned in a manner and as frequently as necessary to protect against allergen cross-contact and against contamination of food, food-contact surfaces, and food-packaging materials.	Sanitation of non-food-contact surfaces. Non-food-contact surfaces of equipment used in the operation of a food plant must be cleaned in a manner and as frequently as necessary to protect against allergen cross-contact and against contamination of food, food-contact surfaces, and food-packaging materials.	(e)	Verify by observation that non-food contact surfaces such as the exteriors of machines, forklifts, storage shelves, etc. are clean. Verify that cleaning non-food contact surfaces is regularly scheduled.	
1.10.6	Cleaned and sanitized portable equipment with food-contact surfaces and utensils must be stored in a location and manner that protects food-contact surfaces from allergen cross-contact and from contamination.	Storage and handling of cleaned portable equipment and utensils. Cleaned and sanitized portable equipment with food-contact surfaces and utensils must be stored in a location and manner that protects food-contact surfaces from allergen cross-contact and from contamination.	(f)	Verify by observation that equipment is not stored on the floor or ground. Are special tables, carts, racks provided for cleaned utensil storage? Are clean and sanitized portable pieces of equipment covered or stored in an area free from possible contamination?	

1.11 Warehousing and Distribution

Req. No.	Requirement	Reference	Citation	Auditor Guidance	Documentation
1.11.1	The storage and transportation of food must be carried out so that it is protected 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.	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.	21 CFR 117.93	Observe that the warehouse has good housekeeping, pallets are stored away from the walls, there is sufficient storage space to allow air circulation around product for cooling, prevention of mold growth and to lessen damage to product due to overcrowding. Is food exposed because of damaged packaging? Are best storage practices being followed to prevent allergen cross-contact?	
1.11.1.1	Incoming trailers and goods are inspected for damage, infestation, off odors, contamination, and proper temperatures.			Verify that there are procedures for receiving or incoming trailers, including inspection for damage, infestation of pests, off odors, contamination, and temperature. Interview employees about the procedures.	
1.11.1.2	Wash certificates are required for bulk tanker trucks for previous loads. The record indicates the previous product shipped.			Review tanker wash tickets. Verify that the previous product shipped is indicated and was a food grade product.	Record

Req. No.	Requirement	Reference	Citation	Auditor Guidance	Documentation
1.11.1.3	Procedures are implemented for outbound shipments, including: proper shipping temperature, trailer cleanliness/condition, verification of odors, etc.			Verify that there are procedures for inspecting outbound containers before loading. Interview employees about the procedures. Observe if trailers are clean, in good repair and if cooling or freezer units are working properly. If tankers are being used verify that they are clean.	
1.11.1.4	Packaging, packing materials, and empty containers must be protected from contamination.			Observe that packing materials, packaging and containers are covered with plastic wrap, cardboard, etc. to protect the materials from the environment. Are outer coverings/boxes torn exposing materials to the environment? Are materials stored on pallets or shelves, and not directly on the floor?	
1.11.1.5	Retained, damaged, or returned product must be identified and stored in a clearly designated area or controlled through an inventory system.			Observe that retained, damaged, or returned product or materials are stored in a designated area and labeled accordingly and ask how they control them so that no contaminated or deteriorated products/materials are used in production.	
1.11.1.6	The facility must have a documented procedure to ensure that ingredients, materials, work in progress, and finished product	<i>A procedure shall be established, implemented and maintained to ensure that purchased materials, work in progress and finished products are used in the correct</i>	<i>GFSI, GMP 17</i>	Verify that there are procedures to maintain appropriate rotation of materials and ingredients. Generally, you would expect	Policy, Record

Req. No.	Requirement	Reference	Citation	Auditor Guidance	Documentation
	are used in the correct order and within the allocated shelf life.	<i>order, and within the allocated shelf life when applicable.</i>		to see the principle of first in/first out applied. Do inventory, shipping, and production records indicate compliance with the policy?	

1.12 Food By-Products for Animal Food

Req. No.	Requirement	Reference	Citation	Auditor Guidance	Documentation
1.12.1	If the facility holds and distributes human food by-products for use as animal food, it must be held under conditions that protect against contamination, including:	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:	21 CFR 117.95 (a)	Ask the facility if they are generating food by-products for animal food. Does the facility have control procedures on storage time and conditions? Have they been implemented?	
1.12.1.1	Containers and equipment used to convey or hold human food by-products before distribution must be designed, constructed of appropriate material, cleaned as necessary, and maintained to protect against contamination.	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.	(1)	Verify that there are procedures for cleaning human food by-product containers and equipment. Observe by inspection if containers are constructed of appropriate material, are clean and in good repair. Interview employees about the procedure.	
1.12.1.2	Human food by-products must be held in a way to protect against contamination from sources such as trash.	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	(2)	Verify by observation. Are trash containers located next to by-product containers?	

Req. No.	Requirement	Reference	Citation	Auditor Guidance	Documentation
1.12.1.3	Human food by-products must be accurately identified.	During holding, human food by-products for use as animal food must be accurately identified.	(3)	Observe that food designated as animal food is clearly labeled as “animal food”.	
1.12.2	Labeling that identifies the by-product by the common or usual name must be affixed to or accompany human food by-products for use as animal food when distributed.	Labeling that identifies the by-product by the common or usual name must be affixed to or accompany human food by-products for use as animal food when distributed.	(b)	Verify by observation that all by-products are labeled with the common or usual name.	
1.12.3	Shipping containers and bulk vehicles used to distribute human food by-products must be examined prior to use to protect against contamination of the human food by-products from the container or vehicle.	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 for use as animal food from the container or vehicle when the facility is responsible for transporting the human food by-products for use as animal food itself or arranges with a third party to transport the human food by-products for use as animal food.	(c)	Verify that the facility has a procedure to inspect shipping containers for condition and to verify that they are suitable to ship human food by-products for use as animal food.	

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1.13 Facility and Grounds

Req. No.	Requirement	Reference	Citation	Auditor Guidance	Documentation
1.13.1	The grounds surrounding the facility must:	Grounds. The grounds about a food plant under the control of the operator must be kept in a condition that will protect against the contamination of food. The methods for a dequate maintenance of grounds must include:	21 CFR 117.20 (a)		
1.13.1.1	Be maintained in a manner which will prevent rodent and insect harborage, reasonably free of litter and debris.	Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant that may constitute a attractant, breeding place, or harborage for pests.	(1) 21 CFR 117.35 (c)	Verify by observation. Look for things such as overgrown vegetation along the side of the building, low areas where water stands, old pallets stacked up or an equipment junk yard, etc. or anything that will attract or harbor pests.	
1.13.1.2	Be properly surfaced and designed to prevent dust and offensive odors and for adequate drainage (minimal standing water).	Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed. Adequately draining areas that may contribute contamination to food by seepage, foot-borne filth, or providing a breeding place for pests.	(2), (3)	Observe if there are low spots in the drives and parking lots with pooling water, if they are paved, dirt, rock or gravel. Observe if dirt and mud are being tracked into the facility.	
1.13.1.3	Include an adequate number of exterior waste containers which are well maintained and in good condition. The frequency or removal of the waste shall be timely. A policy must be documented.	Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed. <i>A procedure shall be established, implemented and maintained for the collection, storage and disposal of waste</i>	(4) <i>GFSI, GMP 12.1</i>	Verify that the plant has a documented waste removal policy. Observe that trash containers are well maintained and not over-flowing. Check the frequency of trash pick-up and verify by observation that it is a dequate.	Policy

Req. No.	Requirement	Reference	Citation	Auditor Guidance	Documentation
		<i>material, including waste water and drainage.</i>			
1.13.1.4	Not be affected by uncontrolled contamination risks from adjacent properties. The facility shall take steps for additional inspection, extermination, or other means to limit any identified risks.	If the plant grounds are bordered by grounds not under the operator’s control and not maintained in the manner described in paragraphs (a)(1) through (4) of this section, care must be exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination.	(5)	Ask if the plant has done a risk assessment for the surrounding area. Observe if there are extra barriers, fences, netting, etc. in place.	
1.13.2	The plant design and construction shall be adequate for the food products produced.	Plant construction and design. The plant must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-production purposes (i.e., manufacturing, processing, packing, and holding). The plant must:	(b)		
1.13.2.1	There must be adequate space provided for necessary maintenance, sanitation, and production activities.	Provide adequate space for such placement of equipment and storage of materials as is necessary for maintenance, sanitary operations, and the production of safe food.	(1)	Observe if the facility is overcrowded. Look for adequate warehousing, storage space and crowding in production areas that prevents adequate cleaning and monitoring for condition. Look for 18 inches of clearance between exterior walls and shelving.	
1.13.2.2	The facility must be designed to prevent contamination of products and materials. Measures may include physical segregation, time, air flow systems, enclosures, labeling, and other effective means.	Permit the taking of adequate precautions to reduce the potential for allergen cross- 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	(2)	Verify that the plant layout and traffic controls are conducive for the protection of finished product and to prevent cross contamination. HVAC systems could be used to prevent contamination of	

Req. No.	Requirement	Reference	Citation	Auditor Guidance	Documentation
		<p>controls and operating practices or effective design, including the separation of operations in which a llergen 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.</p>		<p>processing areas by allergens or dust from other areas.</p> <p>Positive air pressure could be maintained in the production area to establish a hygienic control.</p> <p>Physical segregation and/or labeling of ingredients in the warehouse, scheduling of production runs so that products with allergens are run last, are all examples of appropriate steps.</p>	
1.13.2.3	<p>Bulk storage vessels shall be constructed and protected to prevent contamination.</p>	<p>Permit the taking of adequate precautions to protect food in installed outdoor bulk vessels by any effective means, including:</p> <ul style="list-style-type: none"> 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. 	(3)	<p>Verify by observing if food stored in vessels is adequately protected.</p> <p>Observe if there is evidence of pest activity and if the surrounding area can contribute to pest harborage. Verify that there are pest control devices in place and that they are checked regularly.</p> <p>Look for overhead covers if sampling is occurring from the top of tanker trucks.</p> <p>Any valves or spigots, hoses, or utensils should be protected.</p>	

Req. No.	Requirement	Reference	Citation	Auditor Guidance	Documentation
1.13.2.4	Floors, doors, ceilings, walls and overheads must be in good repair and designed to facilitate proper sanitation and maintenance.	Be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and kept in good repair; that drip or condensate from fixtures, ducts and pipes does not contaminate food, food contact surfaces, or food-packaging materials; and that aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating food, food-contact surfaces, or food-packaging materials with clothing or personal contact.	(4)	<p>Observe if floors, doors, ceilings, walls, and overheads are constructed of durable materials that are easy to clean and maintain, and that they are free of cracks and crevices. Observe that ceilings are free from condensation and mold. Does the plant have drop or false ceilings which could provide places for pest to hide? Observe that walls are made of materials that are impervious to moisture.</p> <p>Is there enough room for employees to perform their work?</p>	
1.13.2.5	There shall be adequate procedures in place to prevent overhead condensation from dripping on to food, food contact surfaces, or food-packaging materials.		(4)	<p>Observe if there is proper ventilation to eliminate excessive condensation, if food contact areas are shielded (drip pans, etc.) to protect condensation from dripping onto it.</p> <p>Look along product flow zones, especially between cold/warm areas for condensation issues.</p>	
1.13.2.6	Catwalks and stiles must be constructed and located to prevent product contamination.		(4)	Observe if catwalks are located above food processing lines, open manways to tankers, if tubs/totes/bins/cleaned	

Req. No.	Requirement	Reference	Citation	Auditor Guidance	Documentation
				<p>equipment and utensils are placed under catwalks, etc.</p> <p>Kick plates or sheeting/catch plate could be used to prevent contamination.</p>	
1.13.2.7	<p>There shall be sufficient lighting in personnel areas, and to permit efficient operations and cleaning where food is examined, manufactured, processed, packed, or held and where equipment or utensils are cleaned.</p>	<p>Provide a dequate lighting in handwashing areas, dressing and locker rooms, and toilet rooms and in all areas where food is examined, manufactured, processed, packed, or held and where equipment or utensils are cleaned; and provide shatter-resistant light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation or otherwise protect against food contamination in case of glass breakage.</p>	(5)	<p>Observe if there is a dequate lighting in production areas, where equipment is cleaned, and where product is inspected and graded. Observe if any lights are not working properly /light bulbs missing or burned out.</p> <p>The rest rooms, other personnel areas, and handwashing areas must be well lit.</p>	
1.13.2.8	<p>Light fixtures and other glass must be properly covered or protected in case of breakage.</p>		(5)	<p>Verify by observation. Observe if the lights are shatter resistant and that light shields/covers are in place.</p> <p>Glass in the production area must be shielded.</p>	
1.13.2.9	<p>Fans and other air-blowing equipment shall be located so to minimize the potential for allergen cross-contact and for contaminating food, food packaging materials, and food-contact surfaces.</p>	<p>Provide a dequate 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</p>	(6)	<p>Verify by observation. Are fans blowing directly onto exposed food, food contact zones or packaging materials?</p> <p>Are fans clean? Does the plant use an HVAC system? If so, is there a PM plan for changing</p>	

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		packaging materials, and food-contact surfaces.		filters and cleaning the system? Are the vents clean?	
1.13.2.10	Buildings shall be reasonably free from excessive dust, heat, steam, condensation, vapors, smoke or fumes.		(6)	Verify by observation. Observe if there is proper ventilation, condensation dripping from ceilings, mold growth, exhaust fans not working properly, excessive amounts of dust accumulated on equipment and ledges, etc.	
1.13.2.11	Doors, windows, and other gateways shall be closed or properly protected with screens, air screens or other protective devices.	Provide, where necessary, a adequate screening or other protection against pests.	(7)	Verify by observation. Observe such things as doors propped opened, missing/torn screens from windows or doors, poorly sealed doors/dock overhead doors.	

REFERENCE LINKS

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