© 2020 Primus Group, Inc. All rights reserved

Primus Standard Audits - Questions and Expectations - v20.06

Good Manufacturing Practices Requirements

GOOD MANUFACTURING REQUIREMENTS - SECTION 1				
Section	**Q #**	**Question**	**Total Points**	**Expectations**
General	**1.1.1**	**Was the operation free from any significant threat to the safety of the product that may be considered critical and warrants an automatic failure? Explain. ANY DOWN SCORE IN THIS QUESTION RESULTS IN AUTOMATIC FAILURE OF THE AUDIT.**	**15**	**There should be no observation of any issue that the auditor considers a significant threat to the safety of the product. Issues include critical food safety situations that may not be considered in the audit template questions and conformance criteria; where a question and conformance criteria cover the topic of the issue within the audit, but the situation discovered warrants an automatic failure - the issue is noted in this question; an issue that is a serious threat to food safety (as opposed to a pre-requisite) and corrective actions are not being implemented are scored here.**
General GMP	1.2.1	Are all cleaning and maintenance chemicals (pesticides, sanitizers, detergents, lubricants, etc.) stored securely, safely and are they labeled correctly?	15	Chemicals are stored in a clean, designated (with a sign), secure (locked) area, and away from food and packaging materials and separated from the production areas. Spill controls should be in place for opened in use containers. Access to chemicals needs to be controlled, so that only workers who understand the risks involved, and have been trained properly, are allowed to access these chemicals.
General GMP	1.2.2	Are "food grade" and "non-food grade" chemicals used appropriately, according to the label and stored in a controlled manner?	10	All chemicals applied should be approved by the prevailing authority for their designated use and used according to label instructions. Only food grade lubricants should be used anywhere near product and packaging materials. "Food grade" and "non-food grade" materials should be stored in separate designated areas and adequately labeled. Grease guns and containers should be labeled adequately. Access to non-food grade materials should be limited to those entrusted with the correct use of chemicals.
General GMP	1.2.3	Are signs supporting GMPs posted appropriately?	10	Highly visible and understood signs supporting appropriate Good Manufacturing Practices (GMP's) (e.g., no eating, chewing, drinking or smoking, hand washing requirements, any specific clothing requirements, etc.) should be posted visibly and in the language of the workers (picture signs are allowed) to remind them of proper practices. Signs should especially be located at the entrance(s) to the production/storage areas, restrooms and break areas.
General GMP	1.2.4	Are the necessary food defense controls implemented in the operation?	10	The operation should have implemented the necessary controls for preventing intentional contamination of the product and high-risk areas. These measures should be based on the risk associated with the operation, as detailed in the food defense plan (1.9.2). Some high-risk areas of the facility include: personnel, visitors, contractors, computers, raw material receipt (raw materials, product and packaging), trucks (incoming and outbound), water sources, storage areas for product, materials, chemicals, production areas, shipping areas, etc.

© 2020 Primus Group, Inc. All rights reserved

Pest Control	1.3.1	Are products or ingredients free of pests (e.g., insects, rodents, birds, reptiles, mammals) or any evidence of them? **ANY DOWN SCORE IN THIS QUESTION RESULTS IN AN AUTOMATIC FAILURE OF THE AUDIT.**	15	Any evidence of pests (e.g., insects, rodents, birds, reptiles, mammals) in products or ingredients are indicators of contamination, posing physical and microbiological hazards. Evidence of contamination constitutes an automatic failure of the audit.
Pest Control	1.3.2	Are packaging supplies free of pests (e.g., insects, rodents, birds, reptiles, mammals) or any evidence of them? **ANY DOWN SCORE IN THIS QUESTION RESULTS IN AN AUTOMATIC FAILURE OF THE AUDIT.**	15	Packaging supplies are considered food-contact surfaces and therefore need to be free of pests (e.g., insects, rodents, birds, reptiles, mammals). Evidence of contamination constitutes an automatic failure of the audit.
Pest Control	1.3.3	Are plant and storage areas free of pests (e.g., insects, rodents, birds, reptiles, mammals), or any evidence of them?	15	Plant and storage areas should be free of pests (e.g., insects, rodents, birds, reptiles, mammals) to prevent possible physical or microbiological contamination.
Pest Control	1.3.4	Is the area outside the facility free of evidence of pest activity?	10	All areas should be free of recurring/existing external pest activity. Evidence of rodents, animals (e.g., dogs and/or birds) in active areas outside the facility is an indication of a pest pressure on the whole building. All possible measures should be taken to avoid attracting pests to the facility perimeter.
Pest Control	1.3.5	Is there an effective pest control program in place? **ANY DOWN SCORE IN THIS QUESTION RESULTS IN AN AUTOMATIC FAILURE OF THE AUDIT.**	15	There should be an effective, proactive pest control program (in-house or contracted) to control rodents (also insects, reptiles and birds where necessary) and prevent infestation. Any down score will result in an automatic failure.
Pest Control	1.3.6	Are pest control devices located away from exposed raw materials, work-in-progress, ingredients (including water and ice), finished goods and packaging, and poisonous rodent bait traps are not used within the facility?	10	Pest control devices should be located away from exposed food products, packaging materials, or equipment to prevent any physical or microbial contamination. Poisonous rodent bait traps should not be located within the facility.
Pest Control	1.3.7	Are pest control devices maintained in a clean and intact condition and marked as monitored (or bar code scanned) on a regular basis?	5	All pest control devices should be maintained clean, in working order and replaced when damaged so that they will accomplish their intended use. Date of inspections should be posted on the devices, as well as kept on file (unless barcode scanned).
Pest Control	1.3.8	Are interior and exterior building perimeter pest control devices adequate in number and location?	5	The distance between traps should be determined based on the activity and the needs of the operation. As a reference, the following guidelines can be used to locate traps. Inside pest control: mechanical traps every 20-40 ft (6-12 m). Outside building perimeter: mechanical traps and/or bait stations every 50-100 ft (15-30 m). Interior and exterior traps should be placed on both sides of doorways. Land Perimeter (if used): within 50 ft (30 m) of buildings and at 50-100 ft (15-30 m).
Pest Control	1.3.9	Are all pest control devices identified by a number or other code (e.g. barcode)?	5	All traps should be clearly identified (e.g. numbered) to facilitate monitoring and maintenance. All traps should be located with wall signs (that state the trap number and also that they are trap identifier signs).
Pest Control	1.3.10	Are all pest control devices effective and bait stations secured?	5	All devices should be correctly orientated with openings parallel with and closest to walls. Bait stations should be locked and tamper resistant in some way (e.g., locks, screws, etc.). Bait stations should be secured to prevent removal and only block bait (no pellets) should be used. If mounted on slabs, then wall signs should be used to aid location.

Storage Areas & Packaging Materials	1.4.1	Does the facility layout ensure separation of ingredients (including ice), products, and packaging stored to prevent cross contamination (this includes iced product pallets stored above pallets of product without adequate protection as well as any allergen cross contamination issues)?	15	All raw materials, products and packaging should be stored off the ground (i.e. on racks, pallets, shelves, etc.). Materials should be properly protected during storage to prevent contamination (e.g., away from chemicals, battery chargers, etc.). Raw materials, finished product and packaging materials should be stored in separate areas to prevent cross contamination. When separate room storage is not possible, the auditor should assess the risks, especially with respect to cross contamination. Special attention should be given to ice storage and where relevant allergen storage.
Storage Areas & Packaging Materials	1.4.2	Is the storage area completely enclosed?	10	All raw material and finished goods should be stored inside. Food contact packaging should be stored inside. Non-food contact packaging should be stored inside, but if stored outside, should be shroud protected.
Storage Areas & Packaging Materials	1.4.3	Is the facility's use restricted to the storage of food products?	5	To avoid any adulteration or possible cross contamination from other items, only essential products, packaging, chemicals and equipment should be stored in the facility.
Storage Areas & Packaging Materials	1.4.4	Are rejected or on hold materials clearly identified and separated from other materials?	10	Rejected or on hold materials should be kept separate and identified from other materials to avoid accidental use or shipping. Make sure that the pallet or rejected product is properly marked i.e. date item was placed on hold, reason and name of the person placing the item on hold. A separate area also helps ensure that there are no accidental uses or shipping of on hold materials.
Storage Areas & Packaging Materials	1.4.5	Are raw products, work in progress, ingredients (including water and ice), finished goods and food contact packaging within accepted tolerances for spoilage and free from adulteration? **ANY DOWN SCORE IN THIS QUESTION RESULTS IN AN AUTOMATIC FAILURE OF THE AUDIT.**	15	Raw products, work in progress, ingredients, finished goods, and food contact packaging and food contact surfaces should be free from spoilage, adulteration and/or gross contamination (21 CFR 110.3g). If legislation exists, then the contamination should be viewed against this legislation (e.g., USDA Grading Standards often include decay tolerances). Spoilage and adulteration would include any physical, chemical or biological contamination including blood and bodily fluids. Measures should be taken to prevent any known or reasonably foreseeable hazard (e.g., Clostridium botulinum in mushrooms). Ice should be made from potable water. This question is designed to allow an auditor to halt an audit when finding gross contamination issues.
Storage Areas & Packaging Materials	1.4.6	Are all storage areas clean, especially the racking structures, lights, ceilings, floor areas by the walls and other hard to reach areas?	10	All storage areas should be kept clean and free from dust, debris and other extraneous materials. This helps avoid pest attraction and contamination of products, ingredients or packaging. Pest activity is easier to detect in a clean area.
Storage Areas & Packaging Materials	1.4.7	Are materials (commodities, packaging, ingredients, processing aids, work in progress, etc.) properly marked with rotation codes (receipt dates, manufacture dates, etc.)?	5	All materials should be properly marked with receipt dates and/or tracking information (lot numbers, code dating) for traceability/recall and stock rotation purposes. This coding should be understood by all workers, in order to ensure FIFO and effective traceback/recall procedures.
Storage Areas & Packaging Materials	1.4.8	Are materials (commodities, packaging, ingredients, processing aids, work in progress, etc.) rotated using FIFO policy?	5	All materials should be rotated using First in First Out (FIFO) policy to ensure items are used in the correct order they are received and within their allocated shelf-life. Materials should be clearly marked or labeled with some kind of rotation coding that is understood by all workers, in order to ensure FIFO and effective traceback/recall procedures. Proper rotation of materials can prevent stock losses due to pest infestation, decomposition, mold and other problems associated with prolonged storage.

Storage Areas & Packaging Materials	1.4.9	Are storage areas at the appropriate temperatures for the specific products being stored?	10	Products should be stored at the correct temperatures. This might mean that the operation has several cold store chambers set at different temperatures.
Operational Practices	1.5.1	Does the process flow, facility layout, worker control, utensil control, internal vehicle use, etc. ensure that finished (processed) products are not contaminated by raw (unprocessed) products?	15	Incoming raw materials should not be a source of contamination to work-in-progress and/or finished goods. Raw product should not be allowed to touch processed product. Raw product handlers should not contaminate finished/processed product - clear controls required. Separate coded utensils required for finished/processed products relative to raw products. Forklift truck should either be dedicated to one area or the wheels are cleaned when going from raw to processed goods areas.
Operational Practices	1.5.2	Are all exposed materials (product, packaging, etc.) protected from overhead contamination (e.g. ladders, motors, condensation, lubricants, walkways, loose panels, degrading insulation, etc.)?	15	Ceilings and/or any overhead fixtures above storage are free from condensation or dust. Ladders or walkways (catwalks) above exposed product or packaging material have kick plates at least 3.5 inches (8 cm) high and are covered in some way that protects the product underneath. Drips or condensate (e.g., from roof, fixtures, ducts, pipes, etc.) should not contaminate food, food contact surfaces or packaging material. Adequate measures should be in place to protect from condensate.
Operational Practices	1.5.3	Are production areas completely enclosed?	15	Production areas are enclosed (walls and roof) with doors either closed or pest protected in some way (e.g., strip curtains, air curtains, speed doors, etc.). Walls can be solid, fine mesh or any other pest proof material, with openings that should be no greater than 1/8 inch (3 mm) or smaller.
Operational Practices	1.5.4	Are production areas clean and well maintained; especially lights, ducts, fans, floor areas by the walls and equipment, and other hard to reach areas?	15	Production areas should be maintained in a clean and sanitary condition.
Operational Practices	1.5.5	Is all re-work / re-packaging handled correctly?	10	Re-work product should be labeled properly to avoid mistaking it for other products and maintaining traceability. Re-work should be handled to prevent contamination from the environment or from other products.
Operational Practices	1.5.6	Are raw ingredients examined before use?	5	Raw materials should be inspected before use, including looking for foreign material contaminants, rotting materials and any unusual issues (e.g., unsealed packaging, visible residues, etc.).
Operational Practices	1.5.7	Are finished products coded (carton and unit packaging) for the day of production?	5	Finished product should be lot coded in order to ensure an effective trace back and recall program and also for inventory control. If required by buyer or legal requirements, packaging labeling should include information about recommended storage conditions and usage.
Operational Practices	1.5.8	Are foreign material control methods (e.g. metal detectors, metal traps, magnets, visual inspection, x-ray machines, etc.) in place and regularly tested (where relevant) to ensure proper operation?	10	Foreign material control systems should be in place where needed. These systems should be frequently checked (recorded) to ensure that they are working correctly with a functioning rejection device (e.g., belt, air jet, etc.). Foreign material issues should be noted as deviations.
Operational Practices	1.5.9	Does the facility use the appropriate test strips, test kits or test probes for verifying the concentrations of anti-microbial chemicals (product contact water, terminal sanitizers, dip stations, etc.) being used, are they in operational condition and are they being used correctly?	15	The strength (concentration, pH, etc.) of anti-microbial chemicals should be checked on a regular basis and recorded. All test solutions/strips should be within date code, appropriate for the concentrations used and stored correctly. If the ORP meter controls the pumps that are injecting the anti-microbial and/or buffer, there should be an independent calibrated ORP probe or other method (e.g., test strip papers, titration) in order to verify injector readings.

Operational Practices	1.5.10	Are hand washing stations adequate in number and appropriately located for worker access and monitoring usage?	15	Enough stations, in working order, should be provided to ensure efficient worker flow (1 per 10 people on site) and be available to all workers and visitors. Hands free is an optimum system for food establishments. Hand washing stations should be located within close proximity of toilet facilities area and lunchroom area. For operations packing or processing items, stations should be accessible from the production areas.
Operational Practices	1.5.11	Are hand washing stations in working order, have water of suitable temperature and pressure, adequately stocked (e.g. disposable towels, unscented soap, etc.) and restricted to hand washing purposes only?	15	Hand washing stations should be used only for hand washing (no storage, food handling, etc.), have water of suitable temperature and pressure and be maintained in good working order with proper drainage. They should be properly stocked with liquid unscented/non-perfumed, neutral or antiseptic soap. Single use paper towels should be used and units properly located; hot air driers are acceptable if properly located. There should be an adequate stock of soap and paper towels.
Operational Practices	1.5.12	Are toilet facilities adequate in number and location and are they adequately stocked (e.g. toilet paper, disposable towels, unscented soap, etc.)?	15	At least one stall per 15 workers. Toilet facilities are available to all workers and visitors and should not open directly into production or storage areas. Restrooms should be stocked with toilet paper, unscented/non-perfumed soap and towels.
Operational Practices	1.5.13	Are secondary hand sanitation stations (e.g., touch-free dispensers) adequate in number and location, and are the stations maintained properly?	5	Secondary hand sanitation is required for items that may be “ready-to-eat” (e.g., herbs, tomatoes, edible flowers, etc.). Secondary hand sanitation (hand dips, gels or sprays) does not replace hand washing requirements (lack surfactant qualities). Secondary hand sanitation stations should be unscented/non-perfumed, have 60% to 95% ethanol or isopropanol and conveniently located in traffic zones but should not be obstructive. Strength checks do not need to be performed for commercially purchased sanitizers that have been purchased already mixed.
Operational Practices	1.5.14	Are foot baths, foamers or dry powdered sanitizing stations adequate in number and location, and are the stations maintained properly?	3	Foot (boot) stations (foamers, foot dip mats, baths, sprays) should be located in areas when crossing into a "clean" zone from an area of potential contamination (e.g., from outside into the packing zone). Stations should be checked and replenished as necessary to ensure effectiveness.
Operational Practices	1.5.15	Are single service containers used for their intended purpose only so that potential cross contamination is prevented?	5	Single service containers are used for their intended purpose only (food contact use, not to hold nuts, bolts, trash or other miscellaneous items) and should not be re-used. Returnable plastic containers (RPCs) (e.g., CHEP, IFCO) should be treated like single service containers and only used for product. If a single service container is used for any other reason than the storage and distribution of food, it should be clearly differentiated as such (e.g., painted another color and labeled).
Operational Practices	1.5.16	Are re-usable containers cleanable and clearly designated for the specific purpose (trash, raw product, finished product, re-work, ice, etc.) such that cross contamination is prevented?	5	Identification of reusable containers (color-coded or labeled) in the language understood by the workers) helps to minimize contamination of products. All re-usable containers should be able to be cleaned (smooth, non-porous, non-toxic) or used with a clean liner to protect against contamination. Bins, boxes, hoppers, barrels, baskets, etc. used for the storage of raw materials, work in progress, ingredients, finished goods or packaging of these items should be stored to ensure that they remain clean and uncontaminated (e.g., covered clean).
Operational Practices	1.5.17	Are devices used to measure, regulate or control temperature, pH, acidity, water activity, and other conditions that affect food safety, working properly and adequately maintained?	3	Thermometers, pH meters, ATP systems, etc., should be working correctly. Where necessary, equipment should be calibrated.

Worker Practices	1.6.1	Are workers washing and sanitizing their hands before starting work each day, after using the restroom, after breaks, before putting on gloves and whenever hands may be contaminated?	15	Worker conformance to hand washing and sanitizing procedures should be assessed as washing hands is the first step in avoiding food contamination. Workers should be observed washing their hands prior to beginning work, after breaks, after using the toilet, before putting on gloves, and whenever hands may have become a source of contamination (e.g., after eating, after using a handkerchief or tissue, smoking, drinking, etc.).
Worker Practices	1.6.2	Are workers' fingernails clean, short and free of nail polish?	5	Fingernails can harbor dirt and debris and can be a source of cross contamination. Therefore, nails should be clean and short to reduce the risk of cross contamination. Fingernail polish and false nails should not be worn, even when gloves are worn.
Worker Practices	1.6.3	Are workers who are working directly or indirectly with food, free from signs of boils, sores, open wounds and are not exhibiting signs of foodborne illness?	10	Workers who have exposed boils, sores, exposed infected wounds, foodborne illness or any other source of abnormal microbial contamination should not be allowed to work in contact with the product, packaging or food contact surfaces.
Worker Practices	1.6.4	Are workers wearing effective hair restraints that contain all hair?	5	Wearing effective hair restraints (i.e. hair nets, beard nets), is required in all operations where product is exposed, including with products that require cooking prior to consumption. Hair restraints prevents hair from falling into the product and prevents workers from unintentionally touching hair, then touching product. Baseball caps and head coverings are allowed in packinghouses, only if they are clean and worn with a hair net covering them that is clearly visible and restrains all hair. Wearing effective hair restraints is required in all operations where product is exposed.
Worker Practices	1.6.5	Is jewelry confined to a plain wedding band and watches are not worn?	5	Workers are not observed wearing jewelry (including earrings, ear gauges, necklaces, bracelets, rings with stones, rings or studs in nose, lip and eyebrow, watches) in the facility. Plain wedding bands are the only exception. Other examples of foreign items may be a source of foreign material contamination include studs, false eye lashes, eye lash extensions, etc.
Worker Practices	1.6.6	Are all workers wearing protective outer garments suitable for the operation (e.g., appropriate clean clothes, smocks, aprons, sleeves, non-latex gloves)?	10	Outer garment policy should consider potential for cross contamination, customer requirements, production risk, product type, etc. Workers should not wear personal clothes with sequins, pom-poms, fur, etc. No sleeveless tops without an over garment. Where dedicated protective clothing is not required/worn, it must be clear that outer street clothes are clean and not a potential source of contamination. Gloves should be non-latex, intact and appropriate for purpose.
Worker Practices	1.6.7	Do workers remove protective outer garments (e.g., smocks, aprons, sleeves, and gloves) when on break, before using the toilets and when going home at the end of their shift?	5	When worn, protective clothing (e.g., aprons, smocks, sleeves and gloves) should be removed when workers leave the work area (e.g., when they go to the toilet facility, lunchroom, outside, etc.). Workers cannot smoke, eat, go outside the building or use the restroom while wearing these garments.
Worker Practices	1.6.8	Is there a designated area for workers to leave protective outer garments (e.g., smocks, aprons, sleeves, and gloves) when on break and before using the toilets?	5	There should be a designated area for workers to leave protective clothing when they are worn (e.g., aprons, smocks, sleeves, and gloves). Workers are observed using the designated area when they leave the work area (e.g., when they go to the toilet facility, lunchroom, outside, etc.).

Worker Practices	1.6.9	Are worker personal items being stored appropriately (i.e. not in the production or material storage area)?	5	Workers should have a designated area for storing personal items such as coats, shoes, purses, medication, phones, etc. Lockers or cubbies are ideal. Areas set aside for workers' personal items should be far enough away from production and material storage area(s) to prevent contamination and avoid food security risks.
Worker Practices	1.6.10	Is smoking, eating, chewing and drinking confined to designated areas, and spitting is prohibited in all areas?	5	Smoking, chewing tobacco, chewing gum, drinking and eating is permitted in designated areas that are away from production and storage areas. Spitting should be prohibited in all areas. Smoking should not be permitted in eating and drinking areas. Drinking is not permitted near the production line.
Worker Practices	1.6.11	Is fresh potable drinking water readily accessible to workers?	10	Fresh potable water meeting the quality standards for drinking water (e.g. US EPA) should be available for workers on-site to prevent dehydration, following local and national laws. Portable drinking water dispensers should be designed, constructed and maintained in a sanitary condition, capable of being closed, and equipped with a tap. The water should be dispensed in single-use drinking cups or by fountains in production areas. Common drinking cups and other common utensils are prohibited.
Worker Practices	1.6.12	Are all items removed from garment (shirt, blouse, etc.) top pockets, and unsecured items are not worn (e.g., pens, glasses on top of head, Bluetooth devices, etc.)?	3	There should be no items stored in workers' top pockets. Items in pockets and otherwise unsecured have the potential to fall into the product.
Worker Practices	1.6.13	Are first aid kits adequately stocked and readily available in the facility, and are blue band aids used?	5	First aid kit(s) should be adequately supplied to reflect the kinds of injuries that occur (including any chemicals stored on-site) and should be stored in an area where they are readily available for emergency access. Date-coded materials should be within dates of expiration. Bandages used in food facilities should be blue in color for easy visual detection, with a metal strip behind the wound pad for detection on lines with metal detectors. Gloves should be worn over all band aids on hands.
Equipment	1.7.1	Are food contact equipment surfaces free of flaking paint, corrosion, rust and other unhygienic materials (e.g., tape, string, cardboard, etc.)?	15	Food contact surfaces on equipment should not have flaking paint, corrosion, rust and/or unhygienic materials, as they can pose foreign material and/or microbiological hazards. Food contact surfaces should be made of non-toxic, non-porous materials. Surfaces should be maintained in good condition.
Equipment	1.7.2	Are non-food contact equipment surfaces free of flaking paint, corrosion, rust and other unhygienic materials (e.g., tape, string, cardboard, etc.)?	10	Flaking paint, corrosion, rust and/or unhygienic materials should not be present on any non-food contact surfaces. Where possible, equipment framework is not penetrated by bolts or studs.
Equipment	1.7.3	Does food contact equipment design, placement, and condition (e.g., smooth surfaces, smooth weld seams, non-toxic materials, corrosion-resistant, no wood or other absorbent materials) facilitate effective cleaning and maintenance?	15	Equipment should be made of appropriate materials that can be easily cleaned and maintained, that are not porous or toxic and can withstand the cleaning process. Equipment should be designed to allow access and easy cleaning (without hollow areas, cleanable design, smooth welds).
Equipment	1.7.4	Are thermometers (independent of thermostat probes) present in all coolers and freezers?	5	All cold rooms should have thermometers to monitor the temperature accurately within the area. The monitoring thermometers should be independent from the thermostat probe.
Equipment	1.7.5	Are all thermometers non-glass and non-mercury?	10	Thermometers should not pose a foreign material risk. Both glass and mercury could be contaminants if the thermometer was to break.

Equipment Cleaning	1.8.1	Are food contact equipment surfaces clean?	15	Unsanitary food contact surfaces (zone 1) can directly lead to contamination of the product. Food debris, bio films, excessive dust, etc., should be cleaned off equipment and facility surface in order to reduce the overall facility bio-burden.
Equipment Cleaning	1.8.2	Are non-food contact equipment surfaces clean?	10	Unsanitary non-food contact surfaces (zones 2, 3) can indirectly lead to contamination of the product. Food debris, bio films, excessive dust, etc., should be cleaned off equipment and facility surface in order to reduce the overall facility bio-burden.
Equipment Cleaning	1.8.3	Are items (totes, bins, etc.) that are used to hold or store product clean?	10	All storage containers should be cleaned and sanitized as frequently as necessary in order to prevent contamination. Cleaning type and frequency should be determined based on the products and processes involved. Containers should be kept covered and protected during storage.
Equipment Cleaning	1.8.4	During cleaning, are food products and packaging materials protected from contamination?	15	To avoid contamination, food products and packaging material should be covered, screened, protected in some way or removed from the area while cleaning is taking place.
Equipment Cleaning	1.8.5	Are cooling units, including coils in coolers and freezers, clean and free of aged, dirty ice?	5	Cooling coils can build-up dust and other contaminants. They should be included in the master sanitation schedule.
Equipment Cleaning	1.8.6	Are all fan guards dust-free and the ceiling in front of the fans free of excessive black deposits?	5	Fan guards should be dust-free to prevent cross contamination. The ceiling in front of the fans (especially cooler units) should be free from excessive black deposits.
Equipment Cleaning	1.8.7	Is stored equipment that is not used on a daily basis stored in a clean condition with food-contact surfaces protected and/or are they retained on cleaning schedules in some manner, even though they are not in use?	10	Equipment should be stored appropriately (e.g., covered, protected and off the floor) to prevent inappropriate use and cross contamination. Alternatively, unused equipment can be left on sanitation and maintenance programs.
Equipment Cleaning	1.8.8	Are all utensils, hoses, and other items not being used, stored clean and in a manner to prevent contamination?	10	All utensils, hoses and other items not being used are stored clean and in a manner to prevent contamination (off ground, dedicated areas, etc.). Hoses should be stored coiled, off the floor and ideally used in such a manner that ground contact is avoided.
Equipment Cleaning	1.8.9	Are maintenance tools that are used in the production and storage areas of the facility clean, sanitary and corrosion free?	3	Tools that are used for repairing equipment in the production and storage areas should be appropriately stored to ensure they do not pose a risk of direct or indirect contamination when in production or and storage areas, clean, free of corrosion and in good working for order i.e. fit for their intended use.
Equipment Cleaning	1.8.10	Are excess lubricants and grease removed from the equipment and are lubricant catch pans fitted where needed?	5	Dripping caused by over lubricating is a potential chemical contaminant to the product. Frequent lubrication using minimal material and use of drip pans are control examples. Note, food grade materials are designed for incidental food contact. All efforts should be made to avoid these materials getting onto the product and packaging.
General Cleaning	1.9.1	Are spills cleaned up immediately?	10	To prevent the attraction of pests, reduce cross contamination and maintain a sanitary environment, all spills must be cleaned up immediately.
General Cleaning	1.9.2	Are waste and garbage frequently removed from production and storage areas?	5	Waste and garbage must be removed on a frequent basis to prevent attraction of pests, reduce cross contamination, reduce bad odors and maintain a sanitary environment.

General Cleaning	1.9.3	Do floor drains flow in a manner that prevents contamination (e.g., from high to low risk areas, from high risk directly to drain system), are they covered, appear clean, free from odors and are well maintained?	5	Floor drains should flow in a manner that prevents contamination, be cleaned on a frequent basis (daily in wet facilities) to remove residues, prevent growth of harmful bacteria and allow for proper drainage. Drains should be covered, and sides and bases should be made of a smooth material that does not trap debris.
General Cleaning	1.9.4	Do high level areas, including overhead pipes, ducts, fans, etc., appear clean?	10	Overhead areas should be cleaned as required to prevent potential contamination.
General Cleaning	1.9.5	Are plastic strip curtains maintained in good condition, kept clean and mounted so that the tips are not touching the floor?	5	Plastic strip curtains may be a source of contamination if they are not maintained clean, intact and fitted properly (so tips are not touching the floor).
General Cleaning	1.9.6	Does personal protection equipment (PPE) for the sanitation crew meet label requirements of chemicals used, and is it in good condition and stored to prevent cross contamination to raw products, work in progress, ingredients, finished goods or packaging?	3	The sanitation crew should wear appropriate safety equipment to avoid any health problems from the chemicals that they use during the cleaning process. All safety equipment should be stored to prevent contamination to raw products, work in progress, ingredients, finished goods or packaging.
General Cleaning	1.9.7	Is cleaning equipment maintained clean and stored properly?	5	Adequate cleaning equipment should be available, free of debris, cleaned and stored correctly between use.
General Cleaning	1.9.8	Is cleaning equipment identified in order to prevent potential cross contamination issues (e.g., production, maintenance, outside, restroom equipment)?	10	Cleaning equipment used for production areas need to be separated (physically and visually) from cleaning equipment used in non-production areas in order to prevent cross contamination from occurring. Sometimes even within production areas, there is a need to differentiate equipment even further (e.g., splitting flooring cleaning materials from equipment cleaning materials).
General Cleaning	1.9.9	Are all items used for sanitation appropriate for their designated purpose (e.g., no steel wool, metal bristles, etc.)?	5	Sanitation equipment should be constructed of appropriate materials that will not contaminate the product. Avoid anything that flakes, is made of pervious materials, is of a similar color as the products, corrodes or might damage the equipment or facility.
General Cleaning	1.9.10	Are toilet facilities and hand washing stations clean?	15	Toilet facilities should be cleaned and sanitized at least daily. Soiled tissue should be flushed down the toilet (not placed in trash cans and/or on the floor).
General Cleaning	1.9.11	Are worker break facilities clean, including microwaves and refrigerators, and no rotting or out of date foodstuffs?	5	All worker break facilities should be clean in order to prevent the attraction of pests. Temperature sensitive foods should be stored in cold boxes or provided refrigerators. Periodic cleaning includes inside microwaves, inside and behind refrigerators, behind and on top of all vending machines, tables, chairs, and lockers to prevent potential pest harborage that may affect the product.
General Cleaning	1.9.12	Is the maintenance shop organized, with equipment and spares stored in a neat and tidy fashion?	5	The maintenance shop should be clean and well organized. An unclean shop can result in cross contamination and pest attraction. Any food consumption in the maintenance shop should be in a designated area that does not pose a risk to tools and equipment.
General Cleaning	1.9.13	Are internal transport vehicles (e.g., forklifts, bobcats, pallet jacks, carts, floor cleaners, etc.), clean, do not emit toxic fumes and are being used in a sanitary manner?	5	Internal transport vehicles (e.g., forklifts, bobcats, pallet jacks, carts, floor cleaners, etc.) should be part of the sanitation program, maintained clean and not allowed to be a vector of cross contamination. Vehicles used in food areas should not be gasoline or diesel powered. Propane (LPG) powered vehicles are acceptable, while electric powered are ideal.
General Cleaning	1.9.14	Are shipping trucks clean and in good condition?	5	Unsanitary (e.g., unclean, damaged insulation, etc.) shipping trucks could be a growth niche for bacteria and a foreign material hazard.

Buildings and Grounds	1.10.1	Are all lights in the facility that could potentially contaminate raw materials, work in progress, ingredients (including ice), finished goods, equipment or packaging shielded, coated or otherwise shatter resistant to protect product from contamination in the event of breakage?	15	All glass lights in the facility that can potentially contaminate finished products, raw materials (e.g. seeds, transplants, soil, media), equipment, or packaging should be shielded, coated or manufactured of shatter-resistant materials to protect product from contamination in the event of a breakage. This includes, but is not limited to items such as light bulbs, emergency lights, windows, truck loading lights (dock lamps), insect trap lights, forklift lights, lights in bathrooms or maintenance shops that open into the production area, etc. End piece fittings on tube lights should be secure. Precautions should be taken to prevent glass contamination in the event of glass breakage.
Buildings and Grounds	1.10.2	Has the operation eliminated or adequately controlled any potential metal, glass or brittle plastic contamination issues?	10	All foreign material risks must be either removed and/or accounted for and controlled. Examples include metal filings (maintenance), office windows, PC screens, brittle plastic from any source, staples, etc.
Buildings and Grounds	1.10.3	Has the facility eliminated the use of wooden items or surfaces?	5	Wood is a porous material and can harbor bacteria. It cannot be cleaned or sanitized effectively. Wooden materials can also splinter and pose a risk of physical contamination. Wet and high humidity areas should not be constructed of wood.
Buildings and Grounds	1.10.4	Is there adequate lighting in the production and storage areas?	5	Proper lighting is necessary for inspection and sanitation procedures to take place. This includes all areas where food is examined, manufactured, processed, packed, or held and where equipment or utensils are cleaned, maintenance areas, restrooms, etc.
Buildings and Grounds	1.10.5	Is ventilation adequate to control dust, condensation, odors and vapors?	10	Ventilation systems (cooling and heating) should be sufficient to control condensation, mold, dust, odors and vapors so that conditions do not exist where raw materials, work in progress, ingredients or packaging materials may be contaminated or tainted. Ventilation equipment should be balanced to provide an adequate air exchange rate to prevent condensation on walls, ceilings or other surfaces in production areas. Ideally, positive air pressure is employed in processing operations.
Buildings and Grounds	1.10.6	Are floor surfaces in good condition, with no standing water, no debris trapping cracks and are they easy to clean?	10	Floor surfaces should be impervious to water, non-absorbent, clean easily and resist to wear and corrosion. Exposed aggregate is hard to clean and will get progressively worse. Floors should be free of wide and/or deep cracks.
Buildings and Grounds	1.10.7	Are the floor drains where they are needed for drainage and cleanup?	5	Drains should be constructed and located in such a manner that they provide adequate drainage in all areas where floors are subject to flood-type cleaning or where normal operations release or discharge water or other liquid waste on the floor. Drains should flow from processed to raw to avoid contamination in processing plants. Facilities that are washing product should have adequate drainage. Discharge water from sinks should not run directly onto the floor. Not applicable in dry facilities with no drains.
Buildings and Grounds	1.10.8	Are closed doors, and windows to the outside pest-proof?	10	Doors, windows, louvers and screens should be maintained, doors should fit tightly with a maximum allowable gap of 1/8 inch (3 mm). Special attention should be given to the maintenance of weather strips. Air curtains and self-closing devices where used, should be operating properly.
Buildings and Grounds	1.10.9	In temperature controlled environments, are docks enclosed and dock doors fitted with buffers/shelters to seal against trucks?	5	Buffers around dock doors should seal against trucks to maintain temperature management. This question should be scored for operations that are handling time/temperature control for safety items. In operations where goods are not time/temperature control for safety, then this question is only scored if the raised dock doors, levelers and buffers are fitted.

Buildings and Grounds	1.10.10	Are dock load levelers and buffers/shelters maintained in good condition, pest proof and debris free?	3	Product debris can attract pests to the area. Gaskets (weather strips) around load levelers should fit tightly to prevent pest entry. This question is applicable only when dock doors have been installed.
Buildings and Grounds	1.10.11	Are exterior walls free of holes to exclude pests, and are pipes, vents, and air ducts designed and protected in order to prevent pest entry (e.g., by using fine mesh)?	5	Walls should be free of holes, crevices and cracks to prevent pest infestations. If pipe holes are needed, they should be protected to avoid pest entry. Vents and air ducts should also be protected. Mesh size should be small enough to prevent insect entry.
Buildings and Grounds	1.10.12	Are interior walls and ceilings free of cracks and crevices to prevent pest harborage and allow proper sanitation?	5	It is important to keep the building in good repair to prevent the intrusion of pests. Damaged walls are difficult to clean and the exposed foam or polystyrene insulation can be a foreign material risk. Ceiling should be free from evidence of roof leaks (stains), holes or other damage, false ceilings are clean and accessible.
Buildings and Grounds	1.10.13	Is an 18" (46 cm) internal wall perimeter being maintained within the facility, with adequate access to these wall perimeters, thereby allowing inspection and cleaning?	5	Aisles and working spaces that are provided should be of adequate width to safely permit the monitoring of pest activity and for workers to perform cleaning and maintenance.
Buildings and Grounds	1.10.14	Is the exterior area immediately outside the facility, including roads, yards and parking areas, free of litter, weeds and standing water?	5	Litter, waste, refuse, uncut weeds or grass and standing water within the immediate vicinity of the building may constitute an attractant or breeding place for rodents, insects or other pests, as well as microorganisms that may cause contamination.
Buildings and Grounds	1.10.15	Are control measures being implemented for the outside storage of equipment, pallets, tires, etc. (i.e. out of the mud, pipe ends capped, stacked to prevent pest harborage, away from the building perimeter)?	5	Incorrectly stored pallets and equipment can provide areas for pest harborage and/or cross contamination. Equipment should be stored at least 4" (10 cm) off the ground and at least 24" (61 cm) away from the building perimeter. Workers should check the stored equipment periodically to ensure that it has not become a pest harborage area or dirty due to rains. Inventory checks should occur in order to ensure that these storage areas do not become full of unnecessary items. Outside storage areas should be within the scope of the pest control program.
Buildings and Grounds	1.10.16	Are pallets inspected to separate and replace dirty or broken pallets, and broken or dirty pallets are not in use?	5	Broken or split pallets can cause a physical hazard. Dirt, mud, food debris, chemical residues and other contaminants on the pallets can cause microbial contamination.
Buildings and Grounds	1.10.17	Is the area around the dumpster/cull truck/trash area clean?	3	The dumpster/cull truck/trash area should be located away from facility entrances, where traffic flow may be a source of cross contamination. The area around the dumpster/cull truck/trash area should be maintained in a clean condition. There should not be any spillage on the ground. There should not be any standing water or liquid seepage around the dumpster/cull truck/trash area and there should not be any foul odor present. The dumpster/cull truck/trash area should be cleaned on a regular basis.
Buildings and Grounds	1.10.18	Are outside garbage receptacles and dumpsters kept covered or closed?	5	All dumpsters and garbage receptacles should have a cover and be kept covered to prevent the attraction of insects, rodents and other pests. Fine mesh lids are acceptable. Just having the lids is not acceptable i.e. when not in use, the dumpsters and garbage receptacles should be closed. Dumpsters that are only used for dry non-food waste (e.g., paper, cardboard, etc.) are exempt from this requirement.
Buildings and Grounds	1.10.19	Are all water lines protected against back siphonage?	5	Back siphonage protection prevents potable water from coming into contact with unsafe water.
Buildings and Grounds	1.10.20	Is the on-site laboratory completely enclosed and separated from production and storage areas?	5	On-site laboratories should not be a source of possible contamination. Pathogen analysis should ideally be contracted to an external testing laboratory. N/A if there is no on-site laboratory.

© 2020 Primus Group, Inc. All rights reserved

FOOD SAFETY FILE REQUIREMENTS - SECTION 2				
Category	**#**	**Question**	**Total Points**	**Recommendations**
Management System	2.1.1	Is the operation registered as a food handling establishment?	10	There should be documentation from relevant state, federal or recognized country authority indicating the facility is registered or permitted as a food handling establishment. If the operation is exempt from registration requirements, the auditee should have written documentation to show this.
Management System	2.1.2	Is there a documented food safety policy detailing the company's commitment to food safety?	5	The documented policy should include a clear statement and detailed objectives of the company's commitment to meet the food safety needs of its products. Everyone in the company should understand the food safety policy and be aware of their role in ensuring that it is met. The policy should be posted in a public area and in the language understood by the workers.
Management System	2.1.3	Is there a designated person responsible for the operation's food safety program?	10	There should be a designated person/persons responsible for the operation's food safety program. They should have documented formal training or trained by someone that has formal credentials that is documented. This training should meet all state and federal requirements.
Management System	2.1.4	Is there an organizational chart showing all management and workers who are involved in food safety related activities and documentation (job descriptions) detailing their food safety responsibilities?	10	The documented organizational chart should show positions and reporting structure of workers whose activities affect food safety within the company. This document should also detail job functions and responsibilities related to food safety. Suitable alternates should be indicated in case someone can not perform the assigned responsibilities at certain moment. Document should be current and accurate.
Management System	2.1.5	Is there a food safety committee and are there logs of food safety meetings with topics covered and attendees?	5	Meetings that are either devoted to, or mention food safety issues, should be recorded as proof of company's ongoing commitment to food safety (minimum quarterly frequency). These meetings should detail Senior Management involvement in the Food Safety program.
Control of Documents and Records	2.2.1	Is there a written document control procedure (including document control register/record) describing how documents will be maintained, updated and replaced?	3	The document control procedure should show how controlled documents are to be written, coded, approved, issued and updated, and should also show how obsolete versions of documents are controlled. If using an electronic record keeping system, the procedure should also detail how electronic records are managed to control access, how changes to records are controlled, including who has edit rights and how electronic records are secured; i.e. back up system.
Control of Documents and Records	2.2.2	Is there a documented and implemented procedure that requires all records to be stored for a minimum period of 24 months (or greater if legally required) or for at least the shelf life of the product if it is greater than 24 months?	5	Food safety related records should be retained for auditing purposes and in case there are legal issues, customer queries, etc. There should be a procedure in place and all monitoring and process control records should be held for a minimum of 24 months regardless of the production item's shelf life. Any records required by law to be kept longer than 24 months should be kept for the legally mandated period. Any records pertaining to long life product should be kept at least for the duration of the shelf life of the product.

© 2020 Primus Group, Inc. All rights reserved

Control of Documents and Records	2.2.3	Are both paper and electronic food safety related documents and records created, edited, stored and handled in a secure manner?	5	Both paper and electronic documents and records that are part of the food safety program (e.g., procedures, policies, training records, testing results, monitoring records, etc.), should be created, edited, stored and handled in a secure manner that deters theft and prevents tampering when not in use. In the case of paper files, they should be generated using ink (not pencil), and if changes are made to records after initial entry, changes should be clearly legible and tracked, avoiding the use of corrective fluid. For electronic records, there should be access control and a back up of all files. When electronic records are amended, they should show what was amended, by whom and when (editing history). Records should be legible and accurate.
Control of Documents and Records	2.2.4	Are records maintained in an organized and retrievable manner?	3	All food safety records and documents should be stored in an organized manner, to allow for quick retrieval of records. This will aid in the detection of issues, the isolation of problems, and the identification of trends where attention is needed. Records should be accessible, even if the operation is seasonal.
Procedures and Corrective Actions	2.3.1	Is there a written and standardized procedure for creating Standard Operating Procedures (SOPs) and their content?	5	There should be a written document that describes how to create SOPs when required to cover any food safety related activities. SOPs should include a date and document number or reference code and detail what is to be done, how it is done, how often, by whom, what recordings are required and any immediate corrective action to perform when deficiencies occur. There should be clear evidence that this system is being followed, based on SOPs reviewed.
Procedures and Corrective Actions	2.3.2	Are the written procedures available to relevant users and is a master copy maintained in a central file?	5	The written procedures should be available to the users and other interested parties involved in performing the activities described in the procedures. A master copy of all SOPs and associated recording forms should be assembled and stored as a reference.
Procedures and Corrective Actions	2.3.3	Is there an incident reporting system, also known as a Notice(s) of Unusual Occurrence and Corrective Actions Log (NUOCA) ?	5	This record documents unusual and infrequent events, remedial actions and preventive actions. These might include incidents like foreign object findings, chemical spills, power outages, packaging issues, glass breakage, fires, etc., as well as any other serious incidents such as natural disasters (e.g., hurricanes, flooding, earthquakes, etc.).
Internal and External Inspections	2.4.1	Are there written procedures for handling regulatory inspections?	3	Written procedures for handling regulatory inspections allow workers to be aware of how to handle the inspection appropriately, including ensuring that the inspector is always accompanied, identified meeting space, rules on taking samples and photographs, how to follow-up after the inspection, corrective action requirements, etc.
Internal and External Inspections	2.4.2	Are there records of regulatory inspections and/or contracted inspections, company responses and corrective actions, if any?	5	Reports of previous inspections are on file and any deficiencies noted have been responded to (date of response, action taken, and signature). Inspections include regulatory (e.g., Federal and State) and third-party audits.

© 2020 Primus Group, Inc. All rights reserved

Internal and External Inspections	2.4.3	Are there documented calibration and/or accuracy verification procedures for measuring and monitoring devices used in the operations that are related to the safety of the product?	10	Equipment used for measuring and monitoring processes related to food safety and/or verification of ingredient label requirements (e.g., for weight or volume of ingredients) should be identified (i.e., catalog, roster, list) and SOPs should be available. Scales/weight or volume measuring devices should have regular verification of accuracy and/or calibration to ensure correct and accurate operation. Calibration procedures should describe the frequency of testing, the testing method and the acceptable range of variation. Corrective actions should be detailed when applicable. Legal requirements, manufacturer recommendations, best practice and experience of equipment drift help to determine the frequency.
Internal and External Inspections	2.4.4	Are calibration and/or accuracy verification records maintained and are they consistent with the requirements outlined in the SOP(s) for instruments and measuring devices requiring calibration?	5	Calibration and/or accuracy verification records should be available for all applicable equipment and show equipment identification, date, testing method, result (variation), and corrective actions
Internal and External Inspections	2.4.5	Is there a current certificate of inspection (or similar record) for backflow prevention assemblies on water lines into the facility?	3	There should be a backflow prevention device on main water lines entering the facility. There should be a record of a trained inspector verifying the principle backflow prevention system on an annual basis (unless there is a stated expiration on the
Release of Items/Product	2.5.1	Is there a documented procedure for handling on hold and rejected items?	5	There should be a documented procedure that explains how items (raw materials, packaging, work in progress, finished product, etc.) that have either been rejected or placed on hold should be handled, including the release of the on hold/rejected items. The procedure should identify who (position/title) is authorized to determine the disposition of materials that are placed on hold and include details on how the affected items are separated in terms of identification system (e.g., when, why, who), and any other physical separation needed to ensure that affected items are not commingled with other goods in such a way that their disposition is not clear.
Release of Items/Product	2.5.2	Is there a documented procedure for dealing with customer and buyer food safety complaints/feedback along with records and company responses, including corrective actions?	10	There should be a documented procedure detailing how to handle food safety related complaints, rejections and feedback. The procedure should require the recording to include (where applicable): • Date/Time of complaint/rejection/feedback • Who made the complaint/gave feedback, • Contact information, • Product description, • Where the product was purchased, • Amount of product, • Product code/date, • Nature of complaint/rejection/feedback, • Corrective actions (including details of cause if known) • Corrective actions taken to prevent reoccurrence. Where appropriate, a trend analysis of food safety feedback should be performed to assist with the development of corrective actions.

Supplier Monitoring/ Control	2.6.1	Is there a written procedure detailing how suppliers and service providers are evaluated and approved, and include the ongoing verification activities including monitoring?	10	The procedure for evaluation, approval and on-going verification, including monitoring of suppliers, on-site service providers and outsourced service providers should include the indicators to be considered for decision making (including food safety hazards), exceptions and the elements the providers should comply with to make sure they meet the defined specifications. This procedure should include monitoring requirements in order to remain approved, and methods for suspending and un-approving suppliers and service providers. The procedure should also detail what is needed (minimum requirements) in the case of working with a supplier in an emergency situation that has not yet been approved.
Supplier Monitoring/ Control	2.6.2	Is there a list of approved suppliers and service providers?	10	There should be a list of approved suppliers and service providers. All incoming products, ingredients, materials (including primary packaging) and services that relate to food safety should be sourced from approved entities. Where exceptions are made (e.g., market conditions), approval from management should be justified and documented.
Supplier Monitoring/ Control	2.6.3	Are there current written food safety related specifications for all incoming products, ingredients, materials (including primary packaging), services provided on-site, and outsourced services?	10	There should be written, detailed, up-to-date specifications for all incoming products, ingredients, materials (including primary packaging), services provided on-site, and outsourced services (including when exceptions will be allowed) that have an effect on food safety, addressing the required Good Agricultural Practices and/or Good Manufacturing Practices. Documented specifications should be easily accessible to workers. The specifications should be reviewed at least annually.
Supplier Monitoring/ Control	2.6.4	Does the organization have documented evidence to ensure that all incoming products, ingredients, materials, services provided on-site and outsourced service suppliers comply with the approval requirements and that all supplier verification activities (including monitoring) are being followed, as defined in the supplier approval procedure?	15	The organization should have the required documentation for approved suppliers to ensure that they are complying with the established supplier/service provider approval procedures, contracts, specifications, regulatory requirements and best practice guidelines. Supplier verification documents should demonstrate that the ongoing approval requirements detailed in 1.7.3 are being met (e.g., third party audits, certificates of analysis, reviews of supplier records, etc.).
Traceability and Recall	2.7.1	Is there a document that indicates how the company product tracking system works, thereby enabling trace back and trace forward to occur in the event of a potential recall issue?	10	The tracking system should be shown in writing or in the form of a flow diagram and demonstrate the product tracking system that is used by the operation. The system should be able to show that it can trace back to the supplier(s) of materials including commodities, packaging, ingredients, processing aids, work in progress, etc., and also show that the system can trace forward and indicate which customer(s) received products. This is usually accomplished by lot coding materials throughout a process and recording these lot codes at different points in the process. The traceability system should be in evidence when touring the operation and also when checking paperwork, and should also include any product that goes through an outsourced process. The auditor should choose a finished product lot code to test the traceability system and have the auditee demonstrate how the code traces back to raw material supplier(s) and traces forward to the customer(s).

Traceability and Recall	2.7.2	Does the organization have a documented recall program including procedures, recall team roles and contact details, external contact listings, requirement for recall effectiveness checks, explanation of different recall classes and handling of recalled product?	15	There should be a written procedure describing how to perform a product recall, a list of recall team members and their contact details, responsibilities and alternates, a referral to customer and supplier contact details, handling of recalled product, explanations of relevant laws (e.g., product withdrawal, recall classes if USA is involved as a country of production or destination, etc.).
Traceability and Recall	2.7.3	Is testing of recall procedures (including trace back) performed and documented at least every six months, and the company can demonstrate the ability to trace materials (one step forward, one step back) effectively?	10	Testing of recall procedures should be performed at least every six months. (For short season crops where the operation runs 6 months or less throughout the year, only one mock recall is required.) Where two mock recalls per year are required, one of the mock recalls should include the primary packaging as part of the exercise. The steps taken to conduct the mock recall as well as the records utilized to demonstrate the program is effective, should be consistent with the scenario identified. Documentation should indicate the date and time the mock recall was initiated, the product or material chosen, the scenario, amount of product produced, affected lot ID's (date code(s), lot code(s), etc.), amount located, and percent located. Mock recall documentation should include copies of documentation that support the trace (forward and back depending on the scenario) from the affected finished good lot through to the production run(s) affected, and therefore, showing if other lots are affected and which other customers might have received affected lot(s). Checks should be carried out to ensure that contact details exist for the affected customers. Documentation should also
Food Defense	2.8.1	Does the company have a documented food defense plan based on the risks associated with the operation?	5	The company should have a documented food defense plan that includes a written **vulnerability** assessment, and controls for the identified risks. Some high-risk areas of the facility include: building access, personnel, visitors, contractors, computers, raw material receipt (raw materials, product and packaging), trucks (incoming and outbound), water sources, storage areas for product, materials, chemicals, production areas, shipping areas, etc. The food defense plan creation should also meet any national or local regulations (including management oversight and approval). Based on this assessment, the operation should create monitoring, corrective action and verification procedures (where appropriate). These procedures should note the recording requirements of the food defense plan. The plan should be reviewed at least once every 12
Food Defense	2.8.2	Is there a current list of emergency contact phone numbers for management, law enforcement and appropriate regulatory agencies?	3	The operation should have a current list of emergency contact phone numbers available for management, law enforcement and appropriate regulatory agencies.
Food Defense	2.8.3	Are visitors and contractors to the company operations required to adhere to food defense procedures?	3	Visitors and contractors should be required to adhere to food defense procedures. This can be evidenced by having them sign a log when arriving to the operation, where they are agreeing to meet the company visitor and contractor food defense requirements.
Chemical Files	2.9.1	Are copies of all Safety Data Sheets (detergents, sanitizers, pesticides, etc.) on file and fully accessible at all times with clear indexes?	5	Copies of Safety Data Sheets (SDS) should be available for all chemicals (e.g., pest control, cleaning, maintenance and sanitizing chemicals, etc.), used to keep workers informed about the chemicals used in the facility, and should also be available in emergency situations.

Chemical Files	2.9.2	Are there copies of specimen labels for chemicals used, where the full label is not immediately accessible (e.g., rodent chemicals, product sanitizers)?	5	When immediate access to a full label is not possible, the specimen label copies should be available. Specimen labels should be kept on file and/or laminated and located where chemicals are used. Also check State legal requirements.
Chemical Files	2.9.3	Are there chemical inventory logs for chemicals, including pesticides, fertilizers and cleaning and sanitizing chemicals?	3	Chemicals within the scope of this question include pesticides, fertilizers, cleaners and sanitizers i.e. sanitation chemicals and food contact chemicals, such as chlorine, etc., and any post-harvest chemicals (e.g., fungicides, wax, ethylene). This also applies to fertilizers that are used in sprout operations. Primary information in the product inventory includes: the product or chemical names, container volumes, number on hand, and location of containers. Inventory by storage area/type of chemical is optimal. The inventory should take into account the arrival of new stocks and any discrepancies should be explained. Minimum frequency for inventory checks should be monthly and a copy should be maintained separate from the chemical storage location(s).
Chemical Files	2.9.4	Are there specific Standard Operating Procedures (SOPs) for the monitoring/testing and changing of recirculated and batch water systems (e.g., dump tanks, flumes, hydro vacuums, hydrocoolers, etc.) and testing of single pass water systems?	10	Water systems should have specific SOPs that describe the process of changing the water, performing and recording antimicrobial strength testing (including parameters, testing frequency, methodology and corrective action requirements), and methods and monitoring procedures for measuring build-up of organic material (turbidity) in recirculated and batch water systems. There should be documentation that verifies and validates the water changing frequency and water testing frequency. Minimum frequency for water changing is at least daily; records of changes are kept. Water may be used for longer if a validated regeneration system (e.g., a water pasteurization/filtration system) is being used. For single pass water systems, there should be a specific SOP that describe the performing and recording anti-microbial sanitizer strength testing (including parameters, testing frequency, methodology and corrective action requirements).
Pest Control Documentation	2.10.1	Is there a documented pest control program, detailing the scope of the program, target pests and frequency of checks, including a copy of the contract with the extermination company (if used), Pest Control Operator license(s)/training (if baits are used), and insurance documents?	15	There should be a documented pest control program in place detailing the scope of the program, target pests and frequency of checks. If performed in-house, the pest-control operators or equivalent should be registered, licensed or have documented formal training (if regulation does not require certification or registration). Note that the person's training and/or license should specify structural pest control or equivalent. Any substitute operator's license credentials should also be on file. If the service is contracted, the pest control contract service/company should be licensed in structural pest control, insured and the contract should be documented (quoting the scope of the program, types of pests it covers and frequency of visits).
Pest Control Documentation	2.10.2	Is there a schematic drawing/plan of the facility showing numbered locations of all pest monitoring devices (e.g., rodent traps, bait stations, insect light traps, etc.) both inside and outside the facility?	10	A schematic drawing or trap map is on file, current and details internal and external traps. All devices (e.g., tin cats, Ketch-Alls, bait stations, glue boards, insect light traps, electronic fly killer units, etc.) should be numbered and clearly identified on the map. The numbers should match what is in the facility. The document should be accurate, dated and should show the type of device.

Pest Control Documentation	2.10.3	Are service reports including IPM observations, created for pest control checks detailing inspection records, application records, and corrective actions of issues noted (in-house and/or contract)?	10	Service reports from the contract pest control company should be available for review if pest control is contracted out. In-house inspection records should be available for review if pest control is conducted in-house. Records should include services performed, date of service, chemicals used, signs of activity, and corrective actions, and trend reports.
Operation Monitoring Records	2.11.1	Are there inspection records for incoming goods (e.g., raw materials, ingredients and packing materials)?	5	There should be records showing incoming materials are being received as per documented procedures and from approved suppliers. Materials should be inspected for pests, foreign materials, damage, tampering, labeling issues, and to ensure that the materials are appropriate for use.
Operation Monitoring Records	2.11.2	Are there inspection logs on incoming trailers (and other forms of transport) for rodents and insects, cleanliness, holes and temperature control of the trailer (for food requiring temperature control for safety and/or as required per buyer specifications)?	10	Incoming trailer (and other forms of transport, e.g., rail cargo carriages) checks should ensure that the trailer was clean, odor free, pest free and in good repair (e.g., no damaged insulation). Inspection records when receiving food materials that are temperature controlled for safety reasons should show that the transport temperature control equipment was working properly, temperature settings were set correctly, product was received at the required temperature and that there were no signs of temperature abuse in transit. The receivers should be aware and follow any special documented instructions and specifications communicated by the shipper/supplier of the materials.
Operation Monitoring Records	2.11.3	Are there records for the necessary process monitoring activities (e.g., pH, water temperature vs. product temperature, metal detection, X-ray, labeling, heating processes, reduction/kill step processes, postharvest pesticides (e.g. fungicides), control of water activity, drying, etc.), showing, for example, monitoring frequencies, results and where necessary the corrective actions?	10	Records should show process control parameters are being met and detail corrective actions (where necessary). Processes include sterilizing, irradiating, pasteurizing, cooking, blanching, freezing, refrigerating, controlling pH, or controlling aw. Corrective actions to also include root cause analysis and preventive actions (where relevant). Any processes and/or chemicals used should meet existing legal requirements (including residue levels), used as per label requirements and meet export requirements (as applicable). See 2.11.4 regarding anti-microbial use. There may be some overlap with preventive controls and/or HACCP topics.
Operation Monitoring Records	2.11.4	Are there records (with corrective actions) that show anti-microbial (e.g., free chlorine, ORP, peroxyacetic acid) strength testing of product contact water and ice solutions prior to start up and throughout the production runs?	10	Product contact water and ice production systems using anti-microbial agents should have records showing that the strength of the solution is within stated parameters. Recirculated/batch water systems should be checked by measuring the "free anti-microbial" as opposed to bound microbial (e.g., testing for free chlorine (or ORP) as opposed total chlorine). Where out of specification results are recorded, there should be corrective action records, including root cause analysis and preventive actions (where relevant).
Operation Monitoring Records	2.11.5	Are there records (with corrective actions) that show anti-microbial strength testing of hand/foot/tool dip stations, and are there stock check and replenishment records for gel and spray stations?	3	The log should include target anti-microbial concentration (ppm) and frequency of verification should be sufficient to ensure adequate anti-microbial strength throughout production run. Where hand gel or spray stations are used, there should be monitoring logs indicating that stations are regularly checked to confirm units are stocked and operational.
Operation Monitoring Records	2.11.6	Is there a tool accountability program for knives and similar cutting hand tools used in the production area?	3	There should be an accountability program in place for knives and similar cutting hand tools to identify potential product contamination. Tool accountability to include inspection of the cutting surfaces for wear and tear as well as a tool inventory at the start and end of each shift. Tools should remain on site when not in use.

Operation Monitoring Records	2.11.7	Is there a pre-operation inspection log?	10	Pre-operation inspections should identify potential problems with the facility, workers or equipment that should be corrected prior to starting production. These inspections and corrective actions should be recorded, and where an operation has multiple shifts, there should be pre-operational inspections for each shift.
Operation Monitoring Records	2.11.8	Is there documented evidence of the internal audits performed, detailing findings and corrective actions?	15	There should be records of the internal audits performed, meeting the frequency defined in the internal audit program. The records should include the date of the audit, name of the internal auditor, scope of the audit, justification for answers, detailing any deficiencies found and the corrective actions taken. An audit checklist (ideally PSA) should be used that covers all areas of the PSA audit, including production area, storage, worker amenities, external areas, worker practices, production processes, etc. No downscore if another audit checklist is used, as long as all areas are covered.
Maintenance & Sanitation Files	2.12.1	Does the facility have a preventative maintenance program and a documented schedule?	10	A preventative maintenance program can help prevent production and ancillary equipment, facility structure and fittings failure that can result in biological, physical or chemical contamination of products. Equipment includes, for example, production line equipment, cooling equipment, compressed air equipment, water treatment equipment, etc. Use of predictive maintenance systems are also acceptable for this question.
Maintenance & Sanitation Files	2.12.2	Are there a logs of maintenance work and repairs and are they signed off when work is completed?	10	A log for maintenance work will assist in keeping track of the condition of the equipment in order to prevent hazards from occurring.
Maintenance & Sanitation Files	2.12.3	Are there logs showing that equipment is properly cleaned and sanitized after maintenance and repair work has been completed?	5	Maintenance and repairs on machinery can leave foreign materials behind or leave equipment, including food-contact surfaces, dirty if the entire work area and equipment is not properly cleaned and sanitized after work is completed. Logs of this post maintenance and repair work sanitation should be recorded.
Maintenance & Sanitation Files	2.12.4	Is there a written cleaning schedule (Master Sanitation Schedule) that shows what and where is to be cleaned and how often?	10	A master sanitation program should be in place that covers all areas of the facility, including production areas, storage areas, break areas, restrooms, maintenance and waste areas. Within these areas, areas such as walls, floors, light covers, overhead pipes, etc. should be included. List should include equipment (e.g., production equipment (food contact and non-food contact), pallet jacks, fork lifts, carts, floor scrubbers, trash cans, cooling equipment (evaporators, cooling coils, drip pans, etc.), lift trucks and company owned trailers, etc.). The master sanitation schedule should include a detailed list of areas and equipment to be cleaned as well as the frequency. Sanitation preventive controls (where relevant) should be scored in the Preventive Controls Addendum.

Maintenance & Sanitation Files	2.12.5	Are there written cleaning and sanitation procedures (Sanitation Standard Operating Procedures) for the facility and all equipment?	10	The facility areas (floors, walls, overheads, etc.), all equipment (food contact, non-food contact, cooling equipment, etc.), internal transport vehicles and in-house owned trailers should be cleaned and sanitized on a regularly scheduled basis, based on written Sanitation Standard Operating Procedures (SSOPs). There should be SSOPs covering the cleaning and sanitizing operations noted in the master sanitation schedule. SSOPs should also be created for dry cleaning operations (where applicable). Procedures should detail what, who, how and when, including chemical details, solution temperature, water pressure, dwell times, any disassembly/reassembly instructions and cleaning verification procedures. See Preventive Controls Addendum regarding sanitation preventive controls (where relevant)
Maintenance & Sanitation Files	2.12.6	Are cleaning and sanitation logs on file that show what was done, when and by who?	10	Sanitation logs should be on file that cover all areas of the facility (e.g., production areas, storage areas, break areas, restrooms, maintenance, etc.), detailing walls, floors, overhead and all equipment (e.g., production equipment (food contact and non-food contact), pallet jacks, forklifts, carts, floor scrubbers, trash cans, cooling equipment, lift trucks, company owned trailers, etc.). Logs should include: date, list of areas/equipment that were cleaned and sanitized, and the individual accountable who signed-off for each completed task. Logs should cover sanitation operations as noted in the master sanitation schedule
Maintenance & Sanitation Files	2.12.7	Are there records showing verification of cleaning and sanitizing chemical concentrations?	5	Where cleaning and sanitizing chemicals are mixed on-site, there should be records of verification of the anti-microbial concentrations. The strength of cleaning chemicals should be checked using an appropriate method for the anti-microbial in use. Frequency of checks should correspond with the SSOP, but at least at mixing and then at a frequency that ensures the availability of the anti-microbial is adequate while the cleaning operation is being done. Corrective actions should be recorded
Maintenance & Sanitation Files	2.12.8	Are there documented procedures and completion records for clean-in-place (CIP) activities (e.g., cleaning re-circulating water systems such as washing flumes, ice injectors, hydrocoolers, chilled water systems, ice makers, etc.), where applicable?	10	Operations utilizing clean-in-place (CIP) should have detailed procedures in place. CIP activities should be monitored to ensure the CIP process is effective and not a source of contamination to the product. Detailed CIP cleaning procedures (including chemicals used, dilutions, water pressure, solution temperature, dwell times, etc.) and records of cleaning should be maintained.
Maintenance & Sanitation Files	2.12.9	Are there sanitation logs on file indicating that floor drains are cleaned on a regular basis (minimum daily in wet and fresh-cut production areas)?	10	It is important to include drains in the cleaning schedule to prevent cross contamination. Drains in wet storage and production areas should be cleaned daily and sanitized regularly to prevent harmful bacteria from growing.
Maintenance & Sanitation Files	2.12.10	Are there records showing cooling units are maintenance serviced and cleaned at least every 12 months or more frequently as required?	10	Records should be available to verify that the cooling units are serviced and cleaned on a scheduled basis. Cooling units should be cleaned and sanitized at least every 12 months or more frequently to prevent harmful pathogens from growing. Maintenance servicing ensures that coolers are working properly and efficiently. Records might include in-house sanitation records, maintenance records and/or contractor records/invoices

Maintenance & Sanitation Files	2.12.11	Is there a routine program and written procedure to verify sanitation effectiveness using rapid post sanitation checks (e.g., ATP measurements, allergen specific proteins)?	15	Rapid post sanitation checks (e.g., ATP (adenosine tri phosphate)) testing provides an instant indication of the hygiene status of equipment and facility surfaces after cleaning and/or prior to start up. Measuring ATP, for example, detects food residues, bacteria, yeast, mold - either living or dead (i.e. all organic matter) to give a measure of cleaning effectiveness. Procedures for use and disposal should be documented, validated for use with product being run, in line with any manufacturer recommendations and should detail sampling strategy, standardized sampling technique, including location of sample and time of sampling, and there should be clear threshold parameters. Records of routine testing (at least daily in processing operations and weekly in others) and corrective actions should be maintained.
Maintenance & Sanitation Files	2.12.12	Is there a documented glass and brittle plastic management procedure (including company glass and brittle plastic policy, glass breakage procedure and where necessary a glass register)?	10	There should be a documented site glass management procedure including company glass and brittle plastic policy, glass and brittle plastic breakage procedure and glass register if necessary (a no glass policy in production, storage or maintenance areas should be the target). If certain glass and brittle plastic items are allowed, a glass register should describe each item, location and quantity; items should be checked on a routine basis. Clean-up procedure after glass or brittle plastic breakage should indicate what equipment to use and include boot and tool checks/decontamination procedures to ensure broken glass or brittle plastic is not unintentionally transported out of the area.
Worker Documentation	2.13.1	Are there records of new worker food safety (GMP) orientation training (with topics covered and attendees) and are all workers required to sign the company's food safety hygiene and health policy?	10	All new workers (including workers in departments such as production, storage, sanitation, maintenance, etc.) should be GMP trained on employment in the language understood by the workers, with records of this training being maintained. All workers should be issued a list of GMP rules in the relevant languages and confirm by signing they understand and agree to abide by the company's food safety policy rules regarding personal hygiene/GMPs and health requirements. Training provided and associated records should meet local and national regulations.
Worker Documentation	2.13.2	Are there logs of ongoing worker food safety education training, including topics covered, attendees, etc.?	10	Ongoing worker training should cover at least GMP food safety hazards and relevant regulatory requirements and guidance. Training records should detail who has been trained, topics covered, trainer details, materials used and when the training occurred. Training provided and associated records should meet local and national regulations.
Worker Documentation	2.13.3	Is there a documented training program with training logs for the sanitation workers, including best practices and chemical use details?	5	Sanitation training should ensure that the workers understand the importance of proper sanitation, cleaning efficacy, how to use the cleaning chemicals and how to understand Sanitation Standard Operating Procedures. Unless sanitation workers attend regular food safety trainings, sanitation training should also include elements of food safety training pertinent to sanitation operations (e.g., hand washing, restroom use, foreign material, etc.). Training logs should have a clearly defined topic(s) covered, trainer(s) and material(s) used/given.

Worker Documentation	2.13.4	Are there written and communicated procedures in place that require food handlers to report any cuts or grazes and/or if they are suffering any illnesses that might be a contamination risk to the products being produced, and include return to work requirements? (In countries with health privacy/confidentiality laws, e.g. USA, auditors can check procedure/policy but not the actual records).	10	There should be documented procedures that are communicated (e.g., worker signature on a training log) to food handlers, requiring them to report any cuts, grazes and/or any illnesses that might be a food safety cross contamination risk. Procedures to note return to work requirements for affected workers. Procedures should cover recording requirements, but auditors should not request to review records where countries have laws covering privacy/confidentiality of health records.
Worker Documentation	2.13.5	Are there worker food safety non-conformance records and associated corrective actions (including retraining records)?	3	There should be records covering when workers are found not following food safety requirements. These records should also show corrective actions and evidence that retraining has occurred (where relevant).
Worker Documentation	2.13.6	Are visitors and contractors required to sign a log stating that they will comply with the operations' personal hygiene and health requirements?	3	All visitors and contractors should sign to say that they understand and will abide by the company rules regarding personal hygiene/GMPs and health requirements (which they have reviewed before entering the food handling areas of the facility).
Testing	2.14.1	Is there a written risk-based, scientifically valid microbiological testing program that may include pathogen testing, and details program design (zonal approach, food contact/non-food contact surfaces, spent sprout irrigation water, test & hold, water, ice, etc.), rationale for organisms tested for, procedures for sampling and testing (surfaces, water, product, ingredients, etc.), timing and frequency of testing, the testing methodology, the lab that performs the tests, and acceptable results/threshold levels for each organism?	15	A written risk-based, scientifically valid microbiological testing program has been developed and is used to verify the effectiveness of cleaning and sanitization programs and/or meet customer or other specific requirements. Program should include design and scope (zonal approach, food or non-food contact, spent irrigation water, test & hold, water, ice, product, ingredients, etc.), rationale for organisms tested for, procedures for sampling and testing (surfaces, water, product, ingredients, etc.), timing and frequency of testing, the testing methodology, the lab that performs the tests, and acceptable results/threshold levels for each organism. Any hold and release (test and hold) activities should also be recorded. There may be some overlap with preventive controls and/or HACCP and/or Preventive Control topics.
Testing	2.14.2	Are there written risk-based corrective action procedures for when unacceptable test results are received, that describe the steps to be taken, assign responsibility for taking those steps, and steps to ensure the cause is identified (e.g., root cause analysis) and corrected to minimize the potential for product contamination?	10	There should be written corrective action procedures detailing actions to take when unacceptable results are received, based on the risk that contamination could result in contaminated food and consumer illness that describe the steps to be taken, assign responsibility for taking those steps, and steps to ensure the cause is identified (e.g., root cause analysis) and corrected to minimize the potential for product contamination. This may include root cause analysis, intensified sampling and testing, review of SOPs, sanitation and maintenance programs, etc.
Testing	2.14.3	Are there records of environmental microbiological test results and does testing meet the program requirements?	15	Testing should be recorded, including organism tested for, the testing methodology, lab that performed the test, details of the sampling sites, when the test occurred and the results (including units of measure). If any issues are detected, corrective actions should be recorded (see 2.16.8). Testing should meet written program requirements.
Testing	2.14.4	Are there records of microbiological tests on water used in the facility (sampled from within the facility) and does the testing meet the program requirements?	15	Testing of facility water should be performed on a routine basis to assure it meets the microbial requirements of potable water. Water samples should be taken from within the facility, in order to assess pipes and tanks (a city water result does not take into account the operations pipes and fittings). Well water should (in addition) be tested at source. Testing frequency should be related to the risk assessment of the production. Testing should meet written program requirements.

Testing	2.14.5	Are there records of microbiological tests on ice used in the facility (either produced in-house or purchased) and does testing meet the program requirements?	15	Testing ice helps check both the water microbial potability and ice equipment hygiene. Testing frequency should be related to the risk assessment of the production. Testing should meet written program requirements.
Testing	2.14.6	Are there records of tests performed on compressed air or other mechanically introduced gases that is used directly on food and food contact surfaces and does testing meet the program requirements?	5	Compressed air or other mechanically introduced gases used in direct contact with product, product food contact areas and the inside surfaces of packaging should be free of contaminants (e.g., particulates, oil, etc.). Testing should be based on a documented risk assessment and controls in place (e.g., use of the air/gas, risk to the product/food contact surfaces and type of process/product). Testing should meet written program requirements.
Testing	2.14.7	Are there records of other tests (e.g., spent sprout irrigation water, product, raw ingredients, etc.) that are performed for any reason (e.g., customer requirements, best practice, regulatory requirements) and does testing meet program requirements?	15	Testing should be recorded, including organism tested for, the testing methodology, lab that performed the test, details of the sampling sites, when the test occurred, the results (including units of measure) and appropriate corrective actions (where relevant). Product testing may include microbiological, heavy metals, pesticides, dioxins, aflatoxins and other natural toxins, etc.
Testing	2.14.8	Are there records of corrective actions taken after unsuitable testing results that describe the steps taken, responsibility for taking those steps, and actions taken to ensure that the cause of contamination has been identified and corrected?	15	There should be documented evidence that corrective actions have been taken when required and were adequate for the specific situation.
Temperature Controlled Storage & Distribution Logs	2.15.1	Are there records of final product temperature checks for temperature sensitive product?	10	Records for final product temperature should be maintained for temperature sensitive products. Temperature requirements of customers and organizations that are coordinating the shipping of the finished products should be considered. Records should show that product is not shipped above temperature requirements (in-house, customer, legal or best practice). Corrective and preventive actions and should be recorded (where relevant).
Temperature Controlled Storage & Distribution Logs	2.15.2	Are there temperature logs for the production area (if refrigerated)?	5	Temperature control is important in limiting microbial growth for temperature sensitive products. Corrective and preventive actions should be recorded (where relevant).
Temperature Controlled Storage & Distribution Logs	2.15.3	Are there temperature logs for storage rooms?	5	Temperature control is important in limiting microbial growth for temperature sensitive products. Corrective and preventive actions should be recorded (where relevant).
Temperature Controlled Storage & Distribution Logs	2.15.4	Are there records of shipping truck trailer (or other transportation systems) temperature checks, indicating the truck trailer temperature settings and that the truck trailer was pre-cooled prior to loading?	5	Truck trailers (or other transportation system, e.g. railway carriages) should be checked to ensure they are pre-cooled when transporting temperature sensitive products, and the truck trailer refrigeration unit set point should be recorded.
Temperature Controlled Storage & Distribution Logs	2.15.5	Are there sanitary condition logs for shipping truck trailers (or other transportation systems)?	5	Truck trailers (or other transportation systems, e.g., railway carriages) should be checked for their sanitary condition and records maintained. Records should reflect the documented procedure.

Allergen Control	2.16.1	Are there no allergen risks handled or stored within production and storage areas?	0	If allergens are handled and/or stored within the facility then the allergen questions in this sub-section should be completed (applicability of some questions will vary depending on variables, such as process steps and how allergen containing materials are handled). Also the allergen hazards should form part of the HACCP and/or Preventive Controls programs. The key concerning allergens (a.k.a. major 8) are Wheat, Eggs, Milk, Soybeans, Crustaceans (Shellfish), Peanuts, Tree Nuts and Fish. Legislation should be reviewed to see if the country of production or countries being exported to have different allergen listings (e.g., mustard, celery and sesame). If there is no allergen handling on site then mark this question “Yes”, state an explanation and mark the rest of the allergen questions as N/A
Allergen Control	2.16.2	Has a documented allergen management plan been developed?	5	An allergen management plan has been developed and documented. The plan gives an overview of the operation’s management of allergen control from product development, raw material procurement (supplier management), goods receiving, raw material storage, production, finished goods storage through to shipping. The plan should cover areas such as how raw material supplier allergen risks are evaluated/mitigated, on-site labeling, sanitation, labeling, worker training, etc. The plan should include an up to date list of allergens handled on site. Some facets of the allergen plan are audited in the rest of the questions in this section
Allergen Control	2.16.3	Are there adequate storage controls (e.g., separation, identification, etc.) that ensure that allergens are not contaminating other materials?	5	Allergen materials and allergen containing materials should be stored in a manner that avoids cross contaminating all other materials. Separated areas are ideal and allergen containing products should never be stored above food products, other than those containing the exact same allergens. Allergens should be tagged as usual (rotation and lot coding), and should also be identified as allergens
Allergen Control	2.16.4	Is there a dedicated allergen production line or adequate clean down and production procedures that prevent allergen cross contamination?	5	Ideally, facilities have separate production line(s) for allergen containing ingredients. If no separate production line is being used, then procedures should be written so as to prevent allergen cross contamination. These procedures might include the specific order of producing allergen containing products and special sanitation SOPs between allergen and non-allergen production runs. Some allergen testing kits (where available for the particular allergen) are also used in order to check the sanitation after an allergen has been used in a product. Where allergen dust is considered a risk, then practices, such as keeping ingredient bins covered, consideration of ventilation flows, etc., should be considered
Allergen Control	2.16.5	Are utensils and work in progress storage containers identified in order to prevent allergen cross contamination?	5	Utensils, such as shovels, paddles, knives, maintenance tools, etc. should be coded in order to differentiate between items associated with producing allergen containing products and products that do not contain allergens. Sanitation equipment (e.g., cleaning pads, mops, brushes, etc.) should also be coded and separated between equipment destined to be used on allergen containing products/processes and nonallergen containing products/processes. Product holding bins, including re-work bins, should be coded in a similar fashion i.e. a separate set of bins for the allergen containing product

Allergen Control	2.16.6	Does re-work handling take into account the issues associated with allergen containing products?	5	Rework of allergen containing products needs to be strictly controlled. Allergen re-work product should be clearly labeled. Allergen re-work should be stored separately from non-allergen re-work, raw materials and product. Allergen re-work should only be used when a similar allergen containing product is being packed/processed. Even the outside of allergen containing condiment packs might be a risk to the foodstuff (e.g., romaine lettuce) that a condiment pack was touching and therefore this foodstuff (e.g., romaine lettuce) should only be re-used for the allergen containing product. Like all re-work, traceability should be maintained, meaning that the use of re-work materials is being properly recorded.
Allergen Control	2.16.7	Are workers trained with respect to allergen risks and the facility allergen cross contamination controls (including hand washing between production runs) and are there records of this allergen training?	5	Workers should be aware of what allergens are, the effects of allergens on allergy sufferers, the actual allergens handled on site and the facility controls to prevent allergen cross contamination. Training should include personnel practices (e.g., hand washing, changing protective garments and gloves, etc.), when moving around the production area between allergen and non-allergen handling. Key operators, including warehouse workers, production workers, label designers, etc. should receive specific training for the risk involved. Training should be recorded.
Allergen Control	2.16.8	Are worker practices adequate and being followed to protect against allergen cross-contact and against contamination of food?	5	Worker practices should be adequate to ensure that necessary precautions are being followed to protect against allergen cross-contact and against contamination of food, food-contact surfaces, or food-packaging materials with allergenic substances.
Allergen Control	2.16.9	Are all products manufactured on site labeled correctly with respect to allergens?	5	Allergen containing products should clearly show on the label the allergens that are associated with the product and meet any laws in the country of production and consumption. The correct label should be on the product. If the allergens form part of condiment inclusion packs, these allergens should still be indicated on the main product label. If an operation is producing allergen containing products that will be used as an ingredient by a subsequent manufacturer, the documentation that goes with the product should underline the allergen contents and also, ideally, the bag and cartons should indicate the allergen contained within the product. If non-allergen containing products are produced on a site where allergens are used, the management should consider the chance of allergen cross contamination and if satisfactory controls to prevent such contamination are in place. If there are any doubts about the adequacy of these controls (e.g., GMPs, etc.), then management should consider using a "may contain" (or a similar clause) on the non-allergy containing products (this is a last resort and should

HACCP - SECTION 3				
Section	**Q #**	**Question**	**Total Points**	**Expectations**
Preliminary Steps	3.1.1	Is there a team with an assigned leader, responsible for the HACCP program at the operation,, with a leader assigned, if applicable, for and the development, implementation and on-going maintenance of the HACCP system?	10	There should be a documented list of the team carrying out the HACCP program in the operation, with one leader or coordinator assigned as responsible. The team should be multidisciplinary and may include people from production, quality, sanitation, maintenance, shipping, procurement, sales, external consultants, etc. The size of the team will depend on the size of the operation and the processes performed.

Preliminary Steps	3.1.2	Is there documented evidence that the HACCP team members have been trained on HACCP principles?	15	The HACCP Coordinator should have a certificate of a formal HACCP training from a recognized organization, institution or trainer providing formal training, taken within the last 5 years. The rest of the team should have at least an internal training (within last 5 years) to make sure they are knowledgeable of the HACCP principles. These trainings should be documented.
Preliminary Steps	3.1.3	Does a product description exist for the products produced?	10	The description should detail the products' composition (ingredients), packaging used, storage conditions, distribution requirements, important food safety characteristics (if any) (e.g., pH, water activity), label instructions, the intended use, statement on whether the product is RTE and who the intended consumer is.
Preliminary Steps	3.1.4	Has the process(es) been flow charted in sufficient detail to completely describe the process or product handling/processing steps?	10	The information (from receiving through to final storage and shipping) on the flow diagram is used to evaluate whether or not hazards exist associated with each step of the process. Groups of similar products going through the same process can be grouped in the same flow chart. Diagram should show re-work processes and when product is diverted to be used for other purposes. Process flows can be augmented by written process descriptions (where helpful).
Preliminary Steps	3.1.5	Is there documented evidence that the flow chart(s) has been verified on-site?	10	Flow diagrams should be verified on-site by the food safety team and the team should make any changes required to the flow diagram. Any significant changes to the process must be accurately reflected in the flow diagram and evaluated to determine if the changes have an impact on the hazards analysis and CCPs in place. The flow chart(s) is signed and dated by the HACCP coordinator to confirm it reflects the process at different moments in time (auditor should confirm how and when flow chart(s) were verified) and there are no missing steps.
Development of the HACCP Plan	3.2.1	Has a documented hazard analysis for the processes been conducted, showing the various types of hazards, their likelihood of occurrence, their associated severity and their control measures? **A ZERO POINT (NON-COMPLIANCE) DOWNSCORE IN THIS QUESTION RESULTS IN AUTOMATIC FAILURE OF THIS AUDIT.**	15	Hazard analyses are required to identify each hazard (biological, chemical and physical) at each stage of the production process. The analyses should evaluate the likelihood of hazard occurrence and potential hazard severity. The hazard analysis document(s) should show the control measures. Each step identified in the process flow diagram should be assessed in the hazard analysis. The hazard analysis should be reviewed when changes occur affecting the product description and/or the process flow.
Development of the HACCP Plan	3.2.2	Have CCP decisions been made with documented justifications and where CCPs are implemented in a specific processing step, have they been developed to control the identified hazard(s)?	15	The CCPs should be created from the documented hazard analyses, i.e. there should be a logical documented approach (such as utilizing a CCP decision tree) showing why the process was deemed a CCP or not. CCP decisions should be properly justified with supporting documents and evidence. The CCPs defined in the hazard analysis should be developed in detail to define the parameters involved and the monitoring requirements needed in order to control the hazard.

Development of the HACCP Plan	3.2.3	Is the HACCP system reviewed when significant changes are made and at least once every 12 months?		The HACCP system should be reviewed by the HACCP team when significant changes are made and at least every 12 months, including the product descriptions, process flows, hazard analyses, CCP decisions, CCP recording and worker training to ensure that the program is up to date and working properly. Where emerging issues, such as recalls, an outbreak, new research, etc., are relevant to the products and processes at hand, consideration of a HACCP review should occur. Documented re-training or educational sessions may be necessary. The review should include a written record which demonstrates each of the elements of the plan have been reviewed, verified as being accurate/appropriate and there should be a change record included in the plan to track changes over time. The HACCP team should inform workers involved of the review outcomes.
Development of the HACCP Plan	3.2.4	Have critical control point (CCP) processing steps been identified that eliminate or reduce food safety hazards to an acceptable level? Informational gathering. If answer is YES, continue with next question. If answer is NO, the rest of section 3 is not applicable.	0	The identification of CCPs in the process will require the development of the criteria for managing it and the execution of the necessary activities in the production line. A CCP should be controllable and the controls should be able to eliminate or reduce the risk to acceptable “safe” levels. Where the operation determined that there are no CCPs (and the auditor is in agreement), no further HACCP development is required, and the rest of the module is not applicable.
Development of the HACCP Plan	3.2.5	Have CCP critical control limits been established and are they supported by relevant validation documentation?	15	A critical control limit (CCL) represents the dividing line used to judge whether a CCP is under control or not. Each Critical Control Point should have one or more critical control limits for each identified hazard. All CCPs should be supported by validation documentation showing that the critical control limits (CCL) are scientifically derived and meet any relevant legal requirements. Validation could take the form of publicly available legislative documents, industry best practice documents, peer reviewed research papers, on site validation studies, etc., or a mix of different validation sources.
Development of the HACCP Plan	3.2.6	Have monitoring requirements and frequencies been determined and documented for the CCPs?	15	Monitoring requirements should detail the actions necessary (observations or measurements) to ensure whether a CCP is under control. Frequencies and requirements of monitoring should be defined and documented for each CCP on the HACCP chart.
Development of the HACCP Plan	3.2.7	Have specific responsibilities been assigned for the monitoring, recording and corrective action implementation of each CCP?	10	Specific responsibilities should be assigned for the monitoring, recording and corrective action implementation of each CCP to ensure compliance.
Development of the HACCP Plan	3.2.8	Have standard operating procedures (SOPs) been created for the monitoring process(es) of the CCPs, which would include how to carry out the monitoring activities?	10	Clear and simple standard operating procedures (SOPs) should be written for each monitoring process(es) of the CCPs. These SOPs should expand the CCP monitoring activities in detail in the form of work instructions, and match what is written in the HACCP Plan.
Development of the HACCP Plan	3.2.9	Have corrective action procedures been established for the CCPs, including a detailed action plan for operators to follow if the critical control limit(s) of a CCP are not met (loss of control/deviation) and plans to adjust the process back into control?	15	There should be a documented, detailed plan with procedures to follow when there is a loss of control (deviation) of a CCP so that adjustments can be made in a timely manner and to assure that the process is back under control. The procedures include details regarding how to handle affected products (if necessary). Corrective action procedures should also include requirements to review the CCP to try and avoid a repeat of the loss of control.
Development of the HACCP Plan	3.2.10	Have recording templates (recording forms) been developed for monitoring the CCPs?	15	Defined record templates are required for recording CCP monitoring. The parameters on the records should reflect those used in the HACCP Plan. These templates should be managed under the document control program.

Development of the HACCP Plan	3.2.11	Have verification plans and schedules been developed for each CCP?	15	Each CCP should have documented verification activities associated with the monitoring that verifies the correct implementation of the HACCP plan (e.g., CCP documentation checks, specific testing associated with the CCP, customer feedback, equipment calibration, etc.). Where verification activities have found that CCPs were not performing as required, there should be records that show that this prompted a review of the relevant part of the HACCP Plan.
Execution of the HACCP Plan	3.3.1	Do all of the documents noted in the HACCP Plan accurately reflect plan requirements for the CCPs?	15	Documents noted in the HACCP Plan should be in place for each CCP, and records should reflect the plan requirements. Using document version control helps ensure that the documents on the production floor match those in the plan.
Execution of the HACCP Plan	3.3.2	Are the CCP monitoring activities and frequencies in compliance with the HACCP Plan and CCP SOPs?	15	The monitoring records should show that testing frequency, parameters and any other details match what is written in the HACCP Plan and CCP SOPs.
Execution of the HACCP Plan	3.3.3	Is there documented evidence that all plant workers have attended a HACCP training, including training for CCP operators?	10	HACCP training is important in ensuring that all workers are knowledgeable regarding the basics of HACCP. This training is especially important for CCP operators, and for those workers, the training should cover the explanation of the procedures in which they are responsible. All training activities should be documented.
Execution of the HACCP Plan	3.3.4	Do CCP operators understand basic HACCP principles and their role in monitoring CCPs?	10	CCP operators should understand basic HACCP principles and have a good understanding of the details of the CCPs that they have been assigned to monitor, including monitoring procedures, critical controls and corrective action requirements. Auditor should interview operators to verify.
Execution of the HACCP Plan	3.3.5	Are CCP monitoring records signed off (or initialed) by the operator(s) who are carrying out and recording the CCP check?	15	Records should be legible in order to show who actually performed the CCP monitoring tests. If initials are used, there should be a way to easily determine who the initials refer to.
Execution of the HACCP Plan	3.3.6	Is there a deviation record detailing documented corrective actions when a deviation/loss of control of a CCP occurs (a critical control limit is exceeded)?	15	When a monitoring or verification step shows a deviation/loss of control against a CCP in the HACCP Plan (including when a critical control limit is exceeded), the incident should be recorded on a deviation record (or similar form), along with actions taken. This includes recording what happened to the affected product, how the situation was rectified and any preventative actions taken to avoid similar issues in the future.
Execution of the HACCP Plan	3.3.7	Are the CCP records reviewed and signed off by the quality control supervisor and/or management (second signatory)?	10	Records should be signed off by the designated person(s) responsible for internal verification of the company's HACCP plan within 36 hours of the original CCP monitoring activity occurring. The sign off should not be done by the same person who carried out the monitoring activities. If any issues are detected, corrective actions should be recorded.

ADDITIONAL QUESTIONS (NOT PART OF OVERALL FOOD SAFETY PERCENTAGE) - SECTION 4				
Management System	4.1.1	Is there a training management system in place that shows what types of trainings are required for various job roles of specific workers, including who has been trained, when they were trained, which trainings they still need to take, and a training schedule?	5	The company has a system in place (e.g., training matrix) that shows what types of trainings are required for various job roles that affect food safety, who has been trained, when they were trained, which trainings they still need to take, and a training schedule. The training records required under specific questions will be reviewed in the applicable section(s).

Management System	4.1.2	Is there documented management verification review of the entire food safety management system at least every 12 months, including an evaluation of resources, and are there records of changes made?	10	There should be written verification of the entire food safety management system at planned intervals (minimum every 12 months). There should be evidence that senior management is involved in the review to ensure its continuing suitability, adequacy and effectiveness and that they are continuing to support and invest in adequate food safety resources (e.g., equipment, services, supplies, personnel training, worker staffing levels, customer requirements/specifications, etc.). The review should determine the need for changes and the changes made should be documented. The documented review should meet any national or local legislative requirements.
Management System	4.1.3	Where specific industry guidelines or best practices exist for the crop and/or product, does the operation have a current copy of the document?	3	There is a current copy of any specific industry guidelines for the crop and/or product available for review.
Control of Documents and Records	4.2.1	Are all records and test results that can have an impact on the food safety program verified by a qualified person independent of the individual(s) completing the records?	5	Records and test results should be reviewed and signed off by a qualified person within 7 days. The verifier is independent of the individual completing the record(s), understands the purpose of the verification and understands what they need to review on the record(s) before they sign (i.e. evidence of training). If any issues are detected, corrective actions should be recorded.
Procedures and Corrective Actions	4.3.1	Is there a documented corrective action procedure that describes the required basic requirements for handling all non-conformances affecting food safety?	5	The corrective action procedure should outline how the company manages corrective actions. Specifically, requiring the determination of root cause, establishment of an action plan(s) to address immediate issue(s) regarding non-conformance(s) (including any actions taken regarding affected product), corrective actions taken, the development of preventive actions to help avoid future occurrences and validation of corrective action. Procedure should require that records of the corrective action activities and their follow-up are completed using the same format with the required information detailed.
Internal and External Inspections	4.4.1	Is there a documented procedure for how internal audits are to be performed at the operations, including frequency and covering all processes impacting food safety and the related documents and records?	10	A written procedure for internal audits should be created covering each operation. The procedure should cover the inspection of the sites, the practices in place, the related documents required, the records generated, the recording system to be used for the audits, the frequency of the internal audits and identification of the person(s) responsible for conducting the internal audits. The internal audit records are assessed in specific questions.

Release of Items/Product	4.5.1	Is there a documented product release procedure available?	5	Product release procedures are needed when the product is approved for shipment or harvest (they do not indicate the release of a product that has been placed on hold). Product release procedures assure that a lot is only released for shipment (sale) when lot meets agreed standards (e.g. specification) or meets agreed testing requirements (e.g. results confirmed negative or within limits results from testing, etc.). This includes crops approved for harvest and where harvested product is direct picked into packaging during harvest (e.g., mushrooms, berries, individually wrapped lettuce) or there is in-field processing/semi-processing. Products should not be released for harvest or shipment without assuring that necessary evaluations have been performed. N/A for organization's that only have authority over the growing activities and operation(s), and not the harvesting activities.
Release of Items/Product	4.5.2	Are there records of product releases kept on file?	5	Product release records are needed to document when the product is approved for shipment or harvest (they do not indicate the release of a product that has been placed on hold). Product release records should show documented evidence that all product that is shipped and harvested is released only when the release procedure has been completed and the product has been "signed off" for by authorized personnel. Records should be available demonstrating the sign off for the "release" of all product shipped. N/A for organization's that only have authority over the growing activities and operation(s), and not the harvesting activities.
Release of Items/Product	4.5.3	Are there records of the handling of on hold and rejected items kept on file?	5	Records should be kept to provide information about any item (raw materials, packaging, work in progress, finished product, etc.) that is rejected or put on hold, including at least: date and time, amount of product affected, reason for being on hold/rejected, name of the person who rejected the product or put it on hold, details of product disposition, date, time, the actions taken, and the signature of an authorized person to release the product.
Supplier Monitoring/ Control	4.6.1	Where food safety related testing is being performed by external laboratory service providers, are these licensed and/or accredited laboratories (e.g., ISO 17025 or equivalent, national and local regulations, etc.)?	5	Food safety related testing that is performed by external laboratory service providers should be done by currently permitted, licensed and/or accredited laboratories for the scope(s) of work being carried out. Examples of these licenses and accreditations include ISO 17025 accreditations or equivalent, national and local regulations in the country of production, etc. Documented evidence of these licenses and/or accreditations should be available
Food Defense	4.7.1	Is there a written food fraud vulnerability assessment (FFVA) and protection plan for all types of fraud, including all incoming and outgoing products?	3	There should be a vulnerability assessment and comprehensive protection plan for all types of food fraud. This includes economically motivated hazards, economically motivated food safety hazards, adulterant substances, mislabeling, theft, tampering, simulation, diversion or gray market, intellectual property rights and counterfeiting. An example of a food fraud scenario that may occur at an operation is when suppliers provide products/materials that do not match their required specifications (e.g. unapproved chemicals, non-food grade packaging material, product substitution).

Food Defense	4.7.2	Are records associated with the food defense plan and its procedures being maintained, including monitoring, corrective action and verification records (where appropriate)?	5	The records required in the food defense plan should be maintained, in accordance with the details of the plan and its associated procedures. These records are also subject to the document control and records requirements of this audit.
Site	4.8.1	Is there a site plan showing the facility location, adjacent sites, roads, water sources, storm water, waste water and other relevant features?	5	There should be a site map or similar document (photograph, drawing) that accurately shows the facility building(s), location of permanent water fixtures (well, mains) and water systems, including any holding tanks and water captured for re-use. Storm water, waste water, septic systems, effluent lagoons or ponds, surface water bodies are also identified.
Site	4.8.2	Is there a facility floor plan showing the layout of the building, production areas, storage areas, water sources and fixtures, layout of equipment and traffic flow patterns?	5	There should be a facility floor plan (map, drawing) indicating production areas, storage areas, water fixtures and drainage, layout of equipment and traffic flow patterns of equipment and workers. The flow pattern for food products, waste material, workers and equipment should prevent raw materials and waste from coming in contact with the finished product. Flow is ideally in one direction and follows a logical sequence from raw material handling to finished product storage.
Site	4.8.3	Has a documented risk assessment been performed to ensure that any food safety hazards relevant to facility location and adjacent land use are identified and controlled?	10	A documented risk assessment should be performed for the facility to identify and control any food safety hazards relevant to the facility location and adjacent land use e.g., animal activity, industrial activity, water characteristics, waste, water treatment sites (settling ponds, land applications, etc.) or any other potential sources of contamination). All national and local laws pertaining to land use and on-site water treatment systems should be followed. Where necessary, for waste water treatment areas, there should be applicable permits on file and evidence of regulatory and/or third party inspections. The risk assessment should be reviewed annually and at least when a significant facility location/adjacent land change occurs.
Operation Monitoring Records	4.9.1	Are there records of visual monitoring and/or testing and changing of recirculated and batch water systems (e.g., dump tanks, flumes, hydro vacuums, hydrocoolers, etc.), for build-up of organic material (turbidity)?	5	There should be records of visual monitoring and/or testing and changing of recirculated and batch water systems during production. Water should be changed when it is dirty and when switching products. Frequency is at least daily. Water may be used for longer if a validated regeneration system (e.g., a water pasteurization/filtration system) is being used.
Maintenance & Sanitation Files	4.10.1	Are there records showing filters in air conditioning, evaporative coolers, ventilation and air filtration units are regularly cleaned and replaced?	5	Records should be made available to verify that filters in air conditioning, evaporative coolers, ventilation and air filtration units are regularly cleaned and replaced. Records might include in-house sanitation records, maintenance records and/or contractor records/invoices.

Testing	4.11.1	Where food safety related testing is being done in-house, is there a laboratory quality assurance manual with validated testing methods and protocols, evidence of training related to sample collection and testing protocols, and relevant records of results?	10	There should be documented evidence that the in-house laboratory is using the correct methods for testing (e.g., validation) and have established protocols to detect errors and to initiate corrective actions. There are records showing that workers handling samples have been trained on proper sample collection and testing protocols. An accredited laboratory should be used when testing is conducted to comply with specific regulatory (e.g. FDA) testing requirements applied to address an identified or suspected food safety problem (e.g. sprout spent irrigation water).
Temperature Controlled Storage & Distribution Logs	4.12.1	Is there a documented procedure for checking truck trailer temperature prior to shipping?	5	There should be a documented procedure to check truck trailer temperature prior to shipment. Where relevant, requirements from the organization that has contracted the carrier should be followed, including the use of time temperature recording devices.
Temperature Controlled Storage & Distribution Logs	4.12.2	Is there a documented procedure for reviewing the sanitary condition of truck trailers that will transport the product?	5	Truck trailers (or other transportation system, e.g. railway carriages) should be checked for their sanitary condition. Attributes checked should include cleanliness, trailer fitness for intended use (design and construction materials), issues from previous loads, pest free, odor free, load segregation, etc. There should be a documented procedure to cover this check. Where relevant, requirements from the organization that has contracted the carrier should be followed.