PRIMUSLABS V14.09 GMP AUDIT SCORING GUIDELINES

Edition v1.2, October 2015
Mandatory as of 1 January 2016

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The PrimusLabs GMP Audit Scoring Guidelines are not exhaustive and detail minimum requirements only by means of short statements related to audit questions. There will be variations in applicability to an operation based on the process(es) and commodities involved. Auditors should interpret the questions and conformance criteria in different situations, with food safety and risk minimization being the key concerns.

Where laws, commodity specific guidelines and/or best practice recommendations exist and are derived from a reputable source, these practices and parameters should be followed if they present a higher level of conformance than those included in the audit scheme system.

Website links shown in this document are there to aid understanding and provide assistance. These links are not a sign of endorsement by PrimusLabs. Furthermore, PrimusLabs accepts no liability for the content of these links. If any of the links do not work, please e-mail auditqa@primuslabs.com, so that we may update our information - many thanks.

Please be aware that there is additional information on the PrimusLabs website, including the actual audit templates at http://www.primuslabs.com/services/StandardGMP.aspx.

This document is designed to be used by all interested parties, especially:

1st Party Auditors, e.g. a QA Manager to audit his/her own operation.
2nd Party Auditors, e.g. a QA Manager who is auditing his/her supplier(s).
3rd Party Auditors, e.g. an auditor/auditing company who is/are independent of the organization being audited.

Useful websites that help further investigate food safety requirements include:

FDA “Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables”
http://www.fda.gov/downloads/food/guidancecomplianceregulatoryinformation/guidancedocuments/produceandplanproducts/ucm169112.pdf
2013 FDA Food Code
http://www.fda.gov/downloads/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/UCM374510.pdf
Guidance for Industry: Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance
http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/fooddefense/ucm083075.htm
Guidance on Inspection of Firms Producing Food Products Susceptible to Contamination with Allergenic Ingredients http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074944.htm
USDA/FDA Food Safety Information Center, http://www.usda.gov/wps/portal/usda/usdahome?navid=food-safety
California Leafy Green Handler Market Agreement G.A.P. Metrics
http://www.caleafygreens.ca.gov/sites/default/files/California%20LGMA%20metrics%2008%2026%2013%20%20Final.pdf

Audit Facility Definitions, Audit Structures and Scoring Systems

Types of facilities in the supply chain (a HACCP section may be added to the standard GMP section and is required for Processing operations):

- **Cooling and Cold Storage**
  Operations that are receiving goods directly from the fields, orchards, etc. after harvest, carrying out pre-cooling and/or cooling activities (ice injectors, top icing, hydrovac pressure cooling, wind tunnels, etc.) and storing at controlled temperatures. If there is any repacking, grading, packing, etc. occurring on site, then the operation is considered a Packinghouse.
- **Packaging**
  Operations that handle and store food contact packaging such as cardboard boxes or cartons, clam shells, bags, etc. This does not include packaging manufacturers.
- **Packinghouse**
  Any operation that is storing (cold or ambient temps), repacking, grading, packing, washing (or not) whole produce, etc. Postharvest treatments (e.g., fungicide, wax) may also be applied. If the item is being sliced, shredded, dried, juiced, frozen or otherwise altered in form then the operation is considered as Processing with HACCP.
- **Processing with HACCP**
  Any operation that is minimally processing or otherwise altering in form by peeling, coring, slicing, shredding, chopping, juicing, freezing, etc. prior to packaging for use by consumer or retailer (e.g., pre-cut salad mixes, sliced apples, etc.).
  1. This includes: Operations that are growing alfalfa sprouts, mung bean sprouts and any sprouts grown in a similar way (e.g., steam rooms).
  2. Leafy greens whose leaves have been cut, shredded, sliced, chopped, or torn, including iceberg lettuce, romaine lettuce, leaf lettuce, butter lettuce, baby leaf lettuce (i.e., immature lettuce or leafy greens, microgreens), escarole, endive, spring mix, spinach, cabbage, kale, arugula and chard. This does not include herbs, such as cilantro or parsley.
     http://www.fda.gov/downloads/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/UCM374510.pdf
- **Storage and Distribution**
  Facilities that are receiving and storing finished goods, normally at controlled temperatures, before further distribution (e.g., regional distribution warehouses). If there is any repacking, grading, packing, etc. occurring on site, then it is considered a Packinghouse. If there is any active cooling, such as ice being applied on-site (top icing, ice injector) or cooling using water (hydro cooling), then operation is considered a Cooling Cold Storage.

PrimusLabs Facility Question Applicability Chart v14.09 Audits

This chart is intended for guidance only. Situations will vary depending on process, product and intended use.

Denotes a question which is *likely* not to be applicable depending on process (e.g. cooling processes, use of water and/or ice, humidity), product and intended use. Auditor will determine actual applicability at time of inspection.

Question #	Question	Storage & Distribution	Cooling & Cold Storage (hydrocoolers, hydrovacs, ice)	Packinghouse (dry)	Packinghouse (washed/high humidity)	Processing
Examples		Cross dock	Broccoli, celery, lettuce, melon, peaches, spinach, sweetcorn,	Blueberries, cranberries, herbs, melon	Apples, asparagus, avocado, citrus, cranberries, melon, tomatoes	Fresh-cut potatoes, fresh-cut salad, frozen blueberries, juice, sliced mushrooms, sliced fruit, sprouts
				Whole onions, whole garlic	Whole potatoes	
1.1.1	There was no 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.					
1.2.1	Are all chemicals (pesticides, sanitizers, detergents, lubricants, etc.) stored securely, safely and are they labeled correctly?					
1.2.2	Are "food grade" and "non-food grade" chemicals used appropriately, according to label and stored in a controlled manner?					
1.2.3	Are 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 any allergen cross contamination issues)?					
1.2.4	Is the storage area completely enclosed?					
1.2.5	Is the facility's use restricted to the storage of food products?					
1.2.6	Are rejected or on hold materials clearly identified and separated from other materials?					
1.2.7	Are raw materials, 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 AUTOMATIC FAILURE OF THE AUDIT.					
1.2.8	Are all storage areas clean, especially the racking structures, lights, ceilings, floor areas by the walls and other hard to reach areas?					
1.2.9	Are materials (commodities, packaging, ingredients,					

Question #	Question	Storage & Distribution	Cooling & Cold Storage (hydrocoolers, hydrovacs, ice)	Packinghouse (dry)	Packinghouse (washed/high humidity)	Processing
	processing aids, work in progress, etc.) properly marked with rotation codes (receipt dates, manufacture dates, etc.)?					
1.2.10	Are materials (commodities, packaging, ingredients, processing aids, work in progress, etc.) rotated using FIFO policy?					
1.2.11	Are storage areas at the appropriate temperatures for the specific products being stored?					
1.3.1	Does the process flow, facility layout, employee control, utensil control, internal vehicle use, etc. ensure that finished goods are not contaminated by raw materials?					
1.3.2	Are all exposed materials (product, packaging, etc.) protected from overhead contamination (e.g. ladders, motors, condensation, lubricants, walkways, loose panels, degrading insulation, etc.)?					
1.3.3	Are packing and/or processing areas completely enclosed?					
1.3.4	Are production areas clean and well maintained; especially lights, floor areas by the wall and equipment, and other hard to reach areas?					
1.3.5	Is all re-work / re-packaging handled correctly?					
1.3.6	Are raw materials examined before use?					
1.3.7	Are finished products coded (carton and unit packaging) for the day of production?					
1.3.8	Does finished product coding clearly link to supplier(s) of incoming materials? (Auditor performs a live traceback test to verify the 2.4.1 documentation).					
1.3.9	Are foreign material control methods (e.g. metal detectors, metal traps, visual inspection, etc.) in place? Are these systems regularly tested (where relevant) to ensure proper operation?					
1.3.10	Does the facility use the appropriate test strips, test kits or test probes for verifying the concentrations of anti-microbial chemicals (product washing water, terminal sanitizers, dip stations, etc.) being used and are they in operational condition?					
1.3.11	Are hand washing stations adequate in number, appropriate in location, in working order, have warm water, adequately stocked (e.g. disposable towels, soap, etc.) and restricted to hand washing purposes only?					
1.3.12	Are toilet facilities adequate in number and location and are they adequately stocked (e.g. toilet paper, disposable towels, soap, etc.)?					
1.3.13	Are secondary hand sanitation stations e.g. touch-free					

Question #	Question	Storage & Distribution	Cooling & Cold Storage (hydrocoolers, hydrovacs, ice)	Packinghouse (dry)	Packinghouse (washed/high humidity)	Processing
	dispensers adequate in number and location? Are the stations maintained properly?					
1.3.14	Are foot dip stations adequate in number and location? Are the stations maintained properly?					
1.3.15	Are single services containers used for their intended purpose only so that potential cross contamination is prevented?					
1.3.16	Are re-usable containers clean and clearly designated for the specific purpose (raw product, finished product, re-work, ice, trash, etc.) such that cross contamination is prevented?					
1.3.17	Are food safety measuring devices working properly and calibrated (where applicable)?					
1.4.1	Are employees washing and sanitizing their hands before starting work each day, after using the restroom, after breaks and whenever hands may be contaminated?					
1.4.2	Are employees' fingernails clean, short and free of nail polish?					
1.4.3	Is there no sign of any employees with boils, sores, open wounds or exhibiting signs of foodborne illness working in indirect or direct contact with food?					
1.4.4	Are first aid kits adequately stocked and readily available? Are blue metal detectable waterproof band aids used?					
1.4.5	Are employees wearing effective hair restraints?					
1.4.6	Is jewelry confined to a plain wedding band and watches are not worn?					
1.4.7	Are all employees wearing outer garments suitable for the operation (e.g. smocks, aprons, sleeves and non-latex gloves)?					
1.4.8	Do employees remove protective outer garments e.g. smocks, aprons, sleeves and gloves when on break and before using the toilets and when going home at the end of their shift?					
1.4.9	Is there a designated area for employees to leave protective outer garments e.g. smocks, aprons, sleeves and gloves when on break and before using the toilets?					
1.4.10	Employee's personal items are not being stored in the production or material storage areas?					
1.4.11	Is smoking, eating, chewing and drinking confined to designated areas; spitting is prohibited in all areas?					
1.4.12	Are all items removed from garment (smock, shirt, blouse, etc.) top pockets?					

Question #	Question	Storage & Distribution	Cooling & Cold Storage (hydrocoolers, hydrovacs, ice)	Packinghouse (dry)	Packinghouse (washed/high humidity)	Processing
1.5.1	Are food contact equipment surfaces free of flaking paint, corrosion, rust and other unhygienic materials (e.g. tape, string, cardboard, etc.)?					
1.5.2	Are non-food contact equipment surfaces free of flaking paint, corrosion, rust and other unhygienic materials (e.g. tape, string, cardboard, etc.)?					
1.5.3	Does equipment design and condition (e.g. smooth surfaces, smooth weld seams, non-toxic materials, no wood, or other absorbent materials) facilitate effective cleaning and maintenance?					
1.5.4	Are thermometers (independent of thermostat probes) present in all coolers and freezers?					
1.5.5	Are all thermometers non-glass and non-mercury?					
1.6.1	Are food contact equipment surfaces clean?					
1.6.2	Are non-food contact equipment surfaces clean?					
1.6.3	During cleaning are foods and packaging protected from contamination?					
1.6.4	Are cooling units including coils in coolers and freezers clean and free of aged, dirty ice?					
1.6.5	Are all fan guards dust-free and the ceiling in front of the fans free of excessive black deposits?					
1.6.6	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?					
1.6.7	Are all utensils, hoses, and other items not being used stored clean and in a manner to prevent contamination?					
1.6.8	Are maintenance tools that are used in the production and storage areas of the facility clean, sanitary and corrosion free?					
1.6.9	Are excess lubricants removed from the equipment and are lubricant catch pans fitted where needed?					
1.7.1	Are spills cleaned up immediately?					
1.7.2	Are waste and garbage frequently removed from packing and storage areas?					
1.7.3	Do floor drains appear clean, free from odors and well maintained?					
1.7.4	Do high level areas including overhead pipes, ducts, fans, etc. appear clean?					
1.7.5	Are plastic strip curtains maintained in a good condition, kept clean and mounted so that the tips are not touching the					

Question #	Question	Storage & Distribution	Cooling & Cold Storage (hydrocoolers, hydrovacs, ice)	Packinghouse (dry)	Packinghouse (washed/high humidity)	Processing
	floor?					
1.7.6	Does personal protection equipment (PPE) for the sanitation crew meet label requirements of chemicals used; is it in good condition and stored to prevent cross contamination to raw materials, work in progress, ingredients, finished goods and packaging?					
1.7.7	Is cleaning equipment maintained clean and stored properly?					
1.7.8	Is cleaning equipment identified in order to prevent potential cross contamination issues e.g. production, maintenance, outside, restroom equipment?					
1.7.9	Are all items used for sanitation appropriate for their designated purpose? (no steel wool, metal bristles, etc.)					
1.7.10	Are toilet facilities and hand-wash stations clean?					
1.7.11	Are employee break facilities clean, including microwaves and refrigerators? No rotting or out of date foodstuffs?					
1.7.12	Is the maintenance shop organized - i.e. equipment and spares stored in a neat and tidy fashion?					
1.7.13	Are internal transport vehicles (e.g. forklifts, bobcats, pallet jacks, trolleys, floor cleaners, etc.), clean, do not emit toxic fumes and being used in a sanitary manner?					
1.7.14	Are shipping trucks clean and in good condition?					
1.8.1	Are products or ingredients free of insects/rodents/birds/reptiles/mammals or any evidence of them? ANY DOWN SCORE IN THIS QUESTION RESULTS IN AUTOMATIC FAILURE OF THE AUDIT.					
1.8.2	Are packaging supplies free of insects/rodents/birds/reptiles/mammals or any evidence of them? ANY DOWN SCORE IN THIS QUESTION RESULTS IN AUTOMATIC FAILURE OF THE AUDIT.					
1.8.3	Are plant and storage areas free of insects/rodents/birds/reptiles/mammals or any evidence of them?					
1.8.4	Is the area outside the facility free of evidence of pest activity?					
1.8.5	Does the operation have a pest control program? ANY DOWN SCORE IN THIS QUESTION RESULTS IN AUTOMATIC FAILURE OF THE AUDIT.					
1.8.6	Are pest control devices (inc. rodent traps and insect light traps) located away from all exposed raw materials, work in progress, finished goods and packaging? Poisonous rodent bait traps are not used within the facility?					

Question #	Question	Storage & Distribution	Cooling & Cold Storage (hydrocoolers, hydrovacs, ice)	Packinghouse (dry)	Packinghouse (washed/high humidity)	Processing
1.8.7	Are pest control devices maintained in a clean and intact condition and marked as monitored (or bar code scanned) on a regular basis?					
1.8.8	Are interior and exterior building perimeter pest control devices adequate in number and location?					
1.8.9	Are all pest control devices identified by a number or other code (e.g. barcode)?					
1.8.10	Are all pest control devices properly installed and secured?					
1.9.1	Are signs supporting GMPs posted appropriately?					
1.9.2	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?					
1.9.3	Has the facility eliminated or controlled any potential metal, glass or plastic contamination issues?					
1.9.4	Has the facility eliminated the use of wooden items or surfaces?					
1.9.5	Is there adequate lighting in the packing and storage areas?					
1.9.6	Are ventilation systems properly designed and functioning to prevent product contamination from condensation, mold, dust, odors and vapors?					
1.9.7	Are floor surfaces in good condition, with no standing water, no debris trapping cracks and are they easy to clean?					
1.9.8	Are the floor drains where they are needed for drainage and cleanup?					
1.9.9	Are doors to the outside pest proof?					
1.9.10	Are dock doors fitted with buffers to seal against trucks?					
1.9.11	Are dock load levelers and shelters maintained in a good condition, pest proof and debris free?					
1.9.12	Are exterior walls free of holes to exclude pests? Are pipes, vents, air ducts designed and protected in order to prevent pest entry e.g. by using fine mesh?					
1.9.13	Are interior walls and ceilings free of cracks and crevices to prevent pest harborage and allow proper sanitation?					
1.9.14	Where used in production, storage or supporting areas do false ceiling areas have adequate access to allow for inspection and cleaning?					
1.9.15	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?					

Question #	Question	Storage & Distribution	Cooling & Cold Storage (hydrocoolers, hydrovacs, ice)	Packinghouse (dry)	Packinghouse (washed/high humidity)	Processing
1.9.16	Is the exterior area immediately outside the facility free of litter, weeds and standing water?					
1.9.17	Are control measures being implemented for the storage of pallets, equipment, tires etc. (i.e. out of the mud, pipe ends capped, stacked to prevent pest harborage, away from building perimeter)?					
1.9.18	Are pallets inspected to separate and replace dirty or broken pallets?					
1.9.19	Is the area around the dumpster/cull truck/trash area clean?					
1.9.20	Are outside garbage receptacles and dumpsters kept covered or closed?					
1.9.21	Are all water lines protected against back siphonage?					
1.9.22	Is the on-site laboratory (where applicable) completely enclosed and separated from production and/or storage areas?					
2.1.1	Is the operation registered as a food handling establishment?					
2.1.2	Is there a documented food safety policy reflecting the organization's ongoing commitment to providing a safe product?					
2.1.3	Is there an organizational chart showing who has food safety responsibilities and to whom they report?					
2.1.4	Is there a designated person responsible for the food safety program?					
2.1.5	Is there a food safety committee and are there logs of food safety meetings with topics covered and attendees?					
2.2.1	Is there a written document control procedure describing how documents will be maintained, updated and replaced?					
2.2.2	Are all records stored for a minimum period of 24 months?					
2.2.3	Are food safety related documents and records stored and handled in a secured manner? Records recorded in permanent ink, not pencil; errors single-lined through and initialed?					
2.3.1	Are there written Standard Operating Procedures (SOPs) that detail work instructions for activities ensuring food safety and Good Manufacturing Practices?					
2.3.2	Are there specific Standard Operating Procedures (SOPs) for the changing and testing of water and ice systems e.g. wash systems, hydrovacuums, hydrocoolers, ice making machines, ice injectors, etc?					
2.3.3	Is there a documented glass and brittle plastic management policy and procedure (including company glass and brittle					

Question #	Question	Storage & Distribution	Cooling & Cold Storage (hydrocoolers, hydrovacs, ice)	Packinghouse (dry)	Packinghouse (washed/high humidity)	Processing
	plastic policy, glass breakage procedure and where necessary a glass register)?					
2.3.4	Are the SOPs available to relevant users and is a master copy maintained in a central file (SOP Manual)?					
2.4.1	Is there is a documented account 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?					
2.4.2	Does the facility have a documented recall program including: procedures, recall team roles and contact details and external contact listings and (in the USA) an explanation of different recall classes?					
2.4.3	Is testing of recall procedures (including trace back) performed and documented at least once every six months? Can the company identify where affected product was sent?					
2.4.4	Is there a written procedure for handling on hold and rejected materials?					
2.4.5	Is there a documented system for dealing with food safety complaints/feedback from consumers and buyers along with records and company responses, including corrective actions?					
2.5.1	Are there written specifications for own grown raw materials, purchased edible raw materials/ingredients, packing materials processing and sanitation chemicals)?					
2.5.2	Are there written specifications for finished goods?					
2.5.3	Is there a list of approved suppliers of purchased raw materials, ingredients and packaging items?					
2.5.4	Is there a written procedure for approval and continued monitoring of suppliers of raw materials/ingredients, packaging materials, processing and sanitation chemicals?					
2.5.5	Does the facility have relevant third party audit reports, supplier third party audit certifications and/or letters of guarantee for purchased edible raw materials/ingredients and processing chemicals?					
2.5.6	Does the facility have relevant third party audit reports, supplier third party audit certifications and/or supplier letters of guarantee for packaging items?					
2.6.1	Are copies of all Materials Safety Data Sheets (detergents, sanitizers, pesticides, etc.) on file and fully accessible at all times with clear indexes?					
2.6.2	Are there copies of specimen labels for chemicals used, where the full label is not immediately accessible e.g. rodent					

Question #	Question	Storage & Distribution	Cooling & Cold Storage (hydrocoolers, hydrovacs, ice)	Packinghouse (dry)	Packinghouse (washed/high humidity)	Processing
	chemicals, product sanitizers?					
2.6.3	Is there a chemical inventory and/ or usage log?					
2.7.1	Is there a documented pest control program, including a copy of the contract with the extermination company (if used), Pest Control Operator license(s) (if baits are used) and insurance documents?					
2.7.2	Is there a schematic drawing of the plant showing numbered locations of all traps and bait stations, both inside and outside the plant?					
2.7.3	Are service reports created for pest control checks detailing inspection records, application records, and corrective actions of issues noted (in-house and/or contract)?					
2.8.1	Are there written procedures for handling regulatory inspections?					
2.8.2	Are there records of regulatory inspections and/or contracted third party inspections, company responses and corrective actions, if any?					
2.8.3	Is there a program for periodic facility/GMP internal (self) inspections and are records maintained detailing corrective actions?					
2.8.4	Is there a program for periodic inspections of food safety system records e.g. pest control records, temperature control records, sanitation records, maintenance records, etc?					
2.8.5	Is there a daily pre-operation inspection log?					
2.8.6	Does the facility have incoming goods (raw materials, ingredients and packing materials) inspection data?					
2.8.7	Are there inspection logs on incoming trailers for rodents and insects, cleanliness, holes and temperature control?					
2.8.8	Is there an incidents report, sometimes called a Notice(s) of Unusual Occurrence and Corrective Actions Log (NUOCA) used for recording infrequent and/or unusual events?					
2.8.9	Is there a current certificate of inspection for backflow prevention assemblies on water lines entering the facility?					
2.9.1	Are there records for the necessary process monitoring activities (e.g. pH, water temperature, heating processes, etc.) showing the monitoring frequencies, results and where necessary the corrective actions?					
2.9.2	Are there records (with corrective actions) that show anti-microbial (e.g. free chlorine, ORP, peracetic acid) strength testing of wash water and ice solutions prior to start up and throughout the production runs?					

Question #	Question	Storage & Distribution	Cooling & Cold Storage (hydrocoolers, hydrovacs, ice)	Packinghouse (dry)	Packinghouse (washed/high humidity)	Processing
2.9.3	Are there records (with corrective actions) that show anti-microbial strength testing of hand/foot/tool dip stations? Are there stock check and replenishment records for gel and spray stations?					
2.9.4	Is there a tool accountability program for knives and similar cutting hand tools used in the production process?					
2.9.5	Are there written procedures for the set-up, calibration, maintenance and verification of foreign material control systems e.g. metal detectors?					
2.9.6	Are there equipment calibration procedures and records for pH meters, ORP meters, thermometers and other measuring equipment related to the food safety of the product?					
2.10.1	Does the facility have a preventative maintenance program and with a documented schedule?					
2.10.2	Is there a log of maintenance work or repairs ordered and is it signed off on work completed?					
2.10.3	Are there logs showing that equipment is cleaned and sanitized after maintenance work has been completed?					
2.10.4	Is there a written cleaning schedule (Master Sanitation Schedule) that shows what and where is to be cleaned and how often?					
2.10.5	Are there written cleaning and sanitation procedures (Sanitation Standard Operating Procedures) for the facility and all equipment?					
2.10.6	Are sanitation logs on file that show what cleaning was done, when and who carried out the cleaning?					
2.10.7	Are there records showing verification of cleaning chemical concentrations?					
2.10.8	Are there documented procedures and completion records for clean-in-place (CIP) activities, where applicable (e.g. cleaning re-circulating water systems such as washing flumes, ice injectors, hydrocoolers, ice makers, etc.)?					
2.10.9	Is there a log indicating that floor drains are cleaned on a regular basis (minimum daily in wet and fresh-cut production areas)?					
2.10.10	Are there records showing cooling units are serviced and cleaned at least every 12 months or more frequently as required?					
2.10.11	Is there a routine program and written procedure to validate sanitation effectiveness on food contact surfaces using ATP bioluminescence testing?					

Question #	Question	Storage & Distribution	Cooling & Cold Storage (hydrocoolers, hydrovacs, ice)	Packinghouse (dry)	Packinghouse (washed/high humidity)	Processing
2.11.1	Are there records of new employee food safety (GMP) orientation training (with topics covered and attendees) and are new employees required to sign the company's food safety hygiene and health policy?					
2.11.2	Are there logs of ongoing employee food safety education training with topics covered and attendees?					
2.11.3	Are there written 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? (Verbal confirmation accepted).					
2.11.4	Is there a documented training program with training logs for the sanitation employees including best practices and chemical use details?					
2.11.5	Are visitors and contractors required to sign a log stating that they will comply with the operations' personal hygiene and health policies?					
2.11.6	Is there an employee non-compliance/disciplinary action procedure? (verbal confirmation accepted).					
2.12.1	Are there records of routine equipment microbiological testing?					
2.12.2	Are there records of routine environmental microbiological testing?					
2.12.3	Are there routine microbiological test on water used in the facility (sampled from within the facility)?					
2.12.4	Are there routine microbiological tests on ice used in the facility (either produced in-house or purchased)?					
2.12.5	Do laboratory test results indicate test procedures meet accepted standards?					
2.12.6	Where testing has been performed for any reason, (e.g. buyer requirements) does the testing meet all the specification requirements (e.g. type of test, test frequency, test methodology, thresholds, corrective actions, etc.) and are proper records of tests with formal corrective actions being maintained?					
2.13.1	Are there records of final product temperature checks for temperature sensitive product?					
2.13.2	Are there temperature logs for the packing room (if refrigerated)?					
2.13.3	Are there temperature logs for storage rooms?					
2.13.4	Are there records of shipping truck temperature checks, indicating that the truck was pre-cooled prior to loading?					

Question #	Question	Storage & Distribution	Cooling & Cold Storage (hydrocoolers, hydrovacs, ice)	Packinghouse (dry)	Packinghouse (washed/high humidity)	Processing
2.13.5	Are there sanitary condition logs for shipping trucks (cleanliness, trailer condition, odor, etc.)?					
3.1.1	Is there a team responsible for HACCP development, implementation and on-going maintenance?					
3.1.2	Is there documented HACCP specific training for the HACCP team, management and operating personnel?					
3.2.1	Does a product description exist for each product produced? Do they contain the products intended use, materials and raw ingredients, and who the intended consumer is?					
3.2.2	Has the process been flow charted? Is the flow chart in sufficient detail to completely describe the process or product manufacturing steps?					
3.2.3	Has a documented hazard analysis for each process flow been conducted, showing the various types of hazard and their associated severity?					
3.2.4	Does the documented hazard analysis show the controls for each identified potential food safety hazard?					
3.2.5	Have CCP decisions been made, have CCPs been identified and where CCPs are noted have they been developed to control the hazards identified in the hazard analysis step?					
3.2.6	Have monitoring requirements and frequencies been determined for the CCPs?					
3.2.7	Are identified CCP critical control limits supported by validation documentation?					
3.2.8	Is there a clear, detailed action plan for operators to follow if the CCP critical control limits are exceeded? Does it describe plans to adjust the process back into control and withhold out of compliance products if necessary?					
3.2.9	Have recording templates (recording forms) been developed for monitoring the CCPs?					
3.2.10	Have specific responsibilities been assigned for the monitoring, recording and corrective action management of each CCP?					
3.2.11	Have verification plans and schedules been developed for each CCP?					
3.3.1	Are all of the documents noted in the HACCP plan in place for real time monitoring of the CCPs?					
3.3.2	Are the CCP monitoring activities and frequencies in conformance with the plan?					
3.3.3	Do CCP operators understand basic HACCP principles and their role in monitoring CCPs? (Interview operators to					

Question #	Question	Storage & Distribution	Cooling & Cold Storage (hydrocoolers, hydrovacs, ice)	Packinghouse (dry)	Packinghouse (washed/high humidity)	Processing
	verify).					
3.3.4	Are CCP monitoring records signed off (or initialed) by the operator(s) who are carrying out and recording the CCP check?					
3.3.5	Are corrective actions detailed in writing when the failure of a CCP occurs?					
3.3.6	Are the CCP records reviewed and signed off daily by the quality control supervisor and/or management as part of the verification plan?					
3.3.7	Is any other CCP verification performed (apart from daily record verification) according to the HACCP Plan?					
3.4.1	Are changes in the process, equipment, ingredients, etc., causing timely reviews of HACCP systems including hazard analysis, CCP decisions, CCP records and staff training?					
3.4.2	Is the plant conducting self-audits of the HACCP program?					
3.4.3	Have standard operating procedures (SOPs) been created for the CCP monitoring processes that include how to carry out the monitoring?					
3.4.4	Are monitoring and verification information reviewed and discussed at management level meetings?					
3.4.5	Are there independent audits e.g. third party audits, of the plant's HACCP program (at least every 12 months)?					
4.1.1	Are the facility external areas and vulnerable entry points (i.e. those that are not permanently locked) surrounded by security fencing?					
4.1.2	Is access to the facility controlled by, locks, swipe cards, alarms or other devices?					
4.1.3	Are inbound food product storage areas (fruits, vegetables, etc.) secure i.e. within the secure compound?					
4.1.4	Are chemicals such as chlorine, citric acid, fungicides and sanitation chemicals stored within secured areas with controlled access?					
4.1.5	Are packaging material (cartons, wrap film etc.) storage areas secure i.e. within the secure compound?					
4.2.1	Are background checks conducted on all personnel with special attention to employees who have access to sensitive areas and/or control of sensitive processes (verbal confirmation accepted)?					
4.2.2	Employees personal items are not being stored in the production and material storage areas?					
4.2.3	Are employees issued non-reproducible identification badges?					

Question #	Question	Storage & Distribution	Cooling & Cold Storage (hydrocoolers, hydrovacs, ice)	Packinghouse (dry)	Packinghouse (washed/high humidity)	Processing
4.2.4	Are visitors (including contractors) also required to be issued with identification e.g. badges, high visibility visitor apparel, etc?					
4.2.5	Are visitors (including contractors) required to "sign in" and sign out" in a visitors log book?					
4.3.1	Does the company make use of sealed and/or locked trailers on inbound loads (excluding open flatbed trucks)?					
4.3.2	Does the company make use of sealed and/or locked trailers on outbound loads?					
4.4.1	Are potable and non-potable water supply clearly identified?					
4.4.2	Are tamper evident/tamper resistant systems (e.g. tamper tags) in place where appropriate?					
4.4.3	Is there restricted access to sensitive water systems, e.g. anti-microbial addition systems (like chlorine injection pumps), that helps ensure that only authorized personnel are able to adjust these systems?					
4.5.1	Does the company have a documented food defense policy based on the risks associated with the operation?					
4.5.2	Is there a current list of emergency contact phone numbers for management, law enforcement and appropriate regulatory agencies?					
4.5.3	Are all personnel required to undergo training on food defense issues and are training records kept?					
4.5.4	Is there is a log of who has access to sensitive areas e.g. a listing of key holders for access to areas like chemical storage?					
5.1.1	There are no allergen risks handled or stored within production and storage areas? If N, then complete Allergens Section (next 6 questions).					
5.1.2	Has a documented allergen management plan been developed?					
5.1.3	Are there adequate storage controls (separation, identification etc.) that ensure that allergens are not contaminating other raw materials?					
5.1.4	Is there a dedicated production line or adequate clean down and production procedures that prevent allergen cross contamination?					
5.1.5	Are utensils and work in progress storage containers identified in order to prevent allergen cross contamination?					
5.1.6	Does re-work handling take into account the issue associated with allergen containing products?					
5.1.7	Are employees trained with respect to allergen risks and the					

Question #	Question	Storage & Distribution	Cooling & Cold Storage (hydrocoolers, hydrovacs, ice)	Packinghouse (dry)	Packinghouse (washed/high humidity)	Processing
	facility allergen cross contamination controls (including hand washing between production runs) and are there allergen training records?					
5.1.8	Are all products manufactured on site, labeled correctly with respect to allergens?					
5.2.1	Is the company labeling retail packaging with the correct country of origin? N/A for food service.					
5.2.2	Is the company labeling the finished goods carton with the correct country of origin? N/A for food service?					
5.2.3	Are there records that support the country of origin labeling e.g. bill of lading, production records, etc.?					
5.2.4	Are steps taken in the storage and production process to ensure that there is no commingling of materials from different countries (unless product will be labeled as such)?					
6.1.1	Does the waste flow, from creation through to leaving the operation including vehicle use and flow, employee control, etc., ensure that facility and products are not contaminated?					
6.1.2	Is there a written procedure requiring transportation vehicles be dedicated to produce, and that animals, animal products or other materials that may be a source of contamination are not allowed to be transported?					
6.1.3	Is there a documented food safety plan covering site and facility?					
6.1.4	Is there a documented continuity and disaster recovery plan?					
6.1.5	Does the facility have documented evidence to ensure that any food safety hazards relevant to waste water treatments (e.g. settling ponds, land applications, etc.) are controlled?					
6.1.6	Has the operation listed the HACCP pre-requisite programs that are in effect at the facility?					
6.1.7	Where operating limits and frequencies been established for the CCPs are they being monitored?					

Audit Template Structures

- *GMP Section*. Covers the physical tour of the facility
- *Food Safety File*. Covers the food safety systems and documentation
- *HACCP Section* (optional at auditee's request, required by some buyers). Please note that sections 1 and 2 act as checks of HACCP pre-requisites.
- *Food Defense Section*, covering both the physical and documented food security requirements. This section is scored – the default system is to score this section separately to the overall audit score. Some buyers require that the food security score be combined with the other sections of the audit – this is optional, please check with your buyer(s).
- *Miscellaneous Questions*. These are scored individually and are not part of the overall audit score.
- *New Questions*. These are scored individually and are not part of the overall audit score. Please note that these questions will be added to the main audit when the next revisions are issued.

The audit format is updated as needed. This may include the layout, the questions themselves and point assignments. The following is the scoring system used for the PrimusLabs GMP audits:

Point System (Weighting) for Individual Questions				
Possible Question Points	Full conformance	Minor Deficiency	Major Deficiency	Non-conformance
15 Point Question	15 points	10 points	5 points	0 points
10 Point Question	10 points	7 points	3 points	0 points
5 Point Question	5 points	3 points	1 point	0 points
3 Point Question	3 points	2 points	1 point	0 points

Each question and conformance has to be looked at individually and scored according to the severity of the deficiency, the number of deficiencies and the associated risks. Detailed conformance requirements are noted in the Point Assignment Guidelines, but some general statements are described below. These statements are superseded by the conformance criteria and users should be aware that some questions do not follow the general statements below (e.g., automatic failure questions).

Conformance Categories	
Full conformance	To meet the question and/or conformance criteria in full.
Minor deficiency	To have minor deficiencies against the question and/or conformance criteria. To have single or isolated non-severe deficiencies (usually up to three) against the question and/or conformance criteria. To have covered most of the question conformance criteria, but not all.
Major deficiency	To have major deficiencies against the question and/or conformance criteria. To have numerous non-severe deficiencies (usually more than three) against the question and/or conformance criteria. To have single or isolated severe deficiencies against the question and/or conformance criteria. To have covered some of the question conformance criteria, but not most of it.
Non-conformance	To have not met the question and/or conformance criteria requirements at all. Having systematic deficiencies against the question and/or conformance criteria (severe or non-severe issues).

Automatic Failure

There are five questions in the facility audits, 1.1.1, 1.2.7, 1.8.1, 1.8.2 and 1.8.5, that if down scored will lead to an automatic failure and an overall score of 0%. The report will include a breakdown of the scores for each section (summary chart), even if an automatic failure question is scored down. **On being immediately informed of the automatic failure by the auditor during the audit, the auditee has the option to have the auditor continue to complete the audit or to have the audit halt at that point (all charges will apply).**

Special Circumstances

Under special circumstances PrimusLabs reserves the right for a certificate not to be issued. These circumstances include the inability to complete the audit, detection of serious food safety issues (in the audit or corrective action processes), deliberate illegal activities, physical acts/threats to an auditor, attempted bribery, falsified records, etc.

Audit Termination

Once an audit has been started, should the auditee wish to stop the audit for any reason other than an automatic failure (see text above) the auditor will complete the report for as many questions as they were able to verify. Questions that the auditor was unable to verify, will be marked as non-conformance and receive a score of zero. For questions unable to be verified the auditor will indicate the audit was terminated at the request of the auditee before the auditor could verify whether or not the audit conformed to the compliance criteria of the question. **A report will be issued and all charges will apply.**

Change of Audit Service

Once an audit has been started it cannot be converted into a pre-assessment audit. This includes when an automatic failure question has been scored down, as noted in the above paragraph. Vice versa, a pre-assessment audit cannot be converted into a standard audit once the service has begun.

The only time a standard audit can be optionally turned into a pre-assessment audit is when the operation is found not to be running on the day of the audit, which can result in the cancellation of the audit (with charges) or the audit can be turned into a pre-assessment (see texts below).

At the opening meeting, an auditor may suggest that the wrong audit template has been chosen and recommend an optimal template for the auditee operation. For example, if a Packinghouse with HACCP Audit is booked but the auditor learns that processed ready-to-eat baby leaf spinach production is occurring on a weekly basis, the auditor will recommend switching to a Processing with HACCP Audit template. If the auditee decides not to use the optimum template that the auditor recommends, the auditor **will indicate in the audit scope which processes were not covered by the audit**. In the example, this would be "audited packinghouse operation, but did not audit the processed leafy greens operation". If an auditee does decide to change service requirements, then the auditor will inform PrimusLabs as soon as possible.

Commodity Selection

The audit report will show a list of commodities that the auditee indicates they handle under the scope of the audit and a list of commodities that the auditor actually saw on the day of the audit. The two lists may or may not be the same, as the auditor indicates what is seen at the time of inspection.

Facility Audit Agenda

Audit agenda's do vary, but the normal pattern of events is as follows:

- **Opening Meeting**. Confirm the appointment details, introduce the auditor(s) and auditee team, confirm scope and the day's agenda.

- **Tour of Operations**. Areas toured depend of the type of facility, but might include raw material storage areas, production, finished goods storage, personnel facilities, maintenance, chemical storage, packaging storage and external areas (e.g., where the dumpsters are located). The auditor might interview some operators.

- **Food Safety File (paperwork section)**. New auditees should have at least three months' worth of paperwork available (unless a short season crop packing facility where the facility is in operation less than three months of the year) – see below for further details. Please note that the auditor cannot accept documentary evidence after the audit has ended. For example, if a pest control document is missing at the time of the audit and the auditee tries to fax it the next day, it cannot be used to alter the score.

- **HACCP Section (if relevant)**. The auditor might look at the HACCP file in the opening meeting in order to orientate themselves about the site program and CCPs. Auditor will interview CCP operators.

- **Food Security Section**. The auditor will have made notes about physical security aspects when carrying out the tour of the operation. <u>These questions are scored.</u>

- **Miscellaneous Questions and New Questions**. Might be covered at any point in the audit, as the topics arise.

- **Auditor "Quiet" Time**. Time required for the auditor to organize notes before delivering the closing meeting.

- **Closing Meeting**. Discuss findings with the auditee team. Auditors are not able to provide either a final score or pass/fail commentary at the end of the audit due to the high number of questions that are asked in the template and the scoring system that is applied. However, auditors do

submit audit reports quickly and auditees should contact PrimusLabs if reports have not been received electronically two weeks after the audit has occurred (at the latest).

It is imperative that the facility is running product, i.e., processing, packing, cooling (whatever functions are usually occurring as on a "normal" day) and that a normal quantity of personnel are on site when the audit occurs in order for the auditor to complete a valid assessment. If the facility is not running and/or there are no production employees or product on site, then the audit will have to be terminated and cancellation charges will be applied, or the audit can continue as a pre-assessment audit. Please ensure that auditee personnel are available to follow the facility tour and are well versed in the areas that are being inspected.

PrimusLabs Documentation Requirements

New Facility Auditees/First Time Facility Auditees

- **In operation for more than three consecutive months** – auditee should have at least three months of documentation available for review. If the facility has less than three months of most of their documentation available for review, a pre-assessment audit is strongly advised. If the auditee has less than three months of most of their documentation available for review and decides to have a regular audit, they should be aware that they **cannot receive full conformance for paperwork questions related to monitoring and that the down score will be based on the amount of paperwork available**.

- **Short season operation, in operation for less than three consecutive months** - auditee should have at least three months of documentation available for review (this may include last season's documentation). Where an operation does not have three months of records available for their current season (e.g., one month of operation per year), auditee should have at least the previous season's records available for review. If the auditee has less than three months of most of their documentation available for review and decides to have a regular audit, they should be aware that they **may not receive full conformance for paperwork questions related to monitoring and that the down score will be based on amount of paperwork available**.

Existing Facility Auditees

- **In operation for more than three consecutive months** – auditee should have at least three months of documentation since the last audit.

- **Short season operation, in operation for less than three consecutive months** – auditee should have at least three months of documentation since the last audit (which can include documentation from the prior season). Where an operation does not have three months of records available (e.g., one month of operation per year), auditee should have at least the previous season's records available for review.

	Operates <three months/year	**Operates >three months/year**
New Auditee	**Three months of records (may include last season's records)**	**Three months of records (may include last season's records)**
Existing Auditee	**Records at least since last audit (or longer) to meet minimum requirement of three consecutive months of records**	**Records since last audit**

For further information about the facility audit process and booking facility audits please go to http://www.primuslabs.com/services/StandardGMP.aspx

Visual versus Verbal Confirmation

Visual confirmation is the default method of auditing, whether on the plant tour or the paperwork section. Scores and comments are assumed to have been visually confirmed, unless otherwise stated. Verbal confirmation should be the exception to the rule and, if auditing properly, these should be rarely used. If a verbal confirmation is accepted, the auditor should write this in the comments section of the question.

How to Use Point Assignment Guidelines

The following sections of this guidance manual are designed to help the users choose the right score for each question, thereby helping to ensure consistency.

This document does not cover all situations and is intended to be a guideline, as opposed as a rule. Auditors are expected to follow the guidelines as much as possible, but it is understood that there will be situations where an auditor should use their discretion. If an auditor does have to make a judgment call and/or tackle a situation not covered by this manual, then the auditor should note the circumstances in the audit report with full justifications. (The auditor should also forward these details to PrimusLabs in a separate note, so that this can be accounted for in the next version of the manual.)

In order to be consistent with the voluntary nature of requesting a third party audit, and in order not to seen to be a legal document, the requirements within the questions are written as "should", and can be scored against. In other questions that use the term "ideally", these statements cannot be scored against, but give the auditee an opportunity for improvement.

Notes in "red" are where the questions and/or conformance criteria have changed significantly since the previous version. Many of the changes are to improve clarification, but some are changes to the actual requirements. Please read carefully to see if these changes impact your particular situation.

At the end of this document, there is a helpful applicability chart that briefly summarizes the use of "N/A" with some of the questions. While there may be technical flaws in the applicability chart, the aim is to ensure auditor-to-auditor consistency.

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Point Assignment Guidelines

Good Manufacturing Practices - Section 1 (Facility Tour)

Management Systems

1.1.1 There was no significant threat to the safety of the product that may be considered critical and warrants an automatic failure? Explain any "no" response. ANY DOWN SCORE IN THIS QUESTION RESULTS IN AUTOMATIC FAILURE OF THE AUDIT.

Visual Confirmation. Total conformance (15 points): No observation of any issue that the auditor considers a significant threat to the safety of the product. Issues covered by this question are critical food safety situations that might not be considered in the audit template questions and conformance criteria. Alternatively, there may be question and conformance criteria that cover the topic of the issue within the audit, but the situation discovered warrants an automatic failure as opposed to a point down score; the auditor will note the issue in this question.

Specific directions for pest and other adulteration (direct observation of product contamination and/or adulteration) are covered in 1.2.7, 1.8.1, 1.8.2 and 1.8.5. This question is intended for other issues that may not be covered by those questions. Scoring reverts back to this question where the auditor must detail their concern. If the auditor spots an issue that is a serious threat to food safety (as opposed to a pre-requisite) and corrective actions are not being implemented, issue may also be scored here.

http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/FDCActChapterIVFood/default.htm

Automatic Failure (0 points) if:

- **There is a significant threat to the safety of the product**.

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Storage Areas & Packaging Materials

1.2.1 Are all chemicals (pesticides, sanitizers, detergents, lubricants, etc.) stored securely, safely and are they labeled correctly?

Visual confirmation. Total conformance (15 points): Chemicals are stored in a designated (with a sign), dedicated, secure (locked) area, away from food and packaging materials and separated from the production areas. Access to chemicals needs to be controlled, so that only personnel who understand the risks involved and have been trained properly are allowed to access these chemicals.

All chemical containers should have legible content labels, including chemicals that have been decanted from master containers into smaller containers. Where chemicals are stored, adequate liquid containment (spill controls) techniques need to be employed (e.g., via secondary containment, absorbent materials, angled sealed floors, spill kits, etc.). Chemical storage should be designed to help contain spills and leaking containers. Large volumes (e.g., 55 gallon drums) in use next to a wash line should be secured in some way (e.g., anchored, chained) and on spill containment. Empty containers should be stored and disposed of safely. Liquids should not be stored above powders.

Minor deficiency (10 points) if:
- Single/isolated instance(s) of chemicals not properly stored.
- Single/isolated instance(s) of improperly labeled or unlabeled chemical containers.
- Single/isolated instance(s) of empty containers either not being stored properly or disposed of properly.
- The chemical storage area is not marked to indicate its use.
- Single isolated instance(s) of chemicals being used without proper attention to chemical spillage.

Major deficiency (5 points) if:
- Numerous instances of improperly stored chemicals.
- Numerous instances of improperly labeled or unlabeled chemical containers.
- Chemical storage is segregated in a designated area, but not locked.
- Chemical storage area(s) has inadequate liquid containment systems.
- Spilled chemicals found in the chemical storage areas (not cleaned up properly).
- Numerous instances of empty containers either not being properly stored or disposed of properly.
- Numerous chemicals being used without proper attention to chemical spillage.

Non-conformance (0 points) if:
- There is no designated area for chemicals.
- There is a designated area for chemicals, but it is not an enclosed or locked area.
- Visible chemical spills in the facility and surrounding grounds that have not been cleaned up.

1.2.2 Are “food grade” and “non-food grade” chemicals used appropriately, according to label and stored in a controlled manner?

Visual/Records confirmation. Total conformance (10 points): All chemicals applied to products (e.g., waxes, coatings, postharvest fungicides and other chemicals) should be approved by the US EPA, FDA or prevailing authority for their designated use and used according to label instructions. This includes following correct dilutions, using only food grade salt in ice injectors, H1 designation on lubricants, etc. Any chlorine bleach that is used for making a sanitizing solution, whether for equipment or raw produce, must be of sufficient purity to be categorized as a “food grade” substance. Some commercially available household chlorine bleaches contain fragrances, thickeners and/or other additives that are not approved for food use. These products are not suitable for making sanitizing solutions. If any chemicals are used to alter or buffer the pH of a sanitizing solution these should also be “food grade.”
Food grade chemicals, including lubricants, greases, etc., are used in all product/packing contact areas. Non-food grade chemicals also include cleaning chemicals and paint. For example, use of domestic polishes which are not intended for food contact surfaces and have strong fragrances should not be used

on food contact surfaces. In addition, office cleaning materials, restroom cleaning materials and truck cleaning materials should be stored separately from production cleaning materials. Food grade chemicals should be stored apart from non-food grade items to eliminate confusion between types. Grease guns should indicate which are for food grade greases and which are for non-food grade use. Non-food grade material use, where required, should not be used in food contact areas and be entrusted to personnel who know how to use the chemicals to avoid contamination issues. Non-food grade materials should not be found in the production/storage areas (unless stored securely, with access to entrusted personnel only).
Potentially useful websites:-
NSF International: Nonfood Compounds http://info.nsf.org/USDA/psnclistings.asp
http://www.codexalimentarius.org/input/download/standards/3/CXS_150e.pdf
http://pods.dasnr.okstate.edu/docushare/dsweb/Get/Document-963/FAPC-116web.pdf

Minor deficiency (7 points) if:
- Single/isolated instance(s) commingling of non-food grade with food grade chemicals.
- Single/isolated instance(s) grease guns not being coded for food grade/non-food grade materials.
- Single/isolated instance(s) of non-food grade materials found/used in the production/storage areas.
- Single/isolated instance(s) of a chemical being used contrary to label or misused in anyway.

Major deficiency (3 point) if:
- Numerous instances of commingling of non-food grade with food grade chemicals.
- Numerous instances of grease guns not coded for food grade/non-food grade materials.
- Numerous instances of non-food grade materials found/used in the production/storage areas.
- Numerous instances of a chemical(s) being used contrary to label or misused in anyway.

Non-conformance (0 points) if:
- No attempt to split non-food grade from food grade materials.
- Systematic use of non-food grade materials found/used in the production/storage areas.
- Systematic use of a chemical(s) (e.g., postharvest fungicide) used contrary to label or misused in anyway. **Auditor should consider reverting to 1.1.1, the general automatic failure question.**
- **Evidence of the use of a non-food grade chemical that has caused product contamination – revert to 1.2.7, automatic failure.**

1.2.3 Are 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 any allergen cross contamination issues)?
Visual confirmation. Total conformance (15 points): All ingredients, 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. 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. When assessing raw contamination of finished goods, the auditor should assess the level of risk (e.g., how “processed” are the finished goods, what kind of packaging is used, etc.). Raw unprocessed items should not be able to contaminate finished washed/processed items. Packaging storage, especially dust from cardboard storage should not contaminate produce items. If mixed food items are stored on site, then there should be controls to prevent contamination issues (e.g., raw eggs should not be stored above raw produce, glass items should be kept in a separated area and always stored near ground level). Wet product is not stored above product – this is especially important where iced product is being stored in conditions where the ice is thawing and dripping. Ice should be manufactured, stored and handled in a manner that eliminates contamination issues. Pay attention to ice tools and how salt for ice making is being stored and handled. Condensate is scored in 1.9.6.

Minor deficiency (10 points) if:
- Single/isolated instance(s) of products or packaging materials stored on the floor or not protected properly.

- Single instance of a pallet or boxes/bags of finished product stored too close to raw product or ingredients.
- Single instance of ice/water dripping from above pallet onto unprotected product underneath.
- Single instance of improper ice storage or handling practices.

Major deficiency (5 points) if:
- Numerous instances of products or packaging materials not protected properly.
- Numerous instances of products or packaging materials stored directly on the ground.
- Isolated instances (no more than three) of raw product or ingredients stored in the same room as bagged/boxed finished product where there is not adequate physical separation and demarcation within the room, i.e. potential risk of raw and processed finished goods cross contamination.
- More than one but less than three instances of ice/water dripping from above pallet onto unprotected product underneath but with no signs of product adulteration.
- More than one but less than three instances of improper ice storage handling practices

Non-conformance (0 points) if:
- Different food items being stored together in a way that poses a cross contamination risk.
- Systematic storage of product or packaging materials directly on the ground.
- Numerous instances of raw product or ingredients and bagged/boxed finished product stored in the same room without adequate segregation; high risk raw and processed finished goods cross contaminating.
- More than three instances of ice/water dripping from above pallet onto unprotected product underneath but with no signs of product adulteration.
- More than three instances of improper ice storage or handling practices.
- **Any signs of product adulteration from poor storage practices – see 1.2.7, automatic failure due to product contamination.**

1.2.4 Is the storage area completely enclosed?

Visual confirmation. Total conformance (10 points): To protect the product and packaging materials from the elements and pests, it is necessary to keep the storage area enclosed and pest proof. Main doors should be kept closed, unless in use. Food contact packaging should not be stored outside. Non-food contact packaging (e.g., cardboard outers) should be stored inside if possible. If some non-food contact packaging is stored outside, then this outside storage area should be included in the pest control program. Outside stored, non-food materials should be covered with a waterproof and dust proof shroud (often made of plastic material).

Minor deficiency (7 points) if:
- Single/isolated instance(s) of a door left open.
- Non-food contact packaging is stored outside, with shroud and storage area is included in the pest control program.

Major deficiency (3 points) if:
- Open areas in the ceiling/roof.
- Food contact packaging is stored outside (even if covered with shroud).
- Non-food contact packaging stored outside but not included in the pest control program and/or is not shrouded.
- Numerous instances of doors left open.
- Storage area is open on one to three sides.

Non-conformance (0 points) if:
- Products and ingredients are stored outside (even if shrouded)
- Storage area has roof but no walls.
- Food contact packaging items are stored outside, without shrouds.

1.2.5 Is the facility's use restricted to the storage of food products?
Visual confirmation. Total conformance (5 points): Only food, food contact products and items related to the process are stored in the facility's storage areas. Sanitation chemicals and maintenance equipment storage should have their own dedicated storage areas away from food and related items.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of storage of non-food items in areas that are used for storing raw material food items, packaging or finished products.

Major deficiency (1 point) if:
- Numerous instances of storage of non-food items in areas that are used for storing raw material food items, packaging or finished products.

Non-conformance (0 points) if:
- Systematic storage of non-food items in areas that are used for storing raw material food items, packaging or finished products.

1.2.6 Are rejected or on hold materials clearly identified and separated from other materials?
Visual confirmation. Total conformance (10 points): All raw materials, work in progress, ingredients, finished goods or packaging that are being rejected or are awaiting final disposition (on hold) should be stored in a designated hold area, in a way that avoids accidental use of these materials in the production process (unless they have been cleared for use). The rejected or on hold items should be tagged as such. The tagged product should not be commingled with other goods in such a way that their disposition is not clear. In a processing audit, there should also be records of items placed on hold (e.g., an on hold/disposition log with item status, date, reason and responsible person for status designation) available for review (scored in 2.4.4). Although this is "ideal" in all facility audits, on hold/disposition records should only be scored for processing templates.

Minor deficiency (7 points) if:
- Single/isolated instance(s) of items on hold or rejected, in a designated area but the items are not being clearly labeled as such.

Major deficiency (3 points) if:
- Numerous instances of items on hold or rejected, in a designated area but the items are not being clearly labeled as such.
- On hold/rejected items are commingled with other goods in such a way that their status is unclear and a potential misuse might occur.

Non-conformance (0 points) if:
- Rejected or on hold products are not clearly separated and identified.

1.2.7 Are raw materials, 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 AUTOMATIC FAILURE OF THE AUDIT.
Visual confirmation. Total conformance (15 points): Raw materials, work in progress, ingredients, finished goods, 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 bodily fluids. This question is designed to allow an auditor to halt an audit when finding gross contamination issues (note pests are covered by 1.8.1 and 1.8.2). Examples might include glass, trash/litter, motor oil in products, etc. Where an issue is observed by an operator in the normal process, auditor should observe the actions of the operator before scoring. Auditors should use their discretion and decide whether the frequency of the contamination warrants an automatic failure.

Examples include pieces of glass, one piece of rodent bait, paint on product or packaging, flakes of rust, etc. Is the issue systematic or a one-off issue? There is no adulteration of ice permitted. Water used for ice for product cooling should be potable. Ensure that ice production and storage areas are inspected. Water directly sourced from rivers, canals, ponds, etc. (i.e., surface water) used to cool, wash, make ice or for other product contact use without proper treatment (i.e., filtration and/or anti-microbial treatment and proper testing (see 2.8.3)) is not considered potable (US EPA drinking water **microbiological** specification (chemical if appropriate) http://water.epa.gov/lawsregs/rulesregs/sdwa/index.cfm or other applicable National standards) and for the purposes of this audit is considered to be adulterated. Use of waste process discharge water from a surface source (e.g., discharged into a pond then re-used as process water) should not be considered suitable for product contact use and for the purposes of this audit is considered to be adulterated.

Potentially useful websites:-
FDA/ORA conformance Policy Guide 555.425, http://www.fda.gov/ohrms/dockets/98fr/990463gd.pdf
US FDA/CFSAN Defect Levels Handbook, The Food Defect Action Levels
http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/sanitationtransportation/ucm056174.htm
http://www.epa.gov/EPA-WATER/2004/November/Day-16/w25303.htm

Minor deficiency (10 points) if:
- There is no minor deficiency category for this question

Major deficiency (5 points) if:
- There is no major deficiency category for this question.

Automatic Failure (0 points) if:
- **Numerous incidences of spoilage or adulteration of either ice or product.**
- **There is a single gross incidence of evidence of unacceptable limits of spoilage or adulteration in raw materials, work in progress, finished goods, packaging or ingredients, including ice.**
- **Untreated surface water or process discharge water from a surface source is used to cool, wash, make ice, etc.**

1.2.8 Are all storage areas clean, especially the racking structures, lights, ceilings, floor areas by the walls and other hard to reach areas?

Visual confirmation. Total conformance (10 points): All storage areas should be clean and well ventilated and protected from condensation, sewage, dust, dirt, toxic chemicals or other contaminants. Ledges should be free of debris and clean. Stored products and packaging should be clean and free from dust, debris and out of place materials, etc. Inside light covers should be clean, free of algae, insects and excessive dirt. Pay special attention to the corners of the stores, girder areas, racking structures and spaces between walls and racking structures.

Minor deficiency (7 points) if:
- Single/isolated instance(s) of floors, walls, ledges, racking and/or ceilings being dirty.
- Single/isolated instance(s) of ingredients and packaging with dust, debris, etc.
- Single/isolated instance(s) of dirty lights/light covers.

Major deficiency (3 points) if:
- Numerous instances of floors, walls, ledges, racking and/or ceilings being dirty.
- Numerous instances of ingredients and packaging with dust, debris, etc.
- Numerous instances of dirty lights/light covers.

Non-conformance (0 points) if:
- Storage areas are very dirty – little or no evidence of cleaning occurring.
- Systematic failure to maintain lights/light covers in a clean condition.

1.2.9 Are materials (commodities, packaging, ingredients, processing aids, work in progress, etc.) properly marked with rotation codes (receipt dates, manufacture dates, etc.)?
Visual confirmation. Total conformance (5 points): All materials should be properly marked with receipt dates and/or tracking information (lot numbers, code dating) for traceability/recall and stock rotation purposes.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of missing receipt dates and/or tracking information on commodities, packaging, ingredients, processing aids, work in progress, etc.
- Packaging missing receipt dates and/or tracking information.

Major deficiency (1 point) if:
- Numerous instances of missing receipt dates and/or tracking information on commodities, packaging, ingredients, processing aids, work in progress, etc.

Non-conformance (0 points) if:
- There are no receipt dates and/or tracking information on commodities, packaging, ingredients, processing aids, work in progress, etc.

1.2.10 Are materials (commodities, packaging, ingredients, processing aids, work in progress, etc.) rotated using FIFO policy?
Visual/verbal confirmation. Total conformance (5 points): All materials are 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 (this does not apply to commodities that undergo ripening treatments or where rotation is dictated by the initial quality inspection). Packaging rotation might be affected by market forces. Having a "Just In Time" ordering policy and thereby having very limited stock volumes, is acceptable as a replacement for FIFO if it can be proven (e.g., the auditor can see that hardly any stock is maintained). "Just In Time" ordering policy does not replace the need to tag materials as per question 1.2.9.

Minor deficiency (3 points) if:
- Single/isolated instance(s) where commodities, packaging, ingredients, processing aids, work in progress, etc. are not rotated using FIFO policy.
- Packaging is not being rotated using FIFO policy.

Major deficiency (1 point) if:
- Numerous instances where commodities, packaging, ingredients, processing aids, work in progress, etc. are not rotated using FIFO policy.

Non-conformance (0 points) if:
- Systematic failure to use FIFO policy on commodities, packaging, ingredients, processing aids, work in progress, etc.

1.2.11 Are storage areas at the appropriate temperature for the specific products being stored?
Visual/verbal confirmation. Total conformance (10 points). All products should be stored at the correct temperatures. Products should be stored in separate chambers if they require different optimum storage temperatures. Check the area/chamber thermometers and thermostats and compare the reading against the types of products being stored in the area.
Where a facility is handling FDA designated time/temperature control for safety foods (TCS)* products, they should be stored at 5^{o}C (41^{o}F) or less.
*Potentially hazardous food (time/temperature control for safety food) includes:

1. (a) An animal food that is raw or heat-treated; a plant food that is heat-treated or consists of raw seed sprouts, cut melons, cut leafy greens, cut tomatoes or mixtures of cut tomatoes that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation, or

garlic-in-oil mixtures that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation.

FDA Food Code 2013: Chapters 1 (Purpose and Definitions) and 3 (Food)
http://www.fda.gov/downloads/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/UCM374510.pdf

Minor deficiency (7 points) if:

- Single/isolated instance(s) of product being stored in areas which are set at the wrong temperature.

Major deficiency (3 points) if:

- Numerous instances of product being stored in areas which are set at the wrong temperature.

Non-compliance (0 points) if:

- Systematic failure to store products at the right temperatures i.e. place the products in the correct storage areas (relative to storage area temperatures).
- Storage room temperature regimes are incompatible with the types of products being stored.
- FDA designated time/temperature control for safety foods (TCS)* products are not stored at 5^{o}C (41^{o}F) or less. **Auditor should consider reverting to 1.1.1, the general automatic failure question.**

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Operational Practices

1.3.1 Does the process flow, facility layout, employee control, utensil, internal vehicle use, etc., ensure that finished goods are not contaminated by raw materials?
Visual Confirmation. Total conformance (15 Points): Incoming raw materials should not be a source of contamination to work-in-progress and/or finished goods. Raw products should not come into contact with finished or processed products, especially processed products that have been washed, cut or thermally treated. There should be plenty of space and separation to help avoid cross contamination issues. Employees who handle raw products should not then handle finished/processed goods without first ensuring that they are free of raw material contaminants. This should include hand washing, glove change etc., but might also include changing into a new set of garments; ideally employees should be dedicated to handling raw or finished/processed goods, but not both within a shift. Utensils, cleaning implements, internal vehicles etc. should not be allowed to be vectors for cross contamination; ideally dedicated coded equipment should be provided for raw and processed goods. Failing this, there should be equipment sanitation steps between uses. Anti-microbial washes are not kill steps with respect to products, though they do reduce microbial loading when properly maintained. Refer to 1.9.8 for drainage flow and discharge.

Minor deficiency (10 points) if:
- Single/isolated instance(s) of employee/utensil/internal vehicle cross contamination.
- Minor process issues where processed materials come into the same area raw materials, but the two products do not touch in any way, i.e. no potential risk of cross contamination.
- Some potential space issues where the process flow is being forced to bring finished and raw material into close proximity.

Major deficiency (5 points) if:
- Numerous instances of employee/utensil cross contamination.
- Serious process flow issues where raw material can potentially cross contaminate finished goods.
- Numerous space issues where the process flow is being forced to bring finished and raw material into close proximity.

Non-conformance (0 points) if:
- Systematic instances/issues with employee and/or utensil cross contamination.
- Process flow issues are observed to result in product raw/finished goods cross contamination.

1.3.2 Are all exposed materials (product, packaging, etc.) protected from overhead contamination (e.g. ladders, motors, condensation, lubricants, walkways, loose panels, degrading insulation, etc.)?
Visual confirmation. Total conformance (15 points): Ceilings and/or any overhead fixtures above lines and storage are free from condensation or dust. Ladders or walkways (catwalks) above exposed product or packaging material have kick plates at least four inches high and are covered in some way that protects the product underneath. Drips or condensate (e.g. from fixtures, ducts, pipes, etc.) should not contaminate food, food contact surfaces or packaging material; adequate measures should be in place to protect from condensate. Condensate is scored in 1.9.6.
1910.23(e)(4) OSHA
http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=9715
Minor deficiency (10 points) if:
- Single/isolated instance(s) of possible overhead contamination.

Major deficiency (5 points) if:
- Numerous instances of possible overhead contamination

Non-conformance (0 points) if:
- No protective devices have been installed to eliminate potential contamination.

- **Any observation of direct contamination of raw materials, work in progress, finished product, ingredient or packaging materials. In this case the score reverts back to 1.2.7**

1.3.3 Are packing and/or processing areas completely enclosed?

Visual confirmation. Total conformance (15 points): Production/packing areas should all be inside the facility i.e. 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 thatshould be no greater than 1/8 inch (3 mm) or smaller. Dust and pest proof wall materials are required for processing operations. Production/packing should also be physically separated from storage areas. In some cases a physical barrier between production/packing and storage areas might be required – this will depend on the type of product being produced and the items being stored. For example, cardboard should not be stored in a fresh-cut processing area. Another example would be storing raw material near where finished fresh-cut product is being stored.

Minor deficiency (10 points) if:
- Production/packing areas are not sufficiently separated from storage areas. There is not a threat of product or packaging contamination.
- Single incident of an open door being left open that is not meshed or fitted with air curtain.

Major deficiency (5 points) if:
- Production/packing areas are not sufficiently separated from storage areas. There may be a threat to product or packaging.
- Numerous incidents of open doors that are being left open and not mesh or fitted with air curtain.
- One or more open walls (with no proofing), but with a proper roof and floor.

Non-conformance (0 points): if one of the following:
- Production/packing area is outside or in an open sided building.
- Production/packing areas are sufficiently not separated from storage areas. There may be a threat to product or packaging from a serious food safety threatening contaminant.
- No roofing (either with or without open walls).

1.3.4 Are production areas clean and well maintained; especially lights, floor areas by the wall and equipment, and other hard to reach areas?

Visual Confirmation. Total conformance (15 points): Production areas should be maintained in a clean and sanitary state. Auditor should check the ceilings, lights, corners, against walls and alongside equipment (look up, look down, look all around). This question is designed to capture any hygiene issues that are not covered by specific issues noted in other questions. This question is the sister question to 1.2.8 which asks about storage area hygiene. Auditor should carefully note which areas are dirty when down scoring in this question.

Minor deficiency (10 points) if:
- Single/isolated instance(s) of floors, walls, ledges or other areas being unclean.
- Single/isolated instance(s) of dirty lights/light covers.

Major deficiency (5 points) if:
- Numerous instances of floors, walls, ledges or other areas being unclean.
- Numerous instances of dirty lights/light covers.

Non-conformance (0 points) if:
- Production areas very dirty – little or no evidence of cleaning occurring.
- Systematic failure to maintain lights/light covers in a clean condition.

1.3.5 Is all re-work/re-packing handled correctly?

Visual/verbal confirmation. Total conformance (10 points): Re-work includes product that has come directly from the end of the line or (where possible) product that has been returned from a customer (but is still in good quality). Re-work possibilities will vary from product to product. Re-work areas in coolers should adhere to all required GMP's. In a cooler or storage and distribution center where the re-packing is routine i.e. a regular activity (more than once per week) as opposed to an occasional unscheduled event, then a packinghouse audit template should be used. If re-packing is occurring more than once per week and a Cooling Cold Storage or Storage & Distribution template is used, the packing lines will be excluded from the scope of the audit.
All re-work should be handled correctly:

- Whole products undergoing re-packing should be in new final boxes and not be commingled with products from other producers and/or lots. Re-use of boxes in tomato, citrus, etc. re-pack operations is permitted only if product is re-packed into a container from the same lot of product and that the container is clean, sanitary and properly labeled. Any misuse of single use containers is scored in 1.3.15.
- Packaging items are opened with clean knives.
- Employees emptying packaging should have washed their hands and (ideally) if company policy, wear clean gloves i.e. should follow company GMP rules for hand sanitation.
- Re-work area is separated from the main production line.
- Product is collected in a clearly designated container before being transferred back to the processing line. Ideally, product should go through the washing step again.
- Outside of packaging does not touch the re-work product as it is being emptied.
- The traceback details are transferred correctly.

Not applicable if there is no re-work/re-packing taking place.

Minor deficiency (7 points) if:

- One of the items above is not being followed.

Major deficiency (3 points) if:

- Two items above are not being followed.

Non-conformance (0 points) if:

- Three or more of the items above are not being followed.

1.3.6 Are raw materials examined before use?
Visual confirmation. Total conformance (5 points): Raw ingredients/products are examined for damage, insect or rodent infestation, foreign materials, rot and decay, temperature abuse, tampering evidences (e.g., broken seals, visible residues, etc.) before use. (Produce that is cored and outer leaves are removed also qualifies as inspected, e.g., lettuce). Visual inspection on conveyor inspection belts is acceptable.

Minor deficiency (3 points) if:

- Single raw material is not examined prior to use.

Major deficiency (1 point) if:

- Numerous raw materials are not being examined prior to use.

Non-conformance (0 points) if:

- No raw materials are examined before use.

1.3.7 Are finished products coded (carton and unit packaging) for the day of production?
Visual confirmation. Total conformance (10 points): All products are appropriately labeled, identified and possess lot numbers and/or date coding information that can be used for traceback and recall purposes. On bulk product, the coding should be identified on the carton or RPC tag. On bagged, clamshells and other pre-packs, the coding should be on the pack itself and also the cartons. Auditee should have records linking the code(s) used to date production/packing (see 2.4.1).

Auditor should check that product specifications (2.5.2) are being followed, as required, regarding date coding. For example, some buyers do not consider Julian date codes to be “readable” and require unencoded date information on the packaging (e.g., pack date, sell-by date, use-by date information). This issue relates to product specifications and is scored in 2.5.2.
Potentially useful website:-

21 CFR Parts 1 and 11 http://www.fda.gov/OHRMS/DOCKETS/98fr/04-26929.htm
US Bioterrorism Act http://www.fda.gov/regulatoryinformation/legislation/ucm148797.htm
Produce Traceability Initiative http://www.producetraceability.org/

Minor deficiency (7 points) if:
- Single/isolated instance(s) of a product not having accurate or readable lot or date code information.
- Single/isolated instance(s) of date coding not matching specification requirements.
- Single/isolated instance(s) of codes on unit packs not matching codes on cartons.
- Bags not being coded, but the cartons are coded and the business is majority bulk packing as opposed to pre-packing (e.g., bags).

Major deficiency (3 points) if:
- Numerous products not having accurate or readable lot or date code information.
- Numerous instances of date coding not matching specification requirements.
- Numerous instances of codes of unit packs not matching codes on cartons.
- Bags not being coded, but the cartons are coded and the business only packs small amounts of bulk product as opposed to pre-packing (e.g., bags).
- Coding pallets only.

Non-conformance (0 points) if:
- No product lot coding and/or code dating either on bags, pre-pack or cartons on the majority of lines.
- Systematic failure for date coding to meet required specifications.

1.3.8 Does finished product coding clearly link to supplier(s) of incoming materials? (Auditor performs a live traceback test to verify documentation reviewed for 2.4.1.)
Visual confirmation. Total conformance (10 points): Incoming materials (raw materials, ingredients, finished goods and packaging) should have traceable lot codes at receipt which follow the item through storage and use in finished product. Auditor should choose a finished product lot code and have auditee demonstrate how the code traces back to raw material supplier(s). The system being used in the production facility should match the written traceability system (2.4.1).

Minor deficiency (There is no minor deficiency for this question).

Major deficiency (3 points) if:
- Single/isolated instance(s) of either incorrect or missing elements or inadequate lot identifiers of the coding system that either limits or stops efficient trace back to the raw material supplier. For example, coding does not clearly link to raw material lots processed on a certain day.

Non-conformance (0 points) if:
- Numerous instances of either incorrect or missing elements or inadequate lot identifiers of the coding system that either limits or stops efficient trace back to the raw material supplier. For example, coding does not properly link to raw material lots processed on a certain day.

1.3.9 Are foreign material control methods (e.g. metal detectors, metal traps, visual inspection, etc.) in place? Are these systems regularly tested (where relevant) to ensure proper operation?
Visual confirmation. Total conformance (10 points): Foreign material control method(s) are in place. Discovery of foreign material issues should be recorded along with relevant corrective actions (might be recorded in the Unusual Incidents Log), see section 2.8 questions. Where necessary, foreign material control systems should be tested to ensure proper operations. The frequency and types of testing are

established in a written program and the frequency is adhered to by QA personnel and documented. Foreign material controls include detectors, traps, visual, sieves, filters and magnets. Also, check that the rejection system/mechanism is being tested as well (e.g., rejection arm timing, alarm system, etc.). Continuous visual inspection is acceptable for whole products. Metal detection should be used for products that have been cut/sliced using an automated cutting machine (e.g., a slice or a shredder). Metal detectors should be tested at least hourly. At least ferrous, non-ferrous and stainless steel (usually 316) test pieces should be used separately to test the metal detectors – other specific metal test pieces should be considered if the plant equipment is made out of other materials. Where available, customer specifications should be used.
Test pieces should be placed as close to the aperture center as possible; embedding test pieces in the product is an ideal method. Discovery of foreign material issues should be recorded along with relevant corrective actions. The auditor should have the auditee check metal detector(s) sensitivity and rejection mechanism while touring the facility.
Potentially useful websites:
OSU Metal Detectors for Food Processing,
http://pods.dasnr.okstate.edu/docushare/dsweb/Get/Document-964/FAPC-105web.pdf
A Guide to Metal Detection in the Food Manufacturing Industry
http://www.loma.com/docs/Guide_to_Metal_Detection.pdf

Minor deficiency (7 points) if:
- Single instance of a processing/packing line in operation that is missing a form of foreign material control method if there are more than two processing/packing lines in operation.
- Single/isolated instance(s) of failure to adhere to established frequency of testing device(s).
- Single/ isolated instance(s) of not using the correct testing methodology.
- Testing frequency for metal detectors is at least every two hours but not at least every hour.
- Single instance of a detector failing a check or not operating properly.
- Not using one of the required test pieces (metal detection).

Major deficiency (3 points) if:
- Isolated instances (two-three) of processing/packing line in operation that is missing a form of foreign material control method if there are more than three processing/packing lines in operation.
- Numerous instances of failure to adhere to established frequency of testing device(s).
- Numerous instances of not using the correct testing methodology.
- Testing frequency for metal detectors is at least every four hours but not at least every two hours.
- More than one instance of a detector failing a check or not operating properly.
- Not using two of the required test pieces (metal detection).

Non-conformance (0 points) if:
- Majority of processing/packing line in operation missing a form of foreign material control method if there are more than three processing/packing lines in operation.
- No foreign material control methods are in place (cut product).
- No established program that specifies the frequency of device testing is in place.
- No established testing methodologies.
- Testing frequency for metal detectors is not at least every four hours.
- No detectors operating properly. If only one detector is used and it is malfunctioning, score non-conformance.
- Not using three of the required test pieces (metal detection).

1.3.10 Does the facility use the appropriate test strips, test kits or test probes for verifying the concentrations of anti-microbial chemicals (product washing water, terminal sanitizers, dip stations, etc.) being used and are they in operational condition?
Visual confirmation. Total conformance (10 points): The strength of anti-microbial chemicals (product and cleaning) should be checked using an appropriate method for the anti-microbial in use (e.g., chemical reaction based test, test probe, ORP meter or as recommended by disinfectant supplier). Any water treatment at source (e.g., well, canal) should be monitored. Solutions that are too weak will be ineffective,

while those too strong may be harmful to employees or product. Where necessary, pH of solutions should also be checked. Methods include dip sticks, test strip papers, conductivity meters, titration, color comparison methods (e.g., tintometers, etc.). All test solutions/strips should be within date code, appropriate for the concentrations used and stored correctly (especially light and temperature sensitive materials). 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., ppm test trip papers) in order to verify injector readings. Probe sensors need periodic cleaning and calibration and may become temporarily saturated by over-injection of anti-microbial or buffer. The auditor should have the auditee check the strength of anti-microbial chemicals while touring the facility.
Potentially useful websites:
http://ucanr.org/freepubs/docs/8149.pdf

Minor deficiency (7 points) if:
- Single/isolated instance(s) of a method not being used correctly.
- Single/isolated instance(s) of a testing procedure being used that is not appropriate for the concentration and/or chemical in use.
- Single/isolated instance(s) of out of date verifying chemicals being used.

Major deficiency (3 points) if:
- Numerous instances of a method not being used correctly.
- Numerous instances of a testing procedure being used that is not appropriate for the concentration and/or chemical in use.
- Numerous instances of out of date verifying chemicals being used.
- ORP meter used to control pumps injecting anti-microbial and or/buffer without an independent probe or other method to verify readings.

Non-conformance (0 points) if:
- Chemical concentrations are not monitored.
- Equipment to monitor anti-microbial chemical concentrations is not available or is not being used correctly.

1.3.11 Are hand washing stations adequate in number, appropriate in location, in working order, have warm water, adequately stocked (e.g. disposable towels, soap, etc.) and restricted to hand washing purposes only?
Visual confirmation. Total conformance (15 points): To ensure efficient employee flow there should be a minimum of one hand wash station for every 10 people up to 100 people and thereafter one hand wash station for every 15 people (http://www.dir.ca.gov/title8/3366.html). Hand washing stations should be located at access to production areas in processing and packinghouse audits and in, or immediately adjacent, to toilet facilities. Within close proximity of/at toilet facilities area and lunchroom area is acceptable for other facility audits. Hand washing facilities should be used only for hand washing (no storage, food handling, etc.). Hand washing stations should be properly stocked with liquid non-perfumed, neutral or “medicinal” scented soap. Scent should rinse away with the foam leaving no lingering fragrance on hands. Single use paper towels should be used and units properly located, however, hot air driers are acceptable if properly located (hot air driers should not be located within production areas since they create aerosols). There should be an adequate stock of soap and paper towels. Hand washing stations should be maintained in good working order with proper drainage and warm water (> 100 ^{o}F, 38 ^{o}C) available for use. Discharge water from sinks should not run directly onto the floor. Care should be taken to ensure that hand wash water temperatures are not too hot when using pre-set mixer faucets (taps). Hands-free operations are an optimum system for food establishments. Cleanliness of hand wash stations is scored in 1.7.10.

Potentially Useful Website:
United States Department of Labor 29 CFR 1910.141(c)(1)(i): Toilet Facilities
http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=9790

http://www.fda.gov/downloads/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/UCM374510.pdf
http://www.dir.ca.gov/title8/3366.html

Minor deficiency (10 points) if:
- Only about 75% of needed hand washing stations are present.
- Single/isolated instance(s) of hand washing stations not in working order .
- Only cold water is available at one or more stations.
- There are no hand washing stations located in visible production entry areas (processing and packinghouse only) where the employee hand washing practices can be monitored.
- Single/isolated instance(s) of soap with a lingering fragrance being used.

Major deficiency (5 points) if:
- Only about 50% of needed hand washing stations are present.
- Numerous instances of hand washing stations not in working order.
- Numerous instances or systematic use of soap with a lingering fragrance being used.
- Using terry cloth re-useable towels or roller towels.
- No paper towels are provided or hot air driers are located within production areas.
- Numerous instances of hand washing stations without warm water available or where water is too hot.

Non-conformance (0 points) if:
- No soap is provided.
- Hand washing stations are inadequate in both number and location (less than 25% of needed hand washing stations are provided).
- There are no functioning hand wash stations. **Auditor should consider reverting to 1.1.1, the general automatic failure question.**

1.3.12 Are toilet facilities adequate in number and location and are they adequately stocked (e.g. toilet paper, soap, disposable towels, trash cans, etc.)?
Visual confirmation. Total conformance (15 points): Toilet facilities are adequate in number and location:
- Toilet facilities should be located within a reasonable distance from the employees' workstation.
- Toilet facilities should be readily available to male and female employees. The number of facilities provided for each sex should be based on the number of employees of that sex.
- Where there are single-occupancy rooms, separate toilet rooms for each sex are not required (sufficient toilets available).
- There should be sufficient toilets for the employees:

Number of employees	Number of toilets
1-15	1
16-35	2
36-55	3
56-80	4
81-110	5
111-150	6
>150	1 additional toilet for each 40 employees

- Urinals for male employees should not make up more than 1/3 of the total male toilets provided.
- Each individual toilet facility should be able to be locked from inside.
- Each toilet facility should be maintained, well lighted and ventilated to outside air.
- In the toilet room, the floor and sidewalls should be watertight. The sidewalls should be watertight to a height of at least five inches.
- The floors, walls, ceiling, partitions and doors of all toilet rooms should be made of a finish that can be cleaned easily.

- Doors should not open directly into areas where food is exposed to airborne contamination, i.e., storage, processing and packing areas. Use of double doors or having a positive airflow system is accepted. In older operations, where doors to restrooms were designed to open into the production areas, i.e. not located in the amenity area or office area, the doors should be kept closed at all times e.g. use a spring loaded door.
- Toilet paper should be available to each person and stored in such a way as to prevent contamination.
- Adequate trash disposal should be available within restrooms.

Potentially Useful Website:
United States Department of Labor 29 CFR 1910.141(c)(1)(i): Toilet Facilities
http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=9790

Restrooms should have hand washing facilities with:
- Non-perfumed, neutral or "medicinal" scented soap. Scent should rinse away with the foam leaving no lingering fragrance on hands
- An adequate supply of soap and paper towels.
- Proper drainage and warm water (> 100 ^{o}F, 38 ^{o}C) available for use.
- If hand washing stations within toilet facilities are the only stations provided then requirements for 1.4.1 apply.
- Cleanliness of toilet facilities is scored in 1.7.10.

Minor deficiency (10 points) if:
- One of the above criteria is not met.

Major deficiency (5 points) if:
- Two of the above criteria are not met.

Non-conformance (0 points) if:
- Three of the above criteria are not met.
- Failure to provide sufficient or adequate restroom facilities.
- There are no functioning toilets. **Auditor should consider reverting to 1.1.1, the general automatic failure question.**

1.3.13 Are secondary hand sanitation stations (e.g., touch-free dispensers) adequate in number and location? Are the stations maintained properly?

Visual confirmation. Total conformance (5 points): In processing, packing and repackaging areas, use of a secondary hand sanitation stations is the last activity an employee performs before taking their position on the line. Secondary hand sanitation is required for fresh-cut operations and for operations producing items that may be "ready-to-eat" (e.g., stone fruit, tomatoes, citrus, etc.). Note that citrus peel is often used in drinks, used for zesting, etc. Secondary hand sanitation (hand dips, gels or sprays) does not replace hand washing requirements (lack surfactant qualities). Secondary hand sanitation stations should be conveniently located in traffic zones but should not be obstructive. Hand dips (if used) should contain a USDA approved food grade sanitizer at a determined concentration. Refer to hand sanitizer manufacturer label for dilutions. Hand dips should be regularly monitored (recorded anti-microbial strength checks) to ensure their effectiveness with corrective actions recorded (e.g., dip solution replenishment and anti-microbial additions). Hand gel and spray stations should be well stocked with a sanitizer approved for direct hand to food contact (e.g., USDA approved or national equivalent) and regularly monitored (recorded checks) to ensure availability with corrective actions recorded (e.g., pack replenishment). Use of a refill alert type dispenser is ideal practice. Dispensers should be located a sufficient distance from the production line to prevent accidental product contamination. The auditor should check that gel pack type stations are stocked and have the auditee check the strength of anti-microbial chemicals in hand dips while touring the facility. Records are scored in 2.9.3. See the applicability chart.

Potentially useful website:
CDC Handwashing http://www.cdc.gov/handwashing/
http://www.fda.gov/food/guidanceregulation/retailfoodprotection/industryandregulatoryassistanceandtrainingresources/ucm135577.htm
http://nelsonjameson.com/learn.php?p=/hand-hygiene.html

Minor deficiency (3 points) if:
- Single/isolated instance(s) of secondary hand sanitation stations not in place or being empty.
- Single/isolated instance(s) of hand dips containing under-strength solutions.
- Single/isolated instance of dispensers not properly located (e.g., too close to line, not conveniently located).

Major deficiency (1 point) if:
- Numerous instances of hand secondary hand sanitation stations not in place or being empty.
- Numerous instances of hand dips containing under-strength solutions.
- Numerous instances of dispensers not properly located (e.g., too close to line, not conveniently located).
- Use of hand gel or spray sanitizer that it not approved for direct hand to food contact (e.g., USDA approved or national equivalent).

Non-conformance (0 points) if:
- There are no secondary hand sanitation stations where needed or all are empty.
- All hand dips checked found containing under-strength solutions.

1.3.14 Are foot dip stations adequate in number and location? Are the stations maintained properly?
Visual confirmation. Total conformance (3 points): This question only occurs in processing audits. Foot (boot) stations (foot dip mats, baths, sprays) should be located in processing areas when crossing into a "clean" zone from an area of potential contamination (e.g., from outside into the packing zone, from raw storage into packing, from bathrooms into processing etc.). Foot dips should contain a USDA approved food grade sanitizer at a determined concentration with routine monitoring of the volume and concentration and the dip solution regularly changed**.** Refer to sanitizer manufacturer label for dilutions. Monitoring and corrective actions are recorded (e.g., dip solution changed regularly and anti-microbial additions). The auditor should have the auditee check the strength of anti-microbial chemicals while touring the facility. Records are scored in 2.9.3.
http://seafood.ucdavis.edu/pubs/sanitize.htm
http://www.extension.org/pages/27405/industry-guidelines-to-prevent-contamination-from-listeria-monocytogenes
Foot dips are not required in packinghouses, but might be considered as an additional control. Employees should be using the foot dips as they enter the processing areas. See the applicability chart.

Minor deficiency (2 points) if:
- Single/isolated instance(s) of foot dips not in place.
- Single/isolated instance(s) of the under strength foot dips or volume not maintained.
- Single/isolated instance(s) of the employees not using the foot dips.

Major deficiency (1 point) if:
- Numerous instances of foot dips not in place.
- Numerous instances of the under strength foot dips or volume not maintained.
- Numerous instance(s) of the employees not using the foot dip.

Non-conformance (0 points) if:
- No foot dip stations where needed.

- All foot dips checked being found to contain under strength solutions or volume not maintained.
- All employees avoiding using the foot dips.

1.3.15 Are single service containers used for their intended purpose only so that potential cross contamination is prevented?

Visual confirmation. Total conformance (5 points): 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. Re-use of boxes in tomato, citrus, etc. re-pack operations is permitted only if product is re-packed into a container from the same lot of product and that the container is clean, sanitary and properly labeled. 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).

Minor deficiency (3 points) if:
- Single/isolated instance(s) of single service container used for other than intended purpose.
- Single instance of product repacked into a container from another lot.

Major deficiency (1 point) if:
- Numerous instance(s) of single service container used for other than intended purpose.
- More than one instance or product repacked into a container from another lot.

Non-conformance (0 points) if:
- Systematic miss-use of single services container, used for other than intended purpose.
- Numerous instances or systematic use of containers being used from different lots for repack.
- **Any observation of direct contamination of raw materials, work in progress, finished product, ingredient or packaging materials. In this case, the score reverts back to 1.2.7.**

1.3.16 Are all re-usable containers clean and clearly designated for the specific purpose (raw product, finished product, re-work, ice, trash, etc.) such that cross contamination is prevented?

Visual confirmation. Total conformance (10 points): Bins, boxes, hoppers, barrels, baskets, etc. used for the storage of raw materials, work in progress, ingredients, finished goods or packaging should be made of food grade materials (21 CFR Part 174-178) and kept in a clean state. The storage of these items should ensure that they remain clean and uncontaminated (e.g., covered clean). In-house re-usable containers should be labeled or color-coded so that their designated purpose can be easily identified. Returnable plastic containers (RPCs) (e.g., CHEP, IFCO) should be treated like single service containers and only used for product (score in 1.3.15). If the trash container is the only re-used container on site and is a specific and unique design, so that it cannot be mistaken for another use, then should not be down scored.

Minor deficiency (7 points) if:
- Single/isolated instance(s) of a dirty product storage container (there is no direct product contamination).
- Single/isolated instance(s) product storage container is clean, but being stored in an area where it might be contaminated and then used (e.g., a centrifuge barrel stored under an overhead production line, without proper protection).
- Single/isolated instance(s) of a re-usable container not labeled or color-coded.

Major deficiency (3 point) if:
- Numerous instances of dirty product storage containers (there is no direct product contamination).
- Numerous product storage containers, which are clean, but are being stored in an area where they might be contaminated and then used (e.g., centrifuge barrels stored under an overhead production line, without proper protection).
- Numerous instances of re-usable containers not properly labeled or color-coded.

Non-conformance (0 points) if:

- Systematic failure to not clean food storage containers.
- There is no cleaning program for the containers.
- Systematic lack of control with respect to storage of clean food storage containers.
- Re-usable containers are used for multiple purposes without the containers being labeled or color-coded.
- **Any observation of direct contamination of raw materials, work in progress, finished product, ingredient or packaging materials. In this case, the score reverts back to 1.2.7.**

1.3.17 Are food safety measuring devices working properly and calibrated (where applicable)?
Visual confirmation. Total conformance (3 points). All pieces of food safety measuring equipment are working properly and calibrated (where necessary). Legal requirements, manufacturer recommendations, best practice and experience of equipment drift help to determine the frequency of testing. Documentation is scored in 2.9.6. Devices include thermometers, pH probes, ATP testing systems, etc. Metal detectors are scored in 1.3.9. The auditor should challenge some equipment by checking (or having the auditee) check the calibration of the equipment, especially if the auditor thinks the equipment might be faulty or the auditee is unsure of the equipment calibration status. Examples would include using an ice slurry for thermometers, a known pH solution for a pH probe, etc. Be sure that all calibration solutions (where used) are within “Use By” date.

Minor deficiency (2 points) if:

- Single/isolated instance(s) of piece(s) of equipment found not to be working properly or out of calibration.
- Single/isolated instance(s) of a calibration solution in use that is past its expiration date.

Major deficiency (1 point) if:

- Numerous pieces of equipment found not to be working properly or out of calibration.
- Numerous instances of calibration solutions in use that are past their expiration dates.

Non-conformance (0 points) if:

- All equipment checked was found not to be working properly or out of calibration.
- All calibration solutions found to be past their expiration dates.

Potentially Useful Website:
Kansas State University Thermometer Calibration Guide
http://www.agr.state.nc.us/meatpoultry/pdf/Thermometer%20Calibration.pdf

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Employee Practices

1.4.1 Are employees washing and sanitizing their hands before starting work each day, after using the restroom, after breaks and whenever hands may be contaminated?
Verbal & visual confirmation. Total conformance (15 points): Employee conformance to hand washing and sanitizing procedures should be assessed. Employees are observed washing their hands before starting work each day, before and after eating, after breaks, after using the toilet, after blowing their nose and after touching anything that may be considered contaminated (e.g., picking items up off of floor, etc.). Hand sanitizing applicability is linked to the question on secondary hand sanitation in section 1.3. Auditors are expected to view hand washing disciplines – in operations where hand washing stations are not visible, this means watching employee movements after breaks (are they using the toilet facility hand wash stations) and noticing if there are signs of soap and paper towel use? Hand washing is a critical part of the food suppliers food safety program – this should be stressed to the auditee.
Potentially useful website:-
A "Safe Hands" Hand Wash Program,
http://www.fda.gov/food/guidanceregulation/retailfoodprotection/industryandregulatoryassistanceandtrainingresources/ucm135577.htm

Minor deficiency (10 points) if:
- Single/isolated instance(s) of an employee who is not complying with the hand washing policy.

Major deficiency (5 points) if:
- Numerous instances of employees that are not complying with the hand washing policy.

Non-conformance (0 points) if:
- Majority or systematic failure of employees to comply with hand washing policies.

1.4.2 Are employees' fingernails clean, short and free of nail polish?
Visual Confirmation. Total conformance (5 points): 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. Use of fingernail brushes might assist in nail cleaning, however, care should be taken to ensure that these brushes are kept clean and regularly replaced or they might they become a cross contamination vector.

Potentially useful website:
Food Code 2013,
http://www.fda.gov/downloads/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/UCM374510.pdf

Minor deficiency (3 points) if:
- Single/isolated instance(s) of dirty and/or long fingernails.
- Single/isolated instance(s) of fingernail polish being worn.
- Single/isolated instance(s) of false fingernails being worn.

Major deficiency (1 point) if:
- Numerous instances of dirty and/or long fingernails.
- Numerous instances of fingernail polish being worn.
- Numerous instances of false fingernails being worn.

Non-conformance (0 points) if:
- Systematic failure to ensure that fingernails are short and clean.
- Systematic failure to ensure that fingernail polish and/or false fingernails are not worn.

1.4.3 Is there no sign of any employees with boils, sores, open wounds or exhibiting signs of foodborne illness working in direct or indirect contact with food?

Visual confirmation. Total conformance (10 points): Employees who have exposed boils, sores, exposed infected wounds, food borne illness or any other source of abnormal microbial contamination should not be allowed to work in contact with food, packaging or food contact surfaces. Employees should be requested to notify their supervisors if they have any concerning symptoms. All bandages should be covered with a non-porous covering, such as non-latex or vinyl gloves.

Minor deficiency (There is no minor deficiency for this question).

Major deficiency (There is no major deficiency for this question).

Non-compliance (0 points) if:

- One or more employees are observed working in contact with food, food contact surfaces or packaging, who has or have exposed boils, sores, infected wounds, showing signs of food borne illness or any other source of abnormal microbial contamination that is a hazard.

1.4.4 Are first aid kits adequately stocked and readily available? Are blue metal detectable band aids used?

Visual confirmation. Total conformance (5 points). 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. In facilities that handle only whole product, blue bandages without a metal strip are acceptable (inclusion of a metal strip is preferred). For facilities handling products that may be perceived as blue (e.g., blueberries), use of band aids that are not blue are permitted if of a color contrasting to product **and** equipment. Auditors should verify by checking the first-aid kit(s).

Minor deficiency (3 points) if:

- Single instance of a facility with metal detection in place having blue bandages without a metal strip.
- Single instance of a facility without metal detection (whole or boxed products) not having waterproof blue bandages.
- Single/isolated instance(s) of first aid kit(s) not having adequate supplies, supplies out-of-date or kit not readily accessible.

Major deficiency (2 points) if:

- More than one instance of a facility with metal detection in place using blue bandages without a metal strip.
- More than one instance of a facility without metal detection in place (whole or boxed products) not having waterproof blue bandages.
- Numerous instances of first aid kit(s) not having adequate supplies, supplies out-of-date or kit not readily accessible.

Non-conformance (0 points) if:

- Blue bandages with a metal strip are not available in a facility with metal detection.
- Blue bandages are not available in a facility without metal detection.
- Systematic failure to provide first aid kit(s) with adequate supplies, supplies out-of-date or kit not readily accessible.

1.4.5 Are employees wearing effective hair restraints?

Visual Confirmation. Total conformance (10 points): Employees (includes maintenance employees and visitors) should be wearing appropriate hair restraints (hairnets, beard nets and moustache covers, where appropriate) that fully contain all hair. Wearing effective hair restraints is required in all operations where product is exposed, including with products that require cooking prior to consumption, i.e. potatoes and/or

outer layer of commodity (rind, peel, skin, etc.) that is not consumed or used as a food item in any way (e.g., storage onions, garlic, etc.).

Baseball caps are allowed in packinghouses only if they are clean and worn with a hair net that is clearly visible and restrains all hair. Bobby pins and hairgrips should not be worn outside hair nets. Hair restraints should a) stop hair from falling onto the product and b) prevent employees from touching their hair and then the product. See the applicability chart.

Potentially useful website:-
21 CFR Part 110.10 http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=110.10

Minor deficiency (7 points) if:
- Single/isolated instance(s) of personnel observed not wearing an appropriate hair restraint or not wearing them properly.
- Single/isolated instance(s) of personnel wearing bobby pins/hair grips on the outside of hair restraints.

Major deficiency (3 point) if:
- Numerous instances of personnel observed not wearing an appropriate hair restraint or not wearing them properly.
- Numerous instances of personnel wearing bobby pins/hair grips on the outside of hair restraints.

Non-conformance (0 points) if:
- The practice of wearing hairnets as an appropriate hair restraint is not enforced in an operation requiring them.
- Hairnets and/or beard-nets are not available for employees

1.4.6 Is jewelry confined to a plain wedding band and watches are not worn?
Visual Confirmation. Total conformance (3 points): Employees are not observed wearing jewelry (including earrings, necklaces, bracelets, rings with stones, rings or studs in nose, lip and eyebrow, watches) in the facility. Plain wedding bands are the only exception.

Minor deficiency (2 points) if:
- Single/isolated instance(s) of personnel observed wearing jewelry or watches

Major deficiency (1 point) if:
- Numerous instances of personnel observed wearing jewelry or watches.

Non-conformance (0 points) if:
- Majority of employees wearing jewelry and watches, i.e. jewelry policy does not exist and/or jewelry policy exists but is not being implemented.

1.4.7 Are all employees wearing outer garments suitable for the operation (e.g. smocks, aprons, sleeves and non-latex gloves)?
Visual confirmation. Total conformance (10 points): An outer garment policy is established. The policy should consider the potential cross contamination and foreign material risks. Suitable protective outer garments are required for employees handling processed products and washed packinghouse products (after the washing step) that are potentially ready-to-eat. Outer garments include: smocks, aprons, sleeves, gloves, etc. For example, smocks worn in processing operations, aprons (minimum) in packinghouses after the wash step. Sleeves are required to prevent product contact with clothing. Items should be laundered in-house or by contract laundering agency. Individual employees should not take garments home for cleaning. Where items are laundered in-house, the auditee should have documented SOP and GMP rules about how these garments are cleaned. If workers sleeves come into contact with washed, ready-to-eat products, then protective waterproof sleeve covers should be used. Glove policy should be clear to employees – auditors will establish policy before making scoring decisions and note

this policy for the audit report. Gloves are not allowed to replace hand-washing requirements. Gloves should be changed after break periods, using toilet facilities, any activity other than handling of food items or when gloves are soiled, torn or otherwise contaminated. If re-useable gloves are used, then they should be made of material that can be readily cleaned and sanitized. Cotton gloves can be used as long as they are covered with a non-latex glove. Clean gloves should be issued at least daily and, as needed, throughout the day and stored properly in-between uses. Gloves should not be taken home for cleaning. Where gloves are used they should be non-latex (e.g., vinyl, nitrile, etc.). This includes gloves in first-aid kits.

http://www.cdc.gov/niosh/docs/97-135/pdfs/97-135.pdf
http://www.latexallergyinfo.com/fc2000.pdf
http://www.latexallergyresources.org/about-latex-allergy
http://www.gloveuniversity.com/
Employees should not wear personal clothes or accessories with sequins, studs, rhinestones, pom-poms, fur, etc. No sleeveless tops without an over garment. See the applicability chart.

Minor deficiency (7 points) if:
- Single/isolated instance(s) of outer garments or gloves being taken home.
- Single/isolated instance(s) of gloves that are not latex free.
- Single/isolated instance(s) of gloves not being replaced when contaminated.
- Single/isolated instance(s) of protective garments not being worn where required (processed products, after wash step in packinghouse).

Major deficiency (3 point) if:
- Numerous instances of outer garments or gloves being taken home.
- Numerous instances of gloves that are not latex free.
- Numerous instances of gloves not being replaced when contaminated.
- Numerous instances of protective garments not being worn where required (processed products, after wash step in packinghouse).

Non-conformance (0 points) if: (one of the following is found)
- An outer garment policy is **not** established.
- Systematic use of gloves that are not latex free.
- Systematic failure to replace gloves when contaminated.
- Systematic failure to wear protective garments where required (processed products, after wash step in packinghouse).
- Systematic non-conformance to the above and/or company policy.

1.4.8 Do employees 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?
Visual confirmation. Total conformance (5 points): When worn, protective outer garments (e.g., aprons, smocks, sleeves, gloves) are to be removed when employees leave the work area (when they go to the restroom, break room, outside, smoking breaks, etc.). Hairnet removal when leaving the work area is not mandated by this audit.

Minor deficiency (3 points) if:
- Single/isolated instance(s) are observed of non-conformance to the above.

Major deficiency (1 point) if:
- Numerous instances are observed of non-conformance to the above.

Non-conformance (0 points) if:
- Systematic non-conformance to the above.

1.4.9 Is there a designated area for employees to leave protective outer garments e.g. smocks, aprons, sleeves and gloves when on break and before using the toilets?
Visual confirmation. Total conformance (5 points): There is a designated area for employees to leave protective outer garments when they are worn (e.g., aprons, smocks, sleeves and gloves). Employees are observed using the designated area when they leave the work area (when they go to the toilet facility, break room, outside, etc.). Employees should not leave protective outer garments on floors, work tables, equipment or packaging materials. Designated area should not be within the toilet facilities, inside the break room, next to personnel clothing or any other area that might be a risk to the outer garments. Garments should not be left touching product, packaging or food contact surfaces.

Minor deficiency (3 points) if:
- Single/isolated instance(s) are observed of non-conformance to the above.

Major deficiency (1 point) if:
- Numerous instances are observed of non-conformance to the above.

Non-conformance (0 points) if:
- There is not a designated area for employees to leave aprons, sleeves and gloves when on a break.
- There is a designated area; however, no employees use this area.
- Any of the items are observed being placed on the floor.
- Systematic non-conformance to the above.

1.4.10 Employees personal items are not being stored in the production or material storage areas?
Visual confirmation. Total conformance (5 points): Employees should have a designated area for storing personal items such as coats, shoes, purses, medication, etc. Lockers or cubbies are desirable. Areas set aside for employee personal items should be far enough away from stored raw or finished products, packaging materials, processing equipment or processing lines to prevent contamination and avoid food security risks.

Minor deficiency (3 points) if:
- Single or isolated instance(s) of personal belongings, personal food, etc. being found in production or storage areas.

Major deficiency (1 point) if:
- Numerous instances of personal belongings, personal food, etc. being found in production or storage areas.

Non-conformance (0 points) if:
- Systematic failure to prevent personal belongings, personal food, etc. being taken into the production area.

1.4.11 Is smoking, eating, chewing and drinking confined to designated areas; spitting is prohibited in all areas?
Visual confirmation. Total conformance (10 points): 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. Potable water should be provided in all places of employment for drinking, 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. Common drinking cups and other common utensils are prohibited. Drinking is not permitted near the production line. Check work areas refuse containers and look in out of sight areas. If food consumption areas are designated within production offices or maintenance areas, then the control of cross contamination, GMPs and access to hand washing facilities should be considered.

Potentially useful website:
21 CFR Part 110.10 http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=110.10
29 CFR Part 1910.41
http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=9790

Minor deficiency (7 points) if:
- Single/isolated instance(s) are observed of non-conformance to the above (includes evidence of smoking, eating, spitting, use of drinking bottles, chewing gum, improper storage of break time food or drinking containers in interior refuse containers).
- Single/isolated instance(s) of designated area not meeting appropriate GMP standards.

Major deficiency (3 points) if:
- Numerous instances are observed of non-conformance to the above (includes evidence of smoking, eating, spitting, use of drinking bottles, chewing gum, improper storage of break time food or drinking containers in interior refuse containers).
- No designated smoking area (unless the site has a non-smoking policy).
- Numerous instances of designated area not meeting appropriate GMP standards.

Non-conformance (0 points) if:
- Systematic consumption of food and beverages outside of designated areas.
- No temperature control storage of break time food.
- Systematic evidence of smoking outside the designated area.
- Systematic evidence of using chewing tobacco in production and storage areas.
- Designated area lacks access to a hand wash station.
- Systematic non-conformance to the above criteria.
- **Any observation of direct contamination of raw materials, work in progress, finished product, ingredients or packaging materials. In this case, the score reverts back to 1.2.7.**

1.4.12 Are all items removed from garment (smock, shirt, blouse, etc.) top pockets?
Visual confirmation. Total conformance (3 points): Observations show that there are no items stored in employees' shirts, blouse and smock top pockets. Ideally, top pockets are sewn up or non-existent. Remember to also check maintenance employees in the production area. Special exception allowed for security identification tags, as long as they are securely fastened to the person.

Minor deficiency (2 points) if:
- Single/isolated instance(s) of items observed in shirt, blouse or smock top pocket.

Major deficiency (1 point) if:
- Numerous instances of items observed in shirt, blouse or smock top pockets.

Non-conformance (0 points) if:
- Systematic use of shirts, blouse or smock top pockets.

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Equipment

1.5.1 Are food contact equipment surfaces free of flaking paint, corrosion, rust and other unhygienic materials (e.g. tape, string, cardboard, etc.)?
Visual confirmation. Total conformance (15 points): Processing and packing equipment and auxiliary supporting equipment is free of flaking paint and other unhygienic materials (e.g., tape, string, cardboard, etc.). Products are not being cleaned of debris using cloths and/or towels. Food contact surfaces are corrosion free. Surfaces are maintained in good condition.

21 CFR 110.3 g Definition. Food-contact surfaces are those surfaces that contact human food and those surfaces from which drainage onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. "Food-contact surfaces" includes utensils and food-contact surfaces of equipment.

Minor deficiency (10 points) if:
- Single/isolated instance(s) of flaking paint, rust or other unhygienic materials which does not pose a threat to product or packing contamination.

Major deficiency (5 points) if:
- Single/isolated instance(s) of flaking paint, rust or other unhygienic materials which may pose a threat to product or packing contamination.
- Numerous instances of flaking paint, rust or other unhygienic materials which do not pose a threat to product or packing contamination.

Non-conformance (0 points) if:
- Inspection shows numerous areas of flaking paint, rust or other unhygienic materials, which may pose a threat to product or packing contamination.
- **Any observation of direct gross systematic contamination of product, ingredient or packaging materials, revert back to Q 1.2.7, automatic failure.**
- **Any observation of any other issue that warrants an automatic failure, revert back to Q 1.1.1.**

1.5.2 Are non-food contact equipment surfaces free of flaking paint, corrosion, rust and other unhygienic materials (e.g. tape, string, cardboard, etc.)?
Visual confirmation. Total conformance (10 points): Non-food contact surfaces should be free from any potential source of contamination, such as flaking paint, corrosion, rust and other unhygienic materials (e.g., tape, string, cardboard, etc.). The surface should be made of smooth material that can easily be cleaned and sanitized.

Minor deficiency (7 points) if:
- Single/isolated instance(s) of flaking paint, rust or other unhygienic materials, e.g., tape.

Major deficiency (3 points) if:
- Numerous instances of flaking paint, rust or other unhygienic materials, e.g., tape.

Non-conformance (0 points) if:
- Systematic evidence of rusting, flaking paint, use of unhygienic materials, e.g., tape.
- **Any observation of direct gross systematic contamination of product, ingredient or packaging materials, revert back to Q 1.2.7, automatic failure.**

1.5.3 Does equipment design and condition (e.g. smooth surfaces, smooth weld seams, non-toxic materials, no wood or other absorbent materials) facilitate effective cleaning and maintenance?
Visual confirmation. Total conformance (15 points):
Equipment should be made of appropriate materials for current use that can be easily cleaned (smooth, non-porous, non- toxic, no dead spots) and maintained in an acceptable condition. Equipment should be

designed to allow access to all areas and there should be no debris trapping areas that cannot be easily cleaned, including hollow structures on supports, rollers, racks, etc. There should be no metal-to-metal contact that results in grinding and, therefore, potential metal contamination. There should be no “bobbly”, debris trapping welds that are hard to clean. Equipment should be mounted off the floor at least 6 inches (15 cm) to allow for cleaning.

Minor deficiency (10 points) if:
- Single/isolated instance(s) of “bobbly” welds, rough surfaces, poorly designed equipment that traps debris.
- Single/isolated instance(s) of hard to reach areas where cleaning is made difficult.
- Single/isolated instance(s) of inferior materials (e.g., porous material construction, wood, non-food grade materials).

Major deficiency (5 points) if:
- Numerous instances of “bobbly” welds, rough surfaces, poorly designed equipment that traps debris.
- Numerous instances of hard to reach areas where cleaning is made difficult.
- Numerous instances of inferior materials (e.g., porous material construction, wood, non-food grade materials).

Non-conformance (0 points) if:
- Condition and/or design of equipment will not allow for effective cleaning under normal conditions.
- Systematic proof of poor design and installation making it difficult to access equipment for cleaning.
- Systematic poor welding, rough surfaces, poorly designed equipment that traps debris.
- **Any observation of direct gross systematic contamination of product, ingredients or packaging materials, revert back to Q 1.2.7, automatic failure.**
- **Any observation of any other issue that warrants an automatic failure (revert back to 1.1.1).**

1.5.4 Are thermometers (independent of the thermostat probes) present in all coolers and freezers?

Visual confirmation. Total conformance (5 points): Independent thermometers or temperature recorders should be present in all coolers and freezers. Thermometers should be separate from the thermostat probes, since there is always a chance that the thermostat system might go down and/or the probes themselves might be incorrect. If multiple probes are in a room with a system able to detect an out-of calibration or broken down probe and able to see the other probes in the room are in working order, then this is also acceptable. Not applicable if coolers and/or freezers are not used.

Minor deficiency (3 points) if:
- Single/isolated instances of thermometer(s) not present in coolers or freezers.
- Only have a single thermostat probe.

Major deficiency (1 point) if:
- Numerous instances of thermometers not present in coolers or freezers.

Non-conformance (0 points) if:
- No thermometers present in coolers or freezers.

1.5.5 Are all thermometers non-glass and non-mercury?

Visual confirmation. Total conformance (10 points): All thermometers should be non-glass and non-mercury in design. Glass should be shielded to prevent product or packing contamination in the event of breakage. Mercury thermometers are not allowed, even if shielded. Mercury is a toxin and mercury thermometers should be disposed of safely at a hazardous waste collection site.

Minor deficiency (7 points) if:
- Single/isolated instance(s) (3 or less) unshielded glass stem thermometer observed.

Major deficiency (3 points) if:

- Numerous (more than 3) unshielded glass stem thermometers observed.

Non-conformance (0 points) if:

- Single instance of a mercury thermometer.
- Single instance of broken glass or glass/mercury thermometer is observed.
- **Any observation of direct contamination of product, ingredients or packaging material, revert back to Q 1.2.7, automatic failure.**

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Equipment Cleaning

1.6.1 Are food contact equipment surfaces clean?

Visual confirmation. Total conformance (15 points): All equipment surfaces that make contact with product should be kept in a clean condition to avoid cross contamination. If the line is already running, check the line surfaces; does the debris look fresh or old? The auditor must clearly point out any issues to the auditee. Food debris, bio films, excessive dust, etc., should be cleaned off equipment and facility surfaces in order to reduce overall facility bio-burden.

21 CFR 110.3 g Definition. Food-contact surfaces are those surfaces that contact human food and those surfaces from which drainage onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. "Food-contact surfaces" includes utensils and food-contact surfaces of equipment, tables, ice machines, ice storage, hydro cooler, etc.

Minor deficiency (10 points) if:

- Single/isolated instance(s) of food contact surface that is unclean.

Major deficiency (5 points) if:

- Numerous instances of food contact surfaces that are unclean.
- Some equipment is not cleaned after the production has ceased for that run time (e.g., after final shift).

Non-conformance (0 points) if:

- Systematic observations of food contact surfaces that are unclean.
- Equipment is not cleaned after the production has ceased for that run time (e.g., after final shift).
- **Any observation of direct contamination of product, ingredients or packaging material, revert back to Q 1.2.7, automatic failure.**

1.6.2 Are non-food contact equipment surfaces clean?

Visual confirmation. Total conformance (10 points): All non-food contact equipment surfaces should be kept in a clean condition to prevent potential cross contamination. Check the equipment surfaces; does the debris look fresh or old? The auditor must clearly point out any issues to the auditee. Food debris, bio films, excessive dust, etc., should be cleaned off equipment and facility surfaces in order to reduce overall facility bio-burden.
"Non-food contact surfaces" include non-food contact surfaces of equipment, tables, ice machines, ice storage, hydro cooler, racking, etc.

Minor deficiency (7 points) if:

- Single/isolated instance(s) of non-food contact surfaces that are unclean.

Major deficiency (3 points) if:

- Numerous instances of non-food contact surfaces that are unclean.
- Some equipment is not cleaned after the production has ceased for that run time (e.g., after final shift).

Non-conformance (0 points) if:

- Systematic observations of non-food contact surfaces that are unclean.
- Equipment is not cleaned after the production has ceased for that run time (e.g., after final shift).

1.6.3 During cleaning are foods and packaging protected from contamination?

Visual confirmation. Total conformance (15 points): Raw materials, ingredients, work in progress, finished goods and packaging should be protected or removed from the area during cleaning. This includes cleaning lines between product runs. Cleaning operations should be carried out in a manner that prevents contamination, such as excessive spray from high-pressure water or air hoses. Cleaning should also not contaminate already cleaned equipment. Not applicable if cleaning practices are not observed.

Minor deficiency (10 points) if:
- Single/isolated instance(s) of cleaning activities having the potential for re-contaminating previously cleaned equipment (e.g., cleaning the floor after sanitizing equipment and observing splash back occurring). Products, ingredients and packaging are protected.

Major deficiency (5 points) if:
- Single instance of activities having the potential for contaminating food and/or packaging. Products, ingredients or packaging are not adequately protected. This includes splash back and lack of production line screening. Auditor should be careful to check that no contamination has occurred (consult non-conformance texts).
- Numerous instances of cleaning activities having the potential for re-contaminating previously cleaned equipment (e.g., cleaning the floor after sanitizing equipment and observing splash back occurring). Products, ingredients and packaging are protected.

Non-conformance (0 points) if:
- Any observation of direct contamination of product, ingredients or packaging materials that adulterates the product with a cleaning chemical or contaminates the product with splash back. **The auditor should observe and see if the auditee takes corrective actions (without prompting). If no action is taken and the contamination is severe (e.g., not just water, but say cleaning chemical and water), then the auditor should consider using the 1.2.7 adulteration option and scoring an automatic failure.**

1.6.4 Are cooling units including coils in coolers and freezers clean and free of aged, dirty ice?
Visual Confirmation. Total conformance (5 points): All coils in coolers and freezers should be clean. There should be no build-up of dust, mold or other airborne contaminants (a good flashlight is useful). There should be no colored ice/dirty ice build-up. Water from refrigeration drip pans is drained and disposed of away from product and product contact surfaces (score in 1.7.3).
Not applicable if there are no cooling units on site.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of unclean coils.
- Single/isolated instance(s) of ice build-up on coils that appears to be old (dirty or off colored).

Major deficiency (1 point) if:
- Numerous instances of unclean coils.
- Numerous instances of ice build-up on coils that appears to be old (dirty or off colored).

Non-conformance (0 points) if:
- All coils that are observed are unclean.
- Ice build-up on all coils that appears to be old (dirty or off colored).
- **Any observation of direct contamination of product, ingredient or packaging materials, revert back to Q 1.2.7.**

1.6.5 Are all fan guards dust-free and the ceiling in front of the fans free of excessive black deposits?
Visual Confirmation. Total conformance (5 points): All fan guards (cooling units and general ventilation) in the facility are clean. There is no build-up of dust or other materials on the fan guards. Check the ceiling in front of the cooling unit for black deposits and signs of cleaning issues. Check and see if there is evidence of cooler unit debris on the floor or products/packaging stored near the cooler.

Minor deficiency (3 points) if
- Single/isolated instance(s) of fan guards that are unclean and/or evidence of issues with the ceilings and pipe fittings in front of the chiller unit. Fan is not located above uncovered product, ingredients or packaging.

Major deficiency (1 point) if:
- Numerous instances of fan guards that are unclean and/or evidence of issues with the ceilings and pipe fittings in front of the chiller units. Fans are not located above uncovered product, ingredients or packaging.
- A single instance where cooling unit debris is noted above finished product and/or packaging, but there is no contamination of food materials or food contact packaging.

Non-conformance (0 points) if:
- Consistent failure to maintain clean fan guards and ceilings/pipe work in front of the fan guards.
- More than one instance where cooling unit debris is noted on finished product and/or packaging but there is no contamination of food materials or food contact packaging.
- Any evidence of cooling unit debris noted directly contaminating food materials or food contact packaging. **The auditor should consider whether this is adulteration and whether to apply Q 1.2.7 and score an automatic failure.**

1.6.6 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 the cleaning schedules in some manner, even though they are not in use?
Visual Confirmation. Total conformance (10 points): All equipment that is not used on a daily basis should be stored clean, with food-contact surfaces protected and off the floor. Not applicable if equipment is all being used. Allowances to be made if the equipment is part of the routine sanitation, even when not in use. Stored equipment should be clean and well maintained.

Minor deficiency (7 points) if:
- Single/isolated instance(s) of clean equipment that is not used on a daily basis and is stored with food-contact surfaces unprotected and the equipment is not part of a routine sanitation schedule.
- Single/isolated instance of equipment being stored in an unclean condition.

Major deficiency (3 point) if:
- Numerous instances of clean equipment that is not used on a daily basis and is stored with food-contact surfaces unprotected and the equipment is not part of a routine sanitation schedule.
- Numerous instances of equipment being stored in an unclean condition.

Non-conformance (0 points) if:
- All equipment that is not used on a daily basis is stored with food-contact surfaces unprotected and the equipment is not part of a routine sanitation schedule.
- All stored equipment that is observed has been stored in an unclean condition.

1.6.7 Are all utensils, hoses and other items not being used stored clean and in a manner to prevent contamination?
Visual Confirmation. Total conformance (10 points): All utensils, hoses and other items not being used are stored clean and in a manner to prevent contamination (off ground, dedicated areas, etc.).

Minor deficiency (7 points) if:
- Single/isolated instance(s) of items not in use, stored inappropriately. There is little potential hazard to product, ingredients or packaging.

Major deficiency (3 points) if:
- Numerous instances of items not in use, stored inappropriately. There is little potential hazard to product, ingredients or packaging.

Non-conformance (0 points) if:
- Any items not in use stored in a manner that may contaminate product, ingredients or packaging.

1.6.8 Are maintenance tools that are used in the production and storage areas of the facility clean, sanitary and corrosion free?

Visual Confirmation. Total conformance (3 points): 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 and storage areas, they should be clean, free of corrosion and in good working order, i.e. fit for their intended use. Special attention should be focused on those tools that are resident in tool boxes, within production areas, tools in the maintenance areas that are ready to be taken into production areas, or are used in the maintenance area on equipment that will be going into the production and storage areas. Sometimes, a maintenance shop might have tools that are used exclusively on external trucks and farm equipment. The auditor should avoid scoring these kinds of tools.

Minor deficiency (2 points) if:

- Single/isolated instance(s) of unclean and/or corroded maintenance tools used on food equipment.
- Single/isolated instance(s) of maintenance tools being stored inappropriately.

Major deficiency (1 point) if:

- Numerous instances of unclean and/or corroded maintenance tools used on food equipment.
- Numerous instances of maintenance tools being stored inappropriately.

Non-conformance (0 points) if:

- Systematic failure to ensure that maintenance tools are clean and/or corrosion free.
- Systematic failures to ensure maintenance tools are stored appropriately.

1.6.9 Are excess lubricants removed from the equipment and are lubricant catch pans fitted where needed?

Visual Confirmation. Total conformance (5 points): Excess lubricants and greases are removed from equipment and there are no observations of leakage or drips. Where drive motors are mounted over product or packaging zones, catch pans should be installed, and where needed, with drainage via hosing to the floor. Cranes, chains and pulley equipment above lines are potential areas where excessive grease might be an issue. Key consideration should be given to where lubricants and greases can leak onto product and product contact surfaces. Lubrication should be frequent and use small amounts of lubricant, as opposed to large amounts of lubricant used on an infrequent basis. Food grade lube should be used where required (see questions in 1.2), but food grade materials are still only for incidental contact and all precautions should be taken in order to prevent these from contaminating the product and product contact surfaces.

Minor deficiency (3 points) if:

- Single/isolated instance (s) of excess lubricants or grease on equipment (no product hazard).
- Single/isolated instance(s) of unprotected motor, axle, pump, etc.

Major deficiency (1 point) if:

- Numerous instances of excess lubricants or grease on equipment (no product hazard).
- Numerous instances of unprotected motors, axles, pumps, etc.

Non-conformance (0 points) if:

- Systematic failure to protect motors, axles, pumps, etc.
- **Observation of serious direct contamination of product, ingredient or packaging materials with a food grade material, revert back to Q 1.2.7, automatic failure.**
- **Any observation of direct contamination of product, ingredient or packaging materials with a non-food grade material, revert back to Q 1.2.7, automatic failure.**

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General Cleaning

1.7.1 Are spills cleaned up immediately?

Verbal & visual confirmation. Total conformance (10 points): To prevent microbial growth and the attraction of pests, reduce cross contamination and maintain a sanitary environment, all spills should be cleaned up immediately. Auditors should look in corners, behind racks and shelving, under machines, etc., looking for old debris. Not applicable if there are no spills.

Minor deficiency (7 points) if:

- Single/ isolated instance(s) of improper cleaning of spills, which do not pose a risk to product or materials.

Major deficiency (3 points) if:

- Numerous instances of cleaning issues related to spills.
- Single/isolated instance(s) of spills that may pose the potential risk of contamination for product, materials, and/or product contact surfaces.
- Single/isolated instance(s) of spills exhibiting mold growth or an off odor i.e. that have not been cleaned up for some time.

Non-conformance (0 points) if:

- Numerous instances exhibiting mold growth or an off odor i.e. that have not been cleaned up for some time.
- Numerous instances of spills that may lead to potential product, materials, and/or product contamination.

1.7.2 Are waste and garbage frequently removed from packing and storage areas?

Verbal & visual confirmation. Total conformance (5 points): Cleaning practices include the frequent removal of garbage and waste from all areas to assure that acceptable levels of sanitation are maintained and prevent the attraction of pests. Garbage containers are included in a regular cleaning schedule, in order to prevent them from developing odors, flies, bacterial growth, etc.

Minor deficiency (3 points) if:

- Single/isolated instance(s) of a waste/garbage removal issue, which does not pose a risk to product, material and/or equipment.

Major deficiency (1 point) if:

- Numerous instances of waste/garbage removal issues, which do not pose a risk to product, material and/or equipment.
- Single instance where waste has an off odor, has attracted flies (unless in mushroom or onion facility) and/or is exhibiting mold growth.

Non-conformance (0 points) if:

- Failure on maintaining the facility areas free of waste and garbage.
- Numerous instances where waste has an off odor, has attracted flies (unless mushroom or onion facility) and/or is exhibiting mold growth.

1.7.3 Do floor drains appear clean, free from odors and well maintained?

Visual Confirmation. Total conformance (5 points):

- All facility floor drains, including covers and internal channels are clean, and free of decayed/old material.
- All facility floor drains are free of odors.
- There is no overflow or excessive standing water in the floor drains.
- Water from refrigeration drip pans is drained and disposed of away from product and product contact surfaces.

- Drains in processing plants, packinghouses with wash steps and high humidity coolers should be cleaned daily. Daily drain cleaning should also occur at coolers that use hydro-vacuum, dry vacuum, ice injectors, and humidifiers (where storage areas are often wet and/or humid), and also any coolers that while not having this sort of cooling equipment, do store products at high humidity.
- Drains should have smooth walls and bases that allows free flow of water without catching debris, and also aid cleaning of the drains.

Auditor will request floor drain covers to be removed for inspection (where necessary). Auditor will use a flashlight to illuminate the bottom of deep drains.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of a facility floor drain that is failing in one of the requirements listed above.

Major deficiency (1 point) if:
- Numerous instances of facility floor drains that are not maintained under acceptable sanitary conditions.
- Numerous instances of facility floor drains that are failing in one of the requirements listed above.

Non-conformance (0 points) if:
- Systematic failure to maintain the facility floor drains in a clean condition.
- **Direct contamination of food product, food packaging materials, or food processing equipment due to poor maintenance or sanitation of drains. Auditor should consider reverting to Q. 1.2.7, the automatic adulteration failure question.**

1.7.4 Do high level areas including overhead pipes, ducts, fans, etc., appear clean?
Visual & verbal confirmation. Total conformance (10 points): Sanitation practices include the scheduled cleaning of overhead pipes, ducts, ceiling supports and structures (e.g. girders), ceilings, etc. Ducts, support structures and pipes are free of excessive dust and spider webs. Mold/mildew and frost build up are kept to a minimum. No blackened areas or stained areas (water damage).

Minor deficiency (7 points) if:
- Single/ isolated instance(s) of any issues mentioned above.

Major deficiency (3 points) if:
- Cleaning of overhead pipes, ducts, ceiling support structures, ceilings, etc., is not considered within the sanitation schedule.
- Numerous instances of any issues mentioned above

Non-conformance (0 points) if:
- Systematic failure to clean overhead structures.

1.7.5 Are plastic strip curtains maintained in a good condition, kept clean and mounted so that the tips are not touching the floor?
Visual confirmation. Total conformance (5 points): All facility plastic strip curtains are clean, free of mold/mildew, black discoloration off-odors, etc. Broken strips are replaced when damaged. Strip curtains should be installed so that the tips are just off the ground (prevents contamination and also is not a forklift safety issue). Strip tips should not touch exposed food products when they pass through the strip curtains – this issue can be scored under the generic question regarding exposed materials in Q 1.3.2. Strip opacity is usually more a personnel safety issue than food safety.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of improperly maintained plastic strip curtain.
- Strip curtains mounted touching the floor.

Major deficiency (1 point) if:
- Numerous instances of improperly maintained plastic strip curtains.

Non-conformance (0 points) if:
- Systematic failure to maintain strip curtains in a good condition.

1.7.6 Does personal protection equipment (PPE) for the sanitation crew meet label requirements of chemicals used; is it in good condition and stored to prevent cross contamination to raw materials, work in progress, ingredients, finished goods and packaging?
Visual Confirmation. Total conformance (3 points): Safety equipment (Personal Protective Equipment (PPE)) is provided for the sanitation crew. The supplied safety equipment should meet all the requirements as shown on the chemical labels of the cleaning agents that are used. Safety equipment storage is organized and segregated from food and packaging materials to prevent contamination. Safety equipment is stored separately, away from personal clothing. Access to sanitation equipment should be restricted to trained employees. Safety equipment should be stored securely to prevent unauthorized use. Safety equipment is in good repair.

Minor deficiency (2 points) if:
- Single/isolated instance(s) of safety equipment not stored correctly or does not appear to have been cleaned prior to storage.
- Single/isolated instance(s) of the safety equipment not being in good repair.
- Single/isolated instance(s) of one piece of required safety equipment not being supplied to employees.

Major deficiency (1 point) if:
- Numerous instances of safety equipment not stored correctly or does not appear to have been cleaned prior to storage.
- Numerous instances of the safety equipment not being in good repair.
- Numerous instances of required safety equipment not being supplied to employees

Non-conformance (0 points) if:
- Systematic failure to supply the correct safety equipment for the employees involved.
- Safety equipment has not been maintained properly or has been compromised in some way.

1.7.7 Is cleaning equipment maintained clean and stored properly?
Visual confirmation. Total conformance (10 points): There should be an adequate supply of cleaning equipment (per procedures employed). Cleaning equipment should be free of debris, cleaned and stored correctly between use. Cleaning equipment should be stored away from the food and operational areas in a designated storage area. Cleaning equipment is stored to prevent it from becoming a source of cross contamination for the product, materials, packing equipment, and, in general, the complete operation. Brooms, mops etc., should be stored off the floor and “head down” in order to avoid them being contaminated by any accidental spills, prevent them from being harborage areas for pests and ensure debris does not contaminate the handle. Squeegees used for condensate control should be stored in dedicated sanitizer solutions and these solutions should be at the correct dilution and part of the sanitizer monitoring system. Auditors should spot check solution strength during the audit. Equipment used for different types of cleaning should not be stored touching each other (see next question).

Minor deficiency (7 points) if:
- Single/isolated instance(s) of the issues mentioned above.
- Single/isolated instance(s) of cleaning equipment that is being stored in areas where it may represent a potential risk to contaminate product, materials or equipment.
- Single/isolated instance(s) of cleaning materials temporarily unavailable.

Major deficiency (3 points) if:
- Numerous instances of the issues mentioned above.

- Numerous instances of cleaning equipment that is being stored in a way that may represent a risk for product, materials or equipment.
- Numerous cleaning materials unavailable.

Non-conformance (0 points) if:
- Systematic failure to properly store cleaning equipment.
- Very poor availability of cleaning materials.

1.7.8 Is cleaning equipment identified in order to prevent potential cross contamination issues e.g. production, maintenance, outside, restroom equipment?
Visual Confirmation. Total conformance (10 points): Cleaning equipment should be “area specific”. Coding should prevent cross contamination. Separation of restroom (toilet facility), outdoor, maintenance and production brushes, mops, etc., is most important. Coding should be made clear to all employees (e.g. using posters). If allergens are used, separated coded equipment for allergen management should have been considered. Sometimes there is a need to split equipment within a production area (e.g., equipment used on the floor versus equipment used on the machinery).

Minor deficiency (7 points) if:
- Single/isolated instance(s) of coding not being applied properly.
- Single/isolated instance(s) of materials not being coded.
- No signs or policies underlining the coding rules for the employees.

Major deficiency (3 points) if:
- Numerous instances of coding not being applied properly.
- Numerous instances of materials not being coded.

Non-conformance (0 points) if:
- Cleaning equipment is not coded (or otherwise distinct).
- Cleaning equipment is coded, but the coding is not being implemented.

1.7.9 Are all items used for sanitation appropriate for their designated purpose? (no steel wool, metal bristles, etc.)
Visual Confirmation. Total conformance (5 points): Steel wool is avoided for use as cleaning equipment. Cleaning utensils used are constructed to prevent potential contamination of product (e.g., without straw bristles, metal bristles, etc.). Ideally, brightly colored plastic bristles are used. Avoid anything that flakes, is made of pervious materials, is a similar color to the products, corrodes or might damage the equipment or facility.

Minor deficiency (3 points):
- Single/isolated instance(s) of unsuitable cleaning materials being used.

Major deficiency (1 point) if:
- Numerous instances of unsuitable cleaning materials being used.

Non-conformance (0 points) if:
- Systematic non-conformance with above.
- Cleaning equipment is unsuitable for the task and is likely to contaminate.

1.7.10 Are toilet facilities and hand-washing stations clean?
Visual confirmation. Total conformance (15 points): Toilet facilities and hand-washing stations are maintained in a sanitary condition:

- Toilet facilities have a drainage installation that allows the waste to be flushed and disposed properly.
- Toilet facility (including hand washing stations) fixtures are in good operating condition and clean.
- Cleaning and sanitizing frequency is at least daily.

- No offensive odors are evident.
- No soiled toilet tissue either on the floor or in trash cans.
- Trash cans are available for hand wash paper towels.
- Hand washing stations are properly plumbed to drainage system.
- Hand washing stations are clean and not blocked.

Minor deficiency (10 points) if:
- Single/isolated instance(s) of non-conformance to above requirements.
- Single/isolated instance(s) of soiled toilet tissues being placed in trash can.

Major deficiency (5 point) if:
- Numerous instances of non-conformance to the above requirements.
- Systematic observation of soiled toilet tissues being placed in trash cans.

Non-conformance (0 points) if:
- Failure to properly maintain areas.
- Single instance of soiled toilet tissues being left on the restroom floor.

1.7.11 Are employee break facilities clean, including microwaves and refrigerators? No rotting or out of date foodstuffs?
Visual confirmation. Total conformance (5 points): Inspection shows that the employee break areas are kept in a sanitary condition and pose no threat of contamination to production or storage areas. Sanitation practices include the periodic cleaning of these areas (including inside microwaves, inside and behind refrigerators, behind, under and on top of all vending machines, tables, chairs, tops of lockers, etc.) to assure that acceptable levels of sanitation are maintained to prevent potential pest harborage that may affect the product. Temperature sensitive food should be kept in chillers or chill boxes, not in ambient conditions (e.g., on break rooms tables, in supermarket bags or in microwaves), where bacteria could grow and might cause food poisoning. Vending machine items should be within expiry date codes. Vending machines should be visibly clean inside and also maintaining desired temperature. Inside of lockers may only be inspected in the presence of the worker after gaining verbal permission.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of finding the issue(s) mentioned above.
- Single/isolated instance(s) of a cleaning issue in the employee break areas.
- Single/isolated instance(s) of out of code product in vending machines.
- Single/isolated instance(s) of foodstuffs being stored at the wrong temperature.

Major deficiency (1 point) if:
- Numerous instances of finding the issues mentioned above.
- Numerous instances of cleaning issues in the employee break areas.
- Numerous instances of out of code product in vending machines.
- Numerous instances of foodstuffs being stored at the wrong temperature.

Non-conformance (0 points) if:
- Failure to properly maintain employee break areas.
- Visible mold/breakdown on items for sale in vending machines.
- Personnel food storage areas are unsanitary.

1.7.12. Is the maintenance shop organized - i.e. equipment and spares stored in a neat and tidy fashion?
Visual confirmation. Total conformance (5 points): Inspection of the facility shows that the maintenance shop is kept clean and organized. Sanitation practices include the periodic cleaning of this area in order to avoid pest harborage conditions that may contaminate the product, materials or equipment. Shop should employ a “clean as you go” policy with respect to metal filings and chips which are generated when metalworking. Shops should not be located near or in production and product and packaging

storage areas, in order to avoid foreign material contamination. Shops that have small break areas should follow all the usual GMP rules to prevent cross contamination, i.e. a segregated area away from equipment, tools and machinery being worked on, hand washing after breaks and care should be taken not to contravene the facility glass policy. Any issues with the break area would be scored down under the question about break areas.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of a cleaning issue in the maintenance shop.

Major deficiency (1 point) if:
- Numerous instances of cleaning issues in the maintenance shop.
- Shop is located in production/storage areas and a minor potential for cross contamination exists.

Non-conformance (0 points) if:
- Failure to maintain the maintenance shop in a clean condition.
- Shop is located in production/storage areas and a major potential for cross contamination exists.

1.7.13 Are internal transport vehicles (e.g. forklifts, bobcats, pallet jacks, trolleys, floor cleaners, etc.) clean, do not emit toxic fumes and being used in a sanitary manner?
Visual confirmation. Total conformance (5 points) if:
- Vehicles and equipment used for moving raw materials, work-in-progress, finished products, and packaging throughout and within the facility are clean, well maintained, and do not transport goods outside the facility (unless cleaned and sanitized before re-entering). Open dock areas are accepted as being within the facility in this instance.
- Internal transport vehicles (forklifts, bobcats (or similar type vehicle)), pallet jacks, trolley, floor cleaners, etc.) used to transport food are in a good state of repair, clean, odor free, free of rodents and insects.
- Internal transport vehicles (forklifts, bobcats (or similar type vehicle), pallet jacks, trolley, floor cleaners, etc.) used in food areas should not be gasoline or diesel powered. Propane (LPG) powered vehicles are permitted, although electric powered are ideal. Trucks and forklifts should not be left idling in enclosed spaces or during loading or unloading of products to reduce health risk and possible tainting of foods.
- A sanitation program for internal transport vehicles is established to assure proper sanitation levels.
- Internal transport vehicles should not be mobile “break areas,” i.e. food and drink should not be stored on the vehicles.
- Floor cleaners should be kept in good condition and cleaned in order to prevent cross contamination. Where relevant, the brushes and fixtures on the floor cleaner might need to be changed or cleaned when moving from one risk area to another.
- Bobcats (or similar type vehicle) used for ice storage areas should be clean and not a cross contamination vector. Ideally, the bobcat used for ice storage is dedicated for the area where the ice is stored.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of finding the issues mentioned above.

Major deficiency (1 point) if:
- Numerous instances of finding the issues mentioned above.

Non-conformance (0 points) if:
- Systematic failure to maintain the transport vehicles in a clean and sanitary condition.
- Systematic use of gasoline or diesel powered vehicles in food areas.
- Multiple instances of cases where the failure to maintain the transport vehicles in a sanitary condition may lead to potential product contamination.
- **Any observation of direct contamination of raw materials, work in progress, finished product, ingredient or packaging materials. In this case, revert back to Q 1.2.7.**

1.7.14 Are shipping trucks clean and in good condition?

Visual confirmation. Total conformance (5 points). Trucks and/or trailers (including in-house delivery and shuttle trucks) used to transport food and packaging are in a good state of repair, clean, odor free, free of rodent and insects. Question is not applicable if there are no trucks on the dock facility when the audit occurs. Trucks should be of the right design for the kind of product they are shipping.

Minor deficiency (3 points) if:

- Single/isolated instance(s) of improperly maintained shipping truck.

Major deficiency (1 point) if:

- Numerous instances of shipping trucks that are not maintained under acceptable sanitary conditions.
- A single instance of shipping truck in an unacceptable sanitary condition, which may contaminate the product.

Non-conformance (0 points) if:

- Systematic failure to maintain shipping trucks in a clean and sanitary condition.
- Multiple instances of cases where the failure to maintain the shipping trucks in sanitary conditions may lead to potential product contamination.
- **Any observation of direct contamination of product, ingredient or packaging materials (except condensate), revert back to Q 1.2.7.**

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Pest Control

1.8.1 Are products or ingredients free of insects/rodents/birds/reptiles/mammals or any evidence of them? ANY DOWN SCORE IN THIS QUESTION RESULTS IN AUTOMATIC FAILURE OF THE AUDIT.

Visual Confirmation. Total conformance (15 points): Raw materials, work in progress, ingredients, finished goods are free from evidence or the infestation of insects/rodents/birds/reptiles/mammals (humans, dogs, etc.). See 1.8.3 for potential indications of pest presence.

Automatic Failure (0 points) if:

- **There is a single incidence of direct contamination on or in products or ingredients**.

1.8.2 Are packaging supplies free of insects/rodents/birds/reptiles/mammals or any evidence of them? ANY DOWN SCORE IN THIS QUESTION RESULTS IN AUTOMATIC FAILURE OF THE AUDIT.

Visual Confirmation. Total conformance (15 points): Packaging supplies are free from evidence or the presence of insects/rodents/birds/reptiles/mammals (humans, dogs, etc.). See 1.8.3 for potential indications of pest presence.

Automatic Failure (0 points) if:

- **There is a single incidence of direct contamination of packaging.**

1.8.3 Are plant and storage areas free of insects/rodents/birds/reptiles/mammals or any evidence of them?

Visual confirmation. Total conformance (15 points): All areas are free of recurring/existing internal pest activity. Specifically there should be:

- No recurring/existing rodent activity and/or bird nesting observed around the interior perimeter or the facility.
- No evidence of animals observed inside the facility such as cats, dogs, deer, etc., including tracks and animal damage.
- No evidence of feces/pellets.
- No evidence of pests including insects, spiders/webbing, rodents, lizards, ants or birds in the facility.
- No evidence of gnawed bags/sacs or rodents on stored stock or numerous excreta on the floor/shelves of any storage area.
- No decomposed rodent(s) or other animals (frogs, lizards, etc.) in traps. The interior traps should be checked often and the dead rodent(s) or other animals removed.

Any live insect activity is an issue and should be graded accordingly. Insects should be at a minimal level on glue boards. The facility should have additional glue boards for replacement/change out.

Potentially useful websites:
Pests of Homes, Structures, People, Pets - UC Pest Notes,
http://www.ipm.ucdavis.edu/PMG/crops-agriculture.html
National Pest Management Standards, Pest Management Standards for Food Plants
http://www.npmapestworld.org/documents/Foodplantstandards2010_000.pdf

Minor deficiency (10 points) if:

- Single/isolated instance(s) of pest activity noted on the interior of the facility, which does not pose an immediate threat of product contamination.
- Single/isolated instance(s) of feces/pellets noted in the interior of the facility, which does not pose an immediate threat of product contamination.
- Single “fresh” rodent found in an internal trap.

Major deficiency (5 points) if:

- Numerous instances of pest activity (including feces/pellets) noted in the interior of the facility, which does not pose an immediate threat of product contamination.

- Pest activity (including fecal matter), which has the potential for contaminating product.
- Two to three instances of “fresh” rodents found in internal traps.

Non-conformance (0 points) if:
- One sighting (including feces/pellets) which has the potential for product contamination.
- Evidence of live animals observed inside the facility.
- Decomposed rodent(s) in trap(s).
- More than three “fresh” rodents found in internal traps.
- **Any observation of contaminated ingredient, product or packaging contact qualifies as an automatic failure under 1.8.1 and 1.8.2.**

1.8.4 Is the area outside the facility free of evidence of pest activity?
Visual Confirmation. Total conformance (10 points): All areas should be free of recurring/existing external pest activity. Specifically there should be:
- No recurring/existing rodent or animal (e.g. dogs, humans, etc.) activity/spoors (significant burrows, trails, feces, tracks) in active areas within operation’s property perimeter. For example, storage (packaging, bone yards), outbuildings (e.g. shade structures), etc.
- No bird nesting/activity observed around the exterior perimeter of the facility or external storage/outbuildings (e.g., pallets, trailers/containers, bone yards, etc.).
- No decomposed rodent(s) or other animals (frogs, lizards, etc.) in bait stations or along perimeter.

There should be no down scores attributed to finding a few (three or less) “fresh” rodents and/or evidence of rodent feeding in the external traps.

Minor deficiency (7 points) if:
- Single/isolated instance(s) of recurring/existing rodent or animal (e.g., dogs, humans, etc.) activity/spoors (burrows, trails, feces, tracks, etc.)
- Single/isolated instance(s) of bird nesting observed around the exterior perimeter of the facility or external storage/outbuildings (e.g., pallets, trailers/containers, bone yards, etc.).

Major deficiency (3 points) if:
- Numerous instances of recurring/existing rodent or animal (e.g., dogs, humans, etc.) activity/spoors (burrows, trails, feces, tracks, etc.).
- Numerous instances of bird nesting observed around the exterior perimeter of the facility or external storage/outbuildings (e.g., pallets, trailers/containers, bone yards, etc.).
- Numerous (more than three) external traps inspected showing evidence of rodent activity.
- Single instance of a decomposed rodent or other animal (frog, lizard etc.) in external traps or along perimeter.

Non-conformance (0 points) if:
- Evidence of significant (infestation level) rodent activity (burrows, trails, feces, tracks, animal spoor)
- Significant bird activity in traffic zones.
- More than one decomposed rodent or other animals (frogs, lizards, etc.) in external traps or along perimeter.
- **Any observation of contaminated ingredient, product or packaging contact qualifies as an automatic failure under 1.8.1 and 1.8.2.**

1.8.5 Does the operation have a pest control program? ANY DOWN SCORE IN THIS QUESTION RESULTS IN AUTOMATIC FAILURE OF THE AUDIT.
Visual confirmation. Total conformance (15 points): The operation has a proactive pest control program (in-house or contracted) to control rodents (also insects, reptiles and birds where necessary) and prevent infestation.

<u>Automatic Failure</u> (0 points) if:
- **The operation does not have a proactive pest control program**.

Potentially useful website:
National Pest Management Standards, Pest Management Standards for Food Plants
http://www.npmapestworld.org/documents/Foodplantstandards2010_000.pdf

1.8.6 Are pest control devices (inc. rodent traps and insect light traps) located away from all exposed raw materials, work in progress, ingredients, finished goods and packaging? Poisonous rodent bait traps are not used within the facility?

Visual Confirmation. Total conformance (10 points): Care should be taken to place pest control devices in such a manner that they do not pose a threat of contaminating product, packaging or raw materials. This includes the following restrictions:

- Poisonous bait stations and other pesticides should only be used outside the facility.
- There should be no domestic fly sprays used within the production and storage areas.
- Block bait as opposed to grain and pellet bait should be used (except for the external use of National Organic Program approved materials).
- If used, insect light traps (ILTs), electrical fly killers (EFKs) or pheromone traps should be regularly cleaned out (kept free from a build-up of insects and debris). Sticky type ILTs should be monitored at least monthly and the sticky board replaced if ineffective. ILTs that use sticking as opposed to zapping methods (EFKs) are preferred.
- If used, insect light traps or electric fly killers should not be placed above or in close proximity (10 feet, 3 meters) to product, food contact surfaces, equipment, or packaging material. Electric fly killers or insect light traps should not be located above dock doors (due to potential forklift damage) or in front of doorways (so attracting insects into the facility). Hallways or dock areas where product passes through are exempt from these distances, as long as product does not stop or is not stored in hallway or dock.
- If used, insect light trap bulbs should be replaced at least every 12 months (this should be recorded), or as more frequently if directed by manufacturers.
- No fly swatters should be evident in production or storage areas.
- No bait should be found outside of bait stations.
- If necessary (e.g., in facilities with high dust levels (e.g., potatoes, onions)) where glue boards may not be practical, multiple-catch traps may be **supplemented** with snap traps inside stations. Snap traps should not use allergen containing baits (e.g., peanut butter). Any supplemental snap traps inside stations should be checked at least weekly and checks recorded (1.8.7).
- Any indoor use of chemicals (e.g., knock down sprays) should be done without contaminating food, packaging, and equipment (see the next bullet point regarding poisonous rodent baits). All applications should be recorded properly (scored 2.7.3), detailing where and when the application occurred and any special methods used to avoid contamination. All applications should be made by experienced, licensed operators following any and all legal requirements and best practices.
- The use of poisonous rodent bait within the facility should not occur. If this use is required, then the area that is being trapped should have all the product and packaging removed prior to the use of the poisonous baits.
- Care should be taken to avoid placing bait traps in close proximity to outside storage areas for products, packaging or raw materials.

http://www.npmapestworld.org/documents/Foodplantstandards2010_000.pdf

Minor deficiency: (7 points) if:

- Single/isolated instance(s) of improperly positioning or maintaining electrical fly traps or insect light traps.
- Single/isolated instance(s) of a fly swatter found in production or storage area.
- Single/isolated instance(s) of grain or pellet baits being used in an outside bait station (external trap).
- Single can of fly spray (or other insecticide) found in the production/storage areas (including chemical/sanitation storage).
- Snap traps being used outside the operation, not contained in trap boxes, not presenting risk to product or packaging and are lacking weekly inspection logs.

- Single/isolated instance(s) of any other issues noted on the conformance criteria.

Major deficiency (3 points) if:
- Numerous instances of improperly positioning or maintaining electrical fly traps or insect light traps.
- Numerous instances of fly swatters found in production or storage area.
- Numerous instances of grain or pellet bait being used in an outside bait station (external trap).
- More than one can of fly spray (or other insecticide) found in the production/storage areas (including chemical/sanitation storage).
- Single instance of bait/poison found inside the facility (inside of a trap).
- Single instance of bait/poison found outside of a trap, outside the facility.
- Single/isolated instances (up to three snap traps) being used inside the operation, not contained in trap boxes and are lacking weekly inspection logs.
- Snap traps using allergenic bait.
- Numerous instance(s) of any other issues noted on the conformance criteria.

Non-conformance (0 points) if:
- More than one instance of bait/poison found inside the facility (inside of a trap).
- Single instance of bait/poison found inside the facility (outside of a trap).
- More than one instance of bait/poison found outside of a trap, outside the facility.
- More than one major deficiency.
- Numerous (more than three snap traps) being used inside the operation, not contained in trap boxes and are lacking weekly inspection logs.
- **Any observation of contamination of product or product contact material qualifies as an automatic failure under 1.2.7).**

1.8.7 Are pest control devices maintained in a clean and intact condition and marked as monitored (or bar code scanned) on a regular basis?

Visual Confirmation. Total conformance (5 points): The following criteria are met:
- If non-toxic glue boards are used, they should be located inside a trap box or PVC piping, etc., and changed frequently ensuring that the surface has a shiny glaze with no build-up of dust or debris.
- If cardboard traps are used (interior and dry areas only) they should be in good repair and marked as monitored (see below).
- If mechanical wind-up traps are used, they should be wound. Winding is checked by triggering the spring device to operate the trap. The trap should be rewound after testing.
- Approximately 10% of the traps, glue boards and bait stations should be checked by the auditor.
- Record of service verification, such as stickers, cards or bar codes should be on the inside of the station and on bottom of glue boards requiring the station to be opened to record data (date and initial of inspector) or to scan. External labeling is allowed on traps with a clear window on top.
- Bait and other poisons should be controlled and applied by a licensed applicator (see 2.7.1).
- Bait in bait stations should be secured inside the bait station on a rod above the floor of the station, or the bait station is designed so bait cannot be removed by a rodent or “float away” in a heavy rain. Bait stations should be tamper resistant. A key should be made available at the time of the audit.
- No bait stations should be missing entire bait.
- No old or moldy bait observed.
- Bait stations and traps should not be fouled with weeds, dirt, and other debris.
- External pest control devices should be checked and recorded at least monthly (weather permitting). Checking more frequently is an ideal situation.
- Internal multiple-catch traps should be checked and recorded at least every two weeks. Checking more frequently is an ideal situation.
- Any supplemental snap traps inside stations should be checked and recorded weekly.

Local regulations may require exceptions/differences to above guidelines. At all times, local regulations should be met but if the audit system requirements are more stringent, these should also be adhered to.

Some contractors use barcode systems that automatically check to see if all traps are monitored on a scheduled visit.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of multiple-catch traps, bait stations, glue boards or snap traps not working properly or adequately maintained (check cards, cleanliness, set/wound, etc.)
- Single/isolated instance(s) of unsecured bait inside bait stations.
- Single/isolated instance(s) of bait stations having moldy bait.
- Single/isolated instance(s) of any other issues noted in the conformance criteria.

Major deficiency (1 point) if:
- Numerous instances of multiple-catch traps, bait stations, glue boards or snap traps not working properly or adequately maintained (check cards, cleanliness, set/wound, etc.)
- Numerous instances of unsecured bait inside bait station.
- Numerous instances of bait stations having moldy bait.
- Numerous instance(s) of any other issues noted in the conformance criteria.

Non-conformance (0 points) if:
- Systematic failure to maintain trap devices.

1.8.8 Are interior and exterior building perimeter pest control devices adequate in number and location?

Visual Confirmation. Total conformance (5 points): As a ***guid****e* (i.e. not expecting the use of tape measures) to number and place traps and bait stations:
- Multiple-catch traps or glue boards in stations or PVC pipes should be positioned between 20 to 40 feet (6 to 12 meters) intervals around the inside perimeter of all rooms with exterior walls. Spacing might be affected by the structure, storage and types activities occurring.
- Multiple-catch traps may be **supplemented** with snap traps in stations if necessary in certain areas (e.g., in areas with high dust levels (e.g., potatoes, onions)) or box mezzanines where large traps or glue boards are not practical.
- Inside the facility, traps should be placed within 6 feet (about 2 meters) of both sides of all outside exit/entry doors. This includes either side of the pedestrian doors. Effort should be made to avoid placing traps on curbing.
- Trapping inside Cooling Cold Storage operations is mandatory. Trapping inside cold rooms within packinghouse and processors is recommended, but it is left to the auditors discretion to review the risks (doors that open to the outside, proofing issues, potential for rodents to be harbored in the materials being stored).
- Bait stations or multiple-catch traps should be positioned in 25 to 75 feet (8 to 23 meters) intervals around the exterior of the building perimeter and within 6 feet (about 2 meters) of both sides of all outside exit/entry doors, except where there is public access (public access is defined as access easily gained by the general public such as parking lots or sidewalks, school areas or areas of environmental concern). Trap placement might be affected by the structure, external storage and type of area (urban, rural etc.).
- Bait stations (where used) should be positioned within 100 feet (30.5 meters) of structures. This may impact fence line/property boundary baiting i.e. bait stations must be within 100 feet (30.5 m) of buildings and at 50-100 feet (15-30.5 meter) intervals. If an exterior fence line/property perimeter program is utilized at distances greater than 100 feet (30.5 m) from structures, then non-bait traps (e.g., multiple-catch traps) should be positioned at 50-100 feet (15-30.5 meter) intervals along perimeter. Auditor should check label for bait and ensure compliance to distance requirements on label.
- Outside packaging and any outside food storage should be protected by an adequate number of pest control devices.

http://www.epa.gov/oppsrrd1/reregistration/rodenticides/finalriskdecision.htm
http://www.npmapestworld.org/documents/Foodplantstandards2010_000.pdf

http://www.npmapestworld.org/docs/ePestWorld/50%20Foot%20Document%20Clarification%20to%20Bell%20%283%2020%2012%29%28Signed%291.pdf

Minor deficiency (3 points) if:
- Single/isolated instance(s) of traps positioned at longer intervals than mentioned above.
- Single/isolated instance(s) of traps missing or not within 6 feet (about 2 meters) of exit/entry doors.
- No bait stations along facility property fence line (auditor discretion on necessity for fence line trapping).
- Traps not located in a single area that should be trapped e.g. coolers (see text above), break area, etc.

Major deficiency (1 point) if:
- Numerous instances of bait stations positioned at longer intervals than mentioned above.
- Numerous instances of traps missing or not within 6 feet (about 2 meters) of exit/entry doors.
- Traps not located in more than one area that should be trapped e.g. packing areas and coolers, building perimeters (see text above).
- Use of snap traps inside boxes as the primary method of pest control.
- No exterior traps.

Non-conformance (0 points) if:
- Trap positioning is such that the number of traps is nowhere near adequate in terms of spacing and coverage of entry points, e.g. one or two traps to cover a large production area.
- Traps not located in numerous areas that should be trapped e.g. packing areas and coolers (see text above).

1.8.9 Are all pest control devices identified by a number or other code (e.g. barcode)?
Visual Confirmation. Total conformance (5 points): The devices are numbered and a coding system is in place to identify the type of device on a map. Auditor should check that the trap map numbering and trap positions match reality. All internal traps should be located with a wall sign (that states the trap number and that it is a trap identifier), in case they are moved.

Minor deficiency (3 points) if:
- Single/isolated instance(s) pest control devices having no visible numbers on them or on the station location.
- Single/isolated instance(s) of missing wall signs.
- Wall signs are not unique i.e. not clear that they are trap identifiers (e.g., just a number).

Major deficiency (1 point) if:
- The devices are marked on the map but the devices themselves are not numbered or the numbering sequence is incorrect.
- Numerous instances of pest control devices having no visible numbers on them or the station location.
- Numerous instances of missing wall signs.

Non-conformance (0 points) if:
- None of the devices are numbered.

1.8.10 Are all pest control devices properly installed and secured?
Visual Confirmation. Total conformance (5 points): Bait stations should be secured to minimize movement of the device and be tamper resistant. Bait stations should be secured with a ground rod, chain, cable or wire, or glued to the wall/ground, or secured with a patio stone (wall signs are required if using patio stones) to prevent the bait from being removed by shaking, being washed away, etc. Bait stations should be tamper resistant through the use of screws, latches, locks, or by other effective means. Note that only traps containing bait are required to be secured. Multiple-catch traps used indoors are not required to be secured to the ground. Auditee may use metal “sleeves” or similar solutions to prevent

displacement, crushing by forklifts, etc. Live traps should be positioned so that the openings are parallel with and closest to the wall. Glue boards should be inside a device (e.g., trap box, PVC pipe, etc.) following manufacturer's recommendations rather than loose on the floor. Auditor discretion applies to traps placed on curbs.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of bait stations not being secured.
- Single/isolated instance(s) of devices "out of position"
- Lacking wall signs for external traps that are secured to a patio block.

Major deficiency (1 point) if:
- Numerous instances of bait stations not being secured.
- Numerous instances of devices "out of position"

Non-conformance (0 points) if:
- Systematic failure to secure bait stations.
- Systematic failure to properly position interior traps.

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Buildings and Grounds

1.9.1 Are signs supporting GMPs posted appropriately?

Visual Confirmation. Total conformance (10 points): Signs for proper GMP's need to be posted visibly and in the language of the employees (visual signs are allowed) in the following areas:

- Before entering areas that require hair nets and smocks.
- Before areas that prohibit food consumption, tobacco products and chewing gum.
- Bathrooms and break-room(s) should have hand-washing signs as reminders to wash hands before eating, returning to work and after using the toilet.

Signage reminding employees and visitors of GMP rules around the site are very useful (but should not cause down score) and these include smock removal prior to breaks, hand dip/gel use (where relevant), not allowing personal items in the production areas, etc.

Potentially useful website:
Food Safety Signs and Posters,
http://healthymeals.nal.usda.gov/resource-library/food-safety/hand-washing

Minor deficiency (7 points) if:

- The signs are not in the workers' language (visuals are acceptable)
- Single/isolated instance(s) of required signs not being in position.

Major deficiency (3 points) if:

- Numerous instances of required signs not being in position.

Non-conformance (0 points) if:

- Systematic failure to place signs in the required positions.

1.9.2 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?

Visual confirmation. Total conformance (15 points): All glass lights in the facility that can potentially contaminate finished products, raw materials, equipment, or packaging should be shielded, coated or manufactured of shatter-resistant materials to protect product from contamination in the event of breakage. This includes, but is not limited to items such as light bulbs, emergency lights, truck loading lights (dock lamps), insect trap lights, forklift lights, lights in bathrooms or maintenance shops that open into 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. Windows and computer monitors in packing areas should be covered with a plastic film to prevent shatter. Inside light covers should be clean, free of algae, insects and excessive dirt.

FDA Food Code 2013: Chapter 6 Section 202.11
http://www.fda.gov/downloads/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/UCM374510.pdf

Minor deficiency (10 points) if:

- Single/isolated instance(s) of unprotected glass in an area that could potentially contaminate finished product, raw materials, processing/packaging equipment or packaging materials.
- Observed missing end piece tube light fittings.

Major deficiency (5 points) if:

- Numerous instances of unprotected glass in an area that could potentially contaminate finished product, raw materials, processing/packaging equipment or packaging materials.
- Single instance of a broken light found within the facility.

Non-conformance (0 points) if:
- Majority of lights are not protected.
- More than one instance of broken lights found within the facility.

1.9.3 Has the facility eliminated or controlled any potential metal, glass or plastic contamination issues?
Visual confirmation. Total conformance (15 points): No metal, glass or plastic issues noted (excluding issues noted under specific questions already noted within this audit). This question is designed to allow the auditor to underline potential foreign material contaminants to the auditee that are not covered by other more specific questions within the audit. Examples include: pins in sign boards within the facility, using "snappable" blades instead of one piece blades, noting broken and brittle plastic issues on re-useable totes and finding uncontrolled glass items like coffee pots, computer screens, clock faces, eye glasses, pens/pencils behind ear, office window glass, etc. in production areas. Plastic coated shatterproof light bulbs are also acceptable without further protection. Auditors should take precaution not to bring glass items into the facility during inspections. If a glass item cannot be replaced immediately or glass is necessary (e.g., a high pressure gauge), then the use of a glass register might be considered (see question in 2.3.3).

Minor deficiency (10 points) if:
- Single/isolated instance(s) of potential foreign material contaminants observed.
- Single/isolated instance(s) of glass item noted in the production/storage areas, but is not accounted for on the glass register.

Major deficiency (5 points) if:
- Numerous instances of potential foreign material contaminants observed.
- Numerous glass items noted in the production/storage areas, but are not accounted for on the glass register.
- Single instance of a broken glass item found within the facility.

Non-conformance (0 points) if:
- Systematic failure to control potential foreign objects on site.
- More than one instance of a broken glass item found within the facility.
- **Any incident of direct product contamination with a foreign material like glass, metal or plastic constitutes a health hazard and is viewed as adulteration. Revert to Q 1.2.7.**

1.9.4 Has the facility eliminated the use of wooden items or surfaces?
Visual confirmation. Total conformance (5 points) if:
- Walkways, storage containers, ladders, platforms, broom/mop handles, utensil handles, etc. should not have wooden parts.
- Wood pallets should be acceptable as long as they are not fragmenting, look clean and are dry. Wooden pallets should never directly touch product.
- Wooden bins for potatoes, onions and other items that require cooking (or some other kill step) prior to consumption or have an inedible skin should be allowed if they are not fragmenting and they are clean and in a good condition. Plastic storage bins are preferred.
- Wooden mushroom growing trays should be allowed in mushroom operations, as long as they are clean and not fragmenting. Mushrooms destined for consumption should not be touching the wooden trays.
- "Wet facilities and high humidity facilities" should not be constructed of wooden walls or ceilings.
- Use of wood tables or similar food contact equipment should be scored under 1.5.3.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of utensils/equipment with wood parts in use in the facility.
- Using wooden bins (that are not fragmenting and are clean and generally in good condition) for potentially ready-to-eat items like apples, stone fruit, citrus, melons, etc.

- Single/isolated instance(s) of structural items (e.g., walls/floors/platforms constructed of wood in wet and/or high humidity facilities).

Major deficiency (1 point) if:
- Numerous instances of utensils/equipment with wood parts in use in the facility
- Numerous structural items (e.g., walls/floors/platforms constructed of wood in wet and/or high humidity facilities).

Non-conformance (0 Point) if:
- Majority of structural items (e.g., walls/floors/platforms constructed of wood in wet and/or high humidity facilities).

1.9.5 Is there adequate lighting in the packing and storage areas?

Visual confirmation. Total conformance (5 points): Adequate lighting should be made available in all areas where inspection operations and inspections are occurring. This includes production areas, storage areas, hand-washing areas, locker rooms, maintenance areas and restrooms. The lighting should be strong enough to allow employees to see clearly so that they can conduct their work in an unobstructed manner. The color of lighting should be such that it does not hide dirt, decay, etc.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of an area that has lights but the lighting is not strong enough. This could be due to burnt out bulbs, missing bulbs, improperly spaced lighting or lighting of insufficient wattage.

Major deficiency (1 point) if:
- Numerous instances of an area that has lights but the lighting is not strong enough. This could be due to burnt out bulbs, missing bulbs, improperly spaced lighting or lighting of insufficient wattage.

Non-conformance (0 points) if:
- Any critical area that does not have lighting, such as areas where processing is conducted, coolers, dock areas, warehousing of packaging or raw materials.

1.9.6 Are ventilation systems properly designed and functioning to prevent product contamination from condensation, mold, dust, odors and vapors?

Visual confirmation. Total conformance (10 points): The ventilation system (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. Ventilation equipment is balanced to provide an adequate air exchange rate to prevent condensation on walls, ceilings or other surfaces in product areas. Ideally, positive air pressure is employed in processing operations.

Where condensation is not adequately controlled by ventilation or is considered inevitable, action should be taken to ensure raw materials, work in progress, ingredients, finished products or packaging materials are not located below areas where condensate may drip. Where this is not possible, facilities should control such condensation by cleaning and sanitizing the surfaces as often as needed, in accordance with the facility's SSOPs.

Where condensation has formed to such an extent on surfaces (that are not being cleaned and sanitized) that raw materials, work in progress, ingredients, finished product or packaging materials may become or are becoming contaminated, the condensation is considered be an adulterant (scoring reverts to Q1.2.7), and creating insanitary conditions. For example, heavily beaded condensation drips from a ceiling of a processing area that are not regularly cleaned and sanitized in accordance with the facility's SSOP's. Another example is condensate from a cooler ceiling or refrigerator unit surfaces (which have not been cleaned or sanitized) that drips onto exposed product or onto product boxes.
Potentially useful websites:

FDA Food Code 2013
http://www.fda.gov/downloads/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/UCM374510.pdf
416.2(d) Ventilation http://haccpalliance.org/sub/news/San_Guide.pdf

Minor deficiency (7 points) if:
- Single instance of finding an issue mentioned above.

Major deficiency (3 points) if:
- More than one instance of finding an issue(s) mentioned above.

Non-conformance (0 points) if:
- Numerous instances of potential product contamination by dust, condensation or objectionable and/or tainting odor.
- **Direct contamination of raw materials, work in progress, ingredients, finished goods, food contact packaging or food contact surfaces by dust or condensation. Revert back to Q 1.2.7, the automatic failure adulteration question.**

1.9.7 Are floor surfaces in good condition, with no standing water, no debris trapping cracks and are they easy to clean?
Visual confirmation. Total conformance (10 points): The floor surfaces in the facility should be suitable for the type of operation being conducted. The floor should be constructed in such a manner that it may be adequately cleaned and kept in good repair. Floor surfaces in all areas should be smooth, without deep cracks or seams, durable, non-absorbent and easily cleanable. Cracks should not trap debris or water. Some hairline floor cracking is allowed, but should be easy to keep clean and not trap debris. Check for concrete breakdown (exposed aggregate, where flooring is exposed to concentrations of different chemicals (e.g., near wash lines, chemical stores, etc.). Assess areas where concrete is broken down and see if there is standing water and debris. Floors should not have low areas that can allow pools of water to form. Pay special attention to areas that have a lot of forklift traffic.

Minor deficiency (7 points) if:
- Single/isolated instance(s) of floor not kept in clean condition or kept in poor state of repair.
- Single/isolated instance(s) of floor with standing water.
- Single/isolated instance(s) of finding the issues mentioned above.

Major deficiency (3 points) if:
- Numerous instances of floor not kept in clean condition or kept in a poor state of repair (e.g., where deep cracks have been found holding debris).
- Numerous instances of floor having standing water.
- Numerous instances of finding the issues mentioned above.
- Any instance where a condition of the floor poses a threat to food safety by potential contamination (e.g., potential for cross contamination i.e. water splash onto exposed product and/or packing).

Non-conformance (0 points) if:
- Systematic failure to keep floors in good state of repair and in clean condition.
- Systematic failure to prevent standing water.
- **Direct contamination of food product, food packaging materials, or food processing equipment due to poor maintenance or sanitation of floors. Auditor should consider reverting back to Q 1.2.7, the automatic adulteration failure question.**

1.9.8 Are the floor drains where they are needed for drainage and cleanup?
Visual confirmation. Total conformance (5 points): Drains should be constructed 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.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of an area(s) having insufficient number of drains.
- Single/isolated instance(s) of an area(s) having blocked or overflowing drains.

Major deficiency (1 point) if:
- Numerous instances of an areas having insufficient number of drains.
- Numerous instances of an areas having blocked or overflowing drains.

Non-conformance (0 points) if:
- An entire area lacking drains.
- **Drains are plugged and overflowing and providing a condition that may contaminate the product, equipment or packaging materials. Auditor should consider reverting back to Q 1.2.7 if product/packaging looks like it is being systematically contaminated.**

1.9.9 Are doors to the outside pest proof?

Visual Confirmation. Total conformance (5 points): All doors to the outside should be designed and properly fitted out to prevent the ingress of rodents and insects into the facility. Doors should have no gaps greater than approximately 1/8 inch (3 mm). If doors have screens, the openings should be no greater than 1/8 inch (3 mm). Gaps are often at the bottom of doors and also at the top of roller doors. Air curtains are acceptable, provided they are operating properly. Personnel doors to the outside should be loaded so that they close properly. Rule of thumb is that if you can see daylight gaps, then further investigation is required. If doors are maintained open during production, with no protection (e.g. air curtain, screen, etc.), they cannot be considered pest proof (scored in 1.2.4/1.3.3).

Minor deficiency (3 points) if:
- Single/isolated instance(s) of a door having a gap greater than 1/8 inch (3 mm).
- Single/isolated instance(s) of personnel doors not closing properly and improper mesh size (where screens are used).
- Single/isolated instance(s) of an air curtain not operating properly.

Major deficiency (1 point) if:
- Numerous instances of doors having gaps greater than 1/8 inch (3 mm).
- Numerous instances of personnel doors not closing properly and improper mesh size (where screens are used).
- Numerous instances of air curtains not operating properly.

Non-conformance (0 points) if:
- Systematic observations of doors having gaps with greater than 1/8 inch (3mm).
- Systematic observations of personnel doors not closing properly and improper mesh size (where screens are used).
- Systematic observations of air curtains not working properly.

1.9.10 Are dock doors fitted with buffers to seal against trucks?

Visual confirmation. Total Conformance (5 points): Where a facility is handling FDA designated time/temperature control for safety foods (TCS)* products, dock doors should be fitted with buffers to seal against trucks. Dock door buffer seals should be in good condition. Trucks backed onto the dock should seal properly in order to avoid pest entry and maintain temperature control in the shipping area and within the truck. Dock door seals ensure that the product is not exposed to the elements and help prevent pest entry. Where dock doors are fitted with buffers on a facility handling non-TCS food, the buffers must meet the above standards. N/A if no buffers fitted and not handling TCS food.
*Potentially hazardous food (time/temperature control for safety food)" includes:

1. (a) An animal food that is raw or heat-treated; a plant food that is heat-treated or consists of raw seed sprouts, cut melons, cut leafy greens, cut tomatoes or mixtures of cut tomatoes that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation, or garlic-in-oil mixtures that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation.

FDA Food Code 2013: Chapter 1 – Purpose and Definitions
http://www.fda.gov/downloads/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/UCM374510.pdf

Minor deficiency (3 points) if:
- Single/isolated instance(s) of a poorly maintained dock buffer.
- Facility handling temperature controlled goods without a dock buffer system (or equivalent temperature management system). Counter measures in place.

Major deficiency (1 point) if:
- Numerous instances of poorly maintained dock buffers.
- Facility handling temperature controlled goods without a dock buffer system (or equivalent temperature management system). Limited counter measures in place.

Non-conformance (0 points) if:
- All dock buffers inspected were poorly maintained.
- Facility handling temperature controlled goods without a dock buffer system (or equivalent temperature management system). No counter measures in place.

1.9.11 Are dock load levelers and shelters maintained in a good condition, pest proof and debris free?
Visual Confirmation. Total conformance (3 points): This question is only scored where raised dock doors are fitted. Dock levelers are clean, pest free and in good repair. Product debris can attract pests to the area. Auditor should inspect under the plates when touring the outside of the facility. Gaskets around dock levelers should fit tightly to prevent pest entry and there should be no gaps.

Minor deficiency (2 points) if:
- Single/isolated instance(s) of improperly maintained shipping dock and levelers.
- Single/isolated instance(s) of a dock leveler not proofed properly against pest entry (e.g., fitted with rubber strips).

Major deficiency (1 point) if:
- Numerous instances of improperly maintained shipping docks and levelers.
- Numerous instances of dock levelers not proofed properly against pest entry (e.g., fitted with rubber strips).

Non-conformance (0 points) if:
- Systematically observing improperly maintained shipping docks and levelers.

1.9.12 Are exterior walls free of holes to exclude pests? Are pipes, vents, air ducts designed and protected in order to prevent pest entry e.g. by using fine mesh?
Visual confirmation. Total conformance (5 points): Exterior walls should be maintained. They should be free of holes and deep cracks that could harbor pests. All pipes on the exterior walls should have caps, mesh screens, etc., to prevent rodents and others pests from entering the facility. Vents and air ducts should also be protected to prevent entry of pests. Any screens on the exterior walls, pipe holes, etc. should have mesh size of no greater than 1/8 inch (3 mm and smaller to prevent insects).

Minor deficiency (3 points) if:
- Single/isolated instance(s) of an exterior wall having holes or deep cracks that could harbor pests/allow pest entry.

- Single/isolated instance(s) of an exterior wall having uncapped pipes, unprotected vents or wire mesh screens greater than 1/8 inch (3mm).

Major deficiency (1 point) if:
- Numerous instances of areas having exterior walls with holes, and deep cracks.
- Numerous instances of wall having uncapped pipes, unprotected vents, or wire mesh screens greater than 1/8 inch (3 mm).

Non-conformance (0 points) if:
- Exterior walls are not maintained.
- Deep cracks and holes throughout the facility walls.
- Vents, pipes and screens are not designed to keep pests out of the facility.

1.9.13 Are interior walls and ceilings free of cracks and crevices to prevent pest harborage and allow proper sanitation?
Visual confirmation. Total conformance (5 points): Interior walls should be maintained and be free of holes and large cracks that can harbor insects and other pests. Pallets and forklift forks are notorious for damaging walls, especially chiller insulation. Damaged walls are difficult to clean and the exposed foam or polystyrene insulation can be a foreign material risk. Exposed insulation can be a contamination harborage area and with heat and water, this becomes an ideal breeding ground for microbes. Ceiling is free from evidence of roof leaks (stains), holes or other damage.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of a finding the issues mentioned above.

Major deficiency (1 point) if:
- Numerous instances of finding the issues mentioned above.

Non-conformance (0 points) if:
- Walls not maintained in an acceptable condition.
- Evidence of ceiling leaks.

1.9.14 Where used in production, storage or supporting areas do false ceiling areas have adequate access to allow for inspection and cleaning?
Visual confirmation. Total conformance (5 points): False ceilings should have adequate access to safely permit monitoring of pest activities and for employees to perform their cleaning duties. Auditor to access these areas and use flash light to assess conformance.

Minor deficiency (3 points) if:
- Single/isolated incidence(s) of an area not having adequate access to safely permit monitoring of pest activities and for employees to perform their cleaning duties i.e. not accessible for inspection.

Major deficiency (1 point) if:
- Numerous incidences of areas having adequate access to safely permit monitoring of pest activities and for employees to perform their cleaning duties i.e. not accessible for inspection.

Non-conformance (0 points) if:
- Systematic failure to have adequate access to safely permit monitoring of pest activities and for employees to perform their cleaning duties i.e. not accessible for inspection.

1.9.15 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?
Visual confirmation. Total conformance (5 points): All storage areas should maintain an approximately 18” (46 cm) distance between the stored items and all walls i.e. enough room to access and inspect. This space is necessary to prevent harborage of pests, to allow proper monitoring of pest activity (inspection

gap) and for employees to perform their cleaning duties. If you have access and can carry out an inspection, then the space is adequate. Staging areas are not required to conform to these requirements. Auditee should ensure that proper and safe access routes to check the wall floor perimeters are available.

Minor deficiency (3 points) if:
- Single/isolated incidence(s) of an area not maintaining required inspection perimeter and/or clearance i.e. not accessible for inspection.

Major deficiency (1 point) if:
- Numerous incidences of areas not maintaining required inspection perimeters or clearance i.e. not accessible for inspection.

Non-conformance (0 points) if:
- Systematic failure to maintain required inspection perimeters or clearance.

1.9.16 Is the exterior area immediately outside the facility free of litter, weeds and standing water?
Visual confirmation. Total conformance (5 points): Facility grounds should be maintained in a clean and orderly condition to prevent attraction of insects, rodents and other pests. Weeds and grass should be maintained in order to help avoid pest harborage. There should be no excessive standing water and/or foul smelling odors. If there is a designated smoking area outside, then there should a disposal can for cigarette butts and butts should not be found on the ground. Car parks should be free from litter, butts, etc., especially if workers are using their cars at break times. When locating a suitable designated smoking area, auditees should consider the need for hand washing prior to returning to the work place.

Minor deficiency (3 points) if:
- Single/isolated instance (s) of an area not maintained properly on the grounds.

Major deficiency (1 point) if:
- Numerous instances of areas not maintained properly on the grounds.

Non-conformance (0 points) if:
- Grounds are not maintained.

1.9.17 Are control measures being implemented for the storage of pallets, equipment, tires, etc. (e.g. out of the mud, pipe ends capped, stacked to prevent pest harborage, away from building perimeter)?
Visual confirmation. Total conformance (5 points): Outdoor storage of equipment is acceptable provided that it is stored in a manner that will prevent the harborage of pests. Pipes should have the ends capped. Equipment on pallets should not have direct contact with the dirt. All items stored should be at least 4 inches (10 cm) above the dirt. Equipment should be neatly stacked. The equipment stock levels should be reviewed regularly in order to avoid building up a store of obsolete equipment. Outside equipment stores should be checked as part of the pest control program, looking for evidence of rodent harborage. Equipment, tires, pallet storage, etc., should be at least 24 inches (61 cm) away from the building perimeter.
Potentially useful website:
National Pest Management Standards, Pest Management Standards for Food Plants
http://www.npmapestworld.org/documents/Foodplantstandards2010_000.pdf

Minor deficiency (3 points) if:
- Single/isolated instance(s) of improper storage of equipment.
- Excessive storage of old obsolete equipment.

Major deficiency (1 point) if:
- Numerous instances of improper storage of equipment.

- Outside equipment storage is not being checked as part of the pest control program.

Non-conformance (0 points) if:
- No provisions are made to keep equipment from harboring pests.
- Evidence of pest infestation (e.g., multiple fecal contamination, nests and live pests).

1.9.18 Are pallets inspected to separate and replace dirty or broken pallets?
Visual confirmation. Total conformance (5 points): Pallets should be maintained in a clean, intact condition, free from mold, pests, or any evidence of pests, food residues, harmful odors, chemical spillage, etc. Washed pallets should be dried prior to use. Broken and/or dirty pallets should be separated for cleaning, repair or return. Broken or dirty pallets should not be used. Auditors should look for broken pallets in the facility, especially in the storage areas. Auditors should look for evidence of pallet segregation by asking to see where the broken pallets are stored.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of broken or dirty pallet(s) in use for raw or packaged product.
- Single/isolated instance(s) of broken and dirty pallet(s) being stored together with pallets in good condition.

Major deficiency (1 point) if:
- Numerous instances of broken or dirty pallets in use for raw or packaged product.
- Numerous instances of broken and dirty pallets being stored together with pallets in good condition.

Non-conformance (0 points) if:
- Systematic failure to separate dirty or broken pallets from good pallets.

1.9.19 Is the area around the dumpster/cull truck/trash area clean?
Visual confirmation. Total conformance (3 points): 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.

Minor deficiency (2 points) if:
- Minor amount of debris around the dumpster(s)/cull truck/trash area.

Major deficiency (1 point) if:
- Major amount of debris around the dumpster(s)/cull truck/trash area.
- Strong odor around dumpster/cull truck/trash area.
- Visible liquid leakage from the dumpster(s)/cull truck/trash area.

Non-conformance (0 points) if:
- Evidence of old trash and spillage around the dumpster/cull truck/trash area, indicating that spills are not cleaned up as they happen.
- Evidence of insects or other pests in or around dumpster/cull truck/trash area.

1.9.20 Are outside garbage receptacles and dumpsters kept covered or closed?
Visual confirmation. Total conformance (5 points): 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.

Minor deficiency (3 points) if:
- Dumpster(s)/garbage receptacle(s) have covers, but they are not being used.

Major deficiency (1 point) if:
- In the case of operations with multiple dumpsters/garbage receptacles, the majority have and are covered, but some are lacking covers.

Non-conformance (0 points) if:
- In the case of operations with multiple dumpsters/garbage receptacles, the minority have and are covered, but majority are lacking covers.
- All garbage dumpsters/receptacles lacking covers.

1.9.21 Are all water lines protected against back siphonage?
Verbal and visual confirmation. Total conformance (5 points): Main water lines entering the facility should be fitted with back-flow protection for the incoming water (no matter what source). Individual water lines within the facility should be fitted with backflow protection where needed (e.g., on hose pipes, inlets to tanks, etc.). The auditor should look for check valves, air gaps and also look for inlet pipes that are submerged below the wash tank fill lines. Water drawn back into the main water system can contaminate fresh water. Where facility has a current certificate of inspection on file (scored under 2.8.9), auditor should still look for issues within the facility (e.g., inlet pipes below wash tank fill lines, dead end on water lines, hoses not in water tanks or on floor, etc.) that may be an issue. Where the site does waste treatment, check for dedicated back flow between waste treatment and site.
Potentially useful websites:
http://water.epa.gov/infrastructure/drinkingwater/pws/crossconnectioncontrol/crossconnectioncontrol_manual.cfm
http://water.epa.gov/drink/

Minor deficiency (3 points) if:
- Single/isolated instance(s) of a minor incoming water line that is not protected in some way (e.g., hose pipe, lacking an air gap for a dump tank inlet).

Major deficiency (1 point) if:
- Numerous instances of minor incoming water lines that are not protected in some way (e.g., hose pipe, lacking an air gap for a dump tank inlet).

Non-conformance (0 points) if:
- Facility officials do not know if there is back flow protection.
- Documentation of back flow protection will be scored under 2.8.9.
- There is no primary mains water backflow protection.
- Waste discharge lacks back flow protection.

1.9.22 Is the on-site laboratory (where applicable) completely enclosed and separated from production and/or storage areas?
Visual confirmation. Total conformance (5 points): To prevent possible contamination from the laboratory, on-site laboratories should be separated from production and storage areas, vented directly to the outside and under negative pressure. Pathogen analyses should be subcontracted to an external testing laboratory. All toxic supplies should be properly labeled and laboratory and laboratory supplies should be restricted to designated personnel only. All waste (including bio hazardous waste) should be properly and safely disposed of, including spent media, laboratory consumables, etc. If retorts are used then full monitoring and calibration service records to be available for review. Where applicable, any national or local regulations regarding the use of on-site labs are to be followed, including any special licensing requirements and regulatory inspections/accreditation. Inspection and accreditation records are to be available for review. Where there is not an on-site laboratory, score N/A.

Minor deficiency (3 points) if:
- Single incident of a door being left open.
- Single incident of laboratory and/or supplies not restricted to designated personnel (e.g., lacking signage).

- Single/isolated incident(s) of toxic supplies not being properly labeled.

Major deficiency (1 point) if:
- Laboratory is not sufficiently separated from production and/or storage areas. There may be a threat to product or packaging.
- Laboratory is not vented directly to the outside and/or not under negative pressure.
- Numerous incidents of toxic supplies not being properly labeled.

Non-conformance (0 points): if one of the following:
- Laboratory is not sufficiently separated from production and/or storage areas. There may be a threat to product or packaging from a serious food safety threatening contaminant.
- Pathogen analyses are being done on-site.
- **Auditor should consider whether to score as an automatic failure under Q 1.1.1.**

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Food Safety File Requirements - Section 2 (Documentation)

Management Systems

2.1.1 NEW QUESTION Is the operation registered as a food handling establishment?

Visual confirmation. Total compliance (10 points): There is documentation from relevant state, federal or recognized country authority indicating the facility is registered or permitted as a food handling establishment. The registration details should match the operation details, for example, address information. This may be the appropriate State or country registration documentation or documentation of the FDA registration requirement of the federal Bioterrorism Act. If the facility is exempt from registration requirements, auditee should have written documentation to show this.
http://www.fda.gov/regulatoryinformation/legislation/ucm148797.htm

Minor deficiency (7 points) if:
- Single instance of error or omission in the registration details.

Major deficiency (3 points) if:
- More than one instance of errors or omissions in the registration details.

Non-conformance (0 points) if:
- There is no registration documentation indicating facility is registered or permitted as a food handling establishment.
- Registration documentation is not current.

2.1.2 Is there a documented food safety policy reflecting the organization's ongoing commitment to providing a safe product?

Visual confirmation. Total conformance (5 points): There should be a signed (by senior management) and dated documented food safety policy statement reflecting the organization's ongoing commitment to providing a safe product. The policy should include statements of the company's commitment to food safety, following food safety laws, adhering to industry food safety best practices and a process of continual improvement. Everyone in the company should understand the food safety policy and be aware of their role in ensuring that it is met (e.g., by training, communicating organizational chart, etc.). The policy should be posted in public **areas, at least in reception area(s), employee sign board(s), etc. The food safety policy may be a standalone food safety document or part of an overall policy statement (including other topics).** The food safety policy may take the form of a "mission statement," provided it meets the requirements detailed above. This question is not applicable to companies with less than 20 employees.

Minor deficiency (3 Points) if:
- Policy lacks an element listed above.
- Single/isolated instance(s) of errors or omissions in the policy.

Major deficiency (1 point) if:
- Policy lacks more than one element noted above.
- Numerous instances of errors or omissions in the policy.
- Failure to communicate the policy to employees.
- Policy is not posted in a public place.

Non-conformance (0 points) if:
- No policy exists.
- Systematic failures to keep records and or corrective actions.

2.1.3 Is there an organizational chart showing who has food safety responsibilities and to whom they report?

Visual confirmation. Total conformance (3 points): There should be an organizational chart of employees whose activities affect food safety that shows role/position and name of person in that role. The document should be current, dated and controlled (under document control policy). Alternates should be indicated on a separate document or reference documentation indicating this information. For very small companies, an individual employee may cover many jobs.

Minor deficiency (2 points) if:
- Single/isolated instance(s) of errors or omissions in the chart functions and reporting structure.
- Document lacks either date or management signature.

Major deficiency (1 point) if:
- Numerous instances of errors or omissions in the chart functions and reporting structure.
- Document lacks both date and management structure.

Non-conformance (0 points) if:
- There is no organizational chart that shows job functions and reporting structure of employees whose activities affect food safety.
- Organizational chart bears no relation to current structure and responsibilities.

2.1.4 Is there a designated person responsible for the food safety program?
Verbal/Visual confirmation. Total conformance (10 points): There should be a designated person(s) in charge of the facility's food safety programs, including food safety document control and verification of sanitation activities. This person(s) is/are ideally a manager within the company, independent of production.

Non-conformance (0 points) if:
- No-one is in charge of food safety programs, including food safety document control and verification of sanitation activities.
- **Auditor should consider whether to score an automatic failure under 1.1.1.**

2.1.5 Is there a food safety committee and are there logs of food safety meetings with topics covered and attendees?
Visual Confirmation. Total conformance (5 points): There should be an active food safety committee, responsible for the strategic maintenance and development of the auditee's food safety plan. If an operation has a HACCP plan, the HACCP team might also look after the food safety issues. The company should be keeping logs and minutes/notes of meetings addressing food safety topics. These meetings might be dedicated to food safety or may be part of another regular meeting (e.g., a production meeting, HACCP meeting, etc.). Meetings should occur at least quarterly. This question is not applicable to small family size companies (less than 20 employees).

Minor deficiency (3 points) if:
- Single/isolated instance(s) of errors and omissions in the meeting logs (e.g., not noting who was attending the meeting).
- Single/isolated instances(s) of meetings not being held at the minimum specified frequency.

Major deficiency (1 point) if:
- Numerous instances of errors and omissions in the meeting logs (e.g., not noting who was attending the meeting).
- Numerous instances of meetings not being held at the minimum specified frequency.

Non-conformance (0 points) if:
- Food safety committee has not been created.
- The auditee does not have logs of food safety meetings.

Control of Documents and Records

2.2.1 Is there a written document control procedure describing how documents will be maintained, updated and replaced?
Visual confirmation. Total conformance (3 points): There should be a record of all documents used, when they were issued and updated with the current revision status to help avoid using obsolete documents. Document examples include pre-requisite programs, SSOPs, SOPs, other work instructions, raw material and finished product specifications, etc.
The procedure should specify:

- Who is responsible for document control (i.e. making sure documents are updated and securely stored).
- How documents are updated and amendments are approved (e.g., paper versions signed-off, computer records password protected, etc.).
- How changes are identified (e.g., date, issue number, different colored text or font, etc.).
- How the inadvertent use of obsolete documents is prevented.

Minor deficiency (2 points) if:

- Single/isolated instance(s) of errors or omissions in the procedure.

Major deficiency (1 point) if:

- Numerous instances of errors or omissions in the procedure.

Non-conformance (0 points) if:

- There is no written procedure

2.2.2 Are all records stored for a minimum period of 24 months?
Visual confirmation (5 points): Food safety related records **(documents and/or electronic files)** should be retained for auditing purposes and in case there are legal issues, customer queries, etc. 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 two years 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.
http://www.fda.gov/food/guidanceregulation/fsma/ucm247548.htm

Minor deficiency (3 points) if:

- Single/isolated instance(s) of records not being retained for the required length of time (two years unless legally longer storage is required or the product has a longer shelf life than 24 months).

Major deficiency (1 point) if:

- Numerous instances of records not being retained for the required length of time (two years unless legally longer storage is required or the product has a longer shelf life than 24 months).

Non-conformance (0 points) if:

- Records are kept less than 24 months.
- Records are kept less than the required time mandated by law for a particular product.
- Records are kept for less than the shelf life of the product.

2.2.3 Are food safety related documents and records stored and handled in a secured manner? Records recorded in permanent ink, not pencil; errors single-lined through and initialed?
Visual Confirmation. Total conformance (10 points): Documents and records that are part of the food safety program (e.g., procedures, policies, programs, training records, testing results, monitoring records, etc.), should be stored securely. Paper files and computer data files should be stored in a secured place, with access control and backed up**. Electronic files should be "backed up" (e.g. stored in two locations, off-site storage), changes to electronic files should be traceable (file change history with electronic signature or system clearly identifies individual approving changes) and meet the requirements of 21 CFR Part 11.** Paper files

should be generated using permanent ink not pencil, and if changes are made to records after initial entry, changes should be single-lined through (and initialed by the person making the change) so that the original information is still legible, avoiding the use of corrective fluid. Any evidence of records being falsified is a non-conformance (e.g., records already filled out for the next day).
21 CFR Part 11: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=11

Minor deficiency (7 points) if:
- Records kept in cabinet or room but in an open area, where access is not always controlled.
- Single/isolated instance(s) of records found with correction fluid, pencil or erasable ink.
- Single/isolated instance(s) of records with amendments where the original texts are not legible.
- Single/isolated instance(s) of computer records lacking amendment histories.

Major deficiency (3 point) if:
- File cabinet(s) or room does not have locks.
- Documents are kept on the computer but lacking data management controls (e.g., not recording changes to documents, limited editing access, etc.).
- Numerous instances of records found with correction fluid, pencil or erasable ink.
- Numerous instances of records with amendments where the original texts are not legible.
- Numerous instances of computer records lacking amendment histories.
- Computerized documents and/or records are not being backed-up.

Non-conformance (0 points) if:
- There is no physical restriction to accessing documents and records i.e. documents are not stored securely.
- Documents kept on the computer, but there are no password controls.
- Systematic use of correction fluid, pencil or erasable ink in records.
- Systematic failure to ensure that original texts are legible when amendments have been made to records.
- Systematic failure to record amendment histories when records have been computerized.
- Any evidence of records having been falsified. **Auditor should consider whether to score an automatic failure under Q 1.1.1.**

General File Requirements

2.3.1 Are there written Standard Operating Procedures (SOPs) that detail work instructions for activities ensuring food safety and Good Manufacturing Practices?

Visual Confirmation. Total conformance (5 points):
As part of the Food Safety Management System, there should be written Standard Operating Procedures (SOPs) for food safety activities and good manufacturing practices that, when followed, help prevent food safety hazards from occurring. The SOP's should detail what is done, how it is done, how often, by whom, what recordings are required and any corrective action procedures when there are problems. Auditors should try and score SOP specific issues under existing specified questions (e.g., handling rejected materials in question 2.4.4, changing and testing of water and ice systems in question 2.3.2). Use this question to score down for missing SOP's, if a specific question covering a particular task is not already part of the audit. Ideally, there should be an index of SOP's and the recording forms associated with these SOP's.
At minimum, operations should have written SOPs for the following important tasks (where applicable):

- Goods receiving/supplier approval
- Temperature control Foreign material control (e.g., metal detection)
- Chemical monitoring procedures (anti-microbial, wax, fungicide, ethylene gas, ozone generators, etc.)
- Pest control (if done in-house)
- Allergens
- Shipping
- Personnel hygiene requirements
- Food safety training

Minor deficiency (3 points) if:

- Single/isolated instance(s) of SOP's with errors or omissions in the information within the SOP's.
- Single/isolated instance(s) of important SOP's being omitted.

Major deficiency (1 point) if:

- Numerous instances of SOP's with errors or omissions in the information within the SOP's.
- Numerous instances of important SOP's being omitted.

Non-conformance (0 points) if:

- Majority of SOP's have not been written properly.
- Majority of SOP's are missing.

2.3.2 Are there specific Standard Operating Procedures (SOPs) for the changing and testing of water and ice systems e.g. wash systems, hydrovacuums, hydrocoolers, ice making machines, ice injectors, etc?

Visual Confirmation. Total conformance (10 points): Water and ice systems should have specific SOPs which describe the process of changing the water and performing and recording anti-microbial sanitizer strength testing). Procedure should indicate target and minimum anti-microbial sanitizer levels, process for adjusting when levels drop below target levels, frequency of testing, procedures to independently verify sanitizer levels and corrective action requirements. 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 than daily if a validated regeneration system (e.g., a water pasteurization/filtration system) is being used. **This question is applicable to single pass and multiple systems.** This question is not asked in the Storage and Distribution Audits.

Minor deficiency (7 points) if:

- Single/isolated instance(s) of errors or omissions within the SOPs for water changing and testing relating to water and ice systems.
- Single/isolated instance(s) of errors or omissions in the validation documentation for water changing and testing relating to water and ice systems.

Major deficiency (3 point) if:

- Numerous instances of errors or omissions within the SOP's for water changing and testing relating to water and ice systems.
- Numerous instances of errors or omissions in the validation documentation for water changing and testing relating to water and ice systems.

Non-conformance (0 points) if:
- SOPs for water changing and testing relating to water and ice systems do not exist.
- SOPs do not address the frequency of water changing and/or testing.
- There is no validation documentation for water changing frequency and/or water testing frequency. **Auditor should consider reverting back to Q 1.1.1, the general automatic failure question.**

2.3.3 Is there a documented glass and brittle plastic management policy and procedure (including company glass and brittle plastic policy, glass breakage procedure and where necessary a glass register)?

Visual Confirmation. Total conformance (5 points). There should be a written glass and brittle plastic policy and procedure, which should state:
- Where glass is prohibited and where glass is allowed.
- Policy should state how employees should report missing or broken spectacles or contact lenses and to whom they report the issue.
- If certain glass items are allowed, then a glass register should exist describing each item, location and quantity. The glass register should only list items that could not be replaced with a less dangerous material. The glass register should not be abused by allowing glass items on site that are usually viewed as poor GMPs (e.g., allowing glass drinking bottles into production areas, unprotected glass light bulbs). Glass register items should be checked on a routine basis (at least monthly) to ensure they are not damaged/cracked, etc. Checks should be documented.
- Glass breakage procedure including requiring recording what happened, recording what happens to potentially affected raw materials (including packaging), product and equipment, recording future preventative actions and especially where to record the incident details (e.g., in the NUOCA log).
- Clean-up procedure after glass breakage should indicate what equipment to use and include shoe/boot and cleaning equipment checks/decontamination procedures to ensure broken glass is not unintentionally transported out of the area.

Minor deficiency (3 Points) if:
- Policy lacks an element listed above.
- Single/isolated instance(s) where glass breakage details have not been recorded properly.
- Single/isolated instance(s) of glass register items not being checked on a routine basis.

Major deficiency (1 point) if:
- Policy lacks more than one element noted above.
- Numerous instances where glass breakage details are not being recorded properly
- Numerous instances of glass register items not being checked on a routine basis.

Non-conformance (0 points) if:
- No policy exists.
- There has been a glass breakage but no records exist.
- Systematic failures to check glass register items on a routine basis.

2.3.4 Are the SOPs available to relevant users and is a master copy maintained in a central file (SOP Manual)?

Visual Confirmation. Total conformance (5 points): The SOP's should be available to the users and any other interested parties. A master copy of all SOP's and recording forms should be collated in order to create (an) SOP Manual(s), sometimes called a Quality Manual. SOP's should be used by relevant employees (e.g., QA employees, production, sanitation, etc.). SOP's can be used for training and for reference. The number of copies of SOP's depends on the size of the company and the types of processes involved. In the event of electronic

SOP's, access should be allowed to all relevant employees, however there should be controls in place to prevent unauthorized editing.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of SOP's not being made available to relevant employees.
- Single/isolated instance(s) of SOP's and recording forms being omitted from the Master SOP file (SOP Manual).

Major deficiency (1 point) if:
- Numerous instances of some SOP's not being made available to relevant employees.
- Numerous instances of SOP's and recording forms being omitted from the Master SOP file (SOP Manual).

Non-conformance (0 points) if:
- SOP's are not accessible to relevant employees.
- A master file (SOP Manual) containing the SOP's and recording forms that are being used, has not been created.

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Traceability

2.4.1 Is there a documented account 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?
Visual confirmation. Total conformance (10 points): A written document (narrative) should be available for review, either within the recall program or as a separate document that shows the facility traceability system. **This may be a text explanation or a flow chart.** The system should be able to show that it can trace back to the supplier(s) of materials 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 evident when touring the facility and also when checking paperwork. The written traceability system should match the system that is being used in the production facility. Recording batches of packaging is required for some products where packaging recalls might occur (e.g., modified atmosphere packaging, juice bottles, etc.). Recording packaging batches is not required for packaging that is not usually the cause of a recall (e.g., cardboard boxes). Cooling Cold Storage & Storage and Distribution auditees that operate in a third party capacity for their clients might have their own traceability system, or have adopted their client(s'). While either route is acceptable, if the individual client(s') traceability systems are used, then the auditor will check each individual traceability system on site. Cooling Cold Storage & Storage and Distribution operations should have a system that can traceback from outgoing lots back through their process to the incoming lots.

The tracking system must meet the requirements for "one step back, one step forward" as per the FDA requirements. Any national, local or importing country legal requirements should be followed.
Potentially useful websites:
http://www.fda.gov/OHRMS/DOCKETS/98fr/04-26929.htm,
http://www.fda.gov/downloads/iceci/compliancemanuals/regulatoryProceduresManual/UCM074312.pdf
http://www.fda.gov/regulatoryinformation/legislation/ucm148797.htm

Minor deficiency (7 points) if:
- Single/isolated instance(s) of the written traceback system not reflecting what is happening in the production facility.
- Single/isolated instance(s) of clarity issue(s) in the traceability explanation (text or flow chart).
- Omitting packaging traceability (where packaging is sometimes the subject of a recall issue e.g., MAP packaging, juice bottles).

Major deficiency (3 points) if:
- Numerous instances of the written traceback system not reflecting what is happening in the production facility.
- Numerous instances of clarity issues in the traceability explanation (text or flow chart).
- Single/isolated instance(s) of either incorrect or missing elements of the traceability system that either limits or stops efficient trace back or trace forward of the production process. For example, not recording which lot codes are going to which customer, thereby requiring that all customers are contacted in the case of a recall.

Non-conformance (0 points) if:
- Systematic failure of the written traceback system to reflect what is happening in the production facility.
- Numerous instances of either incorrect or missing elements of the traceability system that either limits or stops efficient trace back or trace forward of the production process. For example, not recording which lot codes are going to which customer, thereby requiring that all customers are contacted in the case of a recall. The production step not properly recording what raw material lots are processed on a certain day.
- No written down traceability system.

2.4.2 Does the facility have a documented recall program including: procedures, recall team roles, their contact details, external contact listings and (in the USA) an explanation of different recall classes?
Visual confirmation. Total conformance (15 points): A written current recall program should be available for review. Documentation should include basic procedures and responsibilities, current facility contact listing with alternates and out of hour's numbers. Contact listings for customers and suppliers should also be part of the recall program, although these might be viewed as confidential (if so, then these listings must at least be referred to in

the recall program). Listings should be reviewed regularly. In the USA (or when importing), an explanation of recall classes (Class I, II, III) should be in the recall program. Ideally, contact numbers for attorneys, media specialists (for getting the recall information to the various press outlets), local enforcement officials (e.g., State and City Health Boards) are a good idea (these are optional and should not cause a down score if missing). Cooling Cold Storage & Storage and Distribution auditees that operate in a third party capacity might not have supplier and customer contact details, but they should have their client(s) details as part of their recall program. Cooling Cold Storage & Storage and Distribution have the option of creating their own recall program or using those provided by their clients. If latter option is used, then the auditor will check each individual recall program on site.
Potentially useful websites:
FDA Recall Policy, http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/default.htm
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=7&showFR=1

Minor deficiency (10 points) if:
- One element of the written recall program is missing or is outdated.

Major deficiency (5 points) if:
- Two or more elements of the written recall program are missing or are outdated.

Non-conformance (0 points) if:
- The facility does not have a recall program.

2.4.3 Is testing of recall procedures (including trace back) performed and documented at least once every six months? Can the company identify where affected product was sent?
Visual confirmation. Total conformance (10 points): A "mock" recall should be performed at least twice in the last 12 months (approximately six month intervals). One of the tests should include a trace (one step forward, one step back) of the food contact packaging material. Operations with less than six consecutive months of operation should have at least one mock recall per season. Documentation should indicate the date and time the mock recall was initiated, the product chosen, the mock scenario (reason for needing a mock recall), amount of product produced, affected lot ID's (date code(s), lot code(s), etc.), amount located, percent located, time product was located and time mock recall was completed. Scenario should be varied to provide experience in a range of conditions. Some examples include customer complaints for foreign materials, test results (buyer, government, in-house) detecting issues such as pathogens, pesticide residues, etc. Mock recall documentation should include copies of documentation that support the trace 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). Recall/trace documentation should support the scenario. Checks should be carried out to ensure that contact details exist for the affected customers. Documentation should also include any "lessons learned" from the process i.e. an evaluation of how the mock recall procedure went and what improvements the auditee could identify to improve their recall process (e.g., speed up the process, improve tracking system, etc.). Documentation should state "Mock Recall", especially the document that shows the scenario, so that at a later date, no one is confused as to whether this was a mock or a real recall. Auditors should remember that mock traceback and recall will vary considerably depending on the scenario chosen. Recalls should be completed within two hours with 100% of chosen product located and also any products with common ingredients. This also includes tracking culled product that becomes a raw material for another food producer or processor. For example, culled apples at a packing house may be sold as a raw material to a juicer, culled potatoes or melons may be sold as dairy cattle feed, etc. Mock recalls might note that product had been culled and rejected in some situations. Auditees are not expected to call or otherwise contact any suppliers or customers when carrying out mock recalls. If a live (real) recall has occurred in the last year, then this can be used to meet the requirements of this question, but the documentation details noted above should be in place.

Minor deficiency (7 points) if:
- Three or less elements of the mock recall are missing.
- Five percent or less of product was not located.
- A few gaps noted in the logic of the traceback documentation.
- Not noting "lessons learned" from mock recall exercise (if there are any).

- Total time to complete mock recall took longer than 2 hours but not more than 3 hours.
- There has been only one documented mock recall or trace in the last 12 months.

Major deficiency (3 points) if:
- Four or more elements of the mock recall are missing
- More than five percent of product was not located.
- Lacking documentation that proves how the traceback and recall system identified all affected items and customers.
- Total time to complete mock recall took more than 3 hours.
- There is no record of a mock recall or trace in the last 12 months.

Non-conformance (0 points) if:
- There is no record of a mock recall or trace in the last 15 months.
- Mock recall was initiated, but could not be completed.

2.4.4 Is there a written procedure for handling on hold and rejected materials?

Visual confirmation. Total conformance (10 points): A documented procedure exists that explains how raw materials, ingredients, finished goods and packaging materials should be handled, that have either been rejected or placed on hold. The procedure should include details on how the affected lot(s) is/are separated from other lots in terms of tagging systems and recording details (date showing when the items were placed on hold/rejected and the reason for being on hold/rejected and the name of the person who put the product on hold) and any other physical separation to ensure that affected items are not commingled with other goods in such a way that their disposition is not clear. Authorized personnel should sign (with date and time) a "release" for any product placed on hold or rejected, detailing actions taken (e.g., disposition, re-work, food bank, etc.). In a processing audit there should also be records of items placed on hold (e.g., an on hold/disposition log) available for review. This is "ideal" in other facility audits i.e. on hold/disposition records should only be scored for processing templates.

Minor deficiency (7 points) if:
- Single part of the procedure is omitted.
- Single/isolated instance(s) of the procedure not being applied in the production and storage areas.
- Single/isolated instance(s) of errors or omissions in on hold records.

Major deficiency (3 points) if:
- Procedure missing more than one part, but SOP exists.
- Numerous instances of the procedure not being applied in the production and storage areas.
- Numerous instances of errors or omissions in on hold records.

Non-conformance (0 points) if:
- Procedure has not been created.
- Procedure created bears no resemblance to what is being applied in the production and storage areas.
- There is no record of on hold or rejected materials.

2.4.5 Is there a documented system for dealing with food safety complaints/feedback from consumers and buyers along with records and company responses, including corrective actions?

Visual Confirmation: Total conformance (5 points): There is a documented procedure detailing how to handle client's (buyer and/or consumer) food safety complaints and feedback. It is important to keep the complaints and feedback related records on file to support company policy/procedure. The policy and records should include (where applicable):
- Date/Time of complaint/rejection,
- Who made the complaint,
- Contact information,
- Product description,
- Where the product was purchased,
- Amount of product,

- Product code/date,
- Nature of complaint,
- Corrective actions,
- Corrective actions taken to prevent reoccurrence.

Ideally foreign material complaints have photographs of the issue found. Other examples of issues that are viewed as potentially food safety related include tainting, sickness and sometimes decay issues. Where there are many (e.g. more than five in a month) complaints, a degree of analysis and review is expected.
If a corporate office/sales department handles complaints, there should be a summary report communicated to relevant personnel, to indicate the types and frequency of complaints. Where the auditee claims to have received no complaints/rejections, the auditor should verify that a complaint recording system is in place and has the necessary elements listed above.
Where an auditee is a co-packer and/or third party contract cooler or storage facility, they are still required to have a system that deals with their client's food safety complaints that might have involved their portion of the supply chain. For example, a glass complaint could have come from any part of the supply chain (unless the glass type is identified) and, therefore, a record of the issue, investigation and response from a third party co-packer or storage operation would be needed.

Minor Deficiency (3 points) if:
- Single/isolated instance(s) of omissions and incorrect data in the records, including corrective actions.
- More than five complaints/rejections received, but no trend analysis or review carried out.

Major Deficiency (1 point) if:
- Numerous instances of omissions and incorrect data in the records, including corrective actions.

Non-conformance (0 points) if:
- There are no records of complaints/rejections and responses (complaints do occur).
- The company does not have a system for handling complaints/rejections

Supplier Control

2.5.1 Are there written specifications for own grown raw materials, purchased edible raw materials/ingredients, packaging materials, processing and sanitation chemicals?
Visual confirmation. Total conformance (3 points): There should be current written specifications for own grown raw materials, purchased edible raw materials/ingredients, packaging materials and processing and sanitation chemicals. Note that "processing chemicals" includes any processing aids (e.g., anti-microbial used in wash water, waxes, post-harvest fungicides, etc.).

This question is only relevant in the Cooling Cold Storage and Storage & Distribution audits where the company buys "XYZ" to then use/store and sell. Not applicable if acting as a third party storage operation or third party co-packing operation (i.e. have no say in purchase of raw materials).

Minor deficiency (2 points) if:
- Single/isolated instance(s) of errors or omissions in the records.
- Single/isolated instance(s) of missing (a) specification(s).

Major deficiency (1 point) if:
- Numerous instances of errors or omissions in the records.
- Numerous instances of missing specifications.

Non-conformance (0 points) if:
- There are no written specifications.
- Failure to maintain specifications.

2.5.2 Are there written specifications for finished goods?
Visual confirmation. Total conformance (3 points): There should be current written specifications developed by the customer and/or company for finished goods (i.e. finished product specifications). Where relevant, the specification may include the following information: product name, weight/quantity, product code, date code information, description, ingredients, nutritional information, allergen statement, storage instructions, shelf life, country of origin, packaging information, product testing, bar code, etc. Specifications should be available to relevant staff. Auditor should check that specifications are being followed and where the specification requires product testing, auditor will verify that testing requirements are being followed as required.
This question is only relevant in the Cooling Cold Storage and Storage & Distribution audits where the company buys "XYZ" to then use/store and sell. Not applicable if acting as a third party storage operation or third party co-packing operation (i.e. have no say in the purchase of finished goods).

Minor deficiency (2 points) if:
- Single/isolated instance(s) of errors or omissions in the specifications.
- Single/isolated instance(s) of missing (a) specification(s).

Major deficiency (1 point) if:
- Numerous instances of errors or omissions in the specifications.
- Numerous instances of missing specifications.

Non-conformance (0 points) if:
- There are no written specifications.
- Failure to maintain or follow specifications.

2.5.3 Is there a list of approved suppliers of purchased raw materials/ingredients, packaging materials and processing and sanitation chemicals?
Visual confirmation (5 points): There should be a list of approved suppliers of raw materials, ingredients (including ice), and chemicals (including processing (wash water) and sanitation chemicals) and packaging. All products, ingredients and packaging are purchased from approved suppliers. Where exceptions are made (e.g., market

conditions), approval from management should be documented. There should be evaluations of vendor facilities i.e. third-party audit reports, second party auditee evaluations or certificates.

This question is only relevant in the Cooling Cold Storage and Storage & Distribution audits where the company buys "XYZ" to then use/store and sell. Not applicable if acting as a third party storage operation or third party co-packing operation (i.e. have no say in purchase of raw materials or packaging items).

Minor deficiency (3 points) if:
- Single/isolated instance(s) of errors or omissions in the records.
- Single/isolated instance(s) of purchasing exceptions made (i.e. not of list of approved suppliers) without management approval.

Major deficiency (1 point) if:
- Numerous instances of errors or omissions in the records.
- Numerous instances of purchasing exceptions made (i.e. not of list of approved suppliers) without management approval.

Non-conformance (0 points) if:
- There is no list of approved suppliers.
- There is a list of approved suppliers but purchasing exceptions to it is the norm.

2.5.4 Is there a written procedure for approval and continued monitoring of suppliers of purchased raw materials/ingredients, packaging materials processing and sanitation chemicals?
Visual confirmation. Total conformance (3 points): There should be a written procedure for approval and continued monitoring of suppliers of raw materials, ingredients (including ice, processing aids, chemicals (including sanitation and processing (wash water) chemicals)) and packaging materials to ensure all purchased or otherwise received materials conform to specified requirements (specifications). The results of any evaluations and follow-up actions should be documented.
Written procedures should include:
- Details of requirements that suppliers should meet
- How potential suppliers are evaluated and selected
- Requirements that suppliers notify the auditee of any changes in the product or service

This question is only relevant in the Cooling Cold Storage and Storage & Distribution audits where the company buys "XYZ" to then use/store and sell. Not applicable if acting as a third party storage operation or third party co-packing operation (i.e. have no say in purchase of raw materials).

Minor deficiency (2 points) if:
- Single/isolated instance(s) of errors or omissions in the procedure.

Major deficiency (1 point) if:
- Numerous instances of errors or omissions in the procedure.

Non-conformance (0 points) if:
- There is no written procedure.

2.5.5 Does the facility have relevant third party audit reports, supplier third party audit certifications and/or supplier letters of guarantee for purchased edible raw materials/ingredients, packaging materials and processing chemicals?
Visual confirmation. Total conformance (15 points): The auditee should have current third party audit certificates on file, audit reports with corrective action documentation (where appropriate) or dated letters of guarantee for product raw material, processing chemicals (wash water chemicals) and other ingredients that are purchased. Letters of guarantee should indicate that the items supplied meet any and all legal standards, best practice guidelines and agreed specifications, and that they intend to continue to meet these guidelines for all materials that they provide to the customer i.e. continuing letter of guarantee (otherwise letters are deemed to have a 12

month expiration date from the date noted in the document). Letters of guarantee for products are not required if it's their own product (e.g., "in-house grown") that is being packed, although certificates for auditing are worth noting. Pay special attention for letters of guarantee/certifications/audit reports for imported goods.

This question is only relevant in the Cooling Cold Storage and Storage & Distribution audits, where the company buys "XYZ" to then use/store and sell. This question is not applicable if acting as a third party storage operation or a co-packer, as long as the client(s) utilizing the auditee's service have provided a letter/agreement releasing the auditee from the responsibility of inspecting incoming raw materials.

Minor Deficiency (10 points) if:

- Single/isolated instance(s) of omissions or incorrect data in the records.

Major Deficiency (5 points) if:

- Numerous instances of omissions or incorrect data in the records.

Non-conformance (0 points) if:

- No records.
- Failure to maintain records.

2.5.6 Does the facility have relevant third party audit reports, supplier third party audit certifications and/or supplier letters of guarantee for packaging items?

Visual confirmation. Total conformance (10 points): The auditee should have on file current third party audit certificates, audit reports or letters of guarantee for packaging and film items that are purchased. Letters of guarantee should indicate that the materials supplied meet any and all legal standards, best practice guidelines and agreed specifications, and that they intend to continue to meet these guidelines for all items that they provide to the customer i.e. continuing letter of guarantee (otherwise letters are deemed to have a 12 month expiration date from the date noted in the document). Pay special attention for letters of guarantee/certifications/audit reports for imported goods.

This question is only relevant in the Cooling & Cold Storage and Storage & Distribution audits, where the company buys "XYZ" to then use/store and sell. Not applicable if acting as a third party storage operation or third party co-packing operation (i.e. have no say in purchase of packaging items).

Minor Deficiency (7 points) if:

- Single/isolated instance(s) of omissions or incorrect data in the records.

Major Deficiency (3 points) if:

- Numerous instances of omissions or incorrect data in the records.

Non-conformance (0 points) if:

- No records.
- Failure to maintain records.

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Chemicals

2.6.1 Are copies of all Materials Safety Data Sheets (detergents, sanitizers, pesticides, etc.) on file and fully accessible at all times with clear indexes?
Visual confirmation. Total conformance (5 points): MSDS are available for all chemicals (e.g., pest control, cleaning, maintenance (especially those used on line) and sanitizing chemicals, etc.) used in the facility. When purchasing or selecting cleaning and maintenance materials that come into direct contact with product (including materials used on food contact surfaces), facility purchases or selects materials that are appropriate for their intended use. Choose a sample of at least three chemicals while on the plant tour to check against MSDS file. MSDS are accessible at all times and are stored in the appropriate departments. The filing system is organized, for quick access to information. Computer records (e.g., MSDS stored on memory stick, CD or computer) are allowed if auditee can demonstrate they are readily accessible to employees. Only MSDS for products which are used at the plant should be included in the "active" file. Ideally, have copies of regulatory approvals (where available) on file for cleaners and chemicals that are used on items that come in direct contact with product.

Potentially useful websites:
CDMS Label / MSDS Information, http://www.cdms.net/manuf/manuf.asp
MSDS Databases, http://www.msdssearch.com/DBLinksN.htm
http://www.fda.gov/Food/IngredientsPackagingLabeling/FoodAdditivesIngredients/default.htm
http://info.nsf.org/usda/psnclistings.asp

Minor deficiency (3 points) if:
- MSDS are available but filing system is not organized (e.g. tabulating, indexing, etc.) in manner that allows for easy navigation.
- Single/isolated instance(s) of missing MSDS's for a chemical that is currently being used.
- Limited access to MSDS's for employees using the chemicals.

Major deficiency (1 point) if:
- Numerous instances of missing MSDS's for chemicals that are currently being used.

Non-conformance (0 points) if:
- No MSDS are on file.
- The use of a chemical that is not regulatory approved for use on food contact surfaces.
- The use of a chemical that is not appropriate for its intended use.

2.6.2 Are there copies of specimen labels for chemicals used, where the full label is not immediately accessible e.g. rodent chemicals, product sanitizers?
Visual confirmation. Total conformance (5 points): Specimen labels should be available for chemicals (pesticides, cleaning and sanitizing chemicals, etc.) that are decanted out of their original containers. Examples include rodent bait, cleaning chemicals, liquid soap packs, hand dip solutions, etc. Specimen labels are important, since if for some reason there is a need to find a label of a decanted/diluted concentrate, then this can be done quickly. Specimen labels might be kept on file (or stored on memory stick, CD or computer if auditee can demonstrate they are readily accessible to employees) and/or be displayed in an accessible area in the plant (e.g., clipped to hose pipes). Not applicable if all chemicals are used in the presence of the full label on the container. Only labels for products used at the plant should be included in the "active" file.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of missing specimen label(s) for a decanted chemical(s) that is/are currently being used.

Major deficiency (1 point) if:
- Numerous instances of missing specimen labels for decanted chemicals that are currently being used.

Non-conformance (0 points) if:
- No specimen labels for decanted chemicals being used.

2.6.3 Is there a chemical inventory and/or usage log?

Visual confirmation. Total conformance (3 points): Chemical usage logs and/or chemical inventories should be on file. Chemicals within the scope of this question are to be limited to cleaners and sanitizers i.e. sanitation chemicals and food contact chemicals, such as chlorine for water flumes, hydrocoolers, etc. 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.

Minor deficiency (2 points) if:

- Single/isolated instance(s) of missing chemical usage logs and/or inventories.
- Single/isolated instance(s) of omission(s) or error(s) in the chemical usage logs and/or inventories.
- Single/isolated instance(s) of new deliveries not being accounted for.
- Single/isolated instance(s) of minimum inventory frequency not being maintained (if usage logs are not being utilized).

Major deficiency (1 point) if:

- Numerous instances of missing chemical usage logs/inventories.
- Numerous instances of omissions or errors in the chemical usage logs and/or inventories.
- Numerous instances of new deliveries not being accounted for.
- Numerous instances of minimum inventory frequency not being maintained (if usage logs are not being utilized).

Non-conformance (0 points) if:

- No chemical usage logs/inventories are on file.

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Pest Control

2.7.1 Is there a documented pest control program, including a copy of the contract with the extermination company (if used), Pest Control Operator license(s) (if baits are used) and insurance documents?
Visual confirmation. Total conformance (15 points): There should be a documented pest control program in place detailing 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 persons 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). Insurance document should ideally name the auditee as "additional insured". When licensing legislation does not apply (e.g., in certain countries), there should be evidence of on-going training. Auditors should check documentation for expiry dates.

Minor deficiency (10 points):
- One piece of documentation is not in place or is not current.
- Single/isolated omission(s) in the written program.

Major deficiency (5 points):
- Two pieces of documentation are not in place or are not current.
- Numerous omissions in the written program.

Non-conformance (0 points):
- More than two pieces of documentation are not in place or are not current.
- Written program does not resemble what is happening in practice at all.

2.7.2 Is there a schematic drawing of the plant showing numbered locations of all traps and bait stations, both inside and outside the plant?
Visual confirmation. Total conformance (10 points): 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 out in the facility. Ideally, the map should be dated, since placement will vary over time.

Minor deficiency (7 points) if:
- The location map does not distinguish between the different types of devices.
- Single/isolated instance(s) of trap(s) missing from the plan.
- Single/isolated instance(s) of trap(s) numbering being incorrect.

Major deficiency (3 points) if:
- Numerous instances of traps missing from the plan.
- Numerous instances of traps numbering being incorrect.

Non-conformance (0 points) if:
- No map.
- Majority of traps are not included on the map.
- Map does not represent actual physical placement of traps at all.

2.7.3 Are service reports created for pest control checks detailing inspection records, application records, and corrective actions of issues noted(in-house and/or contract)?
Visual confirmation. Total conformance (10 points): 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 (see below), signs of activity and corrective actions, trend reports. Match operator signature on

service logs with licenses/certificates on file. Records should show when insect light trap bulbs are changed. Where the contracted pest control has left their client details of an issue or a recommendation (e.g., excessive gap at the bottom of a door), then the client should acknowledge the issue(s) and note corrective action(s) completed (where relevant). Specimen labels and MSDS sheets for chemicals used are scored under section 2.6. Where chemicals are used, records should detail:

- Product name of materials applied
- The EPA or product registration number (as required by law)
- Target pest
- Rate of application (percent of concentration)
- Location or site of application
- Method of application (if applicable)
- Amount of pesticide used
- Date and time of application
- Signature of applicator

Potentially useful website:
National Pest Management Standards, Pest Management Standards for Food Plants
http://www.npmapestworld.org/documents/Foodplantstandards2010_000.pdf

Minor deficiency (7 points) if:

- Single/isolated instance(s) of missing or incomplete information/records (e.g., pest activity, trap replacement etc.).
- Single/isolated instance(s) where contracted pest operators action points have not been acknowledged and completed.
- Single/isolated instance(s) of not noting chemical use details.

Major deficiency (3 points) if:

- Numerous instances of missing or incomplete information/records (e.g., pest activity, trap replacement, etc.).
- Numerous instances where contracted pest operators action points have not been acknowledged and completed.
- Numerous instances of not noting chemical use details.

Non-conformance (0 points) if:

- No service reports.
- Systematic failure to maintain service reports.
- Systematic failure to record chemical use details.

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Internal and External Inspections

2.8.1 Are there written procedures for handling regulatory inspections?

Visual confirmation. Total conformance (3 points): Procedures are written for employees to follow when regulatory agencies inspect the facilities with respect to any facet of the operation that impinges on food safety. Regulatory agencies of interest in the USA could be FDA, USDA, OSHA, Health Department, etc. and State enforcement organizations. Outside the USA, equivalent agency visits should be considered. The procedures should include, at a minimum, rules for always accompanying inspections and rules on taking samples. This policy should be communicated to key personnel, including the receptionists. Inspection policies must not contravene bio-terrorism laws and restrict access to documents that have been covered by these laws.

Minor deficiency (2 points) if:

- If one of the above elements of the policy is missing.
- If the receptionist(s) has/have not been briefed properly.

Major deficiency (1 point) if:

- If two or more of the above elements of the policy are missing.

Non-conformance (0 points) if:

- A written procedure for handling regulatory inspections is not available for review.

2.8.2 Are there records of regulatory inspections and/or contracted third party inspections, company responses and corrective actions, if any?

Visual confirmation. Total conformance (5 points): 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 (Federal and State) and third party (including last PrimusLabs audit). Auditors are requested not to look at second party visit records, since sometimes they include confidential quality and product development information. This question is not applicable if there have been no regulatory or third party inspections in the past year and there has never been a PrimusLabs audit in the past. Evidence of corrective actions is important, since there are legal implications if a company was warned of an issue and cannot prove that it has taken corrective actions and later has a serious incident which could have been prevented.

Minor Deficiency (3 points) if:

- Single/isolated instance(s) of corrective actions not being recorded.
- A single audit inspection report is missing in the last year.

Major Deficiency (1 point) if:

- Numerous instances of corrective actions not being recorded.
- More than one audit inspection report is missing in the last year.

Non-conformance (0 points) if:

- There are no records of previous inspections and corrective actions taken, although there have been inspections in the last year.

2.8.3 Is there a program for periodic facility/GMP internal (self) inspections and are records maintained detailing corrective actions?

Visual confirmation. Total conformance (10 points): There should be a program for periodic internal (self or first party) inspections of the facility operations, including production storage, staff amenities, external areas, production processes, personnel practices, etc. See question 2.8.4 for internal audits of food safety records. Inspection should include:

- Inspection frequency. Frequency depends on type and size of operation (auditor's discretion). Processing plants should have at least a monthly frequency. Packinghouses, coolers and storage operations ideally have a monthly frequency, but at least a quarterly frequency.
- Zonal, checklist methods, etc. are all acceptable. Entire facility (inside and out) should be included.

- Who conducted the inspection
- Documented findings
- Note corrective actions (including completion date)

Self-auditing (self-diagnostics) is a key part of the facility's food safety program.

Minor Deficiency (7 points) if:
- Single/isolated instance(s) of follow up/corrective actions not noted.
- Single/isolated instance(s) of incomplete or missing records.
- Single/isolated instance(s) of areas/issues missing on the inspection program.

Major Deficiency (3 points) if:
- Numerous instances of follow up/corrective actions not noted.
- Numerous instances of incomplete or missing records.
- Inspection frequency is not adequate, relative to the type of business and the number of issues that require monitoring.
- Numerous instances of areas/issues missing on the inspection program.

Non-conformance (0 points) if:
- Systematic failure to maintain records.

2.8.4 Is there a program for periodic inspections of food safety system records e.g. pest control records, temperature control records, sanitation records, maintenance records, etc.?
Visual Confirmation. Total conformance (5 points): Recording systems for food safety related topics should be subject to internal (self or first party) inspections on a routine basis to ensure that they are being completed properly (e.g., using the right log, right frequencies, recording results correctly, recording corrective actions etc.). This question focuses on auditee's self-diagnostic checking of their own documentation. If done correctly, this should help the auditee maintain their systems and also aid in any external audits or investigations. Ideal audit frequency is monthly, but should performed be at least quarterly.

Inspection should include:
- Inspection frequency. Processing plants should have at least a monthly frequency. Packinghouses, coolers and storage operation ideally have a monthly frequency, but at least a quarterly frequency.
- Which records are checked (e.g. log, checklist) – may be random or scheduled
- Who conducted the inspection
- Documented findings (e.g., obsolete log in use, recording results correctly, recording actions, logs not signed off, pencil used, etc.)
- Note corrective actions (including completion date)

Self-auditing (self-diagnostics) is a key part of the facility's food safety program.

Minor Deficiency (3 points) if:
- Single/isolated instance(s) of follow up/corrective actions not noted.
- Single/isolated instance(s) of incomplete or missing records.

Major Deficiency (1 point) if:
- Numerous instances of follow up/corrective actions not noted.
- Numerous instances of incomplete or missing records.
- Inspection frequency is not adequate, relative to the type of business and the number of issues that require monitoring.
- Some areas/issues missing on the inspection program.

Non-conformance (0 points) if:
- Systematic failure to maintain records.

2.8.5 Is there a daily pre-operation inspection log?
Visual confirmation. Total conformance (5 points): Food handling departments are inspected daily before operation begins. This should be a start-up check of all potential issues, not a repeat of the daily sanitation completion record which is covered in 2.10.6.
The daily pre-operational check should include:

- Examination of equipment to verify cleanliness
- General housekeeping of storage and production areas
- Checking that the production line is ready to start safely
- Checking that personnel meet the GMP requirements
- Corrective actions in the case of non-conformance

Basically, a last minute quick check that all is well and the production can start. Pre-operational system design can vary (e.g., may be zone specific (zonal), topic specific or a mixture of designs). Use of bio-luminescence devices i.e. ATP measuring equipment, is something an auditor should note in the comments and, if used, auditor must check to ensure that the results and corrective actions are being recorded correctly (see question 2.10.11).

Minor Deficiency (3 points) if:

- Single/isolated instance(s) of omissions or incorrect data in the records.

Major Deficiency (1 point) if:

- Numerous instances of omissions or incorrect data in the records.
- Persistent repetition of corrective action without long-term solution.

Non-conformance (0 points) if:

- No records.
- Failure to maintain records.

2.8.6 Does the facility have incoming goods (raw materials, ingredients and packaging materials) inspection data?
Visual confirmation. Total conformance (5 points): Incoming goods should be inspected for visible issues (e.g., decay, foreign materials (contamination), odor, damage and labeling issues) and any other safety/food security related issues. Packaging is ideally checked routinely, but records can be maintained by exception (e.g., as deviation incidents and recorded as unusual occurrences). This is an acceptable practice where issues are rare. Inspection data for products are not required if “own product” (e.g., in-house grown commodity) is being packed.

This question is only relevant in the Cooling & Cold Storage and Storage & Distribution audits, where the company sells product. This question is not applicable if acting as a third party storage operation or a co-packer as long as the client(s) utilizing the auditee’s service have provided a letter/agreement releasing the auditee from the responsibility of inspecting incoming materials.

Minor Deficiency (3 points) if:

- Single/isolated instance(s) of omissions or incorrect data in the records.

Major Deficiency (1 point) if:

- Numerous instances of omissions or incorrect data in the records.

Non-conformance (0 points) if:

- No records.
- Failure to maintain records.

2.8.7 Are there inspection logs on incoming trailers for rodents and insects, cleanliness, holes and temperature control?
Visual confirmation. Total conformance (10 points): There should be written records (separate log or on bill of lading, etc.) of trailer (a.k.a truck body, lorry body) inspections. Designated personnel should be responsible for inspecting the incoming vehicles and checking/documenting the following:

- Interior is clean, odor free, pest free and in good condition i.e. free of damage.
- Refrigerated vehicles and the products inside are in conformance with specified temperatures.
- Records of rejections and any corrective actions (where relevant).

Not applicable if flatbeds are used. Truck cleaning certificates are acceptable as sanitation completion records for in-house trucks in question 2.10.4 and 2.10.6, but do not replace the inspection log requirements of this question. Packaging supply trucks can be recorded by exception, but are ideally routinely inspected and recorded.

Minor Deficiency (7 points) if:
- Single/isolated instance(s) of omissions or incorrect data in the records.

Major Deficiency (3 points) if:
- Numerous instances of omissions or incorrect data in the records.

Non-conformance (0 points) if:
- No records.
- Failure to maintain records.

2.8.8 Is there an incidents report (sometimes called a Notice(s) of Unusual Occurrence and Corrective Actions Log (NUOCA)) used for recording infrequent and/or unusual events?
Visual confirmation. Total conformance (5 points): The company has a log or report detailing deviations, incidents, process failures, unusual occurrences, etc. (e.g., foreign objects, chemical spills, rejected packaging, downtime, etc.) that are not recorded on other logs. These should have corrective action records (where relevant). This log helps avoid creating multiple logs for events that do not occur very often. Often called a NUOCA log (Notice(s) of Unusual Occurrence and Corrective Action Log). If product testing is performed (microbiological, heavy metal, pesticides, dioxins, aflatoxins, etc.), and there are out of specification results, there should be a NUOCA. Useful to consider recording issues that might or might not temporarily affect production (e.g., loss of power, blocked drains, weather damage, earthquakes etc.) since at a later date, if there are product issues, these events might be of significance.

Minor Deficiency (3 points) if:
- Single/isolated instance(s) of omissions or incorrect data in the records.

Major Deficiency (1 point)
- Numerous instances of omissions or incorrect data in the records.

Non-conformance (0 points)
- No records.
- Failure to maintain records.
- If there is a critical food safety issue with either incomplete or no proper corrective actions
- **If there is a critical food safety issue with either incomplete or no proper corrective actions, the auditor should consider scoring down under Q 1.1.1.**

2.8.9 Is there a current certificate for inspection of backflow prevention assemblies on water lines entering the facility?
Visual confirmation. Total conformance (3 points): There should be a backflow prevention device on main water lines entering the facility and backflow prevention devices on individual water lines within production areas. A trained inspector (e.g., appropriately certified plumber) should verify the principle backflow prevention system every 12 months (unless there is a stated expiration on the certificate). Wells are also required to have backflow prevention devices to prevent cross connection or backflow during pump priming or maintenance. This question is still applicable even if local and/or national legislation does not require this type of inspection/testing. If the valve type is one that cannot be inspected or tested, then auditee should have documentation supporting this on–site (e.g., valve manufacturer's documentation).

Potentially useful sites:

http://ccdeh.com/resources/documents/food-safety-guidelines-1/122-california-plan-check-guide-for-retail-food-facilities-1/file
http://www.usc.edu/dept/fccchr/introduction.html
http://www.mindspring.com/~loben/water.htm

Minor deficiency (2 points) if:

- Last inspection and certification was done over a year ago, but not greater than 18 months ago.

Major deficiency (1 point) if:

- Last inspection and certification was done over a year ago, but not greater than 24 months ago.

Non-conformance (0 points) if:

- Last inspection and certification was done over 24 months ago.
- No inspection or certification records

Process Control

2.9.1 Are there records for the necessary process monitoring activities (e.g. pH, water temperature, heating processes, etc.) showing the monitoring frequencies, results and where necessary the corrective actions?

Visual confirmation. Total conformance (10 points): There should be appropriate logs in use for all process monitoring activities, including postharvest treatments. These may be combined on a single log or on multiple logs. The records should include corrective actions to be filled in when the process is outside the established limits. If monitoring is not continuous, then the amount or frequency of monitoring should be sufficient to verify the process is in control and **auditee should be able to support monitoring frequency being used**. Where produce is immersed in water and has been shown to be susceptible to microbial infiltration from water, the water temperature differentials and time/depth of submersion during immersion should be controlled in accordance with current regulation, industry guidelines or best practices. For example, for tomatoes FDACS, USDA and the University of Florida-GAPs require postharvest water be maintained at temperatures 10 ºF (5.6ºC) or higher above the fruit pulp temperature and water temperature should be monitored at least hourly. These guidelines also require that tomatoes not be submerged in more than one foot of water for more than two minutes. Potentially useful website:
http://fshn.ifas.ufl.edu/FoodSafety/news-resources/Packinghouse%20Audit%2010-11.pdf
Note that product washing is often detailed further in the HACCP section.

Minor Deficiency (7 points) if:
- Single/isolated instance(s) of omissions or incorrect data in the records and corrective action details.
- Single/isolated instance(s) of omissions or errors in the frequency of monitoring.
- Single/isolated instance(s) of incorrect parameters being monitored.

Major Deficiency (3 points) if:
- Numerous instances of omissions or incorrect data in the records and corrective action details.
- Numerous omissions or errors in the frequency of monitoring.
- Numerous instances of incorrect parameters being monitored.
- No supporting documentation of the monitoring frequency being used.

Non-conformance (0 points) if:
- No records.
- Monitoring frequency is insufficient to verify the process is in control.
- Monitoring parameters in use are insufficient to verify the process is in control.
- Failure to maintain records properly.
- **If there is a critical food safety issue with either incomplete or no proper corrective actions, the auditor should consider scoring down under Q 1.1.1.**

2.9.2 Are there records (with corrective actions) that show anti-microbial (e.g. free chlorine, ORP, peracetic acid) strength testing of wash water and ice solutions prior to start up and throughout the production runs?

Visual Confirmation. Total conformance (10 points): Wash water and ice production systems using anti-microbial agents (e.g., hypochlorite (chlorine), aqueous chlorine dioxide, peroxyacetic acid (PAA) and ozone) should have records showing that the strengths of the solutions are within parameters. Recycled/reused water systems (e.g., flumes, wash tanks, ice injectors, hyrovacuums, etc.) and single pass systems (e.g. spray bars) should be using an approved anti-microbial. Recycled/reused 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 to total chlorine). In single pass systems, it is acceptable to measure total chlorine (100-200 ppm, pH 6.5-7.5). See links below for data and research on threshold levels for free and total chlorine, ORP, peroxyacetic acid (PAA) and pH level parameters. As a guide, recycled chlorine systems should be expected to have parameters such as ≥10 ppm free chlorine and/or >650mv ORP (pH 6.5-7.5) and peroxyacetic acid systems at ≤80 ppm PAA (rinsed with potable water), chlorine dioxide ≥1 ppm. Other anti-microbials (e.g., ozone, electrolyzed water, etc.), should meet

manufacturer recommendations (**auditee should have proof of parameter derivation**) and be approved for use in wash water. Frequency of checks should be relative to the stability of the system, but at least pre-start, then at a frequency that ensures the availability of the anti-microbial is adequate while the system is running. As a minimum guide, a fresh-cut facility should be checked every 30 minutes, whereas whole washed product water anti-microbial levels should be checked hourly. Corrective actions should also be recorded. These steps may be covered in a HACCP plan (sanitizing of flume water). Any water treatment (e.g., chlorine, reverse osmosis, UV light, active carbon) at the source (e.g., well, canal) should be monitored and records available.

Potentially useful websites:
Journal of Food Protection, Vol. 74, No. 3, 2011, Pages 352–358
http://naldc.nal.usda.gov/download/49558/PDF
http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=173.315
http://onfarmfoodsafety.org/wp-content/uploads/Chlorination-of-Water-for-Fluming-and-Cleaning-Fresh-Fruits-and-Vegetables-and-Cleaning-Equipment.pdf
UC Davis, http://ucanr.edu/datastoreFiles/234-406.pdf
UC Davis, http://ucanr.edu/sites/GAP/news/Water_Disinfection/
http://www.caleafygreens.ca.gov/sites/default/files/LGMA%20Accepted%20Food%20Safety%20Practices%2008.04.2010.pdf

Minor deficiency (7 points) if:
- Single/isolated instance(s) of records showing solution strength out of parameters without adequate documented corrective actions.
- Single/isolated instance(s) of errors or omission in the records.
- Single/isolated instance(s) of total chlorine being recorded when free chlorine or ORP would have more been suitable (e.g., in chlorinated recycled water systems).
- Single/isolated instance(s) of checks not carried out at the required frequencies.

Major deficiency (3 points) if:
- Numerous instances of records showing solution strength out of parameters without adequate documented corrective actions.
- Numerous instances of errors or omission in the records.
- Numerous instances of total chlorine being recorded when free chlorine or ORP would have more been suitable (e.g., in chlorinated recycled water systems).
- Numerous instances of incorrect parameters being stated.
- Numerous instances of checks not carried out at the required frequencies.
- No supporting documentation of the monitoring frequency being used.

Non-conformance (0 points) if:
- Water/ice testing and water changes are not being recorded.
- Recorded solution strengths systematically out of parameters i.e. an unstable system (even if documented corrective actions exist).
- Systematic errors and omissions in the records.
- Total chlorine has been recorded throughout the system, when free chlorine or ORP should have been recorded (e.g., in chlorinated recycled water systems).
- Frequencies of checks systematically do not meet requirements of prior to start up and throughout the production runs.
- No evidence of water anti-microbial parameters has been stated/incorrect parameters being used. **The auditor should consider whether to apply Q 1.2.7 and score an automatic failure in view of the risk of cross contamination.**
- Single pass water system is in use without anti-microbial being used. **The auditor should consider whether to apply Q 1.2.7 and score an automatic failure in view of the risk of cross contamination.**
- Recycled/reused water system is in use without an anti-microbial being used. **The auditor should consider whether to apply Q 1.2.7 and score an automatic failure in view of the risk of cross contamination.**

2.9.3 Are there records (with corrective actions) that show anti-microbial strength testing of hand/foot/tool dip stations? Are there stock check and replenishment records for gel and spray stations?
Visual confirmation. Total conformance (3 points): The company should have a log sheet for evaluating the hand and/or foot and/or tool dip (where appropriate, see applicability chart) stations solution strength. The log sheet should include target anti-microbial concentration (ppm) and frequency of verification. The figures recorded must match the type and graduation of the testing system being used. An omission would include where an out of spec concentration is recorded but there is no record of corrective actions. Foot dips are required in fresh-cut, ready-to-eat processing audits (see 1.3.14). Any operation with hand, foot or tool dips is required to keep monitoring records (uncontrolled dips are a hazard). Where hand gel or spray stations using prepared solutions are used, there should be monitoring logs indicating stations are regularly checked to confirm units are stocked and operational.

Minor Deficiency (2 points) if:
- Single/isolated instance(s) of omissions or incorrect data in the records.
- Single/isolated instance(s) of dips or stations being omitted from the logs.

Major Deficiency (1 point) if:
- Numerous instances of omissions or incorrect data in the records.
- Numerous instances of dips or stations being omitted from the logs.

Non-conformance (0 points) if:
- No records.
- Failure to maintain records.

2.9.4 Is there a tool accountability program for knives and similar cutting hand tools used in the production process?
Visual Confirmation. Total conformance (3 points): There should be an accountability program in place for knives and similar cutting hand tools (e.g., scissors, hand corers, etc.) used in production areas for trimming, etc., to identify potential product contamination. This should include records of inspection of cutting surfaces for wear, as well as inventory of quantities in/out on each shift. Production hand tools should remain on-site under the operation's control. Question is non-applicable if knives or other hand tools are not used in the production area or for maintenance tools, such as wrenches, screw drivers, etc.

Minor deficiency (2 points) if:
- Single/isolated instance(s) of errors or omissions in the records.

Major deficiency (1 point) if:
- Numerous instances of errors or omissions in the records.

Non-conformance (0 points) if:
- There are no records for tool accountability.
- Production hand tools do not remain under the control of the company (e.g., taken home by employees).

2.9.5 NEW QUESTION Are there written procedures for the set-up, calibration, maintenance and verification of foreign material control systems e.g. metal detectors?
Visual confirmation. Total conformance (10 points): There should be a written procedure detailing the set-up, calibration, maintenance and verification tests of detector systems. The procedure should include:
- Initial set-up by qualified personnel
- Calibration for actual product being run
- Documentation of calibration and set-up
- Frequency of verification checks using actual product at start-up, during production and at the end of production.
- Documentation of verification checks at start-up, during production and at the end of production.

Metal detectors should be tested at least hourly. At least ferrous, non-ferrous and stainless steel (usually 316) test pieces should be used separately to test the metal detectors. Other specific metal test pieces should be considered if the plant equipment is made out of other materials. Test pieces should be placed as close to the aperture center as possible; embedding test pieces in the product is an ideal method. Discovery of foreign material issues should be recorded along with relevant corrective actions. Note that metal detection is often detailed further in the HACCP section.

Minor deficiency (7 points) if:
- Single instance of a processing/packing line in operation missing a form of foreign material control method if there are more than two processing/packing lines in operation.
- Single/ isolated instance(s) of errors in the written procedure/not using the correct testing methodology.
- Testing frequency for metal detectors is at least every two hours but not at least every hour.
- Single instance of a detector failing a check or not operating properly.
- Not using one of the required test pieces.

Major deficiency (3 points) if:
- Isolated instances (two-three) of processing/packing line in operation missing a form of foreign material control method if there are more than three processing/packing lines in operation.
- Numerous instances of errors in the written procedure/not using the correct testing methodology.
- Testing frequency for metal detectors is at least every four hours but not at least every two hours.
- More than one instance of a detector failing a check or not operating properly.
- Not using two of the required test pieces.

Non-conformance (0 points) if:
- Majority of processing/packing line in operation missing a form of foreign material control method if there are more than three processing/packing lines in operation.
- No detectors operating properly. If only one detector is used and it is malfunctioning score non-conformance.
- No foreign material control methods are in place (cut product).
- Systematic errors in the written procedure/no established testing methodologies.
- Testing frequency for metal detectors is not at least every four hours.
- Not using three of the required test pieces.

2.9.6 Are there equipment calibration procedures and records for pH meters, ORP meters, thermometers and other measuring equipment related to the food safety of the product?

Visual confirmation. Total conformance (10 points): Equipment for monitoring processes (hand held and automated) related to food safety (e.g., thermometers, ORP meters, flow meters and pH meters) are calibrated regularly to ensure correct and accurate operation**.** Documented calibration procedures should describe the frequency of testing, the testing method, the acceptable range of variation and corrective actions to take when calibration test does not fall into acceptable range of variation. Corrective actions should be recorded when applicable. Legal requirements, manufacturer recommendations, best practice and experience of equipment drift help to determine the frequency of testing. Scope of this question includes both internal and external calibrations i.e. internal where the company checks the equipment for themselves, versus an external test where equipment is sent away or an outside specialist company comes on site and checks the equipment in situ. Proof of calibration includes records, invoices, dated machines labels and corrective actions (where applicable).

Minor Deficiency (7 points) if:
- Single/isolated instance(s) of omissions in the procedure(s).
- Single/isolated instance(s) of omissions or incorrect data in the records.
- Single/isolated instance(s) of piece/set of equipment omitted from the scheme.

Major Deficiency (3 point) if:
- Numerous instances of omissions in the procedure(s).
- Numerous instances of omissions or incorrect data in the records.
- Numerous instances of pieces/sets of equipment omitted from the scheme.

Non-conformance (0 points) if:

- No procedure
- No records
- Failure to maintain records.

Potentially useful website:-
http://www.agr.state.nc.us/meatpoultry/pdf/Thermometer%20Calibration.pdf

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Maintenance & Sanitation

2.10.1 Does the facility have a preventative maintenance program with a documented schedule?
Visual confirmation. Total conformance (10 points): There should be a formal preventative maintenance program. The maintenance program should have a schedule showing routine inspections, lubrications, part replacements etc. at appropriate frequencies (daily, weekly, monthly, etc.). There should be preventative maintenance completion records. All records are kept on file and organized in an easily retrievable manner (including any database systems). In complex operations (e.g., juice processors), auditor can choose specific pieces of equipment to check the planned maintenance schedules and completion records for the chosen pieces of equipment.

Minor deficiency (7 points) if:
- Single/isolated instance(s) of incomplete records.
- Single/isolated instance(s) of pieces of equipment missed off the schedule.
- Minor improvements are required in filing or organization of records.

Major deficiency (3 points) if:
- Numerous instances of incomplete records.
- Numerous instances of pieces of equipment missed off the schedule.
- Files are not easily retrieved and poor filing practices.

Non-conformance (0 points) if:
- No program.
- Systematic failure to maintain records.

2.10.2. Is there a log of maintenance work or repairs ordered and is it signed off on work completed?
Visual confirmation. Total conformance (10 points): There should be a log for repairs/maintenance service orders/work orders and completion of work. This log may include: date/time, targeted equipment/area, reason for service required, who is requesting, who is being informed, observations, date and signature when repair is completed. Logs are kept on file in an easily retrievable manner.

Minor deficiency (7 points) if:
- Single/isolated instance(s) of incomplete records.
- Minor improvements are required in filing or organization of records.

Major deficiency (3 points) if:
- Numerous instances of incomplete records.
- Files are not easily retrieved and poor filing practices.

Non-conformance (0 points) if:
- No logs are on file.
- Systematic failure to maintain records.

2.10.3 Are there logs showing that equipment is cleaned and sanitized after maintenance work has been completed?
Visual confirmation. Total conformance (5 points): The company keeps records of all maintenance work and signature of a designated employee to confirm that the equipment has been sanitized after maintenance work has been completed and before being used again. If the equipment has been worked on in the production area (as opposed to being transferred to the maintenance shop), then the area surrounding the recently maintained equipment should also be sanitized (records of this sanitation should be maintained).

Minor Deficiency (3 points) if:
- Single/isolated instance(s) of omissions or incorrect data in the records.

Major Deficiency (1 point) if:

- Numerous instances of omissions or incorrect data in the records.

Non-conformance (0 points) if:
- No records.
- Failure to maintain records.

2.10.4 Is there a written cleaning schedule (Master Sanitation Schedule) that shows what and where is to be cleaned and how often?
Visual confirmation. Total conformance (10 points): The company should have a master sanitation program that covers the entire area of the facility, including equipment. The schedule should state what is to be cleaned and when (how often). Areas should include (where applicable): processing, packing, product storage, dry storage, waste areas, restrooms and break areas. Within these listings there should be details like floors, walls, light covers, pipes, ceilings, evaporators, cooling coils, drip pans, drains, drain lines and reservoirs, named equipment and equipment parts and surfaces, including internal transport vehicles (forklifts, Bobcats, floor cleaners, pallet jacks, etc.). Floor cleaners should be kept in good condition and cleaned in order to prevent cross contamination. Where relevant, the brushes and fixtures on the floor cleaner may need to be changed or cleaned when moving from one risk area to another. In-house delivery and shuttle trucks should be included in sanitation schedules, have SSOPs and cleaning records.
Infrequent schedules i.e. weekly and above, are usually created for several reasons (e.g., cleaning areas and equipment that are not cleaned daily) using a different cleaning technique/chemical than what is used on a daily schedule and/or doing a more “in depth” clean of equipment. Note that all cleaning mentioned on the schedule should be covered somewhere in the cleaning procedures and also in the sanitation logs. Schedule should be kept on file in an easily retrievable manner.
Master sanitation schedule should include what is to be cleaned and when:
- List of areas, equipment, internal transport vehicles, in-house delivery trucks, etc.
- Frequency of cleaning (daily, weekly, monthly, quarterly, annually, etc.)

Minor deficiency (7 points) if:
- Single/isolated instance(s) of errors or omissions in the schedules i.e. missed areas/equipment (including internal transport vehicles, in-house delivery trucks) and/or no frequencies being set.

Major deficiency (3 points) if:
- Numerous instances of errors or omissions in the schedules i.e. missed areas/equipment (including internal transport vehicles, in-house delivery trucks) and/or no frequencies being set.

Non-conformance (0 points) if:
- No schedules.
- Schedules exist but they are not reflecting what actually occurs.

2.10.5 Are there written cleaning and sanitation procedures (Sanitation Standard Operating Procedures) for the facility and all equipment?
Visual confirmation. Total conformance (10 points): There should be written cleaning and sanitation procedures for all equipment and areas. These are also called Sanitation Standard Operating Procedures (SSOP’s). This includes production line equipment (named equipment and equipment parts and surfaces), floors, walls, light covers, pipes, ceilings, evaporators, cooling coils, drip pans, drains, drain lines and reservoirs, internal transport equipment (e.g., forklifts and Bobcats where shovels come into contact with ingredients such as ice, pallet jacks, trolleys, floor cleaners, etc.). In-house delivery and shuttle trucks should be included in sanitation schedules, have SSOPs and cleaning records. A surface cannot be properly sanitized unless it is effectively cleaned. Use of a sanitizer is required unless there are justified exceptions that are fully documented. Procedures should respect the label (e.g., rinse/no-rinse sanitizers, dwell time, etc.) and match operations noted on the master sanitation schedule (2.10.4).These procedures should include:
- Item/area to be cleaned with cleaning methods, including the level of disassembly required for cleaning
- Frequency of cleaning
- Safety precautions (tag outs, personnel safety with respect to chemicals, etc.)
- Chemical (name, dilution) and utensils used

- Specific preparation procedures regarding dilution (unless purchased as ready-to-use) for the specific chemicals or sanitizers being used and verification testing instructions and records (where appropriate).
- Detailed cleaning and sanitation methods following the standard order:
  1. Dry clean (note equipment used)
  2. Rinse (note equipment used)
  3. Clean (note equipment used
  4. Rinse (note equipment used)
  5. Sanitize (note equipment used and dwell time)
  6. Rinse (if label requires)
- Special instructions with respect to cleaning
- Assigned responsibility for each task.
- Logs/records of cleaning
- Verification procedures (visual, ATP, microbial) and acceptance criteria

http://www.extension.org/pages/27405/industry-guidelines-to-prevent-contamination-from-listeria-monocytogenes#General_plant_sanitation

Minor deficiency (7 points) if:
- Single/isolated instance(s) of errors and omissions within the SSOPs.
- Single/isolated instance(s) of omitted procedure(s) for a piece of equipment, internal transport vehicle or facility area.

Major deficiency (3 points) if:
- Numerous instances of errors and omissions within the SSOPs.
- Numerous instances of omitted procedures for a piece of equipment, internal transport vehicle or facility area.

Non-conformance (0 points) if:
- No written procedures have been developed.
- Procedures exist but they are not reflecting what actually occurs.

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2.10.6 Are sanitation logs on file that show what cleaning was done, when and who carried out the cleaning?

Visual confirmation. Total conformance (5 points): The auditee has sanitation logs that cover the entire area of the facility and all equipment. Logs are kept on file in an easily retrievable manner. The logs should be cross-checked against the master sanitation program (2.10.4). Logs of infrequent cleaning should be checked. Logs should include:
- Date
- List of areas/equipment that have/has been cleaned
- Individual accountability and sign-off for each task completed
- Verification of task completed
- Any deviations against the set SSOP's

Minor deficiency (3 points) if:
- Single/isolated instance(s) of incomplete records, discrepancies against the master sanitation schedule or other omissions.

Major deficiency (1 point) if:
- Numerous instances of incomplete records, discrepancies against the master sanitation schedule or other omissions.
- Missing infrequent cleaning logs.

Non-conformance (0 points) if:
- No sanitation logs.
- Sanitation logs exist but they are not reflecting what actually occurs.

2.10.7 NEW QUESTION Are there records showing verification of cleaning chemical concentrations?

Visual confirmation. Total conformance (5 points): 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 (e.g., chemical reaction based test, test probe, ORP meter or as recommended by disinfectant supplier). Solutions that are too weak will be ineffective, while those too strong may be harmful to employees, product or equipment. Methods include, dip sticks, test strip papers, conductivity meters, titration, color comparison methods (e.g., tintometers, etc.). 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 also be recorded. Not applicable where pre-mixed chemicals are bought and used.

Potentially useful websites:
http://ucanr.edu/datastoreFiles/234-406.pdf

Minor deficiency (3 points) if:
- Single/isolated instance(s) of omissions or errors in the records.

Major deficiency (1 point) if:
- Numerous instances of omissions or errors in the records.

Non-conformance (0 points) if:
- Cleaning and/or sanitizing chemical concentrations are not monitored.

2.10.8 Are there documented procedures and completion records for clean-in-place (CIP) activities, where applicable (e.g. cleaning re-circulating water systems, such as washing flumes, ice injectors, hydrocoolers, ice makers, etc.)?
Visual confirmation. Total conformance (5 points). Where operations utilize clean-in-place (CIP)* (e.g., as part of the process of cleaning re-circulated flume system pipes and pumps), the CIP procedure should be detailed and include:
- Identity of equipment to be cleaned
- Frequency of cleaning
- Safety precautions (tag outs, personnel safety with respect to chemicals, etc.)
- Chemical (name, dilution) and utensils used.
- Specific preparation procedures regarding dilution (unless purchased as ready-to-use) for the specific chemicals or sanitizers being used and verification testing instructions and records (where appropriate).
- Detailed cleaning and sanitation methods following the standard order:
  1. Dry clean (note equipment used)
  2. Rinse (note equipment used)
  3. Clean (note equipment used, any dwell times)
  4. Rinse (note equipment used)
  5. Sanitize (note equipment used and any dwell times)
  6. Rinse (if label requires)
- Special instructions with respect to cleaning
- Assigned responsibility for each task
- Logs/records of cleaning
- Verification procedures (visual, ATP, microbial) and acceptance criteria.
- Required temperatures for chemical dilutions used
- Required flow rates and dwell/cycle times for the CIP process
- Specific details on how re-circulated chemicals are drained and rinsed out of the CIP system (to avoid contamination issues)

The chemical label details, equipment manufacturer's instructions and company safety rules are to be followed. Records of CIP cleaning should be maintained.

*Clean In Place (CIP) – cleaned in place by the circulation or flowing by mechanical means through a piping system of a detergent solution, water rinse and sanitizing solution onto or over equipment surfaces that require

cleaning. CIP does not include the cleaning of equipment such as band saws, slicers or mixers that are subjected to in-place manual cleaning without the use of a CIP system.
http://www.fda.gov/downloads/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/UCM374510.pdf

Minor deficiency (7 points) if:
- Single/isolated instance(s) of errors and omissions within the SSOPs.
- Single/isolated instance(s) of omission(s) in procedure or records for a piece of equipment or facility area.

Major deficiency (3 points) if:
- Numerous instances of errors and omissions within the SSOPs.
- Numerous instances of omissions in procedure or records for a piece of equipment or facility area.

Non-conformance (0 points) if:
- No written procedures have been developed.
- There are no records.
- Procedures exist but they do not reflect what actually occurs.

2.10.9 Is there a log indicating that floor drains are cleaned on a regular basis (minimum daily in wet and fresh-cut production areas)?
Visual confirmation. Total conformance (5 points): There is a log that indicates that floor drains are cleaned on a daily basis in wet packinghouse areas and fresh-cut processing areas. Wet storage area drains should be cleaned daily. Auditors should use their discretion when auditing dry facilities, but the minimum drain cleaning frequency should be weekly.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of incomplete records or omissions.

Major deficiency (1 point) if:
- Sanitation schedule or log does not indicate that floors and drains are cleaned, but sanitary condition of floor and drains is checked every day on the pre-operation inspection.
- Numerous instances of incomplete records or omissions.

Non-conformance (0 points) if:
- There is no written evidence (schedule or log) that floor drains are cleaned.

2.10.10 Are there records showing cooling units are serviced and cleaned at least every 12 months or more frequently as required?
Visual confirmation. Total conformance (10 points): Records should be made available to verify that the cooling units are serviced and cleaned on a scheduled basis. Records might include in-house sanitation records, maintenance records and/or contractor records/invoices. Note that contracts, invoices etc., must clearly state the services provided as per any other record. A cleaning and servicing at least once in the last 12 months is a minimum requirement, but usually frequency is higher, especially in high humidity/wet operations and also with chiller units that are known to become dirty at a faster rate than others (e.g., next to open doors).

Minor Deficiency (7 points) if:
- Single/isolated instance(s) of omissions or incorrect data in the records.

Major Deficiency (3 points)
- Numerous instances of omissions or incorrect data in the records.

Non-conformance (0 points)
- No records.
- Failure to maintain records.

2.10.11 Is there a routine program and written procedure to validate sanitation effectiveness using ATP bioluminescence testing?
Visual confirmation. Total conformance (5 points): Rapid post sanitation checks, e.g. ATP (adenosine tri phosphate) testing provides an instant indication of the hygiene status of product contact surfaces by measuring the ATP from food residues, bacteria, yeast, mold - either living or dead (i.e. all organic matter) in order to measure cleaning efficiency. There should be a procedure detailing sampling strategy, standardized sampling technique (including location of sample and time of sampling) and there should be pass/fail parameters. The detection of non-specific ATP provides a reliable quick indicator of cleaning efficiency and hygienic status (therefore, a good pre-operational tool), but for the purpose of this audit, is not a replacement for specific microbiological testing or for ensuring that the allergen specific proteins have been removed from a production surface.
This question is N/A for Cooling Cold Storage and Storage and Distribution audits if there are no food contact surfaces. Note that hydrocoolers and ice machines count as food contact surfaces. Ideally, the incubation of pathogen specific rapid tests does not occur on site. Where this does occur, the auditee must follow the rapid test manufacturer's instructions regarding disposal and have records to show this is occurring (autoclave use and calibration, sanitizer strength and duration, etc.).

Potentially useful website:
http://www.foodquality.com/details/article/821955/What_ATP_Sanitation_Systems_Cannot_Do.html

Minor deficiency (3 points) if:
- Single/isolated instance(s) of equipment being missed off the swabbing schedule, incorrect frequency.
- Single/isolated instance(s) of a record or records showing high counts relative to threshold but no corrective action documentation.
- Single/isolated instance(s) of errors or omissions in the procedure.

Major deficiency (1 point) if:
- Numerous instances of equipment being missed off the swabbing schedule, incorrect frequency.
- Testing is sporadic and not on a scheduled basis.
- Numerous records showing high counts relative to threshold but there are no corrective actions documented.
- Numerous instances of errors or omissions in the procedure.

Non-conformance (0 points) if:
- There are no records of equipment ATP testing.
- There is no procedure for sampling strategy, technique or threshold limits.

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Personnel

2.11.1 Are there records of new employee food safety (GMP) orientation training (with topics covered and attendees) and are new employees required to sign the company's food safety hygiene and health policy?

Visual confirmation. Total conformance (10 points): The company has logs of GMP orientation (new hire) training with the topics covered, trainer name and materials used and given to new hires. Training should be given prior to new hires starting to work. Materials to be given to new hires after training should be in the relevant language(s) and cover personal hygiene and GMP rules including hand washing, foreign material issues (including no sequins, studs, false finger nails, finger nail polish, false eyelashes, eyelash extensions, badges, etc.), eating/drinking, smoking, specific clothing rules, etc. Food safety training should be given to all employees working in the production and storage areas, including temporary employees and agency employees. New employees should be requested to read (in the relevant language), confirm they understand and agree to abide by the company's food safety policy rules regarding personal hygiene/GMPs and health requirements (e.g., they are free from diseases that might be a food safety cross contamination risk). A copy of the signed food safety policy should be kept on file and a copy given to the employee.

Minor Deficiency (7 points) if:

- Single/isolated instance(s) of errors and omissions in the records or food safety hygiene and health policy.
- Up to three points missing off the GMP requirements listing.
- Training materials and/or food safety policy are not in the relevant language(s).
- Training occurring, but relevant materials are not being given to the trainee after the training.
- Training occurs, not before starting to work, but within the first week.
- Single/isolated instance(s) of employees not being trained or not signing a document stating that they will comply with the operations' personal hygiene and health policies.

Major Deficiency (3 point) if:

- Numerous instances of errors and omissions in the records or food safety hygiene and health policy.
- Over three points missing off the GMP requirements listing (or GMP listing does not exist).
- Numerous cases of employees not signing a document stating that they will comply with the operations' personal hygiene and health policies.
- Training occurs, not before starting to work, but within the first month.
- Numerous instances of employees not being trained.

Non-conformance (0 points) if:

- No records of training or employees not being trained.
- No specific orientation given or given after the employee has been working for more than one month.
- Failure to maintain records.
- The company does not have a document for employees to sign stating that they will comply with the operations' personal hygiene and health policies.
- Systematic failure of employees to sign a log stating that they will comply with the operations' personal hygiene and health policies.

2.11.2 Are there logs of ongoing employee food safety education training with topics covered and attendees?

Visual confirmation. Total conformance (10 points): The auditee should have logs of ongoing food safety educational training with clearly defined food safety topic(s) covered, trainer(s) and material(s) used/given. There should be logs of employees who have attended each session. Food safety training might be part of other training events (e.g., part of occupational training). Some kind of food safety training of employees should occur on at least a quarterly basis, but ideally monthly. Full annual food safety refresher training sessions are encouraged but do not replace the ongoing more frequent training unless a short season facility (e.g., less than 3 months duration). Ongoing training might focus on key areas (e.g., hand washing, eating and drinking etc.) and maybe note issues found in recent internal and external audits (e.g., wearing beard nets, jewelry issues).

Minor Deficiency (7 points) if:
- Single/isolated instance(s) of logs having errors or incomplete information (e.g., missing one of the following: training topic, trainer or material information).
- Training has occurred but on a few occasions full attendance logs have not been kept and/or not all personnel were covered.

Major Deficiency (3 points) if:
- Numerous instances of logs having errors or incomplete information (e.g., missing one of the following: training topic, trainer or material information).
- Training has occurred but on many occasions full attendance logs have not been maintained.
- Some key topics (e.g., hand washing), have been omitted from the training.
- Only annual refresher training has occurred and the operation runs for more than 3 months of the year.

Non-conformance (0 points)
- Failure to maintain records. No records of training.
- Many major topics have been omitted from the training program (e.g., hand washing, eating/drinking rules, jewelry policy, etc.).

2.11.3 Are there written 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? (Verbal confirmation accepted.)
Visual and verbal confirmation. Total conformance (3 points): There should be documented procedures that are communicated to food handlers, requiring them to report any cuts, grazes and/or any illnesses that might be a food safety cross contamination risk. The procedures should indicate to whom the food handlers should report, how the issue is recorded and appropriate actions to be taken for a particular issue. Auditee records may be viewed as confidential and therefore a verbal confirmation should be gained.

Minor deficiency (2 points) if:
- Single/isolated instance(s) of errors or omissions in procedure.

Major deficiency (1 point) if:
- Numerous instances of errors or omissions in the procedure.

Non-conformance (0 points) if:
- There is not a documented procedure in place.
- A procedure is in place but it has not been communicated to food handlers.

2.11.4 Is there a documented training program with training logs for the sanitation employees including best practices and chemical use details?
Visual Confirmation. Total conformance (5 points): Sanitation training should ensure that the employees understand the importance of proper sanitation; cleaning efficacy, how to use the cleaning chemicals and how to understand Sanitation Standard Operating Procedures. Training would also ideally include worker safety issues, (e.g., use of personal protective equipment, accident prevention, what to do in case of an accident, procedures for avoiding electrical hazards when cleaning, etc.). Recorded training should occur at least on a 12 month basis.

Minor Deficiency (3 points) if:
- Single/isolated instance(s) of logs having errors or incomplete information (e.g., missing one of the following: training topic, trainer or material information).
- Training has occurred but on a few occasions full attendance logs have not been kept and/or not all personnel were covered.

Major Deficiency (1 point) if:
- Numerous instances of logs having errors or incomplete information (e.g., missing one of the following: training topic, trainer or material information).
- Training has occurred but full attendance logs have not been maintained on many occasions.

Non-conformance (0 points)
- No records or no training has occurred.
- Failure to maintain records.

2.11.5 Are visitors and contractors required to sign a log stating that they will comply with the operations' personal hygiene and health policies?
Visual confirmation. Total conformance (3 points): All visitors and contractors should sign to say that they will abide by the company rules regarding personal hygiene/GMPs (e.g., hair nets, clothing/smocks, hand washing, jewelry, eating, drinking, smoking, etc.) and health requirements (i.e. they are free from diseases that might be a food safety cross contamination risk). The rules and policies should be clearly stated in relevant languages. This requirement may be included in the visitor sign in/out book (4.2.5).

Minor deficiency (2 points) if:
- Single/isolated instance(s) of visitor(s) and contractor(s) not signing a log stating that they will comply with the operations' personal hygiene and health policies.

Major deficiency (1 point) if:
- Numerous instances of visitors and contractors not signing a log stating that they will comply with the operations' personal hygiene and health policies.
- Policy is not in the relevant language(s) of the visitors/contractors.

Non-conformance (0 points) if:
- The company does not have a log for visitors and contractors to sign stating that they will comply with the operations' personal hygiene and health policies.
- Systematic failure of visitors and contractors to sign a log stating that they will comply with the operations' personal hygiene and health policies.

2.11.6 Is there an employee non-conformance/disciplinary action procedure? (Verbal confirmation accepted.)
Verbal Confirmation. Total conformance (3 points): The auditee should have a record for employee non-conformance and corrective actions detailed. Auditee records might be viewed as confidential and therefore a verbal confirmation should be gained. There might be a tier system, which includes verbal and written disciplinary actions. There might be immediate termination for gross misconduct.

Minor Deficiency (2 points) if:
- Option for minor down score exists, but at present, no known good examples exist.

Major Deficiency (1 point) if:
- Disciplinary system is not used for GMP violations.

Non-conformance (0 points)
- No records or no disciplinary system.

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Testing

Potentially useful websites:
CDC Disease Information, http://www.cdc.gov/diseasesconditions/
FDA Bad Bug Book, http://www.fda.gov/downloads/Food/FoodborneIllnessContaminants/UCM297627.pdf
EPA Drinking Water Standards, http://www.epa.gov/safewater/mcl.html#mcls
USDA, Water Quality Information Center, http://wqic.nal.usda.gov/

2.12.1 Are there records of routine equipment microbiological testing?
Visual confirmation. Total conformance (10 points): There should be records of routine equipment microbiological swab testing, for production and storage facilities that either have a wash step or involve high humidity storage. This testing should be designed to assess the equipment sanitation process. Production facilities that require swab testing will most likely be producing (or storing in the case of coolers) items that are consumed in a raw state (uncooked, potentially ready-to-eat) and with edible (e.g., peaches, apples, citrus, etc.) or inedible (e.g., melons, papaya, mango, avocados, etc.) peel or rinds. While the peel or rind is not eaten in some products, the method of handling and/or preparation poses a risk that requires these items to be considered as "potentially ready-to-eat". This question is generally not applicable for products that require cooking i.e. potatoes and/or outer layer of commodity is not used as a food item in any way (e.g.. storage onions, garlic, etc.), although testing in any operation is based on risk assessment. If there is any doubt whether a product is consumed raw i.e. not cooked (e.g. cranberries, Brussels sprouts, asparagus, in-shell nuts, etc.), then it is assumed that raw consumption does occur and swabbing is applicable. Testing frequency and when and what to test for should be related to the risk assessment of the production involved. As a minimum guide, a fresh-cut facility should be carrying out weekly swabbing, whereas low risk products (e.g., apples, citrus) should be swabbing at least monthly. Choosing where to swab, should be done by assessing the main pieces of equipment that might need swabbing, based on risk and ease of ability to clean. If out of specification results are detected, then full details of corrective actions should be noted. Cooling operations should include ice injectors, vacuum tubes (both wet (hydro) and dry) in the microbial testing rotation. Auditor should note the type of tests being carried out, frequency of testing, laboratory name, results status and confirmation of corrective action records (where relevant). See the applicability chart.
http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm073110.htm
http://www.hc-sc.gc.ca/fn-an/legislation/pol/policy_listeria_monocytogenes_2011-eng.php#scien

Minor deficiency (7 points) if:
- Single/isolated instance(s) of equipment being missed off the swabbing schedule, incorrect frequency.

Major deficiency (3 points) if:
- Numerous instances of equipment being missed off the swabbing schedule, incorrect frequency.
- Testing is sporadic and not on a scheduled basis.

Non-conformance (0 points) if:
- There are no records of equipment microbiological testing.
- Out of specification results recorded (e.g. high counts, positive results for pathogens) but corrective actions not properly documented. **Auditor should consider reverting to Q 1.1.1, the general automatic failure question.**

2.12.2 Are there records of routine environmental microbiological testing?
Visual confirmation. Total conformance (10 points): There should be records of routine facility environmental microbiological swab testing, for production and storage facilities that either have a washing step or involves high humidity storage. This swab testing should be designed to assess the facility sanitation process. Generally, produce operations use environmental testing in the production and storage areas for *Listeria* spp. as an indicator to detect potential harborage of the pathogenic species *Listeria monocytogenes*. Other pathogens to consider include *Salmonella* spp., pathogenic *E. coli*, Clostridium, Campylobacter, *B.cereus*.
Production facilities that require testing will most likely be producing or storing (in the case of coolers) items that are consumed in a raw state (uncooked, potentially ready-to-eat) and with edible (e.g., peaches, apples, citrus, etc.) or inedible (e.g., melons, papaya, mango, avocados, etc.) peel or rinds. While the peel or rind is not eaten in

some products, the method of handling and/or preparation poses a risk that requires these items to be considered as “potentially ready-to-eat”. This question is generally not applicable for products that require cooking i.e. potatoes, and/or outer layer of commodity is not used as a food item in any way (e.g., storage onions, garlic, etc.), although testing in any operation is based on risk assessment. If there is any doubt whether a product is consumed raw i.e. not cooked (e.g. cranberries, Brussels sprouts, asparagus, in-shell nuts, etc.), then it is assumed that raw consumption does occur and swabbing is applicable. Testing frequency and when and what to test for should be related to the risk assessment of the production involved.
As a minimum guide, a fresh-cut facility should be carrying out weekly swabs, whereas low risk products (e.g., apples, citrus) should be swabbing at least monthly. Choosing where to swab should be done by assessing the areas that might need swabbing based on risk issues observed (e.g., drainage, condensation issues, etc.). If out of specification results are detected, then full details of corrective actions should be noted. Auditor should note the type of tests being carried out, frequency of testing, laboratory name, results status and where relevant confirmation of corrective action records. See the applicability chart.
http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm073110.htm
http://www.hc-sc.gc.ca/fn-an/alt_formats/pdf/legislation/pol/policy_listeria_monocytogenes_2011-eng.pdf

Minor deficiency (7 points) if:
- Single/isolated instance(s) of environmental testing not occurring at the right frequency.

Major deficiency (3 points) if:
- Numerous instances of environmental testing not occurring at the right frequency or testing is sporadic and not on a scheduled basis.

Non-conformance (0 points) if:
- There are no records of environmental testing.
- Out of specification results recorded (e.g., high counts, positive results for pathogens) but corrective actions not properly documented. **Auditor should consider reverting to Q 1.1.1, the general automatic failure question.**

2.12.3. Are there routine microbiological tests on water used in the facility (sampled from within the facility)?
Visual confirmation. Total conformance (10 points): There should be microbiological tests on water used in the facility on a routine basis to assure it meets the US EPA (http://www.epa.gov/safewater/mcl.html#mcls) microbiological requirements of potable water). Testing frequency should be related to the risk assessment of the production:
- Processors of ready-to-eat products (e.g., baby leaf spinach, sliced apples, etc.) should test at least monthly.
- Facilities that have water coming into contact with product (excluding products to be cooked (e.g., potatoes)) i.e. wash steps, hydrocooling, etc. should test at least quarterly.
- Otherwise, minimum frequency is at least every six months.

If there is any doubt whether a product is consumed raw i.e. not cooked (e.g., cranberries, Brussels sprouts, asparagus, in-shell nuts, etc.), then it is assumed that raw consumption does occur and testing frequency is applicable. Water samples should be taken from the within the facility to account for the sites piping, holding tanks, etc. City water samples http://www.epa.gov/safewater/dwinfo/index.html are still good information to have, but if there is no site sample, then this question should be scored major. Results of water sample testing for total coliforms and/or *E. coli* should meet the US EPA drinking water **microbiological** specification http://www.epa.gov/safewater/mcl.html#mcls. If out of specification results are detected, then full details of corrective actions should be noted.
Where industry schemes (e.g., Leafy Greens Marketing Agreement (LGMA)) or specific legislative requirements are higher than audit requirements, the higher requirements should be followed and will be scored against. For example, LGMA rules require one sample per water source, collected and tested for generic *E. coli* prior to use if >60 days since last test of the water source. Additional samples should be collected and tested at least monthly during use. Refer to http://www.caleafygreens.ca.gov/ for additional information.

Potentially useful websites:

http://nepis.epa.gov/Exe/ZyPDF.cgi/P100EEXN.PDF?Dockey=P100EEXN.PDF
http://www.access.gpo.gov/nara/cfr/waisidx_02/40cfr141_02.html
http://edocket.access.gpo.gov/cfr_2003/julqtr/pdf/40cfr141.63.pdf
http://edocket.access.gpo.gov/cfr_2002/julqtr/40cfr141.63.htm

Minor deficiency (7 points) if:
- Single instance of water testing not occurring at the right frequency.

Major deficiency (3 points) if:
- Only water testing records available are from the City Water Board.
- More than one instance of water testing not occurring at the right frequency.

Non-conformance (0 points) if:
- No microbiological test results are available.
- Last test was done over 12 months ago.
- Single out of specification microbiological test result without proper corrective action documentation. **Auditor should consider reverting to Q 1.1.1, the general automatic failure question.**

2.12.4 Are there routine microbiological tests on ice used in the facility (either produced in-house or purchased)?
Visual confirmation. Total conformance (5 points): There should be routine microbiological tests on ice used in the facility. Testing frequency should be related to the risk assessment of the production and use:
- Processors of ready-to-eat products that use ice in their process should test at least monthly.
- Facilities that have ice coming into contact with product (excluding products to be cooked) (e.g., ice injectors, top icing, etc.) should test at least quarterly.
- Otherwise, minimum frequency is at least every six months.

If there is any doubt whether a product is consumed raw i.e. not cooked (e.g., cranberries, Brussels sprouts, asparagus, in-shell nuts, etc.), then it is assumed that raw consumption does occur and testing frequency is applicable. Ice samples should be taken from actual ice used to account for the sites piping, holding tanks, ice making equipment and ice storage, etc. Results of ice sample testing for total coliforms and/or *E. coli* should meet the US EPA drinking water **microbiological** specification http://www.epa.gov/safewater/mcl.html#mcls. If out of specification results are detected, then full details of corrective actions should be noted.

If an auditee is procuring ice from an outside vendor, the above requirements are still valid and the auditee should obtain testing results in order to gain full credit for this question, although some points will be awarded for letters of guarantee.

Where industry schemes (e.g., Leafy Green Marketing Agreement (LGMA)) or specific legislative requirements are higher than the audit requirements, these industry scheme and legal requirements should be followed and will be scored against.
http://nepis.epa.gov/Exe/ZyPDF.cgi/P100EEXN.PDF?Dockey=P100EEXN.PDF

Minor deficiency (3 points):
- Single instance of ice testing not occurring at the right frequency.

Major deficiency (1 point):
- Only water testing records available are from the City Water Board.
- More than one instance of water testing not occurring at the right frequency.
- Only a current (dated within last 12 months) letter of guarantee (for externally supplied ice) is available.

Non-conformance (0 points):
- No microbiological test results are available.
- Last test was done over 12 months ago.
- Ice is used from an outside source but there is no current (dated within last 12 months) letter of guarantee and no ice micro test.

- Single out of specification microbiological test result without proper corrective action documentation. **Auditor should consider reverting to Q 1.1.1, the general automatic failure question.**

2.12.5 Do laboratory test results indicate test procedures meet accepted standards?
Visual confirmation. Total conformance (5 points): All testing laboratory reports should indicate that testing procedures meet accepted standards, i.e. pesticide residue testing should meet AOAC or similar equivalent and microbiological test procedures should meet BAM, USDA or similar equivalent. Documented evidence of this should be available on lab reports indicating the testing procedures used.

Minor Deficiency (3 points) if:
- Single/isolated instance(s) of omissions or incorrect information detailing procedures followed.

Major Deficiency (1 point) if:
- Numerous instances of omissions or incorrect information detailing procedures followed.

Non-conformance (0 points) if:
- Lab reports do not indicate the test procedure(s) followed.

2.12.6 NEW QUESTION Where testing has been performed for any reason (e.g. buyer requirements) does the testing meet all the specification requirements (e.g. type of test, test frequency, test methodology, thresholds, corrective actions, etc.) and are proper records of tests with formal corrective actions being maintained?
Visual confirmation. Total conformance (5 points): There should be documented evidence that tests from the laboratory meet all the specification requirements, are accurate and reliable. Evidence includes detailed test procedures (type of test, frequency of testing, methodology, thresholds, corrective actions, etc.) with test results and corrective actions that verifies monitoring is occurring as specifications require.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of errors or omissions in the records.
- Single/isolated instance(s) of missing (a) specification(s).

Major deficiency (1 point) if:
- Numerous instances of errors or omissions in the records.
- Numerous instances of missing specifications.

Non-conformance (0 points) if:
- There are no written specifications.
- Failure to maintain specifications.

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Temperature Controlled Storage & Distribution

2.13.1 Are there records of final product temperature checks for temperature sensitive products?
Visual Confirmation. Total conformance (10 points): There should be records which show actual product final temperatures after processing and/or prior to dispatch for temperature sensitive products i.e. FDA designated time/temperature control for safety foods (TCS)*. Air temperature recordings are not acceptable for this question (see 2.13.3). Records should show that product is not shipped above temperature requirements (in-house specifications, buyer specifications, best practice requirements or legal requirements).
*Potentially hazardous food (time/temperature control for safety food)" includes:

2. (a) An animal food that is raw or heat-treated; a plant food that is heat-treated or consists of raw seed sprouts, cut melons, cut leafy greens, cut tomatoes or mixtures of cut tomatoes that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation, or garlic-in-oil mixtures that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation.

FDA Food Code 2013: Chapter 1 – Purpose and Definitions
http://www.fda.gov/downloads/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/UCM374510.pdf

Where temperature sensitive products are not handled, this question is not applicable.

Minor Deficiency (7 points) if:
- Single/isolated instance(s) of omissions or incorrect data in the records.

Major Deficiency (3 points)
- Numerous instances of omissions or incorrect data in the records.

Non-conformance (0 points)
- No records.
- Failure to maintain records.

2.13.2 Are there temperature logs for the packing/processing room (if refrigerated)?
Visual confirmation. Total conformance (5 points): There should be temperature logs or recording thermometer printouts on file. Not applicable if packing/processing room is not refrigerated. The issue of using an independent probe, separate from the thermostat probes and systems is covered under 1.5.4.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of errors or incomplete records, including corrective actions.

Major deficiency (1 point) if:
- Numerous instances of errors or incomplete records, including corrective actions.

Non-conformance (0 points) if:
- No temperature logs are on file (and the processing room is refrigerated).

2.13.3 Are there temperature logs for storage rooms?
Visual confirmation. Total conformance (5 points): There should be temperature logs or recording thermometer printouts on file. Holding temperatures in refrigerated storage rooms should not exceed 41 ºF (5 ºC) for microbiologically sensitive raw materials, ingredients or products (e.g., cut tomatoes, cut melons, leafy greens)*. Not applicable if products are held at controlled high ambient temperature (e.g., whole tomatoes, bananas, etc.). The issue of using an independent probe, separate from the thermostat probes and systems is covered under 1.5.4.

- Leafy greens whose leaves have been cut, shredded, sliced, chopped, or torn includes iceberg lettuce, romaine lettuce, leaf lettuce, butter lettuce, baby leaf lettuce (i.e., immature lettuce or leafy greens), escarole, endive, spring mix, spinach, cabbage, kale, arugula and chard and does not include herbs such

as cilantro or parsley. Lettuce and other leafy greens cut from their root in the field with no other processing are considered raw agricultural commodities and are not included in the definition of “cut leafy greens” and are therefore not considered a potentially hazardous food requiring time/temperature control for safety (PHF/TCS) food, as defined and applied in the 2013 Food Code.

Potentially useful websites:
http://www.fda.gov/downloads/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/UCM374510.pdf
http://www.fda.gov/food/guidanceregulation/retailfoodprotection/industryandregulatoryassistanceandtrainingresources/ucm218750.htm

Minor deficiency (3 points) if:
- Single/isolated instance(s) of errors or incomplete records, including corrective actions.
- Single/isolated instance(s) of temperatures exceeding 41 ºF (5 ºC) for microbiologically sensitive raw materials, ingredients or products.

Major deficiency (1 point) if:
- Numerous instances of errors or incomplete records, including corrective actions.
- Numerous instances of temperatures exceeding 41 ºF (5 ºC) for microbiologically sensitive raw materials, ingredients or products.

Non-conformance (0 points) if:
- No temperature logs are on file (and the storage room is refrigerated).
- Records show temperatures systematically exceed 41 ºF (5 ºC) for microbiologically sensitive raw materials, ingredients or products. **Auditor should consider reverting to Q 1.1.1, the general automatic failure question.**

2.13.4 Are there records of shipping truck temperature checks, indicating that the truck was pre-cooled prior to loading?
Visual confirmation. Total conformance (5 points): Refrigerated items should not be loaded on to trucks which have not been pre-cooled prior to loading. The temperature of the truck refrigeration unit set point should be recorded to indicate truck was cooled to the appropriate temperature prior to loading. To confirm truck has been cooled and refrigeration unit has not malfunctioned there should be a check of internal truck insulation (e.g., an infrared surface probe or “touch-test” to confirm truck has been cooled). Corrective actions should be recorded when out of specification results are noted. Not applicable if products are not low temperature controlled in transit (e.g., onions). Temperature and time loggers are encouraged, especially for long haul trips, but should not form part of any down score, since the decision to use temperature time loggers are often made by the buyer(s) as opposed to the auditees at present.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of error, incomplete or missing records (including missing corrective actions).
- Single/isolated instance(s) of out of specification temperatures without corrective actions noted.

Major deficiency (1 point) if:
- Numerous instances of errors, incomplete or missing records (including missing corrective actions).
- Numerous instances of out of specification temperatures without corrective actions noted.

Non-conformance (0 points) if:
- No temperature logs are on file.
- Systematic failure to record truck temperatures.

2.13.5 Are there sanitary condition logs for shipping trucks (cleanliness, trailer condition, odor, etc.)?
Visual confirmation. Total conformance (10 points): There should be sanitary condition logs for shipping trucks detailing cleanliness and/or any off-odors. Corrective actions should be detailed. This may be indicated on bill of lading. Truck cleaning certificates are acceptable for the sanitation section of the question, but these should be for

each load for brokered trucks and on a regular frequency for in-house trucks. Even with certificates, the trucks should be checked for cleanliness.

Minor deficiency (7 points) if:
- Single/isolated instance(s) of errors, incomplete or missing logs.
- Single/isolated instance(s) of an issue noted without corrective actions detailed.

Major deficiency (3 points) if:
- Numerous instances of errors, incomplete or missing logs.
- Numerous instances of issues noted without corrective actions detailed.

Non-conformance (0 points) if:
- No sanitary condition logs are on file.
- Systematic evidence of failure to record sanitary condition of trucks.

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HACCP Program – Section 3

Potentially useful websites:-
FDA HACCP Overview, http://www.fda.gov/food/guidanceregulation/haccp/ucm2006801.htm
HACCP Alliance, http://haccpalliance.org

HACCP Team

3.1.1 Is there a team responsible for HACCP development, implementation and on-going maintenance?
Verbal confirmation. Total conformance (15 points): There should be a formally identified group of people in charge of development and maintenance of the Hazard Analysis Critical Control Point (HACCP) program, along with their corresponding responsibilities. Ideally, the group should be comprised of individuals from different areas of the company, such as top management, quality management, production, maintenance, sanitation, QC, etc. Consider including resources from outside (e.g., suppliers, buyers, consultant, trade association, university, extension office, etc.). One member of the team should be designated as the HACCP Coordinator. If the company is too small (less than 20 people) to have a HACCP team, there should still be one individual designated as the HACCP coordinator. That individual is responsible for the implementation of the HACCP program, along with any changes and updates to the HACCP program.

Minor deficiency (10 points) if:
- Team has been put together but lacks key representation (e.g., maintenance).
- No one person has been designated as the HACCP coordinator.

Major deficiency (5 point) if:
- The team or individual is assigned, but does not meet regularly to review the HACCP program.
- A large company where only a single individual has been designated to develop the operational HACCP Plan.

Non-conformance (0 points) if:
- The HACCP team or the individual assigned to manage the HACCP program has not kept the program updated.
- There is no HACCP team or HACCP Coordinator.

3.1.2 Is there documented HACCP specific training for the HACCP team, management and operating personnel?
Visual confirmation. Total conformance (10 points): At least one person on the HACCP team should have formal training i.e. certification from a training course accredited by the International HACCP Alliance or equivalent (e.g., a recognized educational establishment/university, etc.) providing a minimum of two days/16 hours training. This formally trained HACCP individual should be a company employee available (verify by checking records) for plan development and self-audits of the HACCP plan(s). The other HACCP team members and other key employees (CCP monitoring and verification employees) should have thorough HACCP training (in-house or external) given by someone who has HACCP experience and has attended an accredited International HACCP Alliance course (or equivalent). CCP operators should be specially trained for their function(s). All other site employees should receive basic overview training i.e. what is HACCP, the seven principles and what are the CCPs on site. Basic training might form part of the new hire orientation package. Senior management should receive training (HACCP requires “buy in” from all levels). Records of training should be kept and also certificates (where relevant). All employees should be trained to understand the principles of HACCP and the plan implemented in the facility. Training should be scheduled on a regular basis and documented. The training should be tailored to the people and their positions within the company.
http://www.haccpalliance.org/sub/index.html

Minor deficiency (7 points) if:
- Not all plant employees are trained in HACCP (but all key operators and majority of employees have been trained).
- Senior management have not received HACCP training.
- Single/isolated instance(s) of omissions or incorrect data in the records.

Major deficiency (3 point) if:

- HACCP coordinator has not completed a certified HACCP training course.
- CCP operators have not been trained in their specific functions.
- Numerous instances of omissions or incorrect data in the records.

Non-conformance (0 points) if:

- No formal training session developed for employees.
- No records of training being maintained.

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Review of the Written HACCP Plan

3.2.1 Does a product description exist for each product produced? Do they contain the products' intended use, materials and raw ingredients, and who the intended consumer is?
Visual confirmation. Total conformance (10 points): Product description(s) should clearly indicate the item(s) intended use i.e. does it need washing, peeling or cooking prior to consumption, etc. by the consumer, reflect the label of the product (unit packed product). Product description should indicate whether the item is perishable or long life and if there are any special storage requirements. Product descriptions should define the potential risk associated with the product, materials used and also who are the intended customers (general public, restricted to certain sectors (e.g., people not suffering from a certain allergy, diabetic issues, etc.). The product description can be generic if the products and processes are similar. Where the products and/or processes are not similar to each other, specific product descriptions are required.

Minor deficiency (7 points) if:
- Single/isolated instance(s) of errors or omissions on a product description.

Major deficiency (3 point) if:
- Numerous instances of errors or omissions on product descriptions.
- In an operation with multiple products/processes that are not similar, a single product description is not available.

Non-conformance (0 points) if:
- No product descriptions exist.
- Systematic errors or omissions on the product description(s).
- In an operation with multiple products/processes that are not similar, more than one product description is not available.

3.2.2 Has the process been flow charted? Is the flow chart in sufficient detail to completely describe the process or product manufacturing steps?
Visual confirmation. Total conformance (15 points): Process flow charts should have been created for each HACCP plan. The flow chart should show each step of the process under control of the operation, so that the hazard analysis can be completed properly. The flow chart should indicate the raw materials, ingredients and materials used in all preparation steps, all equipment used, blending steps, processing steps, rework, returned products and products destined for further processing, packaging materials (carton and unit packaging) and packaging equipment. Each step should show any holding times, temperature regimes and tagging. For example, a step termed "packing" in an apple packinghouse is incorrect since it omits to detail many of the processes (e.g. dump tanks, selections, washing steps, waxers (with fungicide), drying, packing the boxes and coding). In operations with multiple products but similar processes, a single process flow may be used. Where there are multiple products but with different processes, then individual process flows are required. Insufficient detail, missing steps, etc., will undermine the hazard analysis process.

Minor deficiency (10 points) if:
- Single/isolated instance(s) of errors or omissions on the process flow chart(s).

Major deficiency (5 point) if:
- Numerous instances of errors or omissions on the process flow chart(s).
- In an operation with multiple products/process that are not similar, a single flow chart is not available.

Non-conformance (0 points) if:
- Systematic errors on the flow chart(s).
- No process flow chart(s).
- In an operation with multiple products/processes that are not similar, more than one flow chart is not available.

3.2.3 Has a documented hazard analysis for each process flow been conducted, showing the various types of hazard and their associated severity?

Visual confirmation. Total conformance (15 points): A hazard analysis identifies and evaluates hazards and determines if control measures are in place to prevent, eliminate or reduce the food safety hazard to an acceptable level. A detailed hazard analysis for each process flow should have been conducted and **documented**. At each step of the process, from raw material receipt, through processing and packing, storage and distribution, the hazard analysis should look at the severity of all potential food safety hazards that may be reasonably expected to occur in terms of specific biological, chemical and physical or other issues. Examples of specific biological hazards include *Listeria monocytogenes, Salmonella* spp*.,* Enterohaemorrhagic *E. coli* (EHEC), Shiga toxin-producing *E. coli* (STEC), *Cryptosporidium parvum, Cyclospora cayetanensis*. Chemical hazards include mycotoxins, pesticide residues, sanitation chemicals, lubricants, allergens. Physical hazards include stones, metal, glass, and brittle plastic. Evaluation should include all ingredients, equipment, processing steps (e.g., receiving, dump tanks, brush bed systems, recycled wash systems including hydro-vacuum coolers, ice injectors, flume washers, etc., single line wash systems, ice manufacturing, inputs including packaging and post-harvest treatments, etc.) and packaging materials.

FDA Guidance for Industry: Juice HACCP Hazards and Controls Guidance First Edition; Final Guidance: http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm072557.htm

21 CFR Part 120.8 (a): http://www.gpo.gov/fdsys/pkg/CFR-2011-title21-vol2/pdf/CFR-2011-title21-vol2-sec120-8.pdf

Minor deficiency (10 points) if:

- Single/isolated instance(s) of errors or omissions on the hazard analysis chart(s).

Major deficiency (5 point) if:

- Numerous instance(s) of errors or omissions on the hazard analysis chart(s)
- In an operation with multiple products/processes that are not similar, a single hazard analysis chart is not available.

Non-conformance (0 points) if:

- Multiple systematic errors on the hazard analysis chart(s).
- No process hazard analysis chart(s).
- In an operation with multiple products/processes that are not similar, more than one hazard analysis chart is not available.

3.2.4 Does the documented hazard analysis show the controls for each identified potential food safety hazard?

Visual confirmation. Total conformance (15 points): The controls for each identified hazard should be documented on the hazard analysis chart. More than one control measure may be required to control a specific hazard and more than one hazard may be controlled by a specific control measure. Consider whether pre-requisite control measures can be applied to each hazard. The hazard analysis should indicate if an adequate control step for this potential risk exists further down the process (see 3.2.5).

Minor deficiency (10 points) if:

- Single/isolated instance(s) of errors or omissions in documented controls for identified food safety hazards.

Major deficiency (5 point) if:

- Numerous instance(s) of errors or omissions in documented controls for identified food safety hazards.

Non-conformance (0 points) if:

- Multiple systematic errors in documented controls for identified food safety hazards.
- No control measures identified.

3.2.5 Have CCP decisions been made, have CCPs been identified and where CCPs are noted, have they been developed to control the hazards identified in the hazard analysis step?

Visual confirmation. Total conformance (15 points): CCPs should be developed with adequate detail and defined parameters. The CCP's should be created from the documented hazard analysis i.e. there should be a logical documented approach showing why the process was deemed a CCP or not. CCP's are often steps that if not controlled will lead to a food safety issue, and also, there is no step further down the process that controls the issue. A CCP should be controllable and the controls should be able to eliminate or reduce the risk to acceptable "safe" levels. **Where it has been determined that there are no CCPs, no further HACCP plan development is necessary (regular HACCP team meetings to review any changes in process or procedures are required – 3.4.1, 3.4.2).** In this instance, where no CCPs have been identified, questions relating to the creation of the HACCP plan are relevant but those relating to monitoring of CCPs should be scored N/A.

Minor deficiency (10 points) if:
- Single fault in the logic of one CCP decision.
- Single CCP developed that does not meet the criteria for a CCP.

Major deficiency (5 point) if:
- More than one fault in the logic of the CCP decisions.
- More than one CCP developed that does not meet the criteria for a CCP.
- One (where there are multiple) CCP has been omitted.

Non-conformance (0 points) if:
- No CCP's have been developed in the hazard analysis step even though clearly CCPs did exist.
- More than one CCP has been omitted in a plan where there should be multiple CCPs.
- A single CCP has been omitted in a plan where there is a single CCP.
- **If controls in place are inadequate to assure the safety of the product, then the auditor should consider scoring under Q 1.1.1.**

3.2.6 Have monitoring requirements and frequencies been determined for the CCPs?
Visual confirmation. Total conformance (15 points): Monitoring requirements and frequencies should have been determined for the CCPs. Where monitoring is not continuous, the type and frequency of monitoring should be sufficient to ensure the CCP is under control. Frequency should be specified; using "as needed" is not accepted as a stated frequency. The requirements i.e. what is to be done, should be specified on the chart. Requirements should include the critical control limits (CCL's) i.e. the maximum and/or minimum parameters of what is being monitored e.g. with a metal detector, the sensitivity of the detector setting should be stated and size/type of test pieces used, or with an anti-microbial the minimum concentration required should be stated. Other CCLs may include temperature parameters, pH, flow rates, dwell time, etc. Where no CCPs have been identified then this question should be scored N/A.

Minor deficiency (10 points) if:
- Single/isolated instance(s) of omissions or errors in the monitoring requirements.
- Single/isolated instance(s) of omissions or errors in the frequency details.

Major deficiency (5 point) if:
- Numerous instances of omissions or errors in the monitoring requirements.
- Numerous instances of omissions or errors in the frequency details.
- A single CCP (where there are multiple CCP's) is lacking monitoring requirements or frequency details.

Non-conformance (0 points) if:
- More than one CCP is lacking monitoring requirements or frequency details where there are multiple CCP's in a plan.
- A single CCP is lacking monitoring requirements or frequency details in a plan where there is a single CCP.

3.2.7 Are identified CCP critical control limits supported by validation documentation?
Visual confirmation (5 points): All CCP's should be supported by validation documentation showing that the critical control limits (CCL) and the associated testing frequency are scientifically derived and meet any relevant legal requirements. Where publicly available validation is not available, the auditee should have performed validation

studies to support their stated critical control limits. For example, ORP limits for chlorinated recycled water systems could be stated in research papers and State documentation (e.g., Leafy Greens Marketing Agreement). Another example, metal detection limits could be supported by validation studies that show that smallest test probes possible were used and meet the FDA guidelines. http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074554.htm. Where no CCPs have been identified, this question should be scored N/A.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of omissions or incorrect CCL validation details, including testing frequency.

Major deficiency (1 point) if:
- Numerous instances of omissions or incorrect CCL validation details, including testing frequency.

Non-conformance (0 points) if:
- There is no documentation to support CCP critical control limits.
- Systematic omissions or incorrect CCL validation details, including testing frequency.

3.2.8 Is there a clear, detailed action plan for operators to follow if CCP critical control limits are exceeded? Does it describe plans to adjust the process back into control and withhold out of compliance products if necessary?
Visual confirmation. Total conformance (15 points): The corrective action details should note the critical control limit issue that has occurred, what corrective actions were carried out, including what happened to potentially affected product and also how the process was "repaired" or "amended" in order to get the process back to the required control level. The HACCP plan corrective action sections should state where the corrective action details are to be recorded. Corrective actions should ensure that the CCP has been brought under control and require that a review is conducted in order to prevent a recurrence of the situation. Where no CCPs have been identified, this question should be scored N/A.

Minor deficiency (10 points) if:
- Any one of the above criteria is missing in the corrective action plan details.
- Single/isolated instance(s) of omission or errors in the corrective action details.

Major deficiency (5 point) if:
- Two of the above criteria are missing in the corrective action plan details.
- Numerous instances of omission or errors in the corrective action details.

Non-conformance (0 points) if:
- More than two of the above criteria are missing in the corrective action plan details.
- Systematic errors in corrective action plan details.

3.2.9 Have recording templates (recording forms) been developed for monitoring the CCPs?
Visual confirmation. Total conformance (10 points): Monitoring records should have been designed to record the CCPs that have been identified. The records should match the details noted in the HACCP plan and have CCPs identified by name and number, what is being measured, the frequency of the measurement, the critical control limit, the operating limit, the responsible person(s) or team and the corrective action(s) required in the case of a measurement not in compliance. Recording forms should have a specific document code as part of the document control program (2.2.1). Where no CCPs have been identified, this question should be scored N/A.

Minor deficiency (7 points) if:
- Single/isolated instance(s) where information or requirements on the recording template does not match what is noted in the HACCP plan.

Major deficiency (3 point) if:
- Numerous instances where information or requirements on the recording template does not match what is noted in the HACCP plan.

Non-conformance (0 points) if:
- Systematic failure to have information or requirements on the recording template matching what is noted in the HACCP plan.
- Single instance where a CCP has been created, but a record for the monitoring data has not been developed.

3.2.10 Have specific responsibilities been assigned for the monitoring, recording and corrective action management of each CCP?
Visual confirmation. Total conformance (10 points): Specific responsibilities should be assigned for the monitoring, recording and corrective actions of each CCP. If CCP records are not being completed properly, this may be an indication that the CCPs have not been assigned correctly. The responsibility should be clearly indicated on the HACCP chart by at least naming the function (e.g., QA Technician), who is responsible for monitoring, recording and executing corrective action related to an individual CCP. All records and documents associated with monitoring CCPs should be signed by the person(s) doing the monitoring, either physically or electronically. Where no CCPs have been identified, this question should be scored N/A.

Minor deficiency (7 points) if:
- Single instance of a CCP not being assigned (to either a person or group), where there are multiple CCPs.

Major deficiency (3 point) if:
- Numerous instances of a CCP not being assigned (to either a person or group), where there are multiple CCPs.

Non-conformance (0 points) if:
- No CCPs have been assigned to either a person or group.

3.2.11 Have verification plans and schedules been developed for each CCP?
Visual confirmation. Total conformance (10 points): Verification activities related to each CCP on the HACCP chart should be clearly detailed. Verification activities should include a verification of the CCP monitoring records by a HACCP trained supervisor or manager, checking that the CCP monitoring records have been completed properly and that CCPs are kept under control, reviewing deviations and product dispositions (including any corrective action work). Note that a CCP operator cannot verify their own work. Verification activities might include microbial testing, customer complaints and any other information that CCPs might help generate. Verification information might help improve and develop the HACCP program, but should show that the plan is being implemented correctly, is controlling the risk to an acceptable level (or eliminating the risk) and where this is not the case, this should be indicated on the verification paperwork, along with corrective action details (e.g., reviewing a CCP, a process flow, a hazard analysis step, etc.). Where no CCPs have been identified, this question should be scored N/A.

Minor deficiency (7 points) if:
- Single/isolated instance(s) of errors or omissions in the verification details on the plan.

Major deficiency (3 point) if:
- Numerous instances of errors or omissions in the verification details on the plan.
- Single instance in a plan with multiple CCPs, where verification details have not been noted.

Non-conformance (0 points) if:
- No verification plans have been developed for any CCP.

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Execution of the HACCP Plan

3.3.1. Are all of the documents noted in the HACCP plan in place for real time monitoring of the CCPs?
Visual Confirmation. Total conformance (15 points): All documents noted in the HACCP plan should be in place for real time monitoring of the CCP(s). Check current logs against the HACCP plan and check that document version codes match. Check to see if the right version of the log is being used i.e. if the plan was updated and new parameters were chosen and the forms were revised, are the revised forms being used by the CCP operators. Usually this is monitoring logs, but if logs are mentioned in the verification section of the CCPs, these also must be checked. Electronic records should be checked to ensure that the correct version is being used. Where no CCPs have been identified then this question should be scored N/A.

Minor deficiency (10 points) if:
- Single instance of a CCP log in place, but the "version" of the log in use is different from that in the HACCP plan i.e. the details are different or there are omissions.

Major deficiency (5 point) if:
- Numerous instances of CCP logs in place, but the "versions" of the logs in use are different from those in the HACCP plan i.e. the details are different or there are omissions.

Non-conformance (0 points) if:
- Systematic failure to control the "versions" of the CCP logs being used.
- Single CCP monitoring requirement not being recorded.

3.3.2. Are the CCP monitoring activities and frequencies in conformance with the plan?
Visual Confirmation. Total conformance (15 points): CCP monitoring activities and frequencies are in conformance with the plan. Check current logs against the HACCP plan. Auditor should carefully check the frequencies and allow some slight variations (minutes either way of target frequency). The critical control limits should exactly match those mentioned in the HACCP plan. Operational limit issues are scored in 3.2.7. Note that if a monitoring test is done more frequently than stated, it is not necessarily a fault (i.e. point loss) if "it is in the spirit" of the plan. Where no CCPs have been identified, this question should be scored N/A.

Minor deficiency (10 points) if:
- Single/isolated instance(s) where information or requirements on the recording template does not match what is noted in the HACCP plan.

Major deficiency (5 point) if:
- Numerous instances where information or requirements on the recording template does not match what is noted in the HACCP plan.

Non-conformance (0 points) if:
- Systematic failure to have information or requirements on the recording template matching what is noted in the HACCP plan.
- Single instance where a CCP has been created, but a record for the monitoring data has not been developed.

3.3.3. Do CCP operators understand basic HACCP principles and their role in monitoring CCPs? (Interview operators to verify.)
Verbal and Visual Confirmation. Total conformance (15 points): CCP operators should be aware of basic HACCP principles, specifically CCPs in their area(s) and their responsibilities for taking appropriate action should the limits be exceeded. This can be determined through casual employee interviews, with the approval of the audit host. The visual part of this confirmation is matching what the CCP operator says versus what is written in the HACCP documentation and also what is written in the CCP monitoring logs. Where no CCPs have been identified, this question should be scored N/A.

Minor deficiency (10 points) if:
- Single/isolated instance(s) where the CCP operator(s) are lacking in basic knowledge about HACCP principles.
- Single/isolated instance(s) where the CCP operator(s) are not able to explain correctly, details about the CCP's they are monitoring (e.g., what to do if the critical control points are exceeded).

Major deficiency (5 point) if:
- Numerous instances where the CCP operators are lacking in basic knowledge about HACCP principles.
- Numerous instances where the CCP operators are not able to explain correctly, details about the CCP's they are monitoring (e.g., what to do if the critical control points are exceeded).

Non-conformance (0 points) if:
- Systematic failure of the interviewed CCP operator to show basic knowledge about HACCP principle.
- Systematic failure of the interviewed CCP operators to be able to explain correctly, details about the CCP's they are monitoring (e.g., what to do if the critical control points are exceeded).

3.3.4 Are CCP monitor records signed off (or initialed) by the operator(s) who are carrying out and recording the CCP check?

Visual Confirmation. Total conformance (10 points): All CCP monitoring records and documents should be signed off by the person(s) doing the monitoring. Full signatures with printed name (if signature is not legible), initials and electronic signatures are acceptable. If initials are used, care should be taken to ensure that there is no confusion between two individuals who have the same initials (e.g., by using middle initials as well). Where no CCPs have been identified, this question should be scored N/A.

Minor deficiency (7 points) if:
- Single/isolated instance(s) of CCP record(s) not signed off by operator(s).

Major deficiency (3 point) if:
- Numerous instances of CCP record(s) not signed off by operator(s).

Non-conformance (0 points) if:
- Systematic failure to sign off records.

3.3.5 Are corrective actions detailed in writing when the failure of a CCP occurs?

Visual Confirmation. Total conformance (15 points): Corrective actions should be detailed in writing when the failure of a CCP occurs. The CCP failures should be noted in the correct records (as noted in the HACCP plan), should detail what has happened, what was done to correct the issue and if there were any preventative actions taken to prevent reoccurrence. Records should indicate what happened to any affected product and also detail how the process was rectified (as per the requirements of 3.2.10). The corrective action details should match what is described in the HACCP plan. Where no CCPs have been identified, this question should be scored N/A.

Minor deficiency (10 points) if:
- Single/isolated instance(s) of corrective action(s) being recorded, but lacking some details.
- Single/isolated instance(s) of corrective action(s) being recorded, but not meeting the requirements as noted in the HACCP plan.

Major deficiency (5 point) if:
- Single instance of CCP critical control limit breach not being recorded and/or corrective actions not being recorded.
- Numerous instances of corrective action(s) being recorded, but lacking some details.
- Numerous instances of corrective action(s) being recorded, but not meeting the requirements as noted in the HACCP plan.

Non-conformance (0 points) if:

- More than one instance of CCP critical control limit breach not being recorded and/or corrective actions not being recorded.
- Systematic failure to properly record corrective action details or the details recorded in no way meet what is required by the HACCP plan.
- **Auditor should consider reverting to Q 1.1.1, the general automatic failure question.**

3.3.6 Are the CCP records reviewed and signed off daily by the quality control supervisor and/or management as part of the verification plan?

Visual Confirmation. Total conformance (10 points): CCP records should be reviewed and signed off at least daily by the quality control supervisor or manager (second signatory). This should be a separate signature to that of the CCP operator. The individual signing off on these should check the records (e.g., dates, production lines, monitoring results, frequencies, corrective actions, use of correct forms, etc.), since their signature is basically stating that everything is in order relative to the written HACCP plan and associated documents. If discrepancies are found, then the sign off signatory should note the issues and corrective actions that are then taken. Where no CCPs have been identified, this question should be scored N/A.

Minor deficiency (7 points) if:
- Single/isolated instance(s) of CCP records not reviewed and signed off daily by the quality control supervisor or manager (second signatory).
- Single/isolated instance(s) of the CCP records being signed off by the second signatory, but there are issues with the records that have not been highlighted.

Major deficiency (3 point) if:
- Numerous instances of CCP records not reviewed and signed off daily by the quality control supervisor or manager (second signatory).
- Numerous instances of the CCP records being signed off by the second signatory, but there are issues with the records that have not been highlighted.

Non-conformance (0 points) if:
- Systematic failure for CCP records to be reviewed and signed off.
- Systematic errors on the CCP records that are being signed off by the second signatory.

3.3.7 Is any other CCP verification performed (apart from daily record verification) according to the HACCP Plan?

Visual Confirmation. Total conformance (10 points): CCP verification steps as per the HACCP plan should be completed and records maintained. The plan might include microbiological testing, customer feedback, etc. (see 3.2.10). Where verification activities have found that CCPs were not performing as required, there should be records that show that this has prompted a review of the relevant part of the HACCP program. For example, metal contamination complaints, where metal detection is a CCP, should prompt a review of the metal detection operation (metal detection performance, types of metal being scanned for, detection sensitivity (CCL's), employee performance and training). Where no CCPs have been identified, this question should be scored N/A.

Minor deficiency (7 points) if:
- Single/isolated instance(s) of CCP verification activity not being performed as per plan.

Major deficiency (3 point) if:
- Numerous instances of CCP verification activities not being performed as per plan.

Non-conformance (0 points) if:
- Systematic failure to implement verification plan.

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Management Support of HACCP

3.4.1 Are changes in the process, equipment, ingredients etc., causing timely reviews of HACCP systems, including hazard analysis, CCP decisions, CCP records and staff training?
Verbal and visual confirmation. Total conformance (10 points): When any changes are made to the process, equipment, ingredients, etc., all HACCP systems should be reviewed and the HACCP coordinator should inform all employees involved. Re-training or educational sessions may be necessary. Look for evidence of plan change, review of hazard analysis, CCP decisions, CCP records and check to see if key operators were informed/re-trained. All changes should be dated. If no changes have occurred, quiz the auditee to see how they would communicate the changes, if they happened in the future. Records of any re-training should be available. This question applies even where no CCPs were identified in past exercises.

Minor deficiency (7 points) if:
- Single/isolated instance(s) of omissions or incorrect data in the records.
- Single/isolated instance(s) of required employees (e.g., CCP operators, supervisors, etc.) not being informed about changes to the HACCP plan.

Major deficiency (3 point) if:
- Numerous instances of omissions or incorrect data in the records.
- Numerous instances of required employees (e.g., CCP operators, supervisors, etc.) not being informed about changes to the HACCP plan.

Non-conformance (0 points) if:
- Changes to the process, equipment, ingredients, etc., have taken place, but there has been no review of HACCP systems.
- HACCP plan has been changed and none of the required employees were informed.
- Re-training records have not been maintained.

3.4.2 Is the plant conducting self-audits of the HACCP program?
Visual confirmation. Total conformance (10 points). At a minimum, self-audits of the HACCP program by the HACCP team should be done at least every 12 months. Self-audits should ensure that the process flow, hazard analysis and HACCP chart reflect reality and ensure that the program has captured any changes to the process. This includes checking that the product descriptions, process analysis, hazard analysis and CCP decisions are correct and current. Whenever changes are made to the program i.e. new equipment added to the facility, new critical control points added to the plan, new limits added, new packaging is required, etc., then the plan needs to be re-evaluated immediately to determine impact to HACCP plan and related documents. HACCP program reviews should take into account the latest guidelines, legal changes, issues arising from other audits and any other information gained about the production process. Self-audits help verify the effectiveness of the HACCP program, identify deficiencies and help improve the program. Self-audits should be fully documented and signed-off by the HACCP team and senior management, even if no changes are located. If issues are found, there should be detailed corrective action records. Audit records should include the date, personnel involved, areas that were checked, findings and corrective actions (where necessary). This question is relevant even where no CCPs were identified in past exercises.

Minor deficiency (7 points) if:
- Single/isolated instance(s) of the self-audit(s) having omissions or incorrect data.
- Self-audit occurred in the last 18 months, as opposed to the last 12 months.

Major deficiency (3 point) if:
- Numerous instances of the self-audit(s) having omissions or incorrect data.
- Changes to the HACCP plan have been made but the self-audit had not been conducted.
- Self-audit occurred in the last 24 months, as opposed to the last 12 months.

Non-conformance (0 points) if:
- Systematic failure to record self-audits properly.

- Self-audits are not being conducted.
- Self-audit occurred over 24 months ago.

3.4.3 Have standard operating procedures (SOPs) been created for the CCP monitoring processes that include how to carry out the monitoring?

Visual confirmation. Total conformance (10 points): Clear and simple standard operating procedures should be written for each CCP monitoring process that expands in detail the CCP monitoring in the form of work instructions. These SOPs must match what is written in the HACCP plan. These SOPs can be used for training and as reference tools. This question only occurs in audits that have the HACCP module attached. Where no CCPs have been identified, this question should be scored N/A.

Minor deficiency (7 points) if:
- Single/isolated instance(s) of errors and omissions within the CCP SOPs.

Major deficiency (3 point) if:
- Numerous instances of errors and omissions within the CCP SOPs.
- Single instance of a CCP SOP not being created in a system where there are multiple CCPs.

Non-conformance (0 points) if:
- CCP SOPs have not been created.

3.4.4 Are monitoring and verification information reviewed and discussed at management level meetings?

Visual confirmation. Total conformance (10 points): Verification, monitoring, feedback and other ongoing HACCP information should be discussed at management level meetings with records of what was discussed and who attended these meetings. These meeting notes should be kept on file and available for review. These meetings should occur at least quarterly, but ideally monthly. These meetings can be combined with other topics (e.g., pre-requisite food safety topics like sanitation, pest control, etc.). If the company is too small to have a HACCP group (less than 20 people), the designated HACCP coordinator (3.1.1) will be responsible for the HACCP program and question is N/A. Where no CCPs have been identified, this question should be scored N/A.

Minor deficiency (7 points) if:
- Single/isolated instance(s) of errors and omissions in the meeting logs (e.g., not noting who was attending the meeting).
- Single/isolated instances(s) of meetings not being held at the minimum specified frequency.

Major deficiency (3 point) if:
- Numerous instances of errors and omissions in the meeting logs (e.g., not noting who was attending the meeting).
- Numerous instances of meetings not being held at the minimum specified frequency.

Non-conformance (0 points) if:
- Meetings reviewing the HACCP progress are not occurring or are not being documented.

3.4.5 Are there independent audits e.g. third party audits of the plant's HACCP program (at least every 12 months)?

Visual confirmation. Total conformance (10 points): Independent (from the operational employees) audits of the HACCP program should occur at least every 12 months (e.g., third party audits, etc.). Records of these HACCP system audits, and corrective actions should be available for review. The audit report must state that HACCP is included in the scope and the audit must review all the key HACCP details (HACCP development, implementation, monitoring and self-auditing of the plan and associated records). If the last PrimusLabs HACCP audit occurred within the last 12 months and there are no other examples, then this is allowed to be used to meet this questions requirements (if the last PrimusLabs audit is greater than 12 months, then the rules below must be applied). This question applies, even where no CCPs have been identified.

Minor deficiency (7 points) if:

- Last external HACCP audit was over 12 months ago, but no greater than 18 months ago.

Major deficiency (3 point) if:

- Last external HACCP audit was over 18 months ago, but no greater than 24 month ago.

Non-conformance (0 points) if:

- Last external HACCP audit was over 24 months ago.

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Food Defense - Section 4

The food defense section of the audit is scored as a separate percentage to the overall food safety score on the default audit report system. Certain buyers do demand that the food defense and food safety scores are combined to show a single audit score.
The following Food Defense section is based in part on the FDA/CFSAN — Guidance for Industry: Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance. Key elements of this guidance have been included in this audit. For full details of this guidance go to http://www.agri.state.id.us/Categories/InspectionsExams/Documents/secguid6.pdf. FSIS has also created a self-assessment guideline for food processors titled "Food Security Guidelines for Food Processors". These guidelines are available at: http://www.fsis.usda.gov/Oa/topics/SecurityGuide.pdf. The associated self-assessment checklist is available at: http://www.fsis.usda.gov/shared/PDF/Self_Assessment_Checklist_Food_Security.pdf.

The checklist facilitates the process of evaluating an operation's Food Defense status. It addresses all aspects of Food Defense, including plan management, interior to exterior physical security, receiving, storage and shipping, utilities and personnel.
Other potentially useful websites:
FDA Food Security Preventive Measures Guidance,
http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/fooddefense/ucm083075.htm
FSIS Food Security Guidance, http://www.fsis.usda.gov/Oa/topics/SecurityGuide.pdf

Physical Security

4.1.1 Are the facility external areas and vulnerable points (i.e. those that are not permanently locked) surrounded by security fencing?
Visual Confirmation. Total conformance (5 points): Where there is external storage and/or vulnerable (not kept locked) entry points, the facility should be surrounded by a continuous security fence. The fence should be designed to exclude intruders (e.g., height (6ft or greater), thick gauge wire and topped off with barbwire). The facility might use a brick wall perimeter and the top of the wall has barbed wire or some other deterrent. Where there is no external storage and doors are permanently locked, score as N/A.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of damaged fencing observed.
- Single/isolated instance(s) of exposed external areas of the facility lacking fencing.

Major deficiency (1 point) if:
- Fence in place, but not a proper security fence (e.g., not high enough to prevent entry).
- Numerous instances of damaged fencing observed.
- Numerous instances of exposed external areas of the facility lacking fencing.

Non-conformance (0 points) if:
- No perimeter fencing.

4.1.2 Is access to the facility controlled by locks, swipe cards, alarms or other devices?
Visual and Verbal confirmation. Total conformance (10 points): The facility should have security systems in place to prevent intruders, deter intruders and ideally alert the employees to the presence of intruders. These include swipe cards, key locks, pass codes on punch pads, biometrics like palm readers, other technologies and a combination of different systems. Security systems should be used correctly and part of facility discipline. The facility should be locked when not in use (e.g., overnight if there is no nightshift). Consideration should also be given to locking down areas of the facility when these areas are not being used continuously and entry could occur undetected (e.g., an external packaging store that is visited infrequently). Auditors should not score down in busy areas, that are not kept secured (e.g., locked during the day when in operation).

Minor deficiency (7 points) if:

- Single/isolated instance(s) of entry door(s) not properly controlled by a security system (e.g., key lock, alarm sensor, etc.).
- Single/isolated instance(s) of areas that are not locked up in the day and are not frequently being visited by employees.

Major deficiency (3 points) if:
- Numerous instances of entry doors not properly controlled by a security system (e.g., key lock, alarm sensor, etc.).
- Numerous instances of areas that are not locked up in the day and are not frequently being visited by employees.
- No system for controlling swipe cards and/or number combination locks.

Non-conformance (0 points) if:
- No locks on doors.
- Swipe card systems and/or number combination locks in place, but not working and there are no other locking systems.

4.1.3 Are inbound food product storage areas (fruits, vegetables, etc.) secure, i.e. within a secure compound?
Visual confirmation. Total conformance (5 points): Food items should be stored inside a facility or within a secure compound (e.g., a fenced area) (note that this is different conformance criteria relative to the questions in 1.3). If stored outside within a secure compound, there should be protection against potential tampering and contamination (e.g., store away from the fence line) and also ensure that the materials are protected from contamination (e.g., with shrouds).

Minor deficiency (3 points) if:
- Single/isolated instance(s) of product being stored within a secure compound, but not under cover (e.g., a shroud) (therefore exposed to contamination).
- Product is stored within a secure compound, but close to a perimeter fence (therefore potential for contaminant to be applied from outside the perimeter fence).

Major deficiency (1 point) if:
- Numerous instances of product being stored within a secure compound, but not under cover (e.g., a shroud) (therefore exposed to contamination).
- Majority of product is stored inside or within a secure compound, but some occasionally temporary storage of product is occurring outside the secure areas.

Non-conformance (0 points) if:
- Product is routinely stored outside secure storage areas.

4.1.4 Are chemicals such as chlorine, citric acid, fungicides and sanitation chemicals stored within secured areas with controlled access?
Visual confirmation. Total conformance (5 points): All chemical materials are stored inside or within a secure area with restricted access. This is usually a chemical store with access restricted to specific personnel within the company. Chemical materials include sanitation chemicals, product-washing chemicals, etc. Empty containers should also be stored securely until they are either collected or disposed of properly. 1.2.11 also looks at chemical storage, but from a food safety perspective.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of improperly stored chemicals.
- Single/isolated instance(s) of poor security controls with respect to restricted access to chemical stores.

Major deficiency (1 point) if:
- Numerous instances of improperly stored chemicals.

- Numerous instances of poor security controls with respect to restricted access to chemical stores.

Non-conformance (0 points) if:
- There is no designated restricted access chemical storage area.
- There are no restrictions for accessing the chemical stores.

4.1.5 Are packaging material (cartons, wrap film, fruit cups, etc.) storage areas secure, i.e. within the secure compound?
Visual confirmation. Total conformance (5 points): Packaging items should be stored inside a facility or within a secure compound (e.g., a fenced area) (note that this is different conformance criteria relative to the questions in 1.3). If stored outside within a secure compound, there should be protection against potential tampering and contamination (e.g., store away from the fence line) and also ensure that the materials are protected from contamination (e.g., with shrouds).

Minor deficiency (3 points) if:
- Single/isolated instance(s) of packaging being stored within a secure compound, but not under cover (e.g., a shroud) (therefore exposed to contamination).
- Packaging is stored within a secure compound, but close to a perimeter fence (therefore potential for contaminant to be applied from outside the perimeter fence).

Major deficiency (1 point) if:
- Numerous instances of packaging being stored within a secure compound, but not under cover (e.g., a shroud) (therefore exposed to contamination).
- Majority of packaging is stored inside or within a secure compound, but some occasionally temporary storage of packaging is occurring outside the secure areas.

Non-conformance (0 points) if:
- Packaging is routinely stored outside secure storage areas.

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Employee Security

4.2.1 Are background checks conducted on all personnel with special attention to employees who have access to sensitive areas and/or control of sensitive processes (verbal confirmation accepted)?
Verbal confirmation. Total conformance (5 points): Checks such as social security numbers, INS details, interviewing, previous job references, etc. Privacy laws might limit how much investigating a company can carry out and also limit how much documentation an auditor is allowed to look at, hence verbal confirmation is acceptable. While felony checks are ideal and, if they are occurring, this should be noted in the audit commentary. If felony checks are not being carried out, this is not justification for a down score at present.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of employees not receiving basic background checks (social security, INS, etc.).
- Supervisory/management positions are not being checked with respect to previous positions.

Major deficiency (1 point) if:
- Numerous instances of employees receiving basic background checks (social security, INS, etc.).

Non-conformance (0 points) if:
- No checks of any employees are occurring.

4.2.2 Employee personal items are not being stored in the production and material storage areas?
Visual confirmation. Total conformance (5 points): Employees should have a designated area for storing personal items, such as coats, shoes, purses, etc. Lockers are desirable. Areas set aside for employee personal items should be far enough away from stored raw or finished products, packaging materials, processing equipment or processing lines to prevent contamination and avoid food security risks. Please note that this question is the same as what is found in 1.4.10. Since this question occurs in the food safety and food security section, it should be scored the same way in both sections (this is not viewed as double dinging).

Minor deficiency (3 points) if:
- Single or isolated instance(s) of personal belongings, personal food, etc. being found in production or storage areas.

Major deficiency (1 point) if:
- Numerous instances of personal belongings, personal food, etc. being found in production or storage areas.

No points (0 points) if:
- Systematic failure to prevent personal belongings, personal food, etc. being taken into the production area.

4.2.3 Are employees issued non-reproducible identification e.g. badges, company ID cards, etc.?
Visual confirmation. Total conformance (5 points): Employees should have personal identifications that link them to the company. The ID's should have the employee's number, photo and position within the organization. Time cards with photo identification are acceptable. The ID cards, if worn on the outer garments, should be firmly attached so as not to be a food safety hazard. If stored on one's person, this is also acceptable i.e. the ID card can be provided if challenged (if stored in pockets, etc., hand sanitation would be required after showing the ID card, prior to handling product). Control of the ID card, especially with respect to employees leaving the operation should be maintained. All employees should have ID's, including management and agency labor. Agency labor might have agency ID cards (which are checked on arrival). Companies with less than 20 employees are not expected to have an ID system.

Minor deficiency (3 points) if:
- ID's have been issued to all employees, but these do not include photo's.
- Single/isolated instance(s) of employees not having ID cards.

Major deficiency (1 point) if:
- Numerous instances of employees not having ID cards.

- Lack of controls over ID cards when employees leave the operation.

Non-conformance (0 points) if:
- Employees are not supplied identification cards.

4.2.4 Are visitors (including contractors) also required to be issued with identification e.g. badges, high visibility visitor apparel, etc.?
Visual confirmation. Total conformance (5 points): All visitors, including contractors, should be provided with identification (e.g., badges that are valid only for the time that these visitors are on site). The identification cards should be collected when the visitors leave the site. Badge issue and return should be recorded (e.g., in the visitors sign in book). Ideally each badge should have a unique number and this number is recorded in the logbook. The ID cards if worn on the outer garments should be firmly attached so as not to be a food safety hazard. If stored on one's person, this is also acceptable i.e. the ID card can be provided if challenged (if stored in pockets etc., hand sanitation would be required after showing the ID card, prior to handling product). Issue of unique high visibility vests, smocks or bump hats marked with "visitor" to visitors with issue and return recorded (e.g., as part of sign in /sign out process) are also acceptable. Companies with less than 20 employees are exempt from this requirement, score as N/A.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of visitor(s) and contractor(s) who have not been supplied company ID badges or other identification (must specify).
- Single/isolated instance(s) of visitor ID badge(s) or other identification (must specify) issue and return not being recorded (e.g., as part of the sign in and sign book process).

Major deficiency (1 point) if:
- Numerous instances of visitors and contractors who have not been supplied company ID badges or other identification (must specify).
- Numerous instances of visitor ID badges or other identification (must specify) issue and return not being recorded (e.g., as part of the sign in and sign book process).

Non-conformance (0 points) if:
- Visitors (and contractors) are not supplied ID badges or other identification.

4.2.5 Are visitors (including contractors) required to "sign in" and "sign out" in a visitors logbook?
Visual confirmation. Total conformance (5 points): Facility should have a logbook that visitors and subcontractors should be required to sign in and out of (including date, time, reason for visit, visitor's host and employer name). Contractors, whether long term or short term, should also be covered by the site security procedures. If a contractor is going to be on site frequently or for a long time period, the auditee can grant a permanent ID card status. Special attention should be focused on those visitors who do not have to report to the front reception offices (e.g., contracted maintenance employees).

Minor deficiency (3 points) if:
- Single/isolated instance(s) of visitor(s) and contractor(s) not signing in.
- Single/isolated instance(s) of visitor(s) and contractor(s) not signing out.

Major deficiency (1 point) if:
- Numerous instances of visitors and contractors not signing in.
- Numerous instance(s) of visitors and contractors not signing out.

Non-conformance (0 points) if:
- Visitor/contractor sign in and sign out logbook is not being used or does not exist.

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Transport Security

4.3.1 Does the company make use of sealed and/or locked trailers on inbound loads (excluding open flatbed trucks)?
Verbal confirmation. Total conformance (3 points): Inbound trailers i.e. deliveries to the auditee of raw materials (products, packaging, etc.) should be fitted with seals and/or locks in order to maintain security. Seal numbers should be recorded if seals are used. Seals are difficult to demand from material suppliers, if the auditee is not ordering full loads of material. Open flatbed trucks cannot be sealed or locked, therefore mark N/A.

Minor deficiency (2 points) if:
- Single/isolated instance(s) of inbound trailers not being sealed and/or locked.
- Single/isolated instance(s) of seal numbers not being recorded (where seals are being used).

Major deficiency (1 point) if:
- Numerous instances of inbound trailers not being sealed and/or locked.
- Numerous instances of seal numbers not being recorded (where seals are being used).

Non-conformance (0 points) if:
- Inbound trailers are not sealed and/or locked.
- Seal numbers are not being recorded (where seals are being used).

4.3.2 Does the company make use of sealed and/or locked trailers on outbound loads?
Verbal confirmation. Total conformance (3 points): Outbound trailers (shipping) of finished goods should be fitted with seals and/or locks in order to maintain security. Seal numbers should be recorded if seals are used. Seals are difficult to use if the shipping trailer is making multiple drops. Where the auditee has no decision in the choice of trucking company i.e. the trailers are booked by the buyers (not by the auditee), it might not be possible for the auditee to enforce trailer locking or sealing policy. In these cases, this question should be scored N/A.

Minor deficiency (2 points) if:
- Single/isolated instance(s) of outbound trailers not being sealed and/or locked.
- Single/isolated instance(s) of seal numbers not being recorded (where seals are being used).

Major deficiency (1 point) if:
- Numerous instances of outbound trailers not being sealed and/or locked.
- Numerous instances of seal numbers not being recorded (where seals are being used).

Non-conformance (0 points) if:
- Trailers are not sealed and/or locked.
- Seal numbers are not being recorded (where seals are being used).

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Water Supply Security

Potentially use website:
EPA Water Security, http://water.epa.gov/infrastructure/watersecurity/
http://www.epa.gov/watersecurity/pubs/water_security_handbook_rptb.pdf

4.4.1 Are potable and non-potable water supplies clearly identified?
Visual confirmation. Total conformance (3 points): Water lines should be clearly identified if water is used for any particular process and there is more than one source or type of water on site. For example, different water sources or types of water might be used for production as opposed to fire suppression. The aim is to ensure that anyone can tell what water source or type of water is within a pipe or coming out of a tap. Examples of methods used include color-coded pipes, labeled pipes, signs on taps, etc. Where there is only one type of water source used on site, this question should be scored N/A.

Minor deficiency (2 points) if:
- Single/isolated instance(s) of water pipes, taps etc., not indicating potability status where there is more than one water source/type being used on the site.

Major deficiency (1 point) if:
- Numerous instances of water pipes, taps, etc., not indicating potability status where there is more than one water source/type being used on the site.

Non-conformance (0 points) if:
- None of the water pipes, taps, etc. indicate their potability status where there is more than one water source/type being used on the site.

4.4.2 Are tamper evident/tamper resistant systems (e.g. tamper tags) in place where appropriate?
Visual confirmation. Total conformance (3 points): Where appropriate (e.g. incoming water supply), water valves should be fitted with tamper evident or tamper resistant systems. For example, the main incoming water valve could be fitted with a tamper evident chain (sacrificial link), that has to be broken if the valve is opened or closed. Other examples of tamper evident systems may include tamper tags/seals, padlocks, valve chains, zip ties on valves, cage, etc.

Potentially useful website:
EPA Valve Lockout Devices, http://www.epa.gov/watersecurity/pubs/water_security_handbook_rptb.pdf

Minor deficiency (2 points) if:
- Single/isolated instance(s) of incoming water valves not fitted with tamper evident systems.

Major deficiency (1 point) if:
- Numerous instances of incoming water valves not fitted with tamper evident systems.

Non-conformance (0 points) if:
- None of the incoming water valves are fitted with tamper evident systems.

4.4.3 Is there restricted access to sensitive water systems, e.g. anti-microbial addition systems (like chlorine injection pumps), that helps ensure that only authorized personnel are able to adjust these systems?

Visual confirmation. Total conformance (3 points): Areas where the water systems are being adjusted, injected or controlled in some other manner should be protected from tampering. For example, the control box that controls the anti-microbial flow rates into a flume should only be accessible to specified employees (e.g., use of pass codes, locked control boxes). Backflow prevention might be fitted with a tamper evidence system (as per the last question).

Minor deficiency (2 points) if:

- Single/isolated instance(s) of unrestricted access to a sensitive water system.

Major deficiency (1 point) if:

- Numerous instances of unrestricted access to a sensitive water system.

Non-conformance (0 points) if:

- No restrictions to sensitive water systems.

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Food Defense Systems

4.5.1 Does the company have a documented food defense policy based on the risks associated with the operation?
Visual confirmation. Total conformance (10 points): The company should have a documented food defense policy that outlines the operation security controls. These should include policies covering personnel, visitors, contractors, raw material receipt (product and packaging), trucks (incoming and outbound), etc., i.e. any relevant food security risk. There might also be a requirement to ensure that suppliers have proper food defense programs. Documented operational risk management (ORM) systems are acceptable, if they show the controls that have been implemented for the food defense risks that have been identified.

Minor deficiency (7 points) if:
- Single/isolated instance(s) of errors or omissions in the food defense policies.

Major deficiency (3 point) if:
- Numerous instances of errors or omissions in the food defense policies.

Non-conformance (0 points) if:
- Food defense policies have not been documented.

4.5.2 Is there a current list of emergency contact phone numbers for management, law enforcement and appropriate regulatory agencies?
Visual confirmation. Total conformance (3 points): The company should have a current list of emergency contact phone numbers for management, law enforcement and appropriate regulatory agencies. This information may be found as part of the recall plan.

Minor deficiency (2 points) if:
- Single/isolated instance(s) of errors or omissions in the list.
- The list is has not been updated in more than a year (less than two years).

Major deficiency (1 point) if:
- Numerous instances of errors or omissions in the list.
- The list has not been updated in more than two years.

Non-conformance (0 points) if:
- A list of emergency contact phone numbers for management, law enforcement and appropriate regulatory agencies has not been documented.

4.5.3 Are all personnel required to undergo training on food defense issues and are training records kept?
Visual confirmation. Total conformance (5 points): Employees should attend either external or in-house training on food security/defense requirements at least every 12 months. Records should be kept (showing topics and attendance). Training might include checking raw materials, facility security, handling visitors, etc. Training might also include formal operational risk management evaluation. All employees should be trained, but the depth and level might vary depending on the employee's role within the auditee company.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of errors or omissions in the food defense training topics covered.
- Single/isolated instance(s) of errors or omissions in the food defense training attendance records.
- Single/isolated instance(s) of employees not being trained with respect to food defense.

Major deficiency (1 point) if:
- Numerous instances of errors or omissions in the food defense training topics covered.
- Numerous instances of errors or omissions in the food defense training attendance records.

- Numerous instance(s) of employees not being trained with respect to food defense.

Non-conformance (0 points) if:
- Employees are not trained with respect to food defense requirements.
- No records of the food defense training.

4.5.4 Is there a log of who has access to sensitive areas e.g. a listing of key holders for access to areas like chemical stores?
Visual confirmation. Total conformance (3 points): In order to track who has been granted access to sensitive areas and to maintain information about the whereabouts of keys, a documented log should be maintained. For example, the chemical stores should have restricted access and there should be a log of who has access to this area. In many cases, this will be a listing of key holders, however, some operations might use pass codes, palm readers and other technologies. Special attention should be employed when employees leave or move positions within a company (e.g., pass codes should be changed, keys returned and records should be updated). The auditor can challenge the systems (e.g., asking to see key holders keys).

Minor deficiency (2 points) if:
- Single/isolated instance(s) of errors or omissions in the logs showing who has access to sensitive areas.
- Single/isolated instance(s) of employee(s) who should have access to restricted areas, unable to prove that they have this access (e.g., a lost key).
- Single/isolated instance(s) of employee(s) who should not have access to restricted areas that have access i.e. having a key that they should not have, knowing a secure pass code.

Major deficiency (1 point) if:
- Numerous instances of errors or omissions in the logs showing who has access to sensitive areas.
- Numerous instances of employees who should have access to restricted areas, unable to prove that they have this access (e.g., a lost key).
- Numerous instances of employees who should not have access to restricted areas that have access i.e. having a key that they should not have, knowing a secure pass code.

Non-conformance (0 points) if:
- Logs showing who has access to sensitive areas do not exist.
- Pass codes to restricted areas have been publicly displayed in some way.

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Miscellaneous Survey Questions – Section 5

These questions are scored. However, they do not affect either the Food Safety or Food Defense scores.

Allergens

Potentially useful website:
FDA Allergy Inspection Guide, http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074944.htm

5.1.1 Are there allergen risks handled or stored within production and storage areas?
Visual and verbal confirmation. Total conformance (0 points): If the production process includes the handling of allergen containing materials, then the allergen questions below should be completed. The key concerning allergens (a.k.a. major eight) are Wheat, Eggs, Milk, Soybeans, Crustaceans (Shellfish), Peanuts, Tree Nuts and Fish. Other sensitive ingredients that would need further investigation are Sulfites and Artificial Color FDC Nº. 5. If there is no allergen handling on site then mark this question "No", state an explanation and the rest of the allergen questions should be marked N/A (with a statement referring back to this question (e.g., N/A, see question 5.1.1). This question is not designed to cover allergen containing items found in break room vending machines, personal break food stuffs, etc., but ideally auditees should make their employees aware of the potential issues, especially when carrying out hand washing training.

Minor deficiency: There is no minor deficiency for this question.

Major deficiency: There is no major deficiency for this question.

Non-compliance (0 points) if:
- Allergens are handled or stored within production and/or storage areas.

5.1.2 Has a documented allergen management plan been developed?
Visual confirmation. Total conformance (5 points): An allergen management plan has been developed and documented. The plan gives an overview of the operation's management of control from raw material procurement, 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, etc. Some facets of the allergen plan are audited in the rest of the questions in this section.

Minor deficiency (3 points) if:
- Plan lacks a key element.
- Single/isolated instance(s) of errors or omissions in the plan.

Major deficiency (1 point) if:
- Plan lacks more than one key element.
- Numerous instances of errors or omissions in the plan.
- Failure to communicate the plan to employees.

Non-compliance (0 points) if:
- No plan exists.

5.1.3 Are there adequate storage controls (separation, identification, etc.) that ensure that allergens are not contaminating other raw materials?
Visual confirmation. Total conformance (5 points): Allergen materials and allergen containing materials should be stored in a manner that avoids cross contaminating all other materials. Separated areas are ideal and allergens should never be stored above other materials. Allergens should be tagged as usual (rotation and lot coding), but should also be identified as allergens.

Minor deficiency (3 points) if:
- Single instance of improper allergen storage or handling practices.

- Single instance of allergenic items not labeled as allergens.

Major deficiency (1 point) if:
- Isolated instances (no more than three) of improper allergen storing or handling practices or where there is not adequate physical separation and demarcation within the room.
- More than one but less than three instances of allergens not labeled as such.

Non-compliance (0 points) if:
- Allergens being stored together with other items in a way that poses a cross contamination risk.
- Numerous instances of improper allergen storing or handling practices or where there is not adequate physical separation and demarcation within the room.

5.1.4 Is there a dedicated production line or adequate clean down and production procedures that prevent allergen cross contamination?

Visual and verbal confirmation. Total conformance (5 points): Ideally, facilities have separate production line(s) for allergen containing ingredients. If no separate production line is being used, then procedures should be written that avoid allergen cross contamination (e.g., schedule production of non-allergenic items before items with allergens, add allergenic ingredients as late in the process as possible, schedule sanitation immediately after production of foods containing allergens). 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.

Allergens should not come into contact with non-allergenic products, especially processed products that have been washed, cut or thermally treated. There should be plenty of space and separation to help avoid cross contamination issues. Employees who handle allergen products should not then handle non-allergen products without first ensuring that they are free of allergen contaminants. This should include hand washing, glove change, etc., but might also include changing into a new set of garments. Ideally, employees should be dedicated to allergen or non-allergen goods, but not both within a shift. Utensils, cleaning implements, internal vehicles, etc. should not be allowed to be vectors for cross contamination. Ideally, dedicated coded equipment and storage areas should be provided for allergen and non-allergen goods. Where dedicated utensils and equipment are not possible, items must be cleaned prior to use for non-allergenic materials.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of employee/utensil/internal vehicle allergen cross contamination.
- Minor process flow issues where allergenic materials come into the same area as non-allergenic materials, but the two products do not touch in any way, i.e. no potential risk of cross contamination.
- Some potential space issues where the process flow is being forced to bring allergenic and non-allergenic material into close proximity.

Major deficiency (1 point) if:
- Numerous instances of employee/utensil/internal vehicle allergen cross contamination.
- Serious process flow issues where allergenic material can potentially cross contaminate non-allergenic goods.
- Numerous space issues where the process flow is being forced to bring allergenic and non-allergenic material into close proximity.

Non-compliance (0 points) if:
- Systematic instances/issues with employee and/or utensil allergen cross contamination.
- Process flow issues are observed to result in allergen/non-allergenic goods cross contamination.

5.1.5 Are utensils and work in progress storage containers identified in order to prevent allergen cross contamination?

Visual and verbal confirmation. Total conformance (5 points): Utensils, like shovels, paddles, knives, 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 non-allergen containing products/processes. Product holding bins should be coded in a similar fashion i.e. a separate set of bins for the allergen containing product, including rework bins.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of utensils or work in progress storage containers not identified (tagged or color-coded) to differentiate between items associated with producing allergen containing products and products that do not contain allergens

Major deficiency (1 point) if:
- Numerous instances of utensils or work in progress storage containers not identified (tagged or color-coded) to differentiate between items associated with producing allergen containing products and products that do not contain allergens.
- Items are commingled with other goods in such a way that their status is unclear and a potential misuse might occur.

Non-compliance (0 points) if:
- Utensils or work in progress storage containers are not clearly separated and identified.

5.1.6 Does re-work handling take into account the issues associated with allergen containing products?
Visual and verbal confirmation. Total conformance (5 points): Re-work of allergen containing products needs to be strictly controlled. Allergen re-work product should be clearly labeled. Allergen re-work should be stored separately to 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, the traceability should be maintained which means that the use of re-work materials is being properly recorded.

Not applicable if there is no re-work/re-packing taking place.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of an issue with re-work handling.

Major deficiency (1 point) if:
- Numerous instances of issues with re-work handling.

Non-compliance (0 points) if:
- Systematic issues observed in handling how re-work is done.

5.1.7 Are employees 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?
Visual and verbal confirmation. Total conformance (5 points): Employees 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, like hand washing, changing protective garments and gloves etc., when moving around the production area. Key operators, like warehouse personnel, production personnel, label designers etc. should receive specific training. Training should be recorded.

Minor Deficiency (3 points) if:
- Single/isolated instance(s) of errors and omissions in the records.
- Training materials are not in the relevant language(s).
- Training occurring but relevant materials are not being given to the trainee after the training.
- Training occurring, not before starting to work but within the first week.
- Single/isolated instance(s) of employees not being trained.

Major Deficiency (1 point) if:
- Numerous instances of errors and omissions in the records.
- Training occurring, not before starting to work but within the first month.
- Numerous instances of employees not being trained.

Non-compliance (0 points) if:
- No records of training or employees are not being trained regarding allergens.
- No specific allergen orientation training given or given after the employee has been working for more than one month.
- Failure to maintain records.

5.1.8 Are all products manufactured on site, labeled correctly with respect to allergens?
Visual and Verbal Confirmation. Total conformance (5 points): Allergen containing products should clearly show the allergens associated with the product on the label. 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 where allergens are used, 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 (GMPs), etc., then management should have considered using a “may contain” (or a similar clause) on the non-allergy containing products (this is a last resort and should not replace proper GMPs). Labeling should follow the national and local labeling laws.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of missing allergen information on commodities, packaging, ingredients, processing aids, work in progress, etc.

Major deficiency (1 point) if:
- Numerous instances of missing allergen information on commodities, packaging, ingredients, processing aids, work in progress, etc.

Non-compliance (0 points) if:
- There is no allergen information on commodities, packaging, ingredients, processing aids, work in progress, etc.

Potentially useful website:
FDA FALCP 2004,
http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/allergens/ucm106187.htm

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Country of Origin Labeling

Country of Origin Labeling following Department of Agriculture guidelines (7 CFR Part 65) should be followed.

5.2.1 Is the company labeling retail packaging with the correct country(ies) of origin? N/A for food service.

Visual confirmation. Total conformance (3 points). Correct country of origin labeling is being indicated on retail product packaging i.e. bags, bands, twist ties, clamshells, PLU stickers or other labels, individual packages, etc. For produce grown within the United States, the country of origin label requirement will be met by naming the country, state or region in which the produce was grown. For produce grown outside the United States, the country of origin label requirement will only be met by stating the country in which the produce was grown. Food service products are exempt.

Minor deficiency (2 points) if:

- Single/isolated instance(s) of missing country(ies) of origin information on retail packaging.

Major deficiency (1 point) if:

- Numerous instances of missing country(ies) of origin information on retail packaging.

Non-compliance (0 points) if:

- There is no allergen information on country(ies) of origin information on retail packaging.

5.2.2 Is the company labeling the finished goods carton with the correct country(ies) of origin? N/A for food service.

Visual confirmation. Total conformance (3 points). Correct country of origin is being indicated on the shipping cartons i.e. the boxes, cartons, returnable plastic crates, etc., that are used to carry the products (whether bulk product or bagged/pre-packed product. For produce grown within the United States, the country of origin label requirement will be met by naming the country, state or region in which the produce was grown. For produce grown outside the United States, the country of origin label requirement will only be met by stating the country in which the produce was grown. Food service products are exempt.

Minor deficiency (2 points) if:

- Single/isolated instance(s) of missing country(ies) of origin information on finished goods packaging.

Major deficiency (1 point) if:

- Numerous instances of missing country(ies) of origin information on finished goods packaging.

Non-compliance (0 points) if:

- There is no allergen information on country(ies) of origin information on finished goods packaging.

5.2.3 Are there records that support the country(ies) of origin labeling e.g. bill of lading, production records, etc.?

Visual confirmation. Total conformance (3 points). Records exist that show the country of origin of the product and help prove that the label of the finished cartons and bags are correct. Records that might prove country of origin labeling include bill of lading, production records, purchase records, etc.

Potentially useful website: http://www.ams.usda.gov/AMSv1.0/cool

Minor Deficiency (2 points) if:

- Single/isolated instance(s) of omissions or incorrect data in the records.

Major Deficiency (1 point) if:

- Numerous instances of omissions or incorrect data in the records.

Non-compliance (0 points) if:

- No records.

- Failure to maintain records.

5.2.4 Are steps taken in the storage and production process to ensure that there is no commingling of materials from different countries (unless product will be labeled as such)?
Visual confirmation. Total conformance (3 points). Adequate steps are taken to ensure that product is not commingled in storage, production and dispatch. This includes ensuring that batches are processed separately and there is clear differentiation when switching batches with different countries of origin.

Minor deficiency (2 points) if:
- Single/isolated instance(s) of comingling of materials from different countries in storage, production or dispatch.

Major deficiency (1 point) if:
- Numerous instances of comingling of materials from different countries in storage, production or dispatch.
- Material(s) from different countries are commingled with other goods in such a way that their origin is unclear.

Non-compliance (0 points) if:
- Material(s) from different countries are not being stored and/or handled to ensure clear differentiation without clear labeling to indicate countries of origin.

Potentially useful websites:
http://www.ams.usda.gov/AMSv1.0/cool
http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELDEV3103388

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New Questions (Not Part of Overall Food Safety Percentage) – Section 6

These questions are answered Full, Minor Deficiency, Major Deficiency or Non-conformance. These questions do not affect either the Food Safety or Food Defense scores in this audit version v14.09, but will most likely be added in the next versions of the audit as part of the food safety section, where they will be scored.

6.1.1 Does the waste flow, from creation through to leaving the operation including vehicle use and flow, employee control, etc., ensure that facility and products are not contaminated?

Visual Confirmation. Total conformance (10 Points): Process waste, including culls and trash, should be handled to ensure they are not creating a contamination risk to facility or products. The scope of this question is from waste creation though to departure of waste from the property and includes waste flow patterns, whereby traffic (waste containers, cull trucks, other vehicles, personnel) may cross waste flow patterns (e.g., cull trucks hulling culled product to a cattle operation may be vectors for cross contamination). Auditor should observe waste handling practices and procedures.

Minor deficiency (7 points) if:

- Single/isolated instance(s) of employee/waste container/vehicle cross contamination.
- Minor waste flow issues where waste materials come into the same area as raw or finished materials, but the two products do not touch in any way, i.e. no potential risk of cross contamination.
- Some potential issues where the waste flow is being forced into close proximity with finished and raw material.

Major deficiency (3 points) if:

- Numerous instances of employee/waste container/vehicle cross contamination.
- Serious waste flow issues where waste material can potentially cross contaminate finished goods.
- Numerous space issues where the waste flow is being forced into close proximity with finished and raw material.

Non-conformance (0 points) if:

- Systematic instances/issues with employee/waste container/vehicle cross contamination.
- Process flow issues are observed to result in waste flow with product raw/finished goods cross contamination.

6.1.2 Is there a written procedure requiring transportation vehicles be dedicated to produce, and that animals, animal products or other materials that may be a source of contamination are not allowed to be transported?

Visual confirmation. Total conformance (5 points): There should be a written procedure in place that prohibits the transportation of trash, animals, raw animal products or other materials that may be a source of contamination with pathogens in vehicles that transport produce.

Minor deficiency (3 points) if:

- Single/isolated instance(s) of errors or omissions in the procedure.

Major deficiency (1 point) if:

- Numerous instances of errors or omissions in the procedure.

Non-conformance (0 points) if:

- There is no written procedure.

6.1.3 Is there a documented food safety plan covering site and facility?

Visual confirmation. Total conformance (10 points): The operation should have a facility-specific documented food safety plan meeting requirements of the FDA Food Safety Modernization Act (FSMA).This includes:

- A hazard analysis that identifies and evaluates known or reasonably foreseeable hazards for each type of food manufactured, processed, packed or held at the facility. Analysis justifies conclusions reached, including any conclusion that no hazards are likely.
- Preventative controls required are identified and implemented to provide assurances that hazards that are reasonably likely to occur will be significantly minimized or prevented.

- Monitoring procedures documenting preventive controls are consistently performed.
- Corrective actions to correct problems and minimize the likelihood of re-occurrence, evaluate the food for safety and prevent affected food from entering commerce where necessary.
- Verification to ensure preventive controls are consistently implemented and are effective.
- Recall plan detailing steps to be taken, and assigned responsibilities.

The plan should be signed and dated, and updated at least every three years, or whenever significant changes are made in the operation.

Potentially useful websites:
http://www.fda.gov/food/guidanceregulation/fsma/ucm247548.htm
http://www.fda.gov/Food/guidanceregulation/FSMA/ucm334114.htm
http://www.fda.gov/food/guidanceregulation/fsma/ucm334115.htm

Minor deficiency (7 Points) if:
- Plan lacks an element listed above.
- Single/isolated instance(s) of errors or omissions in the plan.
- Single/isolated instance(s) of errors or omissions in records (e.g., corrective actions).

Major deficiency (3 points) if:
- Plan lacks more than one element noted above.
- Numerous instances of errors or omissions in the plan.
- Numerous instances of errors or omissions in records (e.g., corrective actions).
- Failure to update plan every three years, or whenever a significant change in operations has been made.

Non-conformance (0 points) if:
- No plan exists.
- Systematic failures to keep records and/or corrective actions.

6.1.4 Is there a documented business continuity and disaster recovery plan?
Visual confirmation. Total conformance (5 points): Business continuity and disaster recovery (BC&DR) planning are documented processes to help organizations prepare for disruptive events that may impact the ability of the auditee to assure the safety of the food product. Disruptive events may include natural and man-made hazards such as a hurricane or earthquake, a computer virus attack, tampering or even a power outage. Business continuity planning should be orientated to how to continue doing business until recovery is accomplished, whilst disaster recovery should be orientated to recovery after a disruptive event.

The business continuity and disaster recovery plan should list and identify a crisis management team who represent the departments to handle and resolve any critical situations that may occur. Team should meet at least every 12 months (with documented minutes) to review, test and verify the plan. This question is not applicable to small family size companies (less than 20 persons).

The plan should include:

- Current list of team members with office and after hour contact details.
- Contact details for regulatory agencies, corporate personnel, clients, suppliers and other key contacts (e.g., trade association, media representative, consultants, legal team, etc.).
- Written responsibilities for each team member, including contacting regulatory officials, law enforcement, media, etc.
- Documented training for team members on crisis management procedures and responses.
- Written plans for handling critical situations to assure that raw materials, work in progress, ingredients (including ice), finished goods and food contact packaging materials are protected and there are plans for alternate product supply to the customer(s).
- Requirement that QA management determine the status of any raw materials, work in progress, ingredients (including ice), finished goods and food contact packaging materials involved in a critical situation. Evaluation and release to be documented.

Potentially useful websites:
http://www.fda.gov/food/guidanceregulation/fsma/ucm247548.htm
http://www.unitedfresh.org/assets/food_safety/FDA_Food_Safety_Modernization_Act_White_Paper_January_2011.pdf

Minor deficiency (3 Points) if:
- Plan lacks an element listed above.
- Single/isolated instance(s) of errors or omissions in the plan details.
- Single/isolated instance(s) of errors or omissions in records (e.g., evaluation and release).

Major deficiency (1 point) if:
- Plan lacks more than one element noted above.
- Numerous instances of errors or omissions in the plan details.
- Numerous instances of errors or omissions in records (e.g., evaluation and release).
- Failure to meet every 12 months to evaluate the plan.

Non-conformance (0 points) if:
- No plan exists.
- Systematic failures to keep records.

6.1.5 Does the facility have documented evidence to ensure that any food safety hazards relevant to waste water treatments (e.g. settling ponds, land applications, etc.) are controlled?
Visual confirmation. Total conformance (10 points): All national and local laws pertaining to on-site water treatment systems should be followed and this should be documented. There should be applicable permits on file and evidence of regulatory and/or third party inspections or copies of any exemptions. This question only pertains to open water collection areas: settling ponds, land applications. This question is not applicable if there are no on-site wastewater treatments. Not applicable to septic systems or sewer systems.
http://www.p2pays.org/ref%5C05/04874.pdf
http://www.epa.gov/watersecurity/pubs/water_security_handbook_rptb.pdf
http://water.epa.gov/aboutow/owm/upload/2005_08_19_primer.pdf

Minor deficiency (2 points) if:
- Single/isolated instance(s) of errors or omissions in the records.

Major deficiency (1 point) if:
- Numerous instances of errors or omissions in the records

Non-conformance (0 points) if:
- There are no records showing conformance to national and local laws pertaining to on-site water treatment systems (where applicable).

6.1.6 Has the operation listed the HACCP pre-requisite programs that are in effect at the facility?
Visual confirmation. Total conformance (10 points): Pre-requisite programs are the foundation providing basic environmental and operating conditions necessary for the production of safe, wholesome food. List should include a basic program description, who is responsible and where records that confirm the program is completed, documented, monitored and inspected are kept. Where required by regulation, more detailed information on pre-requisite programs may be required.
Examples of common pre-requisite programs include, but are not limited to:
- Allergen control
- Buildings and grounds
- Chemical control
- Cleaning and sanitation
- Complaints and feedback
- Equipment maintenance

- Personal hygiene
- Pest control
- Receiving, storage and shipping
- Specifications
- Supplier control
- Traceability and recall
- Training

http://www.fda.gov/food/guidanceregulation/haccp/ucm2006801.htm

Minor deficiency (7 points) if:
- Single/isolated instance(s) of omissions or errors in list of pre-requisite programs.

Major deficiency (3 point) if:
- Numerous instances of omissions or errors in the list of pre-requisite programs.

Non-conformance (0 points) if:
- No list of pre-requisite programs is available.

6.1.7 Where operating limits and frequencies have been established for the CCPs are they being monitored?

Visual confirmation. Total conformance (5 points):.Operating limits (OLs) and frequencies should be established (where necessary). Operating limit values are intended to be more stringent than critical limits (CLs) and are used to reduce the risk of a deviation from the critical limits. Operating limits are set based on auditees experience with the variability of the operation and with the closeness of typical operating values to the critical limit. Adjustments to the process may be made before the critical limit is violated, avoiding a deviation from a CL and the production of a potentially unsafe food product. Frequency should be specified. “As needed” is not accepted as a stated frequency. Where no CCPs have been identified or operating limits are not applicable, then this question should be scored N/A.
http://edis.ifas.ufl.edu/fs141

Minor deficiency (3 points) if:
- Single/isolated instance(s) of omissions or errors in the operating limit monitoring requirements.
- Single/isolated instance(s) of omissions or errors in the frequency details.

Major deficiency (1 point) if:
- Numerous instances of omissions or errors in the operating limit monitoring requirements.
- Numerous instances of omissions or errors in the frequency details.
- A single CCP (where there are multiple CCP’s) is lacking operating limit monitoring requirements or frequency details.

Non-conformance (0 points) if:
- More than one CCP is lacking operating limit monitoring requirements or frequency details where there are multiple CCP’s in a plan.
- A single CCP is lacking operating limit monitoring requirements or frequency details in a plan where there is a single CCP.

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PrimusLabs Facility Audit Applicability Chart

This chart is intended for guidance only. Situations will vary depending on process, product and intended use.

	Audit/Product	Facility Micro	Equip Micro	Hairnets/ Hair Restraints	Smocks	Hand Dips/ Gel stations	Foot Dips	Example Commodity
1	**Processing Audit**	Y	Y	Y	Y	Y	Y	Fresh-cut salad, sliced fruit, sprouts, sliced mushrooms, juice, frozen blueberries, fresh-cut potatoes
2	**Packinghouse Audit (washed or unwashed , potentially ready-to-eat)**	Y3	Y	Y	Y1	Y	N	Whole: apples, asparagus, avocado, blueberries, citrus, cranberries, herbs, melon, tomatoes
3	**Packinghouse Audit (washed, requires cooking)**	Y3	N	Y	N	N	N	Washed whole potatoes
4	**Packinghouse Audit (unwashed &/or outer layer[2] not an integral part of product)**	Y3	N	Y	N	N	N	Whole onions, whole garlic
5	**Cooling/Cold Storage Audit (with hydrocoolers, hydrovacs, ice injection)**	Y	Y	N4	N	Nq	N	Field-packed broccoli
6	**Storage & Distribution Audit**	Y3	N	N	N	N	N	Cross docking

Note

1 In packinghouses that wash product, smocks or aprons are a "must" after the wash step but ideally throughout the operation.

2 Outer layer i.e. skin is not eaten or used as an integral part of the product e.g. storage onions, whole garlic.

3 Applicable if there are storage areas used to store "wet" products or used as high humidity storage.

4 Applicable when emergency repacking of potentially ready-to-eat products occurs.

Y applicable, do not use N/A

N generally N/A; if operation has implemented then MUST be scored.

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